

Therapy Support Suite (TSS) User Manual

Software Version: 1.9

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1 IMPORTANT INFORMATION

1.1 IMPORTANT INFORMATION ABOUT THE USER MANUAL

Identification The document can be identified by the following information on the title page and on the labels (as required):

- software version of the application program
- User Manual Edition

Page identification Each page footer contains the page, document and section number.

Editorial information The editorial information, e.g. 4/06.11, refers to: fourth edition, June 2011.

Illustrations The illustrations used in the documents (e.g. screenshots, photos, etc.) may differ from the original, if this is of no significance to its functioning properly.

Importance of the instructions This User Manual is part of the accompanying documentation and is thus an integral part of the software. It includes information necessary for the use of the system. The User Manual is intended for the initial approach and reference. Before the responsible organisation may start operating the system, the person responsible for the operation must have been instructed by the manufacturer and must be thoroughly familiar with the contents of the User Manual. The software may only be used by individuals who can prove that they have been instructed on its proper use and handling.

Changes Changes to the technical document will be issued as new editions or supplements. In general, this document is subject to change without notice.

Reproduction Reproduction, even in part, is subject to written approval.

1.1.1 SIGNIFICANCE OF THE WARNINGS



Warning

Risk types and causes

Possible consequences of exposure to risk and measures to avoid them.

Warns the operator that failure to comply with warnings may result in personal injury.

Warnings may deviate from the above model in the following cases:

- If a warning describes several risks
- If a specific risk cannot be detailed

1.1.2 SIGNIFICANCE OF NOTES

Note



Advises the operator that failure to follow the steps as specified may result in the specific function not being executed correctly, not being executed at all, or not producing the desired effect.

1.1.3 SIGNIFICANCE OF TIPS



Tip

Useful information for better software handling.

1.2 INTENDED PURPOSE AND RELATED DEFINITIONS

Therapy Support Suite is a client-server software system that supports medical staff (doctors and nurses) and paramedical staff (technicians and administrators) in the management of dialysis clinics.

1.2.1 INTENDED PURPOSE

Dialysis dose calculation and treatment data display.

1.2.2 MEDICAL INDICATION

Renal failure that requires renal replacement therapy.

1.2.3 INTENDED PATIENT POPULATION

No restrictions on patients expected unless the connected (medical) devices are subject to limitations.

The standard use of Therapy Support Suite is in hospitals; however, outpatient assistance is not excluded.

1.2.4 INTENDED USER GROUP AND INTENDED ENVIRONMENT

The system will be used by physicians, nursing, administrative and technical personnel. Therapy Support Suite is not intended to be used by patients. The system, like client-server software, can be used in any setting where compatible hardware can be used; it is usually used on a PC / work stations in clinical settings.

1.2.5 CONTRAINDICATIONS

None.

1.2.6 UNDESIRED EFFECTS

None.

1.3 IMPORTANT INSTRUCTIONS REGARDING THE OPERATIONS

If the verification of patient data reveals a deviation between parameters prescribed by the physician and those displayed by the dialysis system, the operator must check and correct the system's default settings prior to the start of the treatment. Displayed device settings must be compared with the prescriptions specified by the physician.

The software may only be installed, operated and used by individuals with the appropriate training, knowledge and experience.

Installation operations, extensions, adjustments or repairs are to be carried out only by the manufacturer or persons authorised by the same.



Warning

Clinic or technical support personnel must take necessary precautions and measures to ensure Hardware and Software reliability.



Warning

Data processing is the responsibility of the manager.

To eliminate the possibility of entering wrong values, the operator must ensure that the data entered are correct. The operator must ensure that values read back after being sent to the server correspond to the information entered.

Data loss cannot be excluded.

1.3.1 CONDUCT IN EXCEPTIONAL SITUATIONS

Under unfavourable conditions such as after a disconnected network connection to the server or after program crashes, deviations between the data on the server and those in the client program may occur. In this case it is recommended that the program be shut down and restarted.



Warning

The operator should always have access to patient data (e.g. in written form) for every patient.

1.3.2 INTERACTIONS WITH OTHER SYSTEMS

- Therapy Monitor
- Communication Data Link (cDL)
- Patient OnLine
- Nephrological Cockpit

1.4 SYSTEM REQUIREMENTS

Therapy Support Suite requires the complete installation of a FIS (Fresenius Interface Server) communication server.

Therapy Support Suite must be installed by authorised technical personnel.

1.4.1 IT ENVIRONMENT

Therapy Support Suite is a complex client-server software application comprising dialysis devices, application servers, web servers, database servers, user workstations and a broad range of network equipment (switchers, routers, plugs, connection cables, etc.) to be used inside hospital IT networks.

Clear IT requirements for both hardware and software have been defined for each component of this complex network.

Please see the relevant Service Manual for additional and more detailed information about the IT environment required for operation of Therapy Support Suite.

Note

The recommended client configuration is as follows:

Processor Minimal: Intel or AMD processor 1GHz

Preferred: Intel or AMD processor Dual-Core 2GHz

RAM Minimal: 2 GB

Preferred: 4 GB

Hard disk Minimal: 100 MB for each window user

Video card DirectX 10 compliant

Screen Minimal: 1280x1024 resolution Preferred: 1680x1050

Network Ethernet 100/1000 MBit/s

Note



PCs used in an environment in contact with patients must comply with the EN60601-1-1 standard.

1.5 DUTIES OF THE RESPONSIBLE ORGANISATION

The responsible organisation assumes the following responsibilities:

- Compliance with the national or local regulations for installation, operation, use and maintenance;
- Compliance with workplace health and safety regulations;
- Permanent availability of the Operating Instructions.



Warning

The IT environment must be maintained and protected as defined in the Service Manual.

1.6 OPERATOR RESPONSIBILITY

The following must be observed when entering parameters. The parameters entered must be verified by the operator, i.e. the operator must check that the values entered are correct. Should the desired value deviate from the parameters displayed, the setting must be corrected before activating the function. The current values displayed must be compared with the desired values.

Note

Fault reports



In the EU, users must report any serious anomalies that may occur to the manufacturer. The report must be made to the manufacturer of the device based on the label and to the competent authority in the EU Member State where treatment is performed.

1.6.1 OPERATIONS



Warning

Therapy Support Suite can work properly only once all hardware and software requirements have been met and each component has been installed and configured correctly.

Installation and configuration must be performed by qualified technical personnel.

A hardware or software error can lead to corruption of the treatment data displayed by Therapy Support Suite. Errors in treatment decisions may be made on the basis of these incorrect data.

Treatment data received from the device cannot substitute good clinical judgement. The patient and all available data should be evaluated by the physician.

PC hardware and software requirements as well as installation and configuration instructions are available in the Therapy Support Suite Service Manual.



Warning

It is strongly recommended that the user/principal encrypts the data in the TSS Database. If the database is not encrypted and someone steals the database files, there may be a loss of personal patient data.

1.6.2 DOCUMENTS REFERENCED

- Therapy Monitor Instructions for Use
- TSS Service Manual
- Functional Manual for the DataProtection 1.9.0.0 Plugin

1.7 LIABILITY DISCLAIMER

The software has been developed for the functions described in the User Manual. The manufacturer assumes no liability for personal injury or other damages and excludes any warranty for damages to the system and the software resulting from the use of non-approved or unsuitable accessories.

Please check the list of accessories:

- Therapy Monitor
- cDL Interface
- Patient OnLine

1.8 WARRANTY

Guarantee extensions The extent of the guarantee is stipulated in the respective purchase orders.

Warranty The purchaser's warranty rights are governed by the applicable legal regulations.

1.9 CE MARK

Therapy Support Suite, version: 1.9

C E 0123

Fresenius Medical Care AG & Co. KGaA

Else-Kröner-Str.1

61352 Bad Homburg

Germany

Phone: ++49-(0)6172-609-0

Declaration of Conformity certificate available upon request.

1.10 CERTIFICATES

The products covered by this technical documentation are Class IIa medical devices pursuant to Standard 11 of Annex VII to Regulation (EU) 2017/745 (MDR).

Upon request, the current versions of the CE certificates will be provided by local support.

1.11 SVHC (REACH)

For information on SVHC, pursuant to Article 33 of Regulation (EC) No 1907/2006 ("REACH"), please refer to the following page:

www.freseniusmedicalcare.com/en/svhc



1.12 HELP AND SUPPORT

Please forward any requests to:

1.12.1 MANUFACTURER

Fresenius Medical Care AG & Co. KGaA

Else-Kröner-Str.1

61352 Bad Homburg, GERMANY

Phone: ++49-(0)6172-609-0

www.fmc-ag.com

1.12.2 SERVICE

Fresenius Medical Care Deutschland GmbH

Geschäftsbereich Zentraleuropa

Projektierung & Support Dialyse-IT-Systeme

Steinmühlstraße 24, Anbau 1

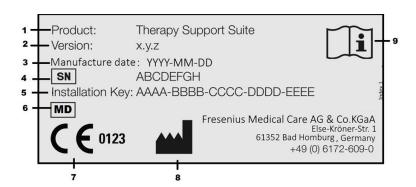
61352 Bad Homburg, GERMANY

Phone: +49 6172 609-7000

Fax: +49 6172 609-7106

E-mail: dialysis-it@fmc-ag.com

1.13 IDENTIFICATION LABEL



- 1. Product
- 2. Version
- 3. Date of manufacture (compilation date on the software product)
- 4. Serial number
- 5. Installation key
- 6. MD (Medical Device)
- 7. CE mark (CE0123)
- 8. Manufacturer contact details
- 9. See User Manual

1.14 SYMBOLS

In compliance with applicable legal and regulatory requirements, the following symbols are used in the Information menu or on the identification label:



See User Manual



CE mark



Manufacturer



Serial number

MD

MD (Medical Device)

1.15 GENERAL DATA PROTECTION REGULATION (GDPR)

GDPR (General Data Protection Regulation) is a law enacted in the European Union to ensure the security and privacy of sensitive data.

The dedicated features listed below have been implemented in the Therapy Support Suite:

- All sensitive patient data in the Therapy Support Suite database have either been encrypted or pseudonymised depending on the configuration;
- All sensitive user data in the FME User Management database have been encrypted;
- All communications between the components of the Therapy Support Suite listed below have been encrypted:
 - TSS Client Vs TSS Server;
 - TSS Server Vs #400;
 - TSS Server Vs #401;
 - TSS Server Vs #55.
- The integrity of all communications is ensured by specific technical features such as cyclic redundancy check;
- Sensitive patient data is used only when strictly necessary, such as, for example, when it is mandatory and vital
 to correctly identify the patient;
- Patients can request a printed report of the most common patient data set processed over a specific time period by the Therapy Support Suite. If a patient requests a different or extended data set, it is possible to generate an agreed report upon request.
- Patients may request that their sensitive data be anonymised or deleted from the Therapy Support Suite. This
 is made possible by the Data Protection Plugin;
- Patients may request a copy of their personal and clinical data in a computer readable format for a defined period of time saved in the Therapy Support Suite.
- Patients may request that their personal data be corrected in the Therapy Support Suite;
- Therapy Support Suite logs all actions performed by users. Logs of the operations performed by each user can be filtered using different search criteria and can be displayed and printed;
- Each user operations log not only records all data entry or deletion operations completed by the user but also the reading, which gives a detailed record of all information read, modified or deleted by any user;
- Therapy Support Suite uses a complex user access management system, which includes user authentication, authorisation, roles, permissions, etc. Only users with the correct permissions can access certain features of the Therapy Support Suite.

- Therapy Support Suite applies a special permission that allows only those users who are using it to edit or delete information entered by other users. Depending on the configurable security level defined by the client, Therapy Support Suite will require users to log in when the application starts up or after a logout due to a system timeout;
- Therapy Support Suite's security measures are configurable;
- Pseudonymisation of sensitive data can be applied during data export or report generation.

Please refer to the DataProtection 1.9.0.0 Functional Manual for further details and information on the functionality provided by this plugin.

1.15.1 SENSITIVE DATA PROCESSED BY THERAPY SUPPORT SUITE

Sensitive patient data (i.e. those data that might be pseudonymised or encrypted) can be defined by users. Therapy Support Suite defines an initial set of sensitive data, comprising a patient's administrative and clinical data, normally identified as sensitive. The default pool of sensitive data is defined as such because these data are involved in identifying the patient's identity, his or her closest relatives or organising transportation.

This data set can be expanded or reduced by selecting the properties of the dedicated fields in the Designer role functionality.

1.15.2 USER TOPICS AND SPECIFIC FEATURES

As already mentioned, Therapy Support Suite has introduced a set of features that ensure data security and privacy, especially when used together with the TSS Data Protection plugin. The plugin enables a user configuration option that provides access to a specific section of the Therapy Support Suite menu. Through this, the following features will be enabled:

- Extract patient data in a legible format
- Physically delete patient data
- Anonymise patient data
- Extract and delete patient data
- Extract and anonymise patient data
- Removal of sensitive data from the clinic staff section if those subjects are no longer authorised to use the system

Please refer to the DataProtection 1.9.0.0 Functional Manual for further details and information.

There is a second specific option (also available without the TSS Data Protection plugin) that can be enabled for each user that allows data export and printing from the Therapy Support Suite.

As explained in detail in the TSS Service Manual, a user, for whom this last option has been enabled, can choose a special data pseudonymisation feature in a scenario where sensitive data is going to be involved in data export or report printing

2 INSTALLATION AND START-UP

Please refer to the Therapy Support Suite Service Manual for all information regarding Therapy Support Suite installation steps.

3 GENERAL PROGRAM OPERATION

Therapy Support Suite has been developed for the user-friendly Windows operating system.

In this document, we assume that the user is familiar with the basic operating functions in Windows. These include functions such as starting and exiting Windows, starting a program, using the mouse (left-click, double-click, right-click) and opening, moving and deleting files.

This chapter describes the basic operating functions of Therapy Support Suite. It also provides information regarding terms and their meanings in the User Manual.

3.1 STARTING AND EXITING THE PROGRAM

Therapy Support Suite can be started in several ways:

The first way is using the icon on the Windows desktop (if available): double-click the Therapy Support Suite icon or right-click the icon and then left-click Open.

The program can also be started using the Start Menu (Start \rightarrow All Programs \rightarrow Fresenius Medical Care \rightarrow Therapy Support Suite)

When the software is loaded, a window is displayed showing the product logo, with the version number in the bottom right-hand corner.



The cursor automatically locates on the user name field. Enter your username and password and click the access button.

If "Login Assistance" was selected when the service was installed, as soon as the first two letters of the user name have been typed, a list of all users whose name starts with those letters will appear.

If the credentials entered are correct, you will be logged on as an active user and allowed to work with Therapy Support Suite. For further information about user management, please refer to the Fresenius Interface Server User Management documentation.

3.2 WINDOW LAYOUT

The Therapy Support Suite application window is divided into three principal areas: the Top Bar, the Navigation Bar and the Summary.

Top Bar



This bar allows the user to access a specific area of Therapy Support Suite. The third tab shows the name of the clinic, and where there are several clinics the user can switch between them without having to log in and out every time. This section shows/hides areas depending on the user permissions of the specific user's account (e.g. an administrator account will see more options than a 'normal' user).

The Suite button on the left-hand side of this section allows the user to perform specific operations related to his/her profile (e.g. activate special roles or view the Therapy Support Suite version).



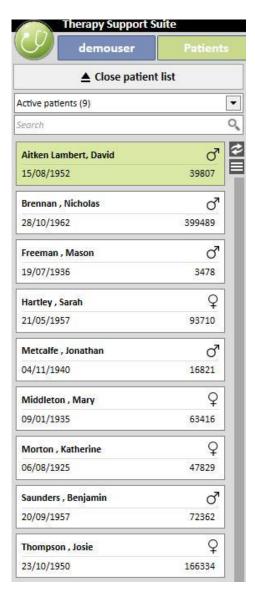
Navigation Bar

This menu contains sub-sections related to the general area selected in the section menu (the screenshot below refers to the Patient menu).



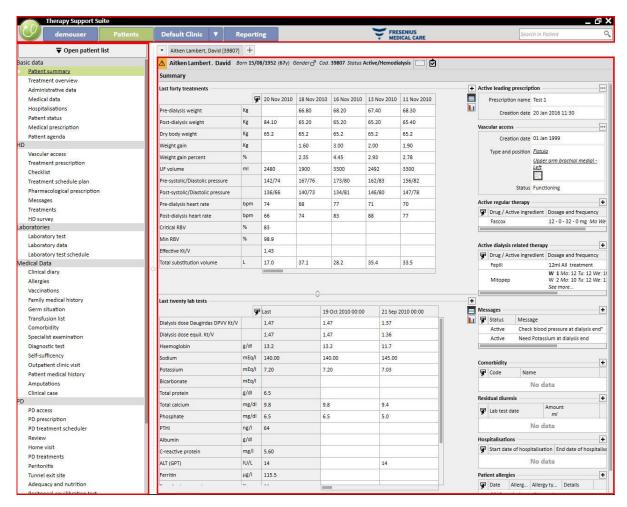
The Patient menu allows patients to be changed quickly with the aid of the "Patient List" window. This window can be opened by clicking the button or pressing **F3** on the keyboard. Display of the patient's photograph is disabled by default.

It can be activated in the "Clinic Manager" role, by clicking on "Configuration parameters" and setting the "Hide patient picture" field to "No".



Summary

This area displays details of the selection made in the Top/Navigation Bar. For example, if a patient is selected from the Patient List, his or her Summary page will be displayed by default in this section.



3.3 WINDOW CONTROL ELEMENTS

The Title bar is in the top of the screen and shows the name of the application on the left, with the following icons on the right:

minimises the program. This does not close Therapy Manager Support Suite but shifts The "Minimise" button it to the task bar where it can be clicked to call it up again. No entries can be made in windows which have been minimised. However, the processing of tasks continues in the background.

allows Therapy Support Suite to be used in a reduced view. If Therapy Support Suite is The "Restore" button restored with a smaller window, re-click the "Restore" button to return to the full-size window.

Click the "Close" button to



exit Therapy Support Suite.

Scroll bar

Click the scroll bar to move the contents of windows or fields up or down as required. If your mouse features a mouse wheel, this is a convenient way of moving the window up and down. If the window or field is displayed in its entirety, the scroll bars are invisible.

Cursor

The cursor (mouse pointer) only appears if a mouse is installed. If the mouse is moved, the position of the mouse pointer changes on the screen. If the computer is just executing a command, the mouse pointer changes its appearance into a wait cursor.

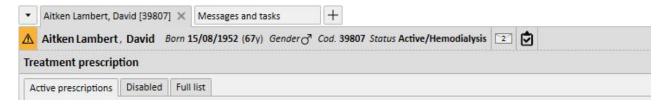
Button

Clicking a button will directly initiate the corresponding function (e.g. create/ save/ delete information).

3.4 TABS

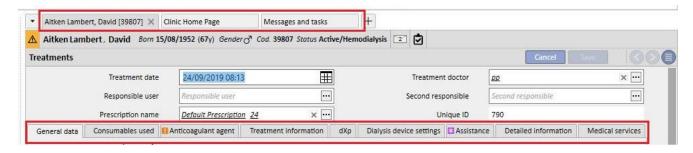
Window tabs

In Therapy Support Suite several tabs can be open at once. You can switch between them by navigating through the window tabs. The tabs can be closed using the close icon, with the exception of the last tab which always remains visible with the close icon deactivated.



Tab

Some sections are divided into sub-areas. In such cases you can navigate through them by clicking your tab of choice. For example, see the second selection in the screenshot below:



3.5 BUTTONS WITHIN THE APPLICATION

Therapy Support Suite features buttons for functions that are required frequently. Clicking on these buttons allows you to directly open tabs or execute commands.

▼ Open patient list	Opens the Patient List
▲ Close patient list	Closes the Patient List (or press F3)
③	Returns to the previous item in a series of data (e.g. Laboratory tests)
	Moves on to the next of a series of data (e.g. Laboratory tests)
	Returns to the initial view of the section (e.g. when you are in a specific laboratory test, clicking this button returns you to the complete list of Laboratory tests)
+	Creates a new empty window tab.
×	Closes the relative window tab
Aitken Lambert , David Born 15/08/1952 (65y) Gender or Cod. 39807 Status Active/Hemod Patient risks Risks Allergies Date Allergy type Allergy type specification Details 2010 Active ingredient (Nunpan) 2009 Food Milk	Click this button in the patient header bar to open the "Patient Risks" window (this button is only displayed for patients with risks)
	Minimises patient details (only the patient's name will be shown, with no additional information)
	Maximises patient details (additional info is shown).
	Displays the data in the window in table mode
	Displays the data in the window in chart mode

	Displays the calendar and selects a specific date
New +	Creates a new item in the current section (e.g. Dialysis treatment, Laboratory test)
Delete	Deletes an item from a collection (this button can only be used by users who have the necessary permissions)
•••	Opens a pop-up that links to another section, (e.g. to open Consumables List/Vascular Accesses from the HD Prescription section). The user must select an item or press the Cancel button to close the pop-up
Cancel	Exits the current section without saving pending changes
Save	Saves the pending changes made to a section. If this button is 'grey shaded' saving is not possible. This occurs when a mandatory field is empty or incorrect or when there are no pending changes
Copy to	Enables the user to make a copy of the current section (e.g. to duplicate the dialysis prescription).
Print	Opens and prints reports related to the current section.
Export Excel	Exports the current view to Excel (e.g. lab tests, HD Treatments). Once the export is complete, the new file will be automatically opened by the default program for the extension .xlsx (for example: Microsoft Excel, Open Office, etc)
Add new	Opens a window and prepares for creation of a new element (e.g. Pharmacological therapy)
Suspend	Opens a pop-up where it is possible to suspend an Active drug.
Terminate	Terminates an Active drug.
Reactivate	Opens a pop-up where it is possible to reactivate a Suspended drug.

Suspended	Opens a pop-up where it is possible to modify the suspension date or cancel the suspension of an active drug for which a future suspension has been inserted.
Delete suspension	Cancels the suspension of a drug before the suspension start date is reached.
Copy to	Creates a pharmacological prescription identical to the one which has just ended, except for the start and end dates.
Print prescription	Opens the pop-up for preparation of the Italian NHS red prescription form.
Select from Shift Group	Used for planning the treatment schedule.
Optimise shift and resources	Used to optimise the planning of the treatment schedule.
Remove all scheduling	Used to remove all the treatment schedules with a single click.
V	Used to switch clinics if TSS is configured for more than one clinic.
Create donor data	Used to access the donor data creation window directly from the administrative data
Export	Used to export inactive patients.
New movement	Used to create a new transplant waiting list movement
New transplant	Used to create a new transplant
See transplant	Used to view a transplant already created
Add failure	Used to record a failure for a transplant already performed

New	Used to create a new entity (for example medical orders or scheduled Laboratory tests)
Perform	Used to perform an outpatient clinic visit
No show	Used to mark a scheduled visit as a no-show
Confirm	Used to confirm the creation of an off-line patient transfer.
Import data	Used to start importing the data of an off-line patient transfer
Import	Used to import the data of an off-line patient transfer
Confirm review	Used to confirm the data imported by means of an off-line patient transfer
View import data	Used to review the data imported by means of an off-line patient transfer
See lab test	Used to display Laboratory tests
Close treatments	Used to close multiple treatments, both PD or HD
Close	Used to close individual treatments/consultation visits
Re-open	Used to re-open individual treatments/consultation visits previously closed
Create treatments from scheduling	Used to create treatments for peritoneal dialysis patients directly from the clinic schedule
Delete real treatments	Used to delete treatments for peritoneal dialysis patients directly from the clinic schedule
New message	Allows the creation of a new message to be sent to one or more recipients

New task	Allows the creation of a new task to be assigned to one or more recipients
Send	Allows a message/task to be sent once the recipients and subject have been entered
Refresh	Updates the list of messages/tasks displayed in the relevant table
Reserve	Allows the current user to book a task for him or herself
Add comment	Adds a new comment to a task
Remove reserve	Allows the current user to remove a booked task
Reject	Closes a task with "Refused" status
Complete	Closes a task with "Completed" status
Archive	Moves the selected messages/tasks to the corresponding section of the archive
Second endorsements	Allows a pop-up to open that shows the second missing approvals for a HD treatment if the option has been enabled.
	Indicates the presence of a "Message" type element
™	Indicates the presence of a "Scheduled Message" type element
	Indicates the presence of a "Task" type element
	Indicates the need for the recipient to confirm/refuse a message
	Indicates the presence of one or more files attached to the message/activity

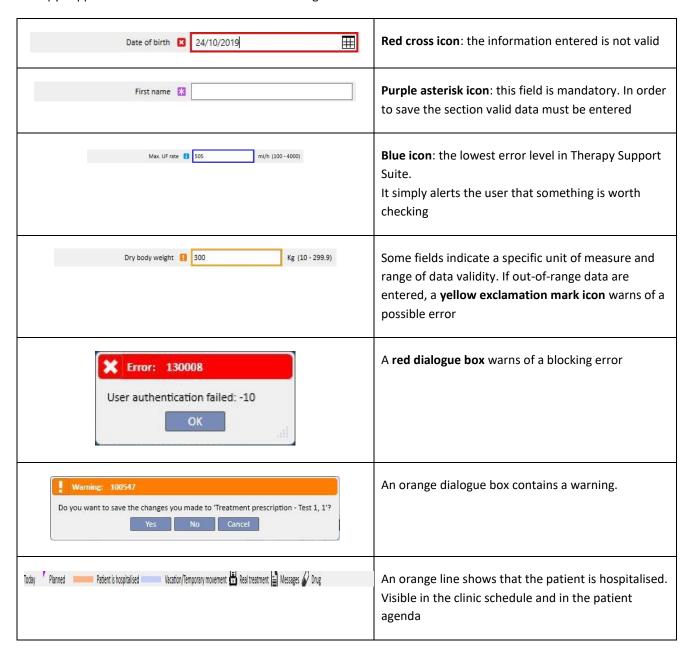
S	Indicates the presence of one or more elements linked to the message/activity
8	Indicates that a task is booked by a user connected to TSS
1	Indicates that a task has been booked by others
See history	Allows the medical data log to be viewed
	Therapy to be administered at home
€ 2	Therapy to be administered during dialysis
	Therapy to be administered as needed
Ш	Suspended therapy
>	Indicates that a medical order is valid for unscheduled treatments
(65)	Copies the PD solution (or volumes or standby time) to the next cycle
	Copies the PD solution (or volumes or standby time) to subsequent cycles of the same base cycle
\$ 3	Copies the PD solution (or volumes or standby time) to the cycle corresponding to subsequent base cycles
[2]	Copies the values of all cycles of a base cycle into the subsequent base cycles (only available on the first cycle of each base cycle)
H	Indicates that the patient is hospitalised
(A)	Magnifies an image or graph to be

	Displays the data of a treatment already performed (viewable in the clinic scheduler)
	Displays the data of a treatment scheduled for the future (viewable in the clinic scheduler by resource)
	Displays the conflicts between treatments (viewable in the clinic scheduler by resource in weekly view)
	Displays the drugs for a scheduled treatment (viewable in the clinic scheduler)
A	Displays the scheduled laboratory tests for a scheduled treatment (viewable in the clinic scheduler)
	Displays the medical orders for a scheduled treatment (visible from the clinic scheduler)
	Selects an image and attaches it to the correlated entity
	Pastes an image in the Windows clipboard
2	Refreshes the current section (e.g. Clinic Scheduler).
⊠.	Roll the cursor over this button to see the preview of the linked image
罗	Selects the columns to be displayed and their order. Available in all sections.
=	Roll the cursor over this button to view the interaction of the drug chosen for administration with the drugs already administered
	Roll the cursor over this button to see whether the drug's active ingredient has already been prescribed.
A	Roll the cursor over this button to see whether the patient is allergic to the active ingredient.

×	Clears the contents of a field (if applicable).
0	Shows the identity of the user who has modified a field (only visible in the Euro transplant data section)
0	Shows the date of the last modification, the expiry date and the user who has modified a field (only visible in the Euro transplant data section)
×	Used to exclude a test from a prescription printout, starting from the scheduled tests by clinic
2	Used to include a test on a prescription printout, starting from the scheduled tests by clinic
2	With the "Designer" role enabled, users can customize the content of the pull-down fields
Drag and drop to add new item	With the "Designer" role enabled, a new value can be created inside a pull-down field.

3.6 INFORMATIVE SYMBOLS USED IN THE APPLICATION

Therapy Support Suite uses a number of icon and dialogue window conventions





Note

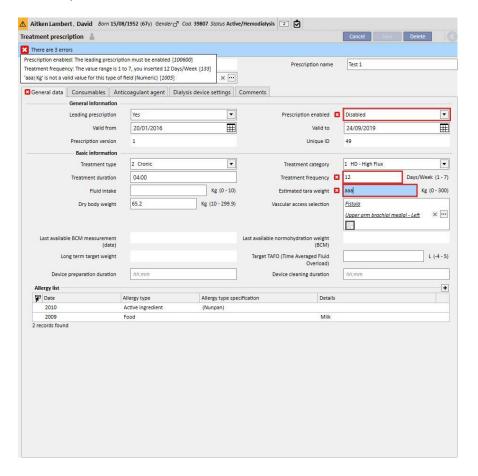
When the cursor is moved over any of the **information symbols**, a message containing the relative information appears.



Note

If a section contains an invalid value information symbol, a number in the tab at the top indicates the number of errors. Drag the mouse over the error icon to show all the descriptions of the invalid data errors.

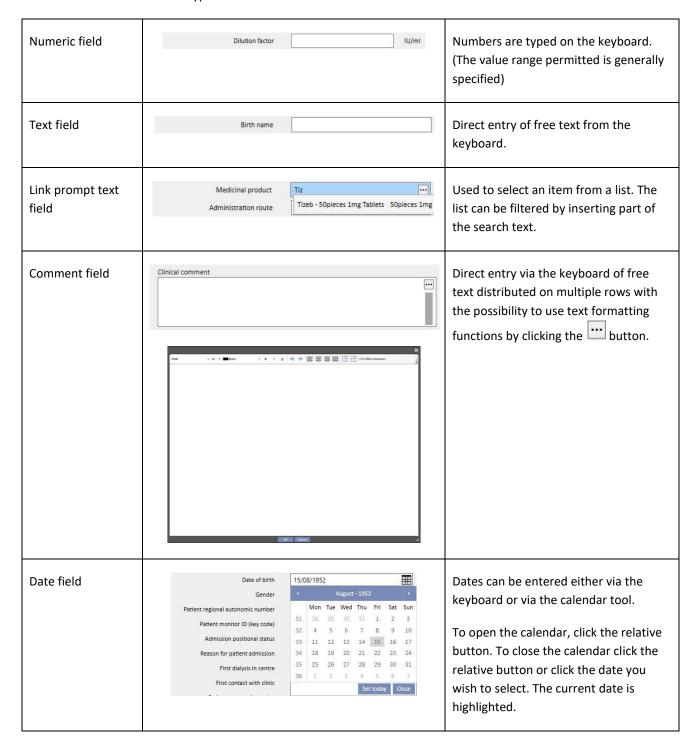
See example below.



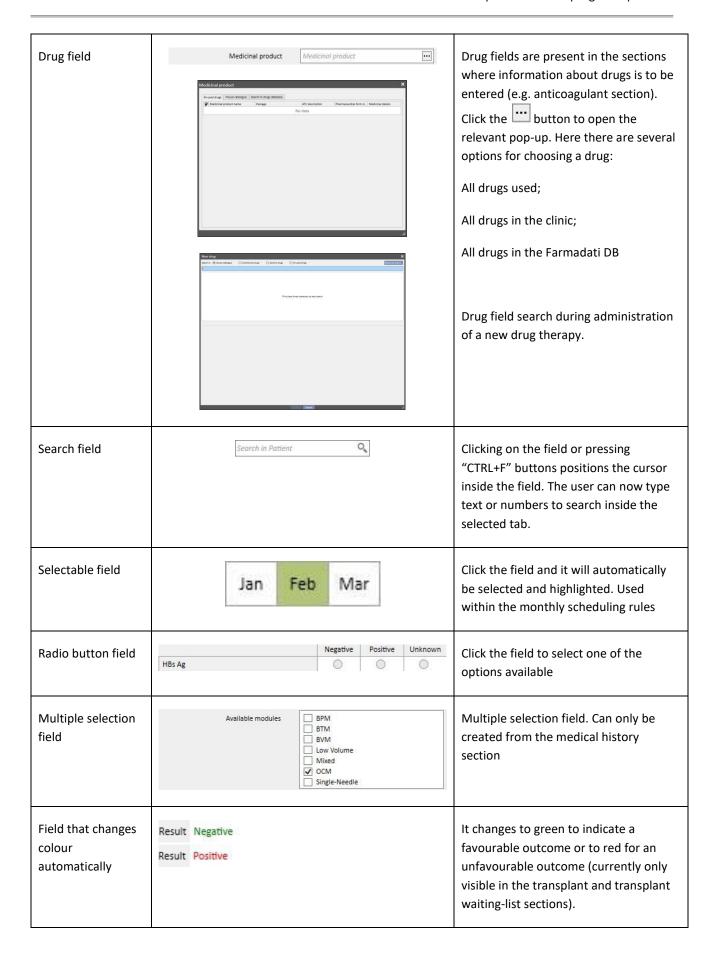
The tab shows the icon related to the most important error.

3.7 INPUT FIELDS AND HOW TO USE THEM

Therapy Support Suite provides the same types of input fields for data entry throughout the program. The way they are used depends on the type of data they are intended to contain. The table below provides an overview of the main characteristics of the different types of field.



Hemodialysis Admission dialysis status Select from a Drop-down lists allow the user to select Admission date "drop-down list" or items from a list. Hemodialysis Hemodialysis (ICU) make a Hemodialysis (Acute) Click the field arrow to open the list. "drop-down" Peritoneal dialysis Click the field arrow or select a value Selection Pre-dialysis Transplant follow-up from the list to close it. Not available Donor candidate Clicking the button opens a user-User-defined list defined list. Users with specific roles in the clinic are able to create or modify these customised lists. Click an item to select a value and exit from the list (or double click the selection) Multi-value field This field can be composed of multiple rows (values). To add a new row, click the button. To delete a row, click the button. I Fill each row with the values required. Disease field Disease fields are found in all sections where a disease has to be recorded (e.g. Renal disease or other disease). Click the button to open the disease "Editor". Then there are three ways to search for the comorbidity (one for each tab: search, search by renal diseases, search by code). Enter the description of the disease; Enter the name of the renal disease; enter the disease catalogue code; Click the disease to complete the field correctly



4 SEARCH FIELD

It is possible to search for elements of menus, messages, patients, entity and data fields using the search box in the top right hand corner.

4.1 START A SEARCH

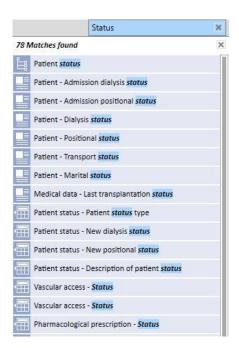
To start a search, click inside the search box or simply press "CTRL+F" on the keyboard. The text search is only carried out within the current section (if you are in the Patient section, the system only looks for the requested text in that section).



To search in the "Dialysis unit" section, click on that section with the cursor.



To start to get results, it is necessary to type at least two characters in the search field. As the user gradually types in more characters the research is updated, gradually excluding results which no longer correspond to the requested search.



The list of results can be hidden by clicking on any part of the screen outside the list. To see the results again, start typing again or press "Send" after clicking on the search box.

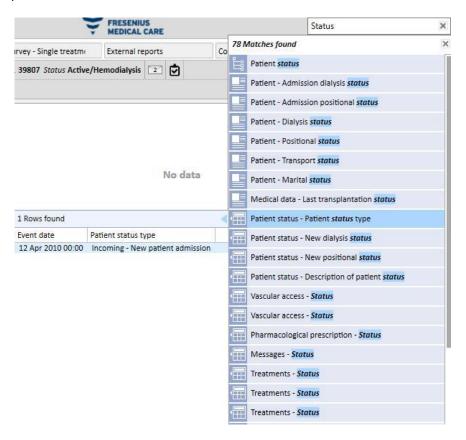
It is possible to remove the typing by clicking on the button on the far right of the search box. The text and the search results are then deleted.

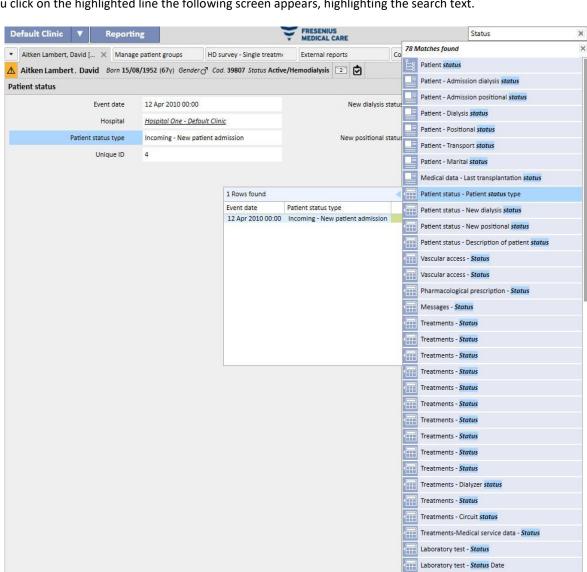
4.2 INTERPRETING THE RESULTS

The results obtained are viewed in the search box. At the top of the list a number appears to show the number of references found. Every element of the list is composed of:

- Icon: this defines the type of entity found:
 - The search text is part of the name of a patient;
 - The search text is part of a line in the navigation menu;
 - The search text is part of the name of an entity field;
 - The search text is part of an email message;
 - The search text is part of the object of a task or its identifier;
 - The search text is part of a data item that can have different values;
- Text: displays the search text inside the path to reach it. The search text appears in bold and is azure in colour.

See a search example below.





If you click on the highlighted line the following screen appears, highlighting the search text.

Laboratory test - Lab test Status Laboratory test - Status Date

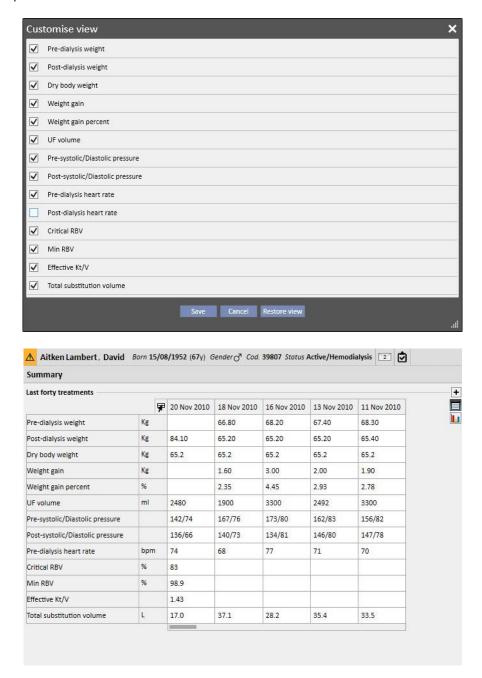
Laboratory data - HCV status (RIBA or Western Blot)

5 PERSONALISING THE VIEW

It is possible to personalise the view of Therapy Support Suite. Two main types of personalisation are possible: pivot view and standard view.

5.1 CUSTOMISATION OF A PIVOT VIEW

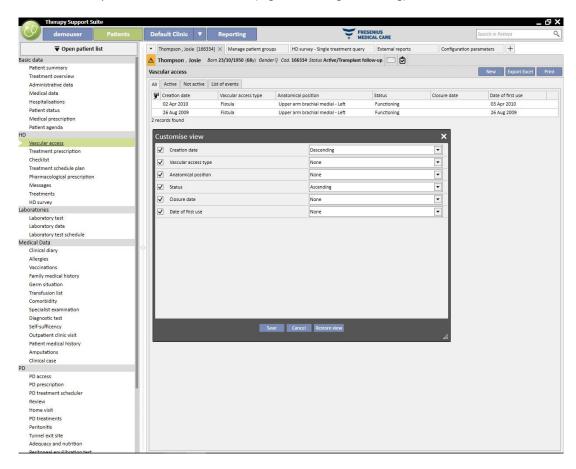
In the case of pivot views (for example the "Patient summary page", "Treatment overview", etc.), by clicking on the customise button it is possible to define which fields we want to see. All are ticked by default, and therefore visible. By removing the tick the field becomes invisible and disappears from the pivot view. It only becomes visible again by ticking the appropriate box.



Within the personalisation it is also possible to change the order of the data viewed, by keeping the mouse clicked on a field and dragging it to the new position.

5.2 CUSTOMISATION OF A STANDARD VIEW

For the standard views, by clicking on the appropriate button it is possible to define which fields we want to see (by using the flag to the left of the field name), and in which order we want to see them (again by dragging), but unlike the Pivot views it is also possible to define the order (e.g. descending, ascending) in which we want to see them.



6 USER MANAGEMENT

User creation and management are administered directly by the Fresenius Interface Server.

For further information, see the documentation on Fresenius Therapy Monitor.

7 SUITE MENU

7.1 SUITE MENU USER MANAGEMENT

7.1.1 ACTIVATION OF ROLES

A role can be activated via the Suite menu. Click on the Suite menu, move the mouse cursor to User Roles and click on the desired role to activate or deactivate it. When a role is active, the symbol appears to the left of its description.



Note



For a role to be displayed in the Suite menu, it has to be activated through the Fresenius Medical Care User Management application.

7.1.1.1 DESCRIPTION OF ROLES

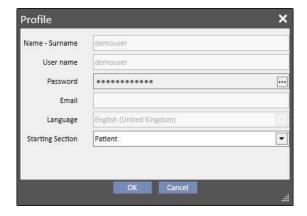
Role	Permissions enabled	Feedback on Therapy Support Suite	References
Administrator	Enables the Therapy Support Suite User Management session and the Batch Commands Window section.	Batch Commands Windows entry in Suite menu.	
Clinic Manager	Access to Menu Entities. Clinic configuration and personalisation of the clinic's list of elements.	"Clinic Master Data" main section available.	

Security Manager	Enables you to see all logging information.	"Logging" main section available. "See Deleted Entities" button available on each Therapy Support Suite view. "Open entity log" button available on each Therapy Support Suite entity form.	Logging Menu
Developer	Shows the system name of each Therapy Support Suite field.	The field name appears under the description label.	
User Activity Viewer	Gives the user access to the User Activity window	"User activity" becomes visible in the suite menu.	Suite menu

7.1.2 USER PROFILE

This section allows you to change your user preferences:

The section of Therapy Support Suite shown after the login



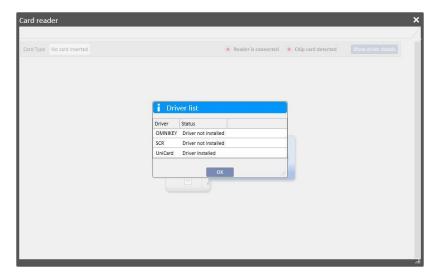
As shown in the following image, by clicking on the three dots next to the field "Password", it is possible to change the password:



7.2 PATIENT CARD READER

This section allows you to prepare a Patient card for integration with other components of TDMS. In other words, it allows management of the patient card to be used as the identifier of the patient in the TDMS components.

- The card reader can be activated via the Suite menu. Click on Suite menu, move the cursor to card reader and click.
- The header informs you about the status of the card reader with 2 LED indicator (whether the card reader is connected or not, chipcard detected or not) that can be green or red depending on the positive or negative status and the button "Show driver details" that will open a pop up where are shown the installed driver. In the header there is also the Card Type field that informs you which type of card is inserted (this can be a Patient card, a BCM card, a Patient card with BCM extension, an empty card or an invalid card if the card is not recognised by the system).



- The Patient card section displays confidential patient data contained in the chip card, listing the last recorded dialysis treatment for the patient at the bottom. The rows of this section show the most important data of every single treatment. By clicking on a row the system opens up the treatment details.
- The BCM section displays the confidential BCM patient data contained in the chip card, listing the last recorded BCM measurements at the bottom. The rows of this section show the most important data of every single measurement. By clicking on a row the system opens up the measurement details.



The Card Reader window provides a set of buttons that let you interact and execute actions on the card:

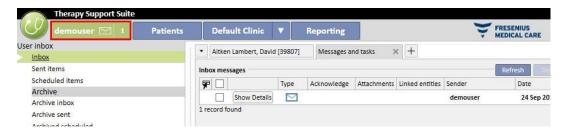
- Create. You can create a new Patient card with BCM extension selecting the patient from the clinic's patient list
- Create BCM chipcard. You can create a new patient card only for BCM selecting the patient from the clinic's patient list.
- Import. You can import different information into Therapy Support Suite from the card:
 - HD treatments
 - BCM measurements
- Update. You can update certain information stored in the chipcard by taking them from Therapy Support Suite.
- **Delete.** You can delete:
 - the entire chipcard
 - the BCM measurements

8 USER

8.1 MESSAGING SYSTEM

8.1.1 USER INBOX

The Therapy Support Suite messaging system allows you to send/receive messages and tasks (activities) to/from clinic staff. The **User tab** button displays information about unread messages.

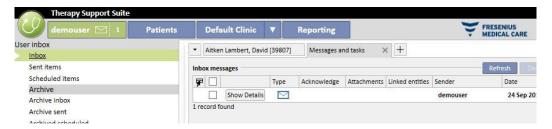


When a new message arrives for the user connected to the system, the user tab button will flash alternately green and azure and the message count will increase. This number is given by the sum of the *Unread messages* with the tasks in a *Received* status and *Reserved by me*.

To open a message or task, click on the **Show details** button.

The **User inbox** section contains six menu entries:

- Inbox: all unread messages received by the user;
- Sent messages: list of messages that have been sent by the user;
- Scheduled messages: messages that have been scheduled for future delivery.
- Archived inbox: all important messages that the user saved (by clicking on "Archive" button). Archived
 messages are marked with a floppy disk icon;
- Archived sent: all important messages that the user saved (by clicking on "Archive" button). Archived messages
 are marked with a floppy disk icon;
- Archived scheduled: all important messages that the user saved (by clicking on "Archive" button). Archived
 messages are marked with a floppy disk icon;

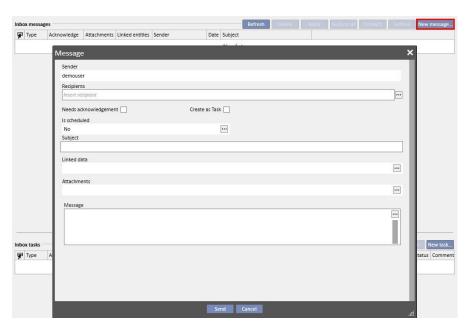


TSS messaging is divided into two different modes: messages and tasks. .

8.2 MESSAGES

8.2.1 CREATE A NEW MESSAGE

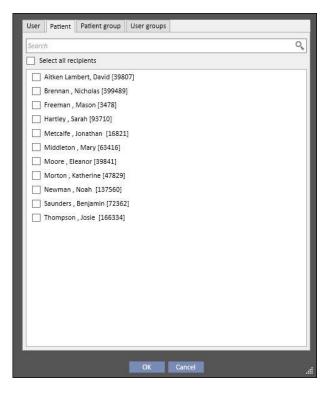
To create a new message, click the button in the email inbox section. To populate the list of recipients you can type their name in the **Recipients** box or select them from the pop-up window by clicking on the button:



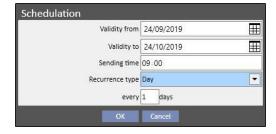
- Recipients: In this custom list there are different ways to identify the recipient of the message;
- Users: This tab lists all users. You may select more than one recipient;



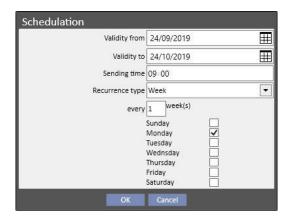
• Patient: This tab lists all patients. Users may select one or more patients to target this message with. In this case all users that go into the Patient Inbox section will see this message;



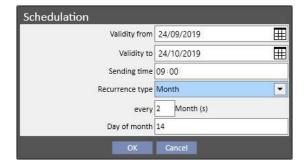
- Patient group: This tab lists the patient groups. The user can select one or more patient groups. The message
 will be displayed in all Inbox sections related to patients belonging to the selected patient groups;
- Group of FIS patients: This tab lists the groups of patients created by FIS. The user can select one or more
 patient groups. The message will be displayed in all Inbox sections related to patients belonging to the selected
 patient groups;
- Sender: Read-only field, filled in automatically with the name of the logged-on user;
- Acknowledgement needed: Allows you to specify if a receipt is required from each receiver who reads the message;
- Create as task: Allows automatic movement to the task mode.
- **Is scheduled**: Enabled only if this is a new message. Custom list that allows you to schedule the message with the following options:
 - Define daily message scheduling:



Define weekly message scheduling:



Define monthly message scheduling:



- **Subject**: Text field containing the title of the message;
- Linked Data: In this custom list you can add to the message entity belonging to a certain patient. By clicking on the button, a pop-up will appear asking you to select a patient and a specific patient's data (prescription, treatment, vascular access, etc.) or entities belonging to the configuration sections (if the user has permissions to view them) or the Dialysis Clinic.
- Attachments: In this field you can select multiple files stored on your computer and attach them to the message;
- Message: Text field where you can insert the body of the message.

8.2.2 PRINT A MESSAGE

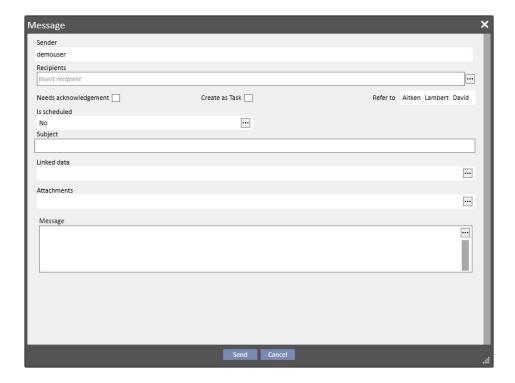
A message can be printed by opening it with a double-click and clicking on the **Print**button in the pop-up window that shows the details of the message.

8.2.3 PATIENT INBOX

In the patient top bar there is an envelope button. When you send messages with a certain related patient, this button shows that someone sent information about the selected patient. By clicking on the envelope button, the **Inbox** section is automatically opened and the sent message (in the example "sent by Test User") is shown. When the message has been read the *mark* on the envelope disappears.



Inside the previous view, by clicking on the button, the message form appears. The only difference is that the Refer to field is automatically filled in with the relevant patient name. This is a read-only field.



8.3 TASKS

Tasks are messages that must comply with a predefined flow of states and that only users (or user groups) and not patients are intended as recipients. Inside the user tab you can find the tasks received in the area at the bottom of the main window.

The progress flow of the states, after the creation of the task, is as follows. The initial state is **Received**. As long as this is the status, the user who generated the task can make changes by opening the task, changing it and clicking on **Refresh**.

When one of the recipients decides to take charge of the task, , he or she can do that by opening the task and clicking on the *Reserve* button, which gives the task a **Reserved** status. For all other recipients the status of the task becomes **Reserved by others**. Hereinafter, these recipients will not be able to operate on the activity unless they add comments to it.

The user who has reserved the task for him/herself, will have to analyse the content and work on it. At the end of the entire activity, based on its outcome, the task can be brought to the **Completed** state, if everything foreseen for that activity has been completed. If the task is incoherent, it can be refused using the **Refuse** option. The activity reservation can also be removed using the **Remove booking** button.

Each time the task progresses, the system will propose a possibility to the user to insert a comment to give a reason for a change of state. A comment is required to move a task to the *Refused* and *Completed* states as well as to *Remove booking*.

It is still possible for a task recipient to add a comment to it. The last comment entered can be updated, but only by the user who entered that comment.

All tasks to which a new comment has been added and that have not yet been read by the user will also appear in bold in the user inbox.

The Completed or Refused tasks can be archived by clicking the appropriate button.

New task

8.3.1 CREATE A NEW TASK

To create a new task, click on the button in the tasks received area. The fields to be filled in are the same as those described for messages with the following differences:

- The list of recipients can only include users and/or user groups
- The Create as task field is automatically selected
- The ability to schedule a task's transmission is inhibited.

Using the same procedure as used for messages, the contents of a task can also be printed.

8.3.2 TASK SECTION FOR THE SELECTED PATIENT

In the patient upper menu bar there is a folder button. When a task is sent with a certain related patient (or a specific patient entity) attached, this icon is displayed with an orange background. The number indicates how many tasks (not completed or rejected) there are for the patient or for one of its entities.



Clicking on the icon will open a pop-up that will list the tasks with their object and their status. If the task has been previously booked by the user connected to the system he or she can easily complete it by clicking on the complete button. Selecting a task in the list will open it in detail.



When navigation in patient entities is open in a *summary* entity, such as, for example, the summary page, or one of the lists that allows a patient entity to be selected, the task counter will display all tasks (not completed or rejected) that are listed for the patient or for one of its entities.

Instead, when navigation is open for a particular entity (e.g. allergy to a particular food) the indicator refers to that specific entity. In this case the user can also create a new task by directly attaching it to the open entity by clicking the **Create a task related to this entity** button from the task pop-up.

The same button is enabled in the pop-up, in the patient summary page and in the treatment overview page. Activating this will create a new task with just the patient attached.

9 PATIENTS

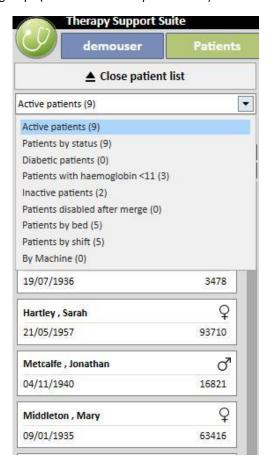
9.1 SELECTING A PATIENT

To select a patient simply click the Patients tab in the Sections menu. The patient list appears automatically. There are several ways to select a patient:

- Use the scroll bar to search through the full patient list;
- Enter part of the patient's name in the search bar. The patient list is updated in real time according to the letters entered in the search bar.

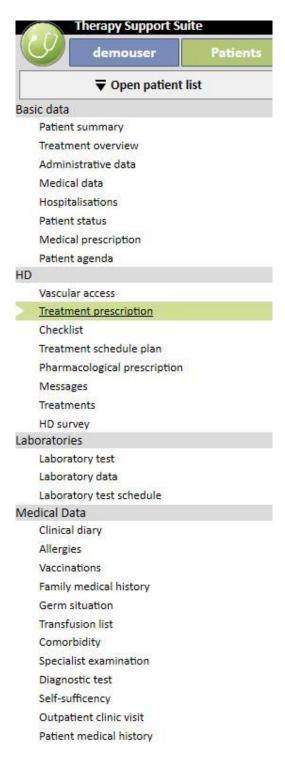


Select one of the patient groups (some of them are pre-entered).



When the zone relating to a specific patient is clicked it turns 'dark grey' and information related to the patient is loaded onto the screen. Double clicking on that area automatically collapses the patient list and the patient menu is displayed on the navigation bar.

The following screenshot shows the patients menu, which appears after selecting a patient and *collapsing the patient list*.



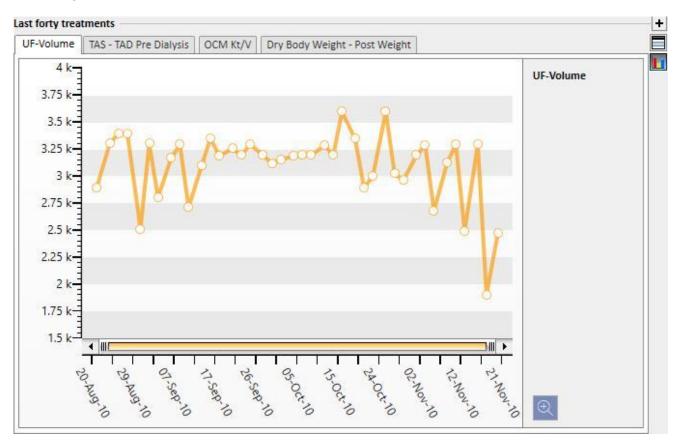
9.2 BASIC DATA

9.2.1 PATIENT SUMMARY

This section is the patient's Home Page. This section lists all the main information about the patient's dialysis history. The screenshots below display the default *summaries* with standard configurations. Users can also customise patient summaries in the "configuration parameters" of the "Master Data" (Clinic Manager) section.

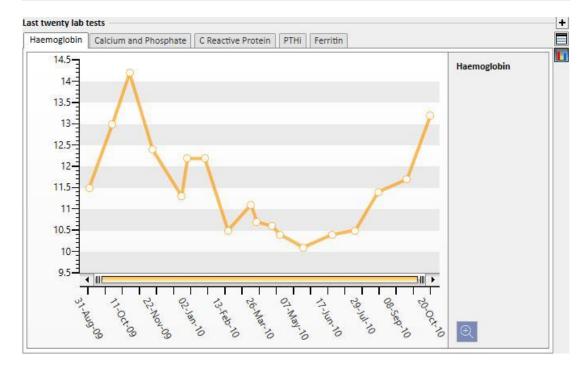
The HD patient dashboard shows:

• **HD Treatment History**: this screen contains the patient's last forty treatments, allowing the user to navigate easily through the details of each treatment, or simply to examine the trend of some key values via the chart view.



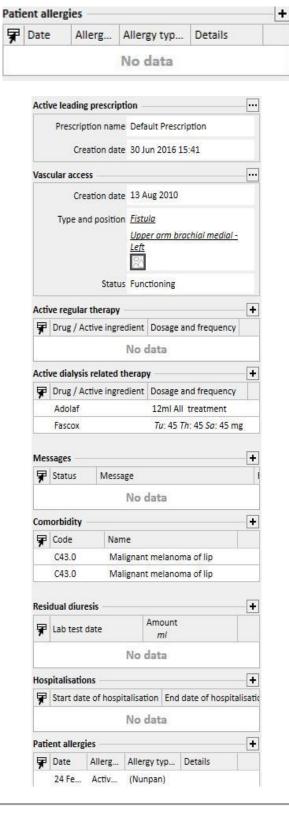
• **Laboratory test history**: this screen displays the patient's last twenty laboratory tests, allowing the user to navigate through them or examine the trend of some key values via the chart view.

	¥	Last	19 Oct 2010 00:00	21 Sep 2010 00:00
Dialysis dose Daugirdas DPVV Kt/V		1.47	1.47	1.37
Dialysis dose equil. Kt/V		1.47	1.47	1.36
Haemoglobin	g/dl	13.2	13.2	11.7
Sodium	mEq/I	140.00	140.00	145.00
Potass <mark>ium</mark>	mEq/I	7.20	7.20	7.03
Bicarbonate	mEq/I			
otal protein	g/dl	6.5		
otal calcium	mg/dl	9.8	9.8	9.4
Phosphate	mg/dl	6.5	6.5	5.0
THi	ng/I	64		ĺ
Albumin	g/dl			
C-reactive protein	mg/l	5.60		
ALT (GPT)	IU/L	14		14
erritin	μg/l	115.5	10	
		100		



- Active prescription: Review or edit the Active Prescription HD.
- Vascular access: Allows the review or change of the active Vascular Access.
- Active home medication: The user can view, modify or add new drugs prescribed to be taken at home.
- Active dialysis related therapy: Allows the view, change or addition of new drugs prescribed for the Dialysis
 Treatment.
- **Medical orders**: Allows all the patient's current medical orders, i.e. those with "active", "suspended" and "scheduled" status, to be checked and edited. New medical orders can also be added to the patient.

- Comorbidities: Shows all comorbidities affecting the patient, allowing the user to change them or add new ones
- **Residual diuresis**: A quick view of the patient's residual renal function based on laboratory test results. The user can modify the laboratory tests or add new ones.
- Hospitalisations: A quick view of the patient's hospitalisations.
- Patient allergies: Allows patient allergies to be viewed and managed.

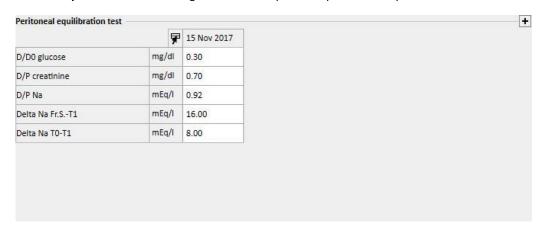


The PD patient dashboard shows:

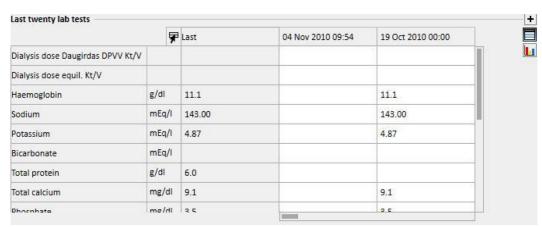
Adequacy and Nutrition: Navigable list of the patient's adequacy and nutrition information.



• Peritoneal Equilibration Test: Navigable list of the patient's peritoneal equilibration test information.



• Last 20 laboratory tests: The patient's last twenty laboratory tests, and trend of certain key values via the chart view.



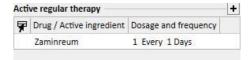
Last PD Prescription: The last PD Prescription can be viewed and edited.



PD Access: The active PD Access can be viewed and edited.



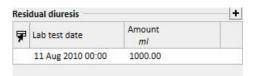
Active home therapy: The user can view, modify or add new drugs prescribed to be taken at home.



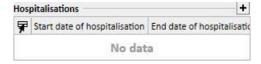
• Comorbidities: All comorbidities related to the patient, allowing the user to modify them or insert new ones.



• **Residual diuresis**: Quick view of the patient's residual renal function based on laboratory test results. The user can modify the laboratory test or add new ones.



Hospitalisations: A quick overview of the patient's hospitalisations.

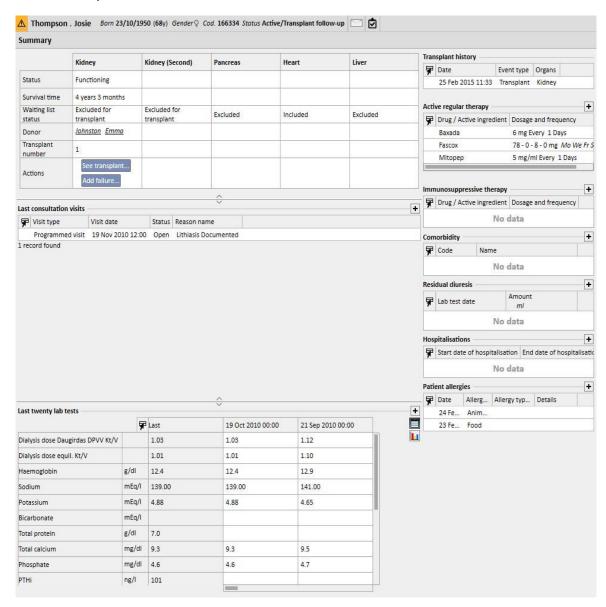


Patient allergies: Allows review and editing of the patient's allergies.

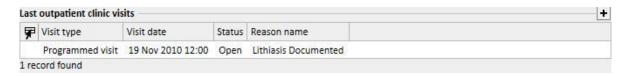


The Transplanted patient summary shows:

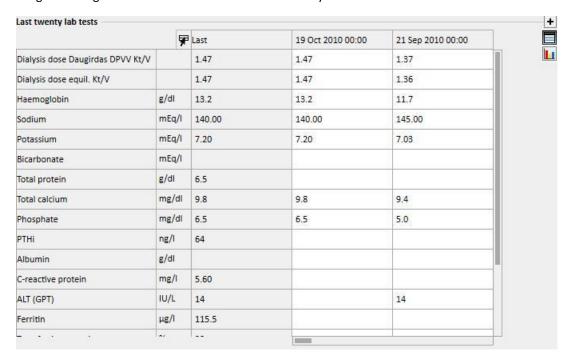
• Transplant summary: this is a summary of the transplants by organ. This section is the same of the one available in the Transplant menu.

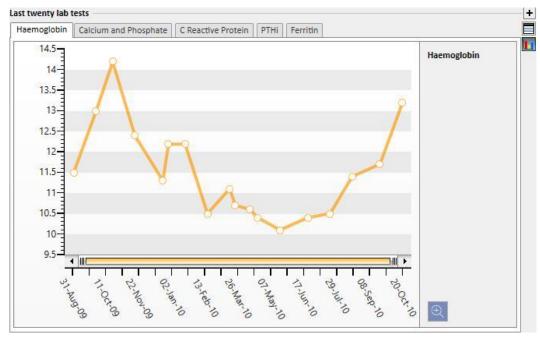


• Outpatient clinic visit history: here the last ten outpatient clinic visits are listed with the option to edit or just see some basic data.



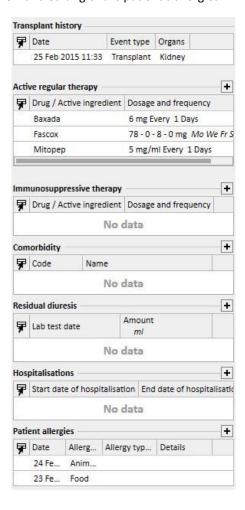
• Laboratory test history: this screen displays the patient's last twenty laboratory tests, allowing the user to navigate through them or examine the trend of some key values via the chart view.





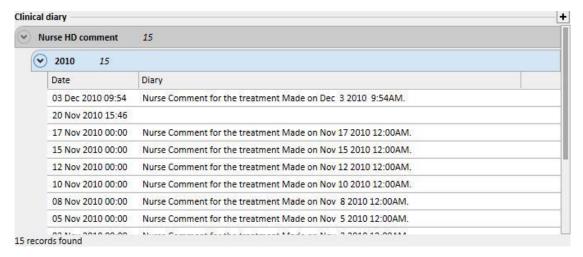
- Transplant history: Allows review and editing of all events related to the patient's transplants.
- Active home medication: The user can view, modify or add new drugs prescribed to be taken at home.
- Immunosuppressive therapy: The user can view, modify or add new immunosuppressive drugs.
- Comorbidities: Shows all comorbidities affecting the patient, allowing the user to change them or add new ones.
- **Residual diuresis**: Quick view of the patient's residual renal function based on his lab results. The user can modify the laboratory tests or add new ones.
- Hospitalisations: A quick view of the patient's hospitalisations.

Patient allergies: Allows review and editing of the patient's allergies.

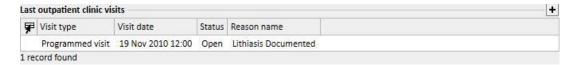


The outpatient dashboard shows:

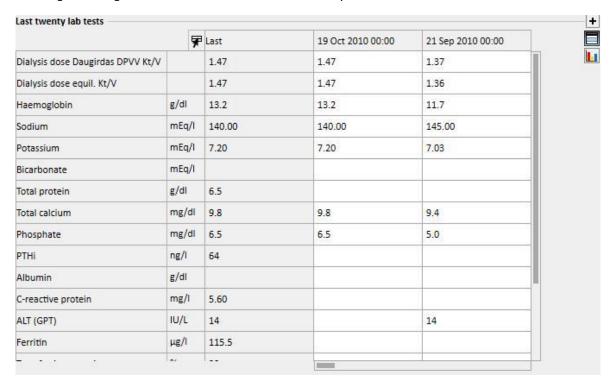
• **Clinical diary**: The Clinical diary section contains information about the clinical history of the patient. The view is very similar, though more compact, than what can be found in the Patient *Clinical Diary* menu item.

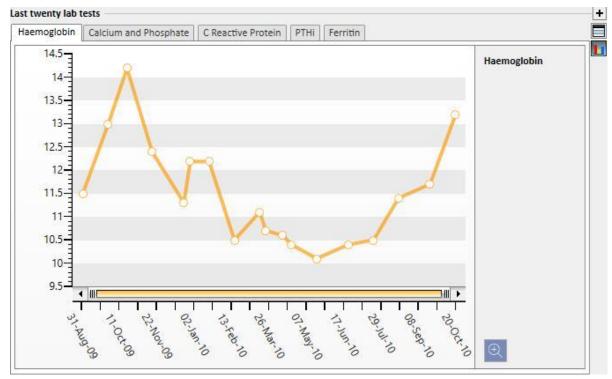


 Outpatient clinic visit history: here the last ten outpatient clinic visits are listed with the option to edit or just see some basic data.

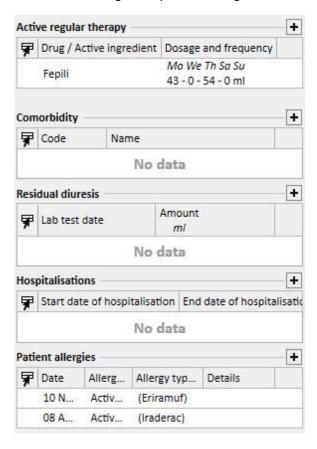


• Laboratory test history: this screen displays the patient's last twenty laboratory tests, allowing the user to navigate through them or examine the trend of some key values via the chart view.





- Active home medication: The user can view, modify or add new drugs prescribed to be taken at home.
- Comorbidities: Shows all comorbidities affecting the patient, allowing the user to change them or add new ones.
- **Residual diuresis**: Quick view of the patient's residual renal function based on his lab results. The user can modify the laboratory tests or add new ones.
- Hospitalisations: A quick view of the patient's hospitalisations.
- Patient allergies: Allows review and editing of the patient's allergies.



The left-hand side of both screens can be customised with a custom query; this allows the user to *enter* a *query* to be displayed instead of: *HD Treatment History, Laboratory Test History, PD dialysis dose, and PD fast peritoneal test*. To this, the user must create a query using the *query builder*. The query must meet the following requirements:

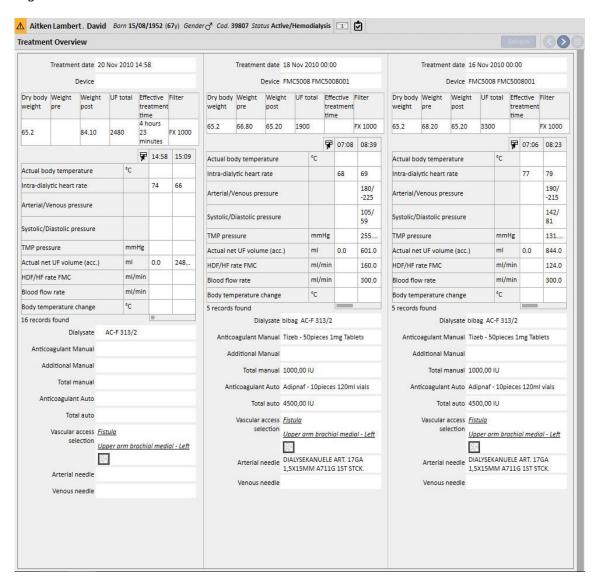
- The query's main entity will be a patient entity but not the patient's administrative data;
- The query must not contain parameters. This means no items must be put in the "Drag and drop field to create a parameter" section;
- The query will be published as a view;

Query Builder is only available if the "Analysis and Reportt" writing module is active.

Once the query has been created it should be linked inside the related group of the Configuration Parameter entity in the Master Data (Clinic Manager) menu.

9.2.2 TREATMENT OVERVIEW

This section shows the principal data from the patient's last three treatments. All the other treatments can be viewed by clicking the arrow button.



9.2.3 ADMINISTRATIVE DATA

This section contains the patient's administrative data, such as name, address, date of birth, etc. For more information about how to edit the individual fields and field types.

As an alternative to the mouse, press the **Tab** key to move from one field to the next. To move back, press the **Shift** key and the **Tab** key simultaneously.

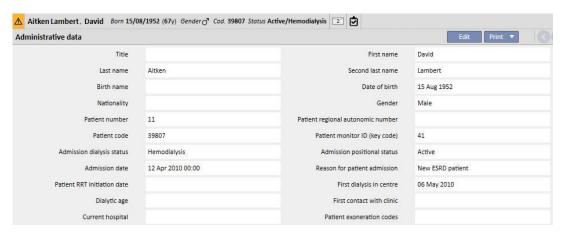
After editing this section the **Save** and **Cancel** buttons will be activated. Click **Save** to store the data in the database. To discard the changes click **Cancel**.



Warning

Patients with the **Gender** field marked "Unknown" will be sent to Therapy Monitor but it will not make them selectable as treatable patients.

By default, the patient's picture is not visible in this section. However, it can be displayed by setting the "Hide patient picture" field to "No" in Master Data, under the "Configuration parameters" item.



Patient code: This is an ID which is automatically assigned by Therapy Support Suite during patient admission and cannot be changed. This ID is the unique identifier of the patient inside Therapy Support Suite.

Patient monitor ID (key code):: This is the ID that identifies the patient's connection between Therapy Support Suite and Therapy Monitor/Patient On Line. This code cannot be changed. It is assigned if one of the following events occurs:

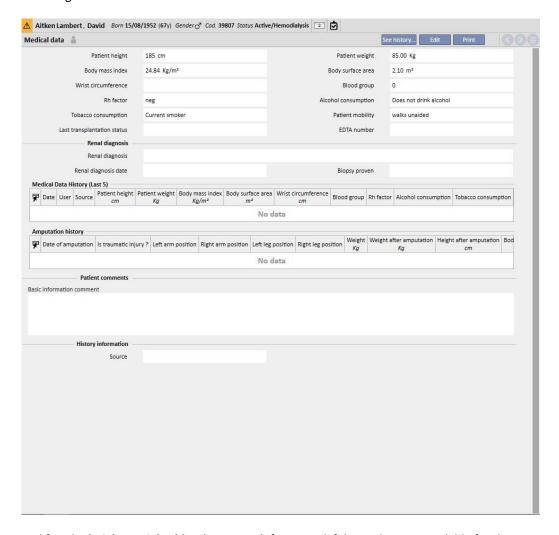
- The patient is admitted with an "Active" **Admission status** and a **Clinic admission procedure** compatible with the patient's need to undergo treatment, namely: "Hemodialysis", "Hemodialysis (Intensive Care)", "Hemodialysis (Acute)", "Home HD" or "Peritoneal Dialysis".
- A **New dialysis status** that compatible with the patient's need to undergo treatment, namely: "Hemodialysis", "Hemodialysis (Intensive Care)", "Hemodialysis (Acute)", "Home HD" or "Peritoneal Dialysis". The destination hospital, for the new status, should coincide with what has been provided for in one of the Therapy Support Suite clinics.
- A Patient Tab is to be created for a patient without a **Patient monitor ID** (key code).
- A Hemodialysis prescription is saved regardless of the patient's dialysis status.

9.2.4 MEDICAL DATA

The Medical Data section contains the patient's basic medical data, such as height, blood group and renal diagnosis. For more information about how to edit the fields and field types.

As an alternative to the mouse, press the **TAB** key to move from one field to the next. To move back, press the **Shift** key and the **Tab** key simultaneously.

After editing this section, the **Save** and **Cancel** buttons will be activated. Click **Save** to store the data in the database. To discard the changes click **Cancel**.

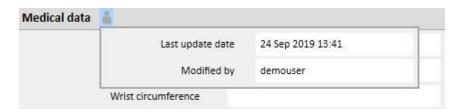


If the user modifies the **height, weight, blood type or Rh factor** and if donor data are available for the patient or if there is a value in the **waiting list field,** the system will ask the user if these data are also to be updated for these sections.



9.2.4.1 MEDICAL DATA (HISTORY)

Modifying any field in the Medical data section and saving will create a log of the values before saving. At the top of this section, the symbol is displayed, which, if pressed, will show when and by which user the last change was made.



Medical data will also be updated following the modification of or addition to the following fields in the following entities:

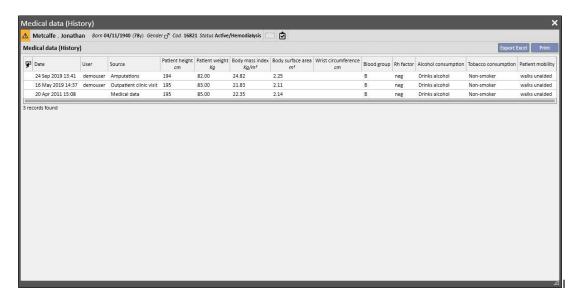
- Medical data: any changes made to the fields of this entity.
- Amputations.
- Donor data: all fields in the medical data section.
- Outpatient examination: weight and height of the anthropometric data section.
- Adequacy or nutrition: (if the PD plugin is enabled) weight, height or wrist circumference.
- POL QA test: (if the PD and POL plugin is enabled) weight and height.

Changes made to the Medical Data can be seen in two sections:

• in the table **Medical data history (Last 5)**, which shows the last 5 changes made.



by clicking on the <u>See history...</u> button, the complete list of all the times that a change in the medical data has been made will be displayed.



n both sections you can see when the change was made, by which user and also in what entity.

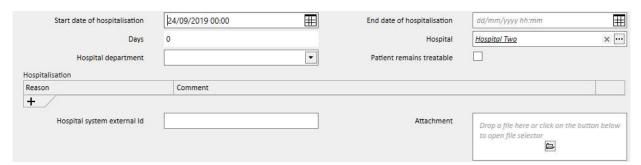
9.2.4.2 AMPUTATION HISTORY

This medical data section shows all amputations undergone by the selected patient.



9.2.5 HOSPITALISATIONS

The patient's hospitalisations can be entered in this section. Simply record the start and end date and the hospital where the patient has been hospitalised. It is also possible to specify the reason for admission. After saving the hospitalisation, the relative transfers are automatically created in the Patient Status section. It is also possible to create hospitalisations which last one day only.



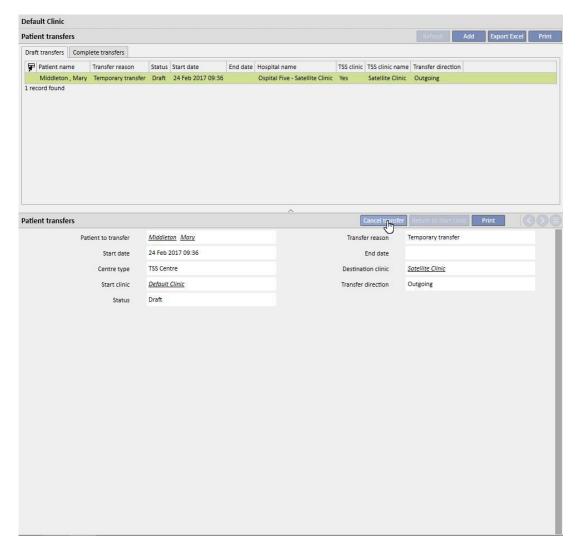
When a patient is hospitalised in a <u>non-TSS clinic</u>, it is possible to specify whether or not the patient remains "treatable".



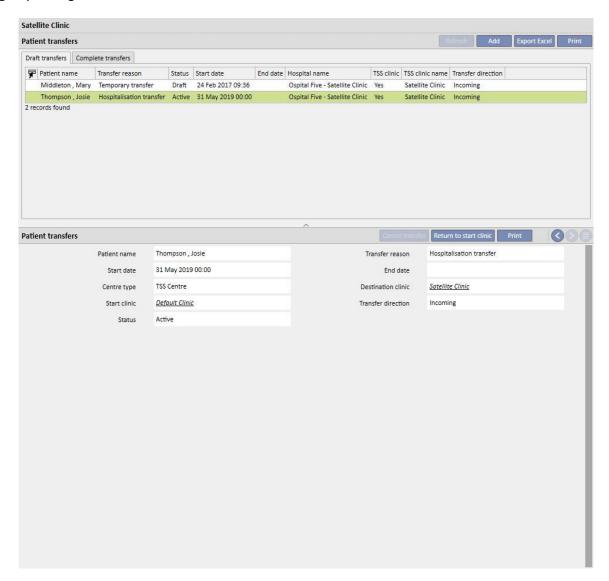
A hospitalised patient who is "treatable", meaning that the relative field is set as true, will still be applied in the "Clinic Scheduler" and his status will not be changed to "Not Active".

It is possible to create hospitalisations "in the same clinic", "in other TSS clinics" and "in external/non TSS clinics".

- In the same clinic: the patient's status does not change and the user can choose the ward to which the patient will be moved. The hospitalisation can be deleted using the "Delete" button (if the user has the necessary user rights).
- In other TSS clinics: this type of hospitalisation can be created by selecting a TSS clinic as the "Ward". When a hospitalisation is saved, the patient's status will depend on the event start day. If the hospitalisation is planned for the future, the patient's status will not change. If instead it starts at the time it is saved (or before) the movement is automatically accepted and the patient will have the status of "hospitalisation -in transit." If the hospitalisation is planned for the future, the clinic that created it can delete it with the "Delete" button (if the user has the necessary permissions) or cancel it in the Clinic Name section of the "Patient Transfers" menu item.

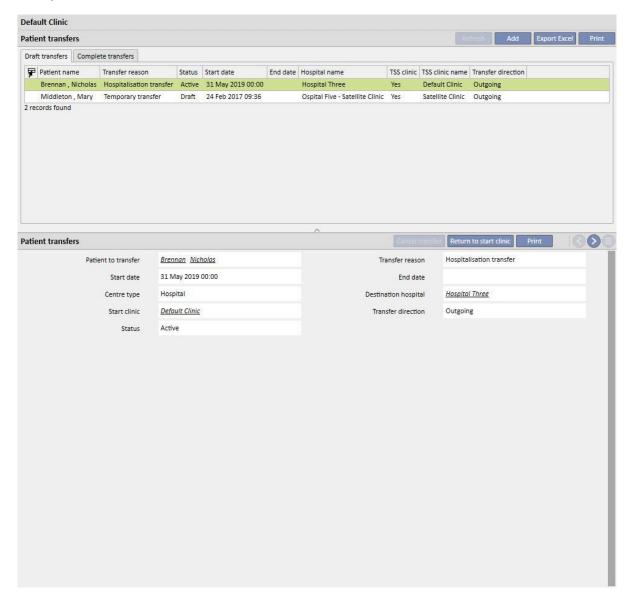


Once the hospitalisation has been accepted, the patient will appear in the list of active patients at the destination clinic. At this point the hospitalisation can no longer be cancelled. It is possible to send the patient back to his clinic of origin by clicking on the "Return to start clinic" button in the clinic name section of the "Patient Transfers" menu item.



Now the patient is no longer present in the destination clinic and has returned to "Active" status in his clinic of origin.

In external/non-TSS clinics: it is possible to create this kind of hospitalisation by selecting a non TSS clinic as "Ward". As it is not possible to see the destination clinic, it is assumed that all hospitalisations are accepted automatically (except those created with a start date in the future). The clinic that created the hospitalisation cannot cancel it (unless the start date is in the future) but can send the patient back to his original clinic by clicking on the "Return to originating clinic" button in the clinic name section of the "Patient Transfers" menu option.



If the end hospitalisation date has been entered, the "Date of return to the originating clinic" will be displayed in the patient data summary bar.

Born 28/10/1962 (56y) Gender of Cod. 399489 Status Transit - temporary/Hemodialysis Return to start clinic 08/06/2019

Each time a hospitalisation is created, a task is automatically generated, which is associated with this type of event, only if the authenticated user is enabled to receive notifications. To do this, the user must be selected among the "Notification Users" or belong to a group selected among the "Notification Groups" in the "Configuration Parameters" in the Master Data section under "Movement Notifications" (see section 4.1.1 of the Service Manual).

The tasks generated by the "Hospitalisation" event will be visible to the user according to these rules:

- internal hospitalisation, task not generated;
- hospitalisation to TSS clinic, tasks generated for enabled users in the departure clinic and destination clinic;
- hospitalisation to non-TSS clinic, tasks generated for enabled users in the departure clinic;

If a clinic does not have users or user groups enabled to receive movement notifications, this type of event will never generate the creation of a task for any user.

A patient who has an active/ongoing hospitalisation will have an "H" symbol displayed in the top summary menu bar. This symbol will be displayed from the day the hospitalisation starts until midnight of the day the hospitalisation ends.

In the case of hospitalisation, on the other hand, the presence or absence of the symbol will depend on the logic set in the configuration parameters in the section "logical configuration of the selection of clinical cases (hospitalisations)" (see section 4.1.1 of the Service Manual). If the hospitalisation does not consider an exact time for its closure, the symbol will be displayed until midnight of the day the hospitalisation ends. If, however, the exact time for the closure of the hospitalisation is set, the image will disappear as soon as the hospitalisation is "closed".



9.2.6 PATIENT STATUS

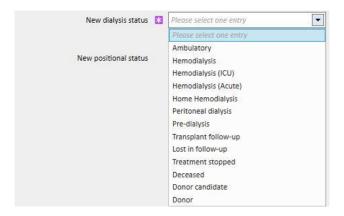
Movements (changes in status or position) relating to patients can be entered in this section. Movements describe changes in the patient's status; for example, entering and accepting a movement in a clinic other than the current one will change the patient's status to "Not Active".

This section is divided into two Tabs: "Patient status" and "Patient change status"



where essentially the second tab shows the structure and the logic described below and related to the "Patient status" tab, relating only to status changes and there are no position changes, to permit a more immediate and exclusive display of these records.

The dialysis statuses available are: Ambulatory, Hemodialysis, Hemodialysis ICU, Hemodialysis Acute, Peritoneal Dialysis, Pre-Dialysis, Transplant follow-up, Lost contact, Treatment stopped, Deceased, Donor candidate and Donor.



The mandatory fields during creation of a movement are Event Date, New Dialysis Status and Hospital.



Additional mandatory fields may appear depending on the value of these three fields (i.e. if the hospital selected is not the current one, a "Transfer type" field appears and must be selected).

All movements accepted to another hospital/clinic compared to the local one, move the patient and modify his status based on the type of transfer performed and the clinic to which he is moved. Even hospitalisation changes the status of the patient.

Following are the various possible combinations for status changes for a patient after a movement:

Type of movement	To the clinic	Status in originating clinic	Patient group in originating clinic	Status in destination clinic	Patient group in destination clinic	
Temporary	TSS	Transit - Temporary	Active	Transit - Temporary / "Originating clinic"	Active	
Temporary	Non- TSS	Transit - Temporary	Active	-	-	
Holiday	TSS	Transit - Holiday	Active	Transit - Holiday / "Originating clinic"	Active	
Holiday	Non- TSS	Transit - Holiday	Active	-	-	
Final	TSS	Active - "Destination clinic"	Inactive	Active	Active	
Final	Non- TSS	Not Active	Inactive	-	-	
Hospitalisation	TSS	Transit - Hospitalisation	Active	Transit - Hospitalisation / "Originating clinic"	Active	
Hospitalisation	Non- TSS	Not Active	Inactive	-	-	

"Originating Clinic" is the name of the clinic the patient is leaving. "Destination Clinic" is the name of the clinic the patient is transferred to. In the event of transfer to a Non-TSS clinic, the patient remains only visible in the "Originating Clinic".

A patient's past movements can also be logged and movements can be scheduled for the future. If the "Deceased" status is assigned to a patient, all the related treatment prescriptions and active drug prescriptions will be deactivated/terminated, while the vascular access will be changed to the "Terminated" status. Movements after death will be deleted. The date of death shown in the administrative data will be set automatically in order to reflect the date of movement and vice-versa.

9.2.6.1 MOVEMENT TYPES

Movement types are split into three groups: Internal Transfer, Incoming and Outgoing.

Internal transfer

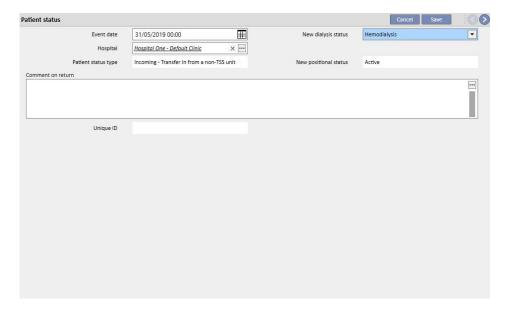
Internal transfers take place in the same hospital. These movements change the patient's dialysis status (Pre-Dialysis, Hemodialysis, Peritoneal Dialysis, Transplant follow-up, etc.).



If the patient is in a "Not active" status, the internal transfer allows the patient to be reactivated.

Incoming

"Incoming" movements are all those movements that indicate the hospitalisation of the patient in the current hospital, while the "New patient admission" movement is created through the "New patient" item. Other examples are the "Transfer in from a TSS centre", "Vacation return" and "Return from a temporary transfer". These movements can occur when the patient is not in the current hospital; this means that the patient previously had an "Outgoing" movement. For an "Incoming" movement the user can add a comment to describe the event.



Otherwise, an "Incoming" movement is generated automatically when the user in the destination clinic clicks the "Return to clinic of origin" button in the clinic name section of the "Patient transfer" menu.

Outgoing

Outgoing movements are used to move patients to other clinics, either TSS or non-TSS. If a hospital other than the current one is selected, the "Transfer Type" field appears. This field can be used to describe the type of transfer, e.g. whether the transfer is for "Vacation", "Definitive", or "Temporary".

Vacation: patient is not in the clinic for a limited period of time. Typically used for patients who are on holiday. It is possible to specify the holiday "End date". The movement is considered accepted as soon as it has been executed. If the destination clinic is a non-TSS clinic, it is considered accepted automatically. At any time, even if a holiday end date has been specified, both clinics can send the patient back to the clinic of origin at any moment by clicking the "Return to clinic of origin" button in the clinic name section of the "Patient transfer" menu item. Once an outgoing movement has been executed, therefore accepted automatically it can no longer be cancelled.



Definitive: for patients permanently transferred to other hospitals. After a definitive transfer, all the patient's data in TSS are switched to "Read-only" mode: all the data in the system are then available but cannot be modified. The movement is considered accepted as soon as it has been executed. If the destination clinic is a non-TSS clinic, it is considered accepted automatically.

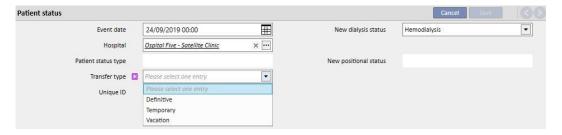




Note

To add a new movement for a "Read-only Patient", the user must have been assigned the rights to the "Enable patient status for read-only patients" section in the clinic configuration parameters.

Temporary: patients who are transferred to another hospital for a limited period of time. The movement is considered accepted as soon as it has been executed. If the destination clinic is a non-TSS clinic, it is considered accepted automatically. Even if an end date has been specified, both clinics can send the patient back to the clinic of origin at any moment by clicking the "Return to clinic of origin" button in the clinic name section of the "Patient transfer" menu item. Once an outgoing movement has been executed and automatically accepted, it can no longer be cancelled.



During a temporary or holiday movement the patient is visible in both clinics. All activities carried out on the patient during the period he is at the destination clinic will also be visible in the clinic of origin once the patient returns to the clinic of origin.

Treatment stopped, Deceased and Lost contact are also considered to be outgoing movements. In the case of "Treatment stopped" a new field, "Stopped by", will appear.



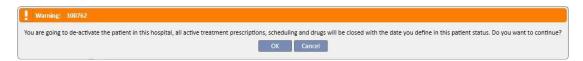
In the case of Deceased, the "Cause of death" can be entered. Neither field is mandatory.



Additionally, at the time of motion rescue, the user will be alerted to all the various sections that will be deactivated by the patient.



If a patient is set to dialysis status equal to "Lost contact" or "Hold on treatment", the user is advised that all medical section sections such as prescriptions, pharmacological therapies, and active schedule plans will be deactivated; aware of this, the user can decide whether to proceed.



If the request has been provided for among the configuration parameters (for more details, see section 4.1.1 of the Service Manual) and when one of the dialysis statuses below is set: Hemodialysis, Hemodialysis ICU, Hemodialysis

Acute, Peritoneal Dialysis, Pre-Dialysis, Outpatient Clinic, or Transplant follow-up and the patient has a waiting-list with all organs excluded, the system asks the user whether he wishes to add organs to the waiting list:



If the user presses the "Yes" button, he is prompted to select the organs for which the "Pre-Included" status will be set on the waiting list by default (4).



Patient Transfer Offline

Patients can also be transferred between clinics that do not belong to the same TSS installation. This type of transfer is carried out by means of an import and export procedure known as "Patient Transfer Offline", described in detail in the relevant section.

Relations with tasks

All temporary, holiday or permanent movements can generate tasks, as explained for hospitalisations (see section 1.2.5 in the User Manual and section 4.1.1 in the Service Manual).

If a user is enabled to receive notifications following a movement, task creation will follow the rules below:

- internal hospitalisation, task not generated;
- temporary/holiday to TSS clinic, tasks generated for enabled users in the departure clinic and destination clinic;
- temporary/holiday to non-TSS clinic, tasks generated for enabled users in the departure clinic;
- final to TSS clinic, tasks generated for enabled users in the destination clinic;
- final to non-TSS clinic, tasks not generated.

9.2.6.2 SETTING THE END OF MOVEMENT DATE

When a <u>temporary or holiday outgoing movement</u> is saved, the program asks the user to enter the end of movement date.



The end of transfer date is used to set the return movement to the departure clinic. This date must be later than the transfer start date.

The user can avoid entering the date in the field shown in the previous screenshots by simply clicking the "OK" button; in this case, the return movement will not be created. The "Cancel" button can be clicked to return to the outgoing movement creation phase.

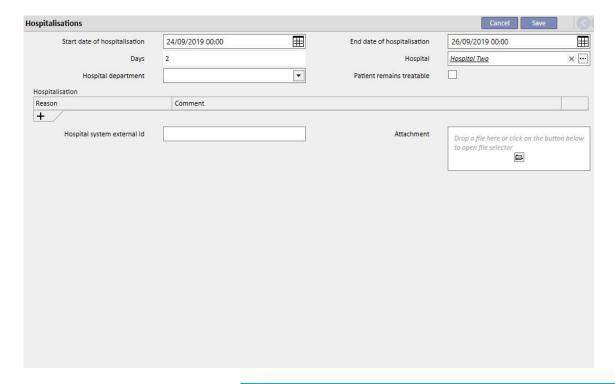
If the end transfer date has been entered, the "Date of return to the originating clinic" will be displayed in the patient data summary bar.



During the transfer period, the patient will be "Not Active" and not "treatable". At the end of this period, set by the user, the patient will be active and treatable again.

Relation to Hospitalisation movements

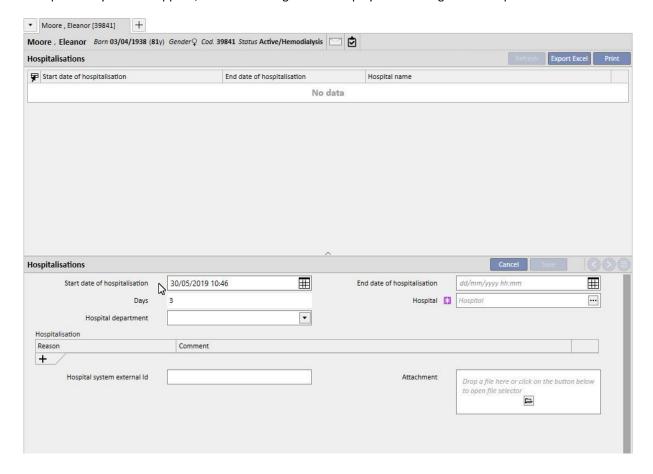
The hospitalisation start and end dates will correspond to two equivalent incoming and outgoing movements. As already explained, the patient will be "Not Active" and not "treatable" throughout the transfer period (unless the user ticks the "Patient remains treatable" field).



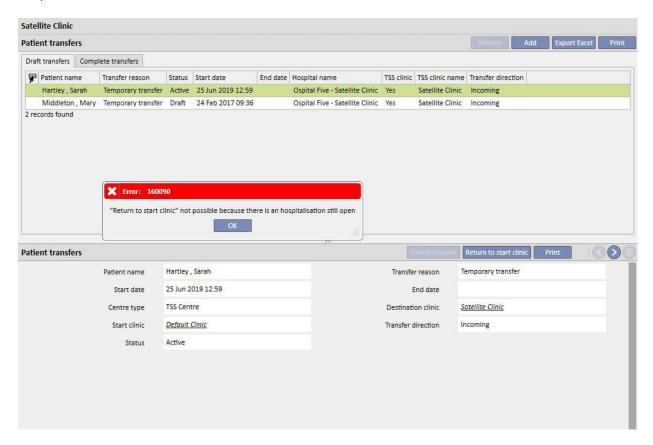


Note

The creation of the transfer end movement depends on whether or not the user enters the end of hospitalisation date, which is not a mandatory field. When a new hospitalisation is created, it will be checked to make sure it does not overlap with other movements created previously. If that happens, an error message will be displayed indicating this overlap.



The same check is also made when a Return to the clinic of origin is performed. In fact in that case, the return movement could create an overlap with an already existing hospitalisations (typically where an end is planned in the future).



9.2.6.3 DELETING A MOVEMENT

A movement can be deleted by modifying it and clicking the "Delete" button.



All movements created with an earlier or equal start date when saved, will be automatically accepted and therefore cannot be deleted.



Warning

Risk for the patient as a result of incorrect patient data being shown

Deleting a movement only affects the patient's status and the relative scheduling when the movement deleted is the latest one. In this case, the patient's position and dialysis status, and the relative scheduling, will be defined by the penultimate movement, which will become the last one.



Note

Movements which originate from a hospitalisation cannot be deleted unless the relative hospitalisation is also deleted.

9.2.6.4 FATHER/SON REFERENCE CLINIC

It is possible that multiple TSS clinics are related by a father/son relationship.

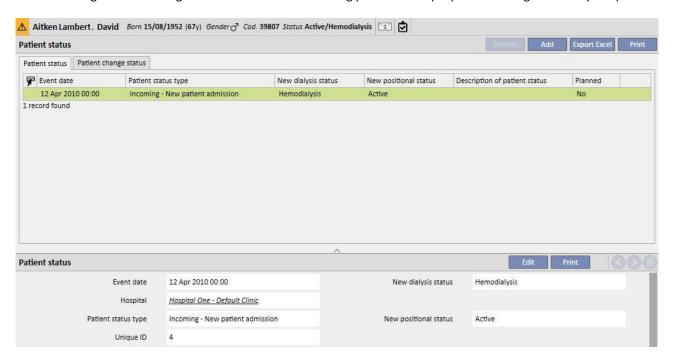
In this case, all patients active in the "son" clinic are visible also in the list of active patients at the father clinic. All of the pharmaceutical prescriptions, laboratory test scheduling, and medical orders that involve the patients of the "son" clinic are not visible from the "father" clinic. Also, it is not possible to add new elements in the aforementioned sections.

Patients active in the "father" clinic are not visible in the "son" clinic.

9.2.6.5 PATIENT STATUS CHANGE TAB

This tab has the same structure as the previous tab with one substantial difference in its applied logic. Differently from the Patient Status tab, the Patient Status Change tab shows the list of events, only changes in dialysis status, excluding the movements made by the Patient.

Because of this new section it is possible to more immediately concentrate exclusively on dialysis status changes without having to scroll through a list of records also including possible multiple position changes made by the patient.



9.2.7 MEDICAL PRESCRIPTION

This section enables the user to create and print medical prescriptions for a patient.

It is possible to create prescriptions for drugs, laboratory tests, specialist examinations and diagnostic tests. In this section it is also possible to print out NHS prescription forms, one or more per section depending on the rules applied for each one.

9.2.7.1 CREATING A MEDICAL PRESCRIPTION

A new medical prescription can be created by clicking the New button.

A form will appear with the date and automatic information filled-in by the system. The working diagnosis of the prescription can be specified in the related field. This field will be displayed on prescriptions for diagnostic tests and specialist examinations.

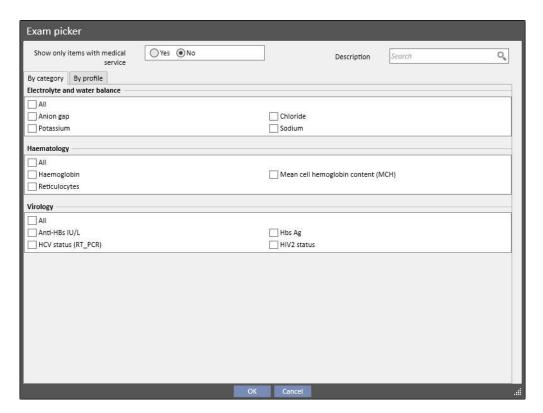
9.2.7.2 LABORATORY TESTS SECTION

In the laboratory tests section, it is possible to create a medical prescription for one or more laboratory tests by clicking the button.



After the button has been clicked the system shows a pop-up, called Exam Picker, where the various categories of laboratory tests are shown. The user can click the checkbox to select/deselect the related laboratory tests. The checkbox can also be used to select / deselect all the tests belonging to a specific group. After making the selection, the user clicks the OK button at the bottom of the pop-up to confirm. The + button can be used to add exemptions to the prescription for the laboratory tests.

The laboratory tests can generate one or more prescriptions, depending on how many are selected in the "Exam Picker".



9.2.7.3 DRUG SECTION

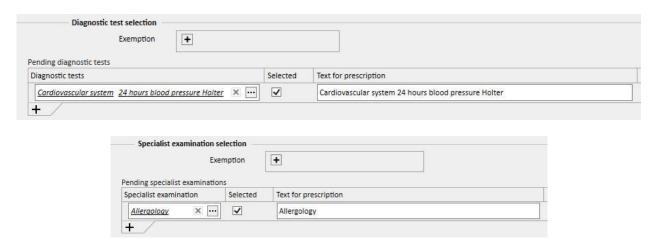
In the drug section the system loads all drugs prescribed to the patient as part of his home pharmacological therapy. To print a drug prescription the user must specify the quantity in the relative field. Once the drug quantity is filled out the system calculates and displays the prescription text field. This is the text that will be displayed on the medical prescription. It can be modified before the medical prescription is saved and printed. It is also possible to select a maximum of two exemptions related to the patient.

After the information has been entered, a prescription is generated for each of the drugs for which a quantity other than 0 has been specified (the example prescription shown in **section 2.7.7** the print-out of a prescription for one of the drugs selected in the next screenshot).



9.2.7.4 DIAGNOSTIC TESTS AND SPECIALIST EXAMINATION SECTION

The diagnostic test and specialist examination section lists all diagnostic tests/specialist examinations which are in 'pending' status on the system. Click the checkbox to select/deselect the relative specialist examination. After a specialist examination has been selected the system calculates and displays the prescription text field. This is the text that will be displayed on the medical prescription. It can be modified before it is saved and printed. It is also possible to select the exemption related to the patient.



9.2.7.5 TEXT PRINTOUT

In this section the user can write free text that will be replicated on the medical prescription: again, it is possible to specify one or more exemptions related to the patient as well as the quantity to be associated with the prescription.



9.2.7.6 MEDICAL PRESCRIPTION PRINTOUT

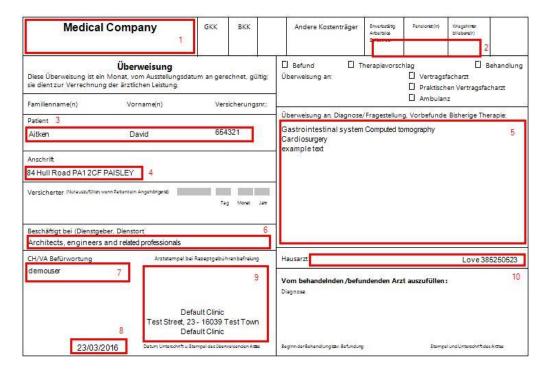
After the form has been filled out and saved, the related medical prescription can be printed by clicking the



The current printing process is governed by country-specific regulations. TSS supports different rule sets and print layouts according to the configuration applied during TSS setup.

Example of printed version of prescription (Italian layout) comprising:

- Information recovered from the patient (1, 3, 4 and 6)
- Exemptions specified for the patient (2)
- Description of the tests prescribed (5)
- User who printed the prescription and printing date (7, 8)
- Dialysis clinic details (9)
- Family doctor (10)





Note

This is an example of an Austrian prescription. The "medical prescription" printout is not available until the correct prescription has been installed. Please refer to the Service Manual for the relative configuration instructions.

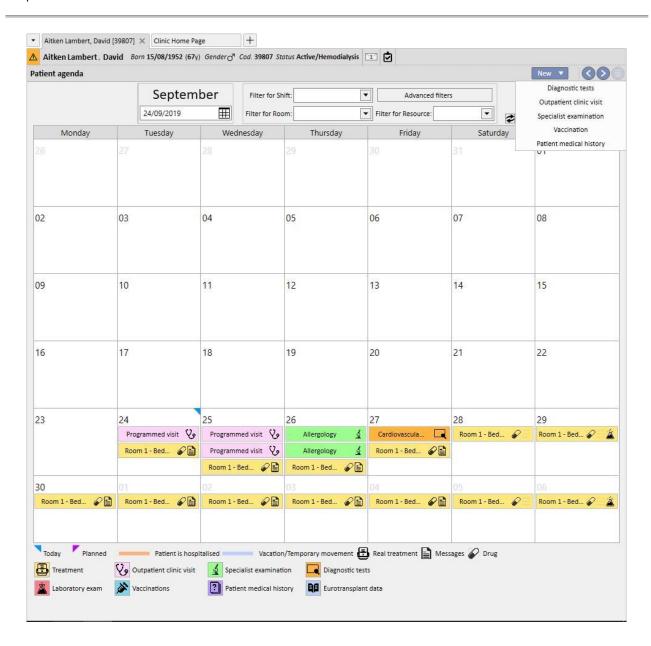
9.2.8 PATIENT AGENDA

This section can be used to display a monthly agenda for the various patient activities that must be performed, or have been performed, at the clinic.

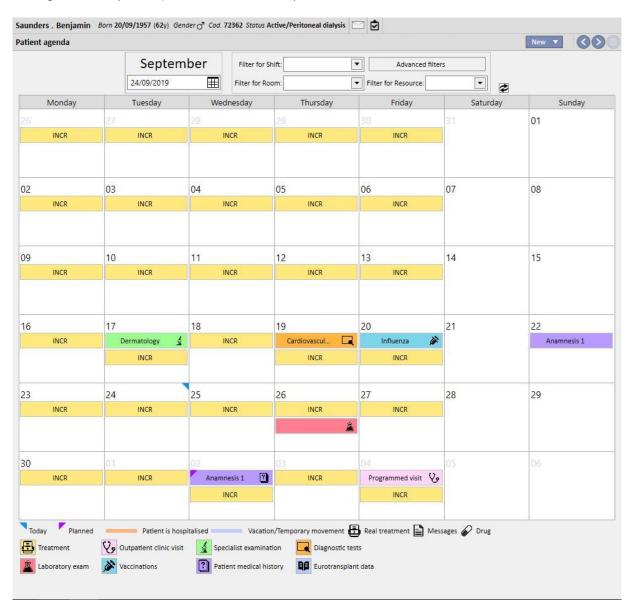
In addition to the display, like in the Clinic Scheduler, the elements displayed in the agenda can be moved or deleted (link in the treatment scheduler).

Specifically, it is possible to see as separate events:

- Hospitalisation periods
- The transfer periods are temporary/holiday
- Treatments administered and their future scheduling:
 - Pharmacological prescriptions
 - Medical orders
 - Laboratory tests
- Clinic Visits
- Specialist examination
- Diagnostic tests
- Vaccinations
- Patient history
- Euro-transplant data

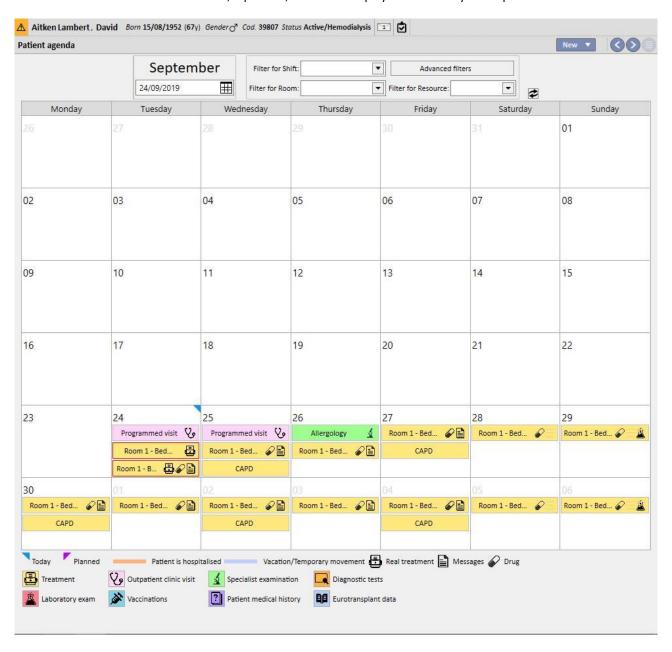


The image that represents the actual treatment (HD or PD) will overwrite its schedule (HD or PD) once the treatment has been created. There is a difference to be highlighted between patients with HD and PD scheduling: in the case of PD treatments, no pharmacological prescriptions, medical orders and laboratory tests will be associated with the relevant calendar day; only the laboratory tests, if they have been scheduled (only a precise date can be specified as a scheduling rule for PD patients), will be visible but independent of the treatment.



This is the representation the agenda of a patient who has only one type of treatment scheduling (HD or PD). In fact, it is also possible that a patient, regardless of dialysis status, has a schedule for both hemodialysis treatments and peritoneal dialysis treatments. In this case, the agenda will show both types of planning: the HD scheduling will show the reference shift and the resource to be used as a description, while the PD scheduling will show the treatment mode.

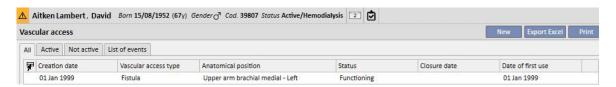
Moreover, on the same day, it is also possible to see the display of several treatments administered regardless of the type (HD or PD), one (or more) actual treatment(s) of one type and the scheduled treatment of the other. The rule for displaying laboratory tests, i.e. whether they are linked to a treatment or displayed individually, will be dictated by the type of treatment planned for that day. At this point we are faced with two types of scenarios: 1) an HD patient, who also has PD schedule plans, will always have the laboratory tests linked as per schedule to an HD treatment; 2) a PD patient, who also has HD schedule plans, will be able to schedule the tests with only the "Specific dates" rule and these will be linked to an HD treatment, if present, otherwise displayed individually in the patient's schedule.



9.3 HD

9.3.1 VASCULAR ACCESS

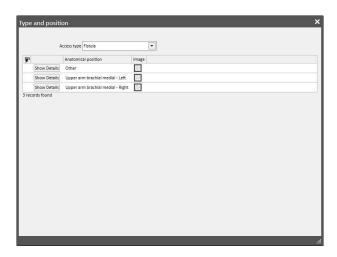
The user can record the patient's vascular access history in this section. To modify an existing vascular access, simply select it from the view and press the Edit button. To create a new one simply click the New button.



This section is divided into two parts: the "Basic data" and the "Follow up". The basic data list general data about the vascular access, for example when it was created, status, date of first use, etc. The follow-up section records the events and actions related to the vascular access's history.

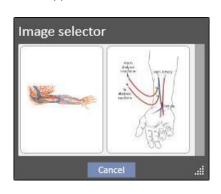
The most important fields are explained below.

Type and position With this custom list it is possible to access the vascular access position editor. After selection of the Access type from a drop-down list (fistula in the example below), the system shows the list of anatomical positions available for that kind of vascular access. Using the mouse to move the cursor over the symbol will show an image of a human body with the selected anatomical position highlighted.





Anatomical schema This is a special field where images and text can be used to provide a clearer description of the vascular access. Click the icon to open a preset selection of body images. Then double click one of them to store the image in the Anatomical Schema field. The user can now draw on the image and write notes by pressing the pencil button and working with the graphic tools that appear.







Created by (first surgeon) and **Created by (second surgeon)** These fields allow up to two surgeons to be chosen who have performed operations regarding this vascular access.

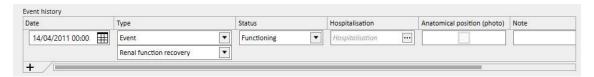
Anaesthesia This multi-value field that records the log of the anaesthesia administered on the patient relative to this vascular access, permitting the specification of the date on which it was administered, the medicine used, and the dose.



Recirculation/Max Flow A multi-value field where different access recirculation and access maximum flow measurements can be recorded for a specific date.



Event log A multi-value field where actions relating to the Vascular Access (creation, incidents, or termination) can be registered. The first event is generated automatically when a vascular access is created.



Status This field is read-only. It is filled-in by actions that define the active/not active status of the Vascular Access.



Date of first use This field is empty initially and indicates the time at which the vascular access was used for the first time.

Termination date This field is read-only and cannot be seen during creation. This is filled-in automatically when an event that causes the closure of the vascular access is created.

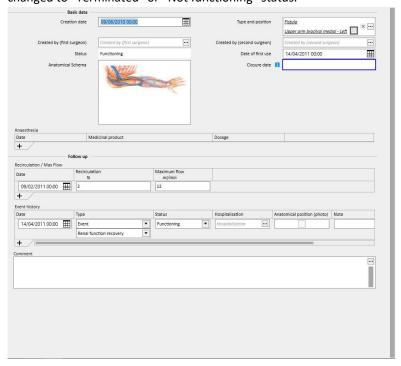


Tip

The user can set the status of a vascular access as "Terminated" or "Not functioning". In this case, if the vascular access is associated with a prescription, Therapy Support Suite Business Logic tries to update the "Vascular access selection" link automatically.

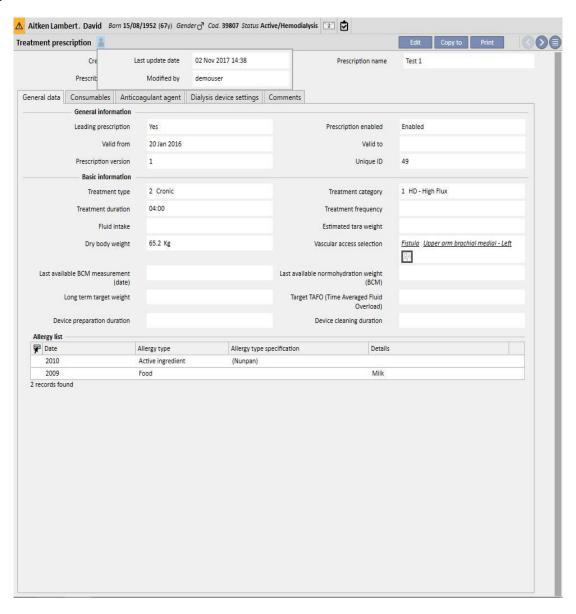
If the patient already has only one active vascular access, the prescription is updated with selection of that vascular access; otherwise it has to be completed manually by the user.

In both cases, an information message appears stating when the vascular access is changed to "Terminated" or "Not functioning" status.

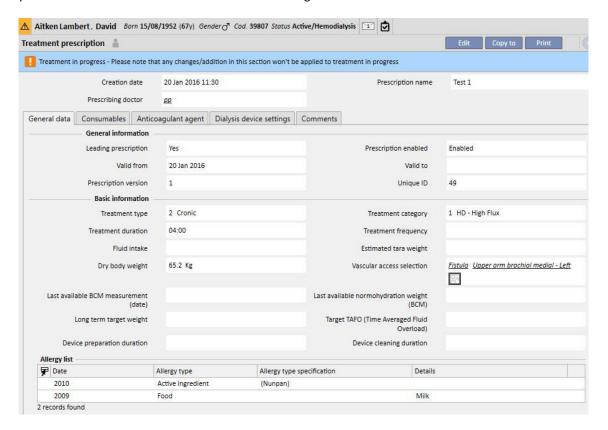


9.3.2 TREATMENT PRESCRIPTION

HD Prescriptions related to a specific patient are recorded in this section. There is a logging system which allows the user to keep a record of every change made to the prescription throughout its lifetime. Only the last version of a prescription is editable. The older ones are read-only but can be copied into a brand new prescription. When a modification is made, if the current version of the prescription is linked to at least one treatment, a new version is created. This means that a record is kept of the prescriptions relating to all the treatments performed. There will be a male bust icon next to the HD Prescription label, clicking on it the date of the last change and who made it will be displayed.

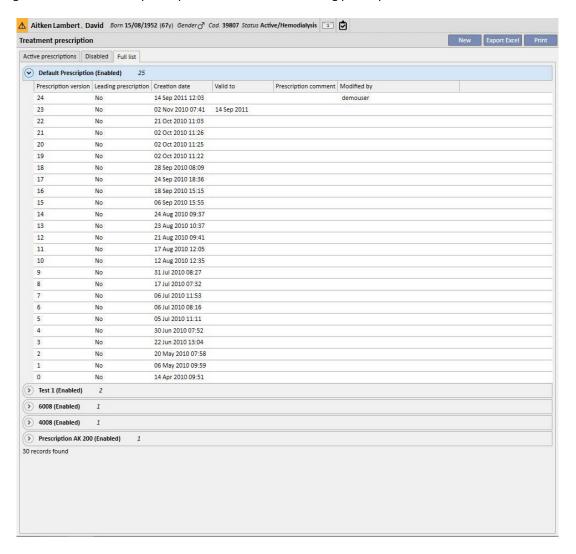


When a prescription already used for a treatment is switched to edit mode, a message appears warning that the prescriptions data linked to the treatments will not be changed.



Therapy Support Suite is able to send data to the Fresenius Medical Care software product Therapy Monitor. Therapy Monitor uses these data to provide pre-settings according to the patient's dialysis prescription to defined dialysis machines (4008, 5008 and 6008). When the main prescription reaches its "valid until" date, if the patient only has two prescriptions, the second prescription automatically becomes the leading prescription. If there are several non-leading prescriptions, the most recently created prescription becomes the new leading prescription.

When the leading prescription is cancelled, if the patient only has two prescriptions, the second prescription automatically becomes the leading prescription. If there are several non-leading prescriptions, a pop-up appears informing the user that another prescription has become the leading prescription.



The treatment prescription form window consists of five tabs.

			D. 1 . 1	
General data	Consumables	Anticoagulant agent	Dialysis device settings	Comments

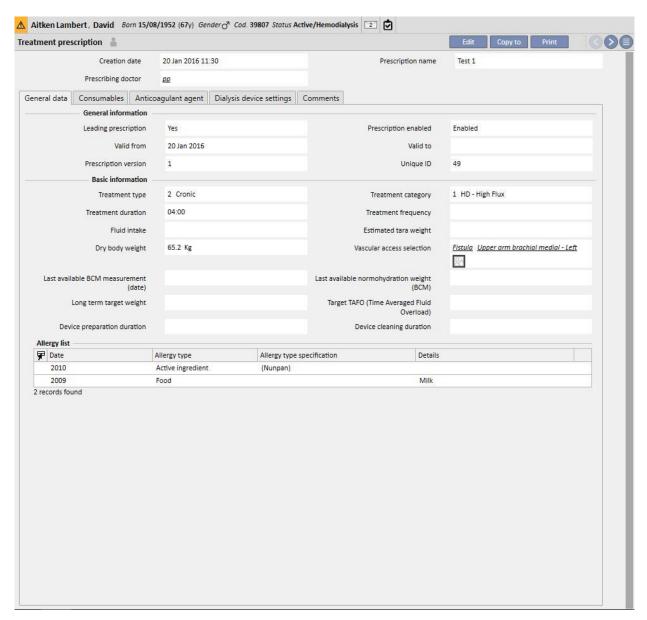
9.3.2.1 GENERAL INFORMATION

The main prescription data (duration, category, and dry body weight) can be entered in this section.

Leading prescription: This field identifies a specific prescription as the leading one. Therefore, when a treatment is created manually, and no scheduling is planned for that day, it is based on the leading prescription. If a patient has more than one prescription, only one can be leading.

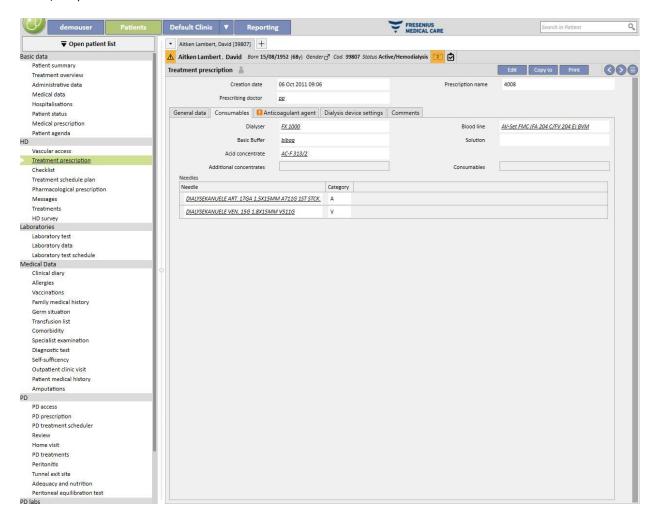
Vascular access selection: This custom list shows all the vascular accesses in use for the patient. The user can select the one to be used for HD treatments based on this prescription.

Allergy list: This is a read-only list that shows all allergies recorded for the patient.



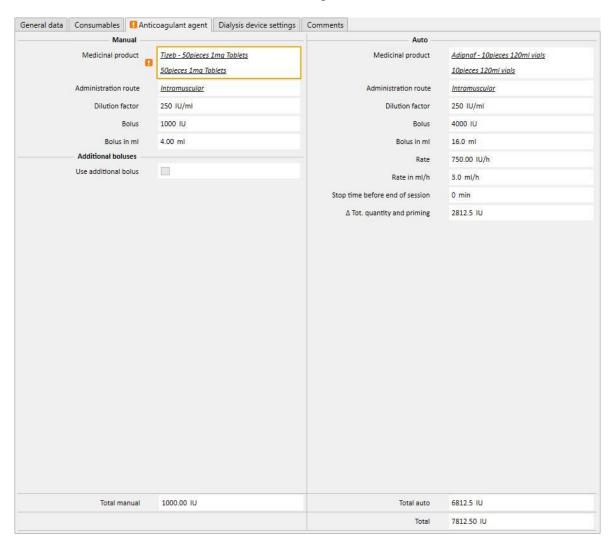
9.3.2.2 CONSUMABLES

In this tab the user can enter consumables that will be used during dialysis (filter, concentrates, saline solution, needles, etc.).



9.3.2.3 ANTICOAGULANT AGENT

This tab is divided into two sections: manual and auto anticoagulant administration.



If the anticoagulant will be administered manually by the nurse, enter the relative information in the Manual section. If the Manual anticoagulant section is filled in, the information will only be visible in Therapy Monitor and on the dXp panel of the dialysis device; the system will not influence the download of the device parameters.

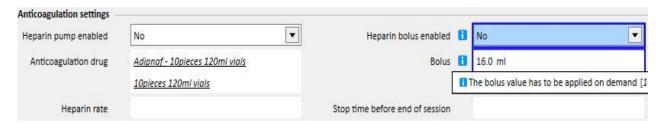
The Auto section must be filled-in to set device's anticoagulant section with the prescription parameters. Therefore, as a general rule, the fields related to the automatic administration of anticoagulant agent during treatment are entered in the "Anticoagulant agent" tab: the "Anticoagulant settings" section of the "Dialysis device settings" tab is then updated automatically by the system.

However, there are some exceptions related to specific cases where the values of the anticoagulant agent can be modified directly in the "Dialysis device settings" tab:

The "Heparin pump enabled" field can only be set as "Yes" if the field "Total" in ml/h related to the "Maintenance dose" in the "Anticoagulant agent" tab (automatic section) contains a value. Conversely, the pump cannot be deactivated if a value has been entered for the maintenance dose.



The "Heparin bolus enabled" field can only be set as "Yes" if the "Total" in ml/h field related to the "Bolus" in the "Anticoagulant agent" tab (automatic section) contains a value. If the "Heparin bolus activated" field is deactivated, the "Bolus" field of the "Anticoagulant settings" section becomes editable as long as a value has not been inserted for the bolus in the "Anticoagulant agent" tab. In this manner, it is possible to specify a bolus value to be sent to the dialysis device, overriding the value specified in the "Anticoagulant agent" tab.



The modifications made directly in the "Anticoagulant settings" section of the "Dialysis device settings" tab are overwritten every time the Auto section of the "Anticoagulant agent" tab is modified. When the data are saved, the user is alerted to these changes by a message specifying the fields that have been modified, and confirmation to proceed to save will be requested.

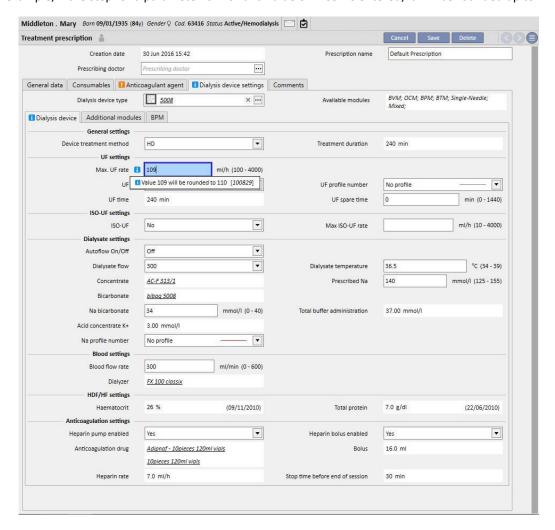


The dilution factor field is mandatory in TSS. However, if this field is removed in the TMon treatment, a warning message will be displayed.

9.3.2.4 DIALYSIS DEVICE SETTINGS

This tab shows all the dialysis device settings. Different settings will be shown depending on the dialysis device type (5008, 4008, 6008, AK200, ARTIS). Some fields come directly from other sections (treatment duration, consumables, anticoagulant). The rest of the fields must be filled in according to the clinical set-up of the device, applying the following rules:

- For the dialysis prescription to be saved, the mandatory parameters must be filled in because the dialysis treatment cannot be started without them
- In the "Dialysis device" section some fields accept values within a specific range; if a value is entered which is not within this range, an error message appears;
- Some parameters only accept values within a specified step: if an invalid value is inserted, the system will automatically round it up to the step required, and a message appears on the interface to notify the user. For example, if the step for a parameter is "10" and value of "109" is entered, it will be rounded up to "110".

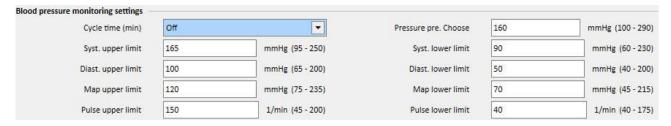


Some settings will be visible or not depending on the "**Dialysis device type**" selected and consequently the modules on it.



Here are the settings for each module:

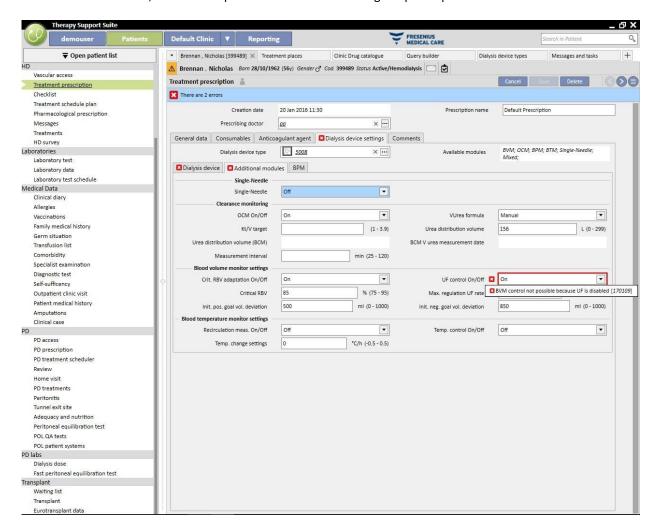
BPM (Setting blood pressure monitoring)



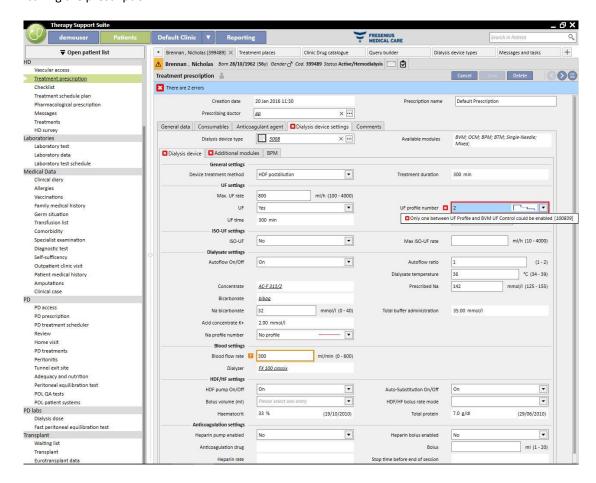
BVM (Setting Blood Volume Monitor)



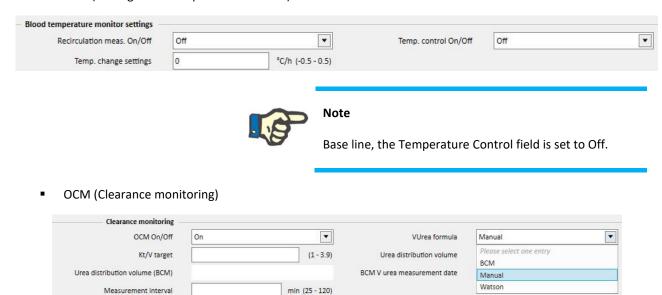
• The "UF control On/Off" can be set to "On" if and only when the UF field (in the UF Settings section) is set to "Yes". Otherwise, an error will prevent the user from saving the prescription.



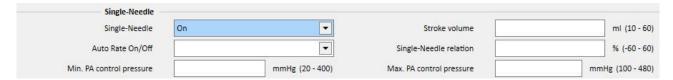
If the "UF control On/Off" is set to "On", it will be possible to set the "Critical RBV", "Max. regulation of UF rate", "Init. pos. goal vol. deviation" and ", "Init. neg. goal vol. deviation". In addition, the "UF profile number" field (of the UF settings section) must be set to "No profile". Otherwise, an error will prevent the user from saving the prescription.



BTM (Setting blood temperature monitor)



- There are 3 possible calculation modes for VUrea:
 - If "Manual" is selected, a value must be entered manually.
 - If you select "BCM" the system will load the value from BCM measurements.
 - If "Watson" is selected, the system will calculate the value using the Watson formula.
- Depending on user selection, all new treatments created will take the value of the Urea distribution volume from one of the three listed above.
- Single-needle



- Mixed
- This module is only available for the 5008 hemodialysis device. If enabled, you can also select "Mixed HDF" and "Mixed HF" items among the "Device Treatment Methods".
- Low volume
- This module is available for hemodialysis devices 5008 and 6008. If the "Low Volume" field is set to "Yes", the ranges for the "Max. UF rate", "Bolus", "Max. regulation of UF rate" (visible in the "Additional modules" section if the BVM module is enabled and the "UF control On/Off" field is set to "On"). Furthermore, to display the "Bolus" field, the "Device Treatment Method" must be either "HDF" or "HF" type and the "Auto-Substitution On/Off" field must be set to "Off" in the "HDF/HF Settings" section.

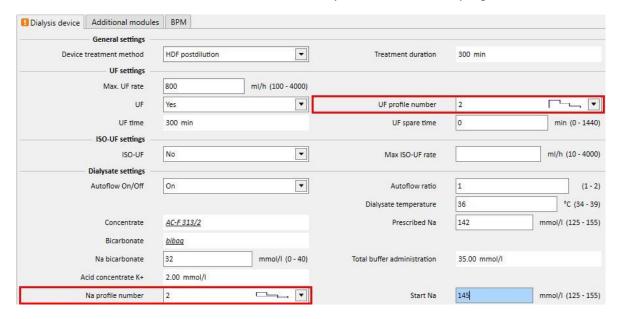
SPECIAL LOGIC

The settings for the dialysis device include some logic, described below. This logic is valid for the FMC 5008, FMC 4008 and FMC 6008 dialysis devices, or (when indicated) only for the specific machine.

Correlation between "Na Profile Number" and "UF Profile Number"

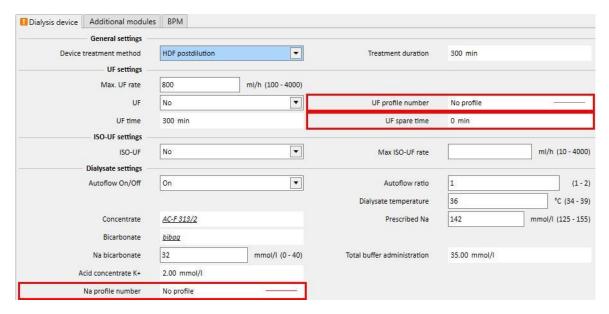
The fields "UF Profile Number" and "Na Profile Number" belonging respectively to the "UF Settings" and "Dialysis Settings" sections are closely correlated, and the following rules apply:

- If either field contains the value "No Profile", the other can contain any value.
- If one of the fields contains a value other than "No profile", the other must contain the same value. For this reason, if the two fields contain a different value, the system will automatically align them.



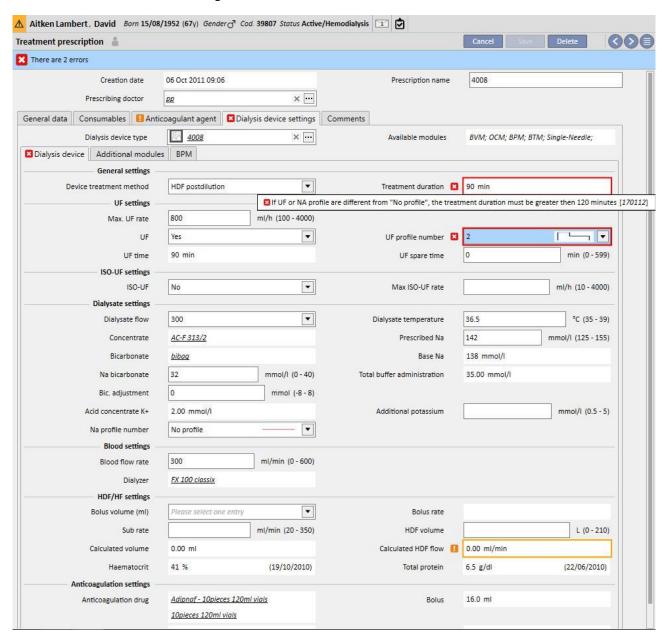
Correlation between "UF", "NA Profile Number", "UF Profile Number" e "UF spare Time"

• If "UF" field is set to "No", the "Profile Number Na" and "UF Profile Number" fields can not be edited and set to "No Profile" while the "UF Free Time" field is set to 0 and rendered non-editable.



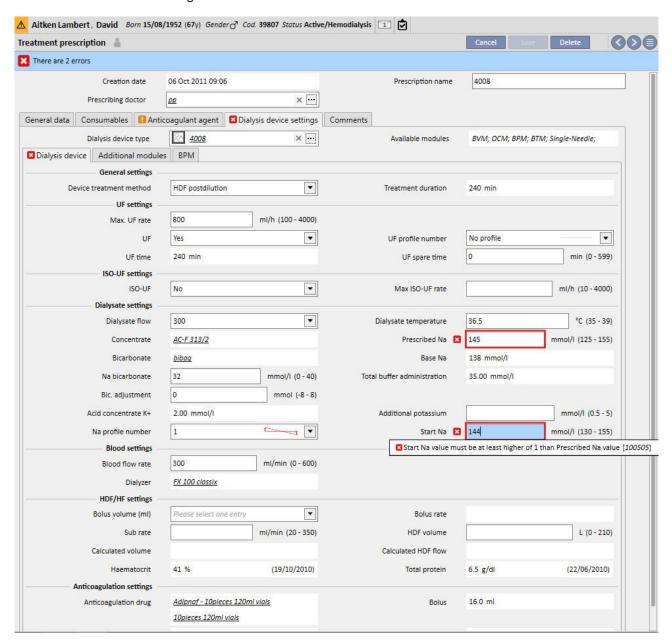
Correlation between the fields "Na profile number", "UF profile number" and "Treatment duration" (only for FMC 4008 devices)

If the "Na Profile Number" field or the "UF Profile Number" field is valued at a value other than "No Profile", the treatment time must be greater than 120 minutes



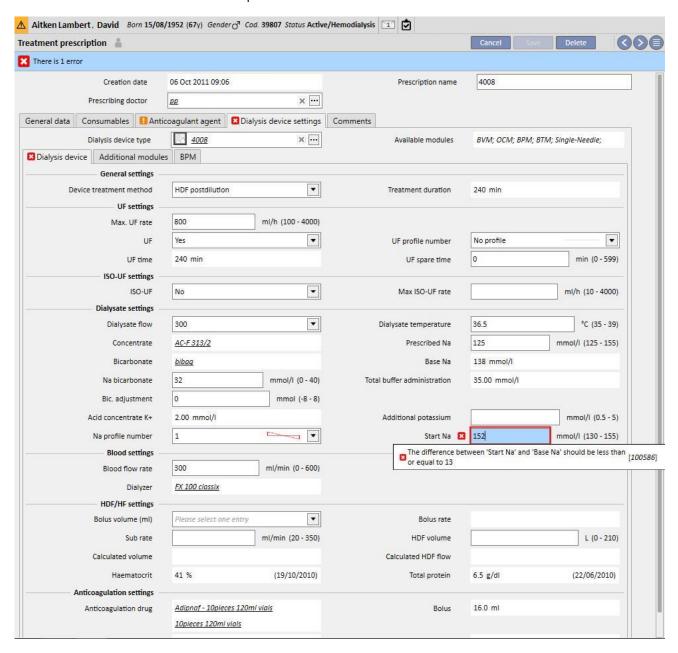
Correlation between "Na profile number", "Start Na" and "Prescribed Na" (only for FMC 4008 devices)

• If the field "NA Profile Number" contains a value other than "No Profile", the "Start Na" field will be visible. Its value must three units greater than the value of the "Prescribed Na" field.



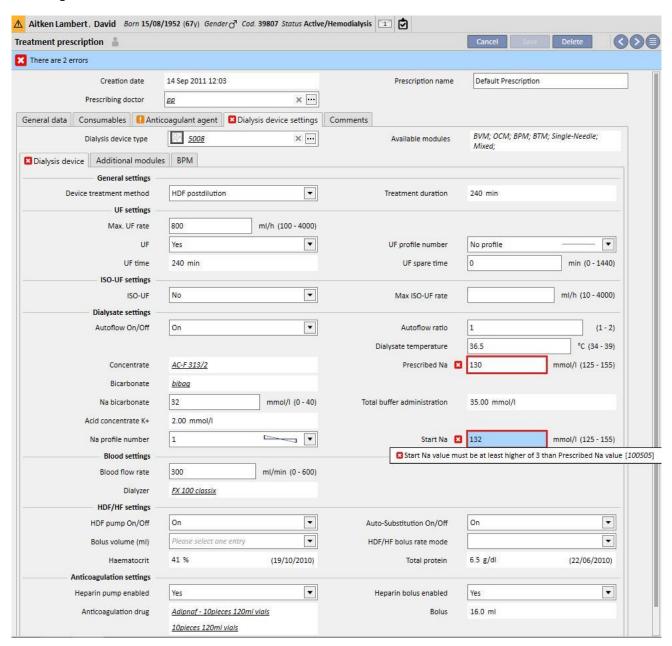
Correlation between the "Na profile number", "Start NA" and "Base NA" fields (only FMC 4008 devices)

• If the "Na Profile Number" field is valued at a value other than "No Profile", the difference between the "Initial" and "Sodium Base" fields can be up to 13.



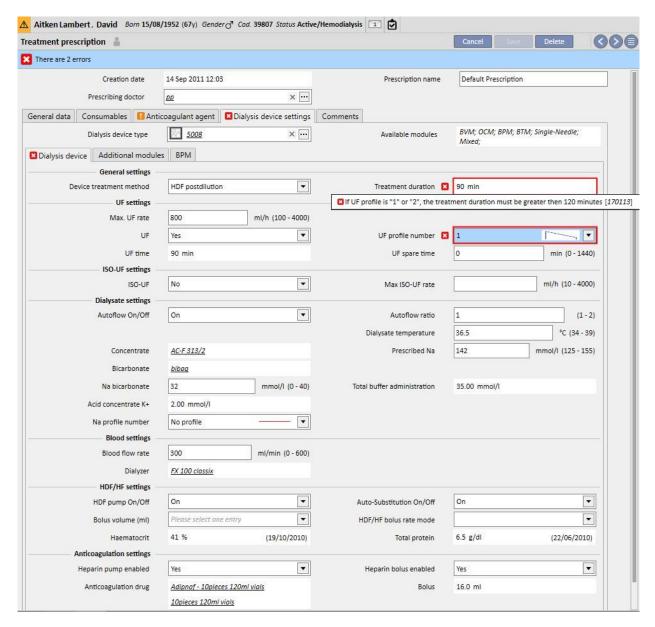
Correlation between fields "Na profile number", "Initial" and "Prescribed" (only for FMC 5008/6008 devices)

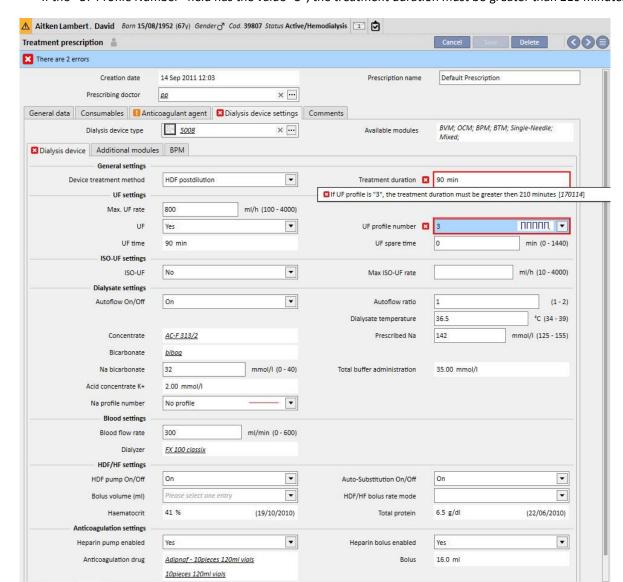
• If the "Na Profile Number" field is valued at a value other than "No Profile", the value of the "Na" field must be greater than at least 3 units above the "At start" field value.



Correlation between fields "UF profile number" and "Treatment duration" (only for FMC 5008/6008 devices)

If the "UF Profile Number" field is valued at "1" or "2", the duration of the treatment must be greater than 120 minutes.

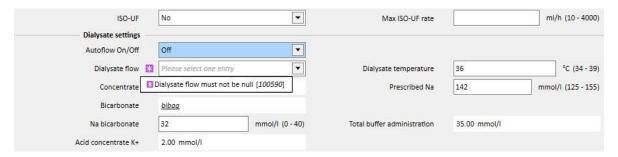




• If the "UF Profile Number" field has the value "3", the treatment duration must be greater than 210 minutes.

Correlation between "Autoflow On/Off", "Dialysate flow" and "Autoflow ratio" (only for FMC 5008/6008 devices)

- If the "Autoflow On/Off" is set to "Off", the "Dialysate Flow" field must contain a value, while the "Autoflow Ratio" field is not visible.
- If the "Autoflow On/Off" is set to "On", the "Autoflow Ratio" field must contain a value, while the "Dialysate Flow" field is not visible. The latter condition is valid for all values set in "Device Treatment Method" (General Settings) with the exception of values regarding "HF" methods, for which both the fields "Autoflow Ratio" and "Dialysate Flow" are visible and editable, but not mandatory.



Logic regarding the "ISO-UF settings" section

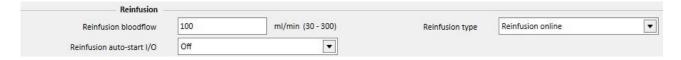


If the "ISO-UF" field is set to "Yes", you can also validate the "ISO-UF time" and "ISO-UF Volume" fields.

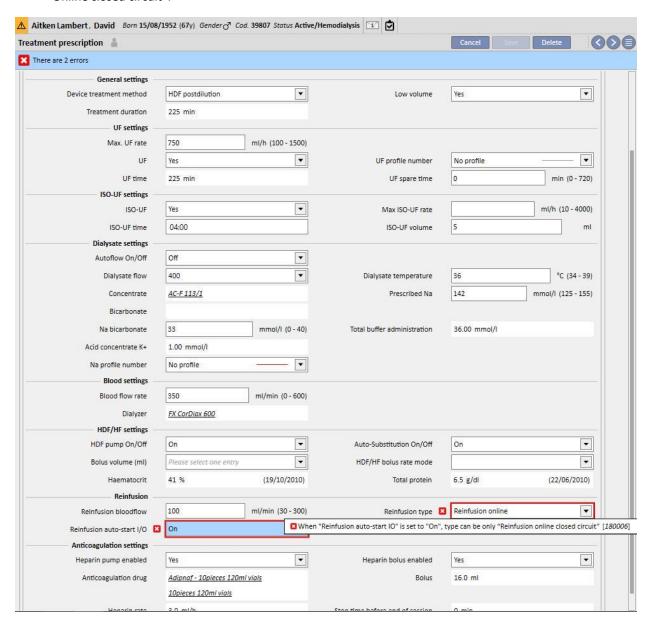
Logic regarding the "HDF/HF settings" (only for FMC 5008/6008 devices)

- If the "HDF Pump ON/OFF" field is set to "Off", the "Auto-replacement On/Off" field cannot be set to "On".
- If the "Auto-replacement On/Off" field is set to "Off", one of the fields between "HDF Volume" and "Flow Sust." must be assigned a value. If neither have a value, of if both have a value, the prescription cannot be saved.
- The "HF/HDF Settings" is correlated with the field "Device Treatment Method" (in the general settings). For some values of this field, the behaviour of the section differs from that described above:
 - If the field "Device Treatment Method" contains the value "HD", the fields listed above are not visible.
 - If the "Device Treatment Method" contains one of the following values, "Mixed HF" or "Mixed HDF" (visible only when the "mixed" module is active) the fields listed above cannot be edited and their values are preet.

Logic regarding the "Reinfusion" (only for FMC 6008 devices)

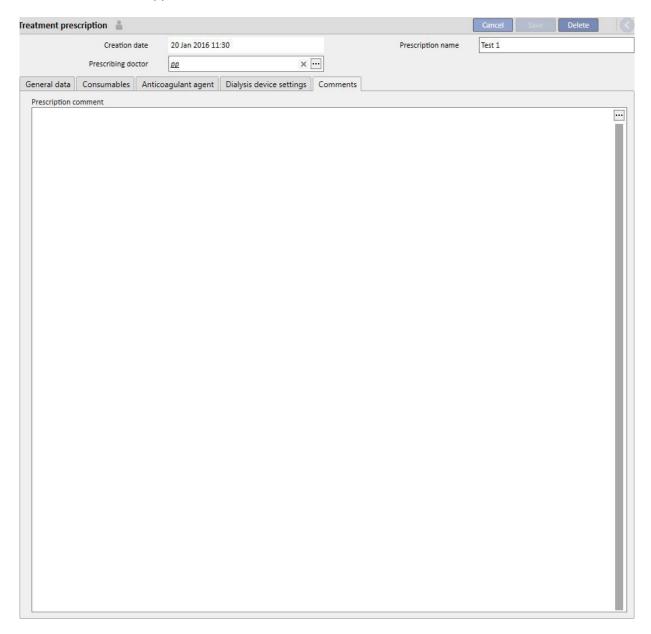


• If the field "Reinfusion auto-start I/O" is set as "On", the field "Reinfusion type" needs to be set as "Reinfusion Online closed circuit".



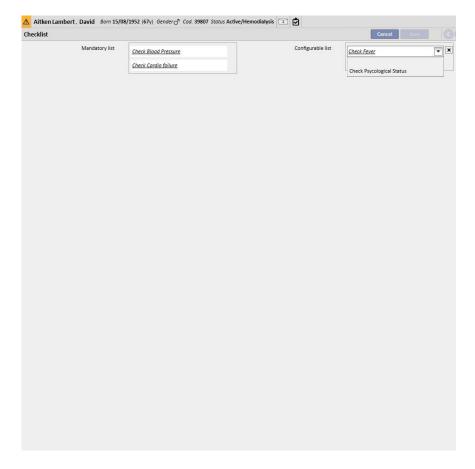
9.3.2.5 COMMENT

In this field a doctor's comment can be added to the prescription and will be read by the nurse during treatments. This field is transferred to Therapy Monitor.



9.3.3 CHECKLIST

In this section it is possible to define a list of checks that nursing staff have to perform during every treatment. The "Check List" contains a list of operations, which the nurse must perform, called the "mandatory list". It applies to all patients. There is also another group of operations called the "configurable list". Both lists can be configured in Master Data by enabling the "Clinic Manager" role. If a Therapy Monitor is connected to the Therapy Support Suite these fields are transferred to the "To Do" section of the Therapy Monitor and can be checked by the nurse. At the end of treatment these fields are transferred to Therapy Support Suite and are visible in the Patient, Treatment data, dXp and dXp item areas. It is important to note that the "Check List" is different from the Events List. The Events List documents events occurring to the patient during treatment and the corresponding actions (drugs, consumables and/or measures) adopted by the staff), while the "Check List" contains the operations which must be confirmed or that are not yet defined before the start of treatment. The order of the configurable lists can be changed at will. Simply hold the mouse button down and drag to the desired position.



Mandatory list. A defined set of operations valid for all patients. The mandatory list can be edited in the "Master Data" (Clinic Manager).

The **Configurable list** contains patient-specific checks which can be selected from a drop-down list. Shows all of the controls defined as not mandatory (regardless of the fact that they have been defined or not in Therapy Monitor). To add additional checks press the button. To delete an item press the button. This list contains all possible optional patient checks specified by the clinical protocol. These checks will be shown in HD Treatment created for the patient, in the dXp tab.

9.3.4 TREATMENT SCHEDULE PLAN

The Treatment Schedule Plan allows the user to define the prescription, day, shift, time and place where a treatment will take place for a specific patient.

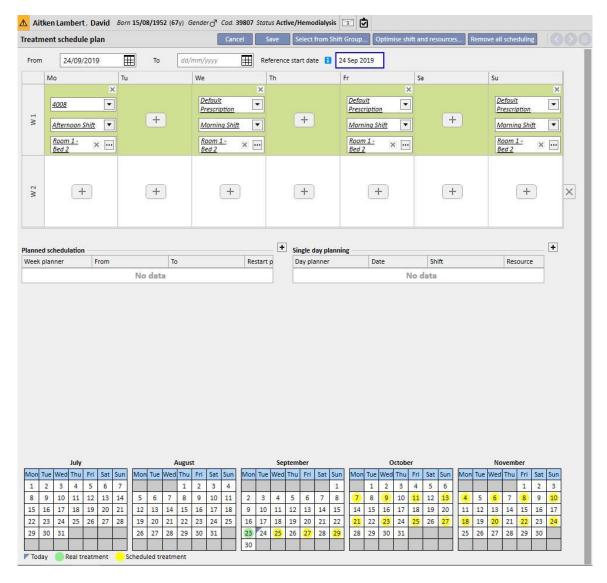
The Treatment Schedule Plan can be viewed and updated by any user with the necessary user rights. It is also possible to enter treatment schedule plans for the future or "exceptions / single days" for the future.



9.3.4.1 DEFINING A TREATMENT SCHEDULE PLAN

Once the treatment plan session is opened the user must specify the date from which it becomes active (it can also be a date in the past or the future). The treatment plan remains active until the end date is reached.

The user can plan treatments on a plan of one or two weeks.



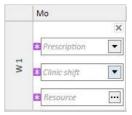
A treatment schedule plan cannot be saved if there are no active treatment prescriptions for the selected patient. In this case a banner informs the user that the prescription is missing when he opens the treatment schedule plan.

9.3.4.2 TREATMENT PLANNING

The days when the treatment will be carried out can be specified individually or set by clicking "Select from the shift group". In the latter case, it is still possible to add schedule plans manually after selecting the shift group.

Selecting a single day

When entering or modifying it is possible to add the treatment plan by clicking on the button in the cell of the grid for the weekday in question.



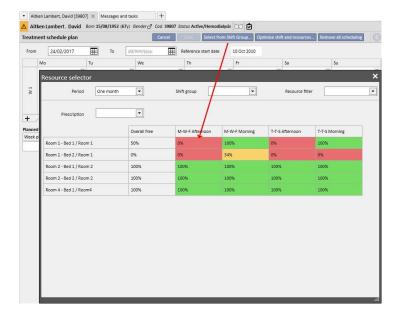
Three mandatory pieces of information must be provided for the plan:

- **The prescription**: The prescription to be followed for the treatment can be selected. The pull-down menu offers all the active prescriptions.
- Clinic shifts: the time of day when the treatment is administered. The pull-down menu offers all the shifts
 defined for the current reference clinic.
- **Resource**: the place where the treatment will take place. The pop-up shows all the rooms of the ward in the reference clinic.

Selection from shift group

The user can indicate several days simultaneously, reading them from a shift group. By clicking on the

button, the user can select a group of shifts. The Shifts and Resources are shown according to the days defined in the group. All previous schedule plans are removed, although additional manual scheduling is possible. However, the user can modify shifts and resources according to his own needs regardless of the values of the shift group.



Here again, the treatment prescription, shift and resource are mandatory fields and values must be filled-in order to save the treatment plan.

Optimise shifts and resources

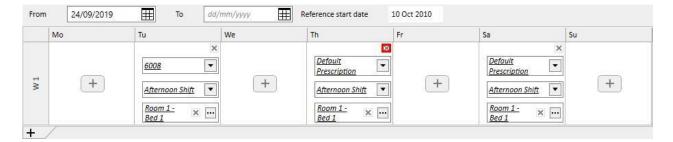
It is possible to optimise the use of shifts and resources via the button. The window which is shown displays the percentage occupation of Resources and Shifts for the days of the week. To make viewing easier, filters have been inserted which reduce the number of elements displayed. Where the percentage is higher, fewer resources are occupied. The choice of one of the indicated resources applies Shifts and Resources to all the schedule plans already entered in the Treatment schedule plan. However, the user can modify the schedule at a later date.

Remove all scheduling

It is possible to remove the entire treatment schedule plan by clicking the planning (the same button is provided inside future planning), single days/exceptions and the planning start date are not removed.

Deleting a single day

The user can remove one or more schedule plans in the Treatment Schedule Plan at any time by clicking on the "x" icon next to the schedule he wishes to delete.

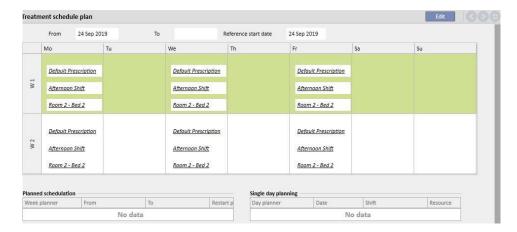


Relationship with the pharmacological therapy

The treatment plan scheduling is closely linked to the pharmacological therapy. During the prescription of a pharmacological therapy during treatment, the days the drug has to be taken are those defined in the treatment schedule plan. Every time the days of the treatment schedule are modified (both the number of days, and changes of days), the pharmacological therapy must be revised.

Reference start date

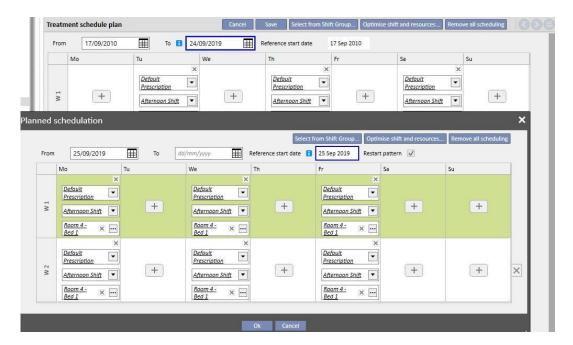
The "Treatment schedule plan" contains a "Reference start date" field which indicates the date when the current plan comes into effect. This value is then used in the pharmacological prescriptions to calculate the current week.



This date is modified automatically only when the number of weeks covered by the treatment schedule plan is modified. For example, if there is switch from a one-week to a two-week pattern, regardless of the days selected, and it will be set at today's date.

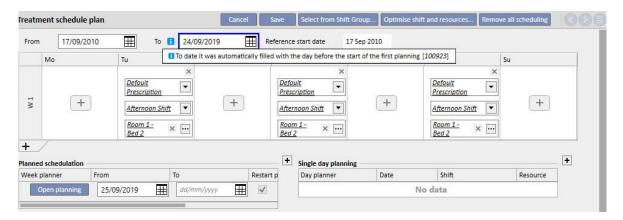
9.3.4.3 FUTURE TREATMENT SCHEDULE PLANS

It is possible to create treatment schedule plans for the future. This is done using the section in the bottom left-hand section of the user interface, as indicated in the screenshot below.

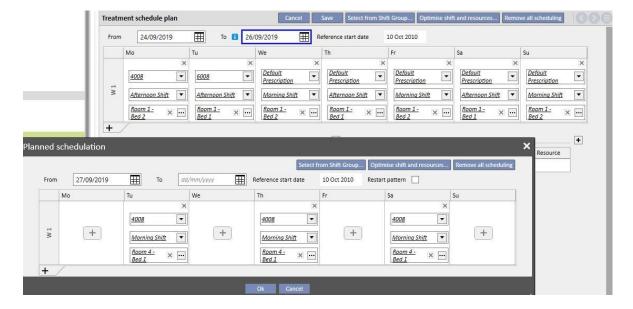


Creating a planned schedule

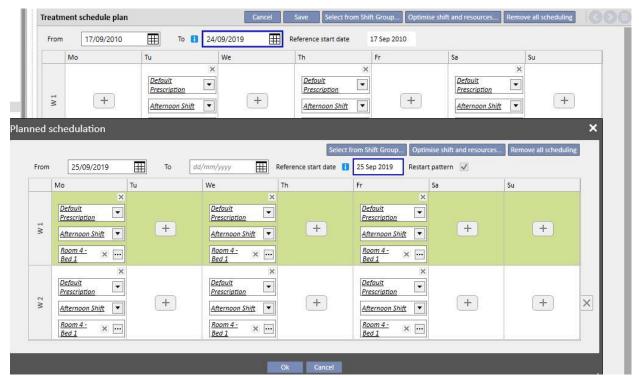
By clicking on the + button it is possible to create a new schedule in the future: the rules for filling-in the relative parameters (scheduling days, shifts, resources) are the same as those described in the previous paragraph regarding the planning of the current treatment, with the exception of the validity dates for the planned schedule. The dates must include an interval after that specified for the current schedule: if the date of the end of the current schedule has not already been entered in the system, when the schedule planned for that date is entered, a date prior to the start of the planned schedule will be proposed by default. (As shown in the example screenshot)



The scheduled treatment plan contains a "Reference start date" field, which is used to calculate the weeks when the future planning will become active. If the future treatment schedule plan has the same number of weeks as the current one, or the previous future plan, this date will not be changed.



Otherwise, if the number of weeks is different, this date will be changed automatically.

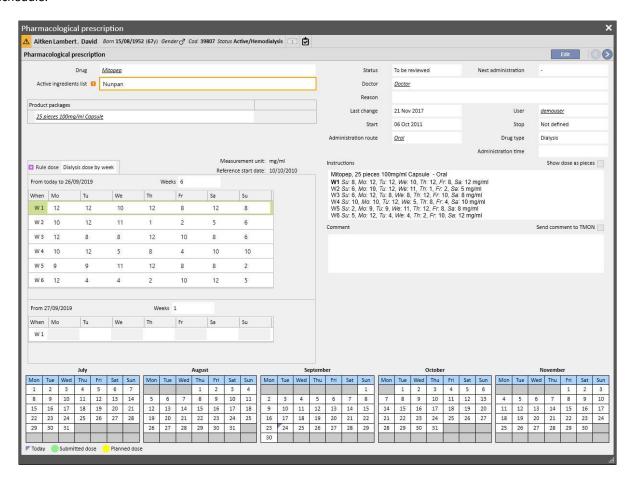


The planned scheduling just created can be modified at any moment, by clicking on "Open Scheduler".

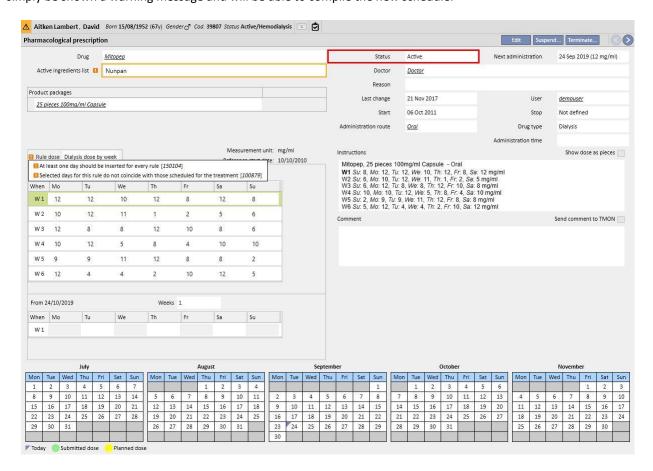
When the start date for the schedule planned for the future is reached, it is deleted from the list of future plans and replaces the current schedule.

No trace of the previous schedule remains.

If there are drugs connected to the schedule plan, with "Dialysis dose by week" as rule, they are set in the "to be reviewed" status "n" days before the date of the start of the planned scheduling, where n is a parameter which can be configured from the "Configuration parameters" heading of the Master Data (Clinic Manager) (for further details see section 4.1.1 of the Service Manual), only if the days of the future schedule are different from the days of the current schedule.



If the number of days (before the pharmacological prescription is to switch to "To be reviewed" status) has not yet been reached, the therapy will remain in the "Active" status, but the new pattern will be shown, and the user will simply be shown a warning message and will be able to compile the new schedule.



Changing the pattern of a schedule plan

Changing the pattern of a schedule involves one of the following:

- Addition of a day
- Removal of a day
- Movement of a day
- Addition of a week
- Removal of a week

In all these cases "Dialysis dose by week" pharmacological prescriptions are switched to "To be reviewed" status, except for point 3, in which case the "Pharmacological prescription review" window will appear to allow therapies to be modified as required.

Restart Pattern Option

If the user wants to restart the treatment planning, even if the new schedule does not change the number of weeks, this can be done by clicking the "Restart pattern" flag.

Restart pattern

This flag is unchecked automatically and set to read-only in all cases where the future schedule will have a different number of weeks from the current or previous one.

Visibility on the clinic scheduler

If the treatment plan schedule contains planned appointments, the pharmacological prescriptions of the clinic's scheduler will always be visible if the associated rule is "Dialysis single dose" or "Month rule", while therapies with the "Dialysis dose by week" rule will only be visible when the "To be reviewed" status has been dealt with.

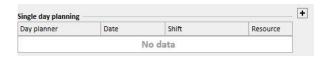
Relationship with the pharmacological therapy

As with the current treatment plan, the planned treatment also has an effect on the Pharmacological Therapy. Every time the days of the treatment schedule are modified (both the number of days, and changes of days), the pharmacological therapy with "Dialysis dose per week" rule must be reviewed.

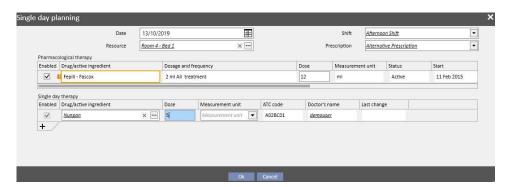
As already mentioned previously, it is also possible to define how many days prior to the start of the scheduling the pharmacological dialysis therapy has to be reviewed. 4.1.1. of the Service Manual.

9.3.4.4 SINGLE DAY TREATMENT PLANNING

From the Treatment Schedule Plan menu it is also possible to create schedules for a single day, also known as exceptions. In this case, the rules to be followed are that the start date must not be in the past and a treatment schedule must have already been saved. If there is an overlap with the current schedule, the single day/exception has greater priority and will therefore be used within the treatment. Once the date of the exception has passed, the data will no longer be visible anywhere.



To create a new schedule for a single day, click the + button shown in the screenshot above.



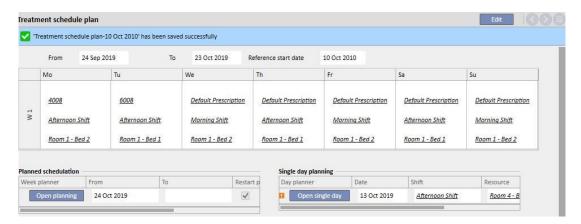
The related pop-up (see screenshot above) will then open, where it is possible to specify:

- The date when the schedule will be applied
- The information regarding the schedule, i.e. shift, prescription and resource

The drugs to be administered to the patient: all drugs in "Active", "Planned" and "To be reviewed" are proposed automatically. If the user wants to administer the drug for the date selected in point 1, he must select the "Enabled" flag (not selected by default) and change the dose, setting it above zero (the drugs proposed automatically cannot be deleted from the table; in order not to administer them it is necessary to set the dose to 0 or to disable them via the "Enabled" checkbox).

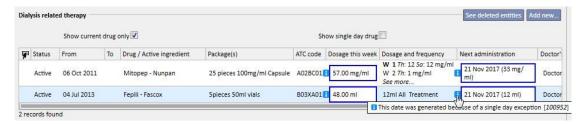
Using the + button in the "Single day planning" table it is also possible to add additional drugs other than those previously proposed by the system. Unlike the drugs proposed by the system, the additional ones added can also be removed.

Once all the information has been entered, the user can save the Schedule by clicking "OK". At this point, the schedule is entered in the relative table and it can be modified at any time by clicking the "Open single day" button.



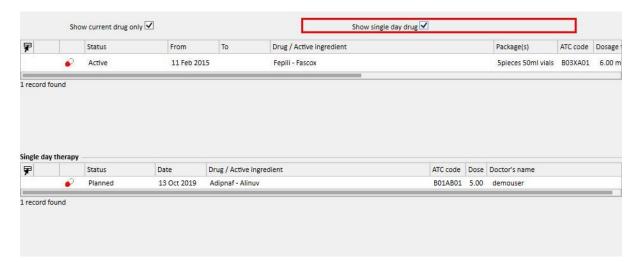
Relationship with the pharmacological therapy

- Deleting a therapy
- When a pharmacological therapy is prescribed in the schedule for a single day (by changing the dose from 0 to a valid value) a link is created between the therapy and the schedule. The therapy cannot be deleted from the "Pharmacological prescription" menu as long as it appears as scheduled in the planning. In this case, a message will advise the user that he must remove the therapy from the schedule before deleting it.
- Displaying the next administration date
- When a pharmacological therapy added on a single day basis impacts the patient's existing pharmacological therapy, an alert is displayed.



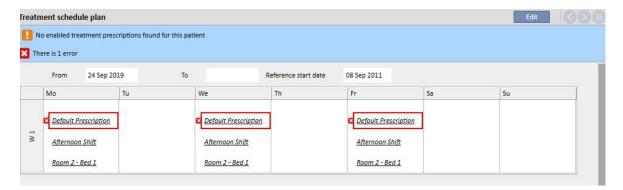
Displaying "Single day therapies"

When a new pharmacological therapy is added as a single day therapy and the drug is not already prescribed for the patient (in the "Pharmacological Therapy" menu), the drug can be viewed by clicking the check button (see screenshot below).



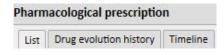
9.3.4.5 INVALIDATION

The treatment prescription has an expiry date after which it cannot be used. If the Treatment schedule plan contains planning which references expired prescriptions, the scheduled treatments are <u>rendered invalid</u> and must be replaced by an active prescription.



9.3.5 PHARMACOLOGICAL PRESCRIPTION

Pharmacological prescription: is a view where drugs can be prescribed for the patient to take at home or during the dialysis therapy. It is divided into three tabs: "List", "Drug evolution history" and "Timeline". In order for this section to work correctly, the drug data must be filled in correctly. For details, refer to the Service Manual.



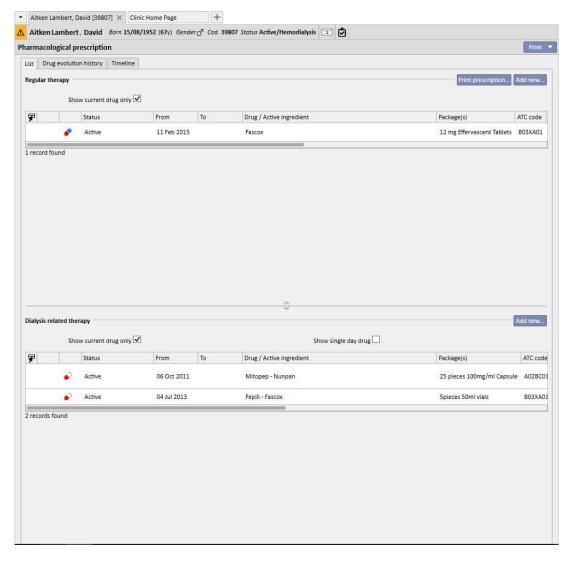
Note



Do not use this section for prescribing drugs already managed in other specific sections of the software (e.g. anticoagulant in HD prescription,...).

9.3.5.1 LIST

This is the main overview, and lists the patient's pharmacological therapies. For easy viewing, it is subdivided into two sections: "Home therapy" and "Dialysis related therapy". This list includes all the pharmacological therapies linked to the patient.



By default, the drugs with a current status other than "Terminated" are displayed. The drugs with "Terminated" status can also be viewed by removing the flag from the "Show current drugs only" checkbox.



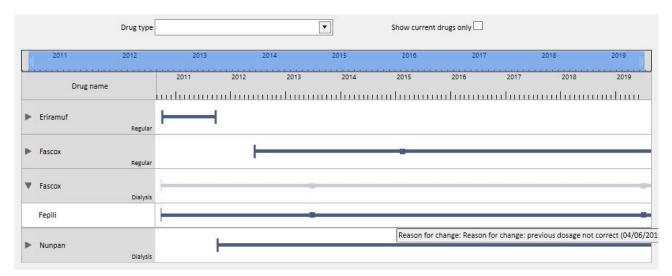
This view is not meant as a registry that highlights all the activities carried out on the drug prescription; rather, it only shows the new versions of drug administration. To create a new version, precise rules must be followed as listed below:

- Home administered drug: at least 24 hours must have passed since the last therapy change and one of the
 following fields must be changed: scheduling days changed, dosage change, change of doctor who changed the
 therapy or change of comment.
- **Drug taken during dialysis treatment**: there must be at least one treatment where this drug was administered, and at least one of the following fields must be modified: *schedule days, dosage, box type or drug name* (referring to the same active ingredient), doctor who changed the therapy or Comment.

If a new version of a drug prescription is being created after a change in dosage, and the "Ask reason for change in dosage" flag has been set as true in the clinic parameters, when the new version is saved a pop-up will appear allowing the user to enter the reason for the change in dosage.

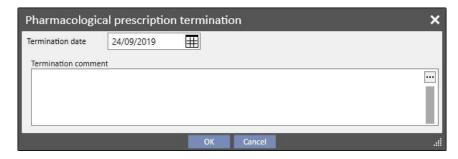


This information will then appear on the timeline, in correspondence with the change in dosage.



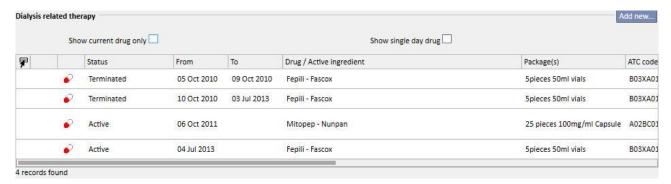
As this section is very important, the meanings of the various columns are explained below.

- Status icon: identifies if the drug is in a "suspended" or "to be reviewed" status by icon
- Drug type: identifies drug type by icon. This can have the following values:
 - Home: home administered drug
 - As needed: drug to be administered as needed
 - Relative to dialysis: drug to be administered during dialysis
- Status: this is the status of the drug. It can have the following values:
 - Active: the patient is taking the drug according to the established rules;
 - Suspended: the patient is not currently taking the drug;
 - Planned: the patient is not yet taking the drug, and will start in the future; if the user now decides to end the drug, it will be removed from the archives and no trace of it will remain anywhere in the system.
 - The prescription automatically becomes Active on the pharmacological therapy start date.
 - **Terminated**: the patient is not taking the drug; when a drug in this status is displayed the button "Copy to" appears, and if clicked, it creates a new pharmacological therapy identical to the Terminated one, the only difference being the start date, end date and doctor fields. It is then the responsibility of the user to modify the new pharmacological therapy as required, and save it.
 - It is possible to terminate a drug prescription by clicking the "Terminate" button, which appears when the drug is displayed, and selecting the date the drug is to be terminated in the pop-up that appears after the button is clicked. If the date chosen corresponds to today's date, the termination will be immediate. This means that for drugs to be taken during treatment, if a treatment is scheduled for that day, the therapy will not appear among those to be administered.



- To be reviewed: this is a condition which occurs for drugs taken during the dialysis treatment and for which the administration rule is connected to the "Treatment planning" of the patient. The "To be reviewed" status indicates that the scheduling of the related treatment has been changed after the creation or modification of the pharmacological therapy. It is possible that the days of the week when the patient must take the drug no longer coincide with the treatment planning. This also occurs for existing drugs that are dialysis therapy and regular therapy, when an allergy is entered after an active ingredient has already been prescribed to the patient.
- **From**: the start date of **this** administration. It is not the date of the creation of the drug prescription, given that the therapy may have been changed over time.

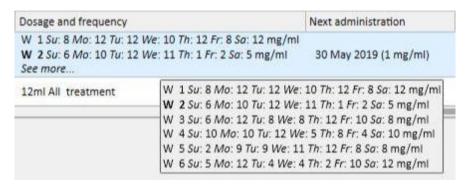
■ **To**: the end date of **this** administration. This information may be absent. Following the termination of a therapy by clicking on the "Terminate" button (and only for the immediate termination of the therapy) the time of the termination will appear, only for the day in question.



• Drug / Active ingredient: if a generic drug is prescribed only the active ingredient will be shown, otherwise the name of the drug and its active ingredient are shown. If the drug has multiple active ingredients, only the first two are shown, followed by "...".

Zaminreum - Alinuv/Eriramuf/Fascox/Hephobase/Iraderac/Nunpan...

- ATC code: this is the ATC classification of the drug.
- **Dosage per week**: this is the dose taken by the patient in the course of a week. In the case of administration over several weeks, the average of the various weeks is calculated.
- Dosage and frequency: this shows the dose and frequency of the dose in detail. In the case of administration over a number of weeks only the first two weeks are shown. The "View in detail" field is then shown: here the other weeks can be displayed by positioning the mouse on them.



- The screenshot above is just an example, given that the content of this field depends on the type of rule of the selected dosage.
- Next administration date: This field is calculated automatically based on the administration rules set. For drugs in Suspended or Terminated status, this field shows the value "-". As soon as a new drug therapy has been saved, this field contains the value "Calculating..." which will be replaced a few seconds later by the next date of administration. The text will read "No treatment schedule defined" when the information cannot be calculated because there is no treatment plan available.
- Name of doctor: the name of the doctor responsible for the pharmacological prescription.
- Comment: a comment can be inserted when creating the pharmacological prescription.
- Action: contains a button which varies according to the drug's status. The possible values are explained below:

• **Suspend**: appears in the case of active drugs; clicking it opens a new window where the user can suspend the drug. The default start date for the suspension is set at today's date, but can be changed to a later date. It is also possible to add a comment to specify the reason for the suspension.



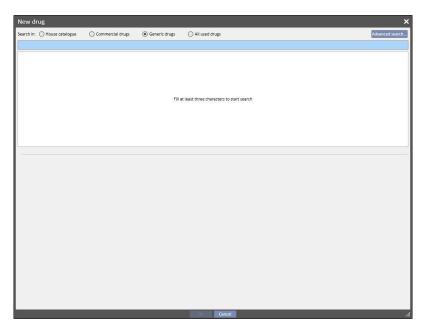
• Suspended: appears in the case of active drugs for which a suspension at a later date has already been inserted. After clicking it, the user can view the suspension and modify both the start date and the comment. The future suspension can also be suspended by clicking the "Delete suspension" button. In this case, the drug becomes active again, and no trace of this operation will remain, given that the suspension had not yet begun and the status of the drug remains unchanged.



Reactivation: appears in the case of drugs which are currently Suspended. After clicking this field the
user can view the suspension entered and the comment entered when it was suspended. The
reactivation date can be entered. If the date entered is today's date, the drug becomes active
immediately. If the date entered is in the future, the drug will remain Suspended, and will be activated
automatically when the date is reached.



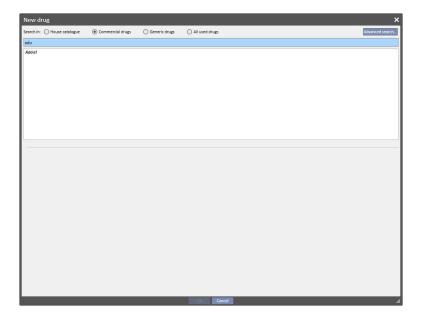
• Add new...: this is used to insert a new pharmacological prescription, both for administration at home and for use during dialysis treatment. Clicking here opens a window to search for the drug, with the cursor already in the right position to start the search. If the user types at least three characters of the drug's name, all those drugs which satisfy the search criteria appear. Please note that the search does not include or visualise the various pack sizes available.



There are four different search modes:

- Clinic catalogue: Searches among all the drugs in the clinic drug catalogue.
- Commercial drugs: Searches among all the drugs in the drug database that are defined as commercial;
- Generic drugs: Searches among all the drugs in the drug database which are defined as generic or only as active ingredient;
- All drugs used: Displays the entire list of drugs already prescribed in the therapies of all patients.

Once the search criteria have been entered, a list of drugs is automatically generated, which may also include warning icons to the left of the drug name.



Messages of this kind do not block the search process for the drug, but just give warnings. The following are the warnings which may appear if a drug with an icon is selected:

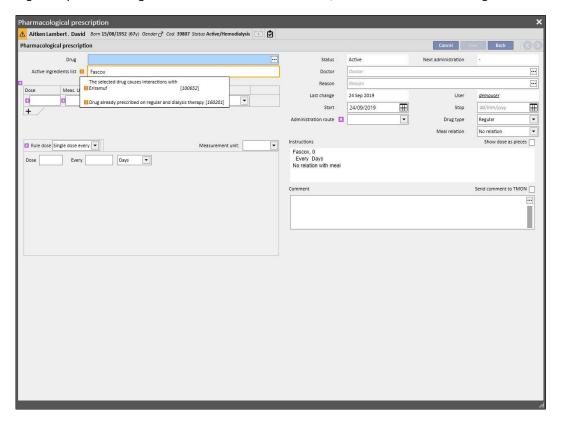
The drug interacts with other drugs which have already been prescribed for the patient.



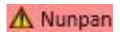
• A drug with the same active ingredient has already been prescribed or is among the regular drugs or the treatment drugs prescribed.



In this case, after clicking on the Yes button, a warning message will appear in the active ingredient field, which tells the user to pay attention because the same active ingredient is already prescribed, but it will allow the drug to be prescribed regardless. In the No button is clicked, the user returns to the drug search view.



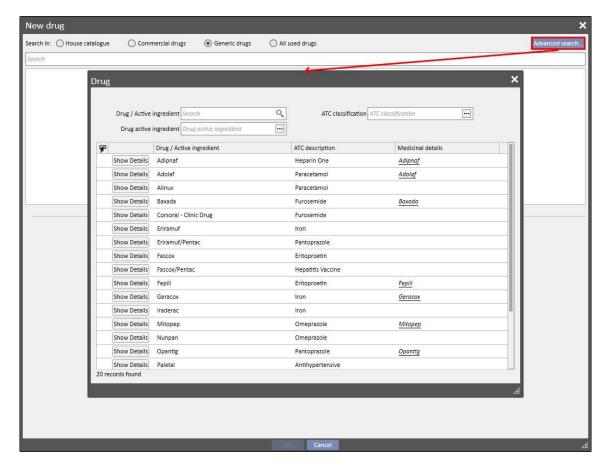
• Take care because the patient is allergic to the active ingredient selected for administration.





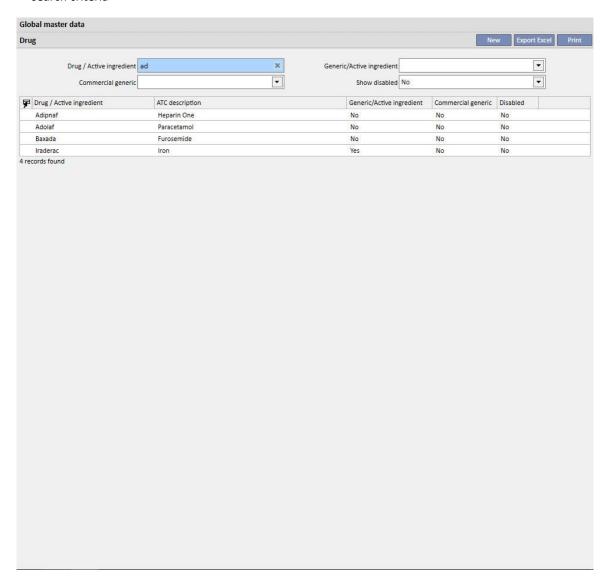
If the drug shows several warning icons, once the drug has been selected all the warning messages will be shown in sequence.

There is also an advanced search, where clicking a button opens a window listing all the drugs, both generic and commercial, in the drug catalogue.

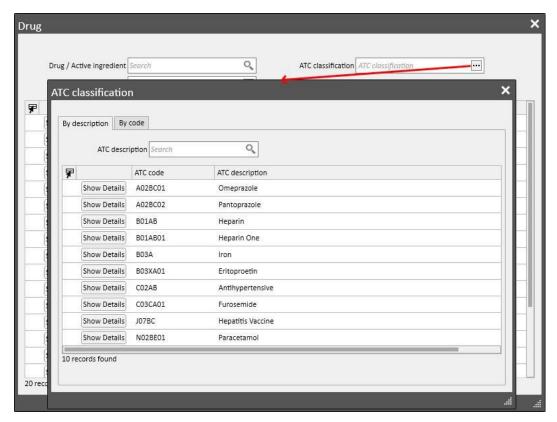


This list can be filtered in three different ways:

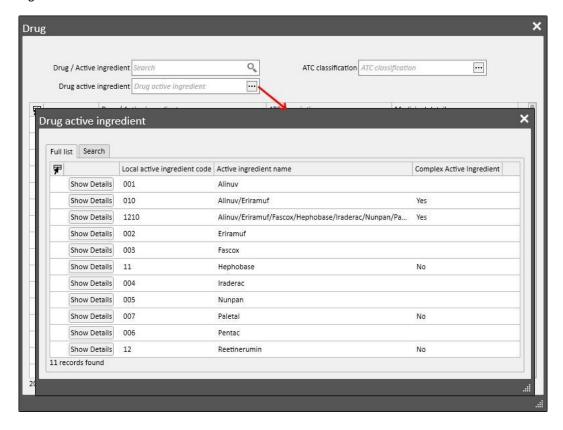
 Drug / Active ingredient: by typing at least one character; the search only shows the drugs which satisfy the search criteria



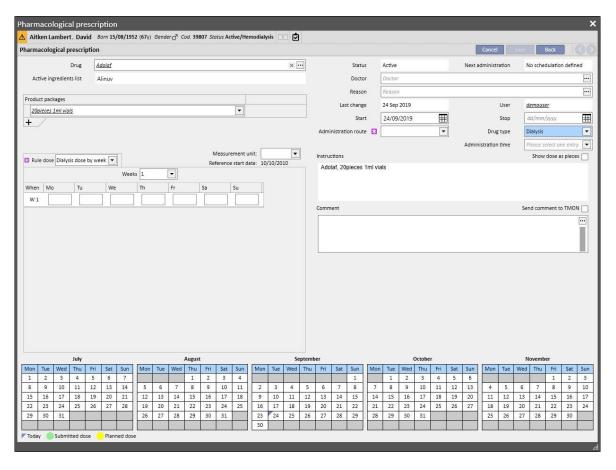
• ATC Classification: by typing at least three characters of the ATC description (the search only shows the drugs which meet the search criteria) or clicking on the button to show a default list of all the ATC classifications.



Active ingredient: by typing at least three characters of the name of the generic drug (the search only shows
the drugs which meet the search criteria), or clicking on the button to show a default list of all the generic
drugs.



Once the search has found the drug to administer, click on the drug or on the OK button to open the window for the pharmacological prescription.



The main difference between a "Home therapy" and a "Dialysis related therapy" is in the definition of the doses, the rules and the packaging of the drug. A detailed description of the single fields/areas is provided below.

Drug definition area: the screen varies depending on whether the search was for a commercial drug or a generic drug/active ingredient:

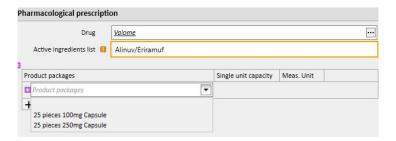
- Commercial drug:
 - Drug: contains the name of the drug; if the drug is not a generic and the corresponding generic is in the drug catalogue (active ingredient, but not *pure generic*), the field will appear as editable and the

user can change the drug, switching from commercial to generic, (by clicking on the $\frac{1}{2}$ icon) and vice versa (selecting the drug from the list via the "...").

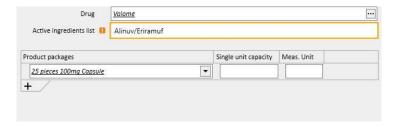


Active ingredients: read only, it contains the name or names of the active ingredients which make up
the drug. (A maximum of two active ingredients are shown). If the drug interacts with other drugs
already taken by the patient, or if the patient is allergic, this field shows a warning message indicating
this;

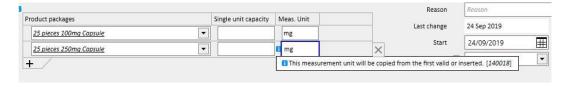
- Product packages: if only one format is defined in the drug database, this one is offered by default; if there are different types the field is left empty, marked as mandatory, with the possibility to choose up to a maximum of three packages. Depending on how the drug catalogue is put together, and specifically the "Weight/capacity of single unit" and "Measurement unit" fields, one or another view will appear:
 - The "Weight/capacity of single unit" and "Measurement unit" fields already contain correct values in the drug catalogue (*See section 4.2.8 of the Service Manual*):



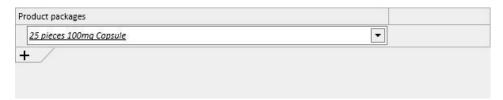
The "Weight/capacity of single unit" and "Measurement unit" do not contain values in the drug catalogue (See section 4.2.8 of the Service Manual). The user is responsible for compiling these fields



• If the user adds another package, and this has also been defined in the drug catalogue without weight and units of measure, the user cannot type in the units of measure related to the second package, which will be copied directly from the first package.



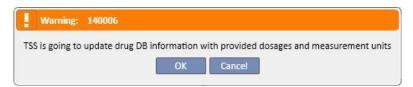
- If two or more product packages exist for the same drug, and the weight and units of measure is not defined for all the packages in the Drug Catalogue, the following situation occurs:
 - Selection of the packaging with weight and units of measure already defined in the drug catalogue:



A package without defined weight and units of measure is added to the drug catalogue:



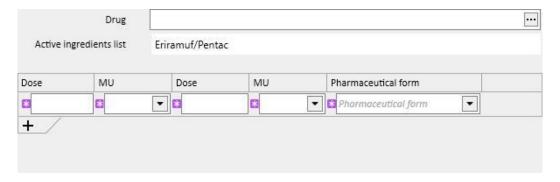
The weight and units of measure must be entered with great care and attention, because when the therapy is saved an info message is shown, which advises the user that the information just entered will update the drug catalogue.



- Clicking the "OK" button saves the pharmacological prescription and amends the drug catalogue; if the user clicks "Cancel" the pharmacological prescription is not saved, and no changes will be made to the drug catalogue.
- Generic drug / active ingredient:
 - Active ingredient: read-only, and contains the name or names of the active ingredients which make up the drug. (A maximum of two active ingredients are shown). If the drug interacts with other drugs already taken by the patient, or if the patient is allergic, this field shows an warning message with the relative information;
 - Dose, units of measure and pharmaceutical form: obligatory fields which are filled in by the user.
 - If the generic drug consists of only one active ingredient, or of three or more active ingredients, the following screen will appear (if the dosage, units of measure and the pharmaceutical form are the same, in the case of 3 or more active ingredients):



• If the generic drug consists of two active ingredients the following table will appear; where different units of measures can be selected on the same line, but with only one pharmaceutical form.



Dose Meas. Unit Pharmaceutical form 10 • • ml Injection 200 Effervescent Tablets • Measurement units must be the same for each package [100860] Pharmacological prescription There is 1 error ... Drug Active ingredients list 🔋 Eriramuf/Pentac Dose MU Dose ΜÚ Pharmaceutical form 5 mg -5 mg • Effervescent Tablets • 20 • 50 c g mg Effervescent Tablets Measurement units must be the same for each package [100860] • 10 mg

• In both cases, it is possible to specify a maximum of three packages, taking care that the units of measure and pharmaceutical form are the same for each package.

Status: A non-editable field, with contents which change depending on the start and end dates specified. The default status is "Active". If the start date is in the future the field will become "Planned". If the end date is before today, the field will become "Terminated".

Next administration date: this label shows the next date of administration for the drug as calculated automatically by the system based on the start date, the planning rule, and in the case of the dialysis therapy, the date of the start of the treatment plan schedule when the therapy is "Active" or "Planned".

When the therapy is in "to be reviewed", "suspended" or "terminated" status, the "-" symbol appears as no information can be calculated. The text will read "No treatment schedule defined" when the information cannot be calculated because there is no treatment plan available.

Doctor: A non-mandatory field; it can be filled with the doctors defined in the "Clinic staff" section of the "Master data" menu who have "Yes" in the "Doctor responsible for the drug prescription" field. If the user's profile corresponds to these criteria, this field is filled-in by default during issue of a new pharmacological prescription.

Last change: Non-editable field. When a new pharmacological prescription is being entered this field is given today's date; when a pharmacological prescription is being modified this field shows the last modification date, and if the prescription is modified it is updated with the current date.

User: Non-editable field. When a new pharmacological prescription is being entered, this field shows the user who is issuing the pharmacological prescription. When a pharmacological prescription is being modified this field shows the last user to modify the prescription, and it is updated with the current user if the prescription is modified.

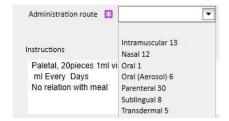
Start: Mandatory field. When a new pharmacological prescription is being entered, this field shows today's date by default, but this can be modified and dates in the past or future (in which case the status becomes "Planned") can be entered. When a pharmacological prescription is being modified, no changes can be made to this field. However, the date will be modified automatically when the rule, dose, or the doctor responsible for the pharmacological prescription changes (for drugs for the dialysis therapy there must be at least one treatment which has used this drug, whereas for drugs for home therapy at least one day must have passed since the last administration).

End: Optional field. It is empty while the prescription is entered and can be set with a date later than or equal to the one entered as *start*. If an active pharmacological prescription is undergoing a modification, it is possible to enter an *end* date which is after or equal to today's date in the event of regular drugs. For dialysis therapy, it is only possible to define an *end* date for an active therapy which is later than the date of the treatment when the drug was last administered.

Administration route: This field can be mandatory or optional, depending on the setting made in the configuration parameters of the clinic configuration function. Another option set in the clinic configuration is the family of administration routes to be displayed:

- Always use complete list: the value of the field can be selected from the complete list of administration routes.
- Use complete list if drug list is empty: the value for the field can be selected from the set of administration routes defined for the family of drugs containing the same active ingredient. If nothing has been set the complete list is provided.

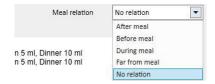
Furthermore, if the drug being prescribed has only one possible administration route set for all the packages in the drug catalogue, the field becomes a read-only field and contains that value by default.



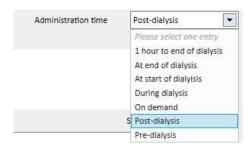
Drug type: Mandatory, pre-filled in field which can only be modified during creation of a new pharmacological therapy. The value of this field changes depending on whether the "Add new..." button was activated from the home therapy section, or from the related dialysis therapy section.



Meal relation: Pre-filled in field only visible for the regular pharmacological prescription. The value of this field is written in the instructions.



Administration time: This field is only visible for the related dialysis therapy prescription.

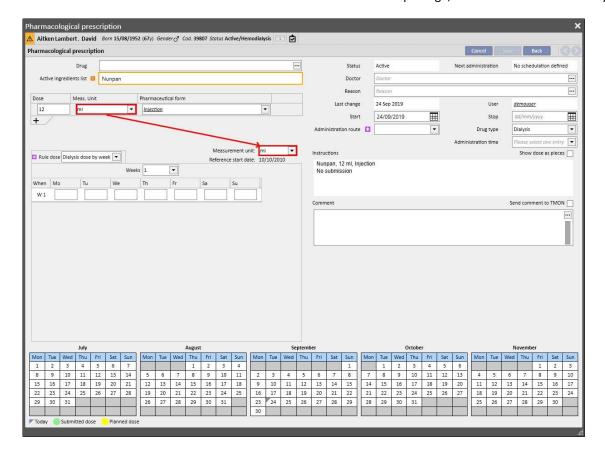


Reason: Optional editable field. It can contain the reason for issue of the pharmacological prescription. The reason can be taken from the disease catalogue. Once it has been selected and the drug has been described, this reason is added to the patient's "Comorbidities". If the reason is already listed under the patient's "Comorbidities", it is not added again.



Measurement unit: Optional field which is filled in automatically or manually depending on how the drug is defined in the drug catalogue, and whether any customised units of measures are present (*See section 4.2.8 of the Service Manual*):

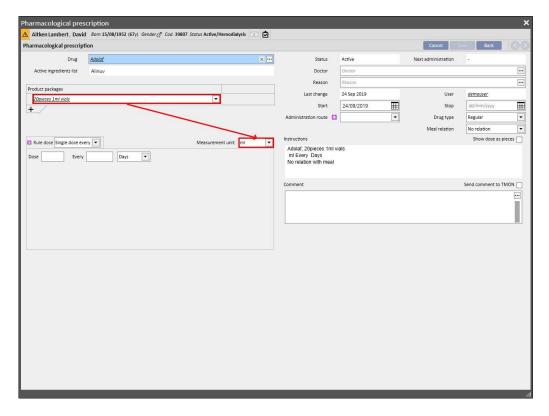
- No customised units of measure: the field cannot be edited, and by default it shows the value associated with the product package or the value set for the active ingredient. In the case of product packages for which no unit of measure is set in the drug catalogue, this field will show the value added by the user.
- One or more customised units of measure are present:
 - Generic drugs: the field is left empty by default.
 - As soon as the user sets the units of measure related to the package, this field is set automatically.



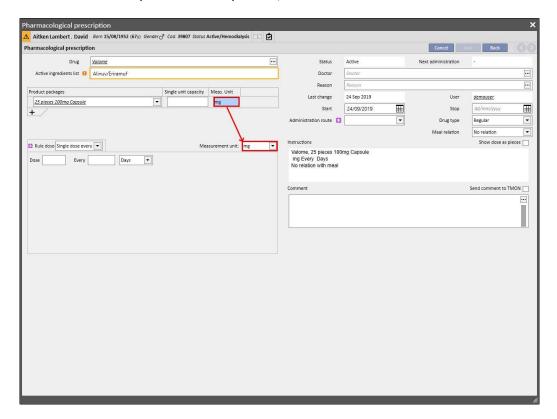
• However, the user can still select a customised unit of measure.



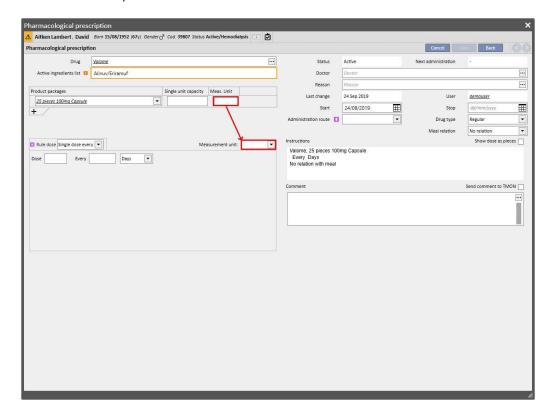
• Commercial drugs: if the selected packaging already has a value in the units of measure field in the drug catalogue, this value is set by default, while the user can still select a customised unit of measure.



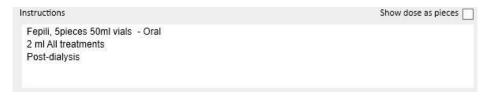
• If the selected package does not have a value in the units of measure field in the drug catalogue, the value entered by the user is set by default, while the user can still select a customised unit of measure.



• The user can also leave the units of measure fields empty. He can therefore modify them later and enter the respective values.



Instructions: Optional, non-editable field which is automatically filled-in according to the rules and dosages specified for the pharmacological prescription.



If the user selects a customised units of measure, it is not possible to show dosage by pieces, and the "Show dose as pieces" field is hidden automatically. If a units of measure belonging to a drug catalogue is selected, the

Show dose as pieces field can be selected to view the written instructions for calculation of the dosage on the basis of the pack size. If not all fields required for calculation of the number of pieces have been filled in, an information message will be shown. The necessary data are "Weight/capacity of single unit" and the units of measure.



If the drug is composed of two active ingredients and the user has selected only one package, the word "unit" will appear instead of the weight of the single unit in the instructions.



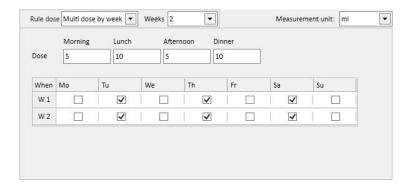
Comment: Optional editable field. It can be used to enter a comment on the pharmacological prescription. If the Send comment to TMON ✓ field is flagged, this comment will be sent to the Therapy Monitor as part of the name of the drug. This "send Comment to TMon" field can be set to always be flagged, configuring the Clinic Manager



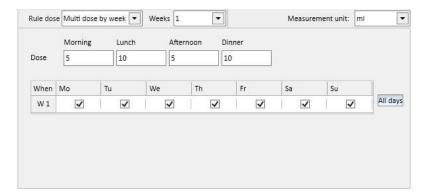
with the Clinic manager.

Dose rule: this section is used to define the rules, doses and frequencies related to the administration mode. It is therefore necessary to distinguish between home therapy and the related dialysis therapy.

- "Home therapy": there are four different administration routes:
 - Multi dose by week: it is possible to set from a minimum of one week (default) up to a maximum of
 eight weeks. The dose can be chosen from Morning, Lunch, Afternoon and Dinner; at least one of
 these values must be inserted. The days of the week for administration of the drug can be selected on
 the right. The number of weeks which appears can vary from one to eight, depending on how many
 have been chosen.



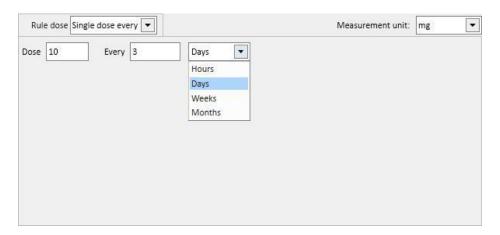
• If only one week is chosen, the button can be clicked to select all days at once. Once they have selected using this method, they can be deselected all together by clicking the same button again, or individually.



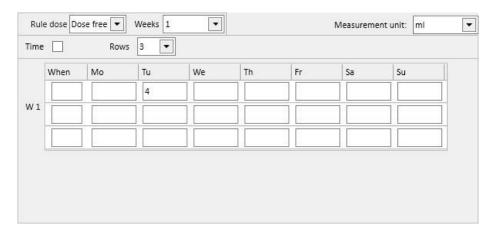
• Dose by week: from a minimum of one week (default) up to a maximum of eight weeks can be set. The dose is written directly in the days of the week; at least one dose must be entered.



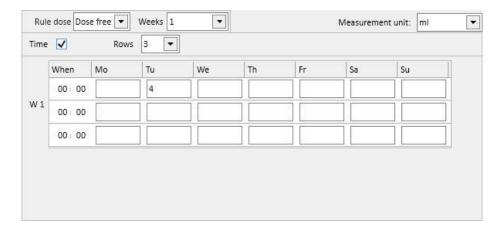
• Single dose every: the user can set the dose and the "every" field (numerical value) and then one of the time intervals available. "Dose" and "every" are mandatory fields, whereas the time interval is set as "Hours" by default.



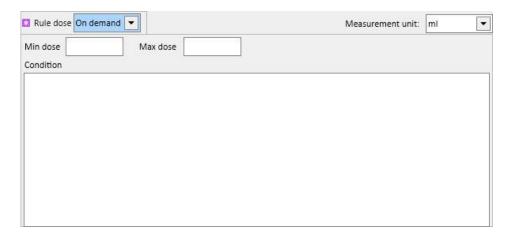
Dose free: this is a highly customisable function allowing selection of the number of weeks from a
minimum of one to a maximum of eight. A maximum of up to six lines can be set for every week
selected. The dose is written directly inside the day fields, and at least once must be entered. The
"When" field can be used to enter free text stating when the doses specified in the relative fields must
be administered.



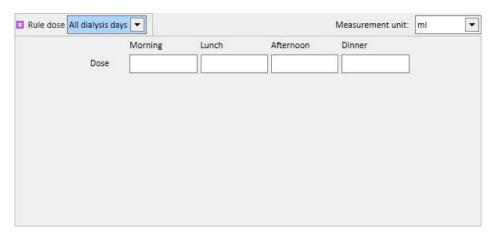
• Flagging the Time I field increases the number of selectable intervals to a maximum of twenty-four, and the field "When" is formatted by default as HH:mm.



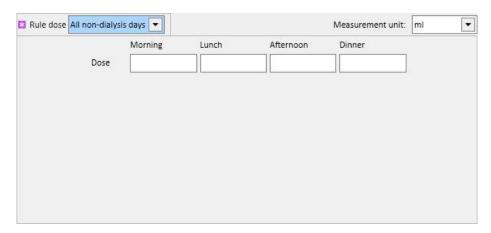
• As needed: a "Minimum dose" and a "Maximum dose" can be specified, for administration in specific conditions that can be entered in the "Condition" free text field



• "All dialysis days": this rule indicates that the prescribed doses must be administered on the days when dialysis is performed. The Morning, Lunch, Afternoon and Dinner doses can be entered.



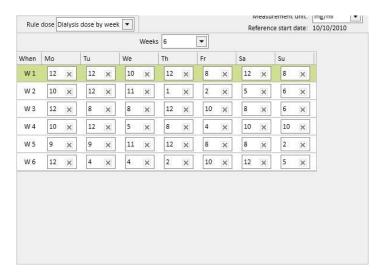
• "All non-dialysis days": this rule indicates that the prescribed doses must be administered on the days when dialysis is not done. The Morning, Lunch, Afternoon and Dinner doses can be entered.



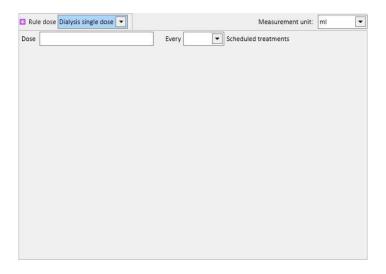
• "Free text": this rule does not define an administration routine but allows the user to write anything he likes in a free text field.



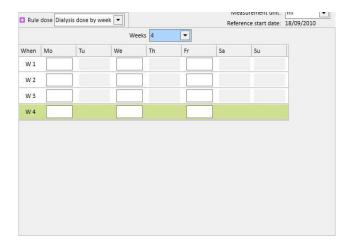
- "Dialysis related therapy": Therapy Support Suite offers a choice of two administration rules:
 - Dialysis dose per week: this type of administration is closely related to the settings made in the "Treatment schedule plan" section. The only days for which it is possible to insert a dose are those for which a treatment has been set in the "Treatment schedule plan" section.
 - In the case of a single-week treatment plan, the drug planning function allows up to eight weeks of planning.



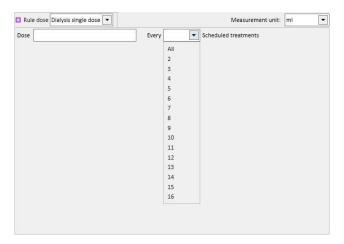
• In the case of a two-week treatment plan, the drug planning permits up to eight weeks of planning, but the user is requested to set a number of weeks which is a multiple of two.



• A green background identifies the current week (based on the treatment schedule plan start date) to help the user manage administrations in case of multi-week rules.



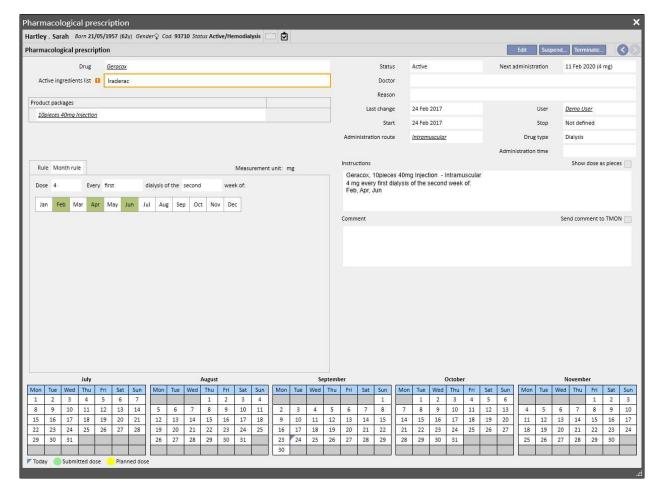
 Dialysis single dose: this administration rule is closely related to the settings made in the "Treatment schedule plan" section. The administration depends on the number of treatments planned and not specific treatment days.



• Month rule: under this rule, the user can set the dose which can be administered once a month if specific conditions are met. Once the "Dose" value has been entered, the user can select at which dialysis treatment (first, second, third or fourth) of which week (first, second, third, fourth or fifth) of the selected months the drug is to be administered. If the selected dialysis treatment number or week number does not occur, the dose will not be administered. The first week of the month is the first full week of 7 days.

The bottom of the therapy screen contains a calendar where the past and future dates for administration of the current medicinal product will be shown, with a five-month time window.

This calendar will display the doses already administered at past treatments (shown in green) and those scheduled for the future (in yellow). Passing the mouse over one of the highlighted days displays the dose administered / scheduled.

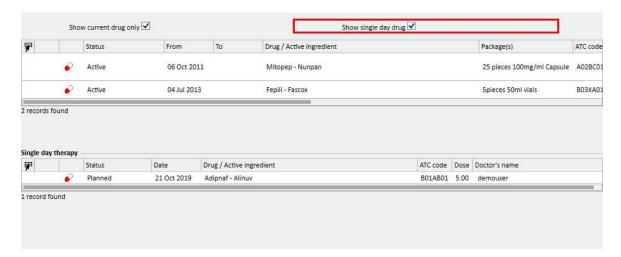


Displaying the drugs scheduled for a single day

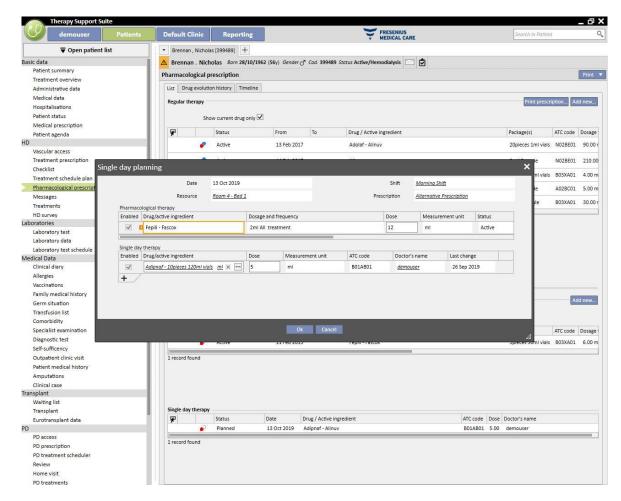
By default only the "normal" dialysis therapies are displayed. It is also possible to see the drugs belonging to the pharmacological therapies prescribed via "Single day scheduling", by deactivating the flag "Show single day drugs" flag.



This will show the list of all drugs scheduled for a single day which are not part of the list of dialysis therapies.

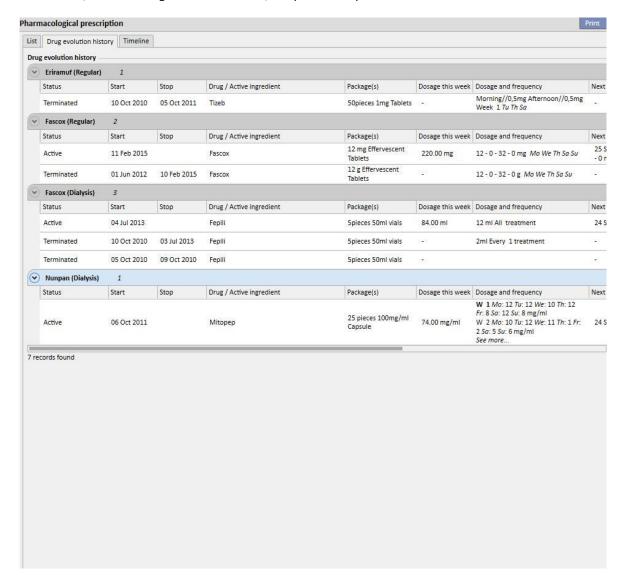


Clicking on an item in this list will show the scheduled single day for which the prescription was issued.



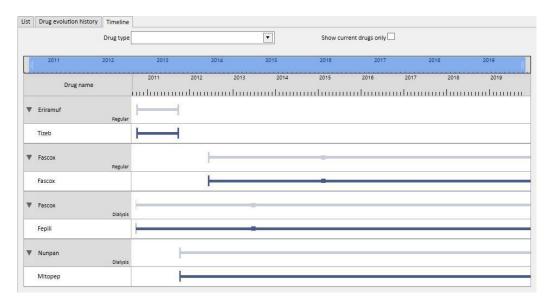
9.3.5.2 DRUG EVOLUTION HISTORY

The drug evolution history shows all the drugs administered to the patient in the "Active" or "Terminated" status, grouping them by active ingredient, but always maintaining the distinction between administration at home and administration in dialysis. Unlike the *List* section, this section does not contain the "Add new..." button or the "action" button. However, once the drug has been selected, it is possible to proceed as described in the List section.



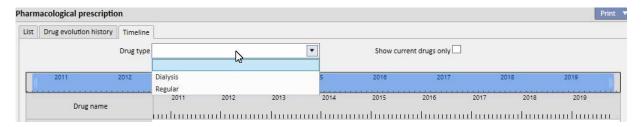
9.3.5.3 TIMELINE

This section contains a graphic overview of the pharmacological therapies administered to the patient. By simply reducing or increasing the width using the mouse on the blue border, it is possible to resize the time window in order to examine a smaller (or longer) period of time in detail.

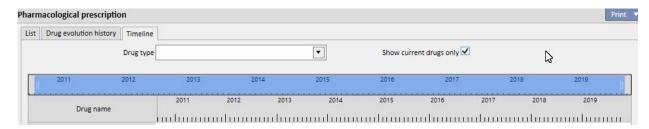


The blue bar can be moved to the left or right to inspect all available dates.

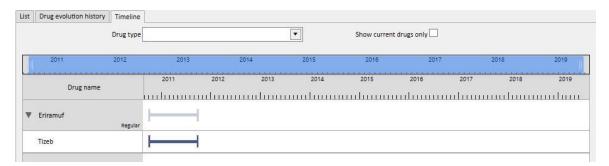
It is possible to filter the drug type by administration route, home or dialysis.



It is also possible to exclude those drugs whose last status is "Terminated" from the overview.



Drugs are grouped by active ingredient, with the active ingredient shown; the selection must be expanded to see the commercial name of the drug.



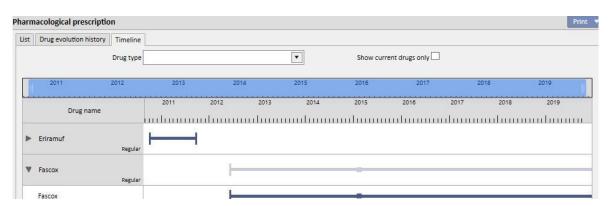
For generic drugs, the active ingredient will always be displayed.

A continuous line indicates that the patient is currently taking the drug.

Empty parallel lines indicate that the drug is currently "Suspended".

No line indicates that the drug has not been and or is not currently being administered.

Moving the mouse above the line displays the name of the drug and the active ingredient, the dose, the units of measure and the package type (vial, capsule, etc.) .



If the same active ingredient is prescribed two or more time, it will be displayed in the following manner.

9.3.5.4 RELATIONSHIP BETWEEN PHARMACOLOGICAL PRESCRIPTION AND TREATMENT PLANNING

As mentioned in *section 9.3.4.3*, there is a strong correlation between the pharmacological prescription for dialysis treatment and the treatment schedule plan. Below, we will see in detail what happens if the treatment schedule plan is modified.

Removal of one or more days from the treatment schedule plan: When a new treatment schedule plan is saved the following message appears which informs us that the drug prescription must be reviewed.



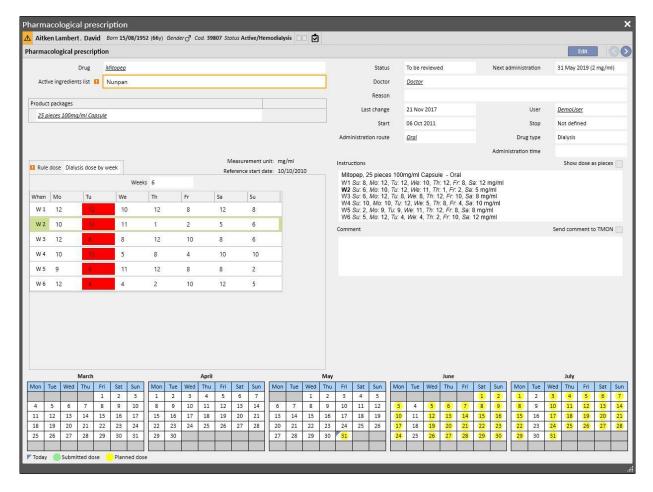
If a "Group of doctors" was specified during the clinic configuration, every member of this group will receive a message in their Inbox advising them that the pharmacological therapy must be reviewed.

If any field in the pharmacological prescription menu is clicked, a red error message will appear as the first line in the window. The status of dialysis therapies in "Active" status for which "Dialysis dose by week" administration rules were selected will be changed to "To be reviewed", and below the "Dosage and frequency" column the days which are no longer planned (after the change to the treatment schedule plan) will appear with a bar through them. For dialysis therapies with "single dialysis dose" rule, changing the number (or detail) of the scheduling days has no impact.



If a drug is in "Suspended" status, it retains this status as it is currently not being administered to the patient. Only when it is reactivated does it change to "To be reviewed" status (unless the user has adapted the pharmacological prescription to the treatment plan schedule while it was suspended).

Once the drug to be reviewed has been selected and edited, the field corresponding to the day removed is highlighted in red, and the only operation possible in that field is removal of its contents.



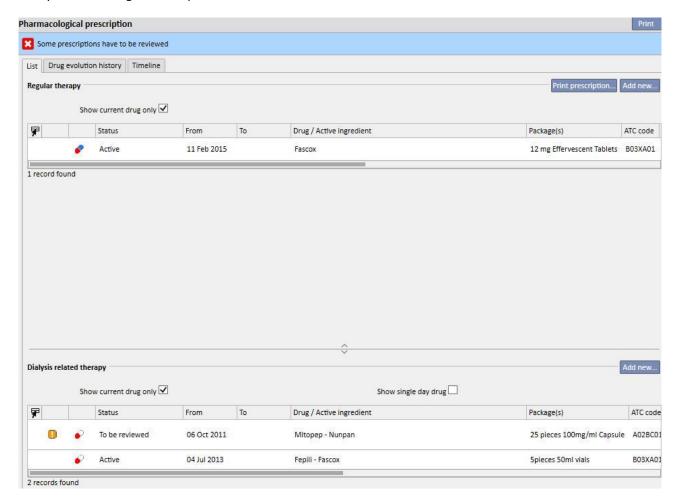
The drug does not become active again until the user removes the day and saves.

Addition of one or more days to the treatment plan schedule: when the new treatment plan schedule is been saved the following message appears informing the user that it is necessary to review the drug prescription.



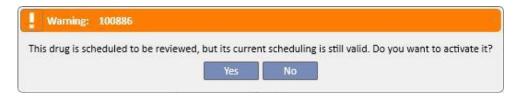
If a "Group of doctors" was specified during the clinic setup, every member of this group will receive a message advising them that the pharmacological prescription must be reviewed.

If the user then clicks on the pharmacological prescription menu item, a red error message appears on the bar above the three tabs. For the drugs in Active status and for those for which administration days have been specified, the drug status changes to "To be reviewed". For drugs with the every number of treatments rule, modifying the number of days of scheduling has no impact.

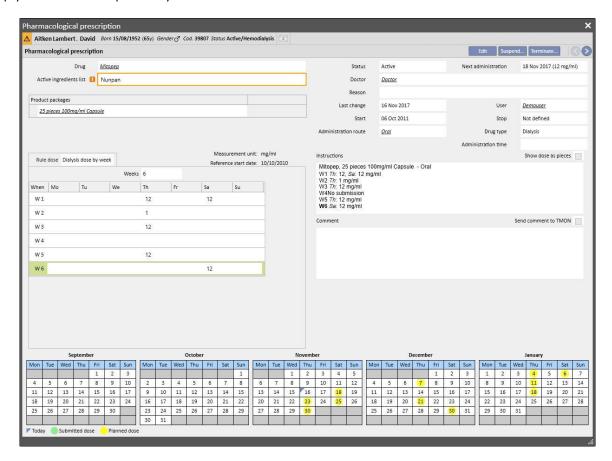


If a drug is in "Suspended" status, it remains in that status as it is currently not being administered to the patient. Only when it is reactivated does it change to "To be reviewed" status (unless the user has adapted the pharmacological prescription to the treatment plan schedule while it was suspended).

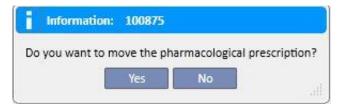
Once the drug to be reviewed has been selected and edited, a new pop-up will appear warning that the drug is in to be reviewed status, but its current pharmacological prescription is still valid because a day has been added, and therefore the user will be asked if he wants to render it active.



If the user clicks on "Yes" the drug automatically becomes active, but the field corresponding to the added day is left empty. It is then the responsibility of the user to enter the correct dose.

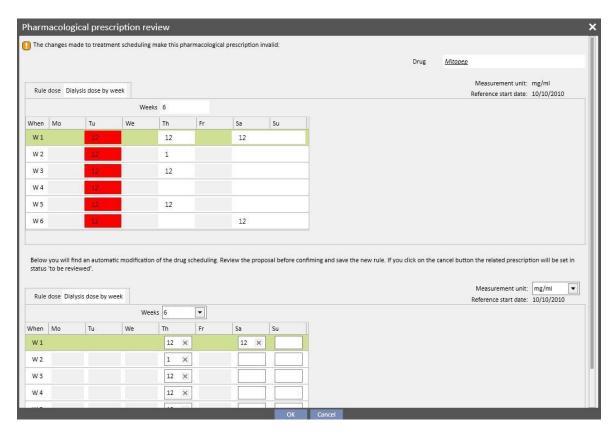


Movement of days within the treatment plan schedule, but without changing the number of days: when the new treatment planning is saved the following message appears, asking the user if he wants to change the pharmacological prescription.



If the user clicks "No", the pharmacological therapies affected by the modification are put in "To be reviewed" status and it will be the responsibility of the user to organise the therapies manually using the Pharmacological prescription menu item.

If the user clicks "Yes", Therapy Support Suite opens a new window offering an arrangement of the new pharmacological prescription; it is the responsibility of the user to accept it as it is, or to modify it as required. Finally, if the user clicks "OK" the drug will switch to "Active" status. If he clicks "Cancel", the drug will remain in "To be reviewed" status.

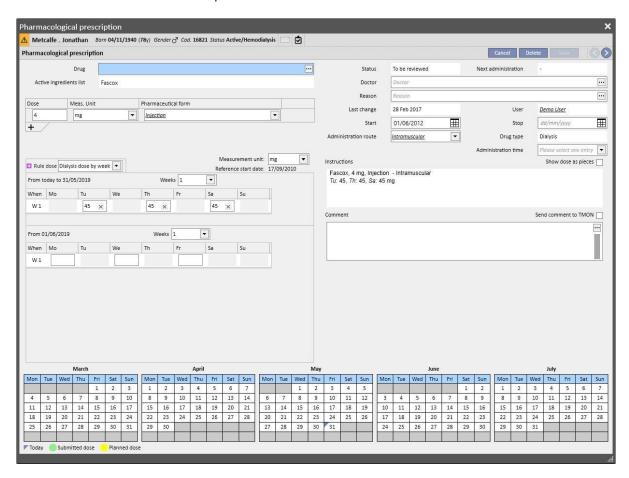


The system opens one window for each of the drugs affected by the modification to the treatment plan schedule.

9.3.5.5 RELATION BETWEEN PHARMACOLOGICAL PRESCRIPTION AND TREATMENT SCHEDULE PLAN

Whenever a Treatment schedule plan for the future is created, the pharmacological therapies with "Dialysis dose per week" rule are switched to the "To be reviewed" status only if the new planning changes the current pattern and only if the number of days set in the "configuration parameters" of the master data have been reached.

When the pharmacological therapies in "To be reviewed" status are opened, it can be seen that the administration rule in the "Dose Rule" section is different for the current treatment plan schedule and each of the planned schedule plans created in the treatment schedule plan menu.





Note

A message informs the doctor whenever:

A prescribed drug causes interactions with a drug which has already been administered;

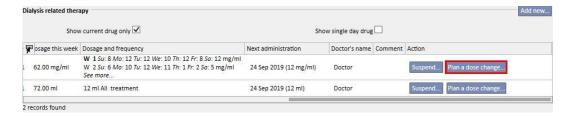
The patient is allergic to one or more active ingredients in the drug;

An active ingredient which the patient is already taking is being prescribed.

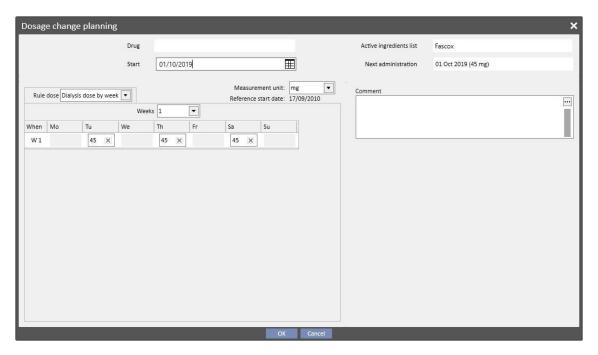
The drug catalogue is being modified.

9.3.5.6 DOSE CHANGE PLANNING

An administration rule for the future can be planned for active therapies using the "Plan a dose change" button, as shown in the screenshot below.



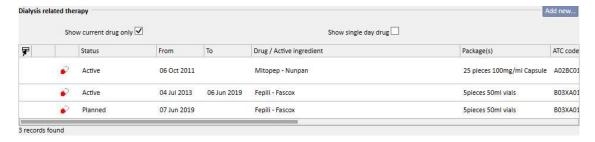
Then a pop-up window opens where it is possible to specify the new administration rule, the date on which the dose change will take effect for the drug in question and add a comment; this last field will take the value present in the latest active version of the prescription.



Once all the information has been inserted, if the user clicks "OK" the change in dose is created and the pharmacological therapy is modified as follows:

The active therapy for which the dose change has been planned is given a termination date, which is the same as the date for the start of the change of dose created previously less one day

A new pharmacological therapy for the same drug is created with "Planned" status, with the data entered previously.

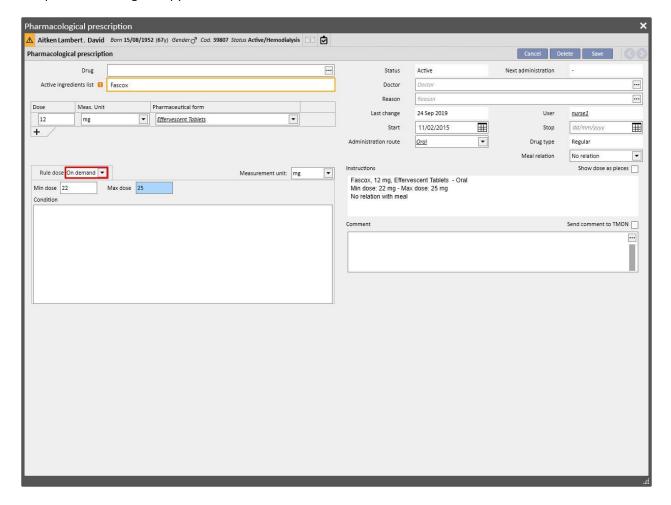


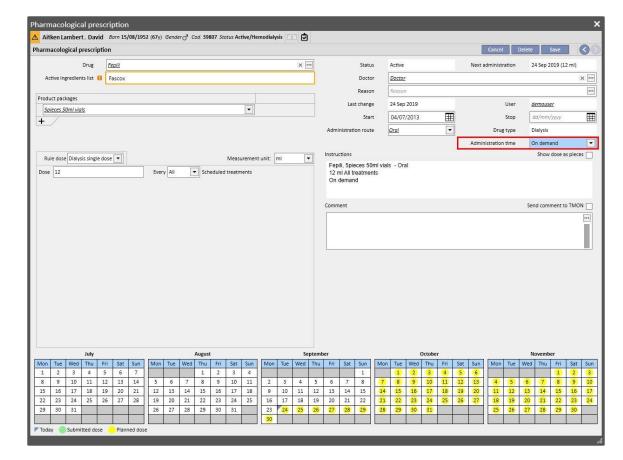
9.3.5.7 SENDING PHARMACOLOGICAL THERAPY TO THERAPY MONITOR

If the Therapy Support Suite is connected to the Therapy Monitor and a new session is started on the Therapy Monitor, as a general rule the following pharmacological therapy is sent to the Therapy Monitor:

- **Dialysis therapy**: all dialysis prescriptions in "active" or "to be reviewed" status required for the given date are sent and may be accepted by Therapy Monitor, except those marked as "as needed" (having the "Delivery Time" field filled in with the value "as needed").
- Home therapy: all active home prescriptions are sent but cannot be accepted by Therapy Monitor, except for those marked as "as needed" (having the "Dosage rule" field filled in with the value "As needed"), which can be passed if specified in the "Configuration parameters" of the "Master data" section (see Service Manual section 4.1.1).
- Therapy as needed: both therapies described in the previous points are sent in this "As needed" category , precisely when marked "as needed".

Example of home drug therapy marked as "as needed":





Example of intradialytic drug therapy marked as "as needed":

For more information, refer to paragraph 3.7.

Some notes about sending the prescription drug to the Therapy Monitor:

By ticking the "Send comment to TMON" checkbox in the details of the therapy itself, that comment will be concatenated with the description of the prescription pharmacologically sent to Therapy Monitor.

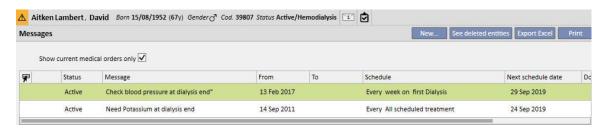
If the description of the pharmacological therapy exceeds the maximum number of characters provided for by Therapy Monitor, the special character [*] will be placed at the beginning of the description to alert the user about possible loss of information.

9.3.6 MESSAGES

"Messages" is a list of instructions which can be sent to Therapy Monitor to allow procedures to be performed on the patient during dialysis treatments. These operations are not included in the dialysis prescription.

9.3.6.1 DISPLAYING PATIENT MESSAGES

Clicking "Messages" on the patient menu displays all the medical orders associated with the patient.



The view permits users by using the "Show current medical orders only" filter, the user can display all the medical orders or only the active ones.

Messages are active if their start date is in the past and the end date is missing or in the future.

Active medical orders can be suspended by specifying the suspension start date. When a medical order is suspended, the message will not be sent to Therapy Monitor even if the rule is valid.

The user can remove suspensions if the suspension start date is in the future. Suspended medical orders can be reactivated. The reactivation date may be in the future.

Messages with start date in the future are in "Planned" status. When the start date is reached they will be activated automatically.

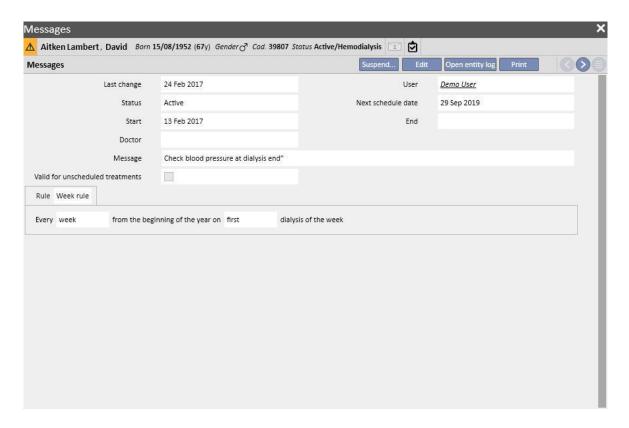
When the end of validity date is reached, the message will be automatically terminated and it will no longer be possible to send the message to Therapy Monitor.

Suspensions can be applied directly from the message list using the buttons in the "Action" column, or by opening the individual message.

A new message can be created by clicking the "New..." button.

The messages that have the "Valid for unscheduled treatments" field selected, will be linked to all treatments received by the patient, even those not scheduled according to the patient's weekly plan. The display of the list of all valid patient messages will differ from the others because an image of a double arrow positioned by default at the beginning of the line.

9.3.6.2 CREATING A NEW MESSAGE



When a message is saved, the **User** and the **Last change** fields are filled in with the name of the user who performed the operation and the date of the change, respectively:

The **Start date** and the **End date** indicate the message's validity period. The **Status** depends on the values of these two dates and any suspensions present.

The **Next date** only appears if the message is in **Active** or **Planned** status. A value will also appear in this field for messages that are suspended but for which a future reactivation has already been entered. This field indicates the next time the medical order will be forwarded.

The **Message** is the contents which will be sent to Therapy Monitor and contains the instructions to be carried out on the patient.

The **Rule** establishes the dialysis sessions at which medical orders are to be sent.

Note



To help the user fill in the fields correctly, Therapy Support Suite provides step by step prompts in this section.

The user has to complete editable fields to activate the read-only ones.

Rules

A Message is sent to Therapy Monitor when it is active and its rule is met, meaning that when the calculated recurrence corresponds to the performance of a treatment (the valid messages for unscheduled treatments will always be sent).

As mentioned, the "Valid for unscheduled treatments" field replaces any type of rule and hides the possibility to select one.

When a Message is defined, if the field has not been checked, one of the five rules available should be selected and configured:

- Every treatment rule: The message is sent to Therapy Monitor by counting the patient's planned dialysis sessions. The message may be sent at every treatment, every two treatments, every three treatments and so on, up to six treatments. As a convention, during creation of the message, the first planned treatment after activation of the message meets the rule.
- Specific dates rule: The message is sent to Therapy Monitor when the treatment is administered on the listed dates. If no treatment is administered on one of the dates, the message will be sent during the first treatment available after the date.
- Days of the week rule: A rule based on a pattern of from one to eight weeks. The user can specify which days of each week the message will be sent. If no treatment is administered on one of the days specified by the rule, the message will be sent during the first treatment available after the recurrence.
- Month rule: The month rule specifies the months in which the message will be sent. The combined boxes allow the user to select the specific week of the month and, even more precisely, the treatment. Exceptions to the week's dialysis sessions are included in the count for deciding whether or not the message is to be sent to Therapy Monitor.
- Week rule: the week rule specifies after how many weeks the message is sent to Therapy Monitor. Since a patient normally has more than one treatment a week, the user can specify during which of the week's treatments the message will be sent. The first week of the current year is taken as reference for the start of scheduling. This week will be the first one considered valid for sending of the order. The first week varies depending on the regional calendar. If there are exceptions to the dialysis sessions, these will be considered for the purposes of calculation of the weekly session when the message is sent.

9.3.6.3 RELATIONS WITH THERAPY MONITOR

If Therapy Monitor is connected to TSS, these fields are transferred to the "Messages" section of "Therapy Monitor" and can be checked by the nurse(s).

Therapy Monitor will show only all those messages where the scheduling corresponds to the interval set by the rule. For definitions of the rules, refer to the "Rules" section.

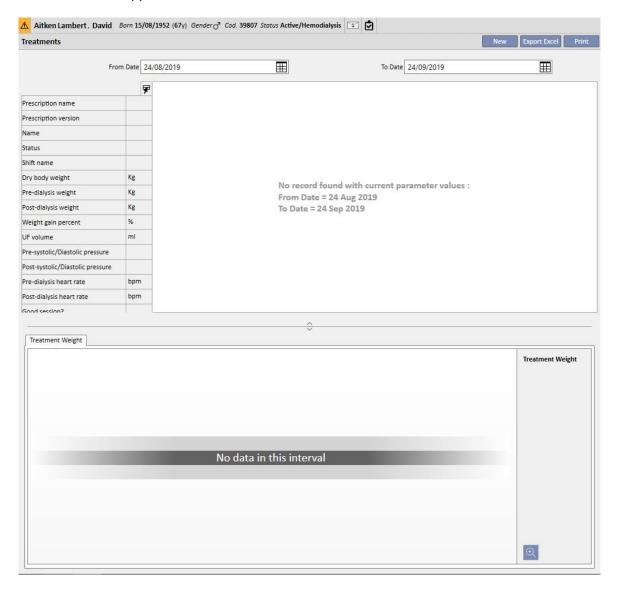
At the end of the treatment these fields are transferred to TSS and are visible in the Patient area, treatment data, dXp, and dXp messages. These messages are not mandatory, so the treatment can be closed even if the messages have not been checked. They can also be sent from "Therapy Monitor" to TSS.

9.3.7 TREATMENTS

This section contains full information about the treatment procedures for the selected patient.

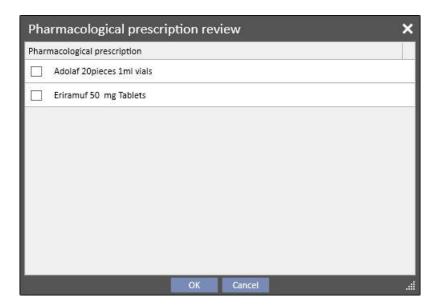
When this section is accessed, the user is shown all the treatments the patient has received in the last month and a chart showing the progression over time of the pre-dialysis and post-dialysis weight. The time span of the dates can be modified.

The user can view the patient's medical history by clicking a single treatment. These data are filled in automatically if the connection with Therapy Monitor is active.



To create a manual HD Treatment simply click the button in the **Treatment** section.

Depending on the status of the patient's Drug Therapy, the treatments already administered for the patient, and the Treatment Planning specified for the patient, the user may be shown a window where he can select the Drug Therapy to associate with the treatment currently being created.



Cases where the pharmacological therapy selection pop-up appears during creation of a new treatment:

A treatment for the same day already exists for the patient: in this case the pop-up shows all the drugs administered in the previous treatment plus the dialysis pharmacological therapies in "Active" and "To be reviewed" status which were not in the first list.

There is no treatment planned for the day for which the user is creating the treatment: in this case the system proposes all the dialysis pharmacological therapies in "Active" and "To be reviewed" status for the patient in question.

A treatment plan (standard) is present for the day for which the user is creating the treatment: the system proposes all the dialysis pharmacological therapies in "To be reviewed" status whose administration rule does not specify the dose for that day.

A "Single day treatment plan" is present: the system proposes all the dialysis pharmacological therapies in "To be reviewed" status which have not been associated with the plan.

A treatment plan is present for the day for which the user is creating the treatment, but it is the result of dragging and dropping a plan via "Clinic Scheduler". In this case all the dialysis therapies in "Active" and "To be reviewed" status are displayed.

Any of these therapies selected are added to the "Patient assistance\Prescribed pharmaceuticals" table with dose "[?]", which indicates that the system cannot calculate the dose to administer for the treatment in the creation phase, and therefore the user must specify it himself.

If the treatment has been created by Therapy Monitor, obviously the pop-up cannot be shown to the user, so all the pharmacological therapies which are proposed by the pop-up according to the rules listed above are automatically entered in the "Patient assistance\Prescribed pharmaceuticals" table with dose "[?]", and are sent directly to Therapy Monitor. It is the task of the user who is using Therapy Monitor to specify the dose.

When a treatment is in "Completed" status, clicking the button closes the treatment. Treatment can reach this state in two cases, i.e. when the value of "post-dialysis weight" is present or when the value of "End time session" is present. To decide which of the two fields to be considered is the user (with a Clinic Manager role) who can choose

the logic to follow when closing a treatment in the "Configuration Parameters" section of the "Master Data" section (see "Service Manual" section 4.1.1).

Automatic generation of reports in PDF format can be associated with the closure. Specifically, the expressions (see "Service Manual" section 4.2.8) set in the "Configure PDF Export" section (see "Service Manual" section 4.2.6), which are enabled and valid for the current clinic, will be assessed.

If the treatment meets the expression criteria, the report associated to the expression which is met will be generated automatically. Depending on the setup, the report may be exported via Filesystem and/or sent via cDL.

The PDF reports created can be viewed in the "PDF export" section (see "Service Manual" section 4.2.7).

When a treatment status is "Closed", its data can no longer be edited. Press the Re-open button to "Reopen" the treatment; its data become editable again.

If the automatic generation of reports in PDF format have been configured and, in Power Tool, the option "Filesystem Undo" has been enabled, when "Re-opening" the treatment, the PDF file connected to the treatment reopened will be deleted/renamed (based on the action configured in Power Tool).

If the last treatment in date order for the patient, administered in the last 2 days, is in the "New" or "In Progress" status, a the following warning message is displayed.

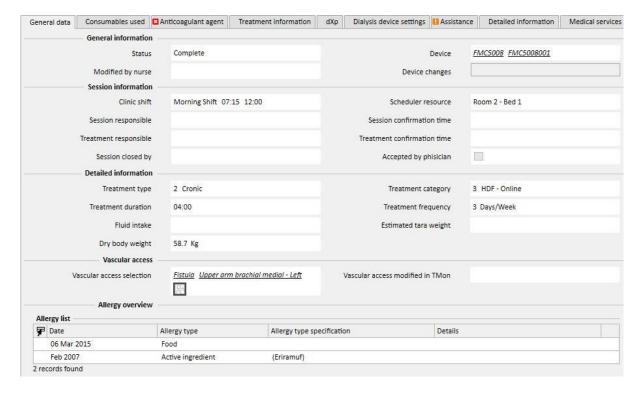
[] Treatment in progress - Please note that any changes/addition in this section won't be applied to treatment in progress

In sections:

- Vascular access
- Treatment prescription
- Checklist
- Pharmacological Prescription
- Medical orders
- Laboratory test
- Below are explanations of all Treatment sub-sections.

9.3.7.1 GENERAL DATA

This section contains all the information taken from the Doctor's prescription with the exception of the following fields:



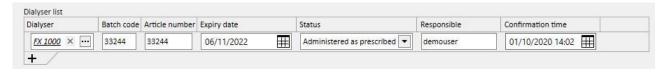
- Status: Read-only field that shows the treatment status (new, in progress, or completed)
- Modified by nurse: Read-only field that shows the last user who changed the treatment and the time of modification.
- Clinic shift: This field shows the shift referred to in the treatment schedule. The user can change these values.
- Scheduler resource: shows the resource referred to in the treatment schedule. The user can change these values.
- Prescription name: This field shows the name of the prescription upon which the treatment is based. The user can change this value.
- Device: This custom list allows the user to select the device on which the patient is treated.

9.3.7.2 CONSUMABLES USED

This section contains information related to the usage of consumables during the treatment. Is possible to add new consumables by clicking the + button or edit information like:

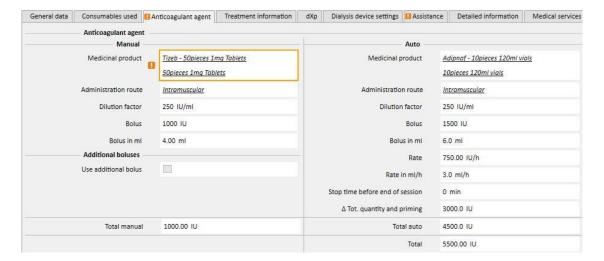
- Product name: This field allows a product to be selected by displaying its name.
- Category: For products that may have more than one category, it shows the category of product belonging to it. The field is read-only and is automatically populated as a result of selecting a product through the field described in the previous paragraph.
- Batch code: contains the code of the batch to which the product belongs.
- Article number: contains the serial number of the product.

- Expiration date: It contains the expiry date of the product.
- **Status**: contains information about the use of the product during treatment, that is, whether it was refused, whether it was used as a prescription, or whether it was added manually by selecting it from the catalogue.
- **Responsible and confirmation time**: these two fields contain information about who has changed the release information to the product and when that change has been made.



9.3.7.3 ANTICOAGULANT AGENT

This section is a copy of the Anticoagulant Agent tab defined in the patient's HD prescription. The user can modify/add values.

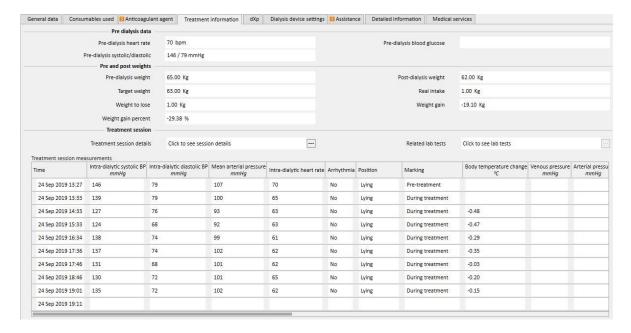


9.3.7.4 TREATMENT INFORMATION

This tab contains various data acquired during the treatment, from the patient's vital signs to the information collected during the initial disinfection of the device.

The treatment information is categorised and displayed in various groups, depending on when it was collected. The first group contains all the measurements taken before the treatment started, while information stored at the bottom of the tab is related to those taken after completion of treatment.

The treatment session contains information collected strictly during the performance of the treatment, such as the patient's vital sign values and all the measurements taken minute by minute by the dialysis device (see "treatment cycle details", next paragraph).



If Therapy Monitor 2.x and the relative plug-ins are installed, a button called **Treatment session details** appears under the "Treatment session weights" table. Clicking on that button will open the pop-up that contains **Treatment cycle** information.

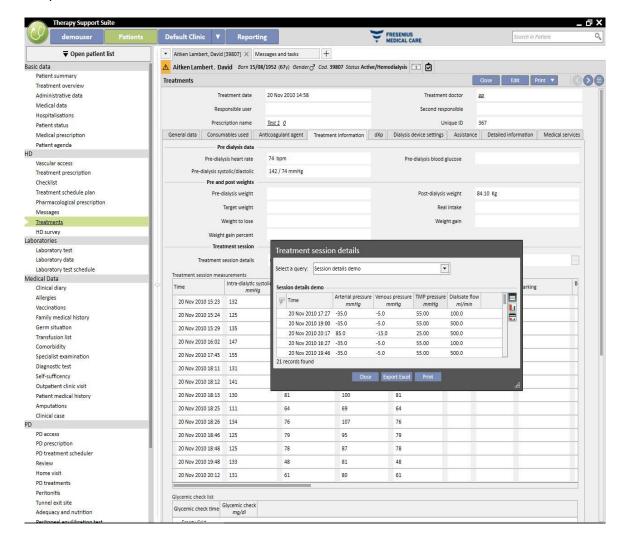
Note



The Kt/V formulas in the post-dialysis information group contain Kt/V values depending on the treatment-related laboratory tests. They are filled in automatically when at least one laboratory test that is more recent than the treatment date and that has urea values inserted is imported into the Laboratory data section.

Treatment session details

This section is particularly important since it contains all the measurements collected by the dialysis device throughout the treatment session. In order to consult these values, the user has to create specific queries using the Therapy Support Suite **Manage HD treatments**. This enables the user to create a list of customised queries in order to decide which dialysis measurements to show in the Treatment session details and whether to show them as charts or tables.



Treatment session measurements

The contents of this table vary depending on whether the TSS installation includes Therapy Monitor:

- If Therapy Monitor is not available, the table contains all the vital measurements made by the nurse during the dialysis session;
- If Therapy Monitor is available, the table contains all the values taken from the "vital values" section of the Therapy Monitor export file. Measurements that do not refer to vital values are completed using values from the "treatment information" section, taken immediately before the timestamp of the current table row.

Treatment-related laboratory tests

The contents of this section depend on whether the TSS installation includes Therapy Monitor:

If Therapy Monitor is not available, the "Laboratory tests" section of the "Treatment session information" section will remain empty, and will simply show the message "no laboratory tests received during treatment session".

If Therapy Monitor is available, the table will contain all the laboratory tests included in the Therapy Monitor export file, for which mapping has been specified in Therapy Support Suite. If no mapping has been specified, the "Laboratory tests" section of the "Treatment session information" section will remain empty, and will simply show the message "no laboratory tests received during treatment session".

Patient weight

This table contains information related to the patient weight during the dialysis treatment:

- Pre Weight
- Post Weight
- Target weight
- Taken weight
- Weight to loose, calculated as: Pre Weight + Taken weight Target weight
- Weight gain (compared with previous treatment)

Note



The "Weight to lose" field shows the weight that the patient should lose before the treatment starts. This field is calculated and also takes into account the "Taken weight" from the prescription. If the amount of "Taken weight" is changed in Therapy Monitor, the "Weight to lose" will not be changed.

Patient temperature

This table contains patient temperature information during the dialysis session.



Device disinfection

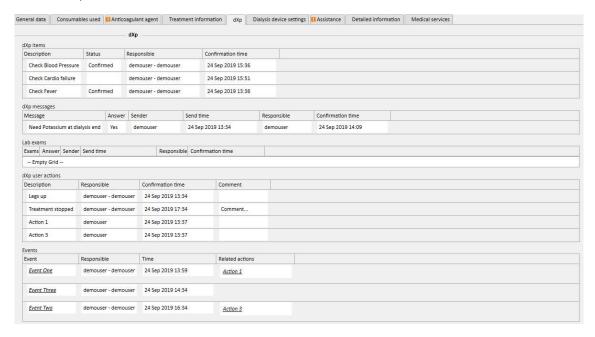
This section contains information about the procedure for disinfection of the dialysis device.



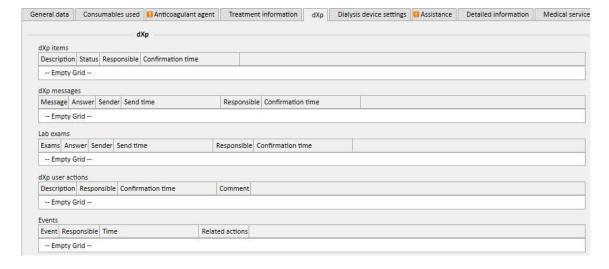
9.3.7.5 DXP (DATA EXCHANGE PANEL)

This section contains a number of information useful for dialysis treatment and can be edited directly on the dialysis device via the Data Exchange Panel (dXp), including:

- dXp Items: in this section, the patient checklists are automatically added to the system.
- dXp Messages: this section automatically adds the prescribed medical orders to the dialysis session system.
- Laboratory Tests: This section automatically adds the prescribed laboratory examinations for the dialysis session from the system.
- User actions on dXp
- Events: The events that occurred during the treatment are recorded in this section. Events and their actions can be added manually or generated after a dialysis session is exported from Therapy Monitor. If events and their actions are added manually, the sections of the treatment to which the actions refer to are also automatically updated. For example, adding an information related to the use of a consumable for an event will also update the relevant table in the Consumables tab.



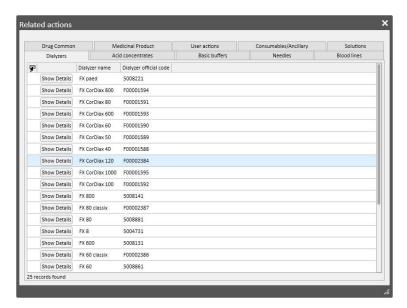
For all the information in this section, the manager and the time when the data was changed or entered can be specified.



As for the "Events" section, these can be received from TMon or managed by the graphic interface.



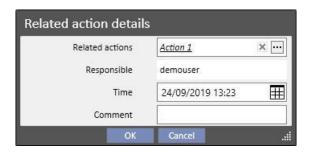
The system allows the following "Related actions" to be added:



In the case of "Medication" or "Medication Package" the system asks for the following information:



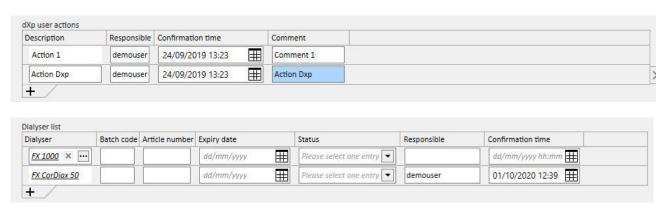
In the case of "User Actions", the following information is required:



In the remaining cases the following information is required:



The Related Actions associated with the events are also added in the respective sections of the treatment:



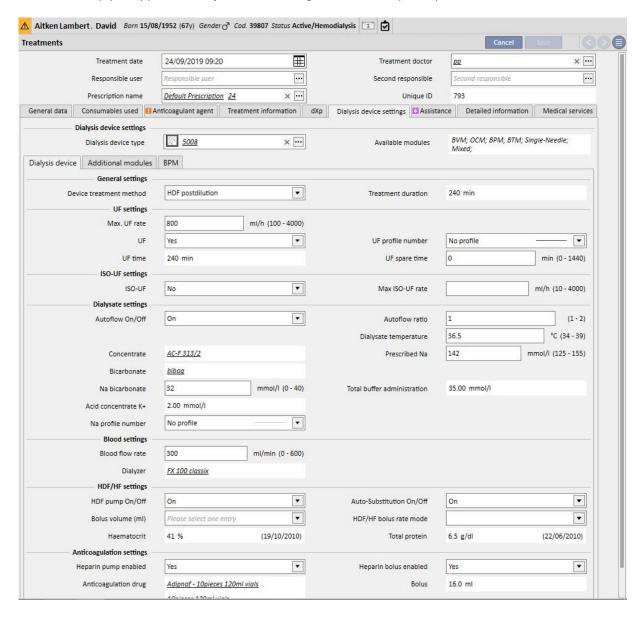
If one or more "Related Actions" is changed or removed from its section, the related event is also updated.

The behaviour of much of the data in this section and its connection with TMon depends on the value of the "Enabled continuous import with TMon (from version 2.2)" configuration parameter. (see section 4.1.1 of the Service Manual).

All details on the operation and the different cases that may arise are explained in the "Continuous Import with TMon" section.

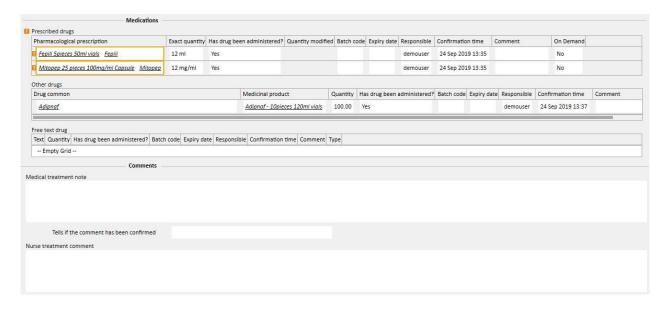
9.3.7.6 DIALYSIS DEVICE SETTINGS

This section is simply a copy of the **Dialysis device settings** section of the prescription.



9.3.7.7 PATIENT ASSISTANCE

This section allows the user to enter information about the treatment quality and any symptoms arising during the treatment. It is also possible to confirm or modify the administration of drugs and enter comments about the treatment.



The prescribed drugs to be taken during dialysis are shown in the "Prescribed drugs" list. For each one, the following information is displayed:

- name;
- exact prescribed quantity;
- indication whether the drug was really administered;
- quantity administered if different from the prescribed quantity;
- batch code;
- name of responsible user;
- time the drug was administered;
- comment;

The name of the drug has a message next to it if the patient is allergic to the prescribed drug. Clicking the name of the drug displays the relative pharmacological prescription.

The exact quantity is derived from the pharmacological prescription and cannot be modified if the treatment took place during a scheduled session. If the treatment takes place outside the treatment plan schedule, the exact quantity becomes mandatory and the value is not derived from the prescription. The "[?]" symbol appears in the exact quantity field to indicate to the user that he must specify the value.

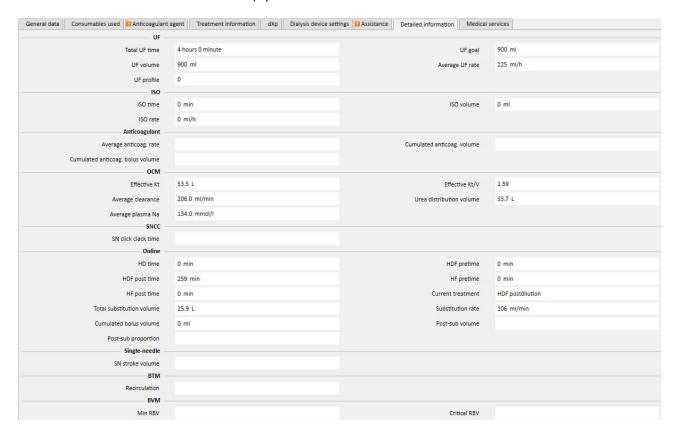
The indication as to whether the drug was administered has four possible values: "Yes", "No", "Yes, but the quantity has been modified", "Refused". This information is mandatory. If the user makes no selection or if selects "Yes", the exact quantity also becomes mandatory. If the user selects "Yes, but the quantity has been modified" only the modified quantity becomes mandatory.

The comment field and the batch code can only be modified by the user if the treatment has been entered manually, while all the remaining fields are populated by Therapy Monitor.

In the "Other drugs" part of the Medications section, a distinction has been made between the drugs administered regularly (at home), and the drugs administered as needed.

9.3.7.8 DETAILED INFORMATION

This section shows detailed information obtained from the dialysis device at the end of the treatment. If Therapy Monitor 2.x and related plug-ins are installed, all information coming from Therapy Monitor will be visible; otherwise, some of these information fields will be empty.





Note

If a treatment is exported from Therapy Monitor, it might be necessary to check whether one or more fields are outside the permitted ranges. Out of range values are marked with a yellow or a red flag. depending on the gravity of the error.



Warning

In case of a malfunction of Therapy Monitor or a network failure, treatment data may not be available.

9.3.7.9 MEDICAL SERVICES

This section shows the services related to the treatment. One or more services can be present for a single treatment.

Every service is characterised by the following information:



- Date: contains the date when the service was provided;
- Services: contains the Principle Code and the Principle Description of the service;
- Quantity: indicates the number of times a service has been carried out for the treatment in question;
- Performed: the following values can be added:
 - "Yes": the service was carried out;
 - "No": the service was not carried out;
 - "Cancelled": the service was cancelled;

Services can be added in two ways:

Manually by the user. In this case the user can add a new service by pressing the button. The user must enter the values in the Date, Services and Quantity fields, while the Performed field is "Yes" by default.



Automatically by the system: In this case a service is automatically added (if not already present) when a treatment is created or modified. "Automatic" services are added when the treatment meets certain criteria as defined in the Expressions (see Service Manual section 4.2.6). For "automatic" services, the Data field is given a default value of the treatment date; the Services field is filled in with the code and description of the service related to the expression which was met, and the Quantity field is given the value 1. Once again, the Performed field is set by default as "Yes".



The services entered can be removed by the user by clicking the button. A service entered manually can be deleted by the user; whereas, a service added automatically by the system cannot be deleted. It can be cancelled by entering "Cancelled" in the Performed field.



If the treatment fields used as criteria in the Expressions are modified, the system recalculates the "automatic" services, while the services entered manually are not modified.

Additionally, if the user has modified the default data related to "automatic" services, the system asks him if he wants to lose the changes he has made to the "automatic services".

9.3.7.10 CONTINUOUS IMPORT WITH TMON

As already mentioned, some session data involved in the exchange of information with TMon, could be linked to the continuous import.

Following the instructions in the dedicated sections of the Service Manual is essential to take full advantage of all the continuous import functions. To enable this function in TSS environment tick the "Enabled continuous import with TMon (from version 2.2)" field in the configuration parameters (Service Manual section 4.1.1), to enable TMon side functions, tick the "Enabled" field of the "import" line in the FIS "Plug-in Configuration" tab, in the "Periodic commands" table (see section "FIS - Configuration" of section 3.2.3 of the Service Manual).

Still from FIS, the time interval that passes from one automatic import to another can be set along with which of the four possible packages that TSS can send ("To Do list", "Instructions", "Patient risks" and "External laboratory").



Warning

Risk for the patient as a result of an incorrect prescription being shown

It is essential to know that:

- Continuous import must be enabled on both TMon and TSS sides, it is highly discouraged to keep only one of the two parameters enabled to avoid wrong behaviour of the sections involved;
- use of TMon version 2.2 or higher is required. Previous versions are not supported;
- continuous data exchange ends when TMon sends TSS the data message "End session time".

The data, divided into their respective packets, that the TSS will send to TMon, if requested, are below:

- "To do list" contains the list of "Checklists" selected for a patient, visible in the corresponding menu item and divided into mandatory and configurable;
- "Instructions" contains a list of messages comprising the combined active and scheduled "Medical Orders" for a patient, any planned "Laboratory Tests" visible from the "Scheduling of Laboratory Tests" menu and the medicine used as an additional manual bolus (if present, it is visible in the patient's "HD prescription" in the "Anticoagulant Agent" section);
- "Patient risks" contains the patient's allergies saved in the "Allergies" section and the "Comorbidities" that pose a risk for the patient. All the data sent will always be shown in the patient summary bar, located at the top, by clicking on the image relating to the patient's risks.
- "External laboratory" contains the list of all the patient's "Laboratory data". The latest laboratory test values, making up the "Laboratory data" section, will be sent to TMon.

All this information is sent to TMon during a session and updated at regular intervals, as configured in FIS settings. Any changes made to the system that provides for a TMon update, whether of values or scheduling, do not take immediate effect. They will be effective only after the update period interval set in FIS.

The continuous import procedure ends when the session is closed by TMon. From this moment on, TSS no longer supports continuous import and the data are no longer exchanged. Notwithstanding the closing of the session by TMon, if the treatment is still "in progress" in TSS, the user will apply a logic other than the "Session end time" value for the treatment "Complete" status (see section 4.1.1 of the Service Manual).

The only way to still exchange data between TSS and TMON after sending the "Session end time" value is to launch a manual session data import from TMON by clicking on the "Import session data" command. Manually importing data this way is always possible during a treatment. If a session is created on a day when a treatment is not scheduled, of all the information that can be scheduled, only the patient's "Checklist" and "Medical Orders", which are valid for unscheduled treatments, will be linked to the session. Only any changes to this type of data will be reflected in the session as a result of continuous import. Any change made to all the other scheduled sections (e.g. medical order scheduled for the next scheduled dialysis) will have no impact on the treatment in progress because, in fact, it is an unscheduled treatment.



Note

A checklist added manually by TMON, with a name equal to one already existing on TSS will not be duplicated. However, the corresponding entry in the "Master data" section will be updated.



Note

If continuous import is enabled during a treatment in progress, alerts displayed during the creation of a medical order, a checklist, or a laboratory test schedule item will not be shown.

Finally, it is not possible to change the details of the description of checklist or medical order information for an item that is used in an ongoing treatment.

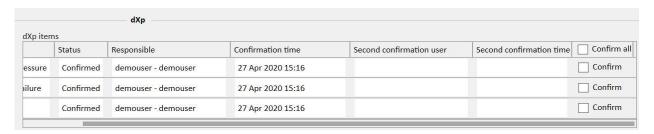
9.3.7.11 SECOND APPROVAL FOR HD TREATMENT

The functionality for second approval of HD treatments must be activated through the configuration parameters of each clinic. It also allows a second user to approve some elements of a treatment. The second user cited, must be different from the user that entered the confirmation of application of the treatment detail in question and must have the active rights to approve.

The sections involved in the HD treatment are listed below:

- All elements in the dXp section
 - Items, messages, lab tests, user actions, events
- Drugs (prescribed drugs, other drugs, drugs in a textual form) and anticoagulant agent manual
- Consumables used (except those for which TMon does not handle confirmation management).

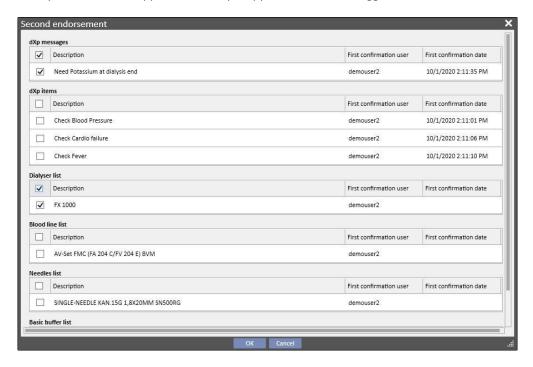
For each section an option allows the second approval to be applied. When elements are grouped in a table, special columns will appear with their approval flags and details (user and date/time). For single sections, the selection option and the second approval details will be found in additional fields of the section.



The "Confirm all" option is in the column header (in the table elements) and allows all the selectable table elements to be selected/deselected.

By definition, when the second approval is active, a treatment cannot be moved to the "Closed" status until all the second approvals have been applied. An exception (applicable with a particular configuration) will allow the possibility to close a treatment without a second approval if the elements do not include any first application/rejection details during the treatment. (See Section 4.1.1 of the Service Manual for configuration details and TMon version compatibility and limitations).

A "Second applications..." button is available in the list of treatment buttons. By clicking on the button, a pop up will show the list of all possible second applications not yet applied for the user logged in.



9.3.8 HD SURVEY

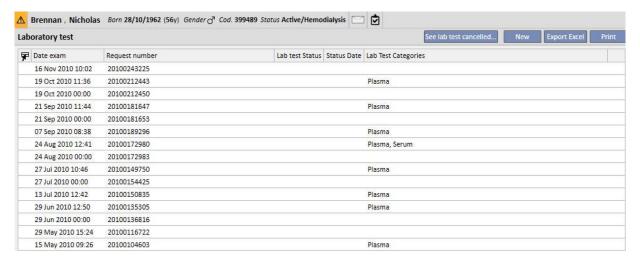
The HD survey enables the user to analyse specific values from the "session details" (sent by the Fresenius 5008 or 6008 during every treatment) starting with a subset of treatments. The procedure for generation of the subset of treatments and the list of values of the "session details" are defined using the functions provided by the query builder.

9.4 LABORATORIES

9.4.1 LABORATORY TEST

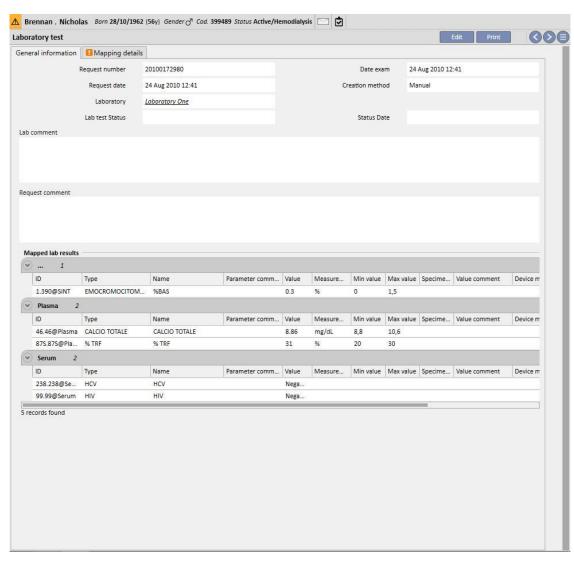
This section contains a list of all laboratory tests performed on the patient as received from the laboratory, before they are processed and imported by the Therapy Support Suite mapping engine. This view shows three different types of information about each laboratory test:

- Test Date: the date when the laboratory performed the test;
- Request number: the lab's ID number for the test;
- Laboratory test categories: a list of all the laboratory test categories covered by the specific request;

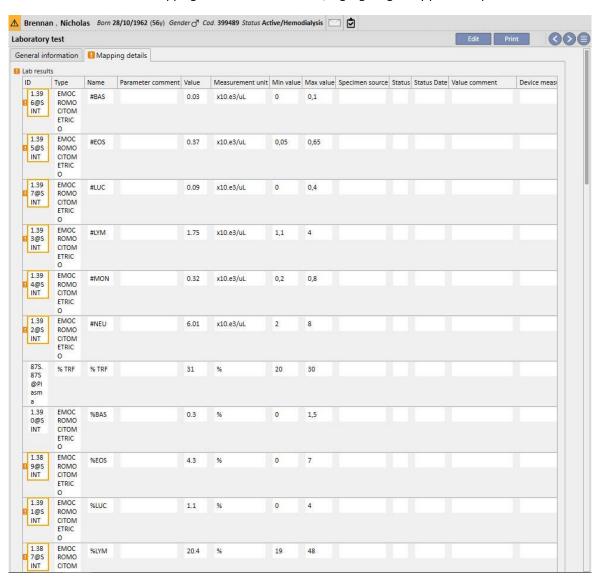


The detail for each laboratory test consists of two different tabs:

• The first shows the general information about the lab test requested selected and the associated results:

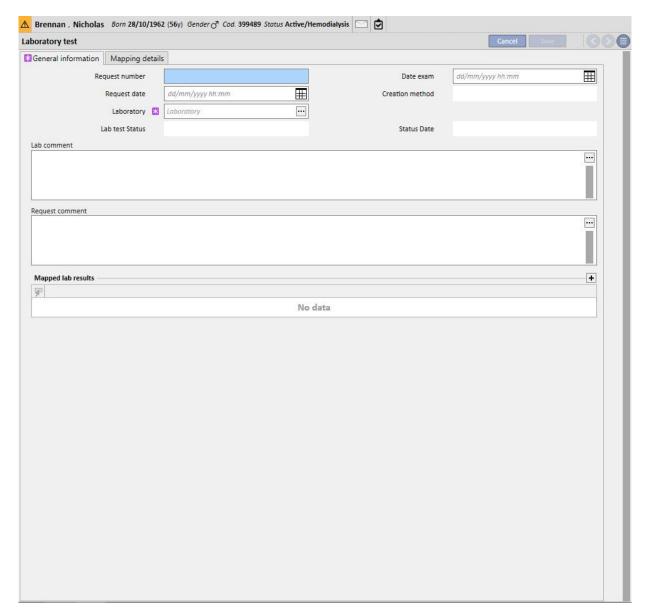


The second shows the mapping of the recorded results, highlighting every potential problem detected.



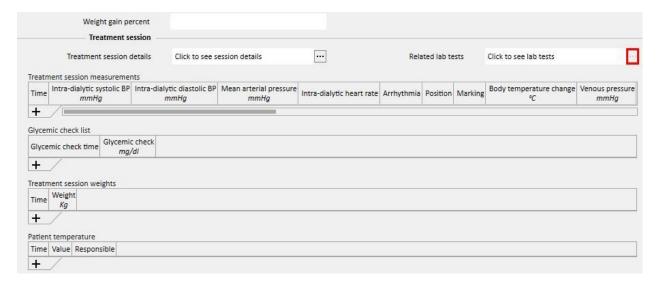
New laboratory tests can be automatically imported into Therapy Support Suite from different sources, which can depend on the hospital information system configuration.

The user can add new laboratory tests manually by clicking the New button in the Laboratory test view and filling-in the following form.



If Therapy Monitor is connected and laboratory tests are exported for which mapping has been specified in Therapy Support Suite, a new entity is created in this section for every single laboratory test performed. If there is more than one measurement for the same type of test, an entity will be created for each measurement performed.

Furthermore, the data from the laboratory tests performed during a Therapy Monitor session, are also visible in the respective treatment by clicking on "..." in the "Relative Laboratory Tests" field, in the "Treatment Information" tab.



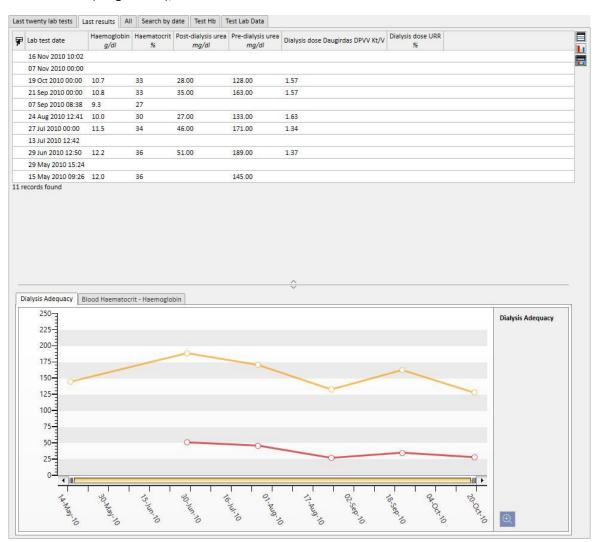
9.4.2 LABORATORY DATA

In this section the user can access the list of all laboratory tests done by the patient. There are three sub-views that show results in different ways:

- Last results: Shows all lab tests from the most recent to the oldest;
- All: Shows all lab tests grouped by year;
- Search by date: The user can choose the time range for the view. By default, it is set as the previous month;

In the "Latest Results" and "All" views, the user can set-up the view as:

- Table view;
- Chart view;
- Mixed view (image below);



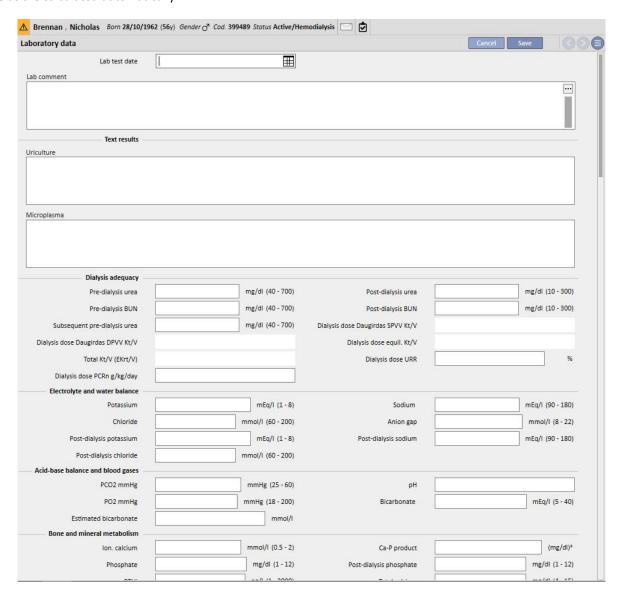
Usually during the start-up of a clinic an automatic import is configured between Therapy Support Suite and the Clinic's Laboratory. However, the laboratory data can be entered manually. New laboratory tests can be entered by clicking the New button.

It is normal practice to add custom fields in the Laboratory Test Data Section.

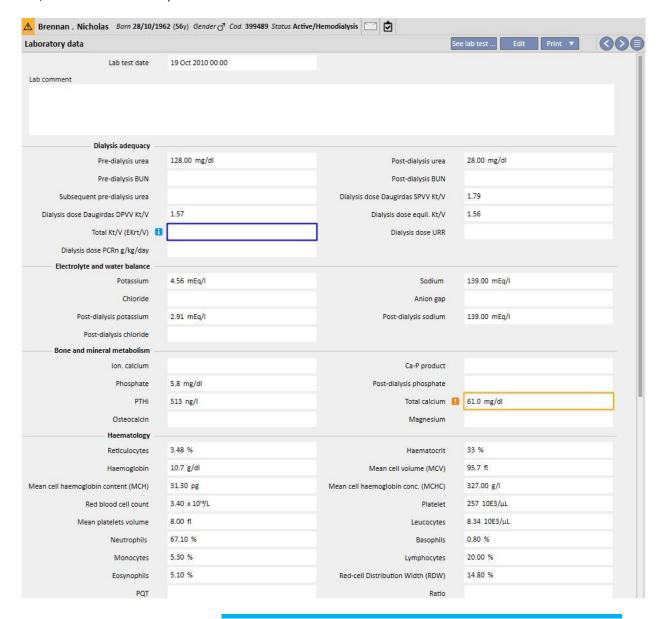
In the Laboratory Test Data section Therapy Support Suite automatically calculates:

- Dialysis Dose of Daugirdas SPVV Kt/V,
- Dialysis Dose of Daugirdas DPVV Kt/V,
- Dialysis Dose equil. Kt/V.

Once the **Pre-dialysis urea** and **Post-dialysis urea** fields of the **Dialysis adequacy** section have been filled in, the above fields are calculated automatically.



If laboratory tests have been entered during a Therapy Monitor session, which are mapped inside Therapy Support Suite, these values will be copied to this section.

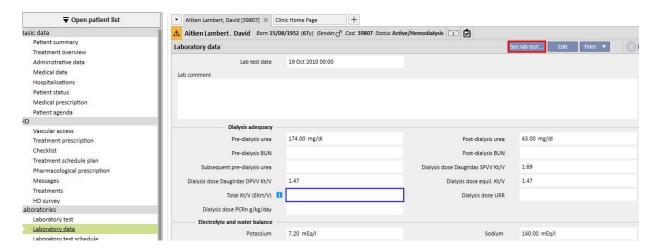


Note

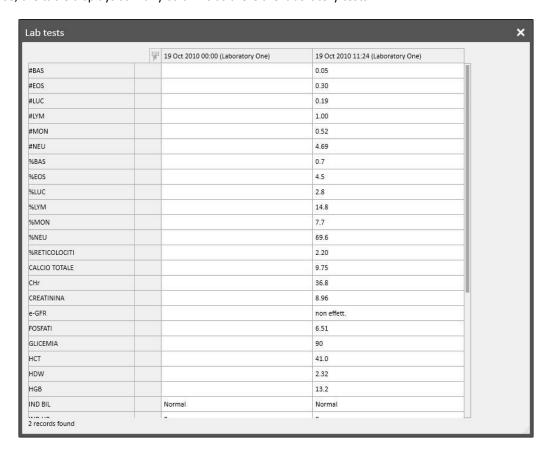
The Kt/V calculation does not start if the patient has not had any HD treatments because the **Post-dialysis weight** value is required. In this case an information message appears near the relative fields.



A table can be displayed with all of the "Laboratory Test" values that generated the relative "Laboratory Data", by opening one and clicking on the "View Laboratory Test" button.



At this point, a new window opens that contains a table with all of the values for the corresponding laboratory test. The "Laboratory datum" can also be generated if multiple "Laboratory tests" have been performed at different times. In this case, the table displays as many columns as there are laboratory tests.



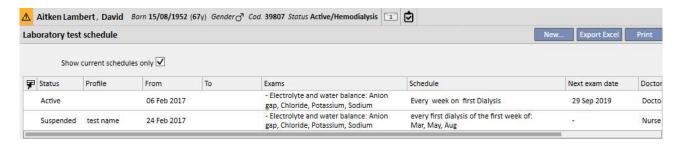
If the "Laboratory datum" has no associated "Laboratory test", the "View laboratory test" button will not be displayed.

9.4.3 LABORATORY TEST SCHEDULE

The laboratory test schedule allows the user to define a set of tests which a dialysis patient must have carried out regularly.

9.4.3.1 DISPLAYING THE PATIENT'S LABORATORY TEST SCHEDULE

All the tests scheduled for the patient are displayed in the "Laboratory test schedule" section. The "Show current schedule plans only" filter allows the user to decide whether schedule plans which are no longer active should also be shown.



Schedules are active if their start date is in the past and the end date is missing or in the future. Active schedule plans can be suspended by specifying the suspension date. During the suspension, laboratory tests are not scheduled.

The user can remove suspensions if the validity period start date is in the future. Suspended schedule plans can be reactivated by specifying the date when they are to become active.

Suspensions can be applied directly from the schedule plans list using the buttons in the "Action" column, or by opening the individual schedule.

Schedules with start date in the future are in "Planned" status. When the end of validity date is reached, the schedule is automatically terminated.

The "New..." button allows a new schedule to be created.

9.4.3.2 CREATING A SCHEDULE PLAN

The days and the tests to be performed can be decided freely or by choosing a preset profile. If there are special requirements concerning a patient, a profile can be selected and then customised.

The schedule shows the date of the Last change and the User who changed it last.

The Schedule type indicates whether the test list and rule will be imported from a preset profile or are to be specified manually.

The Status indicates whether the schedule can generate appointments. Refer to the previous section for the possible statuses and how changes of status take place.

The schedule has a mandatory validity start date and an optional validity end date.

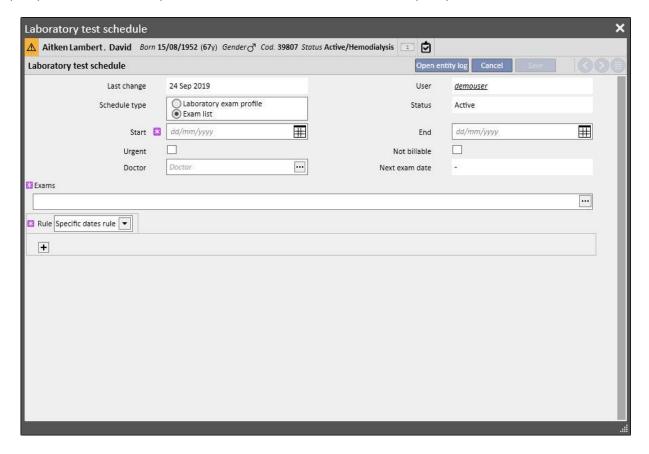
The Urgent and Not billable options refer to fields in the Italian NHS prescription form; anyone not using this can ignore them.

The Doctor field indicates the doctor in whose name the schedule was created. This field is automatically filled in if the user is also a "Treatment doctor" or a "Pharmacological therapy prescriber".

Since the tests are associated with dialysis sessions, they will be displayed in the "Laboratory tests" section of the treatment session's dXp panel.

9.4.3.3 SCHEDULING WITHOUT A PROFILE

To schedule laboratory tests without a profile, select Test list as the Schedule type. In this case, first the user has to specify the list of tests to be performed and then the rule that sets their frequency.



When the Tests field pop-up is open, the user can find the required options by test category or profile.

The rule sets the frequency at which the tests are to be performed. The user has to choose one of the three available and configure it as required.

Specific dates rule: The days on which the patient has to have the tests performed are set by means of a list of dates.



If there is no treatment scheduled on one of the specified dates, the tests will be scheduled for the first treatment planned, provided it is after that date.

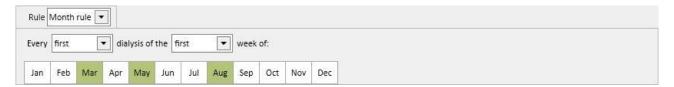
Week rule: The week rule specifies every how many weeks the patient has to repeat the tests. Since a patient normally undergoes more than one treatment a week, the user can specify during which of the week's treatments the tests will be performed.



The image shows a rule where the patient has to repeat the tests every three weeks. The first week of the current year is taken as reference for the start of scheduling. This week will be the first one considered valid for performance of the tests. The first week varies depending on the regional calendar.

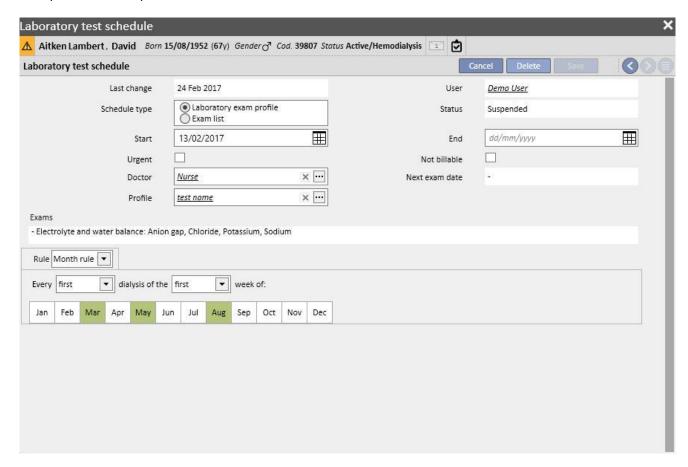
The tests will therefore be performed on the patient in the second dialysis session in the week and repeated every three weeks. If there are exceptions to the dialysis sessions, these will be considered for the purposes of calculation of the session during the week when the laboratory tests are performed.

Month rule: The month rule specifies the months in which the laboratory tests are to be performed. The combined boxes allow the user to select the specific week of the month and, even more precisely, the treatment. As for the week rule, here again exceptions to the dialysis sessions are included in the count for deciding whether or not the laboratory tests are to be performed.



9.4.3.4 SCHEDULING WITH A PROFILE

Profiles are used to group together tests and a rule for association with patients with the same characteristics. Please refer to the Therapy Support Suite Service Manual for instructions for the creation of laboratory test profiles. Once the required profile has been selected for a patient, it will no longer be necessary to set the tests and rule since they will be imported from the profile.

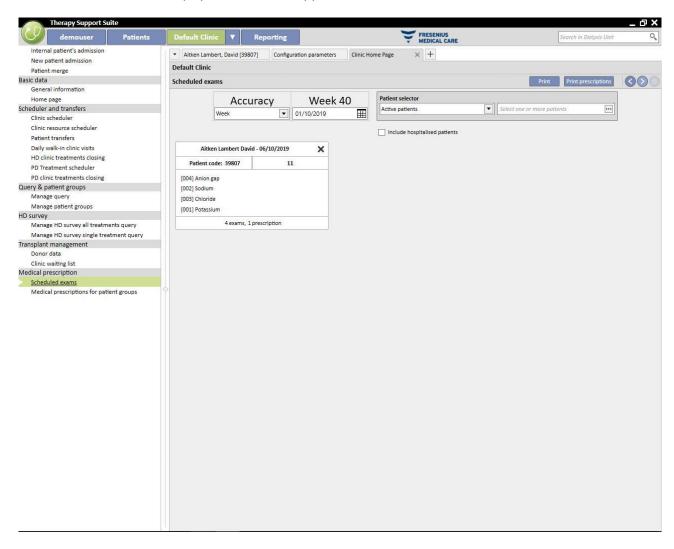


The rule can be further modified for a specific patient. In this case, the information provided in section "9.4.3.1 - Scheduling without a profile" continues to apply.

However, to modify the list of tests a new profile must be set.

9.4.3.5 DISPLAYING THE CLINIC'S LABORATORY TEST SCHEDULE

The scheduled tests can be displayed and if necessary printed from the clinic menu.



The "Weekly laboratory tests" section of the clinic menu displays the scheduling for all patients, week by week. The week displayed can be changed by modifying the date in the filter provided or pressing the navigation buttons.

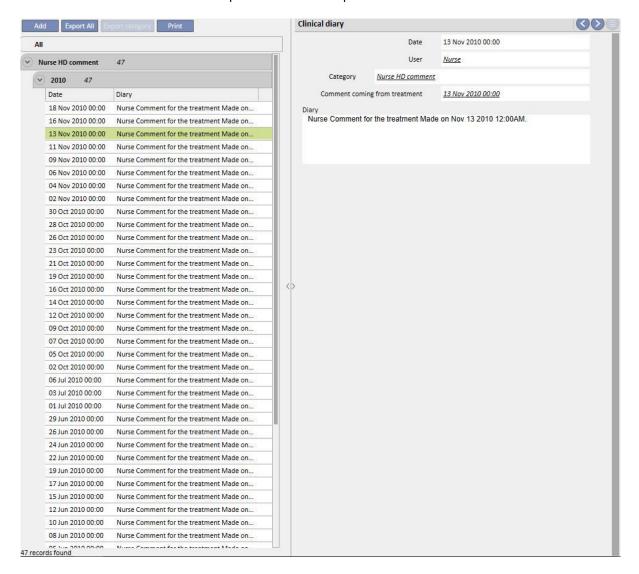
The "Include hospitalised patients" filter allows the user to display the scheduling of tests that should be performed during a patient's hospitalisation, even if this takes place at the same clinic.

If the TSS service is configured to allow the printing of NHS prescriptions, a button for their creation and display will appear.

9.5 MEDICAL DATA

9.5.1 CLINICAL DIARY

The Clinical Diary tab contains information about the patient's medical history. The information to be recorded here is at the discretion of the clinic's staff and depends on the clinical protocol to be followed.

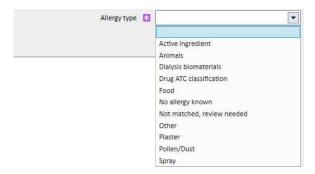


Click the **Add** button to insert a new item. In the commend field (Diary), information to be recorded can be entered. Once this form has been saved, is stored in the patient's diary. The user shown is the full name as recorded in the User Management section. Selecting the category will assign the comment field the last comment entered for this category. This function can be enabled or disabled using the "Configuration Parameters" in the "Master data" section.

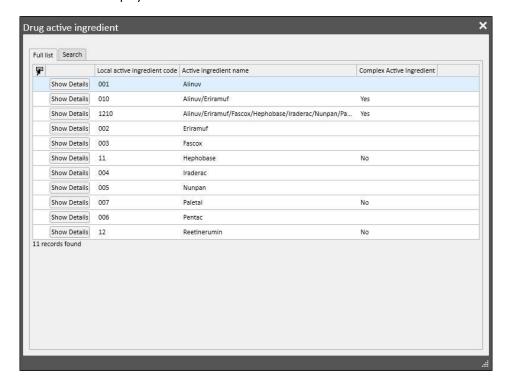
9.5.2 ALLERGIES

The patient's allergies can be recorded in this section. Most of the fields are described below:

 Allergy type: Mandatory field; this drop-down fixed list allows the user to select the type of allergy the patient suffers from.



 Drug active ingredient: If the allergy is to the drug's active ingredient, this field becomes mandatory, and a customised list will be displayed.



• **Drug ATC code**: if the allergy is identified by the drug's ATC code, a customised list appears. A drug can be located within the ATC Code field starting from its description or the code.

If the selected allergy is to an active ingredient or an ATC code which the patient is already taking as a pharmacological therapy, when the user clicks on save the following message will appear:



If the user clicks "Yes", the allergy is saved and the relative drugs are set as "To be reviewed", while if "No" is clicked the allergy is not saved.



Warning

Risk for the patient as a result of indications of allergy being shown

If the patient is allergic to an ATC Code, he will also be allergic to all drugs which derive from it.



Warning

Risk for the patient as a result of indications of allergy being shown

It is very important to record allergies accurately because they are critical for patient safety. The recorded allergies are displayed in several sections, including prescriptions and treatment. This ensures that doctors can always have them under control. Moreover if the patient has an allergy to a specific active ingredient and a doctor tries to prescribe a drug which contains it, the system informs the user accordingly by displaying the following dialogue box:



9.5.3 VACCINATIONS

Vaccinations can be recorded in this section. The most important fields are described below:

Vaccination date: The date in which the vaccine was performed.

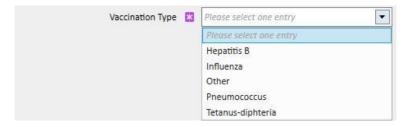
Performed by: The personnel who administered the vaccination.

Batch: Vaccine batch.

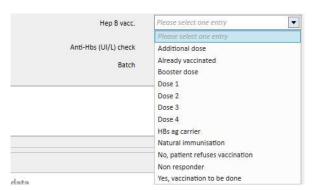
Comment: Free text for additional information.

Vaccination type: This drop-down list allows the user to select the type of vaccination the patient has received.

Based on the value selected, additional fields can be displayed:



- Influenza and Pneumococcal: do not add any field.
- Other: Add the vaccine field, which allows the drug administered to be selected.
- **Tetanus-diphtheria**: Add the fields Vaccine dose and Date next dose.
- Hepatitis B: If the Hepatitis B vaccination is selected, more detailed information will appear:
 - Hepatitis B vaccine: Details of the drug administered as a vaccine.
 - Has the patient received any Hepatitis B vaccination? This prompt asks the user if the patient has already received hepatitis B vaccine in the past.
 - **Date of next dose** and **Vaccine dose**: These fields must be filled in to indicate when the next vaccine must be performed.
 - Vaccination recommended: Yes, if the vaccination is recommended; No, if it is not.
 - **Hepatitis B vaccination: Date of first dose**: Date of first hepatitis B vaccination administered in the clinic. Filled-in automatically by the system.
 - **Hepatitis B vaccination**: This field asks the user to explain why a new vaccination event has been created, e.g. to record a vaccination (dose2, dose3, etc.) or to record other vaccination-related events.

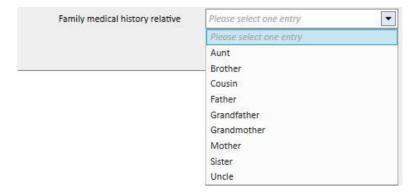


- Vaccination cycle: More information about the vaccination cycle.
- Anti-HBs Check: This field is calculated automatically by the system. The value is *GREEN* if the last laboratory value for anti-Hbs is lower than 10; *YELLOW* if it is between 10 and 100; and *RED* if it is greater than 100.
- Vaccination in double dose: Yes, if the vaccination is in double dose; No, if it is not.
- At the bottom of the window, a list of the most important values of the last 20 laboratory tests is shown.

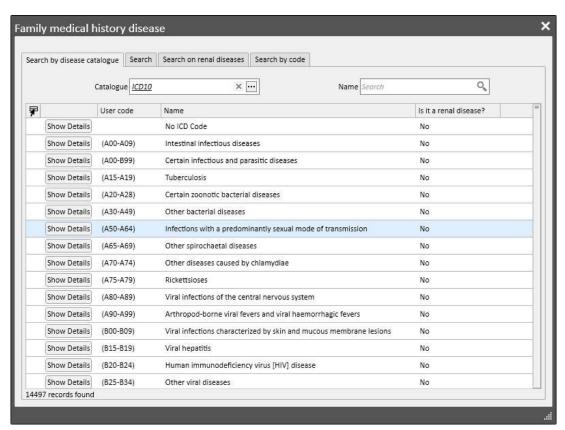
9.5.4 FAMILY MEDICAL HISTORY

In this section information about the clinical disease history of a patient's family members can be recorded. Most of the fields are described below:

• Family medical history for relatives: This drop-down fixed list allows the user to select the patient's family member(s) who are affected by a specific clinical disease.

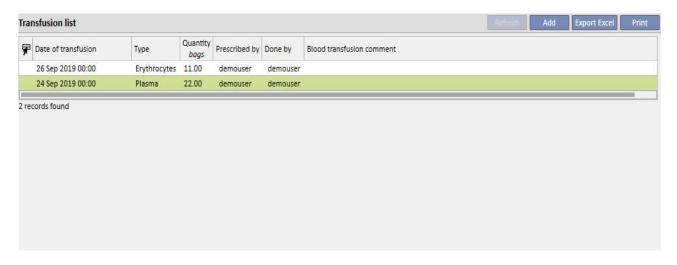


• Family medical history disease: A specific disease can be selected from the disease catalogue. It is possible to filter the catalogue in order to search only among the renal diseases in the chosen disease classification, such as the ICD code. Please refer to the Service Manual for instructions on customisation of the disease catalogue.



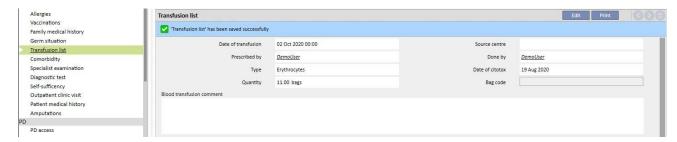
9.5.5 TRANSFUSION LIST

Any transfusions given to the patient can be recorded in this section.



Click on the button to add a new transfusion. The fields present are:

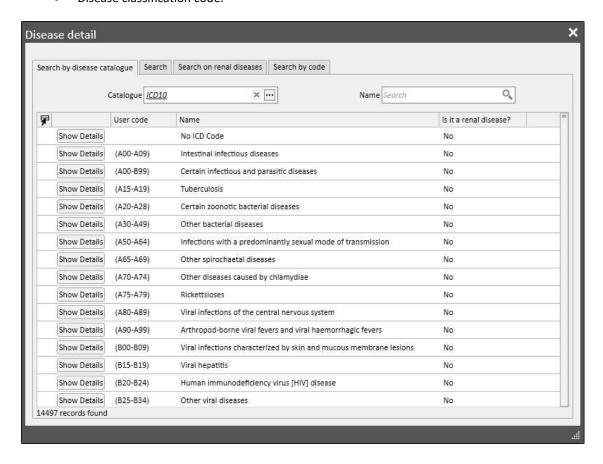
- Date of transfusion: This is the date and time the transfusion is performed.
- Prescribed by: This is the person who has prescribed the transfusion.
- Type: This is the type of transfusion to be performed.
- Quantity: This is the amount of bags used for the transfusion.
- Clinic: Location where the transfusion will be performed.
- **Done by**: The person who will perform the transfusion.
- Date of cytotoxicity: the date on which the cytotoxicity test was performed.
- **Bag code**: The codes of the bags used during the transfusion can be entered.
- Blood transfusion comment: This is a field where comments regarding the transfusion can be entered.



9.5.6 COMORBIDITY

Information about the patient's secondary clinical diseases can be recorded in this section. The most important fields are described below:

- **Disease**: A specific disease can be selected from the Disease Catalogue. The catalogue can be filtered to search only among:
 - Disease catalogues and description;
 - Disease classification description;
 - Renal disease catalogue;
 - Disease classification code.

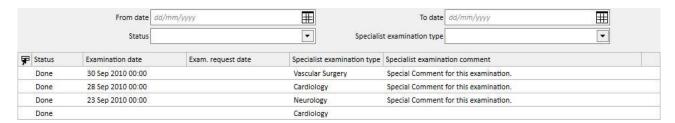


9.5.7 SPECIALIST EXAMINATION

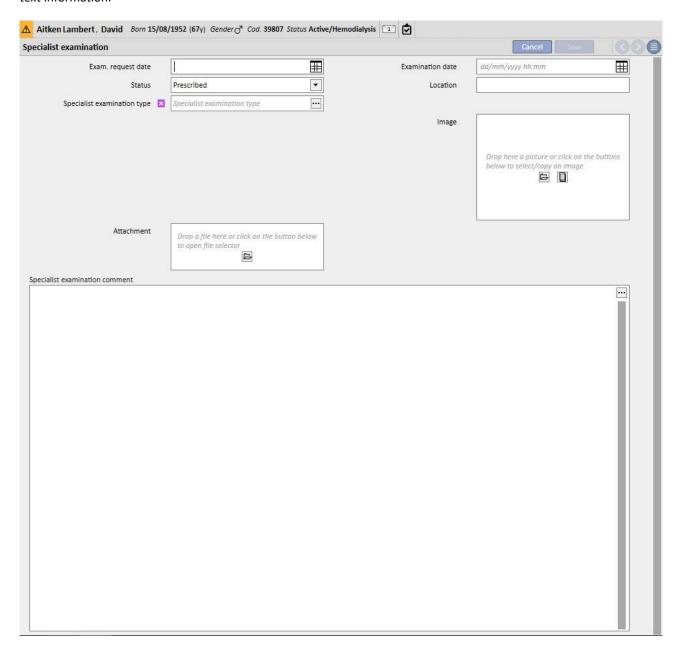
This section contains all the specialist examinations the patient has undergone. Specific specialist examinations not directly correlated to the dialysis session, such as a cardiology examination, can be entered.

These specialist tests can be entered in "Prescribed" status meaning, for example, that they have been prescribed for the patient but not yet carried out, or in "Performed" status, meaning that they have already been performed on the patient and thus already recorded.

Thanks to the filters, specific views can be recreated based on the Status or by Specialist examination type and also for a specific time interval.



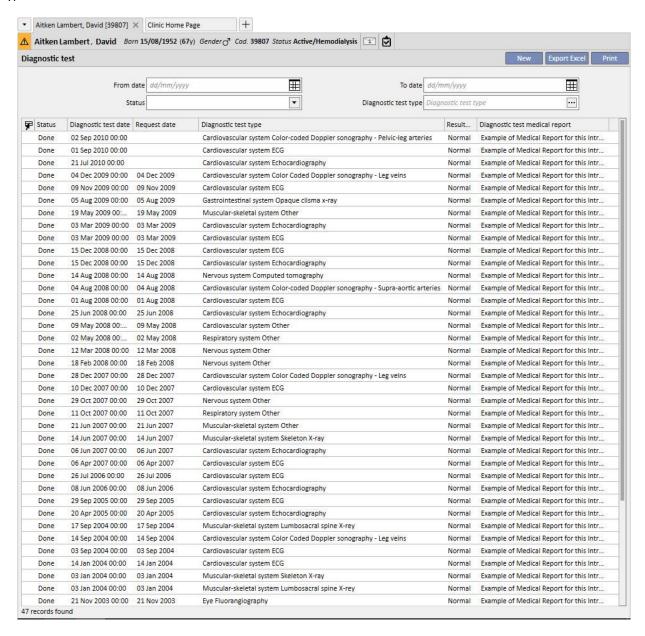
The user can click the button to create a new specialist examination. The examination request date, the actual date of the specialist examination and its status (prescribed, performed or cancelled) can all be entered. The specialist examination type can be used to select the specialist examination required. If the result is Abnormal, the disease code can be entered. The Location field is used to describe where the visit will take place. Furthermore, there are two fields for attachments, (images and standard attachments) and a specialist examination comment field for text information.



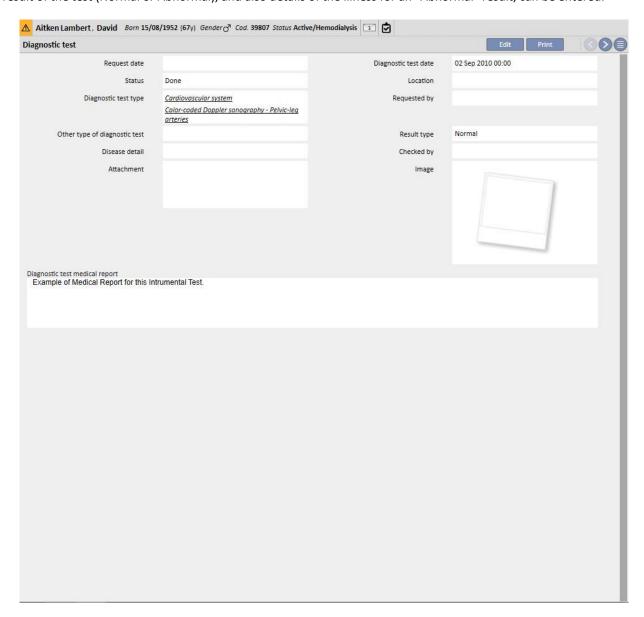
9.5.8 DIAGNOSTIC TESTS

This section contains all the patient's diagnostic tests. Here the user can enter specific diagnostic tests such as an ECG for the cardiovascular system, or for the muscular-skeleton system that are not directly linked to the dialysis sessions, but are necessary for a better assessment of the patient's clinical condition.

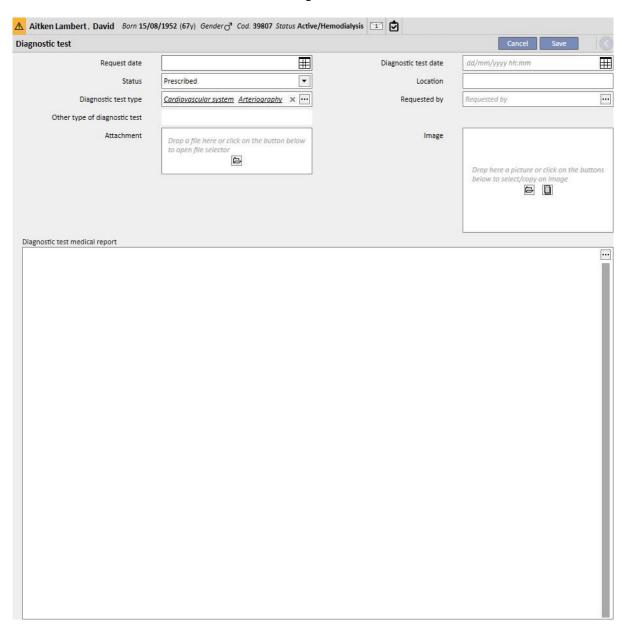
Thanks to the filters, specific tests can be searched for based on a specific time interval, status or by diagnostic test type.



These diagnostic tests can be entered in "Prescribed" field meaning, for example, that they have been prescribed for the patient but not yet carried out, or in a "Performed" status, meaning that they have already been performed on the patient and thus have already been recorded. The Location field is used to describe where the test will take place. The result of the test (Normal or Abnormal), and also details of the illness for an "Abnormal" result, can be entered.



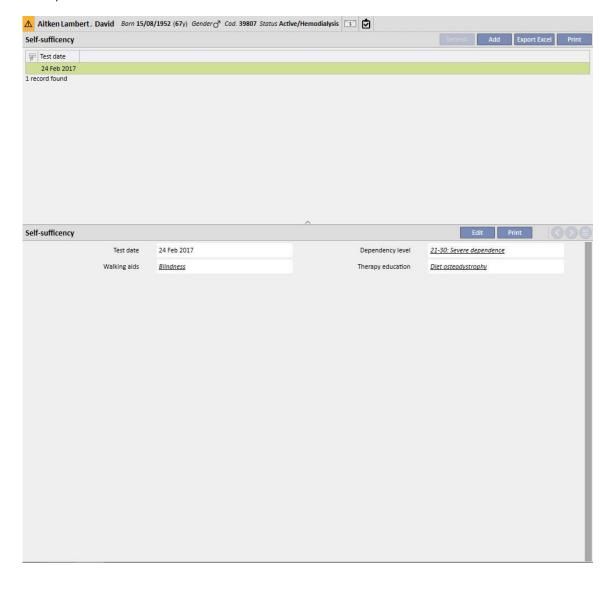
The button can be clicked to create a new Diagnostic test.



9.5.9 SELF-SUFFICIENCY

This section is used to record information about the self-sufficiency level of a specific patient. This level is determined by evaluating the following parameters:

- Walking aids: such as wheelchairs, crutches, hearing aids, etc.
- **Dependency level**: level of dependency, from "independent" up to "totally dependent".
- **Therapy education**: knowledge acquired about the patient on various themes like access care, hemodialysis, diet, etc.

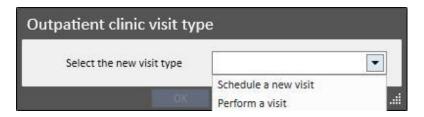


9.5.10 OUTPATIENT CLINIC VISIT

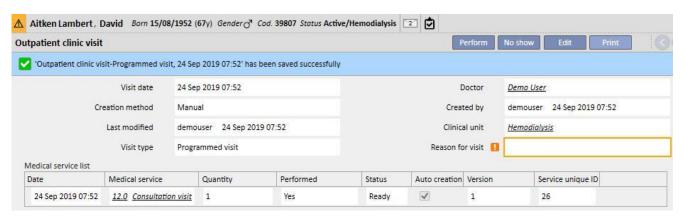
The follow-up visit section can be used to save the data relating to outpatient clinic visits for each patient. The user can specify whether a new visit should be scheduled or performed for each patient.

9.5.10.1 SCHEDULING A NEW VISIT

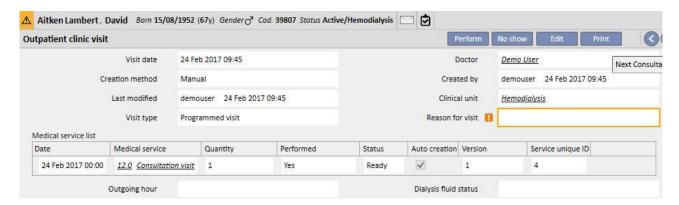
To schedule a new visit for a patient, the user must select "Schedule a new visit" from the two options supplied by the pop-up that appears when the button is clicked.



- Visit date: Date when visit will be performed.
- Doctor: The doctor who prescribed the visit.
- Method of creation: If created manually or if it arrived by interface.
- Created by: The user who created the visit.
- Last change: the user and date of the last change
- Outpatient clinic: The hospital unit where the patient will go for the visit. This list can be defined freely.
- Reason for visit: This list can be defined freely.
- Medical services list: If there are any medical services associated with the outpatient clinic visit, if valid, they will be shown. The user can also add additional services.



A patient may fail to attend a scheduled visit. In this case the user can click the No show button to switch the visit to cancelled status.



9.5.10.2 PERFORMING A VISIT

There are two possible ways of performing a visit. The user can open an existing "scheduled visit" by selecting it from the follow-up visit list and then clicking the button. It is also possible to select "Perform a visit" from the two options provided by the pop-up which appears after the button is clicked.



If the outpatient clinic visit has been performed, it can be closed by clicking the Close button

Automatic generation of reports in PDF format can be associated with the closure of the outpatient clinic visit. Specifically, the expressions (see "Service Manual" section 4.2.9) set in the "Configure PDF Export" section (see "Service Manual" section 4.2.7), which are enabled and valid for the current clinic, will be assessed.

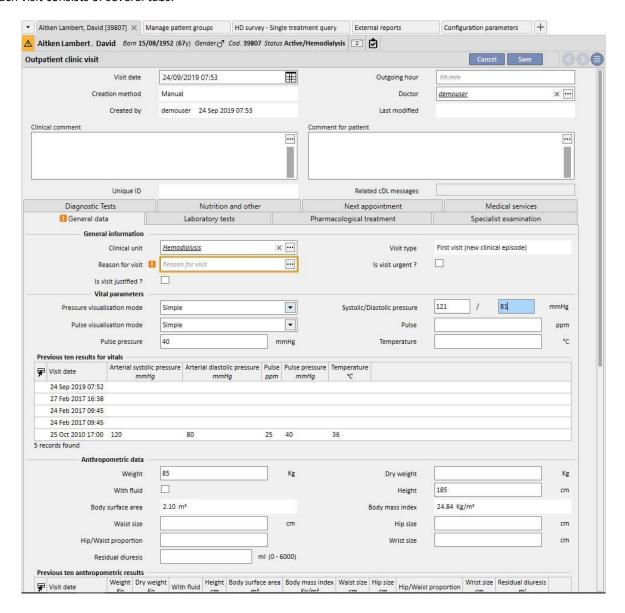
If the outpatient clinic visit meets the defined expression criteria, the report associated to the valid expression will be generated automatically. Depending on the setup, the report may be exported via Filesystem and/or sent via cDL.

PDF reports created can be viewed in the "PDF export" section (see "Service Manual" section 4.2.8).

When the outpatient clinic visit is in "Closed" status, its data can no longer be edited. Press the "Re-open" button to "Reopen" the visit; its data become editable again.

If the automatic generation of reports in PDF format have been configured and, in Power Tool, the option "Filesystem Undo" has been enabled, when "Re-opening" the outpatient clinic Visit, the PDF file connected to the outpatient clinic Visit reopened will be deleted/renamed (based on the action configured in Power Tool).

Each visit consists of several tabs.

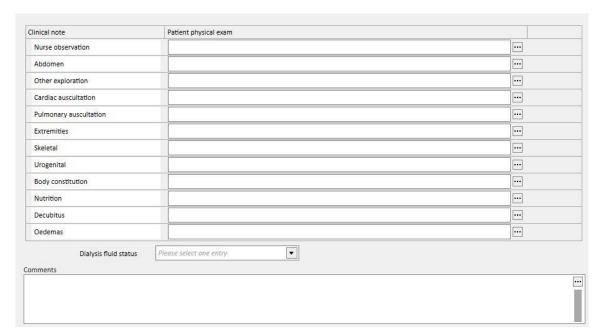


9.5.10.3 GENERAL DATA

The following can be saved in the "General Data":

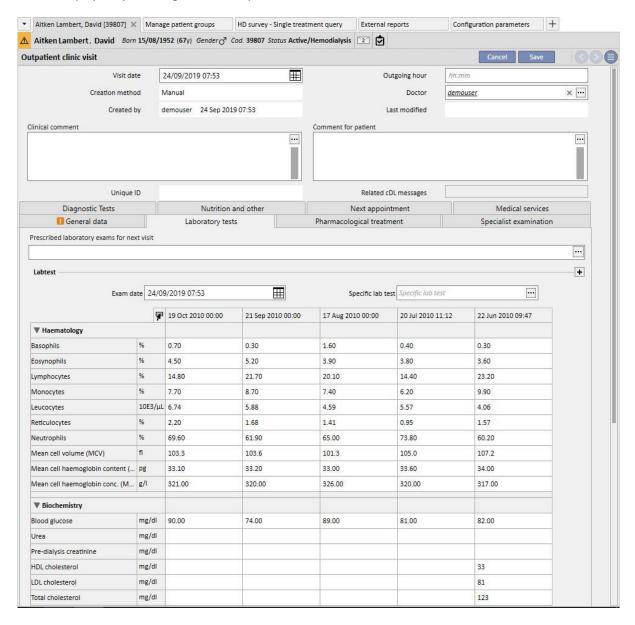
- General information about the visit (Clinic, Reason for visit, etc.).
- **Vital signs**: e.g. arterial pressure, pulse and temperature. For arterial pressure and pulse, the preferred measurement procedure can also be specified.
- Simple: The relative numeric fields provided for systolic/diastolic pressure (or pulse) have to be filled-in.
- Advanced: To fill in the pressure measurement field, the related pop-up must be opened and the rows of the table filled-in with the requested data. Then specify the calculation method to be used.
- Average of all selected measurements: The pressure values are calculated as the average of all selected measurements. To set a measurement as "selected", the user must check the "Used" flag.

- Value of the last selected measurement: The last measurement entered (and flagged as used) is used to fill the pressure measurement field.
- The same options are available for pulse measurements.
- Anthropometric data: list of all the data relating to the patient.
- Clinical notes: this section allows the user to enter data relating to the patient's physical health and dialysis fluid status.

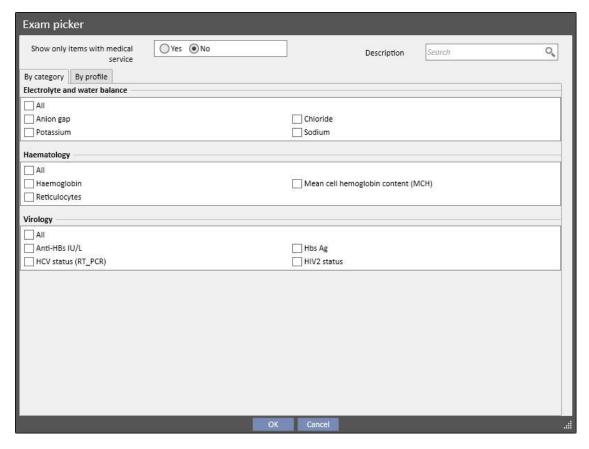


9.5.10.4 LABORATORY TESTS

This tab contains an overview of the patient's last ten laboratory tests, grouped by specific categories. A laboratory test can be displayed by selecting it from the specific list.



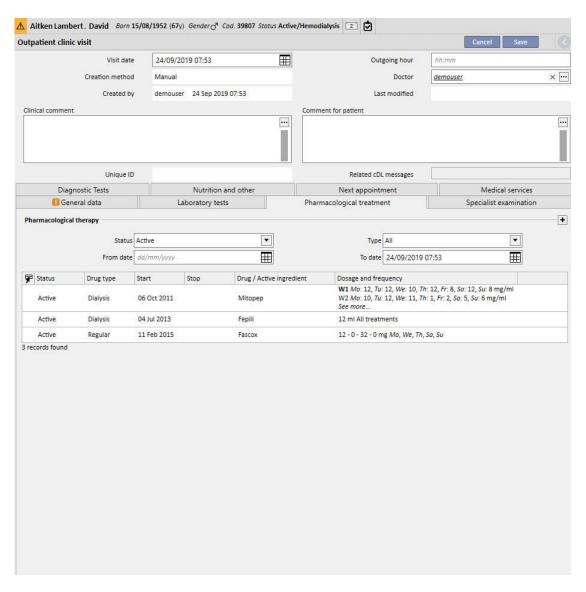
Laboratory tests for the next visit can be prescribed in this screen. The user simply selects the tests required from those offered in the "exam picker" screen.



Groups and tests are freely definable in the master data (Global Manager) section.

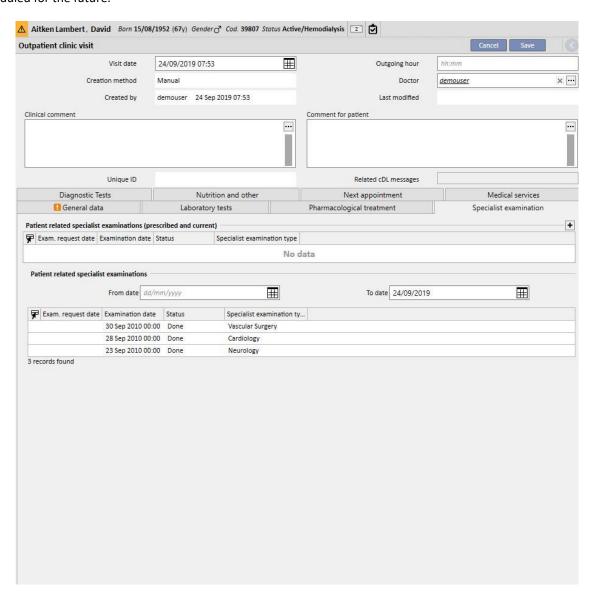
9.5.10.5 PHARMACOLOGICAL TREATMENT

This tab contains an overview of all pharmacological therapies that have been active since the last follow-up visit performed.



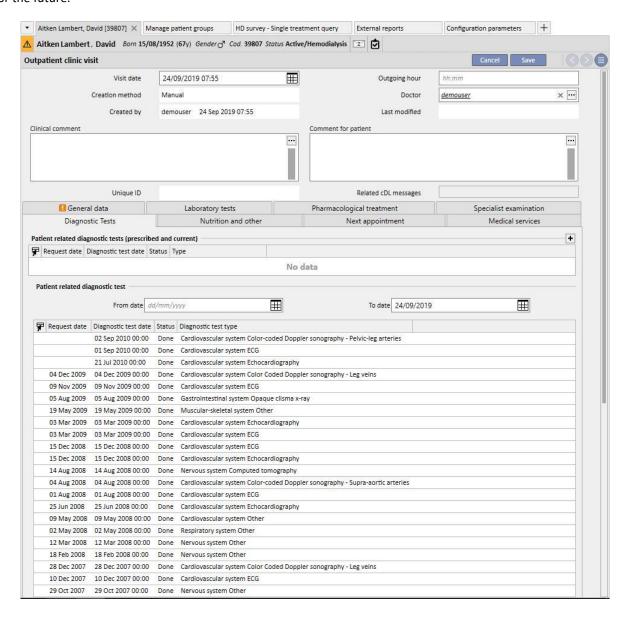
9.5.10.6 SPECIALIST EXAMINATION

This tab contains an overview of all specialist examinations divided between those already performed and those scheduled for the future.



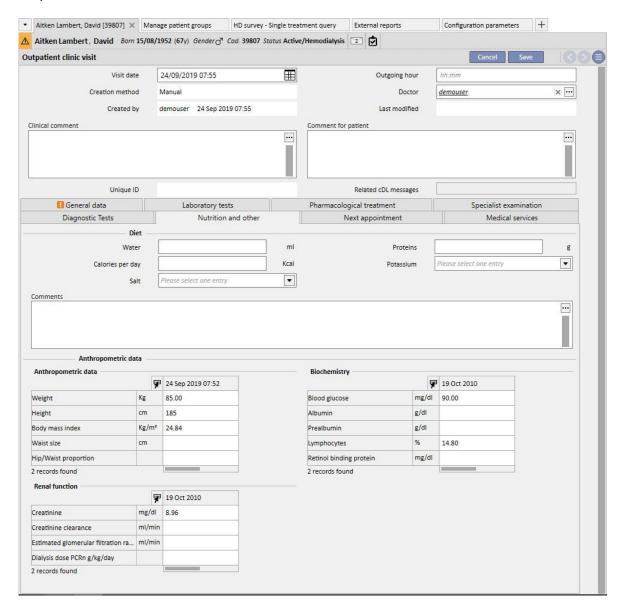
9.5.10.7 DIAGNOSTIC TESTS

This tab contains an overview of all diagnostic tests divided between those already performed and those scheduled for the future.



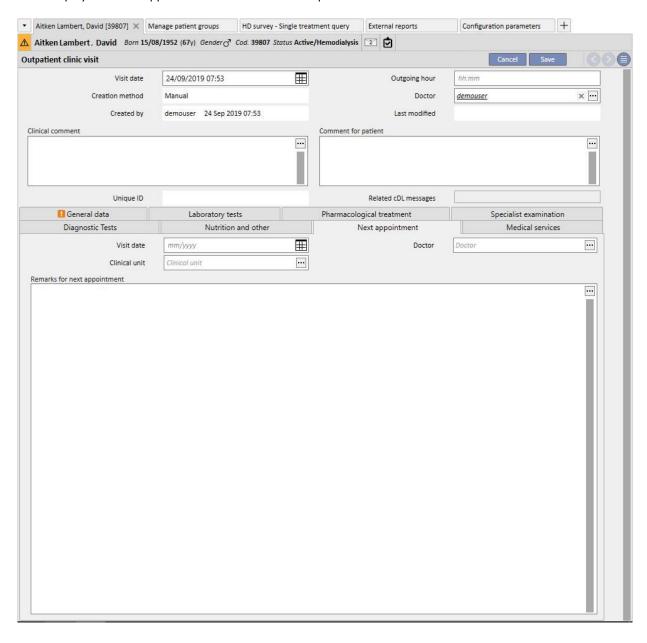
9.5.10.8 NUTRITION AND OTHER

This tab allows the user to prescribe the quantities for specific nutritional parameters such as water, proteins and so on. In this section the system also displays the last two anthropometric measurements and the biochemical and renal function parameters.



9.5.10.9 NEXT APPOINTMENT

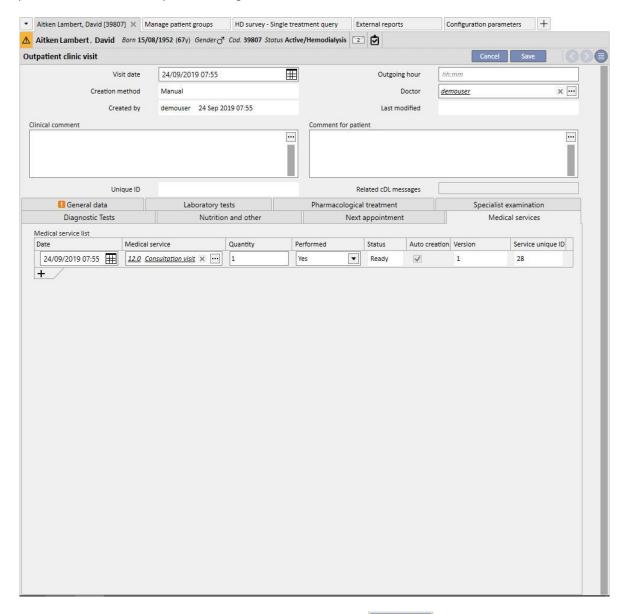
This tab displays the next appointments related to the outpatient clinic visit.



9.5.10.10 MEDICAL SERVICES

This tab displays the medical services related to the outpatient clinic visit. One or more services may be linked to a single visit.

Every service is characterised by the following information:



A report can be printed once the visit has been saved, by clicking the Print button.

The user can display and print a medical prescription by clicking the performed.

9.5.11 PATIENT MEDICAL HISTORY

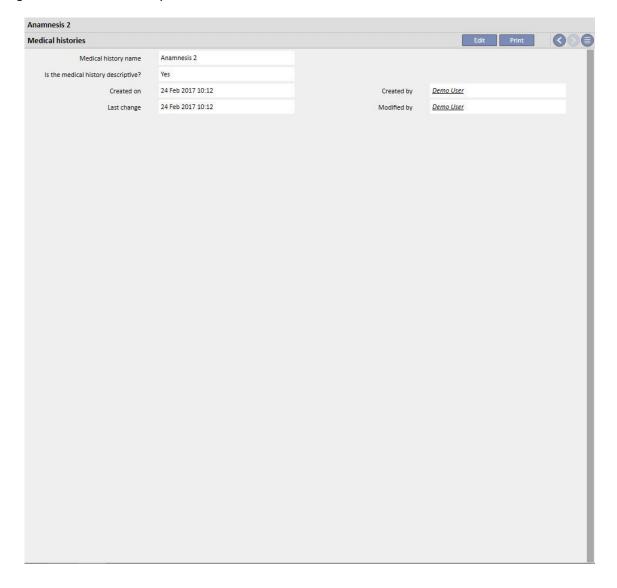
The "Patient medical history" section allows answers to be recorded to several lists of questions defined by the user, called patient medical histories. First, a new medical history is created for the patient and, once the Medical History configuration has been chosen, the list of questions to be answered, set in the chosen configuration, appears.

9.5.11.1 FILLING IN THE MEDICAL HISTORIES

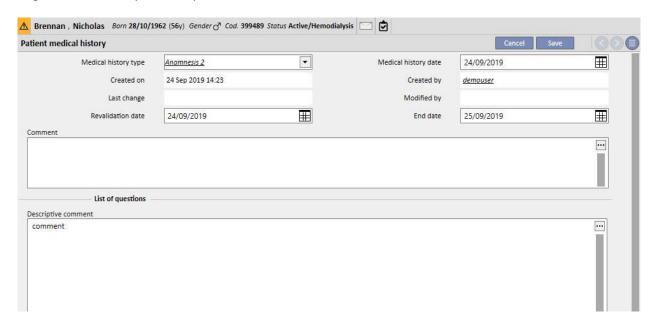
After enabling the "Global Manager" function, the user can configure new medical histories, or modify medical history configurations using the "Master Data (Global Manager)" → Medical History

If a descriptive medical history is selected, the system will provide a multi-line free text field where this can be entered.

Configuration of Medical History 2 from Master Data:



Filling in Medical History 2 for the patient:



If a NON descriptive medical history is selected, the user can configure a number of questions, the answers to which may be of different kinds:

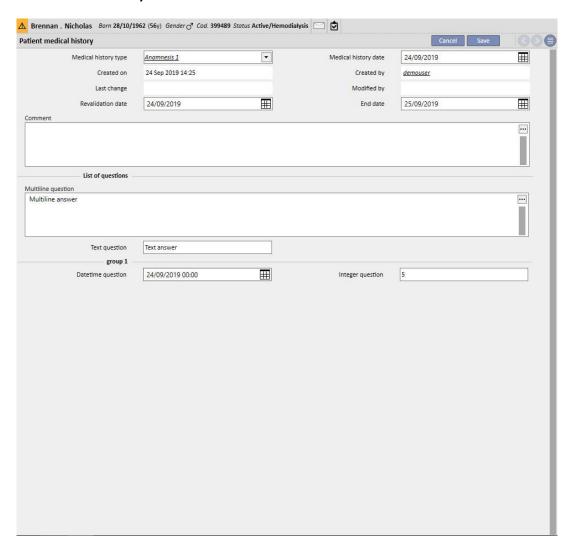
- Attachment: the question requires a file to be loaded in the form as an attachment
- Date/time: the answer is in a date field
- Whole: the answer is in a whole numeric field
- List or checkbox: a list of yes/no answers displayed as a drop-down list or horizontal or vertical checkbox can be configured. If Checkbox display is chosen there is no need to configure the answers because they will be to Yes/No questions
- Multiple line text: the answer is a multiple line descriptive text field
- Multiple choice: a set of multiple choice answers can also be configured
- Numeric: the answer is a numeric field with the option of setting Min, Max, Measurement unit and format
- Image: the answer is a field in which an image can be loaded or drawing using the system's drawing tools
- Text: the answer is a single-line text field

These questions can then be catalogued in groups, setting a group name and the relative set of questions

Creating a Medical History

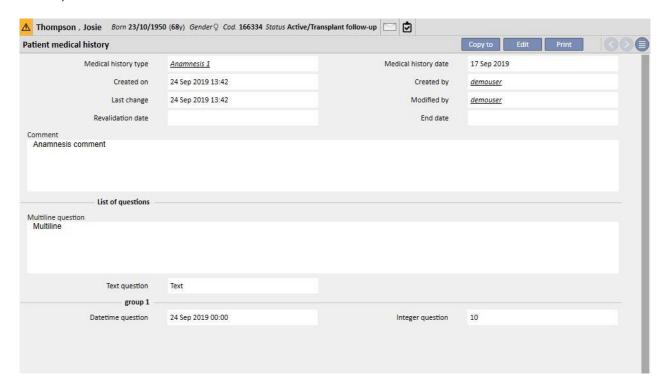


Filling in Patient Medical History 1



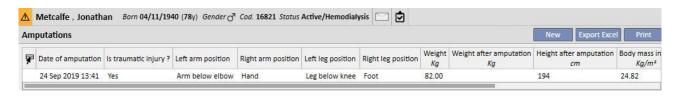
9.5.11.2 COPYING MEDICAL HISTORIES

So users can copy an existing medical history and its fields without having to re-enter the same values, there is a "Copy from" function. Select and open a completed medical history. Click the "Copied from" button in the upper right part of the window to create a new medical history, identical to the one selected. This also permits the values to be modified, if different.



9.5.12 AMPUTATIONS

Amputations can be recorded in this section.



Clicking on New amputation can be entered. The most important fields are described below:

Date of amputation: The date the amputation was performed.

Was it a traumatic accident? Indicate if the amputation was due to an accident or not.

Amputation reason: Allows the reason for the amputation to be added.

Other reasons: Free text to add other reasons.

Amputation position: in this section, indicate which limbs were amputated and to what extent the limb was amputated. The limbs for which amputation can be recorded are the following:

- Left arm position: If this limb is selected, more detailed information will appear:
 - **Nothing:** No Amputation.
 - **Hand:** Amputation of the hand.
 - Forearm: Amputation of the forearm.
 - Arm: Amputation of the arm.
 - Arm to the shoulder: Amputation of the arm up to the shoulder.
- **Left arm correction factor:** If a position is selected, it will automatically put the configured value in the reference section (if configured), otherwise it will be possible to enter a value manually.
- Right arm position: If this limb is selected, more detailed information will appear:
 - **Nothing:** No Amputation.
 - **Hand:** Amputation of the hand.
 - Forearm: Amputation of the forearm.
 - Arm: Amputation of the arm.
 - Arm to the shoulder: Amputation of the arm up to the shoulder.
- **Right arm correction factor:** If a position is selected, it will automatically put the configured value in the reference section (if configured), otherwise it will be possible to enter a value manually.
- **Left leg position**: If this limb is selected, more detailed information will appear:
 - None: No Amputation.
 - Foot: Amputation of the foot.
 - Leg below the knee: Amputation of the leg below the knee.
 - Thigh: Amputation up to the thigh.
 - Leg to the hip: Amputation of the leg up to the hip.
- Left leg correction factor: If a position is selected, it will automatically put the configured value in the reference section (if configured), otherwise it will be possible to enter a value manually.

- **Right leg position**: If this limb is selected, more detailed information will appear:
 - None: No Amputation.
 - **Foot:** Amputation of the foot.
 - Leg below the knee: Amputation of the leg below the knee.
 - Thigh: Amputation up to the thigh.
 - Leg to the hip: Amputation of the leg up to the hip.
- **Right leg correction factor:** If a position is selected, it will automatically put the configured value in the reference section (if configured), otherwise it will be possible to enter a value manually.

Weight: the weight recorded in the Medical Data is entered automatically. However, the weight can also be entered manually.

Weight after amputation: Post-amputation weight.

Body mass index: this field is calculated using the body mass index.

Body surface area: this field is calculated using the body surface area.



10 PATIENT TRANSFER OFFLINE

"Patient Transfer Offline" is used to import and export a patient between clinics in two separate, non-communicating "Therapy Support Suite" installations.

The clinic from which the patient is exported is the "source clinic" and the one to which he will be imported is the "destination clinic".

The patient exported from the source clinic is known as the "source patient" and will be imported "on top of" another patient in the destination clinic. This patient is known as the "destination patient".

Patient data are encrypted in a password protected compressed file with a .zip extension. The password must be entered during both export and import of the data.

This section describes this function and its constituent phases, which are:

- Export;
- Loading the import file;
- Data check;
- Performance of the import;
- Checking of the patient's data and final validation of the import.



Warning

Risk for the patient as a result of incorrect patient data being shown

The user is responsible for checking what information will be imported into the destination clinic and how.

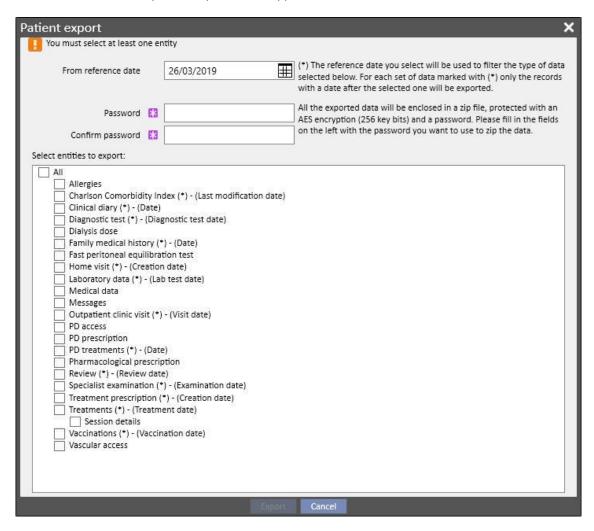
10.1 SOURCE CLINIC - EXPORT

Export of a patient starts from the "Patient status" section. In order to be exported, the source patient must be deactivated by means of an outgoing transfer to a non-TSS clinic.



When this movement is saved, the patient becomes "Not active" and the Export... button appears to indicate that the patient is ready for export.

When this button is clicked, the patient export screen appears.



This screen allows the user to enter:

■ The **reference date** from which the patient's data must be exported. All information created at or found to belong to the period prior to this date will not be exported.

- The password to be applied to the .zip compressed file must:
 - Consist of at least 8 characters
 - Contain at least one numeric character
 - Contain at least one lower case character
 - Contain at least one upper case character
 - Contain at least one non-alphanumeric character.
- The patient **sections** to be extracted to the zip file. Initially, only the data in the list shown will be exported. After this, all the information linked to the data initially extracted will also be exported. This will prevent inconsistency between the data during importation.



Note

The data in the *Master Data – Clinic Configuration* section will not be extracted, and all fields that refer to them will only contain a description of the data not exported.



Note

Information linked to the data extracted but not specified by the user will not be exported in turn.



Warning

Risk for the patient as a result of patient data not being shown

The patient's administrative data are always extracted and there is no need to specify them when setting the export.

Once the date and password have been entered and the sections chosen, the actual export can be performed by clicking the *Export* button.

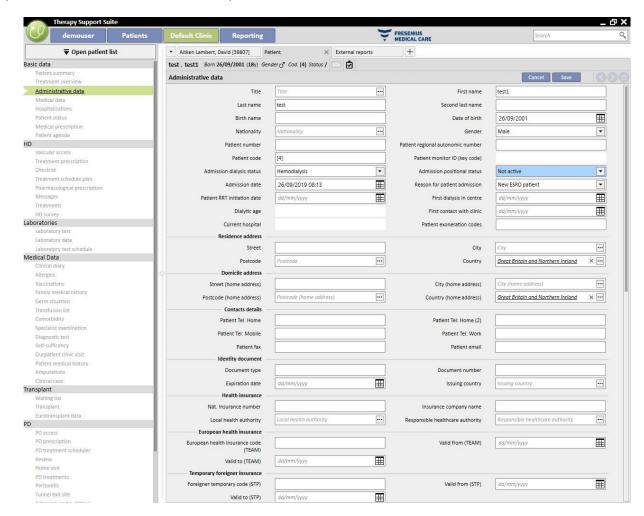
After a short wait (depending on the quantity of data for export), a dialogue window will appear enabling you to save the compressed file containing the patient's data.

Once the file has been saved, the export procedure is closed.

10.2 DESTINATION CLINIC - LOADING IMPORT FILES

Once the user has reached the destination clinic, he can proceed with the first stage of importing the source patient. In this first phase, the destination patient and the transfer will be created, allowing the zip file to be loaded into Therapy Support Suite.

First the user has to access the "Dialysis clinic – Clinic name" – "New patient creation" section. In this section, a new patient must be admitted with the initial positional status "Not Active".



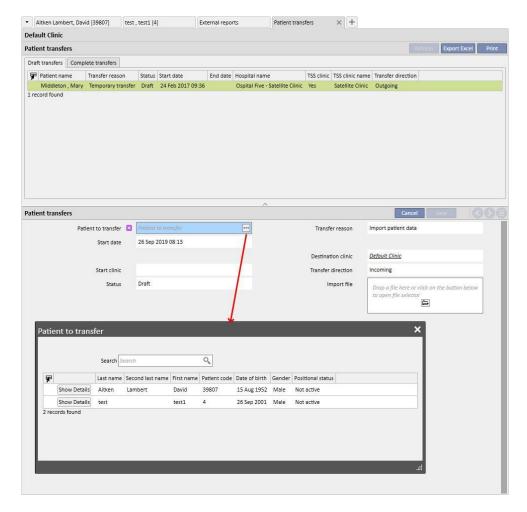
TOP I

Note

The standard procedure involves the admission of a new patient, but a patient can also be imported on any "not active" patient.

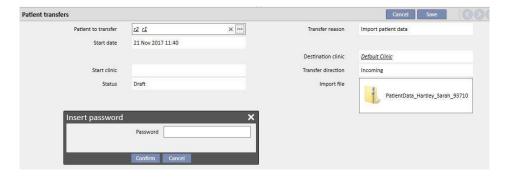
After creating the destination patient, the user must create a new transfer starting from the "Dialysis clinic- Clinic name" – "Patient transfer" section, using the button.

The destination patient can now be selected using the search field.



Once the destination patient has been chosen, the zip file needs to be attached to the transfer via the *Import file* field.

After the file has been chosen, the password can be entered.



Once the password has been entered and the transfer has been saved, the button will appear.

The first patient import phase is now complete.

10.3 DESTINATION CLINIC - DATA CHECK

Once the zip file has been loaded into the system and the destination patient has been selected, the user can proceed with the **data check** procedure.

In this phase, the program will actually <u>load</u> the information in the zip file and will compare it with what is in the destination clinic database. It will also attempt to <u>match</u> the source information with that present at the destination. Once this has been done, the outcome of the <u>data processing</u> operation will be displayed.

The **logic applied for comparing and matching** the data varies from section to section. Although designed to prevent problems and conflicts during matching, these processing tools will not always be able to create strong matches between the data. Conflicts may therefore occur and they must be viewed and then resolved by the user.

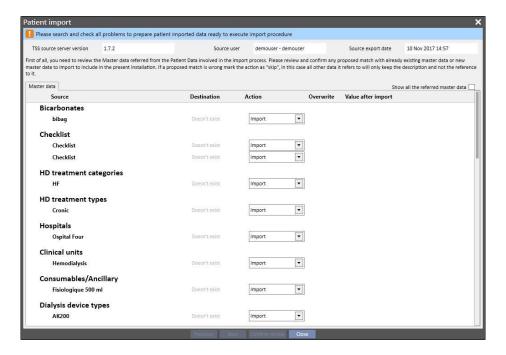


Warning

During this phase, the outcome of the import, meaning what is to be entered as new, what is not to be imported and what is to be overwritten and/or maintained in the destination, will be decided. The user is responsible for viewing and checking the data before performing the import procedure. Failure to check the data correctly may lead not only to poor import of the source patient's data into the destination clinic but also to the loss or incorrect modification of data shared by all sections of Therapy Support Suite.

10.3.1 LAUNCHING THE CHECK PROCEDURE

Click the **Import data** button to launch the procedure that checks and matches the source patient's data with the data in the destination clinic. On completion, the following screen will appear.



Note



The screen shown above only appears when problems occur with regard to the "Master Data" section. Otherwise, the section relating to the strictly patient-related data will be displayed at once. However, in this case the section shown above can still be accessed using the navigation buttons at the bottom of the screen.

10.3.2 DESCRIPTION OF THE GRAPHIC INTERFACE

The heading information extracted from the file appears at the top.

- Source Therapy Support Suite version.
- A brief description of the user who performed the source clinic side extract.
- Date when the export was performed.

Still at the top of the screen, there is a banner that shows the user the current validation status of the import. The confirmation button will not be enabled until all the "matching conflicts" are resolved.

If a **matching conflict** occurs when the program matches a source parameter with one found in the destination clinic, which however is unable to choose the import action. In this case, the action for the element is not populated and <u>the user has to decide how the function is to respond during performance of the import.</u>

The image below shows the message displayed if there are problems to be resolved.

📔 Please search and check all problems to prepare patient imported data ready to execute import procedure

Once all the conflicts have been resolved, the above message will change to the following.



The navigation, start and import confirmation buttons appear at the bottom.



The central part of the screen consists of the tables containing the result of the matching procedure, which will be described in detail in the following points.

10.3.2.1 MASTER DATA



Note

This table contains the details of all the clinics in Therapy Support Suite.

Data are grouped by patient details record type by Therapy Support Suite. Each row of this table contains an item from the patient details record that has been exported and then processed.



The table comprises the following columns:

- **Source**: description of the source clinic information
- Destination: result of the matching and search. This field may contain two different types of value:
 - If the **logics applied for matching** have found a match, they will show the description of the information matched with the source concerned.
 - Otherwise, the message "does not exist" will be displayed, indicating that there is no match for the source information in the destination clinic.
- Action: the type of action to be carried out during the import. A detailed description of what will happen to the function, on the basis of the action chosen, will then be provided.



Note

This field is **mandatory**. The import will not be ready for execution until all the action fields have been filled in.

- Overwrite: if a match is found, it will allow the user to specify whether or not the destination data are to be overwritten.
- Value after import: a calculated field that describes the value of the parameter after the import operation.



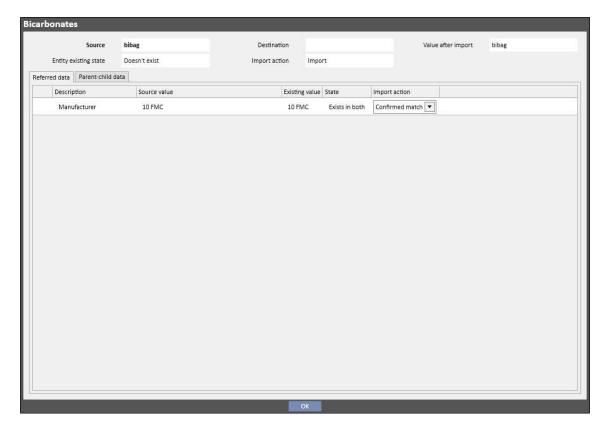
Tip

There is a filter in the top right-hand corner.

Show all the referred master data

When the filter is set as false, it only allows display of the patient details records for which the action field is empty, or is populated with the "Import" action. This will make it easier for the user to view the conflicts and the information that will be added.

Clicking the source description, or double clicking the entire line, opens the screen showing the details of the item.



At the top, the patient details record header data are shown. This information also appears in the main screen; the parameter's **existence state** is also displayed.

Two tables appear below the heading.

Linked data:

This is the list of references to a parameter present in the source, and is structured as a table.

- Description: shows the tab that describes the field.
- **Source**: field description originating from the source clinic.
- Destination: result of the matching and search. This field may contain two different types of value:
 - If the **matching methods applied** have found a match for the reference data, they will show the descriptive value of the matched destination parameter.
 - Otherwise, the message "does not exist" will be displayed, indicating that there is no match for the referenced data in the destination clinic.
- Action: the type of action to be carried out during the import. A detailed description of what will happen during the import, on the basis of the action chosen, will then be provided.

Note

This field is **mandatory**. The import will not be ready for execution until all the action fields have been filled in. In addition, the element that contains links to the unpopulated action will be indicated by warning messages.





The image below shows the case when a patient details record contains links to the action that has not been filled in.



• **Status**: This shows the existing state of the information to which the referred data refer. Further explanations concerning a parameter's existing state will be provided later.

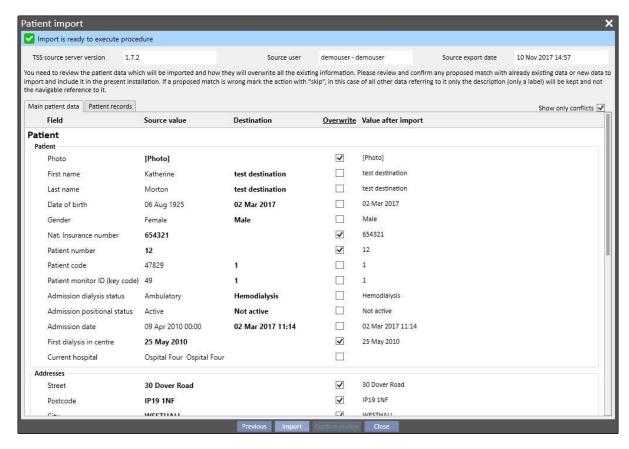
Parent-child data:

This second tab will show all the imported patient details record data that are the children of the item displayed, and an exact replica of the main "Master Data" tab.

10.3.3 MAIN PATIENT DATA

Once any conflicts in the "Master Data" patient details record section have been resolved, the user can click the button to move on to the section where the strictly patient-related data are checked.

The first section, containing the main patient data, will now appear.



This part shows all the fields (if present in the compressed file with the patient's source data) of the following sections:

- "Patient administrative data"
- "Medical data"
- "Charlson Comorbidity Index"

Here again, the information is grouped into sections and displayed in the form of tables. However, each row represents a single field of the section for import.



Warning

Risk for the patient as a result of incorrect patient data being shown

Import and overwrite choices are made on individual fields; the main patient detail record item will always be matched with the one in the destination.

The table comprises the following columns:

- **Field**: shows the tab that describes the field.
- **Source value**: the value of the field, in alphanumeric format, from the source patient.
- Destination value: the value of the field, in alphanumeric format, in the destination.
- Overwrite: allows the user to specify whether or not the destination data are to be overwritten.
- Value after import: a calculated field that describes the value of the parameter after the import operation.



Tip

There is a filter in the top right-hand corner.

Show only conflicts

When the filter is set as true, it only allows display of the patient details records for which the destination field is empty, or is different from the source value. This will make it easier for the user to identify the data that require supervision.



Tip

All the fields in all the sections can be overwritten by simply clicking on the name of the "**Overwrite**" column.

10.3.4 PATIENT DATA

This section shows all the patient's data for import that are not displayed in the section described previously.

Every row contains a patient data item from the source, such as prescription, dialysis treatments, etc. It has the same columns and functions in the same way as the "Master Data" record display screen.



Warning

Risk for the patient as a result of incorrect patient data being shown

The "overwrite" field of the data relating to treatments will be set to true by default.

10.3.5 ACTIONS AND EXISTING STATES

The way in which the function operates during import depends on two factors:

- The existing state of the data item;
- The matched action.

The possible values for the **existing state** are as follows:

- "Exists in import": the source element has been matched to a data item that exists in the destination.
- "Exists in destination": the source element has been matched to a data item that exists in the destination.
- "Does not exist": the source item has not been matched to an item in the destination.
- "Exists in both": this status indicates that the element and all of its links are already in the destination clinic.



Note

Performance of the import <u>is not blocked</u> when this situation occurs. The user is responsible for deciding whether or not to proceed with the import process. A user who continues with an import when the patient data in the source belong to a patient other than the destination patient, must be aware of the fact that an anomaly may be generated. In other words, this may lead to the creation of two patients representing the same actual person, both of them with incomplete data, apart from the fact that it will not be possible to reimport any of the patient data imported by the user.

The table below shows the list of the actions available in relation to the data item's existing state and their effect on the import procedure.

Existing state	Action	Result
"Exists in Import"	"Skip"	The element will not be imported. All source fields linked to the element concerned will have the reference "broken" and only a description of the element will be displayed. There will be no change to the matched element.
"Exists in Import"	"Confirmed match"	The element will be imported: there will be no change to the matched destination data item. All source fields linked to the element concerned will be directed towards the relative matched destination element. All those fields linked to the matched destination patient details record element will not be changed.

Exists in Destination	"Skip"	The element will not be imported. All source fields linked to the element concerned will have the reference "broken" and only a description of the element will be displayed. There will be no change to the matched element.
Exists in Destination	"Confirmed match"	The element will not be imported: there will be no change to the matched destination data item. All fields originating from the source and linked to the element concerned will be directed towards the relative matched destination element. All these fields that refer to the matched patient details record element will show the information relating to the imported element.
"Exists in both"	"Skip"	The element will not be imported. All source fields linked to the element concerned will have the reference "broken" and only a description of the element will be displayed. There will be no change to the matched element.
"Exists in both"	"Confirmed match"	The element will be imported: the linked destination data item will be overwritten. All fields originating from the source and linked to the element concerned will be directed towards the relative matched destination element. All fields that refer to the matched patient details record element will show the information relating to the imported element.
"Does not exist"	The only action that is or can be linked is "Skip"	The element will not be imported. All source fields linked to the element concerned will have the reference "broken" and only a description of the element will be displayed.



Note

The data from the source record can never overwrite the destination if it forms part of the list of drug database sections. There is a special tool for importing information of this type.



Tip

In the event that a link is "broken" by setting an action as "Skip", the red message "Tab only" is displayed on the right-hand side of the field line.

10.3.6 TABLES OF INTERFACE RESPONSES TO CHANGES IN ACTIONS



Note

If one action is replaced by another one, the latter is also applied automatically to all the links that refer to the information concerned.

The table below illustrates the response of the "Patient Transfer Offline" to the change in the action of one of the data displayed in the "Master Data" and "Patient Data" sections tables.

Note



In some cases, when the selected action is changed the following alert message appears:

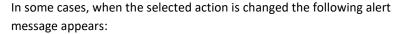


Value of action	Current action is changed to:	Alert message shown?	Button clicked when alert message appears	Expected response
Empty	"Confirmed match"	No	NA	The action of all the links referring to the value just modified will be set as a "Confirmed match". The overwrite field appears (if it belongs to the list of importable sections).
Empty	"Skip"	Yes	"ОК"	The action of all the links referring to the value just modified will be set as "Skip".
Empty	"Skip"	No	"Cancel"	Nothing is changed.

"Confirmed match"	"Skip"	Yes	"ОК"	The action of all the links referring to the value just modified will be set as "Skip".
"Confirmed match"	"Skip"	No	"Cancel"	Nothing is changed.
"Import"	"Skip"	Yes	"OK"	The action of all the links referring to the value just modified will be set as "Skip".
"Import as new"	"Skip"	No	"Cancel"	Nothing is changed.
"Skip"	"Confirmed match"	No	NA	The action of all the links referring to the value just modified will be set as a "Confirmed match". The overwrite field appears (if it belongs to the list of importable sections).
"Skip"	"Import"	No	NA	The action of all the links referring to the data item just modified will be set as "Import".

The table below shows the way the function responds to the various changes in the actions in the links. Here again, an alert message will be shown:

Note







Value of action	Current action is changed to:	Alert message shown?	Button clicked when alert message appears	Expected response
Empty	"Confirmed match"	Yes	"Yes"	All the links of the same type will assume the same action is to be taken. The value matched with the link will assume the same action is to be taken.
Empty	"Confirmed match"	Yes	"No"	Nothing else is changed.
Empty	"Skip"	Yes	"Yes"	All the links of the same type will assume the same action is to be taken. The value matched with the link will assume the same action is to be taken.
Empty	"Skip"	Yes	"No"	Nothing else is changed.
"Confirmed match"	"Skip"	No	NA	All the links of the same type will assume the same action is to be taken. The value matched with the link will assume the same action is to be taken.
"Import"	"Skip"	No	Na	All the links of the same type will assume the same action is to be taken. The value matched with the link will assume the same action is to be taken.
"Skip"	"Confirmed match"	No	Na	All the links of the same type will assume the same action is to be taken.

				The value matched with the link will assume the same action is to be taken.
"Skip"	"Import"	No	Na	All the links of the same type will assume the same action is to be taken.
				The value matched with the link will assume the same action is to be taken.

10.3.108 SAVING AND LOADING PROGRESS

The information and the data check phase status can be saved, allowing the operation to be restarted at a later time. This can be done by clicking the "X" in the top left-hand corner or the "Close" button at the bottom of the screen. At this point the following alert message will appear:



Click "Yes" to close the data check screen and save the progress made.

Click "No" to close the screen without saving the progress made. Click "Cancel" and the screen will not be closed. Whenever the user clicks the **Import data** button, the calculation of the links will be carried out again, to combine the implemented status/progress of the data control with the latest changes made to the information managed by "Therapy Support Suite".

10.4 DESTINATION CLINIC - IMPORTING DATA

Once all the conflicts have been resolved and all the problems have been checked and analysed, the actual importation of the data can be started by clicking the importation.

10.5 DESTINATION CLINIC - PATIENT DATA REVIEW AND IMPORT CONFIRMATION PHASE

After a short wait, which depends on the amount of information to be imported, the user will be informed that the patient's data has been imported. However, some of the links/fields that were "broken" by setting the corresponding action on "Skip" may have to be fixed before the import can be confirmed. In other words, these fields must be checked and re-referenced to an existing parameter.



Until all the links referred to have been checked and fixed, the relative transfer and destination patient will be in "Review" status.

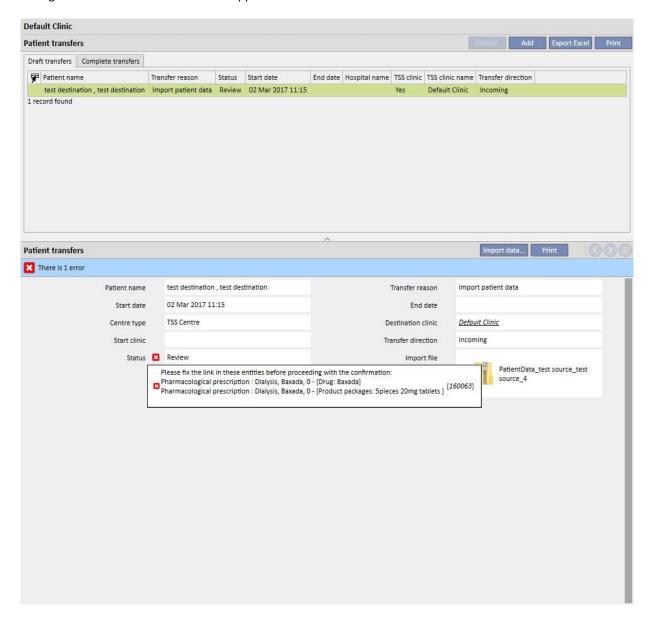
Once all the links listed in the above screen have been fixed, the user can confirm completion of importation of the patient.



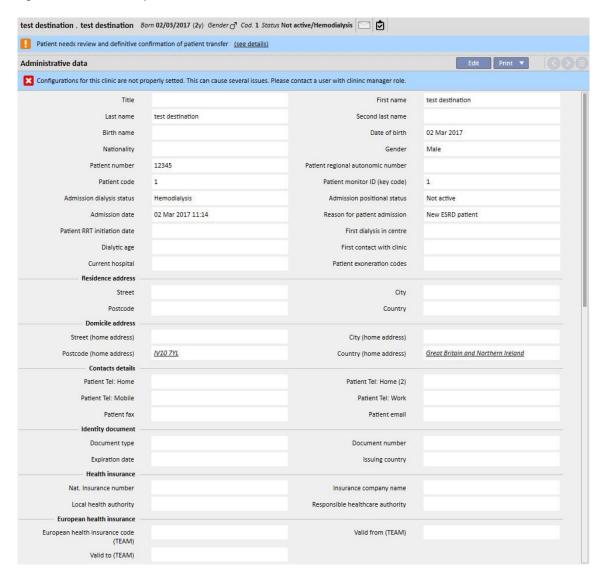
Note

As long as the patient is in this transitional status, he or she will not be displayed in the "Dialysis Clinic - Clinic Name" – "Activity Planning" and "Dialysis Clinic - Clinic Name" – "Resource Planning" sections.

The image below shows how the transfer appears when it is in "Review" status.



The image below illustrates a patient in "Review" status.



A banner appears at the top of the screen indicating that the patient is in this transitional status. Click "See details" to access the screen shown at the start of this point.

10.5.1 "BROKEN" LINKS

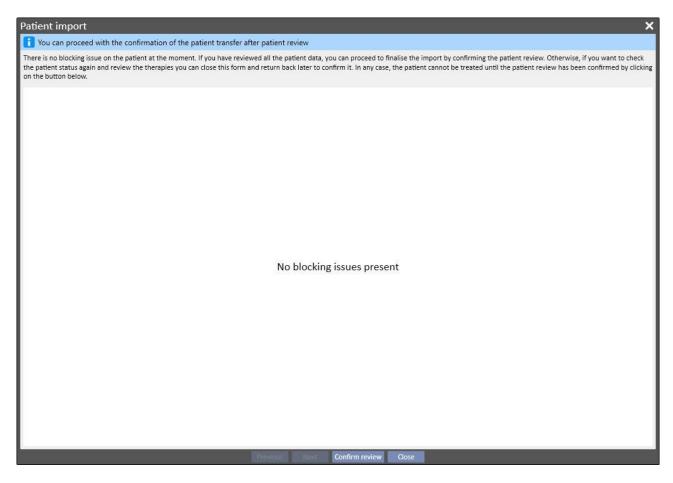
During the control phase, the actions of some elements and the relative links have been set as "Skip". In other words, the value to which the link refers has not been imported by the "Patient Transfer Offline" and therefore it will not be possible to access the parameter to which the connections referred. However, it will still be possible to select another element and thus create a new link. A link in this status is said to be "**broken**".

To avoid the total loss of information content, links referring to data not imported will be provided with a representative description of what the related information was. In other words, they will become little more than a descriptive field.

"Therapy Support Suite" highlights the fact that the information can no longer be accessed by colouring it grey; in some cases, it will be further indicated by an alert or even an error message.

10.5.2 CONFIRMATION OF THE IMPORT

Once all the links indicated have been fixed, the screen will be as follows:



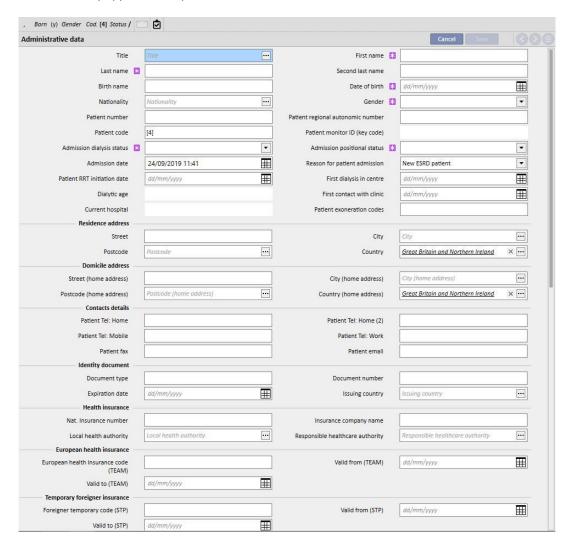
It is now sufficient to click the "Confirm review" button.

After this the patient will become active, the transfer will be complete and the patient offline transfer procedure has been concluded.

11 DIALYSIS CLINIC - CLINIC NAME

11.1 CREATING A NEW PATIENT

A new patient can be created in this section. The system automatically assigns a patient code that identifies the patient in Therapy Support Suite. This code cannot be changed. All the patient's administrative data can be entered. To save the new patient's details, at least, fill in all the fields in purple. Once this information has been saved, the patient will automatically appear in the patient list.



The patient is considered a duplicate if the **First name**, **Last name**, **Date of birth** and **Gender** are the same as those of an existing patient. In this case, admission is only possible if the specific flag in **Configuration parameters** is enabled. When this flag is enabled, the duplicate check can be extended to another text field, in addition to those listed above. (**See section 4.1.1 of the Service Manual**).

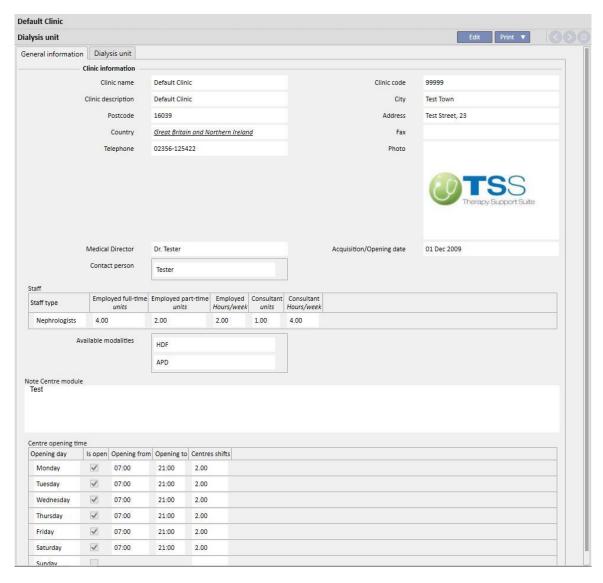
If a duplicate patient is created, both patients (the already existing one and the new one) will be in a blocked status until the merge of both patients is completed. The same blocked status can be triggered by creating a new merge of two patients even if not duplicates. In this blocked situation the patients' data cannot be edited.



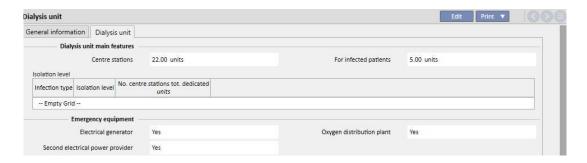
11.2 GENERAL INFORMATION

This section contains:

In the first tab, general Information on the dialysis clinic (name, code, clinic description, address, staff, etc.).



In the second tab, information about the organisation of the clinic's dialysis stations and the emergency equipment installed.

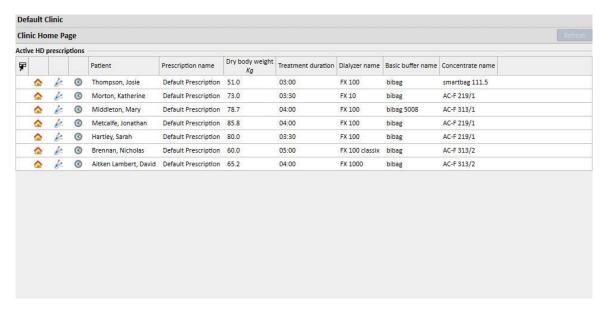


11.3 HOME PAGE

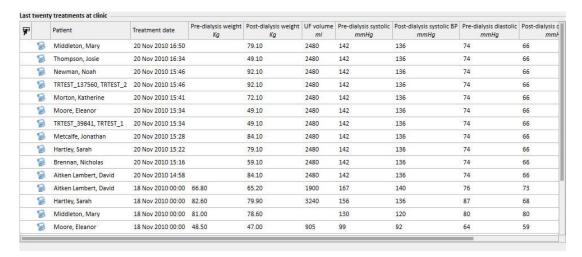
This section contains a quick overview of the patient's key dialysis parameters. It is divided into two main screens:

The first screen contains all active prescriptions.

- Click each line to access the Patient HD prescription;
- Click the button for direct access to the Patient dashboard;
- Click the button for direct access to the Vascular access for the prescription;
- Click the button for direct access to the Treatment schedule;



The second screen contains the last 20 treatments performed in the clinic. Click a row for direct access to the selected treatment.



11.4 CLINIC SCHEDULER

This section provides a complete weekly or monthly overview of the clinic's scheduling and treatments. The navigation buttons next to the time bar display the weeks or months before or after the current date, depending on the precision set in the **Accuracy** filter.

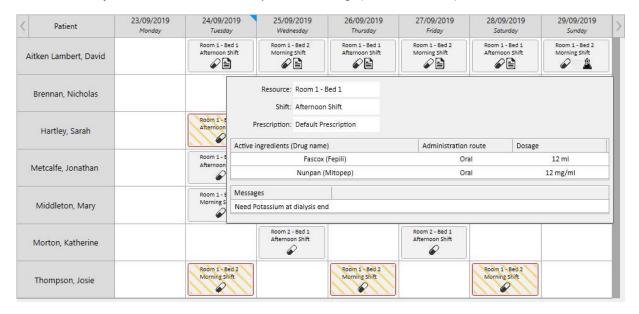
11.4.1 SCHEDULING

Scheduling covers planned recurrent treatments, where no dialysis session has yet occurred. If two or more treatments are scheduled at the same time and using the same bed, they will be displayed with a red border and yellow diagonal bands.



Passing the mouse over a recurring treatment, the following specifications will appear:

- Resource, Shift, Prescription name: taken from "Treatment schedule";
- Therapy, Administration, Dosage: taken from "Pharmacological therapy";
- Medical orders: read from "Medical orders" (see section 9.3.7);
- Laboratory tests: read from "Laboratory test scheduling" (see section 9.4.3);



After clicking on a treatment schedule, more scheduling data information is viewed and changes can be made where necessary:



The images show the Treatment Schedule, the Pharmacological Therapy, the Medical Orders and the Laboratory Tests.

11.4.2 CHANGING THE TREATMENT SCHEDULE

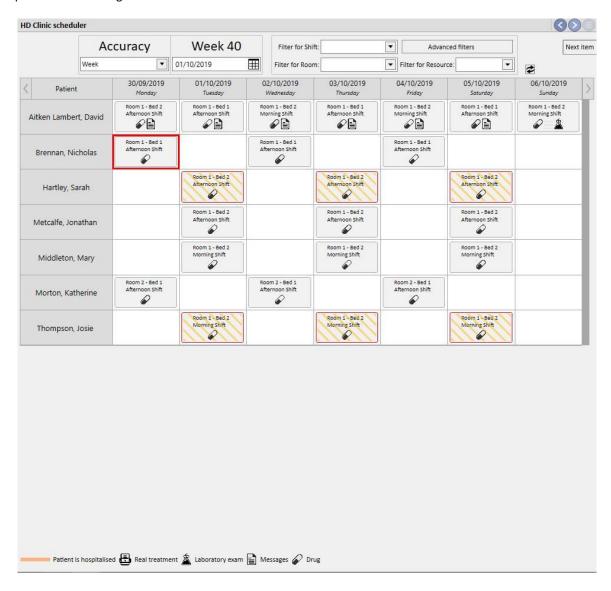
The treatment schedule can be changed by suitably populating the desired fields. Once the date, resource and shift have been changed, the schedule will appear as follows.



Several operations can now be performed, including:

- Click the button to return to the original data;
- Click the
 Open schedule plan
 button to view the original schedule in a pop-up window;
- Click the Delete button to close the pop-up window and delete all pending changes;
- Click the Save button to close the pop-up window and save pending changes;

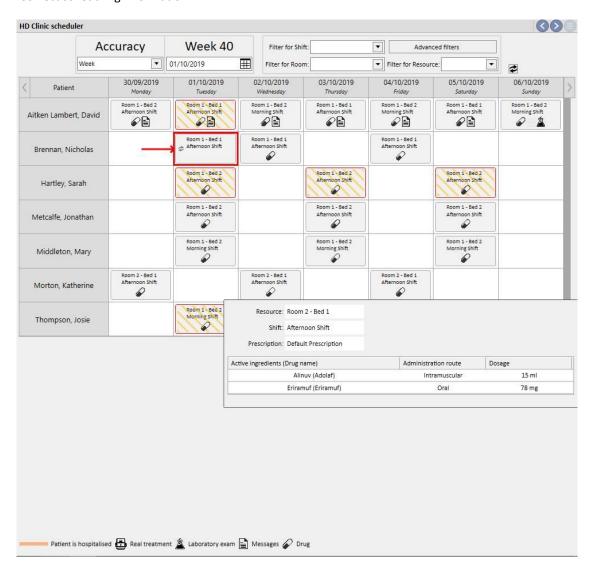
Example: Schedule change



Step 1 - Select schedule to be changed



Step 2 - Correct scheduling information



Step 3 - Scheduler updates its status with new scheduling information

11.4.2.1 DRAGGING

The treatment date can be changed by dragging it to the day desired. Scheduled treatments cannot be dragged into the past or into the same position as an existing scheduled treatment.

If there are drug therapies associated with the treatment, they will be managed as administrations with no specified dosage. A message will notify the user of the change.



11.4.2.2 IMPACT ON THE DRUG THERAPY AFTER SHIFTING A SCHEDULED TREATMENT

Every time the scheduled treatment date is changed, the drug therapy dosage for that treatment is reset. When a treatment is to be performed on the newly scheduled date, the user will be asked to manually confirm the related drug therapy, as described in detail in *Section 9.3.8*

11.4.3 TREATMENTS

The scheduler allows the user to display patients' past recurring treatments. A recurring treatment differs from a scheduled treatment in that the former is marked with a dialysis devce icon.



Past recurring treatments where no treatment was administered are not displayed.

If the treatment icon has a red border, problems occurred during the dialysis session and some messages may appear in the preview.



Click the desired recurring treatment and the associated treatment administered will be opened so that all the data can be viewed.

Recurring treatments cannot be moved.

11.5 PD TREATMENT SCHEDULER

The **PD scheduler** displays all dialysis treatments scheduled and completed for patients during the selected month. Different time intervals can be selected using the filters and navigation arrows.



The scheduler includes scheduled PD treatments and completed treatments. The dates indicated with an orange stripe refer to the patient's admission status.

Moving the mouse over the recurrences, a bubble appears that summarizes the prescription to be used for that date or for that treatment.

Clicking on a scheduled appointment the details are displayed as follows:



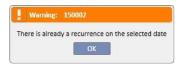
Click on a recurring treatment to open a window with the details of the treatment administered.

11.5.1 CHANGING THE TREATMENT SCHEDULE

8

A scheduled recurrence can be moved to a different date provided that there is no other appointment there already. There are two ways to change a recurrence.

The first method requires clicking on the recurrence to be moved and waiting for the details to appear at the bottom of the window. The **Scheduled date** field permits a new date to be selected and the update to be saved. If there is already a scheduled appointment on the date indicated, the message below appears, and the date cannot be saved.



An appointment date can also be changed by dragging the recurring appointment to be updated to a date where there are no appointments. In this case, there is no need to save because dragging has an immediate effect.

Regardless of the technique used to update a schedule, it will be displayed with the symbol , which acknowledges the schedule exception.

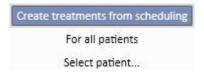
Updated schedules can be returned to their initial status using the button located next to the **Scheduled date** field of the details, and then saving. Alternatively, the appointment can be dragged back to its original date. In this case, the change is effective immediately.

Ø

11.5.2 CREATING PD TREATMENTS

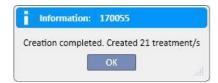
Patient treatments can be created individually in the patient tab or in the **PD treatment scheduler**. To create treatments in the patient tab, refer to the Optional PD Form.

The **PD treatment scheduler** allows recurring PD treatment appointments to be created to replaced schedules in the selected time interval. Creating treatments is performed by pressing the create treatments from scheduling button. A menu asks the user if the treatment should be created for all patients displayed or for only one.



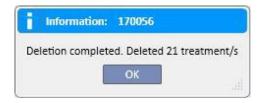
After selecting, creation will start.

At the end of the operation, a message informs the user of the number of treatments created.



11.5.3 DELETING PD TREATMENTS

PD treatments can be deleted in the **PD treatment scheduler** using the button. The system asks the user it the operation should be performed for all patients or only for one as described in the previous paragraph. At the end of the operation, a message informs the user of the number of treatments deleted.



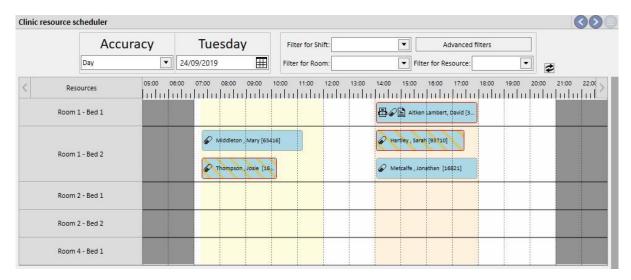


Note

Only treatments not yet closed can be deleted.

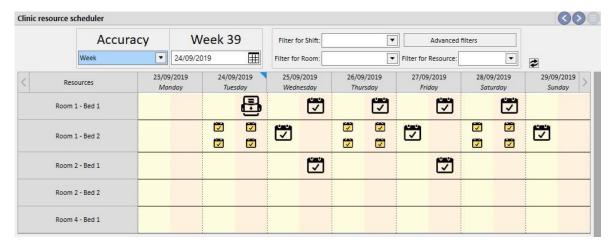
11.6 CLINIC RESOURCE SCHEDULER

This section provides a complete overview of resource scheduling.



The difference compared to the "Clinic Scheduler" is that planning is resource-led (based on rooms and beds).

In the background, with the configured colours, the various shifts are displayed for the current day, and in grey, the times the clinic is closed. In the weekly view, a full view of the resource planning for the entire week is displayed. This makes it easy to identify any empty schedule slots.



Clicking on a specific resource displays details of the treatment scheduled for that resource in that specific time-frame (the same procedure is explained in the "Clinic Scheduler".



11.7 PATIENT TRANSFERS

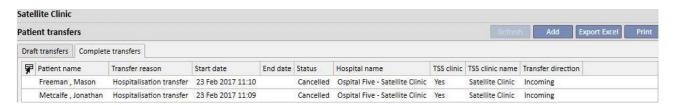
A patient may sometimes be transferred to another Clinic/Hospital. This is documented in Therapy Support Suite by creating the movement of a patient.

Transfers are divided into the following steps:

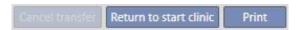
- "Draft": the receiving clinic has not yet accepted the transfer or has accepted a temporary, holiday or hospitalisation transfer;
- "Completed": the receiving clinic has accepted a definitive transfer, or has sent the patient back to the clinic of origin using the "Return to clinic of origin" button.

Draft transfers | Complete transfers

The transfer will start "automatically" once the event date is reached at the "destination" clinic.



If the transfer is temporary, for holidays or hospitalisation, both clinics have the option to return the patient to the original clinic. Once the transfer has been accepted by the destination clinic, this button can still be clicked.



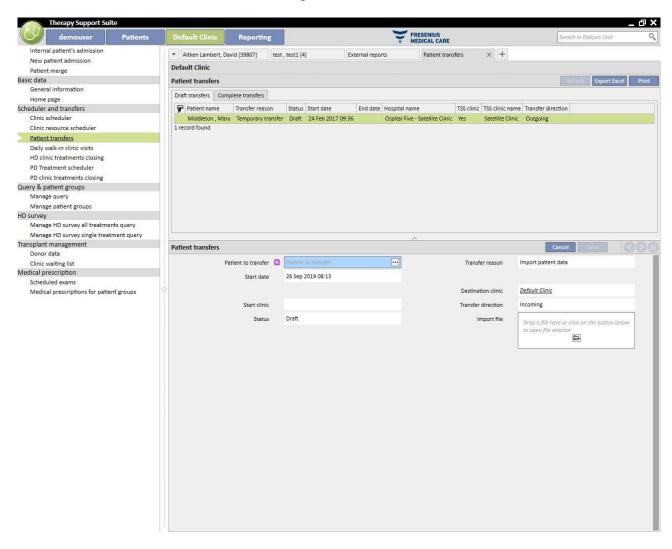


Note

If the movement that ends the transfer has not been defined, it will be created automatically when the "Return to start clinic" button is clicked. Conversely, if the transfer end date has been set, clicking this button will change the date of the return (and/or the date of the end of hospitalisation if the transfer originated from one of these).

11.7.1 CREATING A NEW TRANSFER

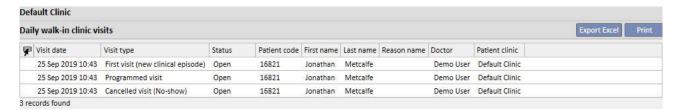
A new transfer can be created from this section using the "Add" button.



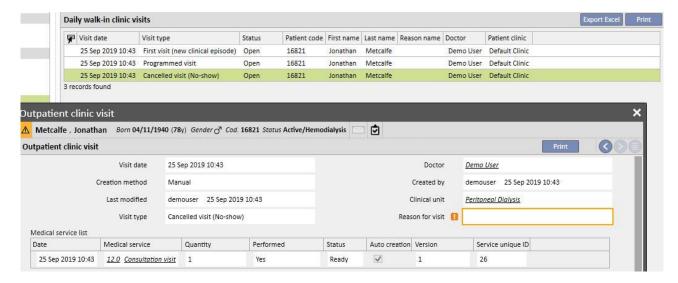
Creation of a new transfer from this section forms part of the importation process described in the "Patient Transfer Offline" section.

11.8 DAILY WALK-IN CLINIC VISITS

In this section, the user can view all the walk-in clinic visits (Completed, Planned or Cancelled) scheduled for the current day for patients belonging to the clinic.



Clicking the individual visit opens a window where its details are displayed.



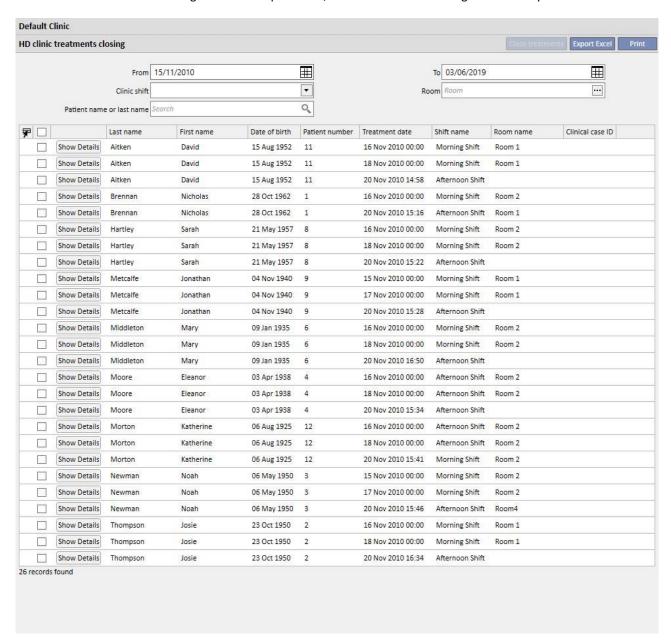
The visit cannot be edited or closed unless it was created inside the clinic. Visits created at other clinics can only be printed.

11.9 CLOSING TREATMENTS

Treatments, whether hemodialysis or peritoneal dialysis, can be closed individually from the patient menu or in bulk from the clinic menu. This paragraph illustrates how to close multiple treatments from the clinic menu.

While there may be slight variations, treatment closure works the same way whether selected from the **Close HD Treatments** or from the **Close PD Treatments** section.

Opening one of the two sections, TSS shows a list of treatments that can be closed, i.e., with a "Completed" status for hemodialysis and an "Open" for peritoneal dialysis. Treatments have a predefined order but it can be changed using the custom view tool. In the image of the example below, see the screen for closing of hemodialysis.

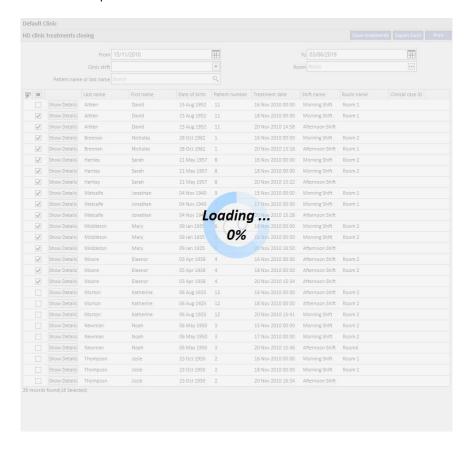


To close a treatment, it is necessary to check the box corresponding to the first column and press the **Close treatments** button.

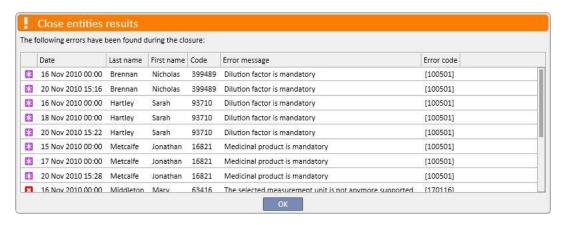
The filters located at the top of the page allow the desired treatments to be found quickly. A selected treatment that is excluded by the filter application keeps the check and can be closed even though it is not displayed. At the bottom of the list, the number of treatments displayed is always visible, followed by the number of treatments selected.

The filters available vary with the type of treatment to be closed. The time interval and the patient name are available for both types of treatment, while **Shift** and **Room** are characteristics of hemodialysis treatments only because they have to be performed at the clinic.

After pressing the **Close treatments** button, the procedure to close the treatments is started. An animation displays the state of advancement of the operation.



At the end of the procedure, any errors that may have made closure impossible are displayed:



Treatments not closed will remain selected so that they are easy to identify for correction. The **Show details** button opens the treatment in a window so that the data can be checked.

If there are no errors, a message informs the user that the operation has been completed.



During treatment closure, the user can continue to work on sections that belong to menus other than the clinic menus. At the end of the closure operation, the treatment closure page is automatically opened so that it is possible to verify if there have been any faults.

A message blocks the user from accessing other sections of the clinic menu during bulk closure.



Treatment closure from the clinic menu performs all operations required for individual closure of the patient treatments, like the PDF export of the treatment (if configured) or the operations defined by any plug-ins installed.

11.10 MANAGING PATIENT GROUPS

The same interface and the same functions found in Query Builder can be used to generate groups of patients.

The patient groups generated can be found (together with the default groups):

In the Patient section at the top of the list of patients. This allows the entire list to be filtered in accordance with the settings of the query;

As the recipients of a message sent from the user's Inbox section;

Patient groups also appear in the report section. In fact, for some reports, multiple printouts for several patients or groups of patients are possible.

To access this section, simply select "Patient Groups" from the Nephrology Clinic menu.

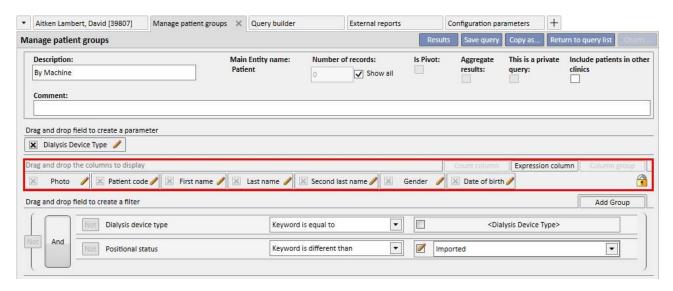
From here it is easy for the user to find his way around the groups of patients already created and to create new ones.

11.10.1 CREATING A NEW PATIENT GROUP

To generate a new patient group, simply click the "New" button. Therapy Support Suite will show the user the same generation interface as for a query, but with some sections and options disabled:

- Charts: there would be no point in creating charts for patient groups.
- This is a private query: patient groups cannot be defined as private.
- "Output values" section: the fields for display are reset and cannot be modified.

Otherwise, the method for creating, saving, publishing (read only) and cancelling queries for patient groups is the same as described in the Query Builder sections.



Note: after a patient group has been published, the user must be enabled to use it via User Management.

Note: If a patient group contains more than 5000 patients and is published, it will never be sent to TMON.

11.11 MANAGING HD SURVEY FOR ALL TREATMENT QUERIES

The "All treatment query management" section allows the Query Builder interface and functions to be used to apply the first filter to a patient's treatments within the HD Survey analysis.

To generate a new query for all treatments simply click the "New" button. Therapy Support Suite shows the user the same query generation interface, but the aggregation of results and private queries are disabled.

Otherwise, the method for creating, saving, publishing (read only) and cancelling the query is the same as described in the Query Builder sections.

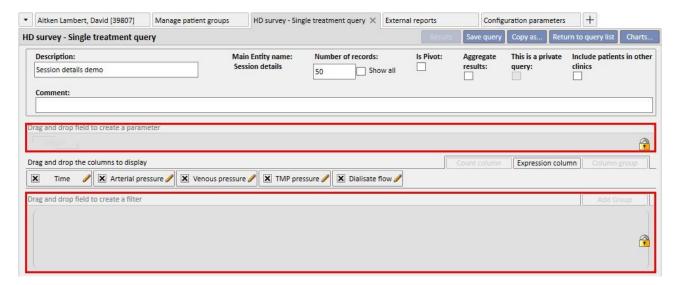
11.12 MANAGING HD SURVEYS FOR SINGLE TREATMENT QUERIES

In the "Single treatment query management" section, the user can use the query builder interface and functions to set the list of values that define the "session details" of interest. These values can then be consulted by choosing a single treatment in the list of the patient's treatments filtered previously with the first filter.

To generate a single treatment query, simply click the "New" button. Therapy Support Suite shows the user the same query generation interface, but the user is only able to modify the values of the "query properties" section (except the private query flag) and the list of output values to be displayed.

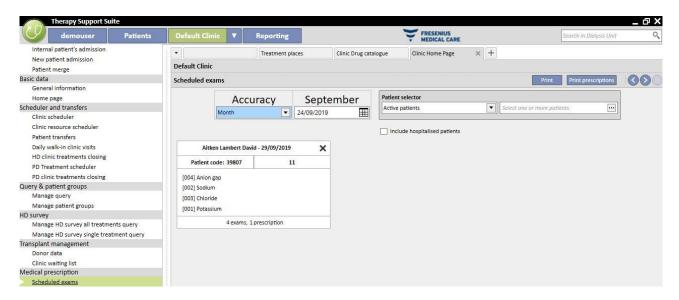
These values can only be selected from the "Session details" entity; in fact, not even the queried entity from which the data was drawn can be changed.

Otherwise, the method for creating, saving, publishing (read only) and cancelling the query is the same as described in the Query Builder sections.



11.13 SCHEDULING TESTS

In this section, the clinic's laboratory test schedule can be displayed. The tests are grouped by patient and date.



The user can filter the laboratory tests by:

- Week
- Month
- Start date / End date
- The tests can also by filtered using the "Patient Selector".
- The user can choose to display or not display the tests of hospitalized patients using the flag:



The group of tests that are to be printed can be chosen. Press the button to exclude the group of tests from the printout:

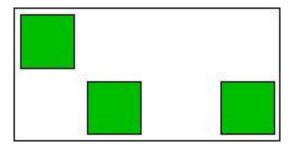
- Press the button to include the group of tests in the printout again.
- If the clinic has activated a plug-in for the printout of medical prescriptions, the displayed.
 Print prescriptions

11.14 PATIENT MERGE

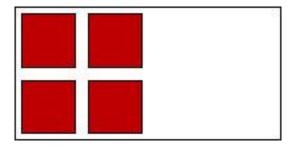
Patient merge is used to combine the data of two patients to form a single patient. The patient merged into another patient is called the "Source Patient", and the patient who receives the information the "Destination Patient".

Make sure that no data are overwritten during the merge process. All information already entered for the destination patient will not be overwritten by the source patient information.

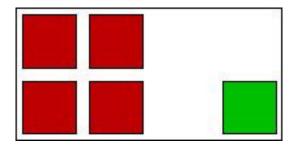
For example: Source Patient before the merge:



Destination Patient before the merge:



Destination Patient after the merge:



For example, if the source patient has a certain drug prescribed as home therapy and the destination patient has the same drug prescribed (always as home therapy), information about the destination patient's home therapy should not be overwritten.

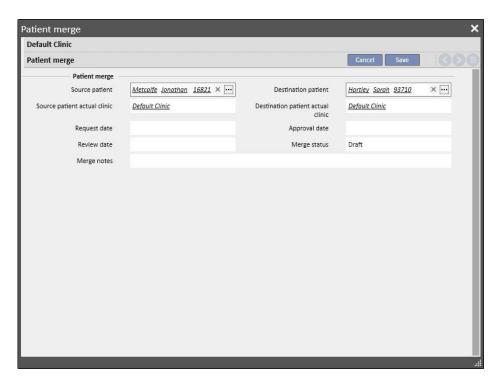
The user is responsible for ensuring that the merge has been done correctly for every section where the merged data are duplicated (e.g. Treatment prescription).

11.14.1 MERGE PREREQUISITES

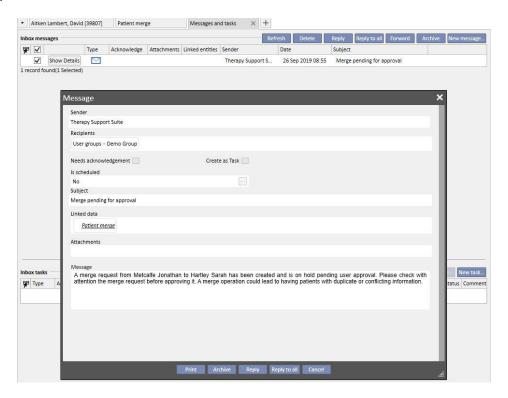
A new merge operation can be defined from the Therapy Support Suite user interface for patients with Active status only. All possible Merge cases (one or more non-existent patients, even with different statuses) are handled by the TSS.

11.14.2 STARTING THE MERGE

To create a new Merge, the user presses the "New" button, then selects two active patients to be merged, and then save.



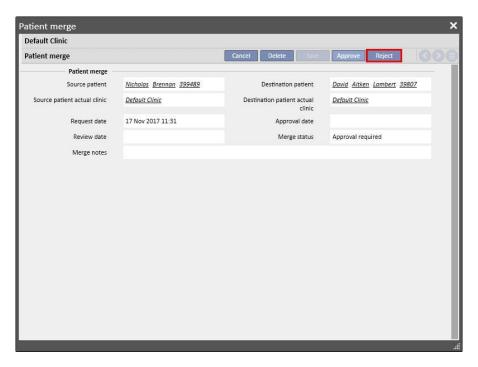
Simultaneously, a message (Inbox) informs all users defined in User Management are notified that a merge process has been requested.



The full list of requested merges is available in the "Patient merge" section of the Dialysis clinic menu. Users can "Approve" or "Reject" every Merge request in this overview.

11.14.2.1 REJECTING THE MERGE PROCESS

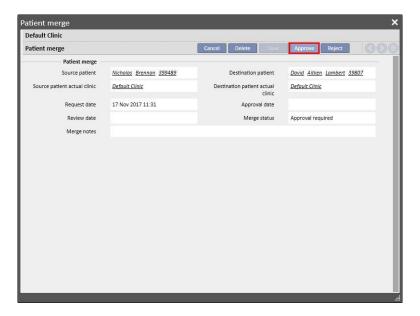
To refuse a merge, select the merge created by clicking on the Edit button. The following page opens:



If the "Reject" button in the "Patient merge" section is pressed, the merge process will not start. The source and the destination patients will not be modified. All that will be left is a row in the "Merge patient" section with "Rejected" status.

11.14.2.2 ACCEPTING THE MERGE PROCESS

To refuse a merge, select the merge created by clicking on the Edit button. The following page opens:



Press the "Approve" button in the "Patient merge" section to start the merge process immediately. For a few moments the status of the merge will be "In execution" (Therapy Support Suite will perform the merge by means of a batch command), and once it has been completed its status becomes "Review requested".

A new message will be sent to all users defined in User Management to notify them that the merge process has been completed, with all the details of the main sections modified. The main sections in the message are:

- Treatment prescription;
- Medical prescription;
- Treatment scheduling;
- Comorbidities;
- Allergies;
- Laboratory data;
- Clinical case.

The user has to review the destination patient data. The two patients involved in the Merge process are marked with an icon in the top menu bar.



11.14.3 MERGE DETAILS

Two scenarios are possible during a merge:

- Only administrative and medical data were merged (because no other information was entered for one of the two patients);
- Some sensitive information was merged (not only administrative and medical data)

11.14.3.1 ONLY ADMINISTRATIVE AND MEDICAL DATA WERE MERGED

If the merge involved only administrative and medical data, the merge can be considered "complete", and the user does not need to complete the merge.

11.14.3.2 NOT ONLY ADMINISTRATIVE AND MEDICAL DATA WERE MERGED

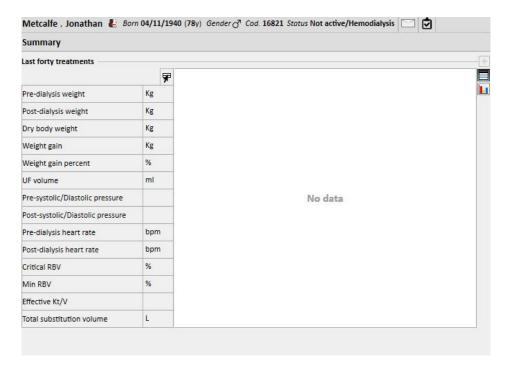
In this case all data were merged from the source to the destination patient. The merge cannot be considered "complete", until the user has **reviewed** all the merged data.



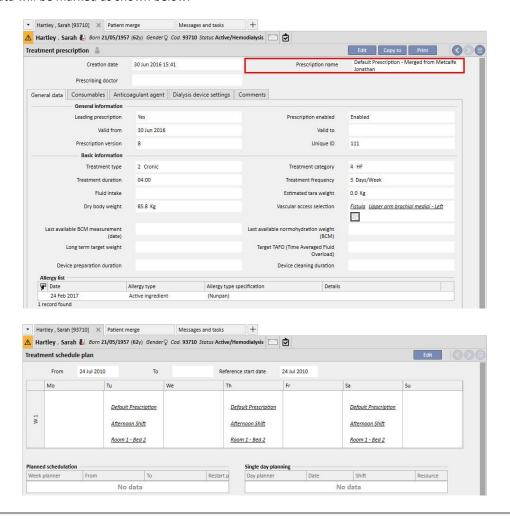
Note

In this state, it is not possible to create treatments with TMON or to use the Card Reader for either patient.

In the Source patient only the "Administrative" and "Medical data" will be visible; the other sections have been emptied.



In the destination patient all the merged data will be visible, and the new "Treatment prescription" and "Treatment schedule" data will be marked as shown below.

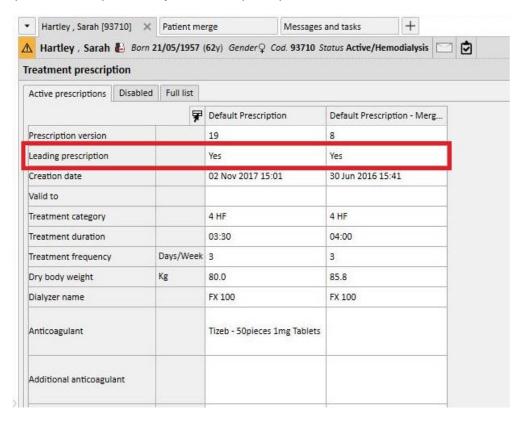


11.14.3.3 REVIEWING THE MERGE

As already mentioned, sometimes the merge has to be reviewed before it can become "Complete". This is a very important section. The critical sections are shown below. Some of them can stop completion of the merge until all conflicts have been resolved.

Blocking sections:

Treatment prescription: if the source and destination patients both have a main prescription, at this point the destination patient will have 2 main prescriptions, and this is not correct. The user has to select one of these prescriptions. If there are other merged prescriptions, the user must verify them. The merge cannot be completed until the patient has just one main prescription.



Not blocking sections:

- Vascular access: There may be two identical vascular accesses with different creation dates. The user must check this information.
- Treatment schedule: If the source and destination patients both have treatment schedules, now after the merge, the destination patient will have the entire treatment schedule. This is not correct because the two patients could have two different schedules. The user should review the schedules.
- Drug therapy: if both the source patient and the destination patients have drug therapies, now, after the merge, the destination patient will have the entire drug therapy. This is not correct and it is also dangerous for the destination patient. The user should review the drug therapy.
- Allergies: if for any reason the two patients have different allergies, the user should review the allergy section, because it could be dangerous for the destination patient.

11.14.4 COMPLETING THE MERGE

After the Data Review, the user can complete the merge. This is done by pressing the "Complete" button in the "Patient merge" section. If there are two main prescriptions, when the user clicks the Complete button the system will stop the merge.

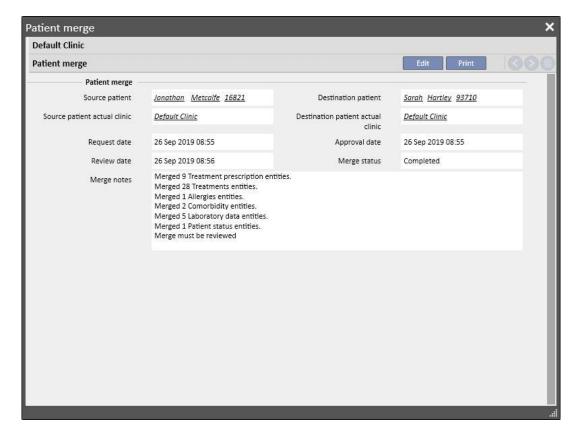
The source patient will become "Not active" and the icon in the top bar will show the patient's merged status.



The destination patient will remain "Active" and there will be no icon to indicate that the patient was involved in a merge process.

For the destination patient, it is now possible to create treatments with TMON and to use the Card Reader.

The merge is shown as "Completed".



11.14.5 PATIENT STATUS

The master patient's status on completion of the merge process is set in accordance with the basic rule that the "strongest" status wins.

Here are some examples:

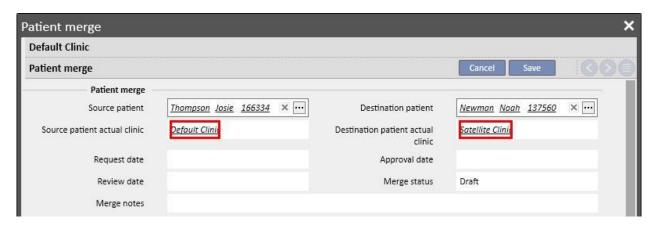
- Before merge: master patient active, slave patient inactive -> After merge: master patient active
- Before merge: master patient inactive, slave patient active -> After merge: master patient active
- Before merge: master patient inactive, slave patient imported -> After merge: master patient imported

The table below contains all the rules for status assignment after merges:

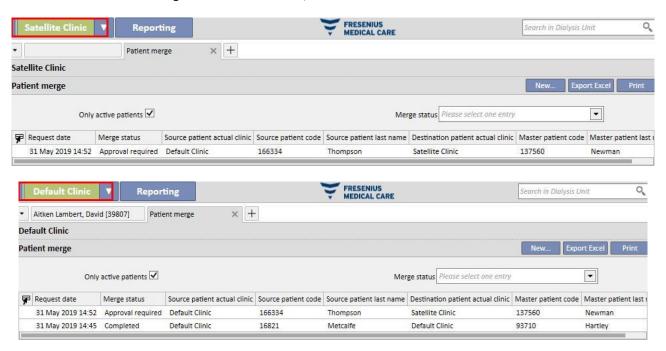
	MASTER PATIENT STATUS			
MERGED PATIENT STATUS				
	Active	Imported	Not Active	In transit
Active	Active	Active	Active	Active
Imported	Active	Imported	Not Active	In transit
Not Active	Active	Not Active	Not Active	In transit
In transit	Active	In transit	In transit	In transit

11.14.6 MULTI-CLINIC MERGES

Patients belonging to different clinics can be merged. In fact, when patients are selected those belonging to other clinics will also appear.



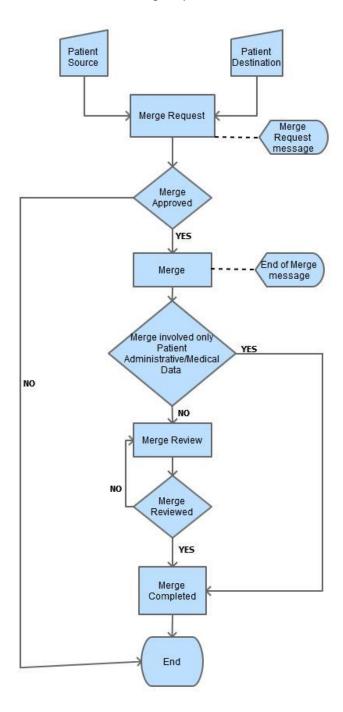
Once two patients belonging to different clinics have been selected and the merge process has been started, it can be viewed from the "Patient merge" menu of both clinics, as the screenshots below show



Once the merge process has started, the procedure is the same as for merges in the same clinic: the only difference is that it will appear in the "Patient merge" menu of both clinics even after completion. The status of the patients involved in the merge will be modified using the same rules as for the merge within a single clinic.

11.14.7 FLOW CHART

A flow chart is provided below to aid in understanding the process.



12 REPORTING

12.1 REPORTS

In this section the user can view and print all the reports installed in the clinic. There are two types of report:

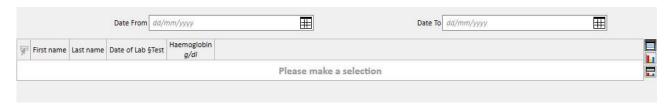
External reports: reports customised inside the clinic.

Custom reports: reports created through Query Builder.

When you print a Custom Report, the "Print Options" window appears, where it can be indicated if the report should contain information about the date and time of printing (at the bottom of the page).

External reports Active Drugs Active Patients by Machine Ambulatorial Visit Database Health Status Dialysis Protocol Blank Dynamic Printout Report Information about Dialysis Medical Orders Per Shift Medication Preparation Report Monthly Report Patient Anticoagulant Patient Treatment Status Patient Treatment Status by Month Patient-Actual Lab Test Regular Medication Treatment Drug at home Treatment Drug for HD Treatment Treatment Preparation Report Treatment Prescription Report Treatment Protocol Custom reports Session details OCM data Test Hb Test Lab Data

To run a report, simply click on its name on the side bar. Some reports open automatically, others require that further parameters be inserted (e.g. treatment date in a dialysis treatment report):



The *Pseudonymise report* option allows a user to extract a report containing pseudonymised sensitive patient data. This option may or may not be available depending on the clinic's configuration parameters (see the specific section in the Service Manual).

After entering the required parameters, press the exported in a variety of formats (Word, Excel, PDF).



Warning

Risk for the patient as a result of an incorrect prescription being shown

Scheduling reports may have unrecognised recurrencies when recalculation is underway.

12.2 DYNAMIC PRINTOUT REPORT

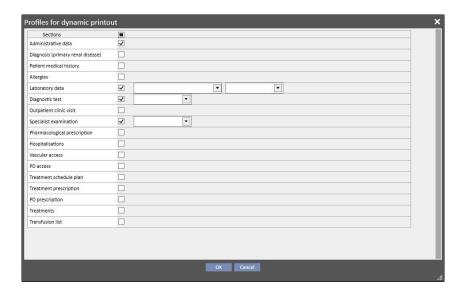
Dynamic Printout Reports are special reports where it is possible to specify which sections to include inside the report itself via the creation of profiles (as described in detail in point 4.2.6 of the service manual).

Profiles are therefore presets which allow the user to specify which subset of information will be printed in the report. For example the user can create one profile to just print personal and medical history data and another which will print a series of information related to the dialysis process (prescription, treatments performed, treatment schedule plan, etc.)

When a Dynamic Printout report is selected, the user is requested to select a patient and a profile (in this case two profiles have been created in the Master Data section, one containing only the patient's administrative data and the other containing a set of information related to the patient's treatment and the relative scheduling)



Once a profile has been selected, clicking Update opens profile parameter compilation screen. This window shows all the sections which are available for the report, with only those found in the profile chosen by the user selected. In this phase it is possible to deselect certain sections or add others.



Extraction filters can be specified for each enabled section (if it supports them). The filters vary depending on the section, for example, allowing the user to extract data in a specific time frame, active\non-active data, or as in the case of laboratory tests, to specify which tests should be included in the report.

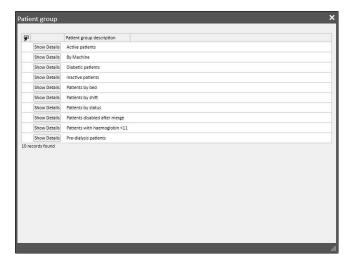
Clicking OK prints the report, with the selected sections filled with data as specified by the user.

As for all reports, dynamic printout reports must be installed via *.tcf before they can be used.

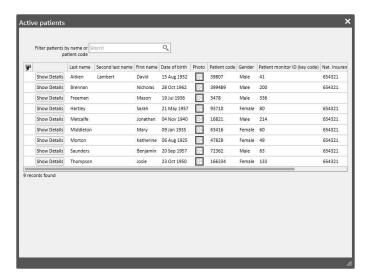
12.3 PRINTING PRESCRIPTIONS FOR GROUPS OF PATIENTS

In the "Medical prescription for patient groups" section, which can be accessed from the clinic menu, it is possible to print the Italian NHS prescription for the laboratory tests of a patient group.

After creating a new prescription the user can enter the date of the prescription and the title and select the laboratory tests to be included in the prescription. To conclude, it is possible to specify a patient group for whom the prescription has to be printed, as shown in the screenshot below.



Once all parameters have been entered, the user clicks "Save and Print" to access the prescription printout interface, where he can select the patients (from the group selected previously) for whom he wants to print the prescription.



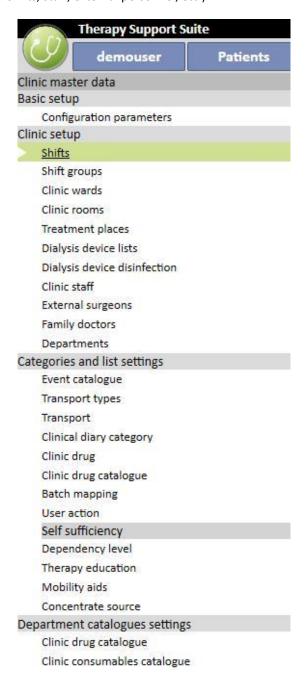
After selecting the patients, the user clicks "OK" to print one or more prescriptions depending on the number of Tests \ Patients selected.

13 CLINIC MASTER DATA

This section is only visible to users with the "Clinic Manager" role activated. When a user enables the "Clinic Manager" role, the "Master data" section appears in the upper menu bar:



Clicking the "Configuration Parameters" button displays a menu in the left of the screen enabling configuration of the clinic's specific parameters (e.g. Shifts, staff, external personnel, etc.):



13.1 BASIC CONFIGURATION

13.1.1 CONFIGURATION PARAMETERS

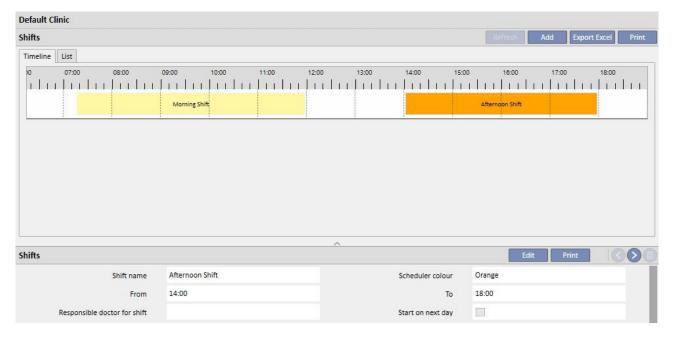
This section is used only for Clinic master data. It should only be used by IT technical support staff. Please refer to the Therapy Support Suite Service Manual for further information.

13.2 CLINIC MASTER DATA

13.2.1 SHIFTS

In this section, the Clinic Manager can specify the clinic shifts (e.g. morning - afternoon - night), where the start and end times, the colour, the head physician and the start of the next day can be configured. These are then displayed in the clinic resource scheduler.

When this section is opened, a timeline that shows the current shift configuration will be displayed. It will then be possible to click on the various shifts to change them, delete them, or add new ones.



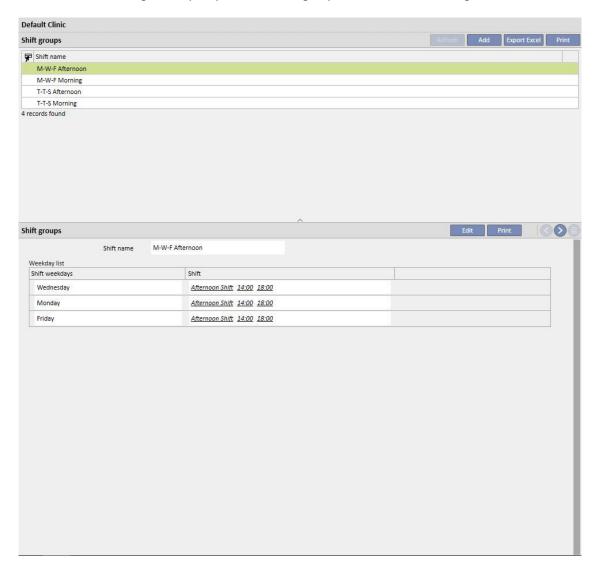
If the end time is less than the start time, it will be considered as the next day.

If the Start-next-day flag is active, the start time will be considered to be the next day following the day the shift is being used. For example, if a shift is used with the control field activated on Tuesday, its start time will be considered to be on Wednesday.

In this last case, if a treatment is created on Wednesday, the prescription selected will be for Wednesday in any case.

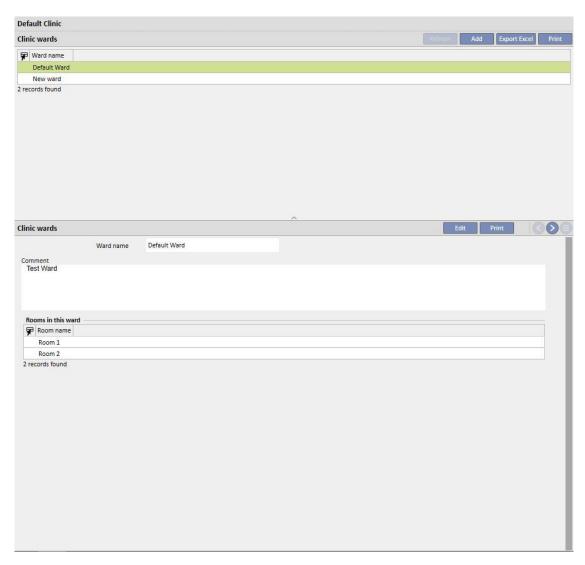
13.2.2 SHIFT GROUPS

In this section the Clinic Manager can specify the clinic shift groups that will be used during treatments.



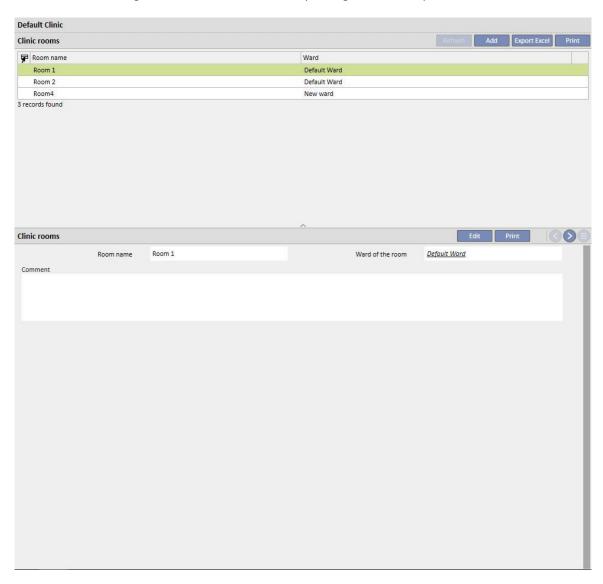
13.2.3 CLINIC WARDS

This section allows the user to manage different wards. The system shows all rooms linked to the ward.



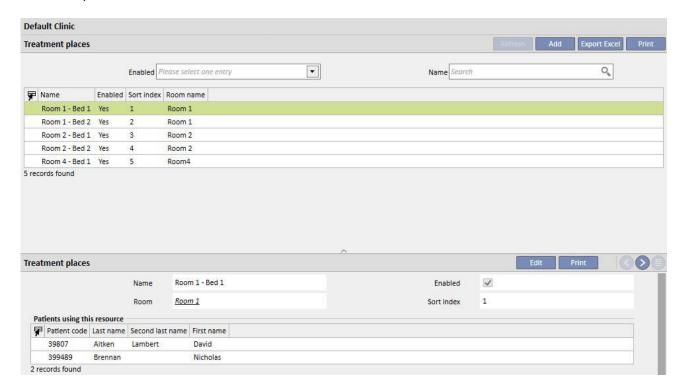
13.2.4 CLINIC ROOMS

This section is used to manage the clinic's different rooms by linking a room to a specific ward.



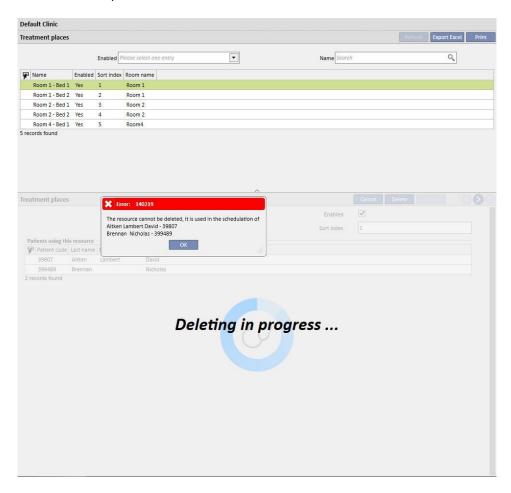
13.2.5 TREATMENT PLACES

In this section the Clinic Manager will enter the beds for every single room in the clinic. Every bed will have a name and a number for sorting. By selecting a resource, if it is occupied, which patients are using it can be seen immediately in the "HD Treatment Schedule Plan" section.



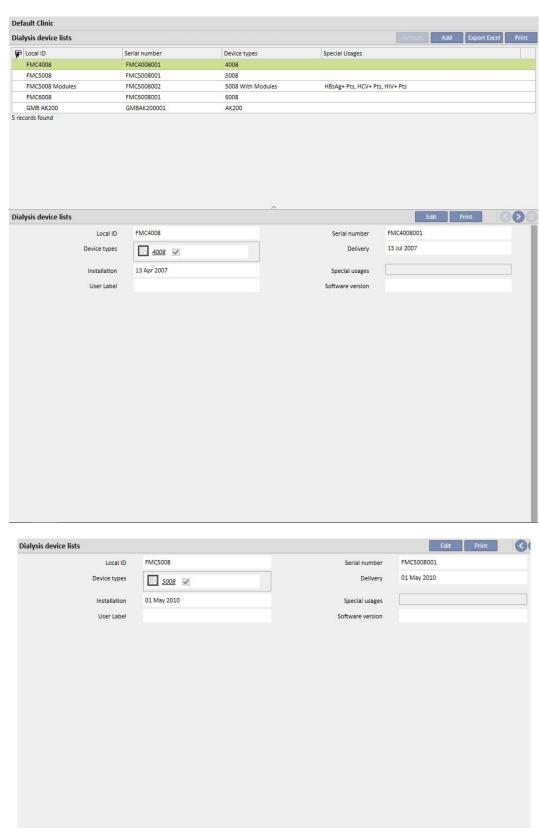
Resources can only be disabled if they are not being used in the patient schedule (HD Treatment Schedule Plan) and are not visible in the clinic scheduler associated with a patient.

Resources can only be deleted if they have never been used (even for old treatments) and if they are not currently scheduled. It is possible that resources that do not currently show any associated patients cannot be deleted because they may have been used in the past to create treatments.



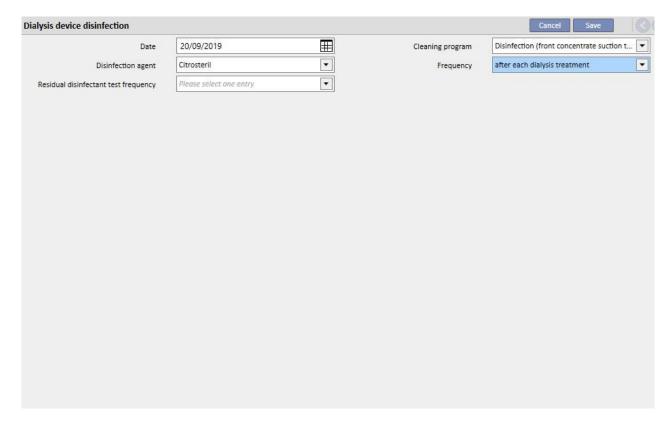
13.2.6 DIALYSIS DEVICE LIST

The "Clinic Manager" can manage all the dialysis devices installed in the clinic in this section.



13.2.7 DIALYSIS DEVICE DISINFECTION

In this section the Clinic Manager can specify which clinic disinfection program is associated with the dialysis devices.

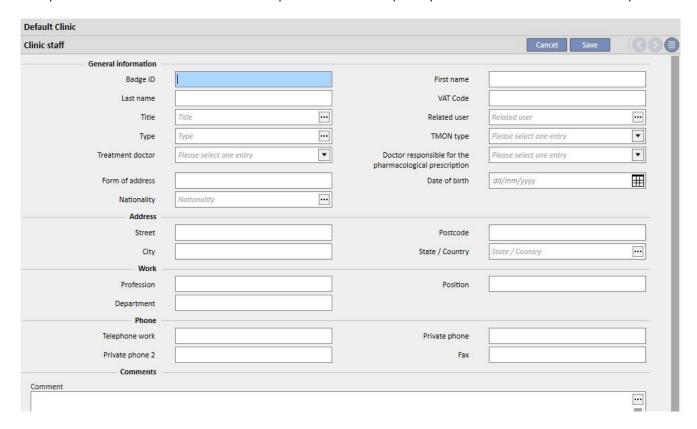


13.2.8 CLINIC STAFF

In this section the Clinic Manager can enter all information related to the clinic staff. The Clinic Manager can define the type of information for each clinic staff member. The following three fields are particularly important:

- Therapy Monitor Type: The "Clinic Manager" can specify the Therapy Monitor category to which each staff member belongs.
- Treatment doctor: The Clinic Manager can specify whether the clinic staff member is the doctor in charge of the treatment.
- **Doctor responsible for the pharmacological prescription**: The Clinic Manager can specify whether the clinic staff member is the doctor responsible for prescribing the pharmacological therapy.

The "print" field contains the text which will be printed in the Italian prescription form such as the doctor's stamp.





Note

The Clinic Staff section is not linked to the TDMS User Management module; it is only used in Therapy Support Suite to link patient information to the members of the clinic's staff.

13.2.9 EXTERNAL SURGEONS

In this section the Clinic Manager can enter the list of external specialist surgeons who are not clinic employees but who are present as private practitioners. The Clinic Manager can include a list of contact details (name, address, office address, telephone and a general comment).

13.2.10 FAMILY DOCTORS

In this section the Clinic Manager can insert a list of all the patients' primary care General Practitioners.

13.2.11 DEPARTMENTS

In this section the Clinic Manager can insert a list of the medical departments in the hospital.

13.3 CATEGORIES AND LIST SETTINGS

13.3.1 EVENT CATALOGUE

In this section the Clinic Manager can customise the list of events that can occur during a treatment session, which the person in charge of the treatment can then send from the data eXchange panel (dXp).

This information is transferred to Therapy Monitor before the treatment session, to allow it to be accessed from the dialysis device dXp panel. After the treatment session this information is returned to Therapy Monitor and then back to Therapy Support Suite, and can be visualised in the dXp (data eXchange panel) tab of the Treatment data section in the Patients menu.



13.3.2 TRANSPORT CATEGORIES

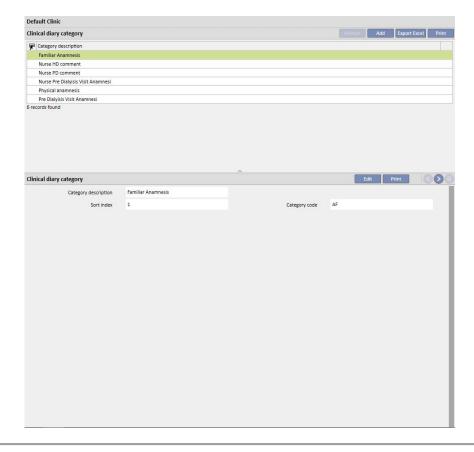
In this section the Clinic Manager can specify the transport types (e.g. taxi, ambulance). These categories will appear in the **Transport** section, **Type** field.

13.3.3 TRANSPORT

In this section the Clinic Manager can specify the means of transport used by the clinic.

13.3.4 CLINICAL DIARY CATEGORY

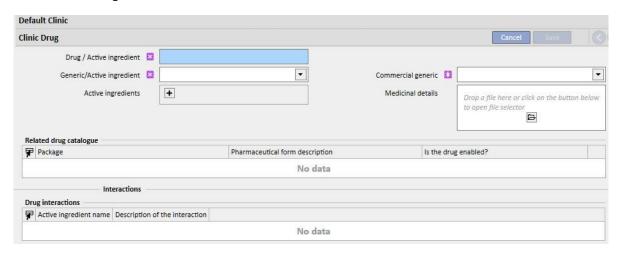
In this section the Clinic Manager can define the Clinical Diary categories. These categories will be seen by the doctor when he enters information in the Patient's Clinical Diary.



13.3.5 CLINIC DRUG

In this section the Clinic Manager can manually enter the drugs used without using the official drug database. For example, drugs made directly at the hospital or at an associated laboratory can be entered. The following information will be requested:

- drug/active ingredient: compulsory field, representing the drug's name;
- two flags, also compulsory, to indicate whether a drug is not generic or an active ingredient;
- active ingredient: this field can be left empty, but once it is selected one or more active ingredients must be entered;
- drug details: optional field where the user can insert an attachment to provide further explanatory details about the drug.



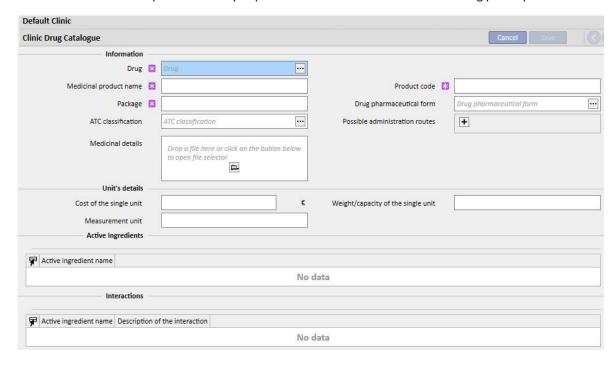
The "Drug catalogue" and "Interactions" sections are compiled automatically when the drug is saved. The first will show all the drug catalogues associated with the drug just entered. The Interactions section will show all the interactions between the selected active ingredient and the other existing active ingredients.

13.3.6 CLINIC DRUG CATALOGUE

In this section the Clinic Manager can manually specify the of drug catalogue used. This section is closely related to the "Clinic drugs" section, since a drug catalogue is only associated to a single clinic drug. Instead, a clinic drug can be associated to many drug catalogues. The following information will be requested:

- Drug: compulsory field where the user must select a drug from the list of drugs;
- Drug name: compulsory field where the user must enter the name of the drug again;
- Package: compulsory field where the user must specify the package details;
- Pharmaceutical form: optional field where the user can specify the drug's pharmaceutical form;
- ATC classification: voluntary field, but important as it is used to check for allergies and to filter anticoagulants in the prescription section;
- Possible administration routes: optional field, where the user can enter the drug's routes of administration;
- Drug details: optional field where the user can use an attachment to further describe the drug;
- Single unit cost: optional field where the user can enter the cost of a single unit;

- Single unit weight/capacity: optional but important field because it is used in the drug prescription.
- Measurement unit: optional but very important field because it is used in the drug prescription.



The "Active ingredient" and "Interactions" sections are compiled automatically when the drug catalogue is saved. These show the list of active ingredients associated with each drug (entered in the Clinic Drug section) and the list of interactions among the active ingredients (selected in the Clinic Drug section) with other active ingredients.

13.3.7 BATCH MAPPING

In this section, the Clinic Manager can map the consumables and assign each a code and an expiry date.

13.3.8 USER ACTIONS

In this section the Clinic Manager can map all the user actions, which will be displayed and can be selected on the Therapy Monitor (if connected).

13.3.9 DEPENDENCY LEVEL

In this section, the Clinic Manager can enter the patient's dependency level with respect to the nursing care required during treatment.

13.3.10 THERAPY EDUCATION

In this section the Clinic Manager can list the types of instruction the nurse can provide so the patient can become independent during a treatment.

13.3.11 MOBILITY AIDS

In this section the Clinic Manager can enter the list of aids the patient might request to improve mobility.

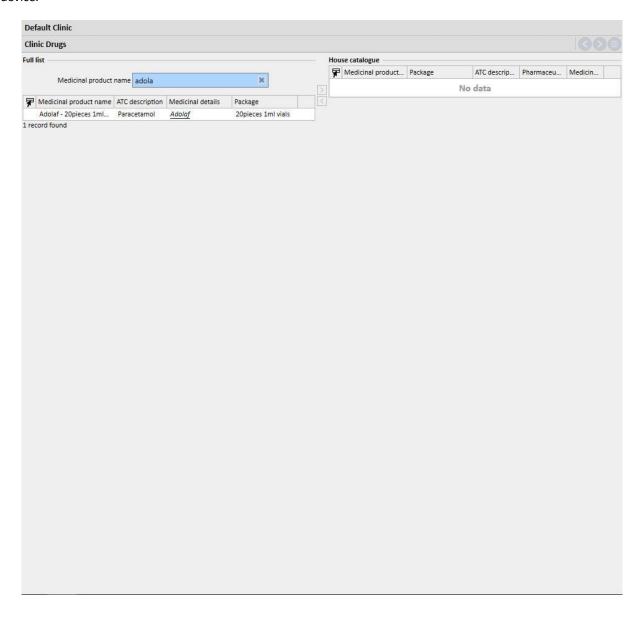
13.4 DEPARTMENT CATALOGUES SETTINGS

13.4.1 CLINIC DRUG CATALOGUE

In this section the Clinic Manager can add drugs to the Clinic Drug Catalogue. The Clinic Drug Catalogue is a subset of the complete drug catalogue. It allows rapid drug searches to be performed in Therapy Support Suite (e.g., in the HD prescriptions section), filtering the list of drugs in the Clinic Catalogue.

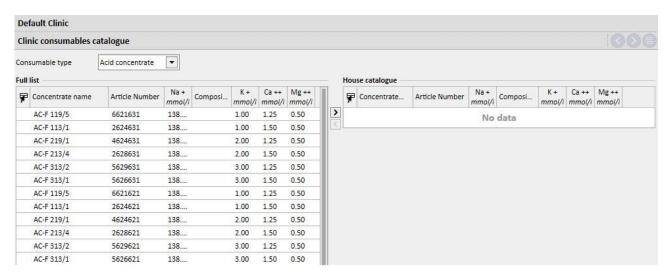
Starting from a drug in the Clinic Drug Catalogue, a drug can be defined as well as one or more recommended doses. The doses selected can be quickly applied in Therapy Monitor.

All drugs saved in the Clinic Catalogue will be available in Therapy Monitor and on the dXp panel on the 5008 CorDiax device.



13.4.2 CLINIC CONSUMABLES CATALOGUE

In this section the Clinic Manager can add consumables to the Clinic Catalogue. When clinic staff enter a consumable in another section of Therapy Support Suite (e.g. in HD prescriptions) they can filter the list of materials by those in the Clinic Catalogue. The contents of this field are transferred to Therapy Monitor.



14 SECURITY MANAGEMENT

14.1 LOGGING

The Logging section has been created to store the list of all events that each user triggers using the application.

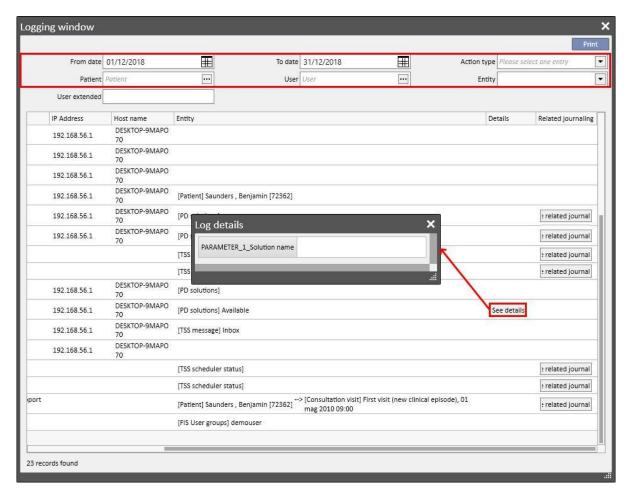
To see the **Log** information it is necessary to enable the *Security Manager* role for the user. When the role is active a **Logging** button appears on the top toolbar.

Clicking on the button opens a list of all actions and events recorded in the application.

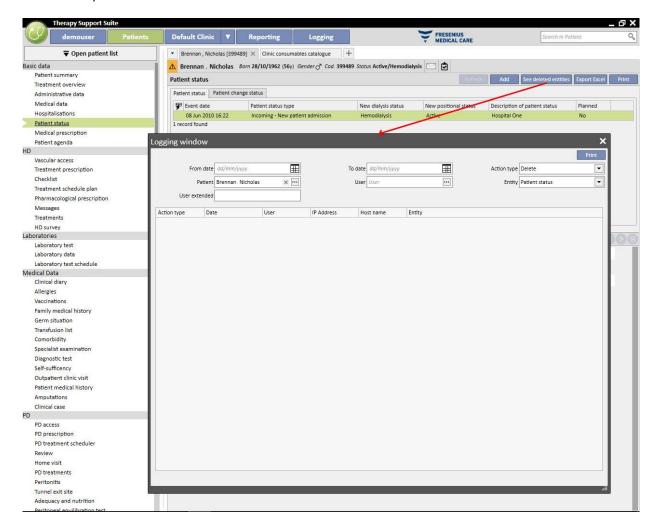
Each row of the list contains information about:

- Action Type (Read, Update, Create, Switch to Edit, etc.).
- Date of action.
- User.
- Entity involved.

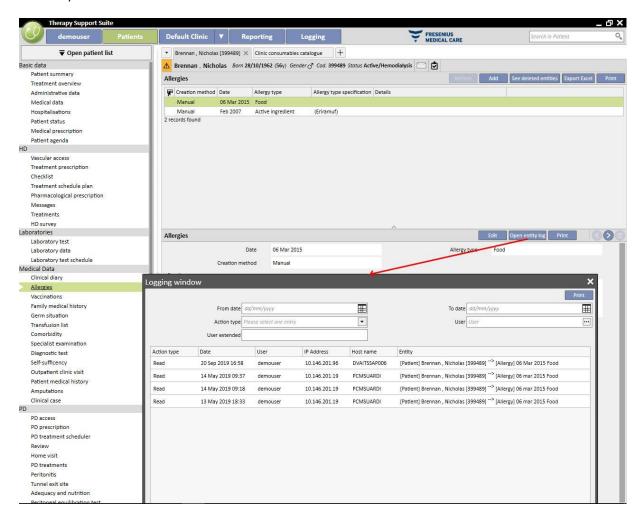
In case of exceptions a button shows the exception details (number of exceptions) to the *Security Manager* user. The complete list can be filtered using the filter fields at the top of the list.



With the *Security Manager* role activated, a new button appears on entity views to show the rows which have been removed and by which user.



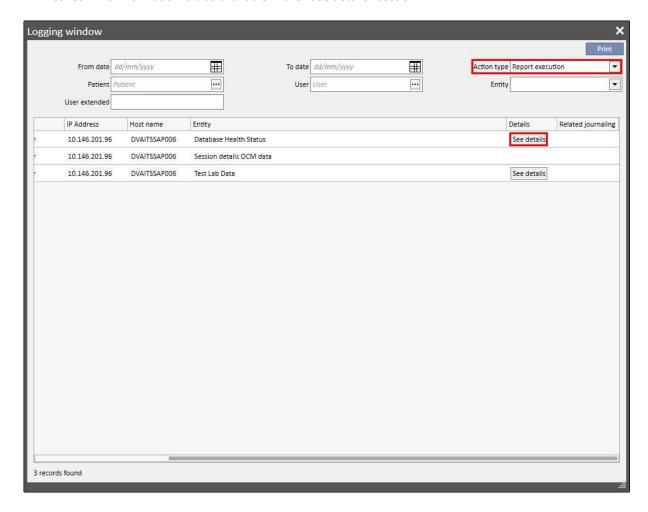
With the *Security Manager* role activated, a new button appears on the entity detail and will show the **Log** list related to that entity.



14.1.1 REPORT LOGGING

Apart from other different activities, the use made by the user of the reports is traced in the Logging section. In particular it is possible to generate evidence logs, filtering by Action Type equal to Print or Execution of reports:

- When a report is executed
- By which user was the report executed
- On which patient(s)
- If the user has printed it out
- How the user has valued the input parameters (if reports provide for them). The input parameters and their evaluation are shown in the "View details" section, which can be consulted by pressing the button of the same name in the tracking records relating to the execution of the reports.
- In the "See details" section there is also information on whether or not the pseudonymisation of sensitive patient data has been enabled.
- In the case of a data export action type, the system also keeps track of the folder where the exported file was saved. This information is also available in the "See details" section.



14.2 JOURNALING

To see the Journaling information it is necessary to enable the Security Manager role for the user.

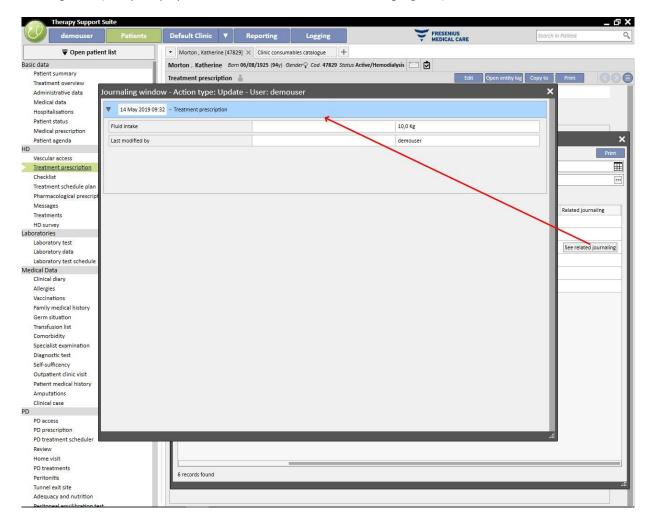
The Journaling enables the Security Manager user to see the list of modifications done by each user on entities.

To see Journaling information it is necessary to click on "See Related Journaling" in the Logging view:

Journaling information is grouped by modified entity;

It is possible to compare all modified fields except for : Scheduling Rules (always displayed in the list but with no differences highlighted).

Scheduling Rules (always displayed in the list but with no differences highlighted).

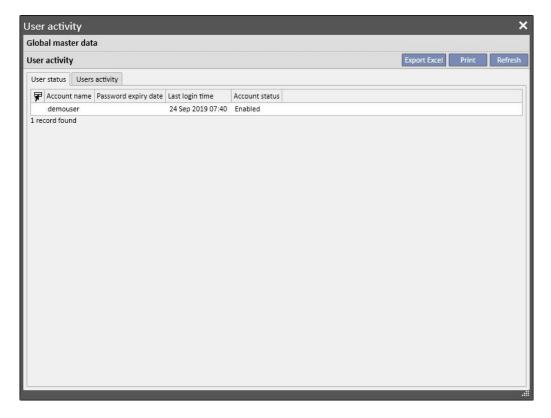


15 USER ACTIVITY

This window includes the data extracted from FIS which present information related to all the users created for the Therapy Support Suite. Clicking on the "Update" button updates the data displayed on the screen. The first screen shows the status of the users and information related to the expiry dates of passwords and the most recent accesses, whereby the second screen is used to monitor the access to Therapy Support Suite and shows information about when and how the users logged on to the system.

15.1 USER STATUS

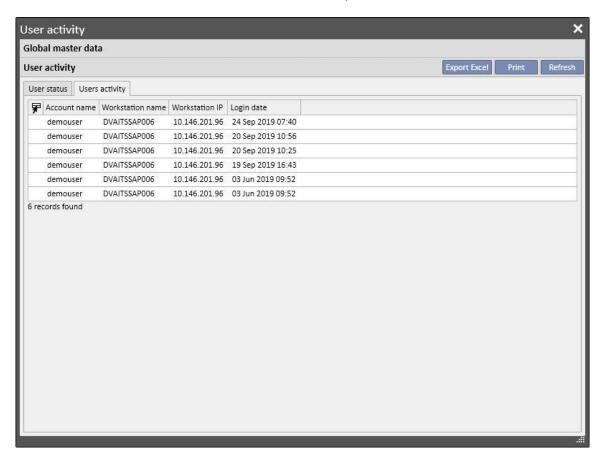
Below is the first screen, and the main items are described below:



- Account name: the user name of the account;
- Expiry date of password: if the option is defined in FIS it is displayed on the day it is obligatory to change the password;
- Last login time: the day and time of the user's last successful access;
- Account status: the status of the account which can be one of the following;
 - Enabled: the user can login
 - Manually disabled: the account has been disabled by FIS;
 - Disabled due to inactivity: the account has been automatically disabled because too much time has passed since the last access;
 - Disabled due to failed login attempts: the account has been disabled because the number of permissible failed logins has been exceeded.

15.2 USER ACTIVITY

This screen shows the access events which have been carried out by all users:



- Account name: the user name of the account;
- Workstation name: name of the host where the user logged in;
- IP of the work-station: IP address of the host where the user logged in;
- Login date: date of access displayed in the line.

16 OPTIONAL MODULE: MULTI-CLINIC MANAGEMENT

16.1 OWNER UNIT MANAGEMENT MODULE

With Therapy Support Suite multiple clinics can be managed, each one with its own patients and specific settings. This chapter describes how to manage and create Clinics.

Enabling the "Global Manager" role you can manage all the clinics managed by Therapy Support Suite using Master Data (Global Manager) -> Owner Units menu. Please refer to the Therapy Support Suite Service Manual for further information.

In this section it is possible to create/delete/modify all Therapy Support Suite clinics. For every clinic it is also possible to specify the reference clinic so a complex organisation can be created.

16.2 MULTI-CLINIC FEATURES

Clinics can be configured using the **Master Data** section enabled through the *Clinic Manager* role and enabled through the *Global Manager* role.

These sections are different and must be used for different purposes:

- Master Data (Clinic Manager) this allows the user to configure a specific clinic: all settings in this section will be linked to the clinic to which the user belongs. Using the Master Data menu, lists can be defined, e.g. personnel, events catalogue and so on or a drug or product or user actions can be specified for a specific clinic.
- The Master Data (Global Manager) section contains settings shared among all clinics created inside Therapy Support Suite: this means that these settings are applied to all the clinics. In this section you can specify, for example, the list of dialysis devices, consumables (blood lines, needles, etc.), vascular access positions, and treatment types that you can use later in order to populate specific clinic lists. See the Therapy Support Suite Service Manual for further information.

For example, if in the Master Data (Global Manager) section the dialysis device list is populated with values "AK200", "5008" and "4008", through the Master Data (Clinic Manager) menu it is possible to specify that, for a specific clinic, only "AK200" and "5008" devices are available. To summarise:

Master Data (Global Manager) is used to define the list of all available dialysis devices inside Therapy Support Suite ("AK200", "5008", "4008", "ARTIS");

Master Data (Clinic Manager) is used to specify which of these devices will be available for each clinic. For example:

- "AK200", "4008" for "clinic 1";
- "5008", "ARTIS" for "clinic 2";

17 OPTIONAL MODULE: INTEGRATION SERVICES

17.1 INTERFACING WITH HOSPITAL COMPUTER SYSTEM

This module allows Therapy Support Suite to be interfaced with the **Hospital computer system** and the **analysis lab** for the exchange of updated information about patients (e.g. administrative data, laboratory data, treatment data, etc.).



Warning

Risk for the patient as a result of an incorrect prescription being shown

The user is responsible for verifying the correctness of data imported from the Hospital Computer System interface.



Note

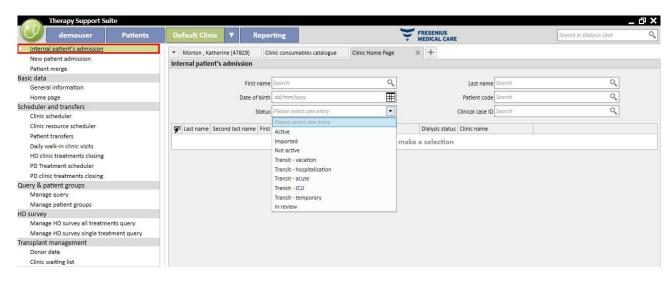
Some Therapy Support Suite fields may become read-only if they have been correctly populated through the information exchange with the Hospital Computer System.

17.2 IMPORTED PATIENT'S ADMISSION

When the **Communication Data Link** module is activated, the user will find a new function in the dialysis clinic section that will permit the patient admission by selecting the patient to be admitted from a list that can be filtered using the Last name, First name, Patient code and patient status. After finding the patient to be admitted, the user simply clicks the patient to start the admission process immediately. In addition, there is a control field that can be configured from Master Data under the "Configuration parameters" item (for more details, section 4.1.1 of the Service Manual), which allows patients to be imported from other clinics.

User can filter the patients by status, the possible statuses are the following:

- Active
- Imported
- Not active
- Transit vacation
- Transit hospitalization
- Transit Acute
- Transit ICU
- Transit temporary
- In review



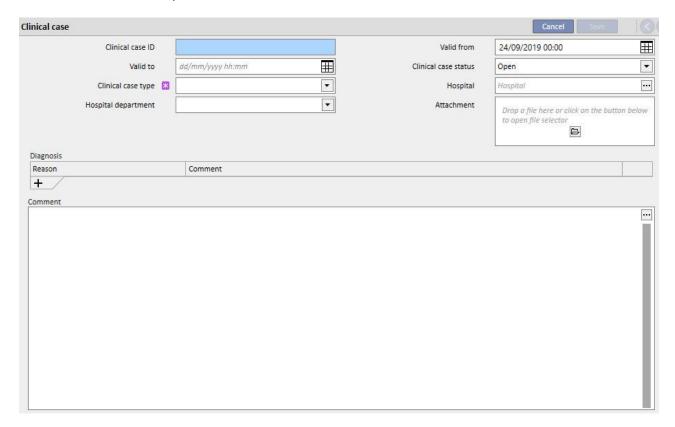
When an inactive patient is imported, a confirmation message will appear. Clicking on Yes, a new popup will appear where the user can select the new admission status of the patient. Once the patient status has been filled in, it will be imported to the desired status. If the patient's clinic is the same as the clinic into which we are making the import, an "Internal Transfer - Patient Reactivation" will be created. Instead, If the patient's clinic is different from the clinic into which we are importing the patient, an "Internal transfer - Patient reactivation from another clinic" will be created.

Instead, when trying to import a patient with an "imported" status, a "New patient admission" popup will appear already filled in with the patient's data, filling in the mandatory fields and saving the patient will be imported.

In all other cases when the patient is already associated to the clinic where we are trying to do the import, a message will appear to inform the user that the patient is already in the list of patients. If the patient is not in the clinic we are using, a message will appear that it is necessary to make a transfer before the patient's data can be managed.

17.3 HOSPITALISATIONS

The patient's hospitalisations can be recorded and edited in this section. The user can select the ID, status, type and period of validity for a clinical case related to the selected patient. Note that hospitalisations will be considered by the internal logic only if they comply with the configurations set in "Configuration Parameters" under "Master Data" (see Service Manual section 4.1.1)



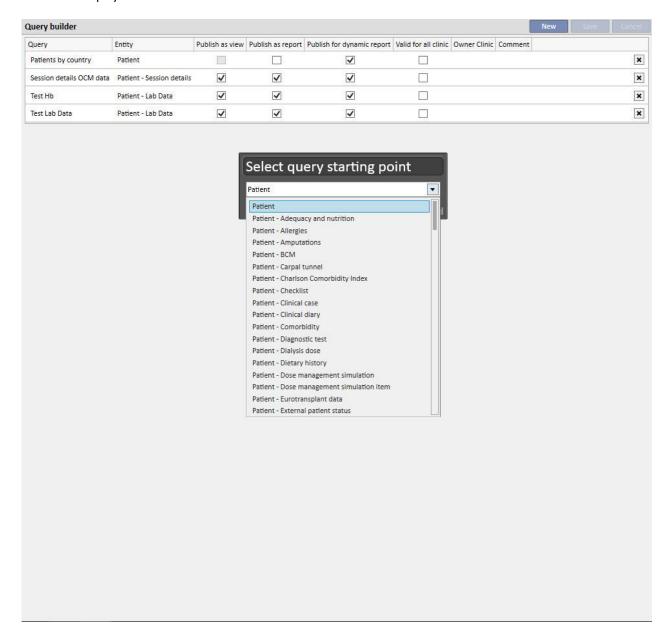
18 OPTIONAL MODULE: ANALYSIS AND REPORTS (QUERY BUILDER)

18.1 QUERY BUILDER

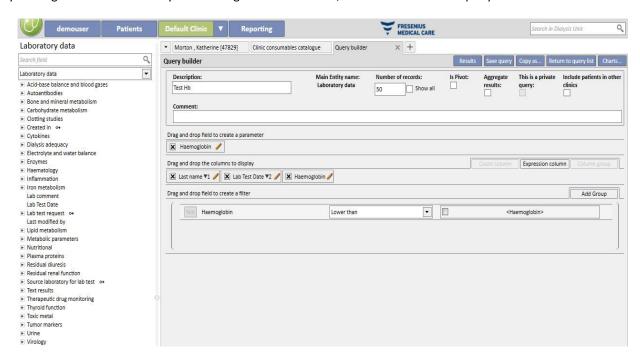
Query Builder is a tool provided by Therapy Support Suite that the user can use to create queries about the data stored in the application. Having the possibility to extract data from the entity, apply filters to them and generate graphics, offers users the possibility to improve the quality of the daily work.

To access Query Builder it is necessary to access the *Clinic* menu and select the *Open* item in the *Query Builder* submenu. The initial view provides a list of queries that have been saved in the past.

From here, it is possible to start creating a new query by clicking on the "New" button. The pop-up that appears permits the user to choose from which entity to select the most important data that the query he or she is creating will have to display.



By clicking on the desired entity and clicking on the OK button, the user accesses the query definition area.



This area consists of five main sections.

18.1.1 LIST OF QUERY FIELDS

The left-hand side of the interface contains a complete list of the Query Builder's query fields. From this list, it is possible to select which fields the query must return and which, for example, should be used as a filter or parameter. The list groups the fields according to the structure of the database. If the user is not able to pinpoint the requested field, he or she can use the search engine that Query Builder provides by typing the description of the field in the first box (*Search field*) at the top of the section in question.

Query Builder offers the possibility to be able to query not only the fields of the entity selected in the past, but also all the fields of the entity related to the Patient and in the same way all the fields of the entity related to the Clinic (this depends on whether the "starting" entity belongs to the Patient menu or to the Clinic menu).

To find fields in different entities than the one selected when the user started to create the query, select the entity that contains the desired field by expanding the list of entities located below the search box.

Laboratory data O, Search field Laboratory data Patient Adequacy and nutrition Allergies Amputations **BCM** Carpal tunnel Charlson Comorbidity Index Checklist Clinical case Clinical diary Comorbidity Diagnostic test Dialysis dose Dietary history Dose management simulation Dose management simulation item Eurotransplant data External patient status Family medical history Fast peritoneal equilibration test Germ situation Home visit Hospitalisations Lab test canceled Laboratory data Laboratory test Laboratory test schedule Medical assessment Medical data Medical data (History) Medical prescription Messages Nurse assessment Nurse visit history Outpatient clinic visit

Apart from the table attributes in the database, Query Builder allows view attributes to be used as searchable fields.

18.1.2 QUERY PROPERTIES

The query definition area is on the right-hand side of the screen. At the top, there is the area for defining the query properties, i.e. the area where the user can specify the following:

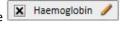
- Query description: The name that will identify the query;
- Comment: A more detailed description of the aim of the query;
- Maximum number of results that will be shown;
- "Is' Pivot" display mode: This is the list of results displayed by column. The desired fields make up the lines. A typical example of this display is the view of the central parts of the patient summary;
- Aggregate results: enables aggregate results with the same value;
- Private query: a query that can only be modified by the user who created it and, if it has been published, only the user who created it can see it in the view of the related section.
- Include patient of other clinics: enabling this flag the results displayed will include patients active in the current clinic and patients that were transferred into the clinic regardless of whether the patient is active or not.
- Pseudonymised data: this flag enables sensitive patient data to be pseudonymised during data extraction.
- Data drawn from other clinics: this flag allows the user to decide whether to extract information from all the dialysis clinics or only from the current one. To display this flag, there must be more than one clinic and that each of these must have enabled the "Enable patient admission from other clinics" field among the parameters in the "Configuration parameters" section of the Master Data (see the specific section in the Service Manual). Queries with this flag highlighted cannot be published as views but can be published as reports.

Description: Patients by country	Main Entity name: Patient	Number of records: 50 Show all	Is Pivot:	Aggregate results:	This is a private query:	Include patients in other clinics
Comment:						
Extract data from other clinics						J

18.1.3 OUTPUT VALUES

The list of fields that the query has to return. It must be defined in the section called "Drag and drop the columns to display". As the title of the section says, to populate the section, simply drag the desired fields from the list of query fields. The only fields that cannot be queried are the prompt Links identified by the or icon. By clicking on this icon, the field is expanded and the user can choose which of the fields of the linked entity he or she wants to drag into the output values section.

Once the field has been dragged to that section, a box appears with a description of it, and the pencil symbol appears on the right-hand side.



Click on this symbol to open a pop-up where the column properties can then be defined:

- Column description: Column title containing the values of the field in question;
- Regrouping clause: How to regroup the values if the "Aggregate results" option was selected;
- To delete a value that is no longer required as an output, simply click on the X to the left of its description.
- Use drag & drop to change the order of the output columns.

■ To reorganise the position of an output column, simply click on its description. A symbol will appear beside it showing the type of ordering (descending, ascending) and the order.



In addition to the entire list of application fields, Query builder enables particular expressions or "Numbers of columns" to appear as output. It also allows the creation of groups of columns in the final view (only in the case of *Pivot* view).

18.1.3.1 NUMBER OF COLUMNS

If the "Aggregate results" option is selected, the results displayed can be dragged to the "Number of columns" column. This column displays the number of results that have been joined in the line in question (e.g. the column may be useful in a query to know how many times the patient was treated on a Fresenius 5008 device).

To edit the description of the column, click on the pencil.

To reset the values inside the edit pop-up, click on the "Refresh" button.

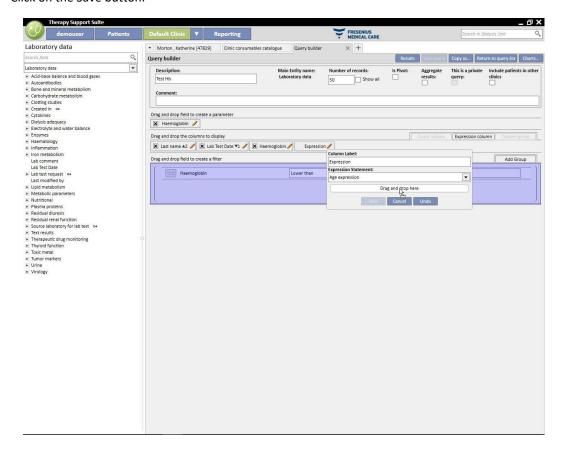
To cancel the input, click on the "Delete" button.

18.1.3.2 EXPRESSION COLUMN

By dragging this option into the results to view, it is possible to apply the calculation of the expression "Age". To do this, after dragging & dropping the option, simply edit the properties of the column. Select "Age expression" statement and drag the Date field, selecting it from the list of available fields (list on the left).

If, for example, the user wants to visualise the age of a patient he should proceed as follows:

- Drag the "Age" item into the values to be displayed in the output;
- In the pop-up that opens automatically, edit the description of the column, and select "Calculate age" in the "Expression Type" list.
- Drag the Date of Birth field from the list of fields of the Patients entity into the pop-up section called "Drag and drop here".
- Click on the Save button.



To eliminate a data field, simply select the "x" button next to the description.



To reset the values inside the pop-up, click on the "Refresh" button.

To cancel the input, click on the "Delete" button.

18.1.3.3 GROUP OF COLUMNS

The option "Group of Columns" can only be activated when the results view is in Pivot mode. With this option, the user can define groups of columns that can be viewed in output inside an expandable view at the user's discretion.

To define the group:

- Select the option and drag it into the section of columns to view;
- Click on the "Group" description to change the label;

Drag the columns from the list of fields (or from those of the output columns) to the area for definition of the group.

18.1.4 FILTER CREATION AREA

The filter creation area is found at the bottom of the screen and is used to define the criteria for the selection of results to view as output. The filter criteria for the results must be expressed in an algebraic expression (e.g. Weight > 50 Kg and Height <= 185 cm).

To define a filter, simply drag & drop filters from the filter field to the filter creation area. Define the criteria from the combo box that appears next to the field name and insert the value to apply to the filter, enabling the data entry box for the value by clicking on the related check-box.



The applicable filter criteria vary from field to field based on the type of field dragged into the filter area. Here are the details of the criteria based on the type of field:

Date:

- Equal to
- Not equal to
- Greater than
- Greater than or equal to
- Less than
- Less than or equal to
- Last <n> days
- Same year
- Same day
- Same month
- Same month and year
- Same week
- Null value

Numeric:

- Equal to
- Not equal to
- Greater than
- Greater than or equal to
- Less than
- Less than or equal to
- Null value

Text:

- Equal to
- Not equal to
- Greater than
- Greater than or equal to
- Less than
- Less than or equal to
- Contains
- Does not contain
- Contains (case insensitive)
- Does not contain (case insensitive)
- Starts with
- Finishes with
- Null value

Predefined list:

- Equal to
- Not equal to
- Null value

Links:

- Equal to
- Not equal to
- Null value

To negate a condition (e.g. haemoglobin is NOT negative) enable the "Not" button (to the left of the field name) with a click.



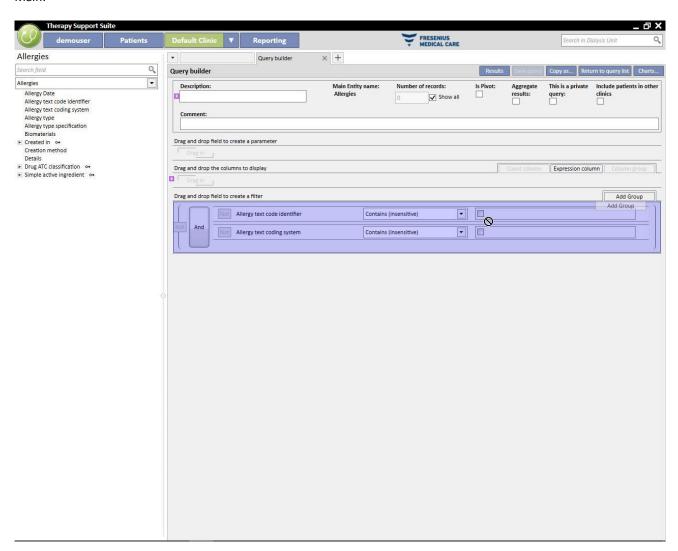
When there are multiple conditions, they are incorporated in a single condition and the predefined algebraic operand is AND. To change to the operand OR click on the button marked "and".



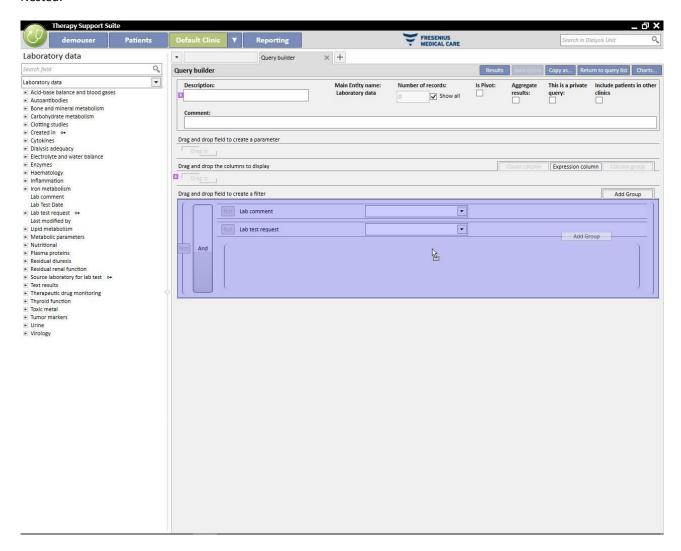
To negate the result deriving from the incorporation of multiple conditions, activate the *Not* in brackets next to the desired condition.

To define nested conditions, or to create different levels of brackets, simply drag the "Add group" button (located to the top right of this section) in the filter area. If one or more groups are already present, when dragging it, the level of brackets in which the new group will be positioned will be highlighted.

Main:



Nested:



A filter can be deleted by clicking on the icon that appears on the right hand side when the mouse is placed over the filter in question.

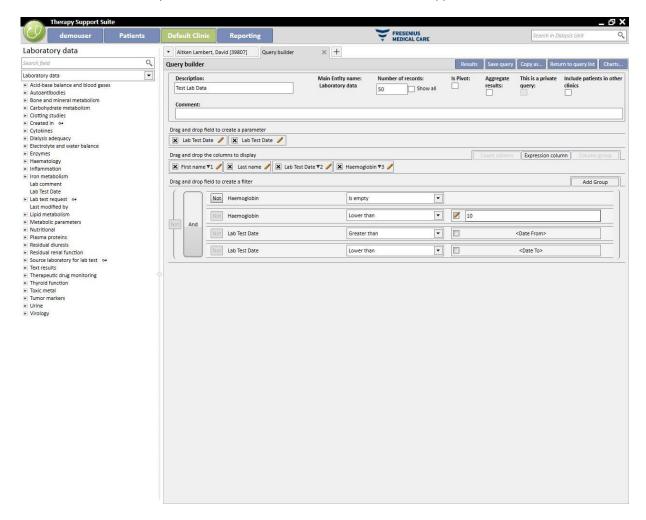
18.1.5 PARAMETER DEFINITION AREA

The above descriptions, related to the filter definition area to apply to the results, call for the user to define a specific value for the filter (greater than 2, less than 4, etc.). To make the query more dynamic, Query Builder offers users the possibility to apply values (parameters) to the filters entered by the user when the data are extracted.

To define the parameters, when creating the query, it is necessary to drag the list of fields from an entity for which you want to apply a filter, not only into the filter definition area, but also into the parameter definition space, which is below the area for defining the properties of the query. By clicking on the pencil, usually you access the properties of the parameters in order to define their description, visibility, whether they are mandatory, the width of visualisation and the typical different characteristics for the various types of prompt:

Date: Accuracy of the date (day, month, year, date and time, only time).

To apply a parameter to a filter, simply drag the parameter from the parameter definition area into the filter area, in the section related to the required filter, dedicated to the value that has to be applied to the filter.



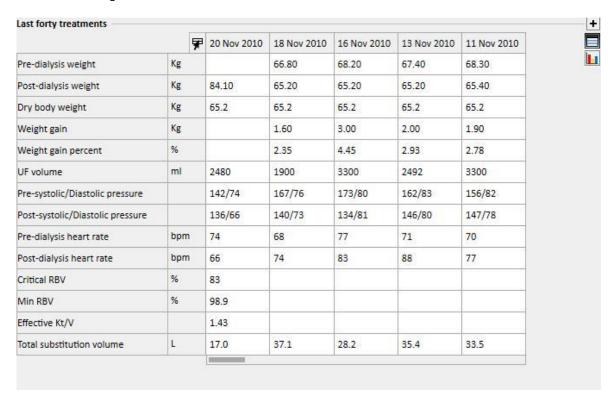
NOTE: Before dragging the parameter into the filter area, click on the pencil icon to deactivate the static filter, if the filter was previously defined as such.

18.1.6 SPECIAL FUNCTIONS

18.1.6.1 IS PIVOT

The "Is' pivot" function allows the user to modify the results view in *pivot* mode. This mode foresees the display of the values defined in the section related to the output values (from the second value onward) as a line of a table. The first value in the list of columns to be shown, acts as a discriminant to determine the columns of the results table. To obtain pivot extractions that make sense, it is good practice to use a discriminant with a Date value to create the columns.

By doing so, Query Builder will generate a column for every date extracted and the list of remaining fields in output will form the remaining lines, allowing the user to examine and compare the values easily, as they are side by side. By ordering the output by date (ascending or descending), it is possible to provide the user with the option to compare the results in chronological order.



18.1.6.2 AGGREGATE RESULTS

Activating the "Aggregate results" function orders the Query Builder to combine all output lines that contain exactly the same results in a single line. By selecting this option, it is possible to verify how in the "Columns to display" section every element that is present will expand by one line with the description "Group by":



By editing the properties of the columns to extract, it is possible to select different logic for aggregation, depending on the type of data shown.

String/predefined list/link:

- Group by (group according to rows with identical values).
- Numeric:
- Group;
- Max (calculates the maximum, for the field in question, of the grouped values);
- Min (calculates the minimum, for the field in question, of the grouped values);

- Average (calculates the average of the grouped values);
- Sum (calculates the sum of the grouped values);

Date:

- Group;
- Group by day (groups lines that refer to the same day in the field in question);
- Group by month (groups lines that refer to the same month in the field in question);
- Group by year (groups lines that refer to the same year in the field in question);

The combination of different logic for grouping permits the user to perform extremely complex extractions (e.g. extract for every patient the average haemoglobin value for every month in the date range defined by the user).

18.1.6.3 PRIVATE QUERY

By activating this option, the query can be modified only by the user who created it, and, if this has already been published as a view, only the user who created the query can view it in the relative section.

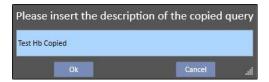
18.1.7 BUTTONS

Two different series of buttons are available for the user based on which section of Query Builder he is in.

18.1.7.1 BUTTONS AVAILABLE IN THE QUERY CREATION PHASE

In the query definition section, there are multiple buttons (as usual, located above and to the right of the windows) to cover various functions:

- Results: this button allows the user to perform the query in question and verify that the results are correct;
- Save a query: needed to save the created query;
- Copy as: the user can create a copy of the open query, changing its name. This operation is useful if he only wants to modify a small part of an existing query, eliminating the need to recreate it from scratch.
- By clicking on the button, a new pop-up window opens where the name of the new query can be specified.



- Click OK to confirm the query. Cancel deletes the changes.
- Return to the list of queries: takes the user to the list of saved queries.
- Charts:: allows the user to start the procedure to associate one or more charts to the extraction. How to generate the charts is described in the next chapter.

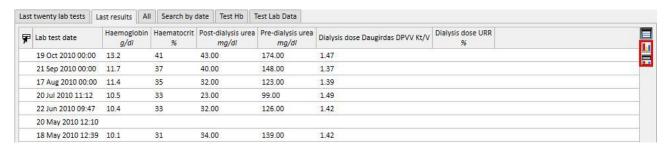
18.1.7.2 CREATE CHARTS

Query Builder also offers the possibility to create charts to be associated with (or to replace) the generated query. To start creating these charts click on the "Charts..." button in the top right of the window. A pop-up window will open. It can be used to perform three different tasks:

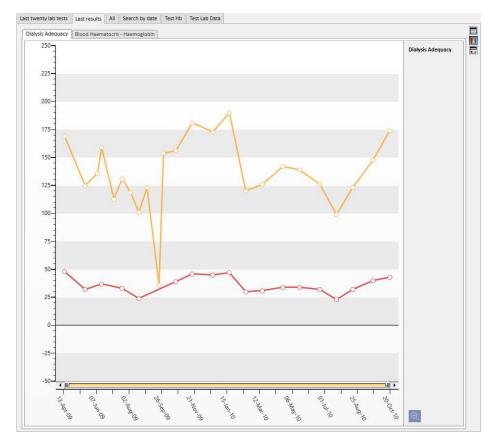
- Choose the chart display style
- Add or create a chart
- Add a tab or group charts together inside a tab
- Choose the chart display style

The charts can be displayed in different ways:

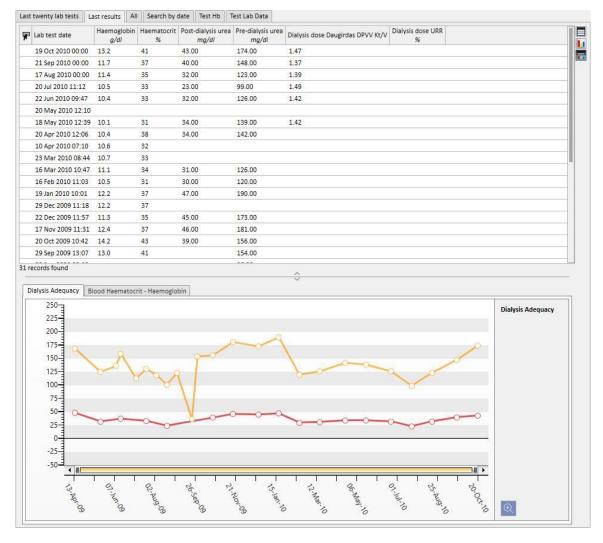
Predefined: the chart will be accessible via a button next to the list of results of the query;



Replace the view: The chart will be displayed as the first window of the query;



• Divided view: the space dedicated to the results of the view will be divided in two. The upper part will contain the grid of results, the lower part the assigned charts.



After selecting a type of view, by clicking on "Add new", the user is guided to the next step in the generation of the chart (see next section). The "Save" button allows the user to save changes, and "Cancel" allows him to cancel them.

Generating a chart

Once the display type has been selected for the chart, it is possible to add new charts by dragging the button "Add chart" as described in the user interface. At this point, a pop-up opens related to the generation of a new chart.



First of all, it is necessary to describe what the chart shows, entering the content in the Description field.

The field Type allows the user to specify the type of chart:

- Point: the values are shown as points in the chart;
- Line: the values are shown as points and are connected by a line;

Define which values to use on the X-axis by specifying them in the field "X-Axis Field". It is necessary to select a Date value for the X-axis, even though the list proposes all the values defined in the "Values to display" section of the related query.

To define a chart correctly, there must be at least one Date field in the output columns to define the time line on the X-axis.

To define which series of values to display on the chart simply drag the required value from the column on the left to the central area of the window.



The list of selectable values is composed solely of the numeric values established as "Columns to display" in the creation phase of the query.

In the central part, after dragging the required values, it is possible to modify the properties of the graphic representation of each value selected (colour and line thickness). To modify the colour click on the select the line thickness expand the



When selecting the values to display it is advisable to select values with the same unit of measurement, otherwise the scale of values on the X-axis will be incongruous.

To define charts with different units of measurement simply create more than one chart, grouping in each one values with the same unit of measurement.

To eliminate a value that has been dragged by mistake, click on the X that appears to the right of the parameter modification area.



Once the data to display have been selected, the user can see a preview of the chart by clicking on the "Preview" button. The "Save" button, as always, saves the changes made, while "Cancel" means that these changes are lost.

Modifying a chart

If the user wants to modify a chart created in the past, simply click (inside the pop-up window that opens after clicking on the "Charts..." button) on the row with the title of the chart, located under the display mode selection option.



Creating tabs and grouping charts together in tabs

The charts can be grouped together in tabs in order to be able to separate them or to show them at the same time together with the related query, thus allowing the user to compare the visualised data easily.

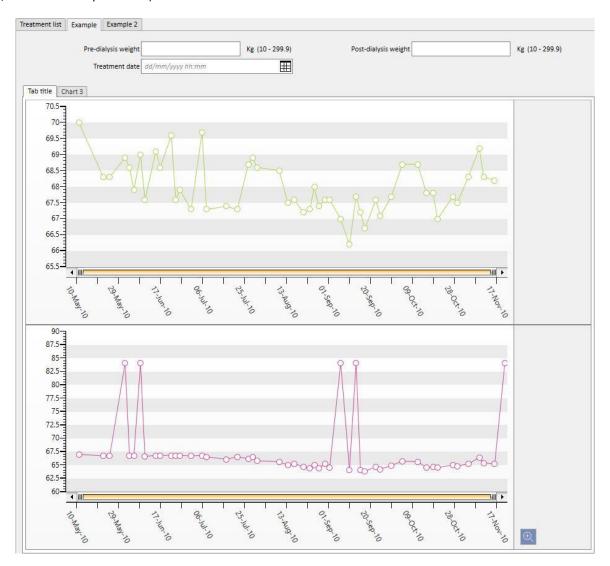
From the "Chart builder" window, it is possible to create new tabs, dragging the control "Add tab" as indicated in the user interface



Here, it is possible to modify the title by clicking on the name itself so that it becomes editable. To insert one of the charts in the tab that has just been created, simply drag it as shown on the user interface, which gives the following result



When the query is executed, the charts will be displayed to the user as shown below (the first two charts on the same tab, the third in a separate tab):



18.1.7.3 BUTTONS AVAILABLE IN THE SECTION WITH THE LIST OF QUERIES

Accessing the Query Builder section using the "Open" menu item in the clinic menu, the following three buttons are available:

- New: Always accessible, and enables the user to create a new query.
- Save: Initially disabled, enables the user to save the modifications made to the query list, for example, the modification of the publication flags (described in detail in the next chapter).
- Cancel: Deletes the modifications made to the query list.

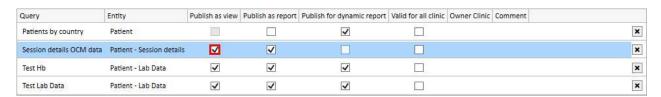
18.1.8 QUERY PUBLICATION

Once saved, the extractions can be made available to TSS users via the operation called "publish".

From the query list, it is possible to decide whether to publish all of them both as a "view" and as a "report".

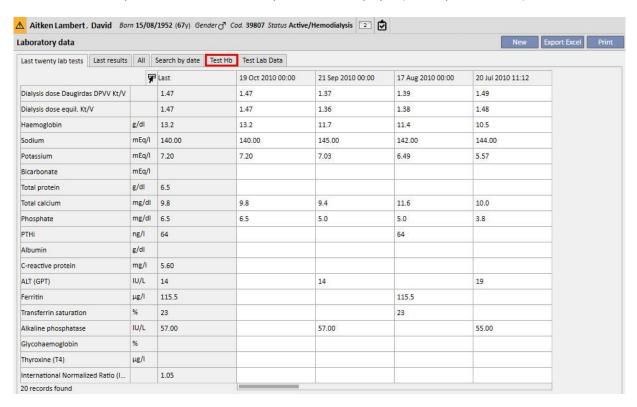
18.1.8.1 PUBLISHING A QUERY AS A VIEW

To publish an extraction as a view, simply enable the option "Publish as view" and save.



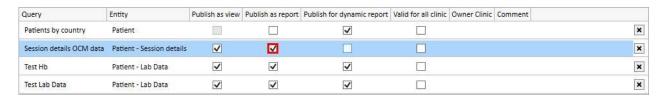
This will allow all users (as long as the query is not private) to find the extraction as the last page of the views related to a selected entity as a starting point for creating the query (which is shown as the second column in the list).

If the entity in question is part of the patients menu, once the query has been published as a view, only those records related to the selected patient will be automatically filtered and displayed (in the specific section).



18.1.8.2 PUBLISH A QUERY AS A REPORT

To publish an extraction as a report simply enable the option "Publish as report" and save.



This will allow all users (as long as the query is not private) to find the extraction as the last option of the section "personalised reports" in the Report menu.



When an extraction is selected from the "Personalized Report" section, a table is displayed containing all of the information returned by the query.



The user can click on a row of the table to display the entity completely, and modify it if desired.

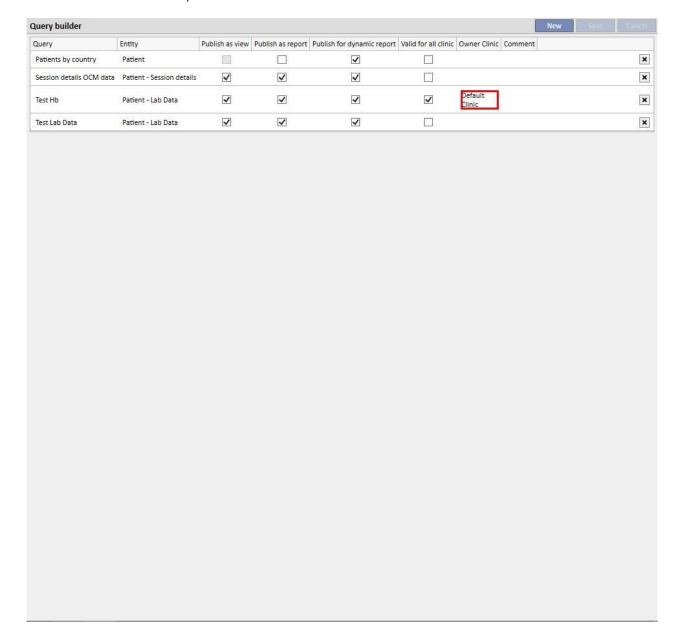
18.1.8.3 PUBLISH A QUERY FOR ALL CLINICS

In a multi-clinic scenario, a query can be rendered visible for all the clinics by activating the option "Valid for all clinics". The query can only be created once without duplications and it is important to note that the data returned will be those from the current clinic and not overall data.

When this option is enabled, the queries will also have an owner clinic, which is the clinic that performed the last save.

The owner clinic is important if the option is disabled and is visible next to the option box.

View from Default Clinic: the option has been activated then saved



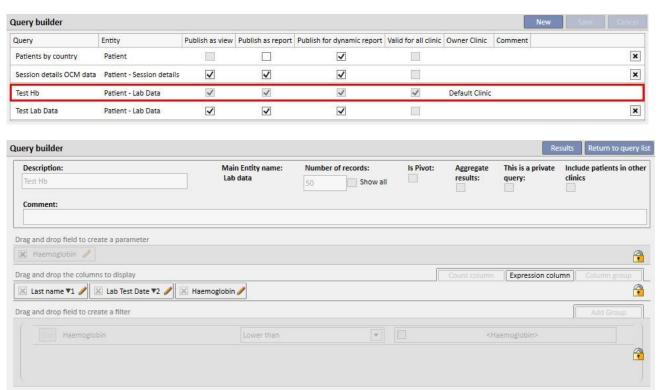
View from Satellite Clinic: the query Hb Test is now also visible for this clinic



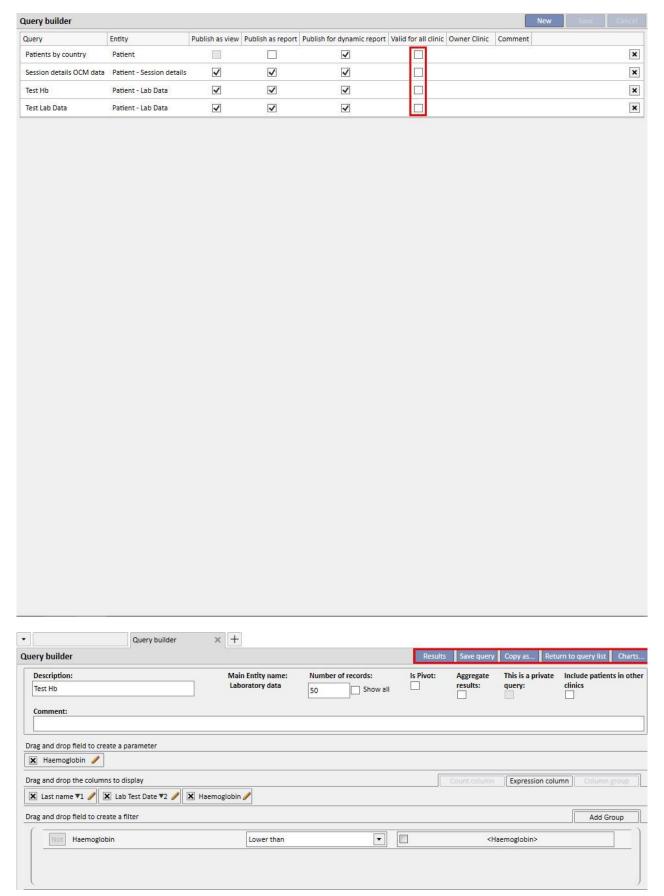
The rights to activate the option "Valid for every clinic" are managed by FME User Management.

If a user does not have the rights to set this option, he will see the following:

• If the query has the option "Valid for all clinics" (set by another user) he can only see the results and cannot modify the query and save the changes

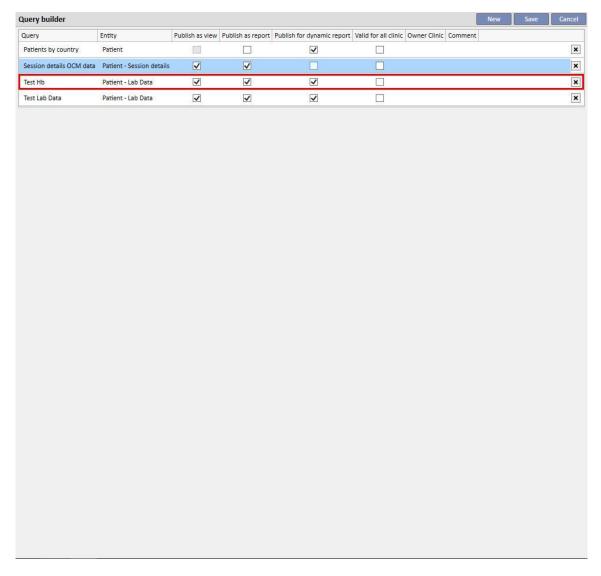


• If the query has the option "Valid for all clinics" deactivated, he will only have deactivated the option but can still update and save the changes



Removing the option "Valid for all clinics", after having saved the modifications, the following scenarios are created:

- If the user is in the owner clinic of the query, it will continue to be available for this clinic but it will not be visible in the other clinics
- Default Clinic: the query remains visible



Satellite Clinic: the query disappears



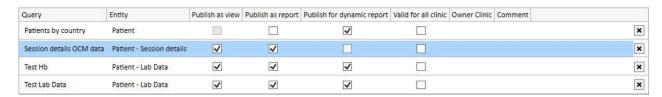
• If the option "Valid for all clinics" is disabled for a query that has a different owner clinic than the user's clinic, the user will be advised that the query will disappear consistently from the list, and he can choose whether to proceed or not



The option "Valid for all clinics" will consistently affect the other options of the same query, in fact if a query has the two options "Publish as a view" and "Valid for all clinics" activated, this will be published as a view for all clinics. Similarly, this will also occur for the other options "Publish as a report" and "Publish as a dynamic report".

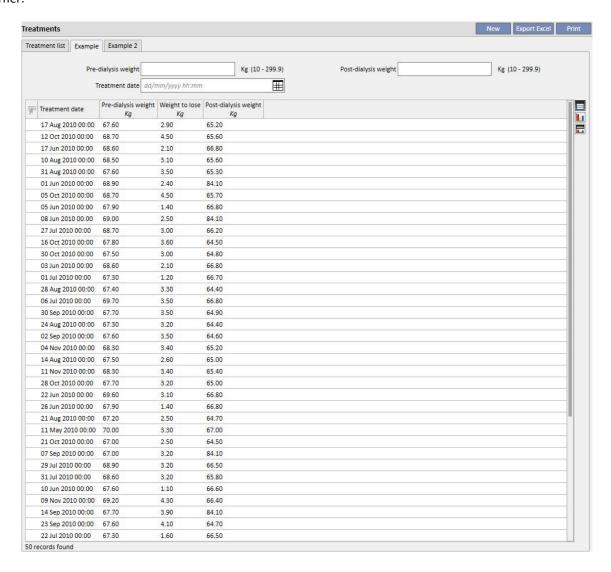
18.1.9 CANCEL A QUERY

A value can be eliminated by clicking on the X that appears to the right of the parameter modification area, assuming the user has activated the possibility to delete records from the Query Builder.



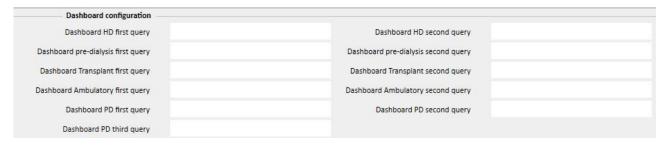
18.1.10 USE OF QUERIES CREATED IN TSS

The queries created (if published as views) can be viewed by navigating in the TSS menu to which they are related. For example, a query created with the start point "Patient treatments" is visible in the "Treatments" menu. All views generated in this manner, after being performed, display the number of extracted results in the bottom left-hand corner:

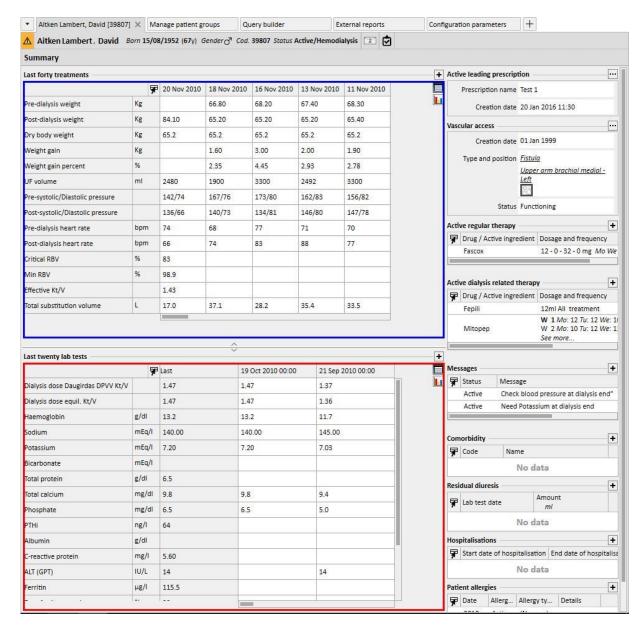


18.1.10.1 PERSONALISING THE SUMMARY PAGE

The patient summary page can be modified (only the column on the left) by defining which extractions should be displayed. To specify which queries to display simply fill-in, in the section "Configuration parameters" of the Master data menu, the group "Configuration of the summary page".



The field "First query of the HD summary page" allows the user to personalise the query, marked with a blue frame in the image below, for a patient in hemodialysis. The field "Second query of the HD Summary page" allows the user to personalise the query marked with a red frame in the image below, for a patient in hemodialysis.



The same applies for the other fields in the group that refer to the summary pages of patients in peritoneal dialysis or pre-dialysis.

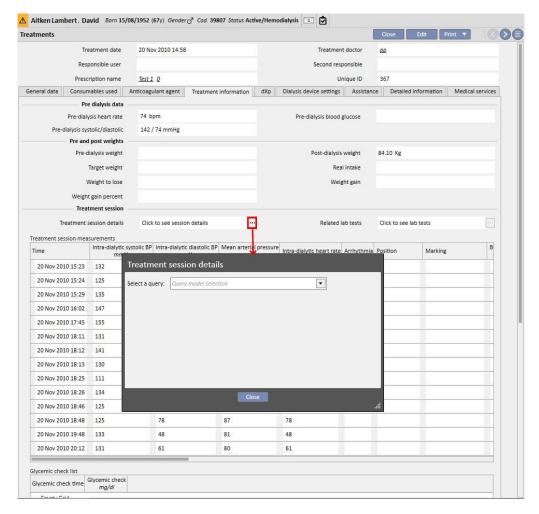
The selectable list of queries, for each of these fields, might not correspond to the complete list of extractions in the Query Builder section. This is because the selectable queries are exclusively those with the following prerequisites:

- The reference entity of the query is not "Patient", but is one of the other entities of the Patients menu;
- The guery has to be published as a view

18.1.10.2 TREATMENT SESSION DATA

As mentioned previously it is possible to consult the data of the dialysis session via the Query Builder. These data include all the values that the device measures and communicates at pre-determined time intervals, as established during the configuration phase.

These data can be consulted in the section "session information" of the treatment entity; by clicking on the button next to "Session details" a pop-up window opens where the user is invited to select a query from a predefined list.



The list mentioned above includes all the extractions generated by the Query Builder (including those from the section "HD Survey Management – query on single treatment" whose main entity is "Session details").



Warning

It is the responsibility of the user to check that the results of Query Builder are correct by checking the patient data. Imprecise results cannot be ruled out.

18.1.11 DATA EXTRACTION BY SPECIFIC DIALYSIS CLINIC

Using the "Created in" query field found under HD Prescription, the treatments for a specific Dialysis Clinic can be filtered. This allows all the treatments performed by a particular clinic to be used as results, regardless of the patient's current status or where the patient is actually located at the time of extraction. This field is divided into four items:

- Father reference clinic
- Classification index
- Description
- IDML

all of which can be used as filters, to distinguish the desired treatments to be extracted.

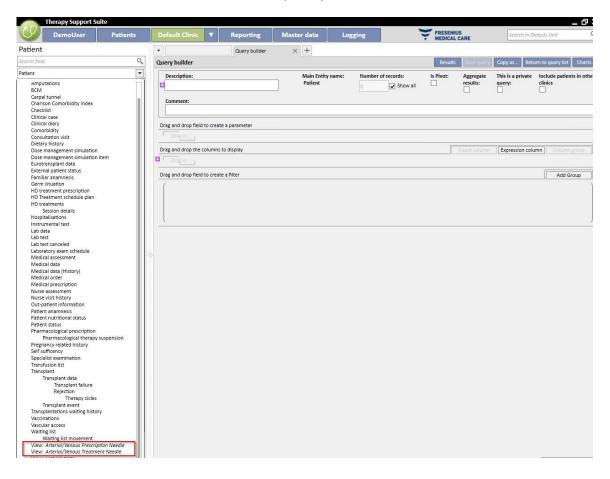
Treatment prescription Search field Treatment prescription Anticoagulant agent ▶ Comments Consumables ▶ Created in o+ Creation date Dialysis device settings General data ▶ Last modified by ↔ Leading prescription ▶ Patient ↔ ▶ Prescribing doctor ↔ Prescription enabled Prescription name Prescription version Unique ID Valid from Valid to

18.1.12 USE NEEDLE VIEWS FOR PRESCRIPTIONS/TREATMENTS AS QUERY FIELDS

As described previously, the, in addition to allowing searchable fields to be selected the attributes of the DB tables, Query Builder also allows view fields to be used. Among these available views, there are:

- Needle for arterial/venous prescription
- Needle for arterial/venous treatment

Using the fields in these views to create queries, it is possible to extract from the results, within the same line, both information about the needle for Arterial prescription/treatment and information about the needle for Venous prescription/treatment. Unlike composing a query using the same fields, which were imported from the tables and not from the views, the results provide for a line for information about the needle for Arterial prescription/treatment and a line for information about the needle for Venous prescription/treatment.



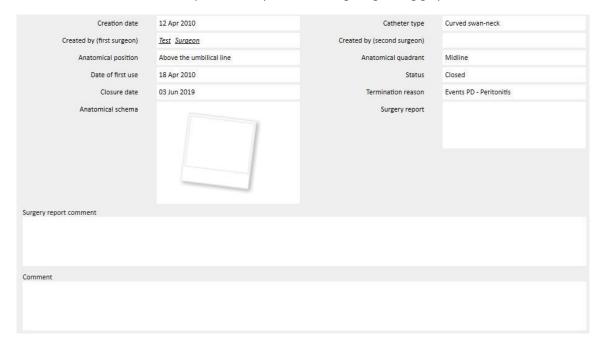
19 OPTIONAL MODULE: PD

19.1 PERITONEAL DIALYSIS

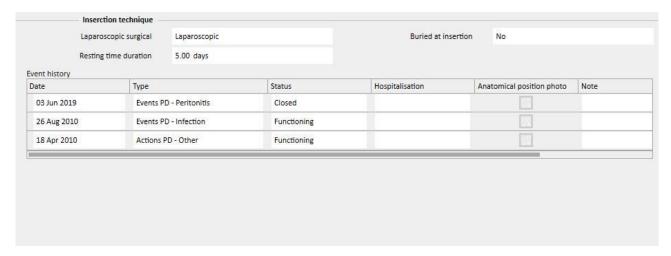
19.1.1 PD ACCESS

The chronological record of the patient's access can be recorded in this section. To modify an existing access, simply select it from the screen and press the Modify button. To create a new access, simply press the "New" button.

- Creation date: this specifies when the access was created.
- Catheter type: in this field the type of access can be specified by choosing it from a predefined list.
- Created by (first surgeon): this field allows the first surgeon to be selected.
- Created by (second surgeon): this field allows the second surgeon to be selected.
- Anatomical position: this field allows the access's anatomical position to be specified, by choosing it from the
 preset list.
- Anatomical quadrant: in this field the anatomical quadrant in which the access was positioned can be specified
 by choosing it from the preset list.
- Date of first use: this is used to specify the data on which the vascular access was used for the first time.
- Status: this field is read-only. It is filled in by actions that define the active/not active status of the access.
- Closure date: this field is read-only. This is filled in automatically by creation of an event that causes the removal of the access.
- Termination reason: this is the reason for removal of the access. The value is drawn from the Event log.
- Anatomical schema: here it is possible to upload a working image using graphic tools.



- Surgery report: this field allows a surgery report to be uploaded as a document attached to the access.
- Surgery report comment: this is a text field that allows additional comments to be added to the Surgery Report.
- **Comment**: this is a summary comment applicable to the entire section.
- The **insertion technique** section allows the user to enter additional details concerning the access insertion technique selecting one from a predefined list.
- Marsupialization: if the insertion involves marsupialization.
- Resting time duration: interval, expressed in days, before starting dialysis.
- **Event log**: This is a *multi-value* field, where the user can record access-related actions (creation, incidents, or termination). The first event is automatically generated when the access is created.



19.1.2 PD PRESCRIPTION

The **PD prescriptions** relating to a specific patient are recorded in this section. Prescriptions are identified by a name.

Selecting a Prescription, the PD prescription section, which comprises two tabs, is opened:

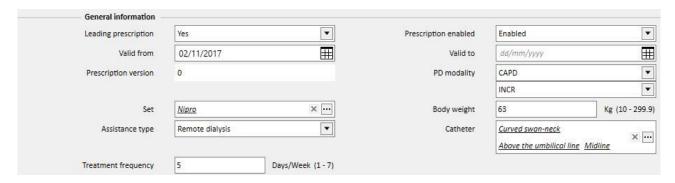
- General data: this is the main tab where all of the dialysis prescription characteristics are defined.
- Comments: on this tab, specific comments relating to the prescription can be added.

19.1.2.1 GENERAL DATA

On the **General data** tab, the user must indicate if the prescription that is being modified is enabled. The prescription has two other dates that define its interval of validity. **Valid from** is mandatory and prefilled whereas **Valid to** does not need to be specified.

The fields that follow are valid for any mode of peritoneal dialysis:

- Catheter: the implanted catheter.
- Theoretical Weight: the patient's dry weight.
- Assistance type: indicates the type of assistance that the patient requires.
- Treatment frequency: is the number of treatments the patient must undergo each week. The field is editable
 by the user and is only for reference for the treatment prescription. There is no correlation with the real
 schedule of the treatments.



The combined field **PD modality** allows the user to choose between the three main methods of peritoneal dialysis: APD, CAPD and Break-in. Sub-procedures can also be defined for APD and CAPD. Based on the choice made, various fields are displayed, characteristic of the type of dialysis.

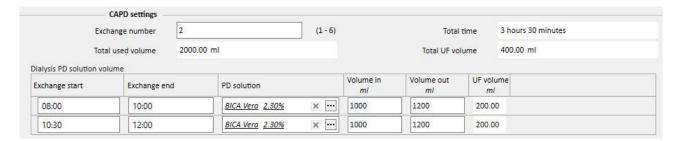
19.1.2.2 CAPD PRESCRIPTION

When CAPD or one of the sub-procedures is selected as PD procedure, a table is shown to allow the information related to the exchanges to be entered. By default a new prescription will show 4 exchanges and the user can change it from a minimum of 1 to a maximum of 6.

The following values must be specified for each exchange:

- Exchange start and end time
- PD Solution to be used, can be selected from a list of PD solutions
- Volume in
- Volume out
- Volume UF

The system will calculate the total of the Volume In, UF Volume and Total Time to complete the exchanges.

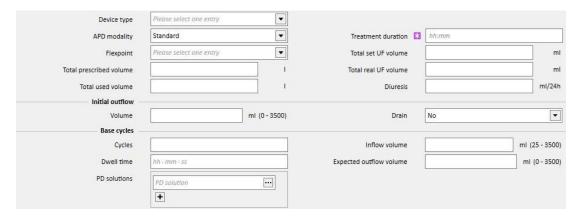


19.1.2.3 APD PRESCRIPTION

The APD peritoneal dialysis modality allows the following fields to be selected:

- Device type: this is the dialysis device the patient must use.
- APD Mode: the APD treatment mode (Adapted APD, PD Plus, Standard, or Tidal). Varying the type of treatment, varies the fields visible for the modality selected.
- Treatment duration: mandatory field that indicates how long the treatment lasts.
- Flexpoint
- Total set UF volume
- Total prescribed UF volume
- Total real UF volume
- Total used volume
- Diuresis
- Initial fill volume
 - Volume
 - Drainage: when this is "Yes", the Initial fill volume cannot be modified

- Base Cycles
 - Cycles
 - · Standby time
 - PD solution
 - Infusion fill volume
 - Expected outlet volume



19.1.2.4 TREATMENT TYPE

The **Treatment type** selected allows the user to define other specific values based on the type.

The Adapted APD mode allows the user to define the Initial cycles in the section: Cycles (initial value of 2), Inflow volume, Expected outflow volume, Standby time e la PD solution. This mode defines a PD solution list to be used during treatment.



The PD Plus mode allows you to define the following fields: **Inflow volume**, **Expected outflow volume** and **Standby time**. This mode defines a **PD solution** list to be used during treatment.



The **Tidal** mode allows the definition of the following fields: **Cycles** (initial value of 4), **Inflow volume**, **Expected outflow volume**. The **Inflow volume** % and **Inflow volume** can be modified in an exclusive manner. The modified Fill Mode field allows the selection of which field can be modified. Instead, the read-only field is calculated with reference to the **Inflow volume** of the **Basic cycles** section. This mode defines a **PD solution** list to be used during treatment.



19.1.2.5 LAST INFLOW

Independently from the APD modality selected will be possible to define value for the last inflow and when necessary manual exchanges.

Last inflow

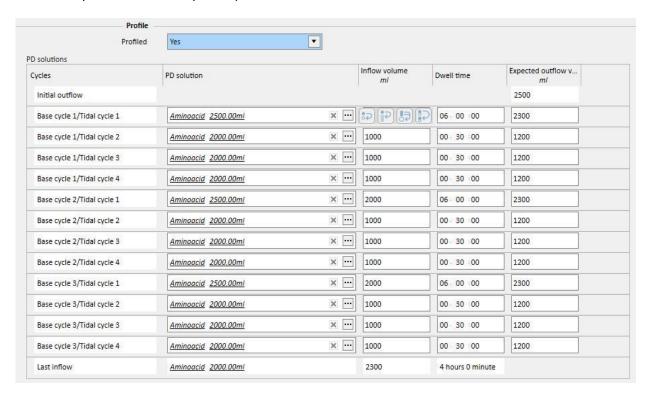
- Last inflow: when is "Yes" will be possible to define the following fields:
 - Last inflow volume
 - PD Solution list
 - Standby time



19.1.2.6 PROFILE

The prescription can be profiled specifying for each cycle the **Inflow volume**, the **Standby time** and the **Expected outflow volume** and which solution to use among those available.

Setting the **Profiled** flag a "Yes" will be created and the profile initialised. Volume and standby fields will no longer be visible in the cycle sections but only in the profile.



A profile is comprised as follows:

- Initial outflow (Volume)
- Cycles provided for by the selected mode according to the settings indicated in the previous sections (Solution, Fill Volume, Standby Time and Expected Output Volume)
- Any Last inflow (Solution, Inflow volume, Standby time)

While the **Initial outflow** and the **Last inflow** show the values read from the respective sections, the cycles can be configured by the user in terms of **Solution**, **Inflow volume**, **Standby time** and **Expected outflow volume**.

If the sections relating to the cycles of the prescription have been previously valued, activating the profiling will show the values in the profile. If the number of solutions foreseen for the type of cycle is one, then the **PD solution** will also be shown in the profile. Otherwise the section will remain empty but the user can choose from the only solutions available in the respective cycle sections.

The fields of each profile cycle, except for the **Initial outflow** and the **Last inflow**, have buttons that facilitate the profile being filled out. They are visible by moving the mouse cursor over the profile fields. The available buttons vary according to the characteristics of the underlying cycle.

Namely:

- Copy to next one : this is visible when there is a cycle after the current one that is the same type. This one copies the value of the current field to the corresponding field of the next cycle.
- Copy to the next ones : this is visible when there are several cycles after the current one and that they are of the same type. This one copies the value of the current field to the corresponding fields of the next cycles.
- Copy to corresponding fields : this is only visible in "Tidal" cycles and sub-cycles and allows you to copy the value of the current field into the corresponding fields of the subsequent corresponding cycles or subcycles. For example, the Inflow volume of the "Base 2/Tidal 3" sub-cycle will not be copied in all subsequent cycles but only in sub-cycle "3".
- Copy cycle : this is visible only in Tidal cycles and allows the whole current cycle in the following cycles to be copied.

Note



The buttons appear on the right of the field you want to copy. It is possible that in clients that can function as tablets the buttons will appear on the left. If the condition is not acceptable, you can change the setting from the Windows Control Panel. In the Control Panel search box, search for "Tablet PC settings"-> "Other" and change the hand used.

If the cycle sections are changed, the profile will automatically be updated. A warning will be shown to the user if the fields in the profile have already been populated manually and they need to be redefined. The events that can lead to profile regeneration are, for example, changing the **Profiled** setting, changing the **APD mode** or changing the number of cycles.

Note



Just changing the number of cycles in the field is sufficient to trigger a profile update: the cursor must be removed.

Note



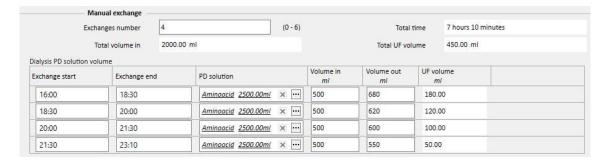
There shall not be more than a total of 200 cycles provided for in a prescription. For Tidal prescriptions, the total is achieved by multiplying the number of basic cycles by the "Tidal" cycles. The **Last inflow** is not counted.

19.1.2.7 MANUAL EXCHANGE

This section allows manual exchanges to be added after the automatic ones. A manual exchange consists of the following fields:

Manual Exchange

- Exchange start and end time
- PD Solution to be used, can be selected from a list of PD solutions
- Volume in
- Volume out
- Volume UF



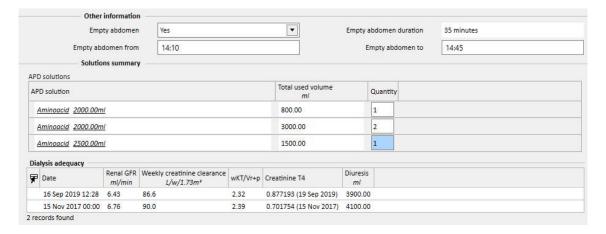
The total of the Fill Volume, UF Volume and Total Time to complete the exchanges will be calculated.

19.1.2.8 OTHER INFORMATION, SOLUTION SUMMARY AND DIALYTIC ADEQUACY

In this **Other information** section, it is possible to specify if the treatment calls for an empty abdomen period. If required, the time interval can be indicated. The duration will be calculated automatically.

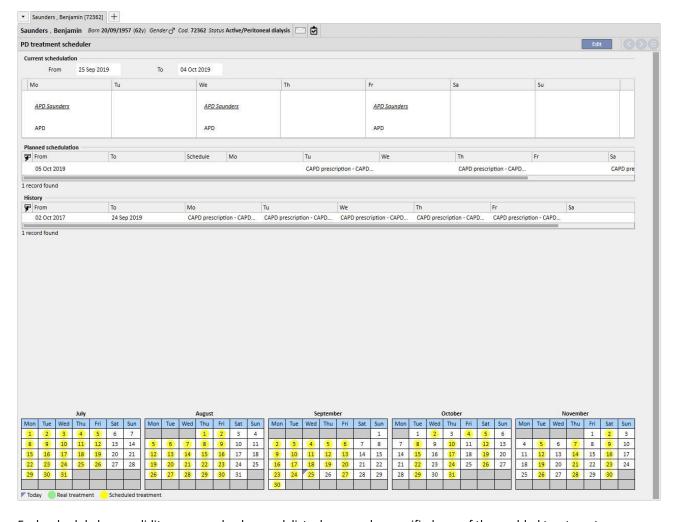
In the **Solution summary** all the solutions used in the prescription will be automatically summarised: with the same solutions, the volumes are added together, keeping the manual part of the treatment separate from the automatic part. The number of bags can then be entered manually.

Finally in the **Dialysis adequacy** there will be displayed some patient information extracted from **Adequacy**, **PET** and from **Laboratory data**.



19.1.3 PD TREATMENT SCHEDULER

In this section the user can define in which day the patient should perform peritoneal dialysis. The plan is divided in three subsections. The main section show the actual plan, the next section show the future plan and the last show the History. The schedule can't be in overlap.



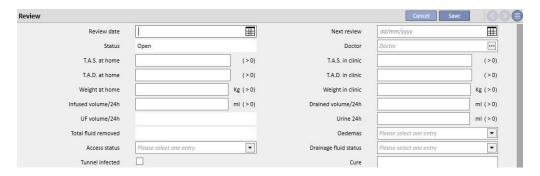
Each schedule has a validity range and a day week list where can be specified one of the enabled treatment prescription to be performed. If the user selects a prescription with a validity interval that is not compatible with the schedule timeline, an error will appear.

When the current schedule reaches its end, it is moved to the list of past schedules. Likewise, when a future schedule becomes valid because of the time it is being moved from the list of future plans to the current one.

At the bottom of the page, you can see a preview of schedule applied to the calendar. Moving the mouse over the desired date displays information containing the scheduled prescription name for that day.

19.1.4 REVIEW

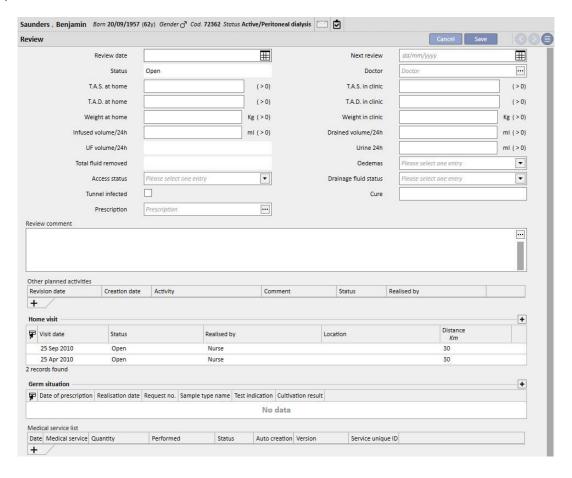
The *Review* menu item is used to save the data from the review of each patient performed in the hospital. This item allows the values taken at home by the patient to be compared with the values taken in the clinic by the nurse. These values are: **systolic pressure**, **diastolic pressure** and **weight**.



Volume and catheter status values can also be entered:

- Infused volume/drained volume / Urine 24h: volume relating to the treatment of the last 24 h.
- Oedemas: information concerning any oedemas at the access can be entered.
- Access status: the status of the patient's catheter.
- Drainage flow status: the status of the fluid drained from the patient.

It is also possible to indicate the status of the tunnel (**infected tunnel**), the name of the **Prescription**, and indicate a **Therapy** and write more details in the **Visit comment** field.



A table entitled **Other planned activities** appears in the lower part of the screen. Rows can be added to plan various types of activities related to the PD patient.

Below this there are two additional tables containing the list of home visits and the results of the germ cultures.

There is also a section containing a **Medical services list** for combination with the PD Review. The user can enter the services by hand, filling in all the compulsory fields.

For PD Reviews, it is possible to set Expressions (see "Service Manual" section 4.2.9) that, once satisfied, will enable the system to enter services automatically.

Click the Close button to set the PD Review in "Closed" status. Here again, automatic generation of reports in PDF format can be associated with closure. Specifically, the expressions (see "Service Manual" section 4.2.9) defined in the "Configure PDF Export" section (see "Service Manual" section 4.2.7), which are enabled and valid for the current clinic, will be assessed.

If the PD Review meets the expression criteria, the report associated with the valid expression is generated automatically. Depending on the setup, the report may be exported via Filesystem and/or sent via cDL.

PDF reports created can be viewed in the "PDF export" section (see "Service Manual" section 4.2.8).

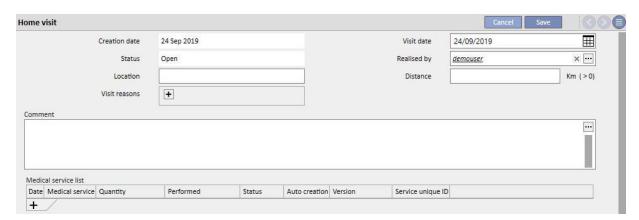
When the PD Review status is "Closed", its data can no longer be edited. Press the Re-open button to "Reopen" the review; its data become editable again.

If the automatic generation of reports in PDF format have been configured and, in Power Tool, the option "Filesystem Undo" has been enabled, when "Re-opening" the PD Review, the PDF file connected to the reopened PD Review will be deleted/renamed (based on the action configured in Power Tool).

19.1.5 HOME VISITS

The **Home visit** section is intended to contain the user's comments (e.g. A nurse) after a visit to the patient's home. The fields proposed in this item are the **Visit date**, the **Location** of the visit, the **Distance** from the hospital and the **Reasons for the visit**. Two "self-populated" fields are related to the **Creation date** of the record and the user who made the visit.

The main section is dedicated to the Visit comment, written by the user, that summarises its results.



There is also a section containing a **Medical services list**, to combine with the Home visit. The user can enter the services by hand, filling in all the compulsory fields.

Also for Home Visits it is possible to set Expressions (see "Service Manual" section 4.2.6) which, once satisfied, will enable the system to enter services automatically.

Click the button to set the PD Home Visit in "Closed" status. Here again, automatic generation of reports in PDF format can be associated with closure. Specifically, the expressions (see "Service Manual" section 4.2.9) defined in the "Configure PDF Export" section (see "Service Manual" section 4.2.7), which are enabled and valid for the current clinic, will be assessed.

If the Home Visit meets the expression criteria, the report associated with the valid expression will be generated automatically. Depending on the setup, the report may be exported via Filesystem and/or sent via cDL.

PDF reports created can be viewed in the "PDF export" section (see "Service Manual" section 4.2.8).

When the Home Visit status is "Closed", its data can no longer be edited. Press the Re-open button to "Reopen" the visit.

If the automatic generation of reports in PDF format have been configured and, in Power Tool, the "Filesystem Undo" option has been enabled, when "Re-opening" the PD Home Visit, the PDF file connected to the reopened PD Home Visit will be deleted/renamed (based on the action configured in Power Tool).

19.1.6 PD TREATMENTS

Peritoneal dialysis treatments consist of:

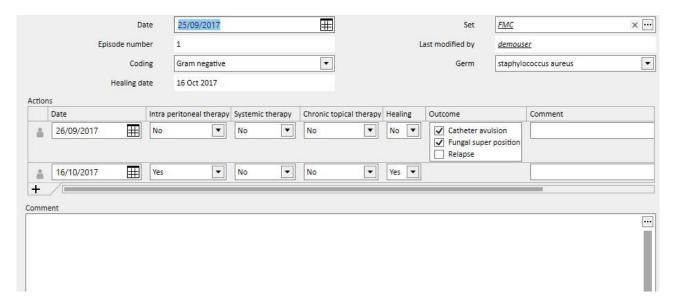
- Date: mandatory field that indicates when the treatment was performed.
- Status: treatment status. When the status is "Closed" the treatment can't be modified.
- Name of the prescription: a reference to the prescription.
- PD modality: a combined field that allows the user to choose between the three main methods of peritoneal dialysis. The field is automatically populated when the Name of Prescription field is set.
- Unique ID: field that uniquely identifies the treatment.
- Services: the list of the services associated with the treatment.

The treatments can be created from the patient menu or using the **PD scheduler** from the clinic menu.

Multiple PD treatments can be "closed" simultaneously from the section Close PD treatments in the clinic menu.

19.1.7 PERITONITIS

The **Peritonitis** section allows the user to introduce peritoneal inflammation with the respective **actions** to treat it. The section is divided into two parts: the first part summarizes the event, the second describes the actions taken by the medical staff.



The first part consists of the following fields:

- Date: the data that the event occurred.
- Set: the dialysis device defined in the dialysis prescription.
- Episode Number: an automatically incremented number that identifies the event.
- Coding: the coding of peritonitis.
- Germs: the type of germ that caused the peritonitis.
- Healing date: the date when the peritonitis is classified as resolved. This field is automatically filled in following an action of Healing equal to "Yes".

The second part lists all of the actions performed by the medical staff. Each action consists of:

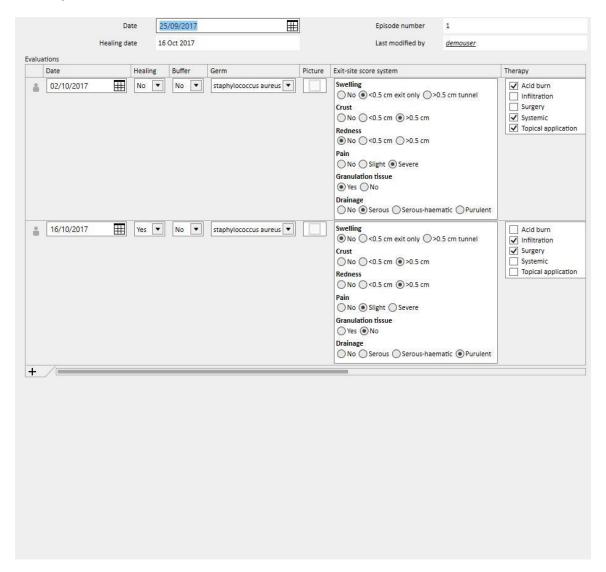
- Date: The date when an action was performed.
- Intra peritoneal therapy
- Systemic therapy
- Chronic topical treatment
- Healing: indicates if the action leads to the patient healing.
- Outcome: is only visible if not healed. There are 3 possible causes and they are not mutually exclusive ("Catheter removal", "Fungal superposition", and "Relapse").
- Comment: free text.

For each action, the user that created it is saved, as well as the last user who modified it.

It is not possible to enter actions that occurred after the date of healing.

19.1.8 TUNNEL EXIT SITE

The **Tunnel exit-site infection** allows the user to enter tunnel infections with their respective evaluations. This item is divided in two parts: the first summarizes the event, the second lists the medical evaluations.



The first part consists of the following fields:

- Date: the data that the event occurred.
- Episode Number: (automatically incremented) number that identifies the event.
- Healing date: the date when the infection is defined resolved. This field is automatically populated following a
 Healing assessment equal to "Yes".

The second part lists all of the evaluations performed by the medical staff. Each evaluation consists of:

- Date: The date when an evaluation was performed.
- Healing
- Buffer
- Germs: the type of germ that caused the peritonitis.

- Picture
- Exit-site score system: the values of the score can be personalised.
- Therapy
- Outcome: is only visible if not healed. There are 3 possible causes and they are not mutually exclusive (Catheter removal, Cuff removal, and Peritonitis)
- Ultrasound comment
- Comment
- Created by

For each evaluation, the user that created it is saved, as well as the last user who modified it.

It is not possible to enter evaluations that occurred after the date of healing.

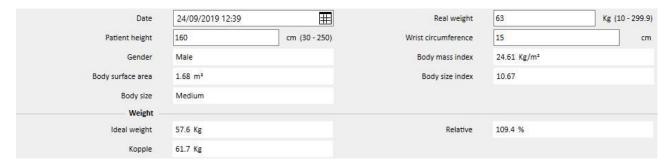
19.1.9 ADEQUACY AND NUTRITION

Adequacy and nutrition consists of different parts and are divided by topic.

19.1.9.1 GENERAL DATA AND WEIGHT

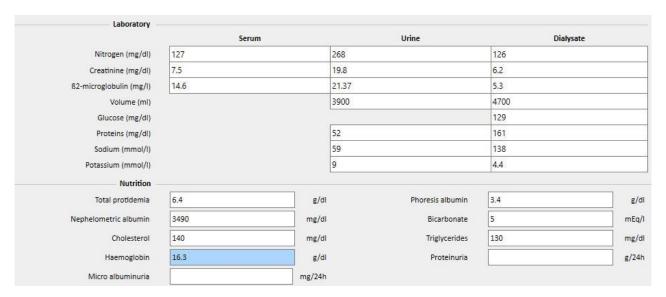
The first section is general and it is possible to indicate the **Date** of evaluation. The user can define medical data such as weight, height and circumference of the patient's wrist. Thanks to these values and to the information regarding the sex of the patient coming from the **Medical data** menu it is possible to determine the **Body mass index**, la **Body surface area**, the **Body size index** and the **Body size** of the patient.

The general data in the **Weight** section allow the definition of the **Ideal weight**, **Relative** and according to **Kopple**.



19.1.9.2 LABORATORY AND NUTRITION

The sections **Laboratory** and **Nutrition** allow the user to populate the input fields used to obtain the results displayed in the following sections. The **Laboratory** divides the entry data in three categories: **Serum, Urine** and **Dialysate**.

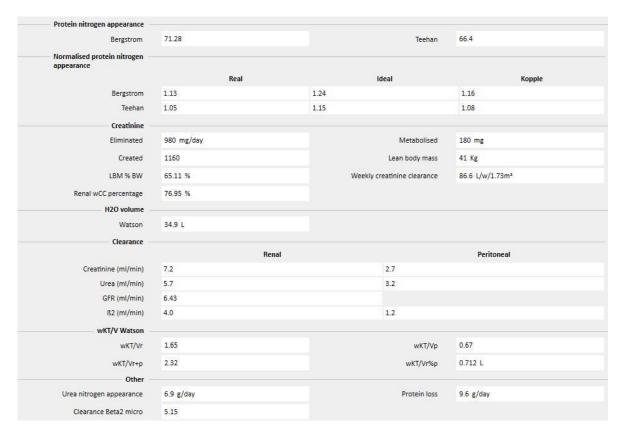


19.1.9.3 RESULTS

The results obtained from the data entered in the **Laboratory** and Nutrition sections are distributed in these sections:

- Protein Nitrogen Appearance (PNA)
- normalised Protein Nitrogen Appearance (nPNA)
- Creatinine
- H2O volume
- Clearance
- wKT/V Watson
- Other

Some results from these sections can be used as input data for processing in other sections. The formulas used as described in the document "TSS - PERITONEAL DIALYSIS FORMULAS" issued on request.

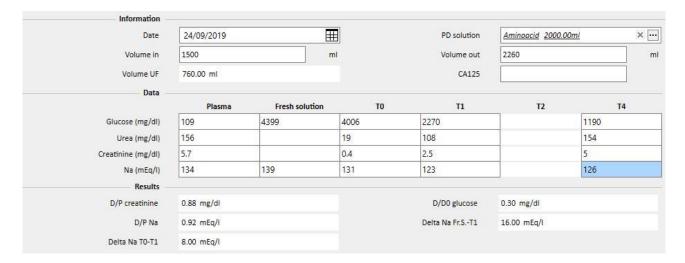


19.1.10 PET (PERITONEAL EQUILIBRATION TEST)

The **PET (Peritoneal Equilibration Test)** is divided into three parts. The first contains general information about the test, such as:

- Test date
- PD Solution
- Volume In and Volume out
- UF Volume (as the difference between Volume in and Volume out)
- CA-125

Instead, the second part allows the user to enter the levels of **Glucose**, **Urea**, **Creatinine** and **Sodium** in the **Plasma**, in the **Solution** and in three of the four time **T** intervals available.



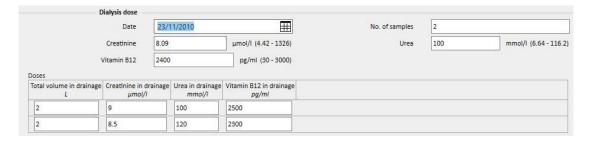
The T1 and T2 columns are mutually exclusive, therefore a value entered in any row of a column disables the other.

The results of the test appear in the third section called **Results**. The calculation does not consider the disabled column. The formulas used as described in the document "TSS - PERITONEAL DIALYSIS FORMULAS" issued on request.

19.2 PD LABORATORIES

19.2.1 DIALYSIS DOSE

This section calculates the results of a test on a Peritoneal Dialysis Dose. The **Creatinine**, **Urea** and **Vitamin B12** levels are taken from the last laboratory test. These data can be updated.



The **number of samples** must be specified in the relative field. This will automatically update the same number in the middle of the table. Once the table has been filled-in with the **Total volume**, **Creatinine**, **Urea** and **Vitamin B12** values of each sample, the system displays the results of the test.



19.2.2 FAST PERITONEAL EQUILIBRATION TEST (FAST PET)

The Fast Peritoneal Equilibration Test consist of two sections: the first receive the incoming data of the test, the second calculate the results. The **Test date** and the **Test duration** are filled in by default with the current date and the duration of four.

The following fields must be filled in:

- Residual kidney function around 200 ml;
- Glucose: Specify the blood glucose level;
- 2 litres volume PD standard: Specify whether a standard 2 litre bag was used;
- Creatinine in dialysis fluid: Creatinine level in the dialysis fluid;
- Glucose in the dialysis fluid: The quantity of glucose in the dialysis fluid;
- Blood creatinine: Creatinine level in the blood;
- Dialysis fluid volume at end of exchange: Dialysis fluid volume at the end of the four-hour test.

TSS calculates the values in the fast peritoneal test according to the fast peritoneal equilibration test guidelines.



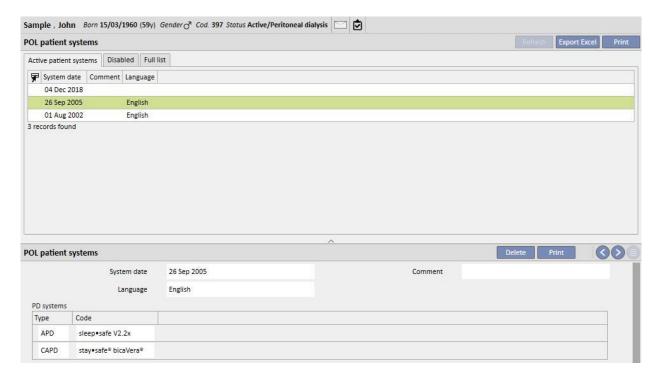
19.3 CHANGES TO FUNCTIONALITY IN CASE OF TSS-PATIENTONLINE INTERFACE

Through the installation of the appropriate plugin you can share data between the **TSS** and the **PatientOnLine** application (hereinafter POL). This interface changes and updates some features inside patient entities.

The TSS acts as the master of personal data, medical data, allergies and amputations. Therefore, any medical data modified on POL will not be sent to TSS. Below is a detailed description of the data that POL sends to TSS.

19.3.1 PATIENT SYSTEMS

TSS stores information about all the systems created by the POL application and used by the patient for peritoneal dialysis. If a system is changed in the POL application after it has already been imported into TSS, then it will be updated. If a system is deleted in POL after an export then in TSS it will be disabled during the next export.



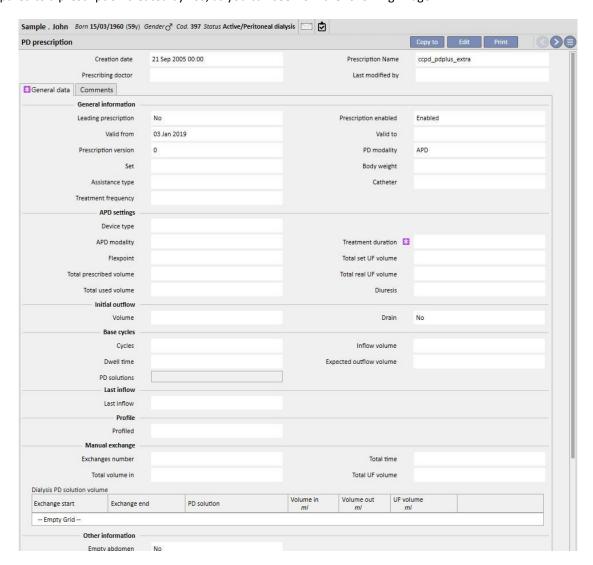
19.3.2 PD PRESCRIPTION

TSS stores all the prescriptions imported from the POL application in the **PD prescription** section. If a prescription is changed in the POL application after it has already been imported into TSS, then a new version of the same will be created. If a prescription is deleted in POL, it will not be deleted in TSS but will be disabled.

The prescriptions exported by POL will be stored in TSS as "Enabled" and as a non-principal prescription: when the POL Plugin is enabled, in fact, it is not compulsory to have the "Main prescription".

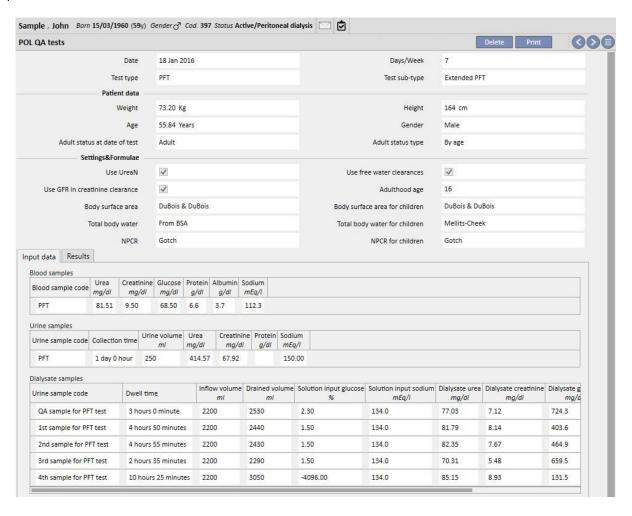
This constraint is also reflected in the Patient Summary section where, for a patient in peritoneal dialysis, all active prescriptions will appear in the prescription list instead of only in the main list.

Using the **Resource** field it is possible to understand if a prescription has been created by TSS or imported by POL. As far as the prescriptions imported by POL are concerned, the fields in the "PD Prescription" section are different, compared to a prescription created by TSS, as you can see from the following image:



19.3.3 QA TEST

TSS stores all QA Tests imported from the POL application in the "POL QA Test" section, including those in the "draft" state. If a QA Test is changed in the POL application after it has already been imported into TSS, it will be overwritten during the next export. Instead if a test is deleted in POL after an export then in TSS it will be disabled during the next export.



19.3.4 BCM DATA

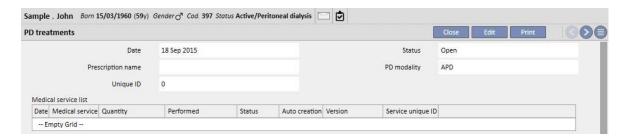
BCM data imported from the POL application is stored in the BCM section of TSS. If BCM data have already been imported from TSS, a subsequent export from POL of the same BCM data will not increase the number of entities present in the BCM section of TSS. If a BCM measurement is deleted from POL and then a new export is performed then the entry will be marked with **Have the measurements been deleted?** to "Yes".

19.3.5 TREATMENT RESULTS

POL sends the results of the treatments carried out to TSS. Treatments can be viewed in the **PD treatments** section. The **Resource** field allows you to identify the treatments created manually in TSS by those forwarded by POL. If a treatment previously exported to TSS is changed to POL and then re-exported, then it will be updated in TSS. If the treatment status is already "Closed" then it will be reopened and updated. A treatment removed from POL will not be modified in TSS.

The **Prescription name** contains the theoretical reference prescription used for the treatment. Since there is no certainty which prescription is used in the PD device, the field can be modified in TSS. In any case, TSS tries to associate one of the available prescriptions provided that the prescription:

- It was created in POL
- It has the same PD modality
- it is valid in the interval when the treatment took place
- is the only one to satisfy the above points



20 OPTIONAL MODULE: TRANSPLANTS

20.1 TRANSPLANT - PATIENT SECTION

20.1.1 WAITING LIST

This section shows the status of the waiting list for the transplant of each organ. The system manages the following organs:

- Kidney
- Pancreas
- Heart
- Liver

The waiting list is created for each patient by default and each organ is set in "Excluded" status.

The patient's waiting list can be modified if he or she is in one of the following dialysis statuses: Hemodialysis, Hemodialysis ICU, Hemodialysis Acute, Peritoneal Dialysis, Pre-Dialysis, Ambulatory, or Transplant follow-up.

The current status of each organ and the relative movements which generated the current status are shown in the first part of this section.



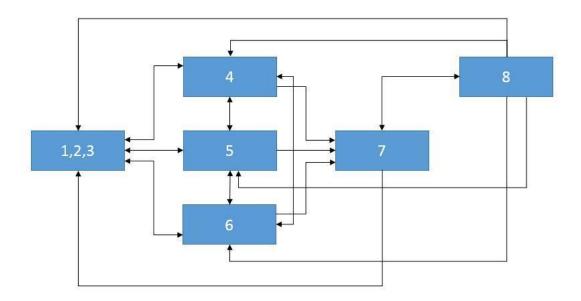
Waiting list movement ↑ Thompson , Josie Born 23/10/1950 (68y) Gender Q Cod. 166334 Status Active/Transplant follow-up Waiting list movement There is 1 error 24/09/2019 14:35 Date \blacksquare Responsible user demouser Waiting list status • Transplant unit ••• Transplant unit Kidney Pancreas Heart Liver Comment

A new movement can be entered by clicking the "New movement" button.

The user must compile the new **Waiting list status** and specify the organ (or organs) involved in the movement (at least one organ must be selected). The possible statuses are:

- Excluded
- Temporarily Excluded
- Excluded for transplant
- Pre-Included
- Pre-Study
- Under Study
- Included
- Call as Reserve

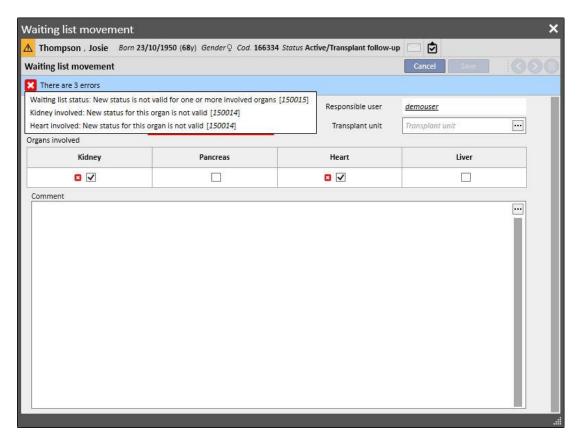
Transition from one status to another is not always permitted. The system checks that changes in status comply with the following workflow (the numbers correspond to the above list)



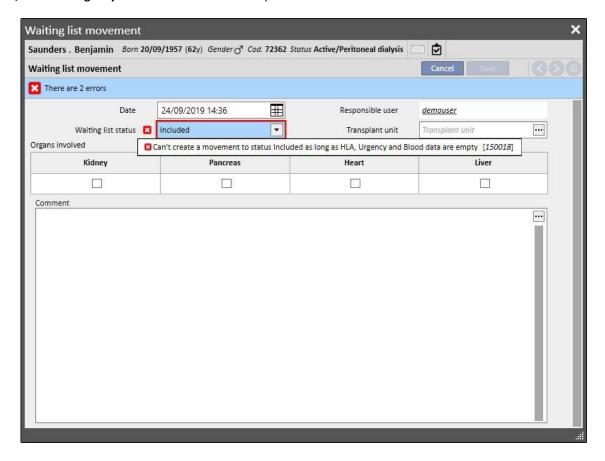
For example, if the organ is in **Excluded** (1) status, the new statuses permitted are **Pre-included** (4), **Pre-study** (5) and **Under study** (6). Direct transition from an **Excluded** status (1,2,3) to the **Included** (7) status is not permitted.

Similarly, if the organ is in **Included** (7) status, the new statuses permitted are **Call as reserve** (8) and all **Excluded** statuses (1,2,3).

The system allows the movement to be entered if all the organs it involves comply with the above workflow and the new status is not the same as the current one:



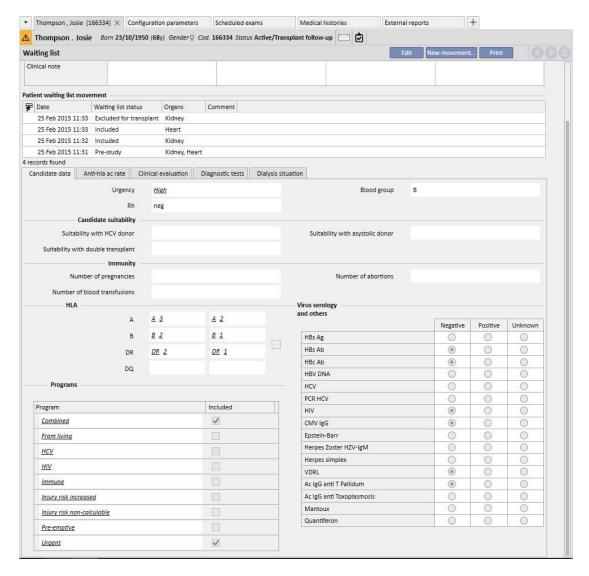
There is also a check which only allows "Included" status to be set if the information concerning **Blood group**, **Rh** factor, HLA and Urgency have been entered for the patient concerned.



The system also allow the entry of past movements which do not cause changes in the current status, unless they are the last movement for the organ concerned. The status, as of the date of the movement, must also comply with the above workflow for movements in the past.

After deletion of a movement entered previously, the system recalculates the current status of the waiting list.

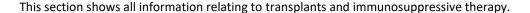
The second part of the **Waiting list** section contains the patient-related information that has to be compiled by the user. The patient's waiting list can be modified when at least one organ is in a status other than **Excluded**(1,2,3).

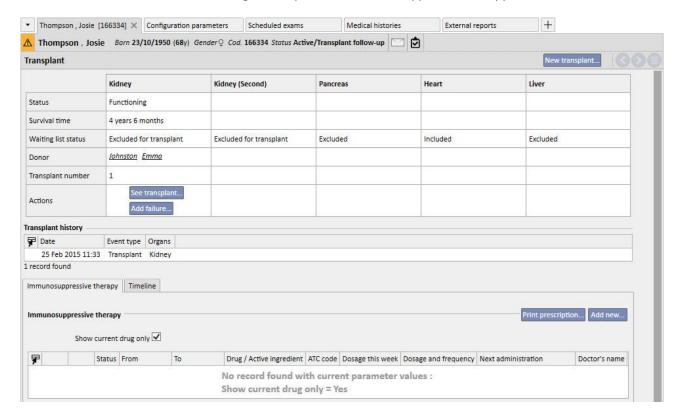


There are 5 tabs:

- Candidate data: contains information about the patient. It should be noted that, if already present, the Blood group and Rh Factor are automatically recovered by the system from the patient's medical data. If no values are available, the user must enter these two items of information before saving the waiting list, and the system will also automatically enter the corresponding values in the Medical data section.
- Anti-HLA AC rate
- Clinical evaluation
- **Diagnostic tests**: shows the patient's diagnostic tests performed since the date of the creation of the first waiting list status change movement.
- Dialysis situations: shows the current clinic, patient status, dialysis status, date of first dialysis and time passed since first dialysis.

20.1.2 TRANSPLANT





The first part of the section contains the **Transplant summary** divided by organ. The information displayed is:

- Status: shows the status of the transplant. It can have the following values: "Functioning" or "Failed".
- **Survival time**: shows the time which has passed since the transplant was performed. If the transplant has failed, it shows the length of time from the performance to the failure of the transplant.
- Waiting list status: shows the current status of the waiting list.
- Donor: shows the donor of the organ.
- Actions: shows the actions which can be taken. The user can display the information about the transplant and, if the transplant is in "Functioning" status, enter its failure.

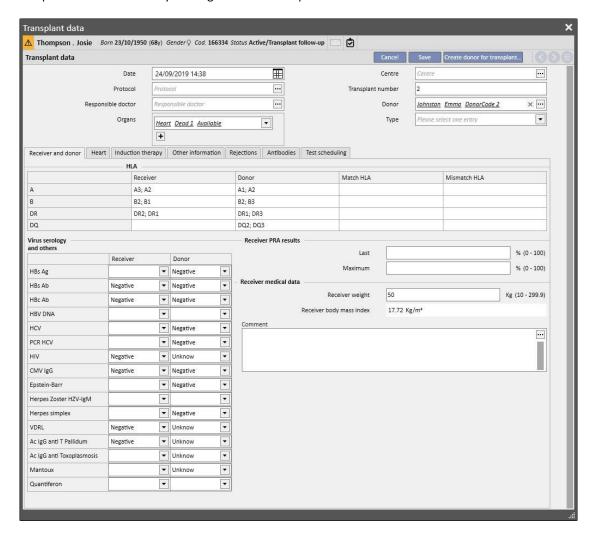
The "Transplant history" table shows all the events relating to the patient's transplants. Clicking each individual line allows the user to view the data relating to the transplant (or its failure).

The drugs administered to the patient as immunosuppressive therapy can be viewed in the "Immunosuppressive therapy" table. These drugs can also be viewed in the "Home therapy" part of the **Pharmacological prescription** section.

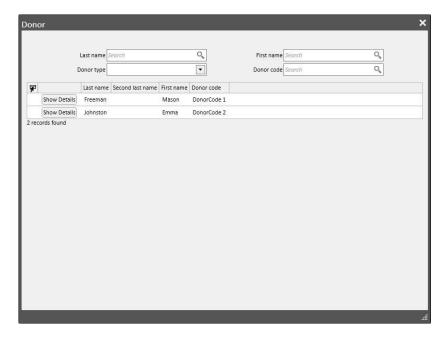
Pressing the "Add New" button enables the user to add a new drug for use in the immunosuppressive therapy. For instructions on the correct entry of the new therapy see the specific section.

20.1.2.1 ADDING A TRANSPLANT

A new transplant can be entered by clicking the "New transplant" button.

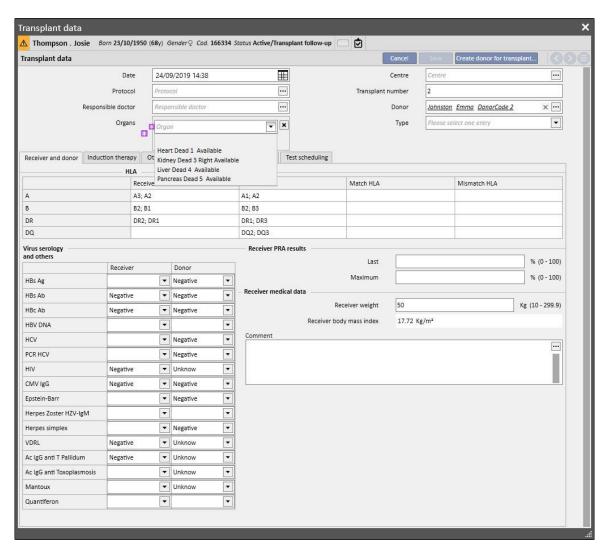


To enter a new transplant, the **Donor** must be defined.



All donors for which the donor data have been entered and who may have at least one organ in "Available" status are displayed. If a patient is defined as **receiver** in the data of a living donor, the latter is set as donor by default.

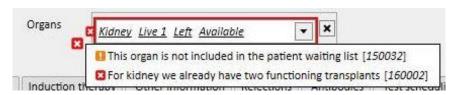
After setting the donor, the user must set the **organs** involved in the transplant. All the organs of the selected donor which are in "Available" status are shown.



The transplant may involve one or more organs. The system signals a warning if the selected organ is not in "Included" status in the waiting list:



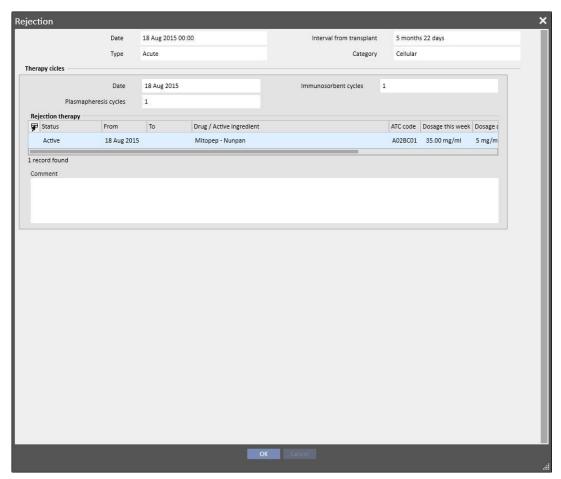
An error is signalled if the user selects an organ for which a still functioning transplant has already been entered:



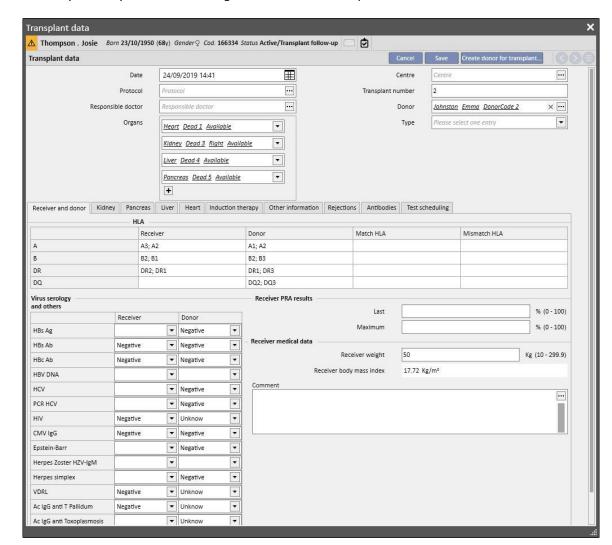
To enter a transplant, the following tabs must be compiled:

- Receiver and Donor: this tab allows comparison of the HLA and Serology between receiver and donor. Other
 information about the donor and receiver is also available.
- Induction therapy: this tab is used to enter the number of cycles of Plasmapheresis and add one or more drugs
- Rejections: this tab allows one or more rejections to be entered. Each rejection includes general information such as Date, Interval elapsed from transplant, Type and Category, and one or more Therapy cycles can also be added to the rejection. Each Therapy Cycle has Date, number of Immunosorbent cycles and number of Plasmapheresis cycles and one or more drugs can be associated to each therapy cycle





- Other information: this tab contains any information about histological tests and information about complications.
- Antibodies: this tab contains a list of one or more antibodies, each of them comprising a Date and the values
 of the class 1 and 2 HLA Antigen
- **Test scheduling:** this tab is used to schedule instrumental tests on the patient.



A tab is then dynamically added for each organ involved in the transplant:

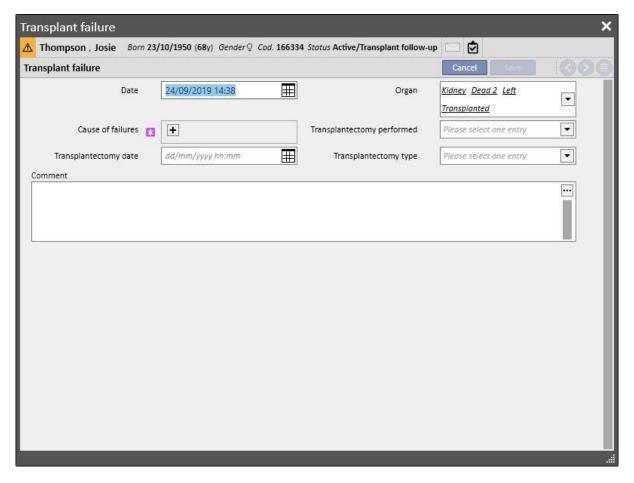
Saving a transplant triggers the following changes:

- The Transplant summary is recalculated. The organs involved in the transplant are set in "Functioning" status
- The "Transplant history" table is updated with the addition of a "Transplant" event.
- If the transplant involves a live donor, a movement which changes the donor's dialysis status is created. The new status set is "Donor"
- A movement which changes the receiver's dialysis status is created. The new status set is "transplant follow-up"
- For each organ involved in the transplant, a movement is entered in the "Waiting list" which changes the status to "Excluded for Transplant"
- For each organ involved in the transplant, the organ's status is changed from "Available" to "Transplanted" in the donor's data.

The system also allows past transplants to be saved for the management of any historic records. In this case, if the transplant entered is not the last in chronological order at the level of the individual order, saving the transplant does not cause any change in the **Transplant summary.**

20.1.2.2 ADDING A FAILURE

A transplant failure can be entered by clicking the "New Failure" button. Unlike a transplant, a failure is added at the individual organ level.



To save a failure, the user must define the organ involved in the failure and specify the cause of the failure.

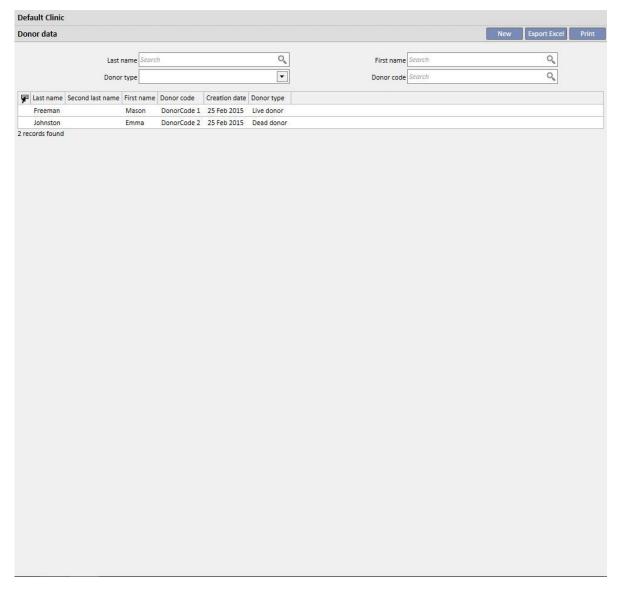
Saving a failure triggers the following changes:

- The Transplant summary is recalculated. The organ involved in the failure is set in "Failed" status
- The "Transplant history" table is updated with the addition of a "Failure" event.
- A movement is entered in the "Waiting list" which changes the status to "Pre-Included"
- For each organ involved in the transplant, the organ's status is changed from "Transplanted" to "Failed" in the donor's data

20.2 TRANSPLANTS - CLINICAL SECTION

20.2.1 DONOR DATA

The "Donor data" section allows the user to manage organ donors within the system.



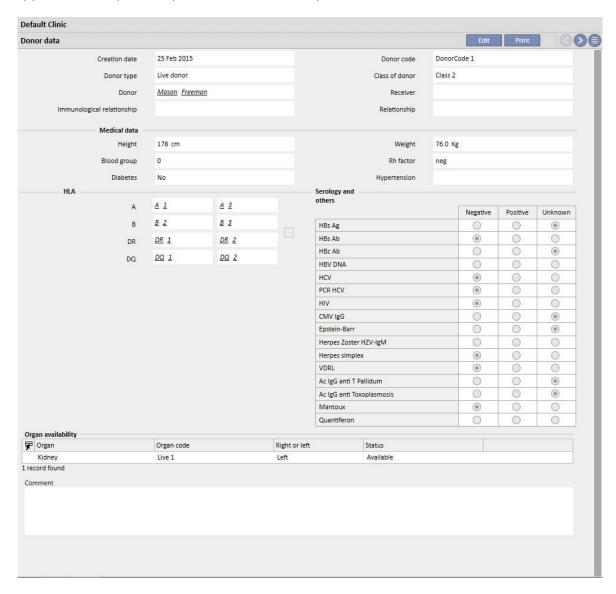
A new donor can be entered by clicking the "New" button.

The system manages two types of donor:

- Live Donor
- Dead Donor

20.2.1.1 LIVE DONOR

To enter a live donor, the "**Donor type**" field must be set at "Live donor". In this case, the live donor must be a patient already present in the system. All patients for whom the dialysis status is set as "**Donor candidate**" are candidates.



If the "Designer" role is enabled, the "Immunological Relationship", "Donor class" and "Relationship" field values (selectable through the drop-down menu) can be customized by clicking on the small pencil icon displayed inside the relevant field. More details can be found in section 4.5.1 of the "TSS Service Manual".

The system also checks that the donor and receiver are not the same patient.

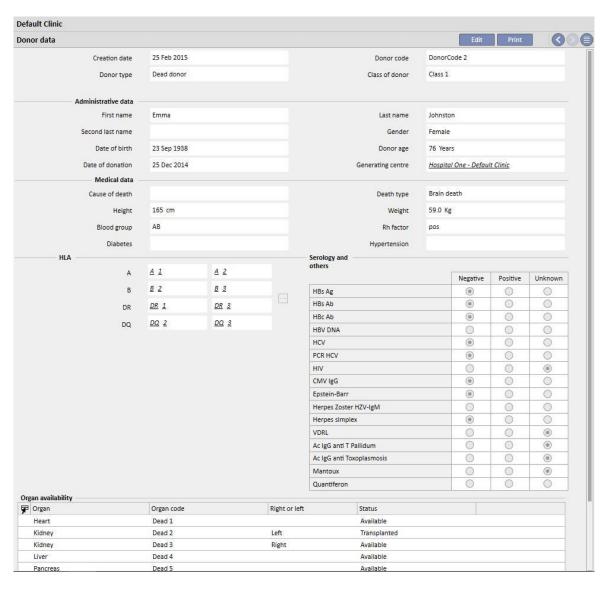


If values are already entered in the **height, weight, blood group and Rh factor** fields, these are the data already entered in the patient's **medical data** section. If the user modifies one of these fields and saves the donor's data, the system asks the user if he also wishes to update the medical data.



20.2.1.2 DEAD DONOR

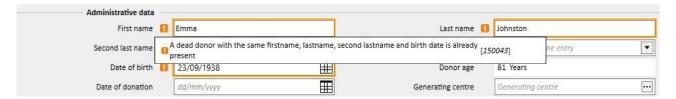
To enter a dead donor, the "Donor type" field must be set at "Dead donor".



In this case the user must enter the administrative data (first name, last name, second last name, gender, date of birth).

The user can also enter medical data such as weight, height, blood group, Rh factor, etc. for dead donors.

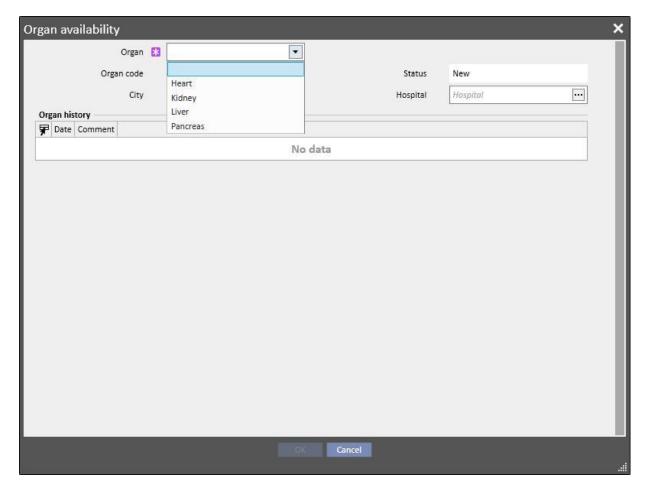
The system shows a warning message if a dead donor with the same first name, last name, second last name and date of birth is already present.



If the "Designer" role is enabled, the "Donor Class", "Cause of Death" and "Type of Death" field values (selectable through the drop-down menu) can be customized by clicking on the small pencil icon displayed inside the relevant field. More details can be found in section 4.5.1 of the "TSS Service Manual".

The other information present in this section, relevant for the donor (whether live or dead) is the **HLA** and **Serology**. This information will be compared with the receiver's details during creation of the transplant.

The user must add the donor's transplantable organs in the organ availability section.

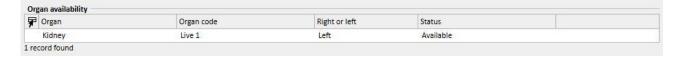


For a live donor, only a single Kidney can be transplanted (specify whether right or left)

For a dead donor, the following organs are transplantable:

- Kidney (specify whether right or left or whether both can be donated)
- Liver
- Heart
- Pancreas

When one or more organs are added and the donor's data have been saved, the organs are set in "Available" status.



For each organ involved in a transplant, the organ's status is changed from "Available" to "Transplanted"

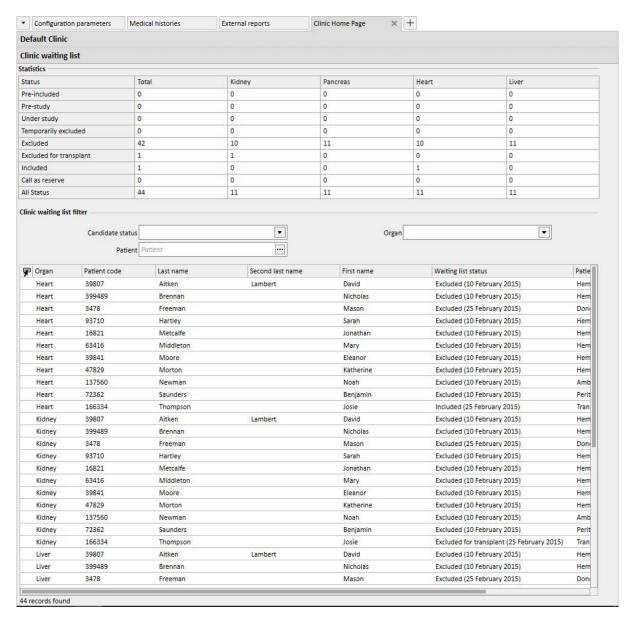


In the event of the failure of a transplant, the status is set as "Failed"



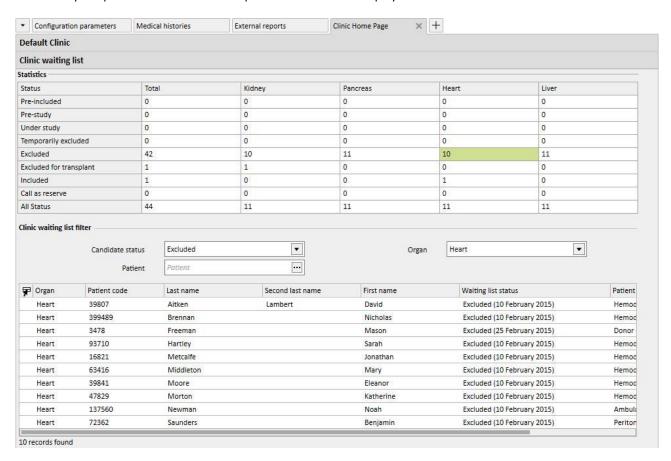
20.2.2 CLINIC WAITING LIST

The "Clinic waiting list" section shows all the information concerning the status of the waiting lists of all the clinic's patients.



The "Statistics" table indicates the number of patients in a given waiting list status for a given organ.

When the user clicks on a box in the "Statistics" table, the system automatically sets the filter of the view underneath so that only the patients who meet the required conditions are displayed.



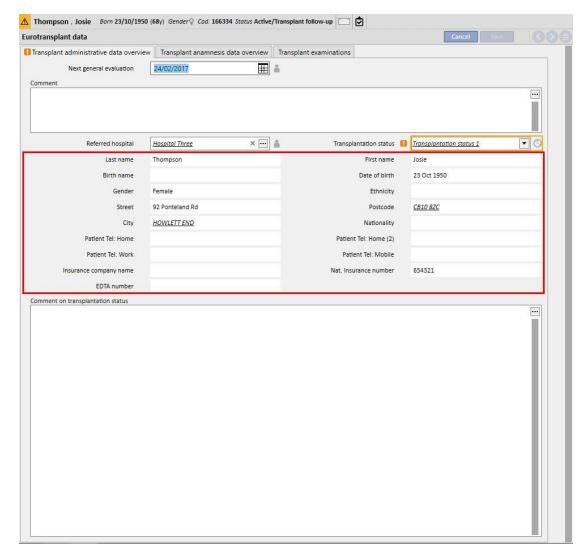
21 OPTIONAL MODULE: EUROTRANSPLANT

21.1 EUROTRANSPLANT DATA

21.1.1 TRANSPLANT ADMINISTRATIVE DATA OVERVIEW

The Eurotransplant section shows all the patient's significant data for Eurotransplant, and comprises 3 screens, divided into TABs:

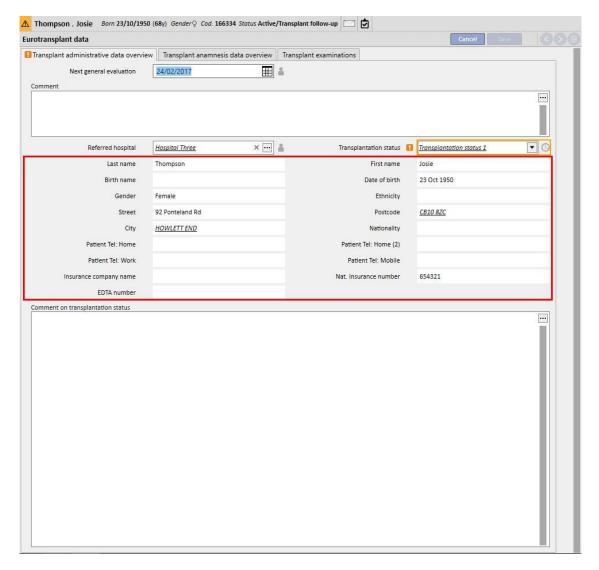
- Administrative data overview: shows general administrative data of relevance for Eurotransplant
- Patient history summary: shows the patient's medical history data valid for Eurotransplant.
- Transplant examinations: shows the list of the examinations performed for Eurotransplant.
- The Administrative data overview screen contains various fields containing the patient's details, others
 editable and relating only to Eurotransplant and others read-only and taken from the Administrative data
 section (red box).



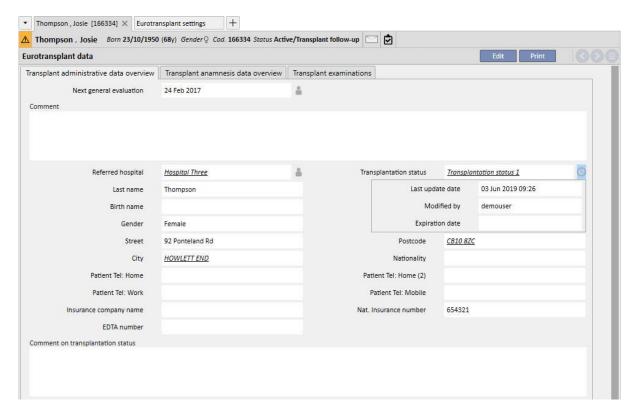
- Apart from the standard validation originating from the type of value stored, some fields in the Eurotransplant section have additional validation arising from the period of validity of the field itself.
- To allow some data to be constantly updated, for some fields the date of the latest change is saved and a validity period is set.
- Once the current date is after the expiry date of the field, a validation warning appears on the field concerned.
- The period of validity of these fields can be defined in the Master Data section and can be specific for a defined "Referral hospital" and are valid for all the patients (see section 4.2.12 of the Service Manual).

We will now take a detailed look at this new type of validation:

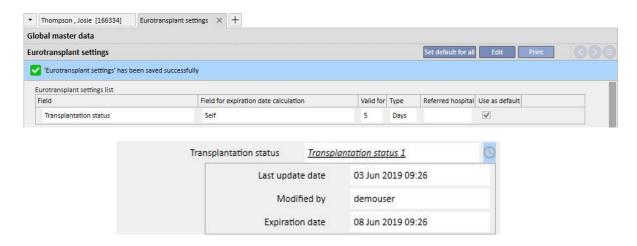
 When the Eurotransplant section relating to a patient is opened for the first time, the fields are empty, with no validation



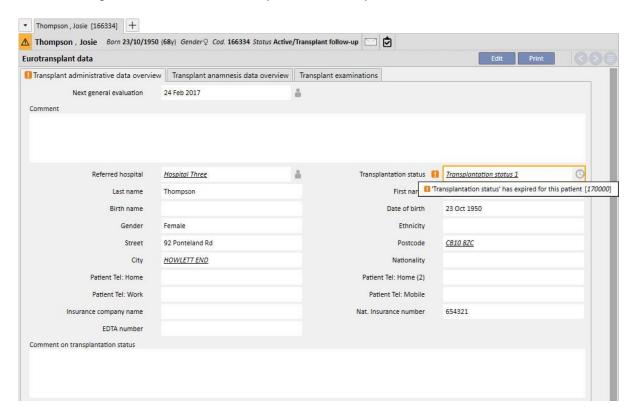
- In this phase the fields with expiry dates cannot be distinguished, so fill in the editable fields in the Transplant Administrative Data Overview screen and save them.
- A clock icon now appears next to the Transplant status field, indicating that this field has an expiry date. This icon is a button, which opens a pop-up menu with 3 values: Last modification date, Modified by and Expiration date.



- The Last modification date is the date when the field was last changed/set, Modified by contains the user who last changed/set the field and the Expiration date is the sum of the Last modification date + Validity period of the field, set in the Master Data section.
- No validity period has been set for the Transplantation Status, so the Expiration Date is empty and the validation is ineffective.
- If a validity period of 5 days is set for the Transplantation Status in the Master Data section, the situation will be as follows

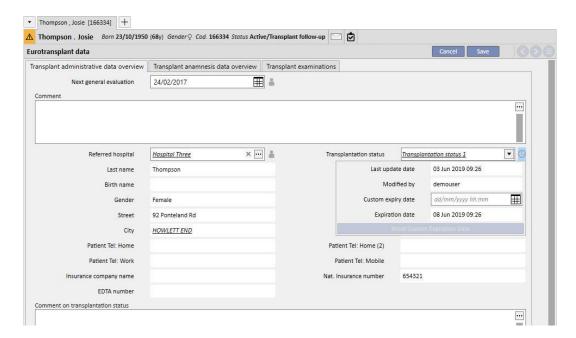


- At this point the validation becomes effective and the value is accepted because the current date has not exceeded the expiration date (in fact, no warning icon is displayed).
- If no change is made to this field for 6 days, on the sixth day this situation will arise.

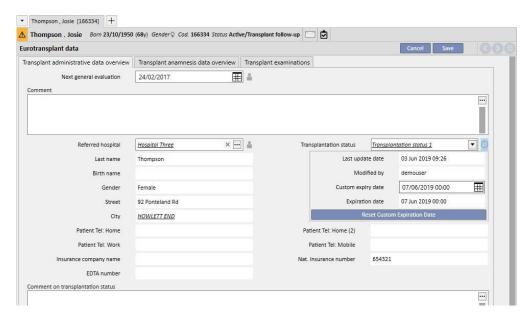


- In this case, we can see that the expiration date validation has failed for this field. The validation is a warning and does not prevent saving of the form.
- The warning informs us that the value we have added is "out of date", so it must be updated so that it is more recent and therefore more reliable. In this case, we can switch to form edit mode and select the new value corresponding to the current date (if the value is still the same, simply select another one and them reselect the current one).

The validation now disappears and the latest update date will be the current date.

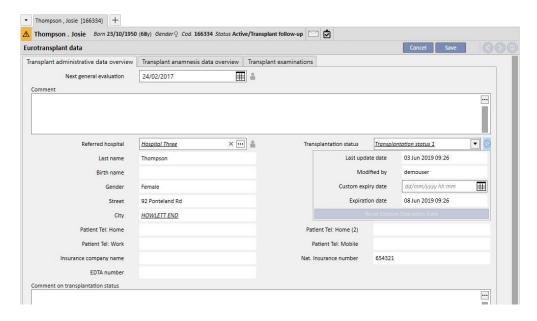


- The pop-up menu therefore shows the current date as the **Last modification date** and the new **Expiration date**; there is no longer a warning on the field, so once the form has been saved the field will be updated correctly.
- To allow the warning to be eliminated even if the up-to-date value is not available for the patient, the user can extend the expiry date of the field concerned for the current patient only, without changing the field's validity period (which can be set from the Master Data section), since this applies to all the patients.
- To do this, set the new expiry date in the Custom expiration date field in the pop-up menu.

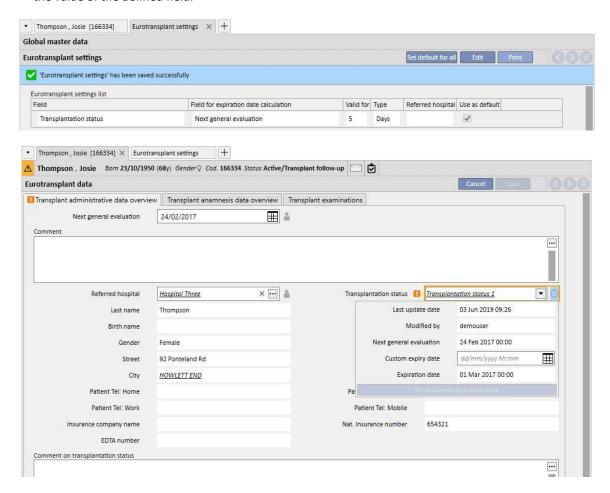


- The Expiration Date will now be the same as the Custom Expiry Date just set, and the warning will therefore disappear. The form must be saved to render the changes effective.
- In some case it will be necessary to delete the Custom Expiry Date to enable the validity period set at the general level to regain control of the Expiration Date. This can be done by clicking the Reset Custom Expiration Date button in the pop-up menu.

• To set and reset the Custom Expiry Date, the user must have been awarded the necessary rights by means of FME User Management and the form must be in Edit mode.



When in Master Data the settings are that the expiration date is calculated based on the value of another
field instead of the last change date of the field itself (see section 4.2.12 of the Service Manual), the popup
will show the last update date (which in this case is not used for the calculation of the expiration date) and
the value of the defined field.



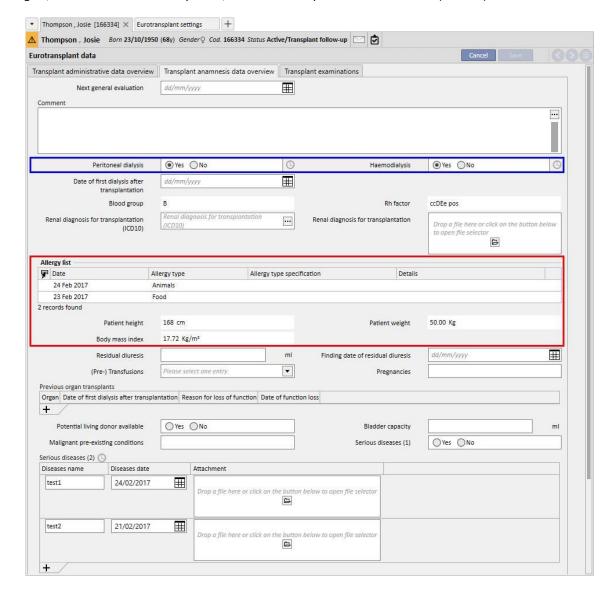
Expiry date management and validation is possible for all Eurotransplant section fields with the clock icon beside them, exactly as described for the Transplantation Status field. For fields with the icon of the human figure next to them, only the user who made the last modification to the field is saved, with no date validation system.



21.1.2 TRANSPLANT PATIENT HISTORY SUMMARY

The central tab of the Eurotransplant section contains a number of fields relating to the patient's medical history. Many of these data must be kept constantly up to date, and their expiry date is therefore managed exactly as for the Transplantation Status, as described in the previous point (blue box).

Here again, there are some read-only fields, taken from the patient's Medical Data (red box).



Note that this section contains the "Serious Diseases (2)" field, which is a table and has expiry date validation. In this case the field is considered to have been updated whenever any field of any line of the table is changed, when a new line (even an empty one) is added or when a line is deleted.



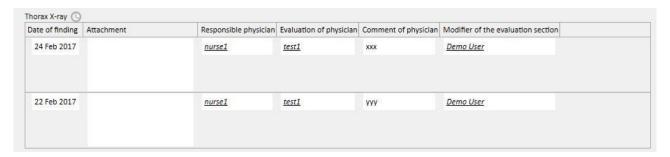
All table fields with expiry date validation behave in the same way as "Serious diseases (2)".

21.1.3 TRANSPLANT EXAMINATIONS

The third tab of the Eurotransplant section contains a long list of fields, most of them of table kind, referring to the patient's examinations (e.g. X-rays, CAT scans, coronary artery angiograms, etc.). All these fields always have to be up to date, so they all have expiry date validation.

Every line of these examinations has the same structure:

- Date of finding: date field relating to the current line
- Attachment: any document attached to the line
- Responsible doctor: doctor responsible for the current line (clinic staff member)
- Doctor's assessment: drop down menu configurable from Master Data (see section 4.2.12 of the Service Manual) containing the physician's evaluation relating to the current line
- Comment of physician: free text field for entering the physician's comment
- Modifier of the evaluation section: the user who last updated the "Evaluation of physician" field of the current line (a value is set automatically by the system)



This part of the form contains a series of read-only values taken from the patient's Laboratory data.

Unlike the administrative data and patient history data, which are unique for the patient, each laboratory parameter contains a set of fields, some with values and others without, and they are repeated over time. In this section, we show a subset of these fields (useful for Eurotransplant) with the date of last update for each field.

In the form below, we can see that the **HBs Ag, HBs Ab Value, HIV status** and **HIV status (ELISA)** values were entered in the Laboratory data of 17/08/2010, and the **HBs Ab** in the Laboratory data of 14/04/2009

HBsAc (mu/mL + Alpha)			Hbs Ag	Negative	(17/08/2010)
HBs Ab		(14/04/2009)	HBs Ab Value	46.80 IU/L	(17/08/2010)
Hbc Ab			HBe Ag		
HBe Ab			HIV status	Negative	(17/08/2010)
HIV2 status			HCV status (RIBA or western blot)		
HCV status (RT_PCR)			HCV Rna		
HCV status (ELISA)	Negative	(17/08/2010)	Cytomegalovirus CMV IgG		
Cytomegalovirus CMV IgM			Epstein-Barr virus EBV IgG		
Epstein-Barr virus EBV IgM			Toxoplasmosis IgG		
Toxoplasmosis IgM			VDRL		
Herpes simplex IgG			Herpes simplex IgM		
Herpes zoster HZV-IgG			Herpes zoster HZV-IgM		
Homocysteine					

22 APPENDIX

22.1 CHANGE THERAPY MONITOR SESSION PRESCRIPTION

This chapter explains the procedure to be followed to solve the problem caused in case of the following scenario:

- A user creates a new session for a patient on Therapy Monitor, and a 5008 prescription can be downloaded from the Therapy Support Suite because it is currently scheduled for that patient.
- For some reason it might be necessary to change the prescription for a Therapy Monitor session in order to work with a 4008 device (for example, a working 5008 device is currently not available at the site).

There are two possible solutions:

If there is no treatment in the Therapy Support Suite, the solution is the following:

- Create a new prescription in Therapy Support Suite for the desired device (for example 4008)
- Schedule it for the selected patient