

Therapy Monitor

Instructions for Use

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1 Important information

1.1 Introduction

These Instructions for Use contain all the necessary information for running the **Therapy Monitor** software system. Before using the software, users must have been instructed by the manufacturer on how to use the software and must be thoroughly familiar with the contents of the Instructions for Use.

This manual serves as a reference guide should questions arise during day-to-day work.

The software must only be used by users who have been instructed in its proper operation and handling.

The **Therapy Monitor** system consists of the **Therapy Monitor** client (comprising the graphical user interface), the FME User Management, the dataXchange panel - dXp (5008/6008 bedside monitoring) and the FIS (Fresenius Interface Server) communication server. The FIS functionality and operation is not part of these Instructions for Use.

The **Therapy Monitor** client fulfills the following requirements:

- Documentation of the hemodialysis treatment in a dialysis center.
- Visualization and input of treatment data. Treatment data is primarily provided online, but can also be entered manually.
- Assistance functions for calculations, such as determining required ultrafiltration parameters based on the current weight of the patient.
- Front-end user application for an external dialysis database, adapted to the requirements and user permissions of nursing staff, the scope and functionality of which is related to the execution of dialysis treatments.

Version

This current issue of the Instructions for Use is valid as of **Therapy Monitor** Version 2.3.

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1.2 How to use the Instructions for Use

Purpose

This manual is intended for:

- study
- reference purposes

Changes

Changes to the Instructions for Use will be released as new editions, supplements, or product information.

In general, this manual is subject to change without notice.

1.2.1 Significance of warnings

Advises the operator of hazards that carry the risk of serious to potentially life-threatening bodily injury to persons, unless the measures for avoiding the risk described are followed.



Warning

Type and cause of risk

Possible consequences of exposure to the risk.

➤ Measures for avoiding the risk.

Warnings can deviate from the above template in the following cases:

- If a warning describes several risks
- If no specific risks can be detailed in the warning

1.2.2 Significance of notes



Note

Advises the operator that failure to observe this information can result in the following:

- Damage to the device
 - Required functions will not be executed at all or not executed correctly
-

1.2.3 Significance of tips



Tip

Information providing useful tips for easy handling.

Important instructions regarding operation

If the verification of patient data reveals a deviation between parameters prescribed by the physician and those displayed by the dialysis device, users must check and correct the system's default settings before starting treatment.

Values displayed on the dialysis device must be compared with the physician's prescription.



Warning**Risk for the patient as a result of wrong treatment parameters**

If the user forgets to save manually changed UF data, changed data will not be used in the upcoming treatment.

- Manual changes of the UF data must be saved in order to become effective.
 - The user is responsible for data handling.
-



Warning**Risk for the patient as a result of wrong treatment parameters**

Entering incorrect UF data can lead to a wrong treatment of the patient.

- Users must make sure that the entered data is correct and that no wrong values are entered.
-



Warning**Risk for the patient as a result of wrong treatment parameters**

Manually changed data might not be saved correctly to the server in case the input or transmission is impaired by software or hardware errors, thus leading to a wrong treatment for the patient.

- Users must check that the displayed data after saving corresponds to the entered information.
 - If displayed data does not correspond to the entered information, the user has to re-enter the correct data, save it and check again.
-

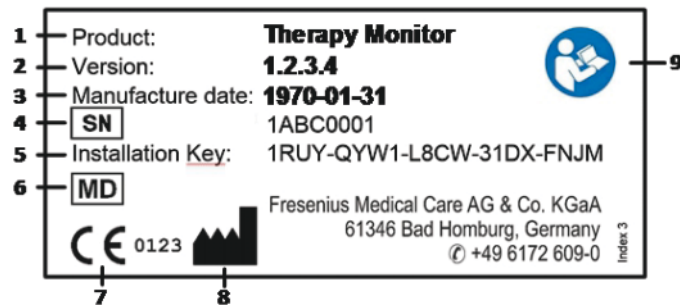


Warning**Risk for the patient as a result of wrong treatment parameters**

In case the server is offline, entered data cannot be saved correctly. As a result, changed data will not be used in the upcoming treatment.

- Manual changes of the UF data must be saved on the server to become effective. Therefore a correct server connection is mandatory.
 - The correct server connection is indicated by the green status indicator signal at the bottom right corner of the screen.
 - A missing connection is indicated by a red signal.
 - User should be aware that loss of data cannot always be prevented.
-

1.3 Identification label



1. Product
2. Version
3. Manufacture date (Build date of the software product)
4. Serial Number
5. Installation Key
6. Medical Device
7. CE Mark
8. Manufacture contact information
9. Follow Instruction for Use

1.4 Glossary

This glossary is a list of terms and abbreviations frequently used in this documentation. Each of these terms is briefly explained:

Active session

A session is active if a dialysis treatment and/or documenting activities carried out by the nursing staff are currently taking place. After all activities are completed, the session is closed and all related data is transferred to the EDBMS. Only active sessions can record data from devices or from staff input.

Closed session

A session that can no longer record data from devices and from user input. Closed sessions are used for documentation and statistics purposes.

EDBMS

External Database Management System

FIS

Fresenius Interface Server

Patient identification card

This card contains a patient ID for automatically logging the patient on to the system.

Session	Data entity that corresponds to a single patient and a single dialysis treatment. All data recorded from devices or manually input by the nursing staff is attached to a certain session. A session can have two states: active and closed.
TMon	Therapy Monitor

1.5 Program description

The program provides a GUI (graphical user interface) for the users.

This software fulfills the following requirements:

- Documentation of the hemodialysis treatment.
- Visualization and input of treatment data. Treatment data is primarily provided online, but can also be entered manually.
- Assistance function for calculations, such as the determination of required ultrafiltration parameters based on the current weight of the patient.
- Front-end user application for an external dialysis database, adapted to the requirements and user permissions of nursing staff, the scope and functionality of which is related to the execution of dialysis treatments.

1.6 Intended purpose

1.6.1 Medical purpose

- The purpose of the **Therapy Monitor** is to acquire, calculate, save, display and transfer parameters of dialysis treatments. It is a multi-user dialysis monitoring and quality assurance system running as a client-server application on a Windows platform.
- Its main task is the collection and administration of treatment-specific data for documentation and evaluation by the doctor.
- Data can be acquired automatically from connected medical devices and via import from an external database. Furthermore, data can be entered into **Therapy Monitor** manually via the client workstation or the dataXchange panel. Derived parameters can be calculated by **Therapy Monitor** itself, based on these inputs.
- All treatment data is saved locally and can be additionally transferred to an external database, for further processing.

1.6.2 Intended patient population

The patient population is defined by the compatible HD devices.

1.6.3 Intended user / environment

- The system will be used by physicians and nursing staff.
- **Therapy Monitor** is not intended to be used by patients.
- The system can be used in stationary clinical areas as well as in ambulatory dialysis wards.
- The installation of the **Therapy Monitor** must be performed by an authorized technician.

1.6.4 Side effects

None

1.6.5 Contraindications

None

1.7 Interaction with other systems

➤ Dialysis Systems:

- 4008 family with:
 - UDL INTERFACE 4008 or
 - BSL 2001i + Cardbox or
 - Option Network and card reader
 - 5008 family
 - 6008 family
 - 2008 family with:
 - UDL EXTERNAL DEVICE
 - Genius
- Scales with:
 - UDL EXTERNAL DEVICE or
 - BSL 2001e
 - Blood pressure monitor with BSL 2001e
 - Ionometer with BSL 2001e
 - External Database Management System (EDBMS): The **Therapy Monitor** data exchange function allows data import and export from/to an External Database Management Systems.
 - PC-Hardware and Server Environment: The **Therapy Monitor** system requires the complete installation of a FIS communication server.

1.8 System requirements

The **Therapy Monitor** system requires the complete installation of a FIS communication server.

The installation of the **Therapy Monitor** must be performed by an authorized technician.



Note

The **Therapy Monitor** must only be used in connection with the dialysis systems 4008 H/S from software version 2.50, 4008 E/B from software version 4.50, 4008 V10 with software version below 11.8, 4008 V10 with network and card reader option from software version 11.8, 5008/5008S from software version 3.52 and 6008.



Warning

Risk for the patient as a result of corrupted data

Therapy Monitor can only work properly when all hardware and software requirements are met and the installation and configuration of all **Therapy Monitor** components were correctly performed.

- PC hardware and software requirements as well as installation and configuration instructions can be found in the **Therapy Monitor** Service Manual.
- Installation and configuration must be performed by a qualified service technician.

1.9 IT Environment

Therapy Monitor is a complex client-server medical software application, working within a hospital IT network that includes dialysis devices, scales, analytic devices, application servers, Web servers, database servers, client work-stations, as well as a large range of network equipments (switchers, routers, plugs, connection cables, etc.).

There are clear IT requirements (hardware and software) for each component of such a complex network.

For details of the IT environment that **Therapy Monitor** needs to operate, please see the **Therapy Monitor** Service Manual, Chapter 5 'IT Environment'.



Note

We recommend a 19" monitor. Resolution should be 1280 x 1024 at 19". Font size should not be scaled but left at normal size (100%). Other settings may result in some letters being cut off when displayed.



Note

A PC operated within the patient environment must comply with the standard according to EN60601-1.

1.10 Operation



Warning

Risk for the patient as a result of corrupted data

Risk for the patient as a result of a wrong therapeutic decision

A software or hardware error can lead to corruption of treatment data displayed by **Therapy Monitor**. Based on this incorrect data, wrong therapeutic decisions can be made.

- The treatment data received from the device does not take the place of good clinical judgment. The patient and all available data should be assessed by the physician.
-



Warning
Risk for the patient as a result of a wrong therapeutic decision

Software and hardware errors can cause a loss of data when device data is exported to the external database management system. A clinician monitoring the patient with the help of data displayed in the external database management system will not notice this data loss and might therefore miss important events happened during the monitored treatment.

- Do not monitor the patient via the external database management system, only.
 - Device data exported during treatment (from **Therapy Monitor** to the external database management system) is for documentation only.
-



Warning
Risk for the patient as a result of unnoticed alarm signals

Network problems can interrupt the connection between a dialysis device and the **Therapy Monitor** system. Thus the transmission of alarm data of a dialysis device can be delayed or lost on its way to the **Therapy Monitor** system.

- Users must ensure that they are close enough to the dialysis device to notice all alarms and warnings it signals.
 - Dialysis device alarms and warnings must not be monitored via **Therapy Monitor**.
-



Note

The TMon system must only be used by qualified, trained staff.

Permanent data changes may only be conducted in the EDBMS.




Note
External connection options

Any additional equipment connected to medical electrical equipment must comply with the relevant IEC or ISO standards (e.g., IEC 60950 for information technology equipment). Furthermore, all configurations must comply with the requirements of the standards for medical electrical equipment (see IEC 60601-1-1 or clause 16 of the 3rd edition of IEC 60601-1 respectively). Anybody connecting additional equipment to medical electrical equipment is considered a 'system installer' and is therefore responsible for ensuring that the configuration complies with the standards for medical electrical equipment. Note that local laws take priority over the above-mentioned requirements. If in doubt, consult the technical service department or your local representative.

1.11 Referenced documents

- 4008 Instructions for Use
- 5008 Instructions for Use
- 6008 Instructions for Use

1.12 Reporting of incidents

Within the EU the user must report any serious incident that has occurred in relation to the device to the manufacturer according to labelling () and the competent authority of the EU member state in which the user is established.

1.13 Certificates

Therapy Monitor is a class IIa medical device according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

The current versions of the EC certificates will be provided by your local service support organization on request.

1.14 SVHC (REACH)

For SVHC information according to Article 33 of Regulation (EC) No. 1907/2006 ("REACH") please use this page:

www.freseniusmedicalcare.com/en/svhc



1.15 Disposal regulations

Dispose the product and its packaging in accordance with local disposal regulations. No special precautions must be taken to dispose the product and its packaging safely.

1.16 Help and support

Please address any inquiries to:

Manufacturer

Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg
+49 6172 609-0
www.fmc-ag.com

**Service
Central Europe**

Fresenius Medical Care Deutschland GmbH
Geschäftsbereich Zentraleuropa
Projektierung & Support Dialyse-IT-Systeme
Steinmühlstraße 24, Anbau 1
61352 Bad Homburg
Germany
Phone hotline: 06172 609 7000
Fax: 06172 609 7106
E-mail: dialysis-it@fmc-ag.com

1.17 General Data Protection Regulation (GDPR)

1.17.1 GDPR compliant-usage

GDPR (General Data Protection Regulation) is a law imposed in the European Union. **Therapy Monitor V2.3** allows a full **GDPR** compliant usage. The following **GDPR**-relevant features are implemented in **Therapy Monitor**:

- All personal patient data in the **Therapy Monitor** database is encrypted;
- All personal user data in the **FME User Management** database is encrypted;
- All communication between client applications like **Therapy Monitor Client**, **dataXchange panel**, or **FME User Management Tool** and the FIS server is encrypted;
- Integrity of all communication is secured by means of specific technical features, such as a cyclic redundancy check;
- Personal patient data is used only when it is strictly needed, for example when it is mandatory and vital to correctly identify the patient;
- Patients can request a printed report of all their personal and medical data that was processed by **Therapy Monitor**, over any given time period. This is achieved by a **GDPR**-specific menu item that extracts data from the **Therapy Monitor** database and exports it to a printable format (PDF);

- Patients can request that their personal data is anonymized/deleted in **Therapy Monitor**. This is achieved by a **GDPR**-specific menu item that can anonymize personal patient data or fully delete patient data in/from **Therapy Monitor** database;
- Patients can request a copy of their personal and medical data from **Therapy Monitor**, over any given time period, in a machine-readable format. This is achieved by a **GDPR**-specific menu item that extracts data from the **Therapy Monitor** database and export it to XML format;
- Patients can request the rectification of their personal data in **Therapy Monitor**;
- All user actions performed in **Therapy Monitor**, **dXp** and **FME User Management Tool** are logged. The user log can be filtered by time, user or patient, and can be viewed, printed and exported to a machine-readable format;
- The user action log records not only the write or delete operations performed by the users, but also the read operations, thus allowing a clear journal of what information was read, modified, or deleted by any user;
- **Therapy Monitor** defines a complex system of user access management, which includes user authentication, user authorization, user roles, user permissions, etc. Only users with the respective permission (right) can access a certain function of **Therapy Monitor**;
- **Therapy Monitor** defines a special right that allows only dedicated users to modify or delete information created by other users;
- Depending on a configurable level of security defined by the customer, **Therapy Monitor** requires users to login when starting the application or every time a saving operation is performed;
- All security measures in **Therapy Monitor** are implemented and configured by default.

1.17.2 Personal patient data processed in Therapy Monitor

Therapy Monitor does not create patient records at all, with or without personal patient data.

Patient data is imported into **Therapy Monitor** from a distinct clinical software application (generically called **EDBMS** – External Database Management System). The data import is based on a well-defined data interface.

According to the **TMon-EDBMS** interface, the following personal patient data is imported from **EDBMS**:

- Patient first name, last name, date of birth and gender;
- Patient address (country, city, street, number, postal code)
- Patient phone numbers (private and business);
- Patient Personal Identification Number;
- Nationality;

- Name and phone number of general practitioner;
- Name and phone number of next of kin.

The rationale for using this personal data is the following:

The patient names and date of birth are used for patient identification. Dialysis devices communicate with **Therapy Monitor** and display patient first name, last name and date of birth on the device screen. The nurse must confirm the identity of the patient before starting the prescription download from **Therapy Monitor**.

The patient address and phone numbers are mainly used for organizing the transport of the patient from/to the dialysis clinic. The patient Personal Identification Number is usually required by the local medical insurance institutions.

The patient nationality is used to provide adequate medical personnel to assist the patient in the clinic, in case the patient does not speak the local language. The general practitioner data is needed for obvious medical reasons. The same applies for the next of kin data.

1.17.3 GDPR specific menu item

A dedicated menu item **GDPR actions** exists under menu File. Only users having a dedicated GDPR user right can access this menu item. The menu item provides the following GDPR-related actions:

- Anonymize the personal data of any given patient from any given time period;
- Delete all dialysis sessions of any given patient from any given time period;
- Export personal and medical data for any given patient and any given time period to an external file, in a machine-readable format (XML);
- Export personal and medical data for any given patient and any given time period to an external file, in a printable format (PDF).



Note

Anonymization and delete operations on personal patient data should be carried out at EDBMS level as well.

For a detailed description of menu item GDPR Actions (see Chapter 3.2.1.4 on page 3-8).

2 Basic information about TMon

2.1 TMon and Windows

The **Therapy Monitor** system (TMon) was developed for the Microsoft® Windows® operating system. You should familiarize yourself with the basic operation of the Windows® graphical user interface before commencing practical work with TMon. Should you already have experience in this regard, please skip this chapter. Otherwise, you may find the following section helpful for starting TMon on your PC. Thank you for understanding that a detailed introduction to the Windows® operating system does not form part of these Instructions for Use.

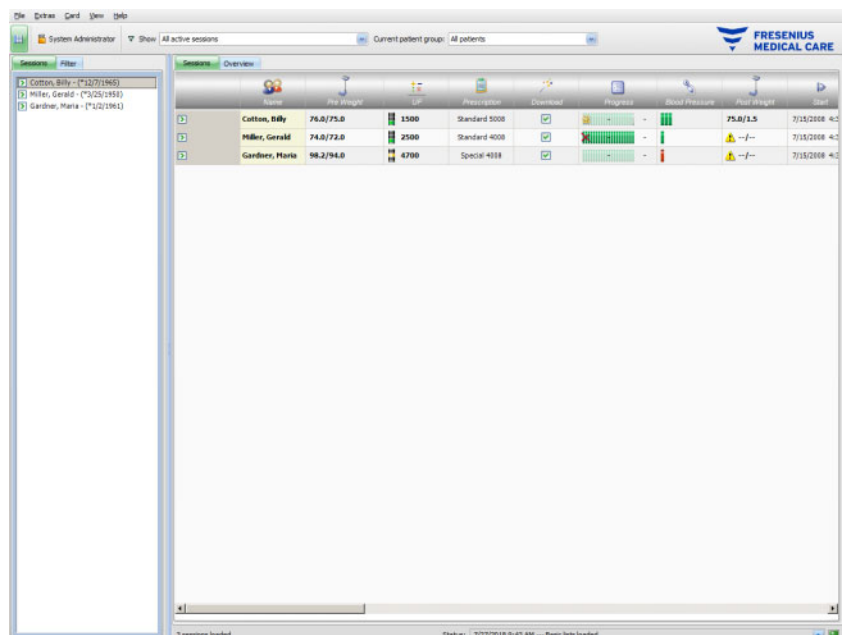
If necessary, please read the basic Microsoft® Windows® User's Guides available in book stores or online.

2.2 How to start the system

Start the computer, switch on the monitor, and wait for the Windows desktop to appear. If available in your version of Windows®, you will find a start menu in the lower left-hand corner, which you can open by clicking on the **Start** button. In the open start menu click **(All) Programs**. Find the program folder **Fresenius Medical Care** and click on it. In the program folder, click on **Therapy Monitor** to start the program.

Alternatively, you can start the program by double-clicking the **Therapy Monitor** shortcut icon on your desktop.

Therapy Monitor window after starting the program:



2.3 This is how the Therapy Monitor works

If you familiarize yourself with the basic operation of TMon in this chapter, it will subsequently be easier to understand the operating concept of the programs.

When started for the first time, the **Therapy Monitor** client sends a list of topics to the FME User Management application. For this reason it is important to first start the **Therapy Monitor** and then close it before starting the FME User Management for the first time, in order to assign the user permissions. Then the **Therapy Monitor** client can be restarted. For details on how to use the FME User Management, see the corresponding Instructions for Use (FME User Management).

To display a patient in the **Therapy Monitor** client on the current treatment day, you will first have to record him once as a **new patient** in the connected EDBMS. This is also where you enter the administrative patient data and store the individual dialysis regime of the planned treatment days (further information on the EDBMS can be found in the corresponding manual).

During this registration procedure, the connected EDBMS automatically issues a patient-specific identification number (monitoring ID). The next step is to program a new patient card. The card editor accesses this identity number and allocates it together with the patient name and date of birth to the card.

The patient now exists in the system and only has to be logged in to the **Therapy Monitor** client before each treatment. This daily login is normally performed automatically when the first measurement is activated by inserting the patient card into the card reader, e.g., at the patient scales. The patient name now appears on the screen and, in the background, data required for this treatment (dialysis regime and particulars) is transferred from the EDBMS to the **Therapy Monitor**.

All appropriately set up **Therapy Monitor** workstations will now display all the activities of the current treatments. Measurement results from the connected medical equipment either appear immediately after each measurement or are updated every minute during the continuous recording of measurement values (e.g., dialysis measurement data). You can complete this automatically recorded treatment documentation with manual additions and adaptations. The selection of **Finish / Close session** at the end of treatment automatically transfers the data of the recorded treatment to the connected EDBMS for long-term storage and evaluation. The same will happen if the **Close multiple sessions** option is used.

By default, you can read the same information on all the TMon clients of a TMon system. As soon as automatically recorded data is received from the connected medical equipment, the screens of all TMon clients are refreshed at approx. 5 second intervals. When you make manual entries in your **Therapy Monitor** client, these entries appear on all other client screens almost immediately.

2.4 Data protection in TMon

The TMon system works with access control.

Using the FME User Management program and selecting the appropriate options, you define the program activities and options for which user authentication is required in terms of username and password. Furthermore, different user groups can be defined (physician, nurse, technician, etc.), employees can be assigned to the corresponding group and user or group permissions can be allocated. For details see the corresponding Instructions for Use (FME User Management).

In case you forgot the user name and/or the password assigned to you, you should contact the head-nurse of the clinic or any other trusted user of FME User Management program. In case of technical problems ask for assistance of the local support or from central support as described (see Chapter 1.16 on page 1-11).

The patient card (see Chapter 2.3 on page 2-2) is kept in the clinic. In the event of losing a patient card, the patient should be instructed to contact the attending medical staff so that they can program a new patient card with the proper patient information.

Depending on a FIS setting, a special **Therapy Monitor** user right named 'Edit/delete data created by other users' can be assigned to users and user groups. A user that does not have this right cannot modify or delete data that was created or edited by other users. Attempting to do so will result in the following error message: 'You do not have permission to edit or delete data created by other users.'

A dedicated GDPR user right can be assigned to users and user groups. Only users having this right are allowed to perform GDPR-related actions, as described (see Chapter 1.17.3 on page 1-13).

A user sub-right named 'Global', under the right 'Change application settings' can be assigned to users and user groups. Only users having this right are allowed to change the security settings of the application, as described (see Chapter 3.2.2.1 on page 3-9).



Warning

Risk for the patient as a result of a wrong therapeutic decision

In case individual user rights are not set according to the individual's qualification and responsibility, a user can edit prescription data in a way she/he is not qualified to judge. The edited prescription can lead to a wrong treatment of the patient.

- User authorizations must only be allocated in accordance with the user group to which the employee belongs.
-

2.5 Malfunctions and what happens if ...

The programs included in the TMon system were carefully developed and comply with a high quality standard.

As with all software, however, malfunctions may arise in exceptional cases. Should an error message be displayed while working with the **Therapy Monitor**, or if the program closes independently, exit the program and then restart it.

A system check and, if required, system correction will automatically be performed when restarting, so no further faults should be expected. However, should the error recur, please contact your service support organization.

2.6 Exiting the program

To close the **Therapy Monitor** program, simply click the **Close** button on the right-hand side of the title bar in the program window.

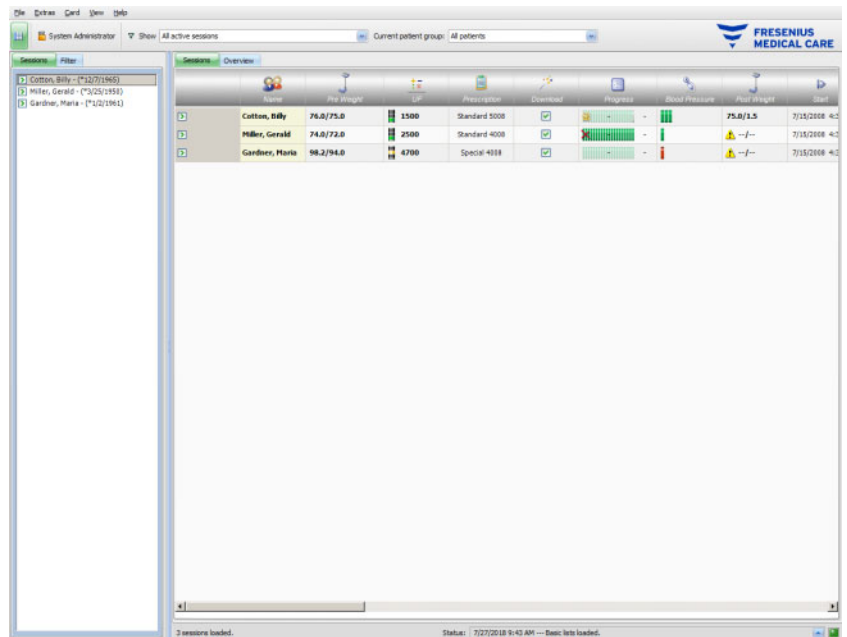


2.7 Window characteristics

2.7.1 Program windows

As Microsoft® Windows® also incorporates a graphical user interface, it uses windows as a graphical control element to display programs in. Appropriately, the **Therapy Monitor** also appears in a program window. The operation of these windows is standardized in Microsoft® Windows® and a short description is given below:

When you start the **Therapy Monitor** program by clicking the **Therapy Monitor** icon, the program window shown in the next figure will appear on the screen.



Main window of the TMon client after opening the program. The program name and version appear on the left-hand side of the title bar at the top of the window.

You can change the size of the program window by clicking the buttons on the right side of the title bar.



(from left to right): **Minimize**, **Maximize/Restore**, **Close**

Clicking the **Minimize** button will make the program window disappear from the screen. The window is reduced to an icon in the taskbar at the bottom of the screen, from where you can reactivate it again by clicking on it.

Clicking the **Maximize/Restore** button will initially reduce the size of the program window to cover less than the maximum screen area. Clicking **Maximize/Restore** again enlarges the window back to its maximum size.

The **Close** button on the right closes the window, and, if the window is the main program window, exits the program. For this reason, only click this button if you really want to exit the program!

In a dialog box, selecting **Close** will only close the dialog box, with any changes being discarded.

The menu bar is positioned below the title bar of the program window. Left-click there to open the individual menus with their different options.

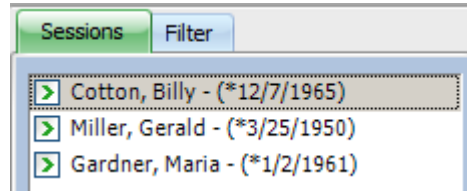


A toolbar is provided below the menu bar.

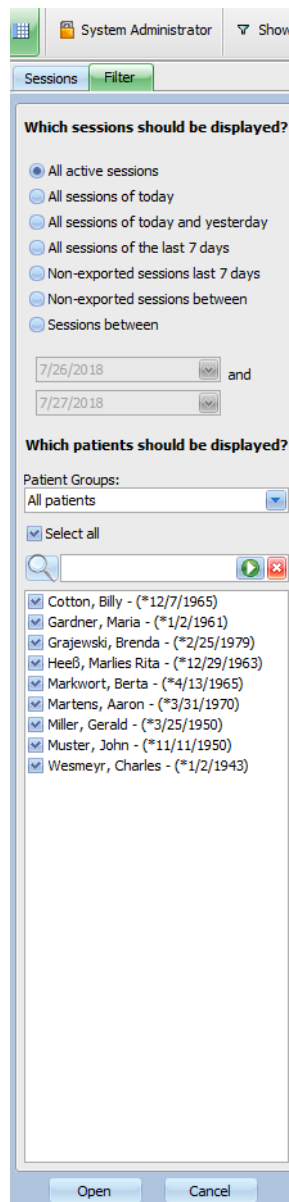
Icon for **Display selection area**: 

The icons enable you to rapidly select certain functions. The example shows the navigation area.

Sessions



Filter



Sessions are displayed in rows in the working area of the program window, each session (row) containing the name of the patient and the treatment activities identified by graphical symbols. Detailed information on these specific TMon functions can be found in the following chapters.


The status line is positioned at the bottom of the window. Here the system displays background information.

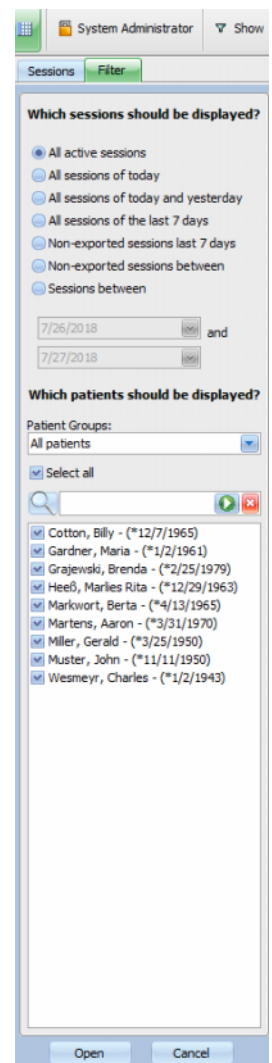
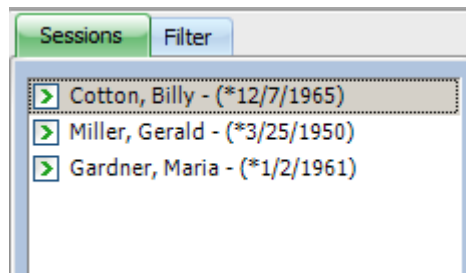


The so-called taskbar is arranged on the lower edge of the screen, in which individual 'tasks' (program and dialog windows) are positioned.

Each opened application is represented as a rectangular symbol button on the taskbar, so that you can quickly alternate between programs by clicking the required button. For instance, if you have opened Word for Windows and the TMon client program, simply click the **Therapy Monitor** symbol button to alternate from word processing to the TMon client (and vice versa). Data collection by the TMon client is not affected by placing the program on the taskbar.

2.7.2 Navigation

After clicking the  icon for **Display selection area**, a **Sessions/Filter** navigation area will open on the left hand side.



2.7.3 Treatment views

There are two possible views, each in a separate tab:

- Sessions: session grid view;
- Overview: customizable overview.

The sessions screen provides everything at a glance, for example:

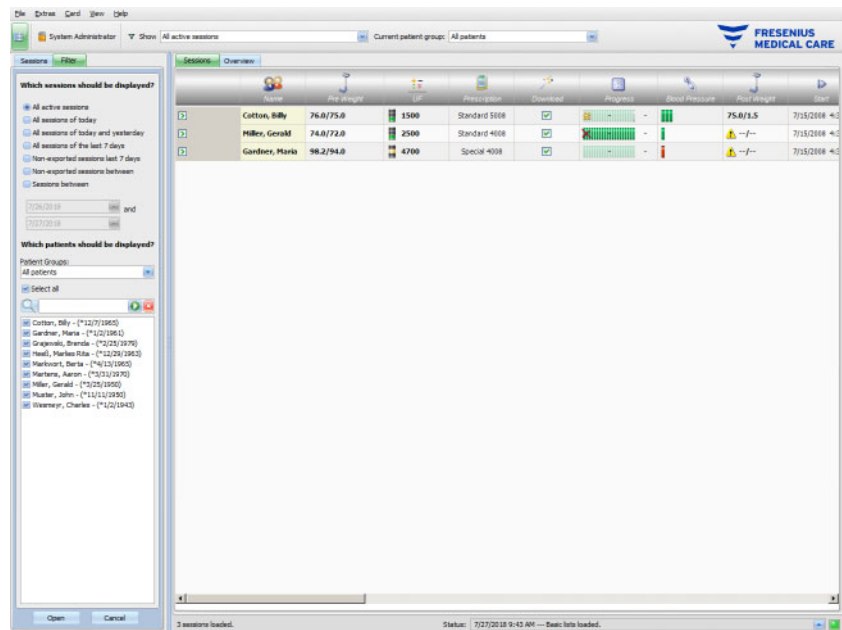
- Which patient is present.
- Which session is currently in progress, which session is completed.
- How long the session has been in progress.
- Which tasks set by the physician have already been performed.
- What kind of problems the patient is suffering from.

The overview screen is a dashboard with customizable cells.

2.7.3.1 Sessions area

Click on the Sessions tab to open this view. The view is organized as a grid, in which each row is a session and each column represents an activity.

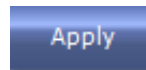
By double-clicking in the respective field in a column of the sessions view, a detail area will appear.



The example shows the detail area referring to the weight dialog.

To enter data or select entries in the individual fields, simply click the respective item or go forward using the **Tab key** or backwards using **Shift + Tab**.

Entries are saved by clicking the **Apply** button.



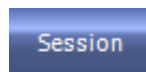
In order to discard your entries click the **Cancel** button.



Explanation of the colored buttons:



Green denotes an 'active condition'.



Blue denotes a 'selectable condition'.



Gray denotes an 'inactive condition'.

In navigation mode (you do not change any data), the **Apply** and **Cancel** buttons are inactive (gray). Once you have changed any data, the detail view enters the edit mode and the **Apply** and **Cancel** buttons become active (blue).

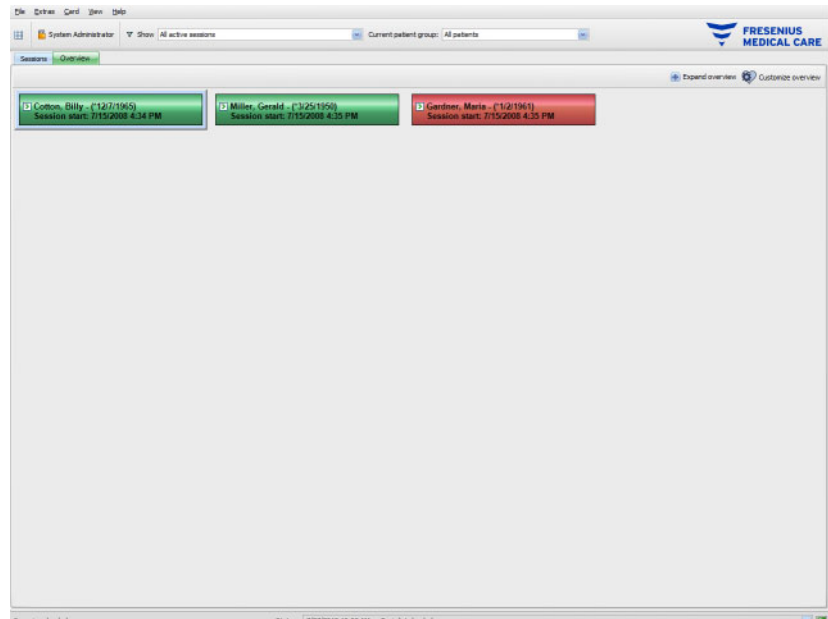
In navigation mode, the detail view is refreshed periodically with data read from the server, since data can change as a consequence of other users actions. In edit mode however, the refresh does not take place in order not to interfere with data that you are entering.

As a consequence, it is possible that during your edit operation, the data that you are editing could be changed from another **Therapy Monitor** client or dataXchange panel in the same detail view and session. In such a case, there will be a blinking symbol near the **Apply** button, to inform you that data has been changed while you were in edit mode.

In such a case, clicking the **Apply** button will save your data, overwriting the data that was changed by the other application, while clicking the **Cancel** button will discard your edited data. Whichever button you click, the detail view will then display the data that currently exists at the server level.

2.7.3.2 Overview area

Click on the Overview tab to open this view. The view is organized as a dashboard in which each cell represents a session. The session content is exactly the same as in the Sessions view and is defined by the same session and/or patient filters. The content of a dashboard cell is fully customizable (see Chapter 3.2.4.2 on page 3-35). The Collapse/Expand options allow viewing only the title bar of the Overview window or the full content.



The header of a cell displays the patient name, date of birth, and the session status (active or closed) as well as the session start time. The color of the header is normally green. If a special condition arises that requires the attention of the staff, the color changes to red.

Special conditions include:

- An alarm is active for the respective session
- The prescribed goal Kt/V cannot be achieved within the remaining treatment time
- The latest blood pressure measurement is outside the limits

Once the special condition no longer exists, the color of the session cell becomes green again.

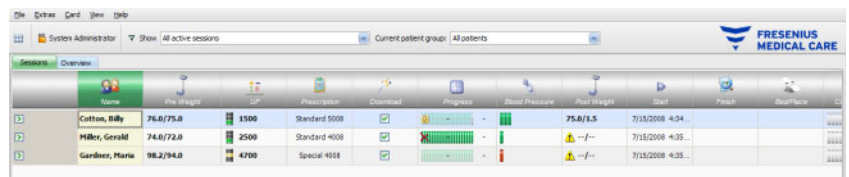
You can select a session cell with the mouse - the cell is then framed in blue.

Double-clicking on a session cell will open the Session view with the relevant session selected and the Custom View for that session.

3 The Therapy Monitor in routine operation

3.1 The main window

The **Therapy Monitor** client program has a user-friendly graphical user interface (GUI). The main window of the **Therapy Monitor** client is divided into the menu bar, the toolbar, the activity bar, and the Sessions/Overview tabs, as illustrated below.



The main window of the **Therapy Monitor** client provides a clear overview of all treatment activities on every treatment day.

3.1.1 The Logout/Login button

This button is the second one from the left on the **Therapy Monitor** client toolbar, and displays the name of the user currently logged in the application.

Click this button if you want to log out from the **Therapy Monitor** client. Depending on a server option, you will still be able to view the patient data, but you won't be able to do administrative tasks. If you want to perform such a task, you will be prompted to log in again.

After log out, the name of the button will change to '**Login**'. You can explicitly log in by clicking the button.

3.1.2 The menu bar

The menu bar is positioned at the top of the working window, and allows you to access important program functions arranged in groups (menus).

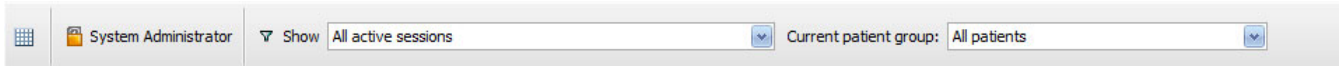


Left-click the menu name to open the individual menus. Entries in gray are inactive and are currently not available due to insufficient user permissions. Information on the function and operation of the individual menus can be found in the chapter Menu Functions.

3.1.3 The toolbar

A toolbar is located below the menu bar. Individual program functions can be quickly selected with the help of the toolbar components.

The first icon is **Display selection area**:

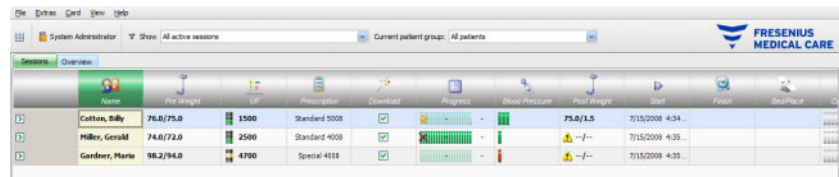


You can filter the sessions by active status or date. The 'Current patient group' filter option allows you to display only sessions of patients assigned to a specific group.

The default filter option **All Patients** is used to show sessions from all patients. Sessions and patient groups can also be selected directly from the toolbar.






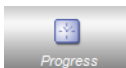


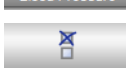
3.1.4 Activity bar

The activity bar is positioned below the toolbar and contains the activities for dialysis, represented by graphical symbols.










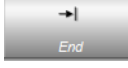

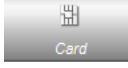
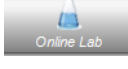

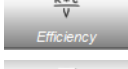


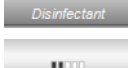






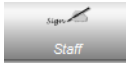

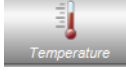

The symbols in the activity bar stand for the following treatment information:

Recommended minimum configuration

-  Patient name and date of birth
-  Pre-dialysis weight and further information
-  UF settings
-  Prescription of the treatment
-  Status of the prescription data transfer to the dialysis system
-  Progress of the dialysis treatment
-  Custom view detail area
-  Measurement values for blood pressure and pulse
-  To Do entries and their status

Further configuration options

	Message exchange data
	Events
	Medication
	Post-dialysis weight and further information
	Session finish
	Information regarding the dialysis place (dialysis station)
	Documentation of the session
	Dialyzer used in treatment
	Start time of the session
	End time of the session
	Patient's risks
	Current location of the patient card
	Online laboratory values for a session
	Type of dialysis system used in treatment
	Kt/V data of the treatment
	Comments
	Consumables used during the session
	Disinfectant check status
	Device state
	Treatment results

	BCM measurements
	Measures
	Responsible staff
	External laboratory values for a session
	Patient temperature values for a session
	Summary data

3.1.5 Status line

The status line is positioned at the bottom of the window.

Here the system displays background information, such as **No session loaded**.



The green status indicator signal indicates that a correct server connection has been established.



A missing connection is indicated by a red signal.

Clicking the arrow on the left of the status indicator signal will open the **Status** list with a history of the main communication operations with the server, such as checking the server version, IP address, list loading etc.



Note

If the window does not display any data, check the status indicator.

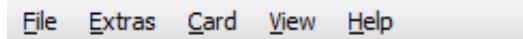
3.1.6 Detail view

Many detail views include data presented in table-like grids, that have several columns. Examples of such detail views are: Messages, Medication, To Dos, Consumables, Events etc.

Depending on the resolution of the screen, column sizes can be smaller or larger. Starting with **Therapy Monitor V2.3**, you can adjust the size of the columns and this adjustment will be persistent. This means that by closing and re-opening **Therapy Monitor** client, the column sizes will be preserved.

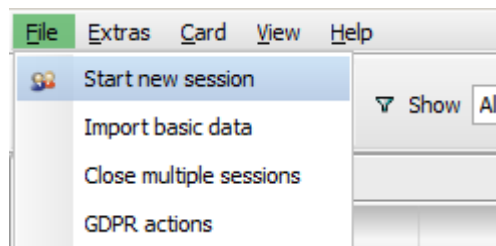
3.2 Menu options

The menu options are divided among the menus File, Extras, Card, View and Help. They allow you to access important program functions.



3.2.1 File

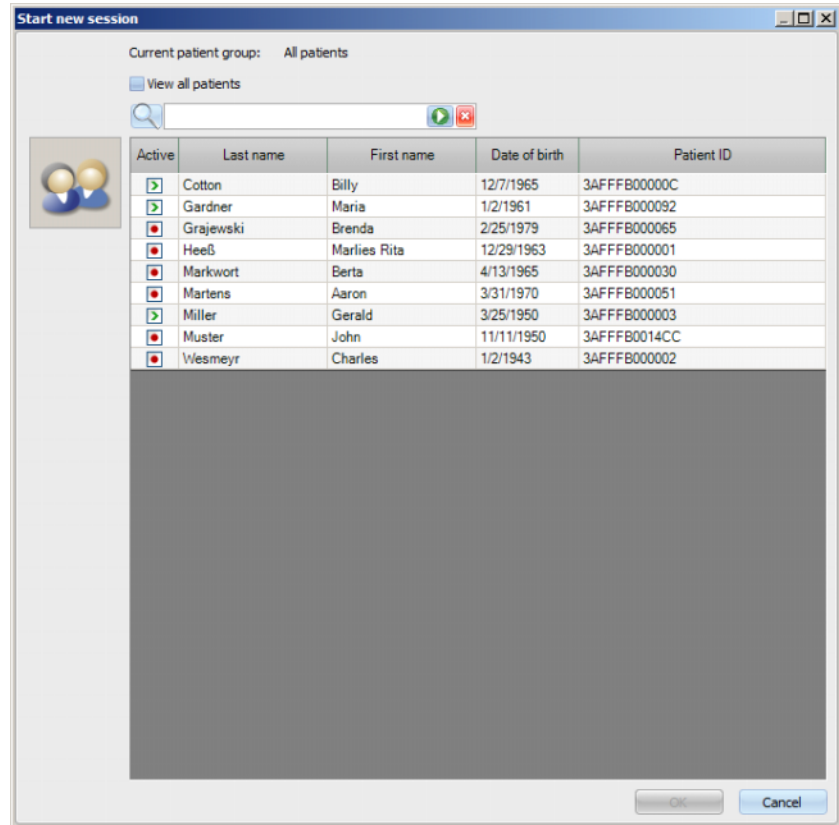
3.2.1.1 Start new session



There are various options for creating a new session.

Generally, a new session (i.e., new dialysis treatment) is automatically started if a new patient identification card is detected in the system and there is no active session already in progress for that patient. If there is an active session for that patient and there was no data input for more than 6 hours (value is configurable at FIS level), this active session is closed and exported, and a new active session is automatically created for the same patient.

A session can also be created manually with the **File, Start new session** menu option. A patient selection screen opens, from which you can select one patient. You can also search for a particular patient. After clicking the OK button, the respective session will be created and loaded a few seconds later.



If there is an active session for the selected patient and that session had no data input for more than 6 hours, that session will be automatically closed and exported and a new active session will be automatically created for the same patient. If data was input within the 6 hours time frame, a warning message appears, asking for user confirmation to close the existing session and to start a new one.

If the user responds with **Yes**, the existing session will be closed without being exported and a new active session will be automatically created for the same patient. If the user responds with **No** the current session is preserved.



Warning

Risk for the patient as a result of wrong treatment parameters

Prescription changes made in the external database management system after the prescription download to the dialysis device has already been performed will not become effective automatically for the current treatment. As a result the latest prescription data is not used for the current treatment.

- After prescription download has been performed, prescription parameters must be changed directly on the dialysis device in order to become effective for the current treatment.

3.2.1.2 Import basic data

If, for instance, you change your dialyzer list or laboratory parameter list, you should perform an import of basic data at this stage. To do this, select the menu option **File, Import basic data**.

Basic data includes the imported lists, such as those already mentioned, but also lists for the patient, consumables, medication, etc. You can monitor the success of the basic data import via the detail area **Patient basic data, Transfer, Basic data**.

Data	Request time	Answer time	Version	Remark
8.1.1 Import database identifier	8/1/2018 10:55:34 AM	8/1/2018 10:55:35 AM	2.2	
8.2.1 Import list of patients	8/1/2018 10:55:35 AM	8/1/2018 10:55:35 AM	2.2	
8.2.2 Import list of dialyzers	8/1/2018 10:55:35 AM	8/1/2018 10:55:36 AM	2.2	
8.2.3 Import list of treatment types	8/1/2018 10:55:35 AM	8/1/2018 10:55:36 AM	2.2	
8.2.4 Import list of anticoagulants	8/1/2018 10:55:35 AM	8/1/2018 10:55:36 AM	2.2	
8.2.5 Import list of device types	8/1/2018 10:55:35 AM	8/1/2018 10:55:36 AM	2.2	
8.2.6 Import list of lab parameters	8/1/2018 10:55:35 AM	8/1/2018 10:55:36 AM	2.2	
8.2.7 Import list of medication	8/1/2018 10:55:35 AM	8/1/2018 10:55:32 AM	2.2	
8.2.8 Import list of wards	8/1/2018 10:55:35 AM	8/1/2018 10:55:32 AM	2.2	
8.2.10 Import list of rooms	8/1/2018 10:55:35 AM	8/1/2018 10:55:32 AM	2.2	
8.2.11 Import list of places	8/1/2018 10:55:35 AM	8/1/2018 10:55:32 AM	2.2	
8.2.12 Import list of events	8/1/2018 10:55:35 AM	8/1/2018 10:55:32 AM	2.2	

3.2.1.3 Close multiple sessions

Sessions can be closed individually from the Finish detail view, but this is inconvenient if you need to close a number of active sessions. The menu item **File, Close multiple sessions** opens a window with all active sessions that meet the necessary conditions to be closed. You can select individual sessions that you want to close.



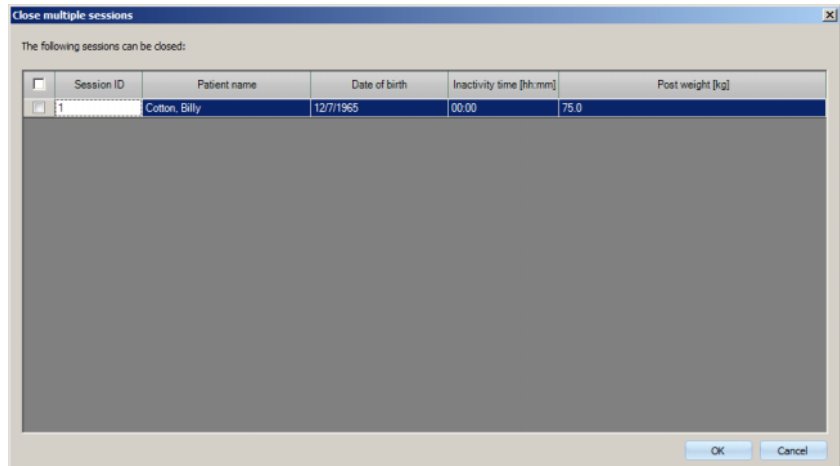
Note

Conditions to close multiple sessions are defined in menu Extras/Options (see Chapter 3.2.2.1 on page 3-9).



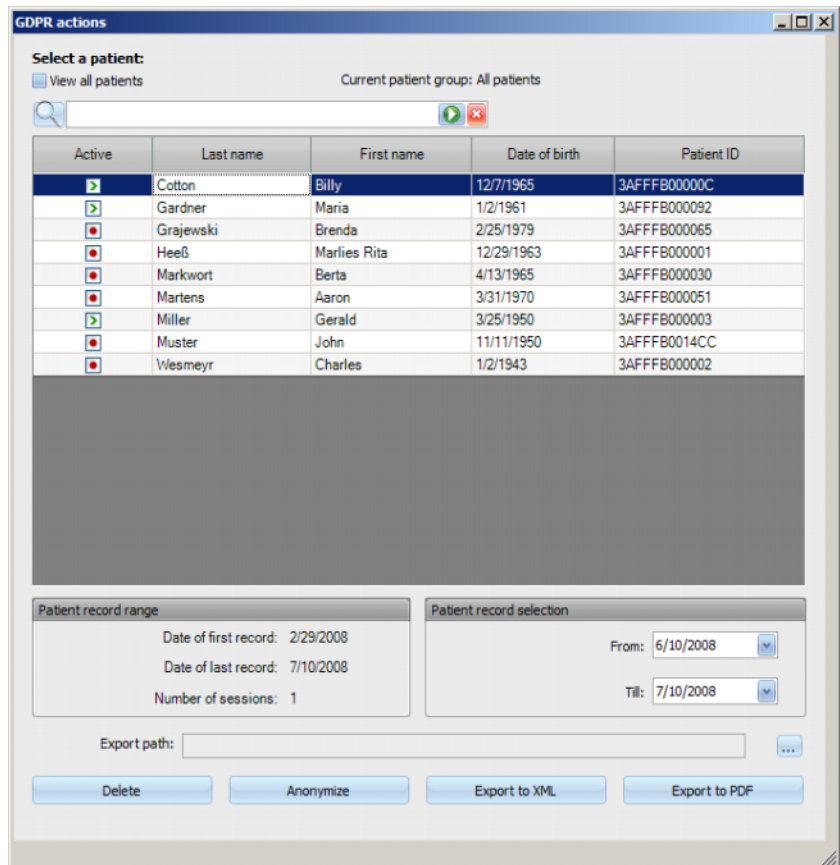
Note

Sessions can be automatically closed if a certain option is set at FIS level. In such a case the system will periodically analyze which sessions fulfill the closing conditions and will automatically close them. Sessions that are automatically closed do not record any staff for the close operation.



3.2.1.4 GDPR actions

This menu item opens a dialogue in which you can first select a certain patient and a certain period.



Once a patient is selected, the information about existing patient records is shown in the **Patient record range** area.

The **From** and **Till** calendar controls in the **Patient record selection** area allows specifying the desired period, within the Patient record range interval. Only data falling into the specified period will be processed. To set the full maximum period, simply clear the from/till dates.

The action buttons **Anonymize**, **Delete**, **Export to XML** and **Export to PDF** performs the GDPR specific actions: anonymize patient personal data, delete all patient data, export to a machine-readable format (XML) and export to a printable format (PDF).

For **Export to XML** and **Export to PDF** you must also specify an **Export path** on the local work-station where the exported files should be saved. A distinct export file will be created for each session, with the name <patient ID>_<session start date> and extension .xml or .pdf. During the export operation, a horizontal progress bar is displayed and the action buttons are disabled.

A summary report in text format will be saved in the same folder.

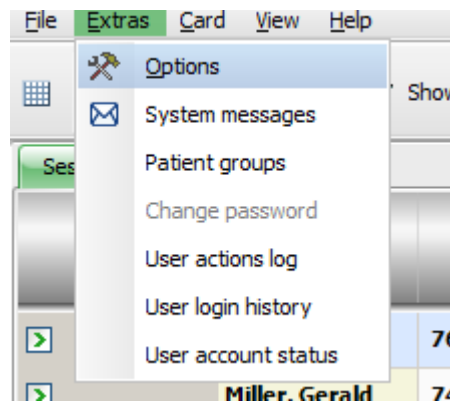


Note

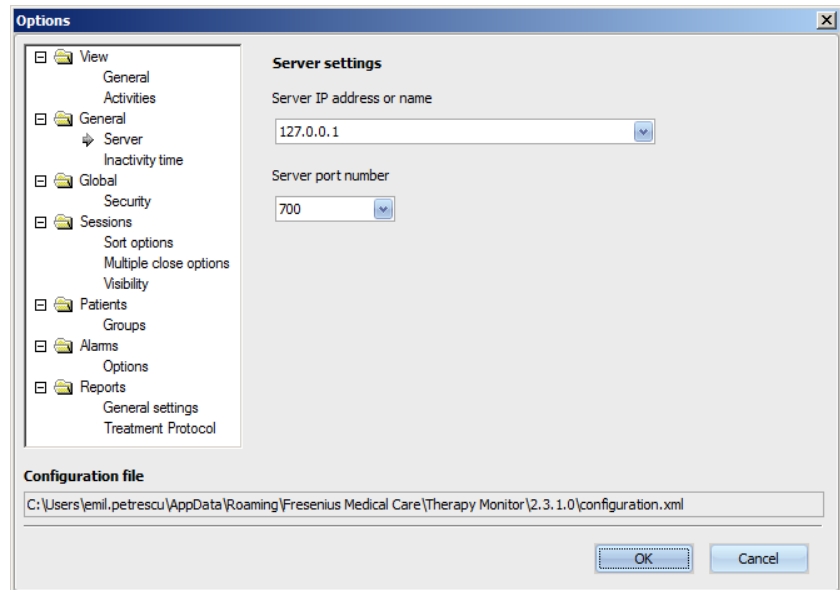
If a large amount of sessions is selected using the filter, the export operation may take a long time. You can interrupt the export operation at any time by clicking the red X button located at the lower right-side of the progress bar.

3.2.2 Extras

3.2.2.1 Options



Using the **Options** menu item, you can customize the program according to the respective needs of the dialysis unit.



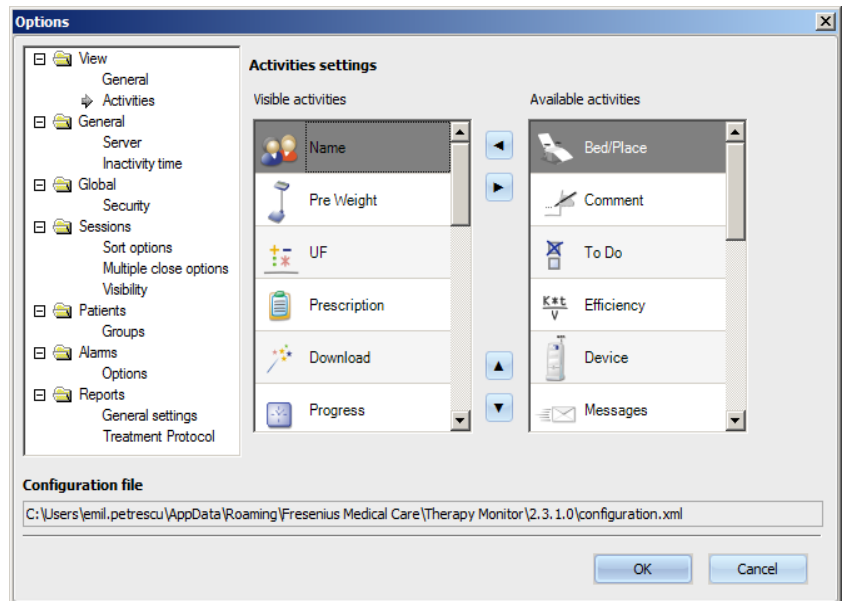
In the **View/General** section you can select whether the Medication menu is to include regular medication or not. Via **View/Activities**, you may customize the display of the session activities in the activity bar of the program. Each activity is represented by a graphical symbol. In this way, the individual treatment data of every patient session can be accessed at any time in the session rows under the graphical symbols of the activity bar.

For displaying more/other graphical symbols go to the entry **Activities settings**. Symbols already visible in the activity bar are shown in the table on the left hand side. The right hand side table **Available items** provides further symbols.

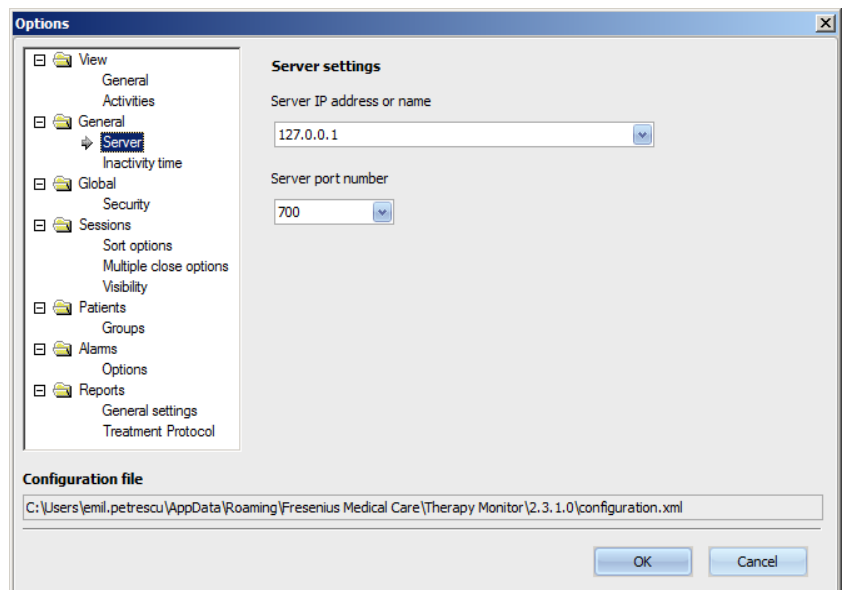
You have the option of adding new activity items or, if applicable, removing them from the activity bar, by using the Left/Right arrow buttons. If you highlight an already displayed graphical symbol in the left table **Visible items** and select the Right arrow button, this will result in the removal of the item, which will then become available in the right table **Available items**. The same in the opposite direction applies to the right table. If an item is highlighted here and the Left arrow button is clicked, this symbol will be placed in the left table and finally in the activity bar as a visible item.

With the Up/Down arrow buttons it is possible to arrange the selected activity items in a desired order, e.g., Patient, Pre Weight, UF, Download, etc. Proceed as follows: highlight the symbol you want to reposition and use the Up/Down arrow buttons to move it to the required position.

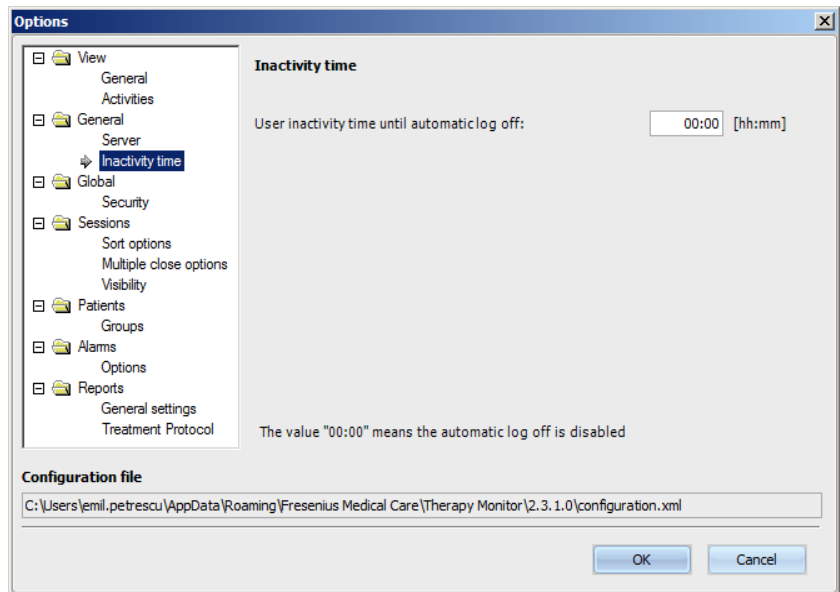
Therefore, you can customize the activity bar to have an overview of the dialysis treatments in progress.



Use the **General/Server** menu item to select the server that your TMon client is communicating with by providing the Server IP address or name and the Server port number.



These settings must only be performed by an authorized technician or by a person instructed by an authorized technician (e.g., the center's system administrator). After the installation of the program, these settings need to be specified only once per workstation.



The **General/Inactivity time** section allows you to define the amount of time after which the user is automatically logged out, providing there was no activity at the current workstation. A value of '00:00' means no automatic logout will take place.

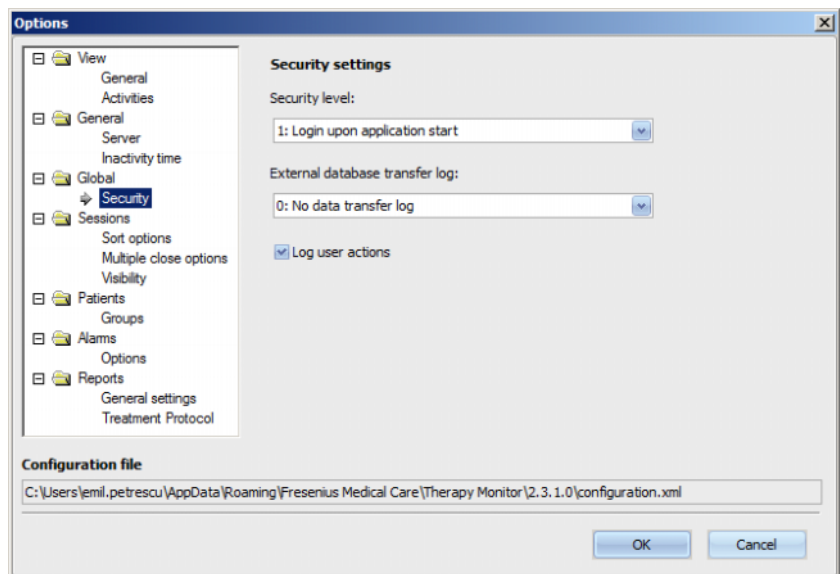


Note

One option of the server controls whether the **Therapy Monitor** window is fully cleared when there is no user logged in.

The **Global/Security** section allows you to define security related options. To access this menu item, you need to have a specific permission assigned through **FME User Management Tool**.

The following options are available:

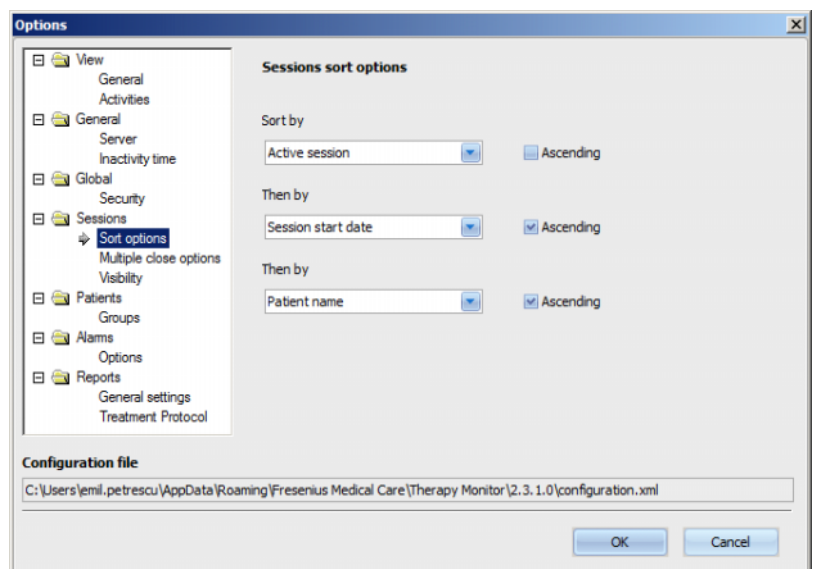


- **User login options** – This allows you to control how users log in to the **Therapy Monitor** client. Possible values are:

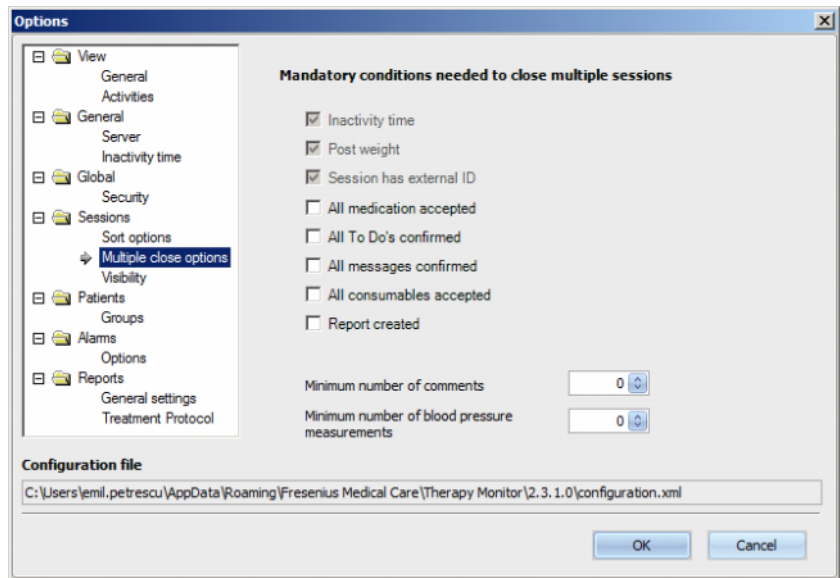
- 0: no login required – available only for demo installations;
 - 1: login upon application start;
 - 2: login upon every save operation.
- **Data transfer log** – This allows you to define how data transferred between **Therapy Monitor** and **EDBMS** is logged at FIS server level. Possible values are:
 - 0: no data transfer log;
 - 1: log data transfer – import only;
 - 2: log data transfer – import and export.
 - **Log user action** – This allows you to define whether or not to log user actions in **Therapy Monitor**. Possible values are:
 - 0 (unchecked): – do not log user actions;
 - 1 (checked): – log user actions.

All security settings are global for all instances of the **Therapy Monitor** client within the clinic. If the user action log is active, all changes performed by users in the **Options** section are logged.

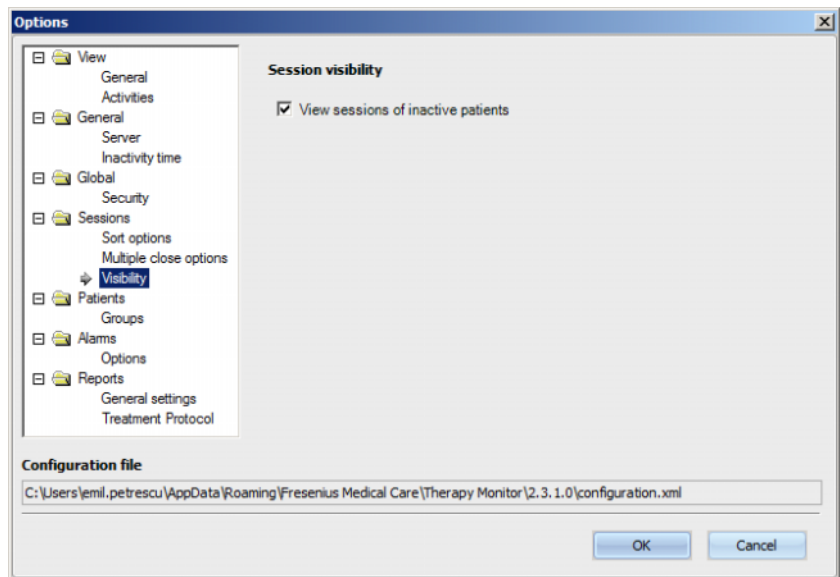
Using the **Sessions/Sort options** it is possible to arrange the sessions by active session, patient name or session start date in either ascending or descending order.



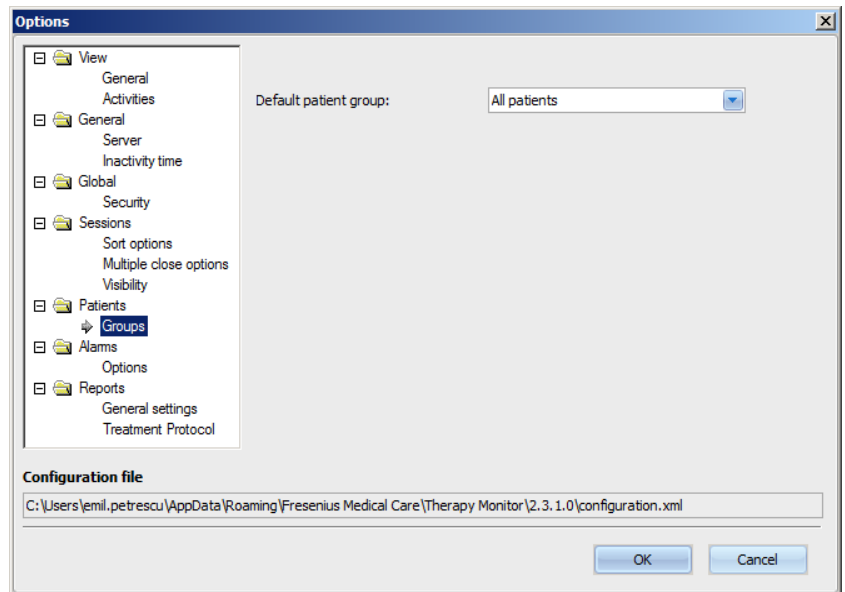
Using the **Sessions/Multiple close options** it is possible to define conditions for closing multiple sessions, both manually and automatically. Certain conditions are mandatory, like inactivity time from device, post-weight and external DB ID, and so cannot be unchecked. All other conditions are freely editable.



Using the **Sessions/Visibility** it is possible to control the visibility of sessions for inactive patients. A patient is considered to be inactive if he/she is no longer in the patient list received from the EDBMS, but was present in the past and has dialysis sessions recorded in **Therapy Monitor** DB.



From the **Patients/Groups** option, a default patient group may be assigned. This group will be used in **Therapy Monitor** on every start.

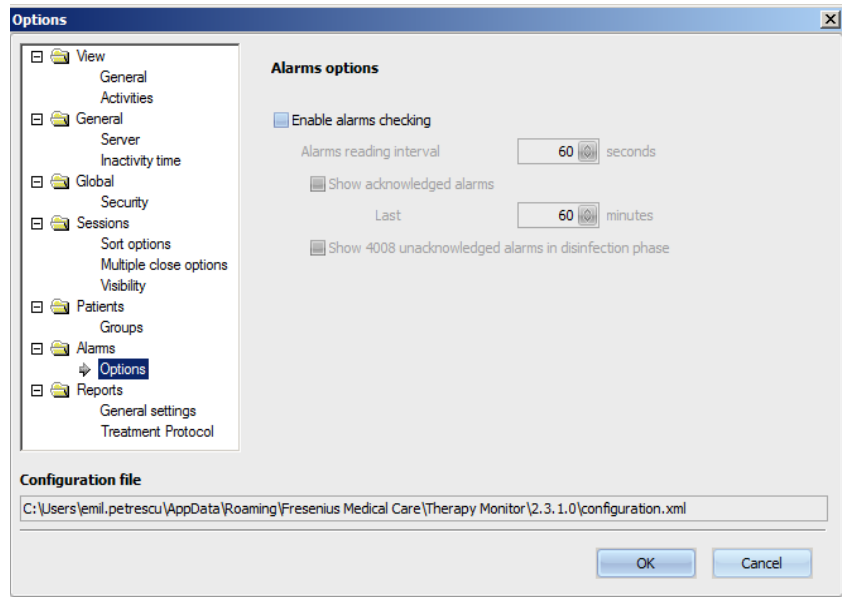


Note

All the settings in this chapter are saved locally on the respective **Therapy Monitor** workstation or at the server level. They are not assigned to an individual user. A patient group can therefore be created and displayed related to a workstation, e.g., for a particular treatment room. Patient groups can be created as described in chapter 3.2.2.3 Patient Groups.

The **Alarms/Options** section allows the configuration of the Alarms pop-up window. Several settings are possible:

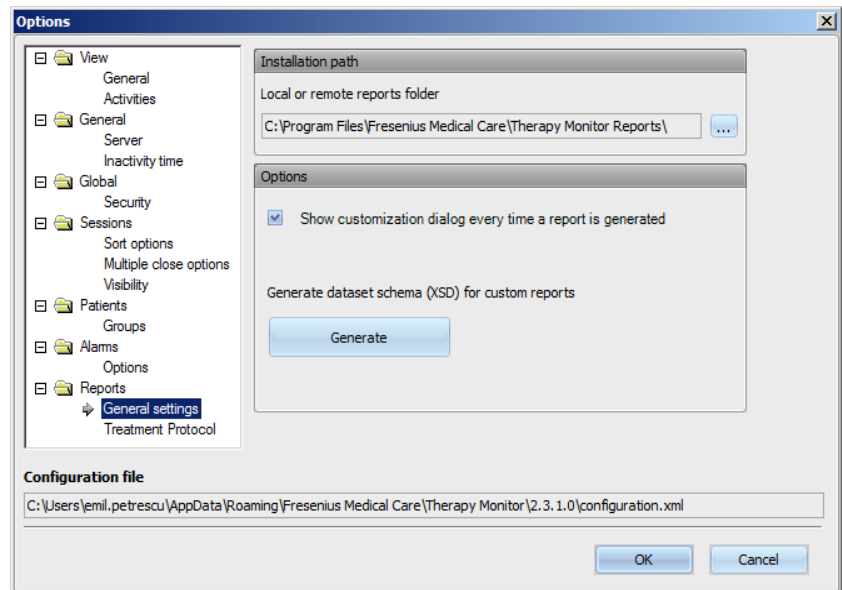
- Enable alarms checking – if active (set), it allows the alarms of the machines to be displayed.
- Alarms reading interval – specifies the refresh rate of the Alarms window.
- Show acknowledged alarms – if checked, the Alarms pop-up window displays also the acknowledged alarms within a specified time frame (last n minutes).
- Show 4008 unacknowledged alarms in disinfection phase – if checked, it allows the unacknowledged alarms that occur during the disinfection phase of the 4008 machine to be displayed.



Note

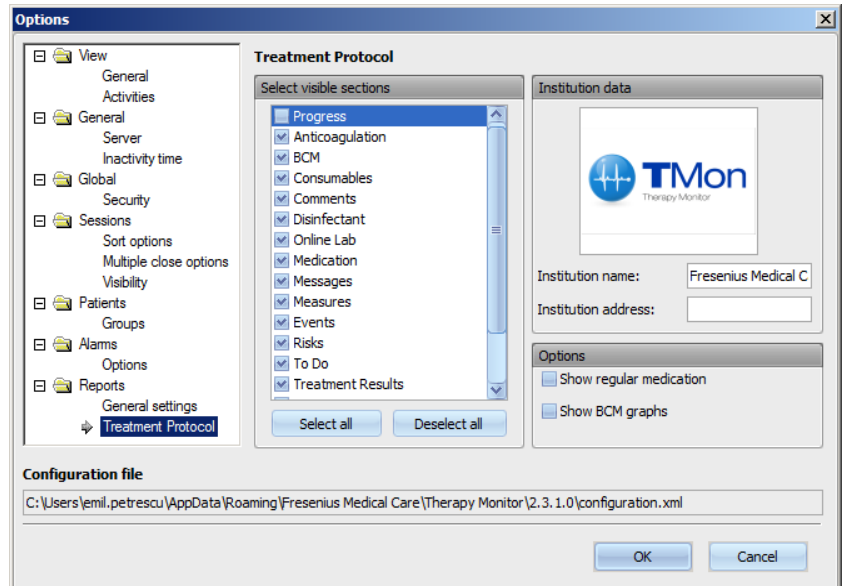
The alarm pop-up window described here displays all of the alarms of every device connected while the patients are being treated, for the active sessions that are visible in TMon client, according to the current patient group and current session filter (see Chapter 3.3.2 on page 3-40). Only device alarms of the selected patient are viewed in the Progress/Overview activity described in chapter 3.4.6 (see Chapter 3.4.6 on page 3-56).

In the **Reports/General settings** menu item, it is possible to specify the installation path for the reports library, to set the option of displaying the customization window every time a report is generated and to save the dataset XSD schema for custom reports.



The topics to be printed in the default report can be selected in the **Treatment Protocol** menu item. You can also view/define institution data such as logo, name and address and activate **Show regular medication** and **Show BCM graphs** options.

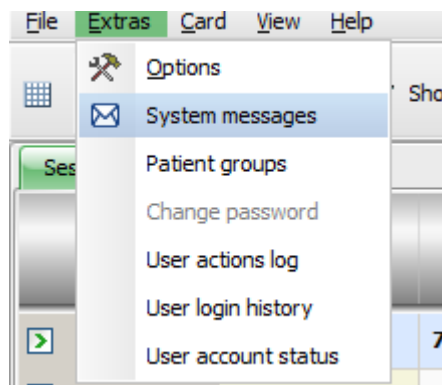
Click the right mouse button to change/insert the logo of your institution that appears in the top left corner of the report. The three options **Load image**, **Default image** and **Clear image** then appear.

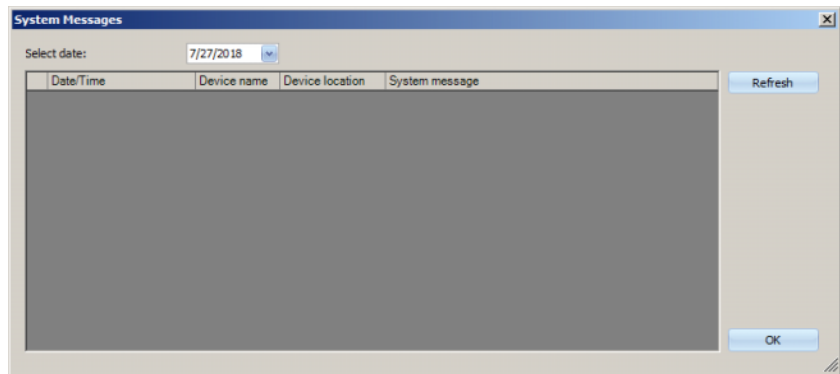


Note

All the settings in this chapter are saved locally on the respective **Therapy Monitor** workstation in a configuration file. The path to this configuration file is indicated in the lower section of the **Options** window. The institution data is saved in the database and is relevant for all workstations.

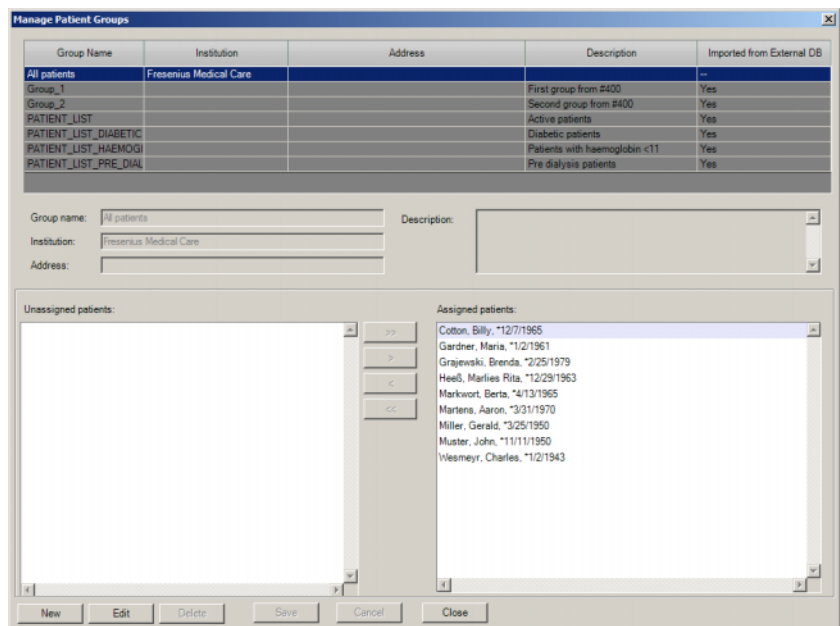
3.2.2.2 System messages





Without any exception, system messages are system-related messages (technical messages), which are important for the center's system administrator. The **Select date** calendar allows you to specify a certain date. Only messages from that date will be shown. The current date is selected by default.

3.2.2.3 Patient groups



This dialog allows patient groups management. Patient groups can be local or imported from an external database. You can add a new local group and edit or delete an existing local group. You have to enter a group name when adding a new patient group. You can add the name, address and the description of the patient group. You can also specify the patients who should belong to the selected group.

The **All Patients** group is a **Therapy Monitor** standard setting. It cannot be removed. The patient list contains all the available patients, and no changes can be made to this list using the **Patient Groups** dialog. Only the institution name and address of this group, and an optional description can be changed.

You can create as many groups as required. A patient can belong to several groups. Imported groups cannot be edited in **Therapy Monitor**.

If you have not saved the changes before closing the dialog, you will be prompted to do so.

3.2.2.4 Change password

If the user management is set to local (not Windows Active Directory) at server level, this option allows the currently logged-in user to change his/her password. The old password must be entered together with the new one.

Depending on settings on FIS level and on User Management level, a user may be forced to change his/her password at the next login. In this case, after a successful login, the change password dialog will pop-up automatically.

3.2.2.5 User action log

The recording of user actions is controlled by an option at FIS level. This dialog allows viewing all user actions referring to patient data. Both write/delete and read actions are recorded. Information like date/time, session ID, patient ID, user name, application (**Therapy Monitor**, dXp), form/page and type of action is presented.

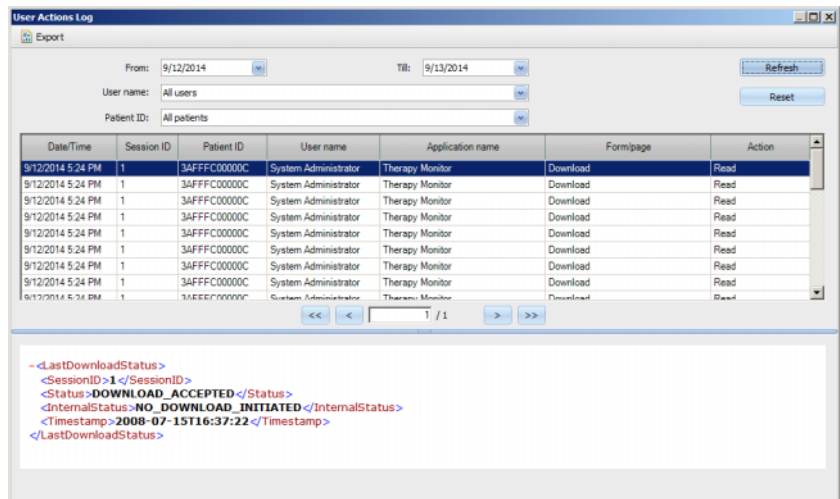
Data can be filtered by means of two calendar controls (From, Till), and/or by user name and/or by patient name/ID. By default all users and patients are presented, for the current date. After selecting filter elements, you need to click on the Refresh button. Clicking on the Reset button resets the filter. You can use the arrow-like buttons to navigate between pages.

In the lower part of the dialog, the currently selected item data is presented. Data can be exported to a text (tab delimited) file that can be easily opened with MS Excel. Click on the Export button on the left at the top and select the destination of the export file.



Note

If a large amount of data is selected using the filters, the export operation may take a long time.



Note

In order to access the menu **User Action Log** you need to have a specific permission assigned through FME User Management.

3.2.2.6 User login history

This dialog allows viewing the history of all user login operations. Information like account name, full user name, user ID, login status, workstation name/IP address, login and logout time is presented.

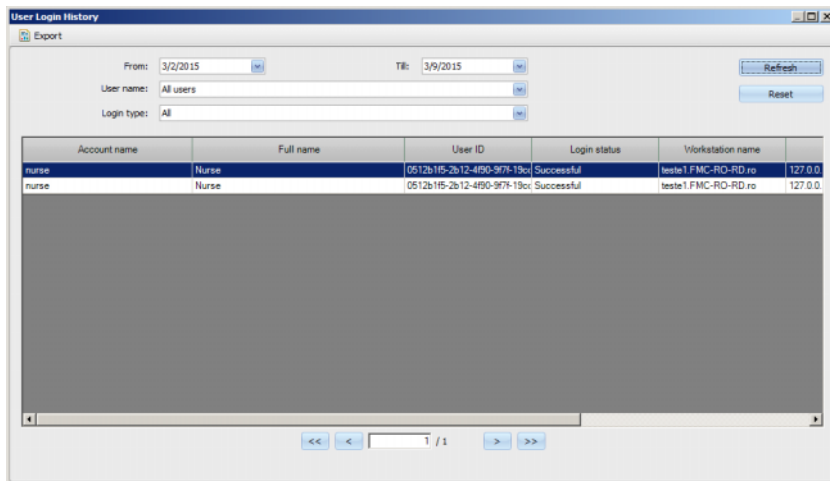
Data can be filtered by means of two calendar controls (From, Till), and/or by user name and/or by login type. Login type includes active logins (user logged in but did not log out), successful logins, and failed logins. By default all users and all login types are presented, for the last week. After selecting filter elements, you need to click on the Refresh button. Clicking on the Reset button resets the filter. You can use the arrow-like buttons to navigate between pages.

Data can be exported to a text (tab delimited) file that can be easily opened with MS Excel. Click on the Export button on the left at the top and select the destination of the export file.



Note

If a large amount of data is selected using the filters, the export operation may take a long time.



Note

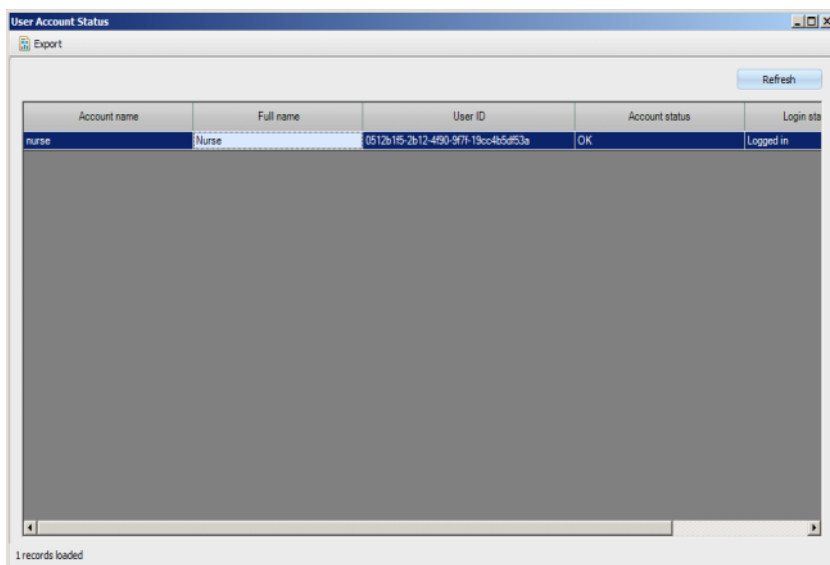
In order to access the menu **User Login History** you need to have a specific permission assigned through FME User Management.

3.2.2.7 User account status

This dialog allows viewing the current status of all user accounts. Information like account name, full user name, user ID, account status, login status and last login time is presented. An account can be valid (OK) or locked by various reasons (manually locked, locked because of a certain number of failed logins, or locked because of inactivity).

You can directly select an account name by typing the first characters of the name in the 'Account name' column.

Data can be exported to a text (tab delimited) file that can be easily opened with MS Excel. Click on the Export button on the left at the top and select the destination of the export file.



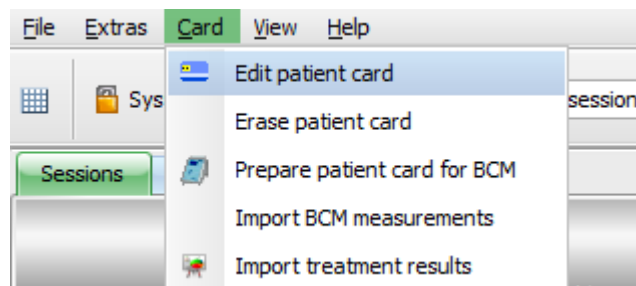


Note

In order to access the menu **User Account Status** you need to have a specific permission assigned through FME User Management.

3.2.3 Card

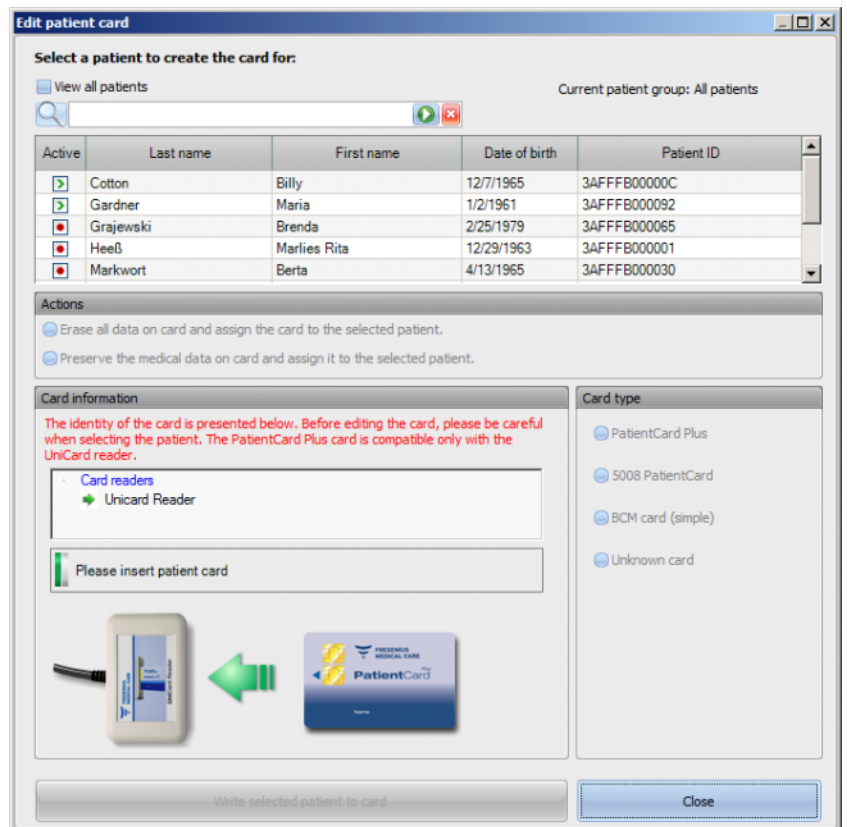
3.2.3.1 Edit patient card



The **Edit patient card** command opens a window in which a patient card can be programmed. A patient selection screen opens, from which you can select one patient. You can also search for a particular patient.

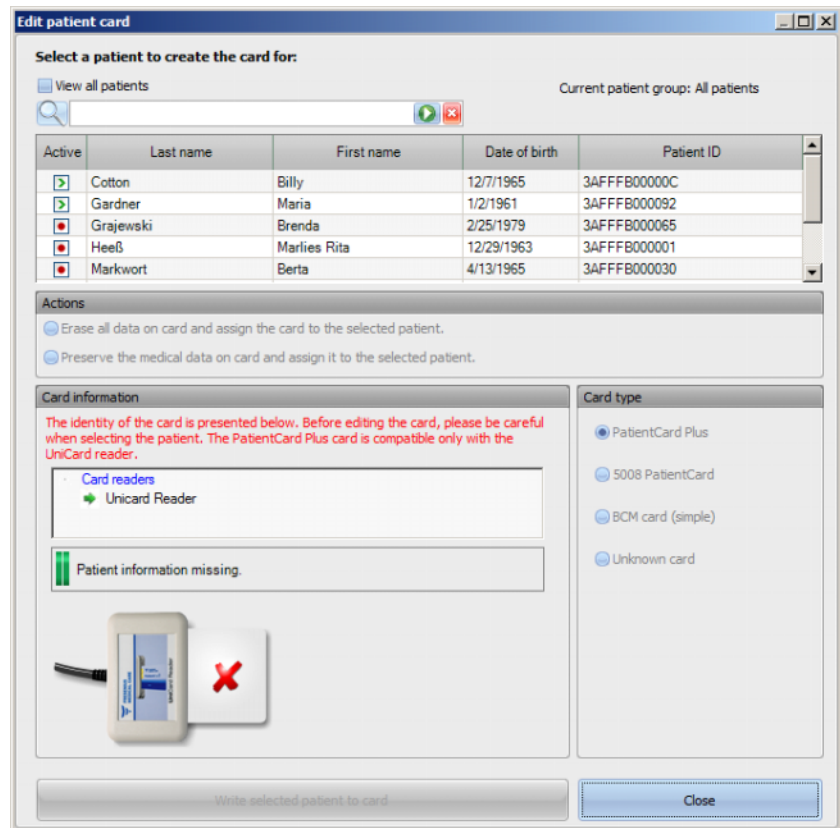
For patients currently undergoing dialysis treatment, a green arrow will be displayed in the **Active** column.

By default you are shown only patients from the current group, but by checking **View all patients** all of them are displayed.



The window displays a card reader selector (useful in case several are installed on the workstation) and the type of the card inserted in the reader.

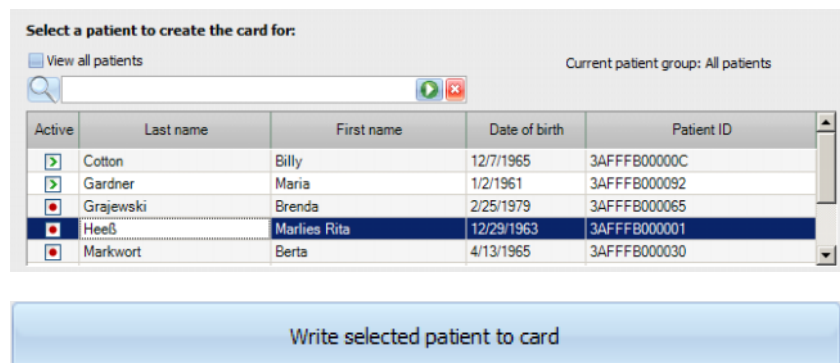
If an empty patient card is inserted into the chip card reader, the following information on the card is received: **Patient information is missing.**



If the patient card contains medical data (like 5008/6008 treatment results or BCM measurements) and the patient identity on the card (name, date of birth) is the same as the selected patient, you may choose to preserve the medical data by selecting **Preserve medical data on card and assign it to the selected patient.** This option cannot be selected if the patient identities differ. In this case, the only option is **Erase all data on card and assign it to the selected patient.**

To create a new patient card, proceed as follows:

In the **Edit patient card** window select a patient by left-clicking the appropriate line (the patient line will be 'highlighted in blue'), then click **Write selected patient to card.**



The following patient data will now be written to the card:
First name, last name, date of birth, patient ID.

Edit patient card

Select a patient to create the card for:

View all patients Current patient group: All patients

Active	Last name	First name	Date of birth	Patient ID
<input type="checkbox"/>	Cotton	Billy	12/7/1965	3AFFFB00000C
<input checked="" type="checkbox"/>	Gardner	Maria	1/2/1961	3AFFFB000092
<input type="checkbox"/>	Grajewski	Brenda	2/25/1979	3AFFFB000065
<input type="checkbox"/>	Heeß	Marlies Rita	12/29/1963	3AFFFB000001
<input type="checkbox"/>	Markwort	Berta	4/13/1965	3AFFFB000030

Actions

Erase all data on card and assign the card to the selected patient.

Preserve the medical data on card and assign it to the selected patient.

Card information

The identity of the card is presented below. Before editing the card, please be careful when selecting the patient. The PatientCard Plus card is compatible only with the UniCard reader.

Card readers

- Unicard Reader

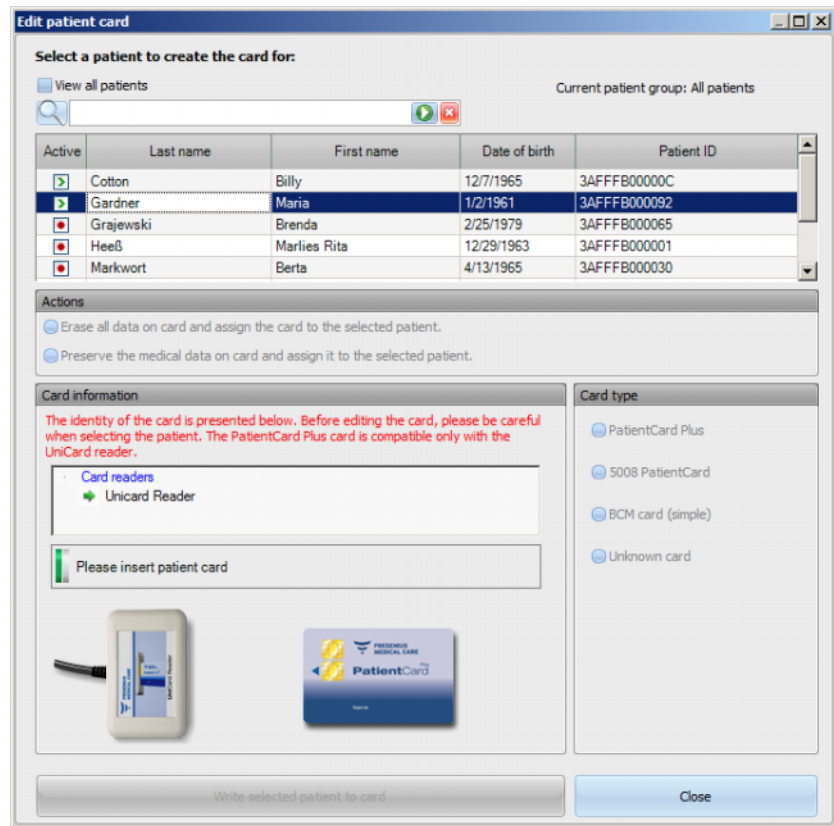
Maria Gardner, 1/2/1961, ID: 3AFFFB000092

Card type

- PatientCard Plus
- 5008 PatientCard
- BICM card (simple)
- Unknown card

The card may be removed from the chip card reader on completion of the writing process.

If the recorded patient card is removed from the card reader, the message **Please insert patient card** will be displayed. Now a new card can be created for a new patient.



If you would like to review your created card with the basic data like first name, last name, date of birth and patient ID, reinsert it into the chip card reader.

Edit patient card

Select a patient to create the card for:

View all patients Current patient group: All patients

Active	Last name	First name	Date of birth	Patient ID
<input type="checkbox"/>	Cotton	Billy	12/7/1965	3AFFFB00000C
<input type="checkbox"/>	Gardner	Maria	1/2/1961	3AFFFB000092
<input type="checkbox"/>	Grajewski	Brenda	2/25/1979	3AFFFB000065
<input checked="" type="checkbox"/>	Heeß	Marlies Rita	12/29/1963	3AFFFB000001
<input type="checkbox"/>	Markwort	Berta	4/13/1965	3AFFFB000030

Actions

Erase all data on card and assign the card to the selected patient.
 Preserve the medical data on card and assign it to the selected patient.

Card information

The identity of the card is presented below. Before editing the card, please be careful when selecting the patient. The PatientCard Plus card is compatible only with the UniCard reader.

Card readers
 Unicard Reader

Maria Gardner, 1/2/1961, ID: 3AFFFB000092

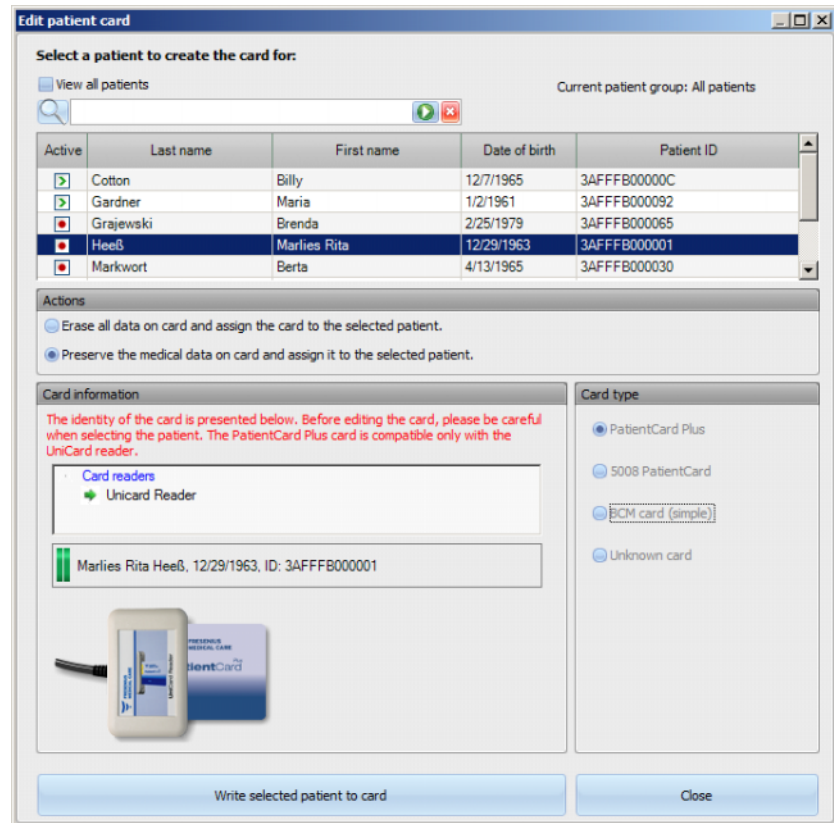
Card type

PatientCard Plus
 5008 PatientCard
 BCM card (simple)
 Unknown card

Write selected patient to card Close

You may also write new basic data of a new patient on an already created patient card (patient was moved to another dialysis center, for example). Follow the procedure already described in the chapter about creating a new patient card.

Select (highlight) a patient and click **Write selected patient to card**.



Click **Close** to close the patient card editor.

Please note that the **Edit patient card** option of TMon client is available only if the associated software drivers and hardware (card reader device) are actually installed on the PC workstation. Depending on the system configuration, it is possible that the patient card editor is not available on every PC workstation.



Warning

Risk for the patient as a result of wrong treatment parameters

In case a session is created manually in the **Therapy Monitor** client a wrong patient may be selected and the wrong patient card may be used at the dialysis device. This may result in wrong treatment with data from a different patient.

- The use of the correct patient card is the responsibility of the user.
- Each patient card must be labeled with the patient name, the patient ID and the date of birth to ensure a correct patient identification.

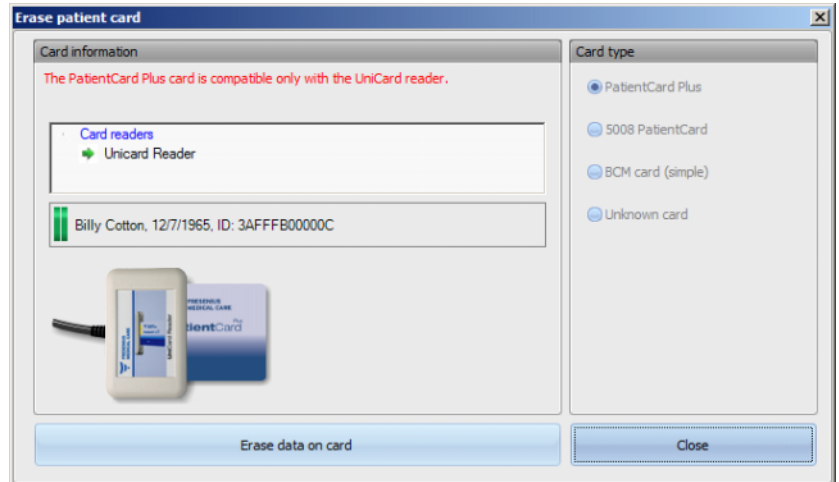


Note

Patient cards of **Therapy Monitor** have to be created with this application. Patient cards created by external systems may not carry the proper center and/or patient identification as defined in **Therapy Monitor**.

3.2.3.2 Erase patient card

This dialog allows erasing a patient card. After erasing the card will not be usable unless it is initialized. In order to erase the card, insert the card in the card reader. The patient identity is displayed.



Click on **Erase data on card**. A confirmation dialog appears.

Click **Yes** in order to erase the card or **No** to abandon the operation.

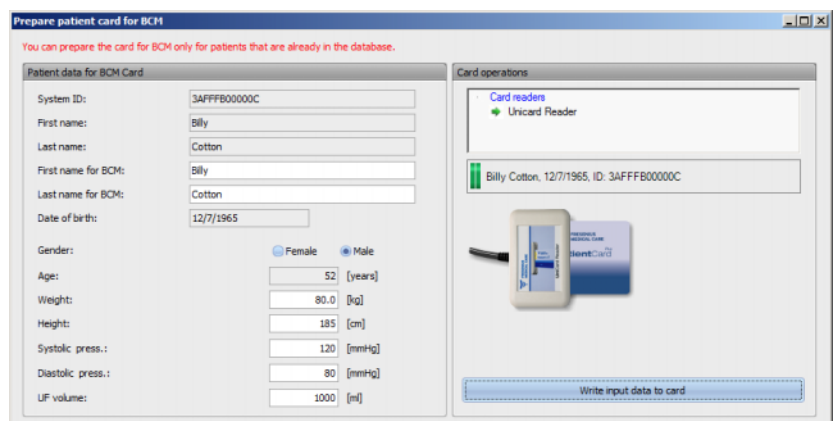
After erasing the card, the patient identity is missing and a special symbol (a red X) is displayed for the card.

When finishing, click on the **Close** button in order to close the dialog.

3.2.3.3 Prepare patient card for BCM

The **Prepare patient card for BCM** command opens a pop-up window that allows you to write the entered data for a BCM measurement to the patient card, on a patient basis.

This operation can be performed regardless the existence of an active session for the patient.



In the panel on the right you can select the required card reader. The panel displays the patient identity from the card. The patient identity must exist in the **Therapy Monitor** database; otherwise an error message is displayed.

In the panel on the left, you can see the patient data. The fields **First name for BCM** and **Last name for BCM** are editable and allows you to define the name that will be displayed on the BCM device. By default these fields are filled with the patient's first and last name. This is useful in case the patient name contains special characters that cannot be displayed by the BCM device. In such a case, the name is marked in red.

The BCM input data which is editable is weight, height, systolic pressure, diastolic pressure and ultrafiltration. The height is pre-set with the height imported from the external database and the blood pressure data is pre-set with the average values of the last 4 weeks (considering the first blood pressure measurement of each session). The weight and ultrafiltration must be manually entered.

The weight and height are mandatory, while the blood pressure and UF are optional.

After filling-in the input data, the button **Write input data to card** becomes active. If the input data is outside device ranges, the invalid data is displayed in red and the button is disabled.

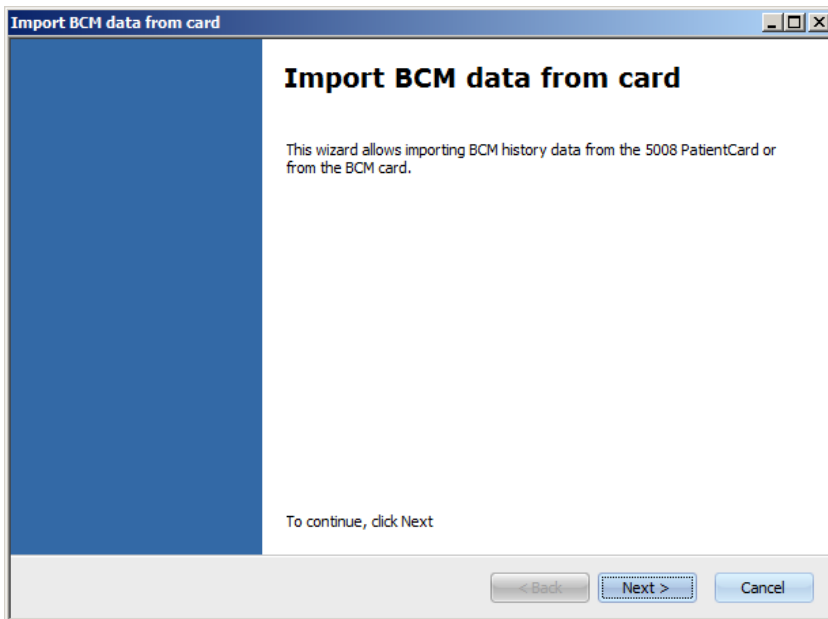
Press the **Write input data to card** to save the data to the patient card. You will obtain a success or an error message and the window is reset to the original state, allowing you to prepare the card for another patient.

When you are done, close the window.

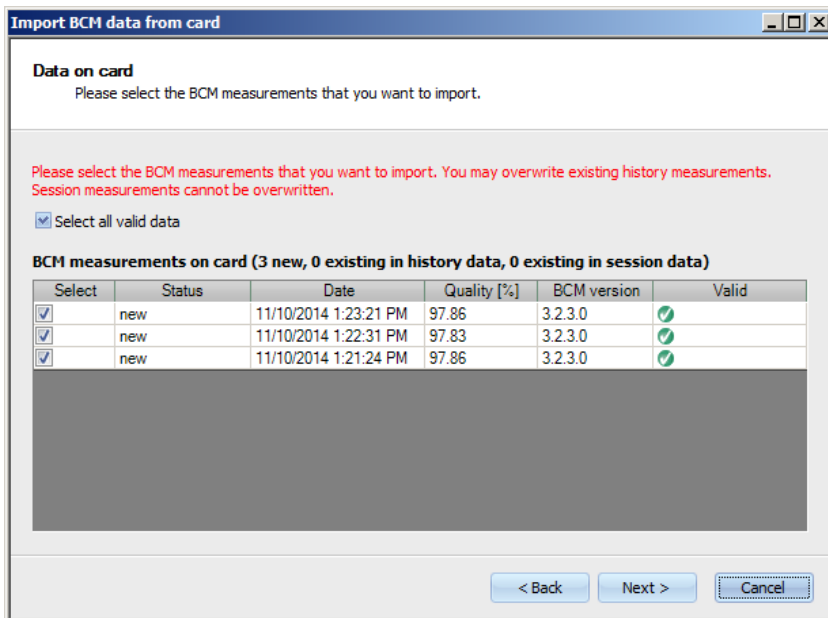
3.2.3.4 Import BCM measurements

The **Import BCM measurements** command opens a wizard that helps you to read historical (non-session based) BCM measurements from the patient card, on a patient basis.

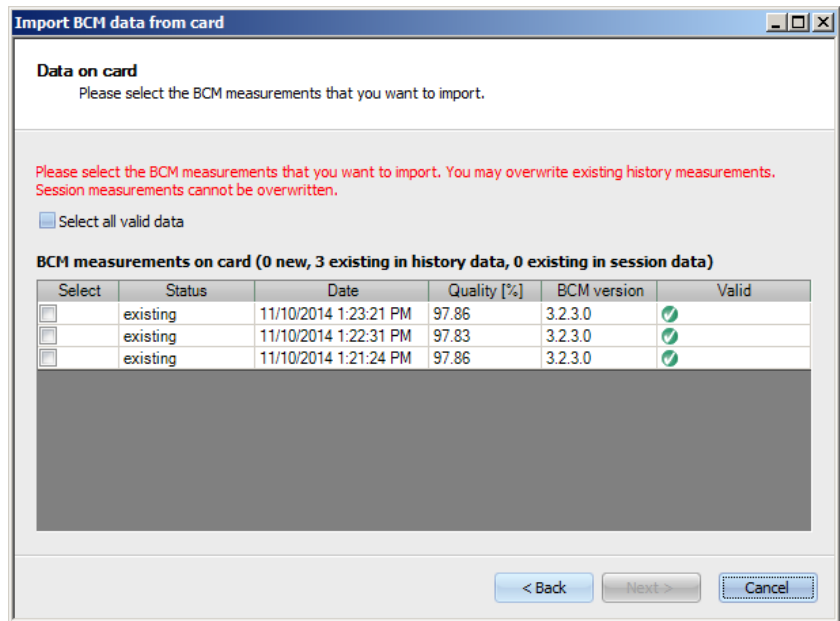
This operation can be performed regardless the existence of an active session for the patient.



Click **Next** to proceed. Insert the patient card in the selected card reader. If the patient identity exists in the **Therapy Monitor** DB, the **Next** button will be active; otherwise a warning message is displayed and the button will be inactive. For compatibility reasons, if the patient ID does not match any ID from the database, the patient name and date of birth are checked against similar data in **Therapy Monitor** database. If one or several patients with the same name and date of birth are identified, you are requested to explicitly select such a patient.



Click **Next** to read the BCM measurements from the card.



The window presents the measurement read from the patient card. The following data is presented: status, date of measurement, quality, BCM device software version, validity. The status can be: 'existing' - the measurement already exists in the database as historical (non-session) data, 'session' - the measurement already exists in the database and is attached to a particular dialysis session, and 'new' - the measurement does not exist in the database.

Click in the **Select** column of each measurement or click the **Select all valid data** to specify which measurements you want to import. Invalid measurements cannot be selected.

After you have made your selection click **Next** in order to import the measurements. The last page of the wizard will present the status of each selected measurement. Click **Finish** to close the wizard.



Note

As a standard operation, you should use only 5008 patient cards. However, for backward compatibility, you can import historical measurements from BCM cards as well. In this case, patient identity is checked based on patient ID from the BCM card and, if no such ID is found, on patient name and date of birth. You will be requested to confirm the patient from the database.

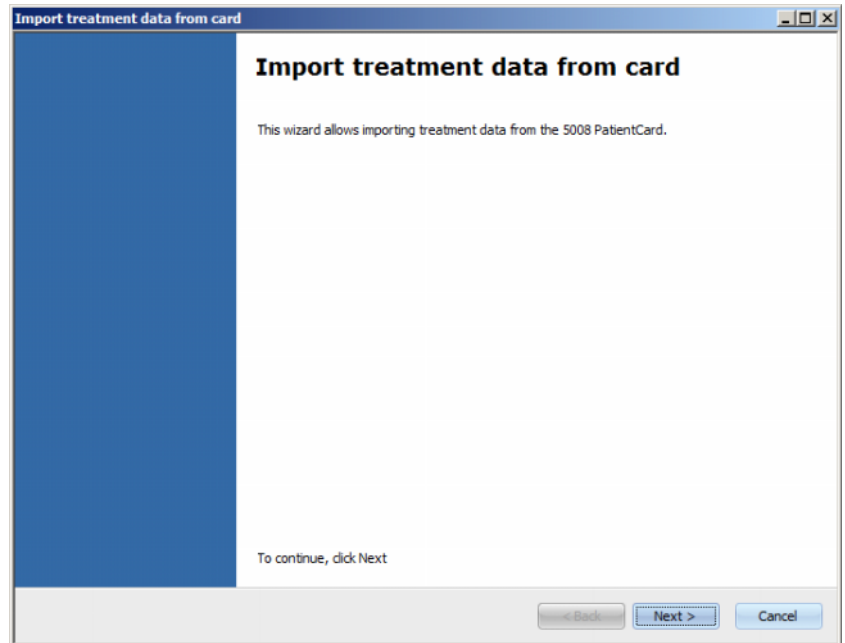
3.2.3.5 Import treatment results

The **Import treatment results** command opens a wizard that helps you to read historical (non-session based) treatment results from the 5008 patient card, on a patient basis.

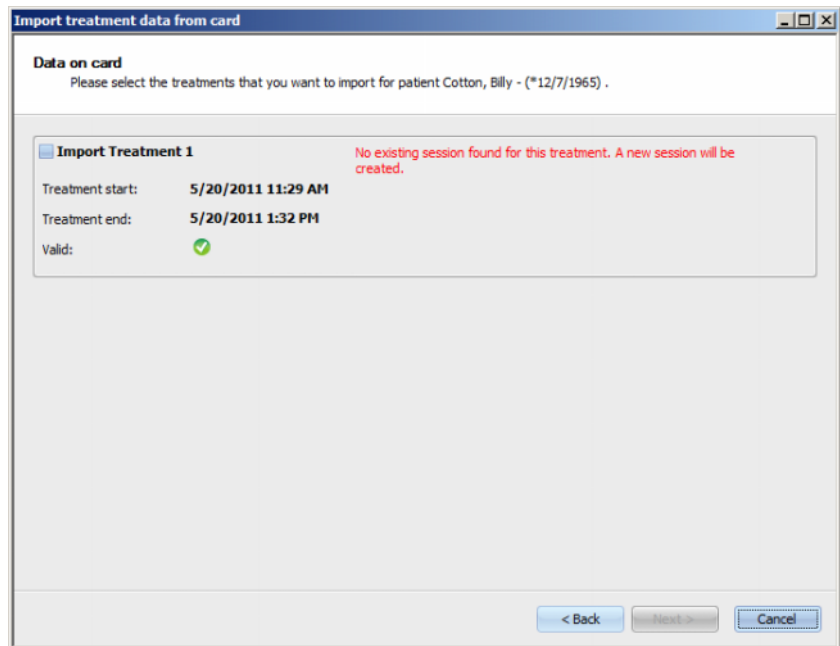
This operation can be performed regardless the existence of an active session for the patient.

Treatment results read from the card are called offline results, as opposed to online results which are sent by the dialysis device at the end of the treatment via the network. A session with treatment results read from the card is called an offline session, as opposed to an online session which has online results.

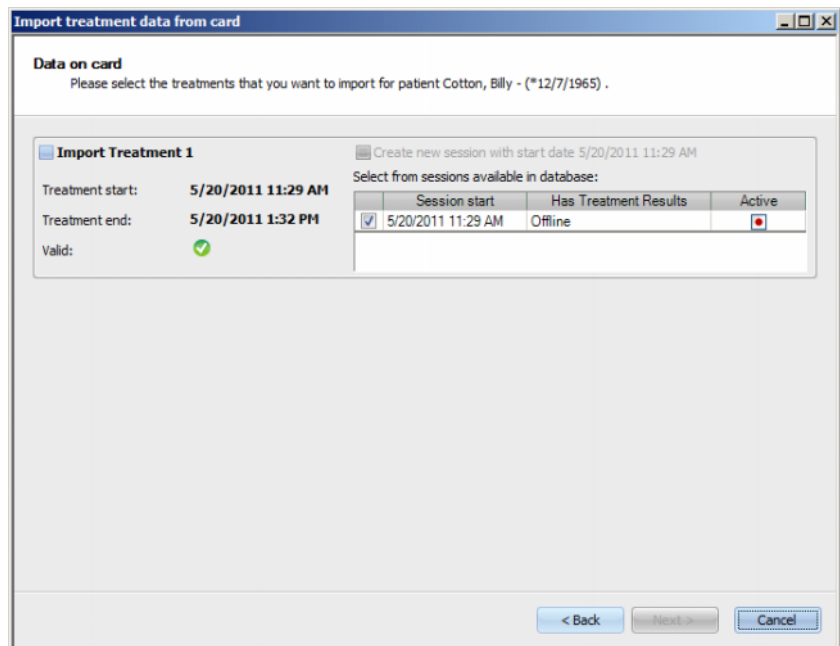
Offline treatment results must be attached to a session. Offline results imported from a patient card may supersede online results.



Click **Next** to proceed. Insert the patient card in the selected card reader. If the patient identity exists in the **Therapy Monitor** DB, the **Next** button will be active; otherwise a warning message is displayed and the button will be inactive. For compatibility reasons, if the patient ID does not match any ID from the database, the patient name and date of birth are checked against similar data in the **Therapy Monitor** database. If one or several patients with the same name and date of birth are identified, you are requested to explicitly select such a patient.



Click **Next** to read the treatment results from the card.



The window presents the treatment results read from the patient card. No more than three treatments must exist on a 5008/6008 card. The following data is presented for each of the three treatments: start date/time, end date/time, the validity status and a list of existing sessions for which the session start date/time is within 24 hours (plus or minus) from the treatment start date/time.

For each session, the session start date/time is displayed, together with the treatment results of the session (offline, online or none) and graphical symbol that indicates the active status (active or inactive).

You can select which treatment you want to import and, for each such treatment, the session to which you want to attach the treatment results. You cannot select the same session for two different treatments. If no such session exists, a checkbox **Create a new session with start date <date>** is active. This option will create a new inactive session, with the session start/date taken from the treatment start/date.

Select the treatments that you want to import and the choice of session for each treatment, and then click on **Next**. The last page of the wizard will present the status of each selected measurement. Click **Finish** to close the wizard.

When importing treatment results for an off-line session, the device data and blood pressure measurements stored on the patient card are imported as well. This data can be viewed in the **Progress** and **Blood Pressure** detail views.

3.2.4 View

3.2.4.1 Language

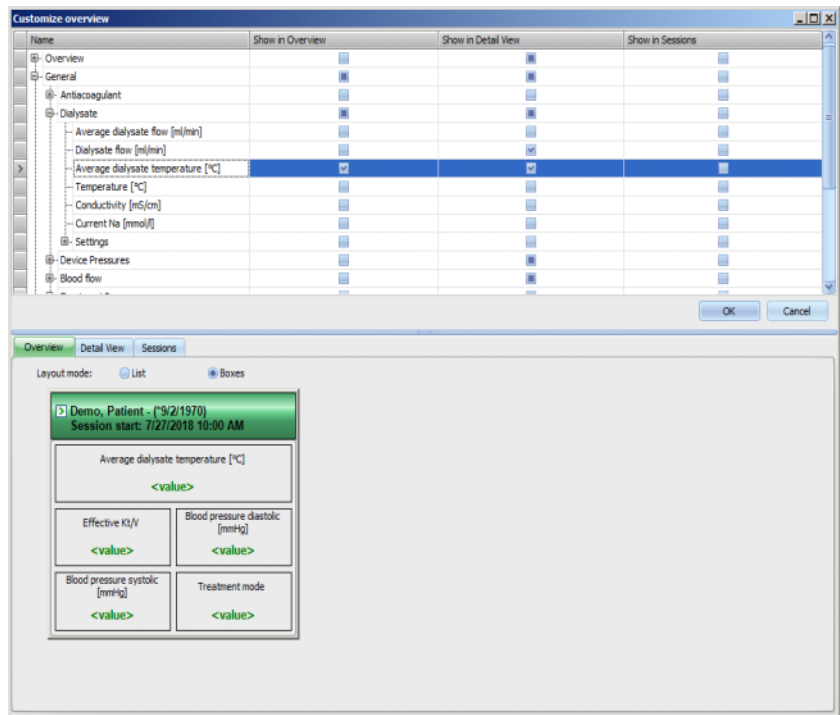
When starting the program for the first time, the language is dependent on the current country setting of the operating system. From the **View/Language** menu item, it is possible to quickly change the program language.

The languages currently available are displayed and will change when there is a new translated language. The list can therefore be continuously extended.

3.2.4.2 Customize Overview

This dialog allows the customization of three user-defined windows: Overview, Detail View and Session work-item. The customizable work-item and detail view are similar to all other such views in **Therapy Monitor**, except for the user-defined content. The overview represents an alternative way to present sessions, in a dashboard style, in which the data cells are also customizable.

In the upper part of the window there is a tree-like list of all the parameters sent by the dialysis devices together with 3 columns of checkboxes, one for each customizable window. In the lower part of the window there are three tabs which show the current definition of each window.



In order to customize a window, select the corresponding tab. By checking/unchecking the corresponding checkboxes, you are able to define the content of window. You can also use the mouse to drag a certain parameter from the tree to the window. Right-clicking on a column header opens a context menu with two options:

Check defaults and **Uncheck all items**.

The first one sets default values for the respective column while the second one clears all the checkboxes of the column.

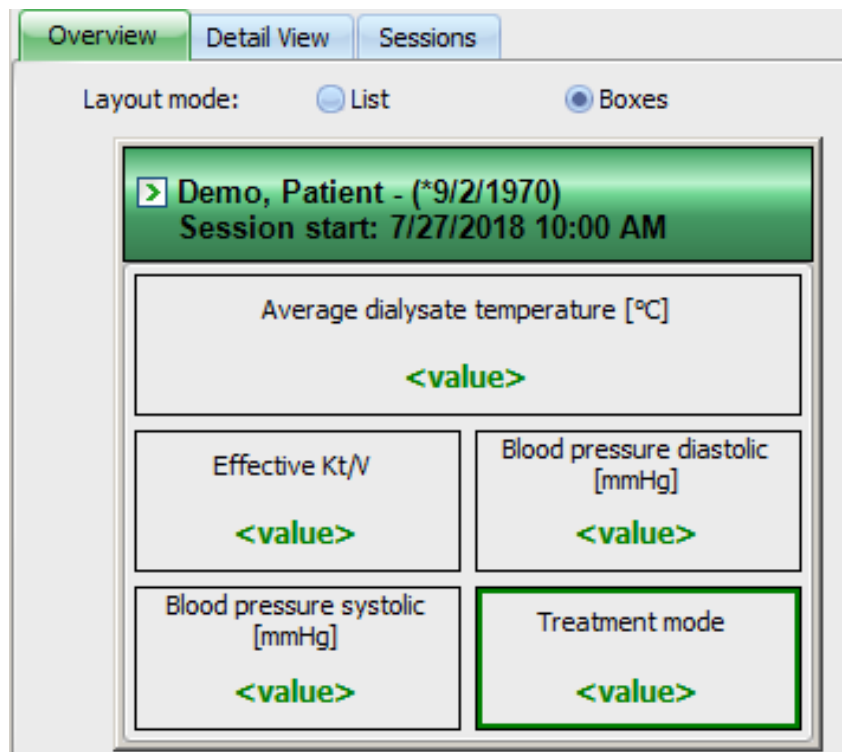
The number of configurable parameters is limited for each window, as follows:

- Session work-item: maximum 2 parameters
- Overview: maximum 5 parameters
- Detail view: maximum 12 parameters (besides 9 default ones, already defined)

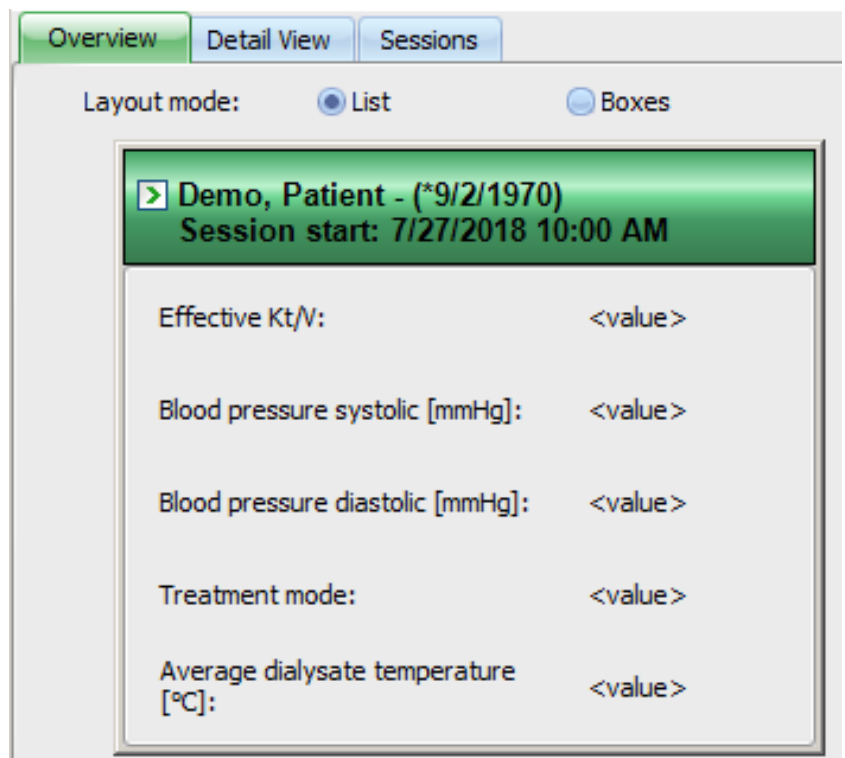
Trying to add more parameters will result in a warning.

Items can be removed, either individually or globally. Right-clicking on a parameter will open a context menu with two options: **Remove** and **Remove all items**. Select the appropriate option.

Within a certain window, the order and/or position of items can be changed. Click on an item and - holding the mouse button down, drag the item to the required position.



In addition, the **Overview** window can be further configured. You can resize the window by dragging the borders with the mouse or you can revert to the default size by right-clicking and selecting the context menu option 'Default size'. The Layout Mode radio-buttons (List, Boxes) allows changing the appearance:



When the customization is ready, you should click the OK button to save the settings. A message window appears, informing that the Overview screen must be reloaded in order to reflect the changes. Click Cancel in order to discard the changes.



Note

Customization is global at the clinic level. All instances of **Therapy Monitor** will reflect the changes immediately.

3.2.4.3 Show alarms

This setting allows you to display the **Alarms** pop-up window. All 5008/6008 and 4008 device alarms for the visible active sessions are displayed in this pop-up window. **Enable alarms checking** from the **Options** window must be activated to receive the alarms. The alarms contain information about patient name, device (generating the alarm), time and type of alarm.

Acknowledged alarms are displayed in green. Unacknowledged alarms are displayed in red.

Unacknowledged alarms from the 4008 disinfection phase (phase 4) are displayed in orange.

3.2.5 Help

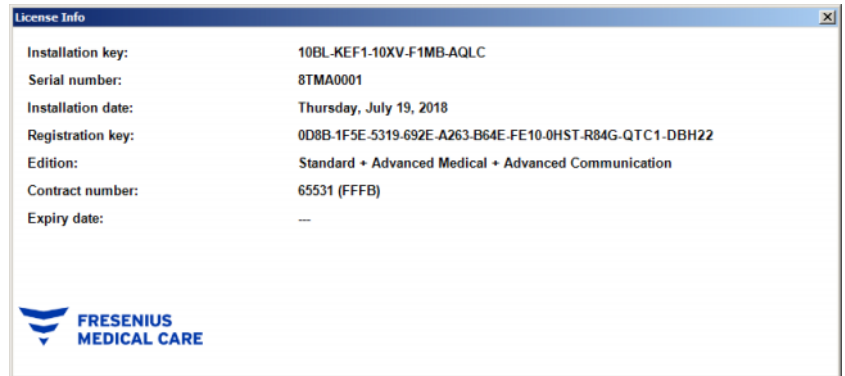
3.2.5.1 About Therapy Monitor

Here you can find information about the version number of the program and the License Agreement.



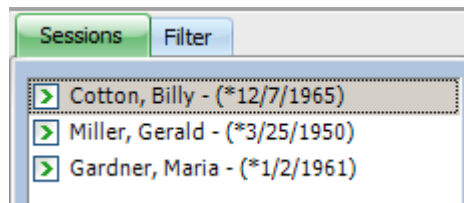
3.2.5.2 License Info

This menu item opens a window in which technical and regulatory details regarding the registration of **Therapy Monitor** can be found. Here you can see the optional packages that were ordered, like Advanced Communications or Advanced Medical, the serial number of the product and so on.



3.3 Therapy Monitor navigation

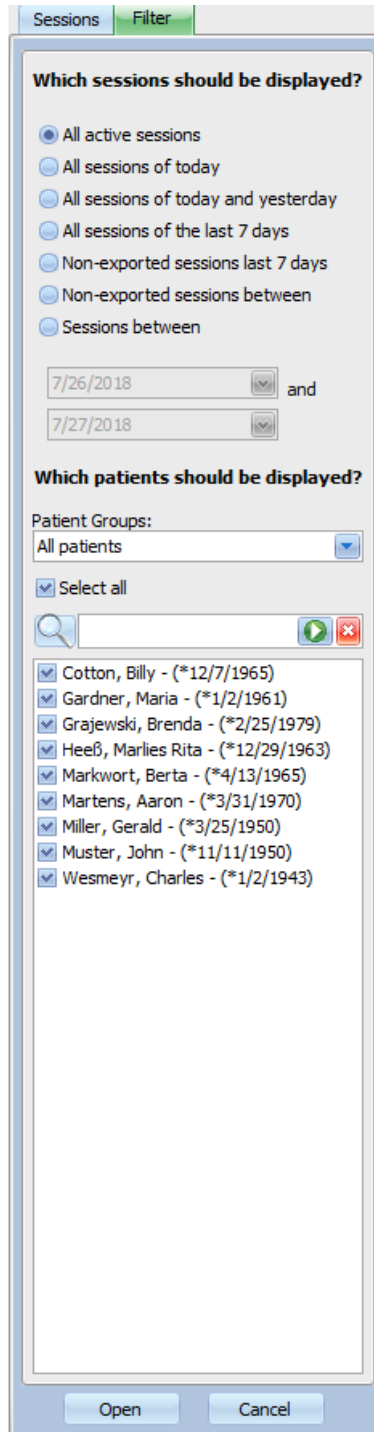
3.3.1 Sessions



Displays the patient sessions (both active and closed) according to the selection made under Filter.

The active sessions have a green arrow to the left of the patient name and birth date. The closed sessions are marked with a red dot to their left.

3.3.2 Filter



Different treatment session periods and different patients can be selected in the **Filter** navigation area.

You can select the patient group for which the patients sessions are to be shown, and you can also show or hide sessions from particular groups by ticking the check box or removing the tick to the left of the patient name.

Open displays the respective selection, and **Cancel** discards it.

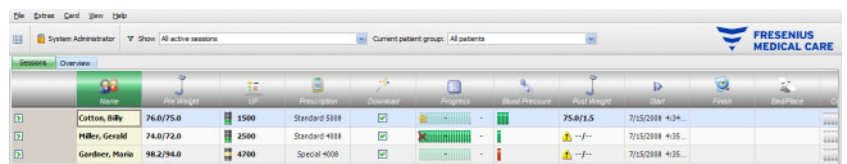
Sessions and patient groups can be filtered from the toolbar as well. Depending on the **Option/Visibility** settings, inactive patients are displayed or not. An **inactive patient** is a patient who is no longer present in the current patient list but who has dialysis sessions stored in **Therapy Monitor** database. Depending on the moment when the respective patient was removed from the patient list, the patient name may be unknown and displayed as '????, ???'. You can also search for a particular patient.

3.4 Detail area of the Therapy Monitor

3.4.1 Name

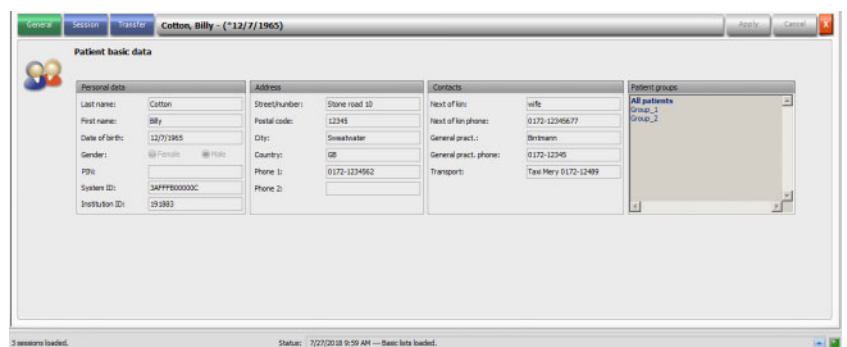
By default, the insertion of the patient card during the first measurement – usually at the patient scales – causes automatic registration of the patient in the system, by creating a new active session.

Manual registration of a patient is only required if devices connected to the system are defective and measurement data from replacement devices not connected to the TMon system is used instead.



Name	Weight	Height	Device	Mode	Flow	Pressure	Temperature	Time	Status
Cotton, Billy	76.6/75.8	1590	Standard 5988		75.8/7.5			7/15/2018 4:34	OK
Hilber, Gerald	74.6/72.8	2500	Standard 4818					7/15/2018 4:35	OK
Gardner, Maria	98.2/94.8	4700	Special 4008					7/15/2018 4:35	OK

When you click on the activity bar in the column below the **Patient** symbol and on the patient name, the **Basic patient data** detail area opens. In order to open a detail view for the first time you must double-click the respective field in the patient grid.



Patient basic data

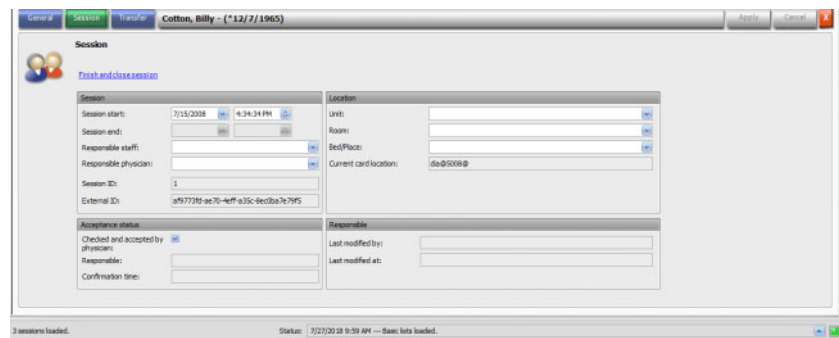
Personal data	Address	Contacts	Patient groups
Last name: Cotton	Street/number: Stone road 10	Next of kin: wife	<input type="checkbox"/> All patients <input type="checkbox"/> Group_1 <input type="checkbox"/> Group_2
First name: Billy	Postal code: 12345	Next of kin phone: 0172-12345677	
Date of birth: 12/7/1965	City: Seewasser	General pract.: Strismann	
Gender: <input type="radio"/> Female <input checked="" type="radio"/> Male	Country: GB	General pract. phone: 0172-12345	
System ID: 34449600000C	Phone 1: 0172-1234562	Transport: Taxi Henry 0172-12489	
Institution ID: 193883	Phone 2:		

3 sessions loaded. Status: 7/27/2018 9:59 AM -- Basic data loaded.

This area contains the personal data, address and contacts of the patient. Here you can also find the Patient Identification Number (PIN), the System ID, and the Institution ID. The groups that the patient belongs to are displayed on the right-hand side.

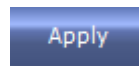
No fields can be edited. System ID and Institution ID are automatically allocated by the system (via the EDBMS) when a patient is newly registered.

If you select the **Session** tab, you can now complete the session for the respective patient. Select **Finish and close session**.



In addition, you may place a tick in a check box, indicating that the session was checked and accepted. You may also select the unit, room and the bed/place, as well as the responsible staff and physician for the session.

To save your changes click the **Apply** button.



If you do not wish to accept your new entries, click the **Cancel** button.



When you first access the **Session** detail area, the Apply and Cancel buttons are gray, but as soon as you make entries in an appropriate field both buttons will turn blue and their function is selectable.

This procedure applies to all further detail areas.

The session end is automatically written by the system as well as the user and time-stamp of the last edit operation.

If you select the **Transfer** tab, the **Import basic data** option will be available.

As soon as a patient logs on to the system with his patient card on the current treatment day, the prescription data from the interlinked EDBMS is automatically transferred to the TMon system and is available in the **Session data** tab menu described above. This current data import ensures that possible changes in the dialysis regime having occurred in-between treatments will be taken into consideration, so always the most current, valid dialysis regime will be available.

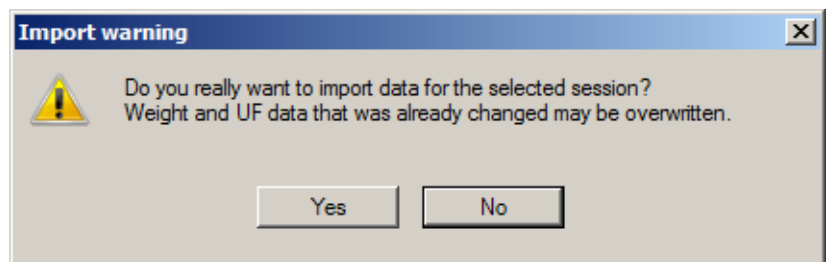


Warning

Risk for the patient as a result of wrong treatment parameters

Prescription changes applied in the external database management system after a dialysis session has already been created in **Therapy Monitor** will not become effective automatically for the upcoming treatment.

- Use the Import session data button to update the displayed dialysis regime before performing the prescription download to the dialysis device.



Click the **Yes** button to import the session data.

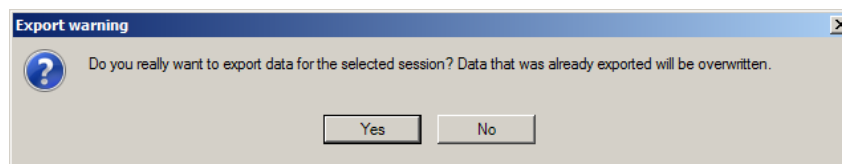


Note

Re-importing the session data will not affect the operations performed so far for the respective session (such as applying a medication or a consumable, confirming a message or a To Do entry, etc.). Only prescribed weight and UF data may be affected in certain circumstances.

Depending on FIS server settings, certain session data categories like Messages, To Dos, Risks and External Laboratory might be automatically periodically re-imported at a predefined time.

You can also export the session data to the EDBMS overwriting the existing session data.



Click the **Yes** button to export the session data.

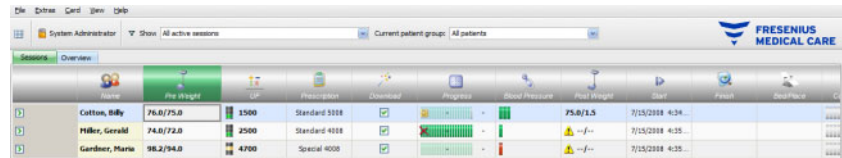
The **Session data** and the **Basic data** tabs show the status of each import/export operation.

3.4.2 Weight data

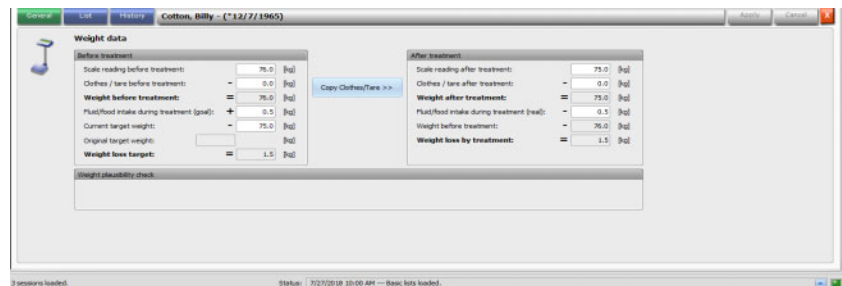
After the patient has been weighted, his pre-dialysis weight is automatically recorded in the **Therapy Monitor**.

The **Weight data** detail area performs a weight plausibility check based on the existing data.

The Pre Weight cell in the activity bar displays the current pre-dialysis weight and the target weight. If there is a plausibility warning, the Pre-Weight cell displays an exclamation mark. If the prescription contains a pediatric option, the cell displays a specific graphical symbol (Teddy bear). The Post Weight cell displays the current post-dialysis weight and the actual weight loss. If there is a plausibility check warning, or there is a weight increase during dialysis, the Post-Weight cell displays an exclamation mark.



When you click on the activity bar in the column below the **Pre Weight** or the **Post Weight** symbols, the **Weight data** detail area opens.



Fields already filled in with patient data contain prescription data from the connected EDBMS or measurement data from scale.

If you want to make changes to weight data for this particular dialysis day, you can only use the white fields as the gray fields cannot be changed.

To enter data or select entries in the individual fields, simply click the respective item or go forward using the **Tab** key or backwards using **Shift + Tab**.

To accept changed data click the **Apply** button, or use **Cancel** to abandon the action.

Permanent weight data changes must only be made in the EDBMS!

For low volume (pediatric) prescriptions, a graphical symbol (Teddy bear) is displayed. If the entered weight is not plausible, with respect to the target weight, an exclamation mark is displayed next to the control and in the Pre Weight activity cell. A plausibility check is performed on target weight as well, with respect to low volume (pediatric) or standard volume (adult) options.

Any change in the data will automatically refresh the detail window settings. After saving the data by means of the Apply button, the activity bar will also be refreshed. This applies to all detail windows in **Therapy Monitor**.



Note

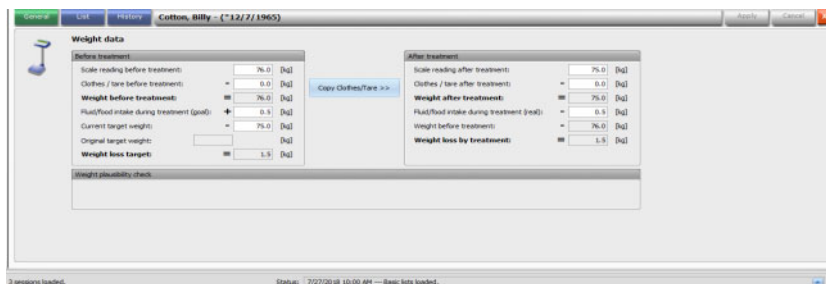
All fields that can be edited have admissible domains for values. If a value is outside the domain, it will be highlighted in red. This applies to all numerical data fields that can be edited in **Therapy Monitor**.

Once the pre-dialysis weight is entered, an automatic calculation of the UF settings is performed. If the UF parameters fixed in the dialysis regime are exceeded, a **red status indicator symbol** appears. Missing calculation input parameters lead to a **missing status indicator symbol**.

For more information on automatic UF calculation refer to the UF Settings chapter.

Important note:

Should you weight a patient repeatedly before starting dialysis, the last determined weight is counted as the valid pre-dialysis weight. As soon as dialysis is in progress, all subsequently performed measurements are regarded as **measurements during dialysis treatment**. If multiple weight measurements are entered after the completion of dialysis, the last recorded weight counts as post-dialysis weight.



The **Copy Clothes/Tare >>** button copies the pre-dialysis clothes/tare value to the post-dialysis one.

If the calculated weight loss is negative (meaning that the patient weight increased during treatment) an exclamation mark is displayed near the control, as well as in the Post Weight activity cell.

This detail area also contains the **List** tab.

The **List/Data** tab documents all weight changes, together with the origin of the change - scale, including bed scale, EDBMS, or user input, and the corresponding timestamp.

The **List/Graphic** tab presents the graphic evolution of the patient weight during the dialysis session.

The **History** tab refers to the sessions already undergone by the patient. It shows the patient's weight before and after treatment and the target weight of previous sessions, both in text and graphical formats.



Warning

Risk for the patient as result of corrupted data
Risk for the patient as a result of a wrong therapeutic decision

Data loss or data corruption cannot be totally excluded while weight data is being transferred from the scale to **Therapy Monitor**. This can lead to incorrect ultrafiltration settings.

- The user must check the weight data displayed in **Therapy Monitor** for correctness and plausibility.
- If in doubt, repeat the weight measurement.



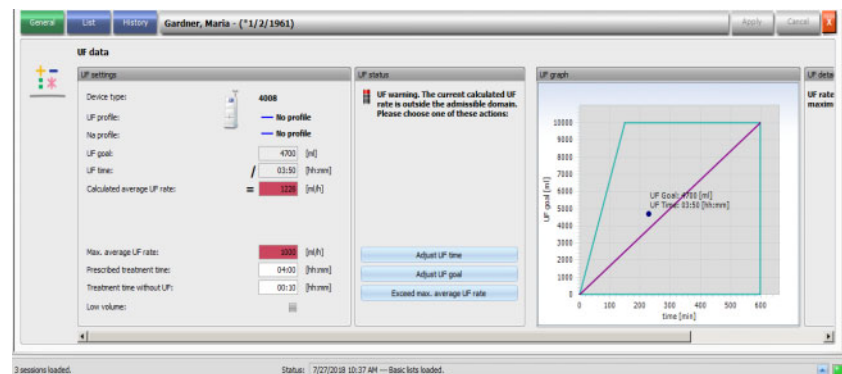
Note

The correct operation of the scales and compliance with their inspection and calibration intervals is the responsibility of the user.

3.4.3 UF

Name	Pre weight	UF	Prescription	Download	Progress	Blood Pressure	Post Weight	Start	Finish	GoalPlace
Cotton, Billy	76.0/75.0	1500	Standard 5008	✓	✓		75.0/1.5	7/15/2018 4:34		
Miller, Gerald	74.0/72.0	2500	Standard 4008	✓	✓	⚠	--/--	7/15/2018 4:35		
Gardner, Maria	98.2/94.0	4700	Special 4008	✓	✓	⚠	--/--	7/15/2018 4:35		

When you click on the activity bar in the column below the UF symbol, the UF data detail area opens. The UF work item is displaying a status indicator (traffic light shape) and the UF goal (only in case the traffic light exists and its color is green or yellow).



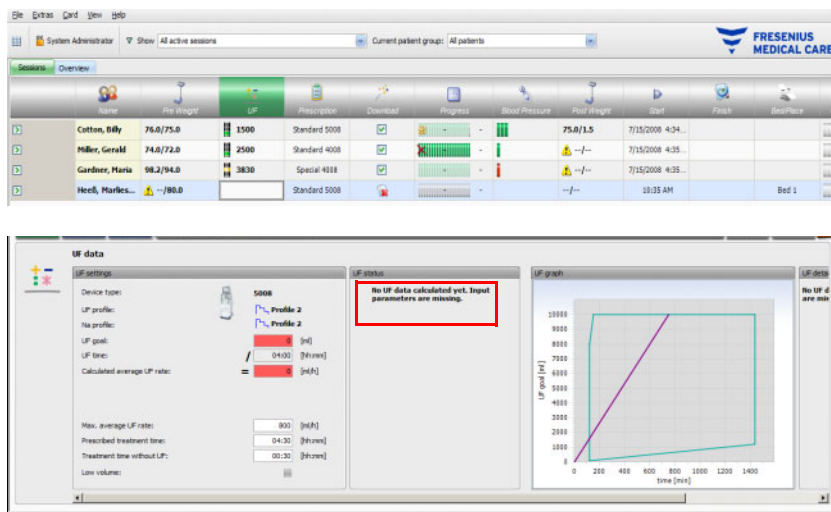
Incorrectly calculated UF settings (see below) often cause a patient’s blood-pressure drop during dialysis, requiring intervention.

The UF assistant integrated in **Therapy Monitor** prevents erroneous calculation and delivers a complete recommendation for UF settings for this treatment day immediately after recording the pre-dialysis weight.

Immediately after input of the pre-dialysis weight measurement, the TMon client performs the automatic UF calculation in the background, determining UF target, UF time and UF rate. This calculation is based on the current weight measurement result, as well as on the maximum UF rate defined in the dialysis regime, additional (fluid intake during treatment) and planned treatment time.

The data of the dialysis regime originates from the connected EDBMS and was automatically imported to the TMon client during login of the respective patient.

Immediately following the measurement of the weight, the calculated UF settings can be viewed in the **Therapy Monitor** UF data detail area. Should you fail to create a dialysis regime in the EDBMS, UF calculation cannot take place. In this case the following note appears in the UF assistant:



This message is also displayed when the dialysis regime was incompletely recorded in the connected EDBMS, especially if no treatment was entered for the current week day.



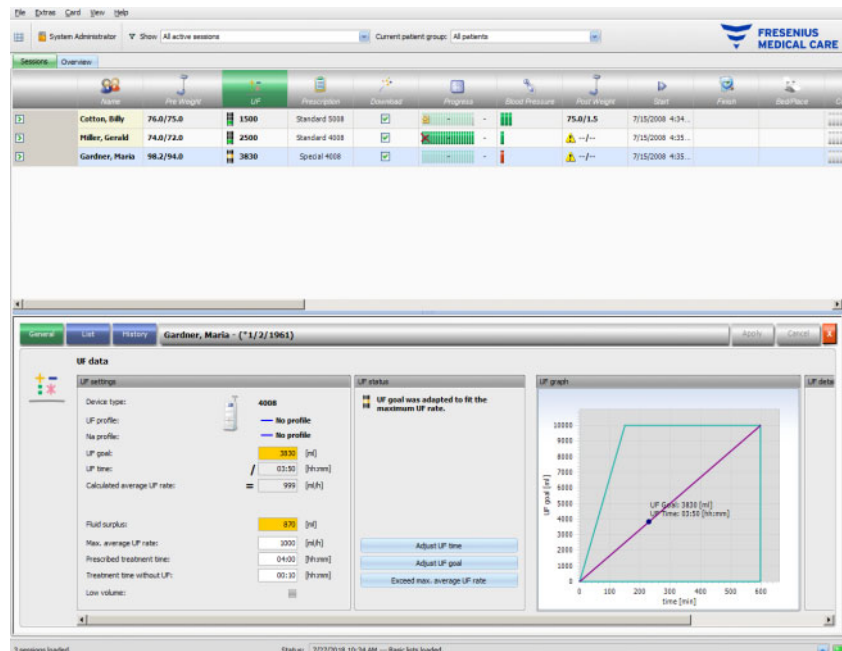
Note

To enable automatic UF calculation, it is absolutely necessary that you create a dialysis regime for each patient in the connected EDBMS, which contains basic information required for the calculation.

Please enter the intended treatment days, required treatment time, target weight (dry weight), estimated fluid intake during treatment, as well as the maximum UF rate. Should ultrafiltration end a few minutes before the end of treatment time, you can specify this duration in the field **Treatment time without UF**.

For low volume (pediatric) prescriptions, a graphical symbol (Teddy bear) is displayed in both the activity cell and in the detail view, and certain UF limits are adjusted, like the maximum UF rate.

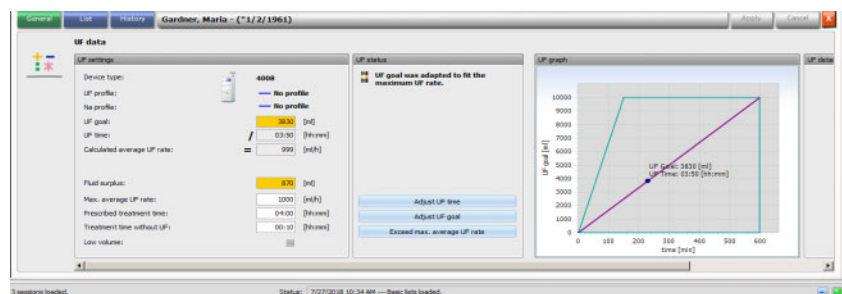
If the TMon client ascertains that beneficial treatment recommendations cannot be calculated on the basis of the available parameters, a red status indicator symbol will appear in the session row under the UF activity and in the UF status area of the open detail window.



In this case the UF dialog displays a red status indicator symbol and a message, stating that the currently calculated UF rate is larger than the maximum UF rate. The **UF graph** area shows the admissible domain for the UF goal and UF time, as well as the maximum UF rate that was prescribed. The **UF details** area displays all the restrictions that are broken by the current data. Please select one of the following actions (click the appropriate button) and then click on **Apply**:

- **Adjust UF time**
- **Adjust UF goal**
- **Exceed max. average UF rate**

For example, select **Adjust UF goal**:



The UF goal was adjusted to the maximum UF rate by calculating the possible UF volume from the maximum allowed UF rate and the pre-selected UF time. Please note that the next dialysis generally requires an even higher UF goal if this option is selected. Most probably, this will then, in turn, exceed the allowed maximum UF rate.

Adjust UF time implies: The TMon client calculates the required UF time on the basis of the UF goal and the maximum admissible UF rate. This means that the UF time is longer than the prescribed one, and an additional UF time exists. The above action usually also increases the estimated dialysis time.

Exceed max. average UF rate implies: The UF parameters will be accepted unchanged. The patient is dialyzed with the unfavorable settings.

Please observe that **Adjust UF time** never decreases the UF time and **Adjust UF goal** never increases the UF goal.

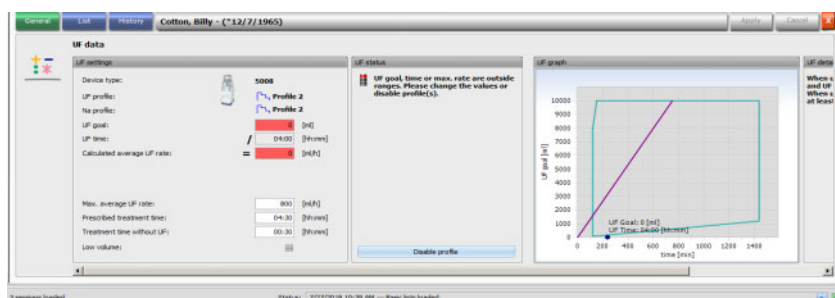
The admissible domain for UF data depends on the prescribed dialysis device (4008, 5008 or 6008) and also on the type of UF operation (with or without UF/Na profile). In case of UF/Na profile, there can be UF data that can no longer be adjusted by increasing the UF time or by decreasing the UF goal. In this case the only possible action is to disable the UF/Na profiles for the current session, by means of the **Disable profile** button.

The **Disable profile** button is available only when no other adjustment is possible.



Note

The EDBMS can prescribe a 'No UF needed' option. In this case the UF goal will be 0 regardless the pre-weight and target weight values.



After you have selected an action, the red status indicator symbol changes to yellow to indicate that the system did determine a transgression during UF calculation, but that the user acknowledged this by selecting an action.

On the basis of the selected example **Adjust UF goal**, you can see what can be achieved as UF target and what finally remains as fluid surplus.

The yellow status indicator symbol not only appears in the **UF data** detail area, but also in the treatment overview.

Name	Pre-weight	UF	Prescription	Overload	Progress	Blood Pressure	Post-weight	Start	Finish	Surplus
Cotton, Billy	76.0/75.0	1500	Standard 5008	🟡	🟢	75.0/1.5		7/15/2018 4:34		
Hilber, Gerald	74.0/72.0	2500	Standard 4008	🟡	🟢			7/15/2018 4:35		
Gardner, Maria	98.2/94.0	3830	Special 4118	🟡	🟢			7/15/2018 4:35		

Besides selecting these actions, you can also perform daily changes in prescription values by altering, for example, the maximum average UF rate, prescribed treatment time or treatment time without UF in the appropriate white fields.

Each input, such as manual changes to a parameter or the selection of an action described above, immediately updates the calculation, so that you are always informed of the effects caused by each change. Click on **Apply** to save the changed data or on **Cancel** to discard the changes.

Also if you enter new values in the **Weight data** detail area and save them by clicking **Apply**, the UF calculation is immediately updated with the new values. This includes the automatic application of the last adjustment action, in case the new weight data would result in an UF invalid state.



Note

General verification of calculated UF specifications is the responsibility of the user.

The **List** tab shows all the changes of the UF data, like time-stamp, source of change like scale, user input, external DB, type and unit of measurement.

The screenshot shows the 'Overview' tab of the therapy monitor. It lists three patients: Cotton, Billy; Miles, Gerald; and Gardner, Maria. Below this, the 'History' tab for 'Gardner, Maria' is open, displaying a table of UF data.

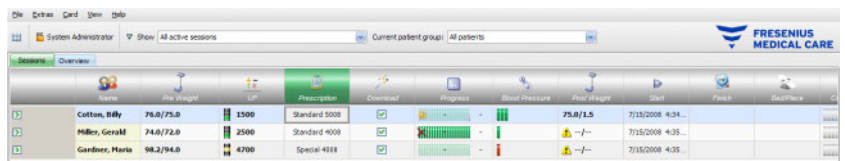
Date/Time	UF Value	UPL	Type	Source
5/23/2017 1:46:18 PM	262 [ml]	1500	UF time	User input / 7Mon
5/23/2017 1:46:18 PM	1010 [ml]	Standard 4100	UF rate	User input / 7Mon
5/23/2017 1:46:18 PM	1	Standard 4100	UF status = valid	User input / 7Mon
7/27/2018 10:25:17 AM	220 [min]	3830	UF time	User input / 7Mon
7/27/2018 10:25:17 AM	999 [ml]	Special 4000	UF rate	User input / 7Mon
7/27/2018 10:25:17 AM	3830 [ml]		UF goal	User input / 7Mon

The **History** tab refers to the sessions already undertaken by the patient. It shows the patient's previous UF values. The fields displayed are the Session start date, UF goal, UF volume and UF rate, both in text and graphical format.

3.4.4 Prescription

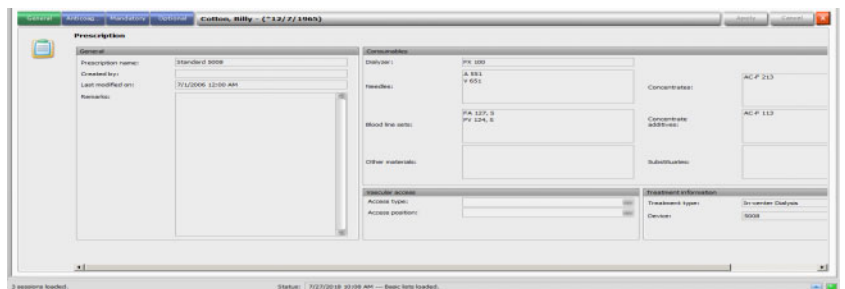
As soon as a patient logs on to the system with his patient card on the current treatment day, the prescription data is automatically transferred from the connected EDBMS to the TMon client. This current data import ensures that possible changes in the dialysis regime having occurred in-between treatments will be taken into consideration, so always the most current, valid dialysis regime will be available.

Please note that changes in the dialysis regime carried out in the EDBMS will not be considered in TMon if they are made after registering the patient for the day's treatment. In this case confirm the **Import session data** button to update the displayed dialysis regime (click on the patient's name in the **Name** column and in the opened detail area select **Transfer** and then click on **Import session data**).



Name	ID	Room	Prescription	Status	Start	End
Cotton, Billy	75.0/75.0	1500	Standard 5008	OK	7/15/2008 4:24...	
Miller, Gerald	74.0/72.0	2500	Standard 4008	OK	7/15/2008 4:35...	
Gardner, Haris	98.2/94.0	4700	Special 4018	OK	7/15/2008 4:35...	

When you click on the activity bar in the column below the **Prescription** symbol for the respective patient, the **Prescription** detail area will appear.



Prescription - Cotton, Billy (7/15/2008)

General	Concentration
Prescription name: Standard 5008	Dialysis: PK 100
Created by:	G 881
Last modified on: 7/15/2008 12:00 AM	P 551
Remarks:	Concentration: AC-P 213
	Concentration: AC-P 113
	Substances:
	Other materials:
	Special access
	Access type:
	Access position:
	Patient information
	Treatment type: In-center Dialysis
	Device: 5008

This detail area contains the current prescription data. The following menu items are available: **General**, **Anticoag**, **Mandatory** and **Optional**.

No changes can be made to the prescription at **Therapy Monitor** level.

The **General** menu item shows data like prescription name, vascular access, prescribed device, consumable, etc.

Consumables	
Dialyzer:	FX 100
Needles:	A 551 V 651
Blood line sets:	FA 127, S FV 124, S
Other materials:	
Concentrates:	AC-F 213
Concentrate additives:	AC-F 113
Substitutes:	

Vascular access	Treatment information
Access type:	Treatment type: In-center Dialysis
Access position:	Device: 5008

The **Anticoag** menu item shows both manual and machine anticoagulation.

The **Manual Anticoagulant** tab is divided into two sections: **Prescribed anticoagulant** and **Applied anticoagulant**. The **Prescribed anticoagulant** section contains data imported from EDBMS and cannot be changed. Anticoagulant data includes an initial anticoagulant described by substance, initial bolus, unit of measurement and conversion factor from ml to IU. Optionally, there can be one or two additional boluses applied after certain times. These additional boluses may be applied with the initial anticoagulant substance or with a second anticoagulant substance, described by substance, unit of measurement and conversion factor.



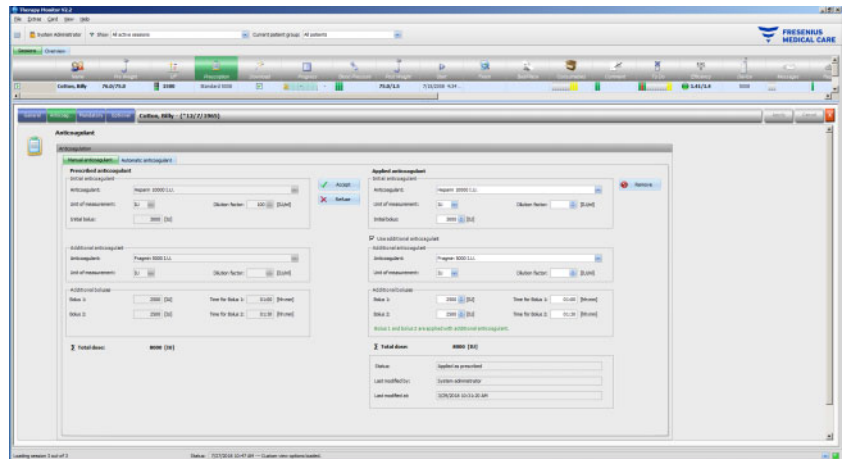
Note

Depending on the EDBMS version, the second anticoagulant substance may be missing.

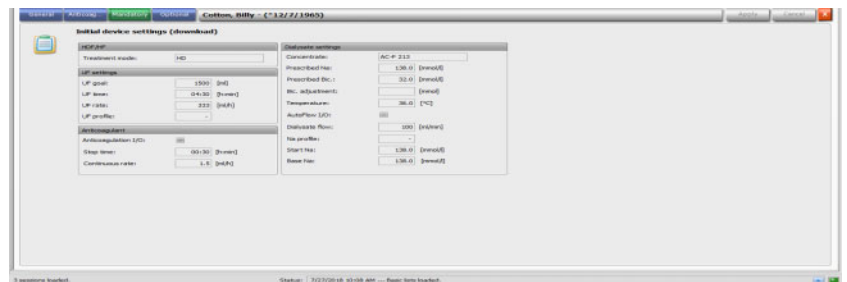
The **Applied anticoagulant** section is initially empty. Click on **Accept** button in order to accept the prescribed anticoagulation data.

You can change the applied anticoagulant substances, the units of measurement (I.U. or ml), the dilution factors, the boluses and the time of application. The time-stamp and user are recorded automatically, as well as the total dose in I.U.

You can delete an applied anticoagulant by clicking on the **Remove** button. Click on **Apply** to save the changes or on **Cancel** to abandon the operation



The data under **Mandatory** and **Optional** menu items - such as UF settings (goal, time, rate, etc.), dialysate settings (concentrate, temperature, dialysate flow, etc.), sodium settings (Na control I/O, goal for Na change, etc.) and reinfusion settings (blood flow, type, etc.), as well as other parameters for specific modules (OCM, BVM, etc.) - will be used by the connected 6008, 5008 or 4008 devices and the treatment will be performed accordingly.



Note

Prescription changes can only be made in the EDBMS.

3.4.5 Device settings

The dialysis system can accept a patient-specific devices presetting (download). Patient-specific data are supplied by an external database.

This data includes, e.g.:

- Patient name with date of birth
- UF data
- Dialysate data

This data is displayed on the dialysis system. It is the responsibility of the user to check that the data is correct and plausible before continuing. After successfully verifying and carefully confirming the data, it is then used as the treatment parameters.

If the user does not confirm this data, it is discarded.

During import, the data is checked for correct format and valid value range. Non-compliance with these settings results in the entire data records being rejected.

Requirements for data transfer:

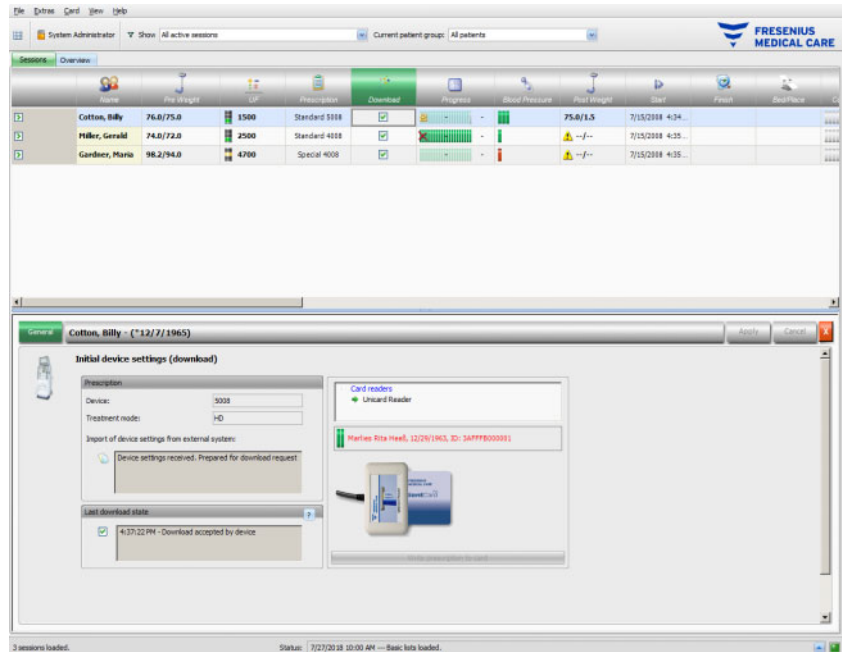
- The Download function in the system is activated.
- The optical detector on the system does not detect blood (OD light).
- The dialysis system must be in the **Preparation** operating mode (with the 4008 system, the T1 test must be completed; with the 5008/6008 Therapy System, the T1 test should be completed).
- A valid patient card must be inserted in the card slot of the dialysis system.
- Successful UF calculation (yellow or green status indicator symbol).
- Successful data import from the EDBMS.
- All values are within the specified value ranges.



Note

If an already confirmed patient card is replaced by another card, the user must verify the new setting values regarding the respective patient.

When you click on the activity bar in the column below the **Download** symbol for the respective patient, the **Initial device settings (download)** detail area will appear under the **General** menu item. This area contains the import status of the device settings/options from the external system and the download status of the data to the connected dialysis system. The detail area contains a card reader control and a button **Write prescription to card**. If valid, the device settings can be written to the patient card. This allows an offline 5008/6008 system (not connected to the network) to import the settings from the card. If the settings are not valid or an incorrect patient card is inserted in the card reader, the button **Write prescription to card** is not active.



Warning

Risk for the patient as a result of wrong treatment parameters
Risk for the patient as a result of a wrong therapeutic decision

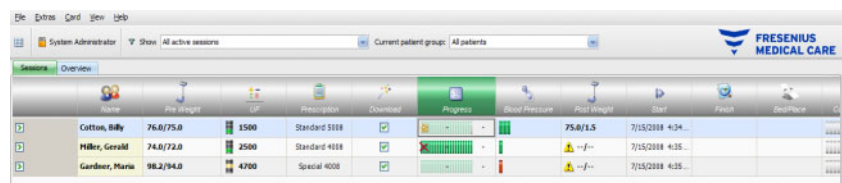
A mix up of patients during data editing or card programming can lead to a wrong treatment for the patient.

- The user must make sure that the data supplied corresponds to the respective patient (to avoid patient confusion).
- The data must never be trusted 'blindly'. Users must check the data for correctness just as they would do when manually entering data on the dialysis device.

3.4.6 System measurement values

The treatment progress for a specific patient is shown in a row below the **Progress** symbol for the current, selected dialysis treatment. The time indicated in the progress bar is the time remaining until the end of dialysis; the time indicated on the right next of the bar is the calculated time when the treatment is expected to be completed. The cell also graphically indicates the presence of the patient card in the device, an alarm at the device and the loss of communication (no data sent by device for more than one minute).

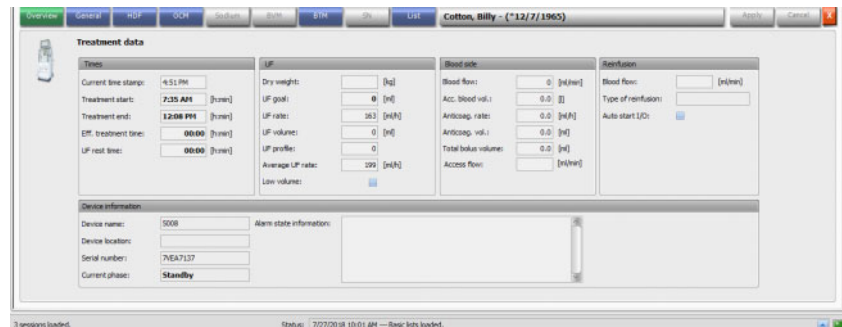
When you click on the activity bar in the column below the **Progress** symbol for the respective patient, the **Treatment data** detail area will appear.



This area contains all treatment data records, subdivided into the equipment features of the dialysis system and the respective treatment mode: Overview, General, HDF, OCM, Sodium, BVM, BTM, SN and List. If a device option is gray, for example SN, HDF, BTM, BVM or Sodium this means that the option is not active during this treatment or in the current device status, e.g., cleaning.

Some examples of Treatment data detail views are illustrated below:

- Overview (time stamps, UF data, blood side data, device information)



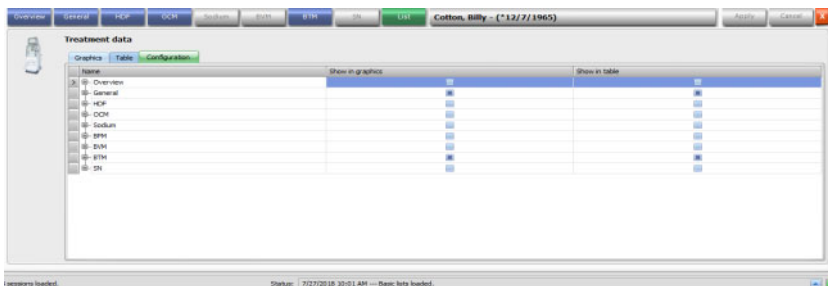
- General (general treatment data)



– OCM (Online Clearance Monitoring)



– List



Use the Configuration tab under the List item to select which parameters will be displayed in graphics or in tables. The **Graphics** page has options for copying the content to clipboard, printing and zooming (these options are common for all graphic charts in **Therapy Monitor** client). The **Table** page has an option to export the data to MS Excel format.

Under **Overview**, you will also find the current alarms of the connected dialysis system for the selected patient.



Graphics

Table



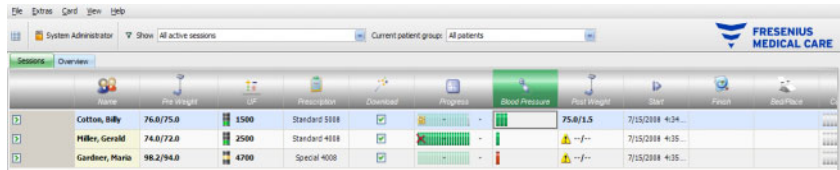
Warning

Risk for the patient as a result of unnoticed alarm signals

Network problems can interrupt the connection between a dialysis device and the **Therapy Monitor** system. Thus the transmission of alarm data of a dialysis device can be delayed or lost on its way to the **Therapy Monitor** system.

- Users must ensure that they are close enough to the dialysis device to notice all alarms and warnings it signals.
- Dialysis device alarms and warnings must not be monitored via **Therapy Monitor**.

3.4.7 Blood pressure



The **Blood pressure** activity allows you to record and to analyze blood pressure measurements for dialysis sessions.

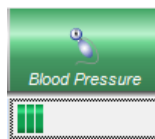
In the activity bar, below the **Blood pressure** symbol for the respective patient, you will see a number of red and green bars with the following meaning:



A green bar means that the measurement value is within the patient-specific alarm limit range.

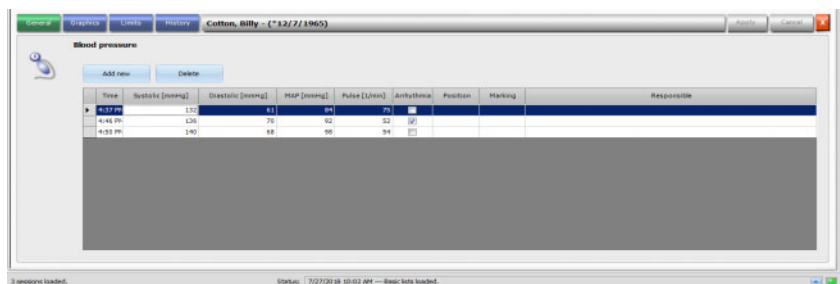


A red bar means that the measurement value is outside the patient-specific alarm limit range.



The number of bars indicates the number of performed measurements.

When you click on the activity bar in the column below the **Blood pressure** symbol for the respective patient, the **Blood pressure** detail area will appear.



The **Blood pressure** detail area contains the automatically recorded measurement data from the integrated blood pressure module in the dialysis system as well as other external measuring devices connected to the **Therapy Monitor**. All measurements are displayed together with time, systolic/diastolic pressure, mean arterial pressure (MAP) and pulse.

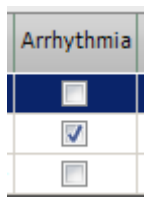


Note

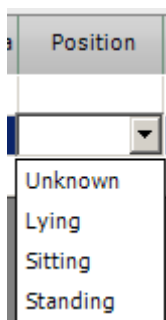
If a certain value is outside the prescribed limits, the corresponding cell is displayed with a red background.

You can also enter blood pressure measurements manually: go to **Add new** (top left, above Time) and create a new line. The system automatically displays the current time. The Systolic column is selected and you may enter the measurement value. Use the tab key to go from column to column to enter the respective measurement value. If you want to remove the newly created line, please select **Delete** (on the right next to Add new).

If you click on the check box in the column under Arrhythmia, a tick will appear in the white check box to indicate that the pulse is currently arrhythmic.

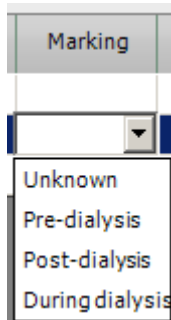


The Arrhythmia column is followed by the **Position** column. A Down arrow is displayed inside the column. Click here or press the Enter key and a selection menu will open.



By clicking the respective criteria (the measurement value was recorded in the lying, sitting, standing or unknown position) or confirming it with the Enter key, the selected criteria will be accepted.

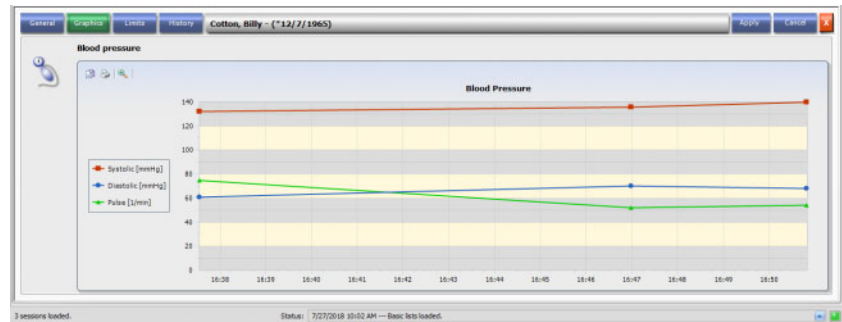
The **Position** column is followed by the **Marking** column.



As already described, click the respective criteria or acknowledge with the Enter key.

Then click the **Apply** button to save the entered data. Select the **Cancel** button to discard the data. The **Responsible** column is automatically filled in with the current user name.

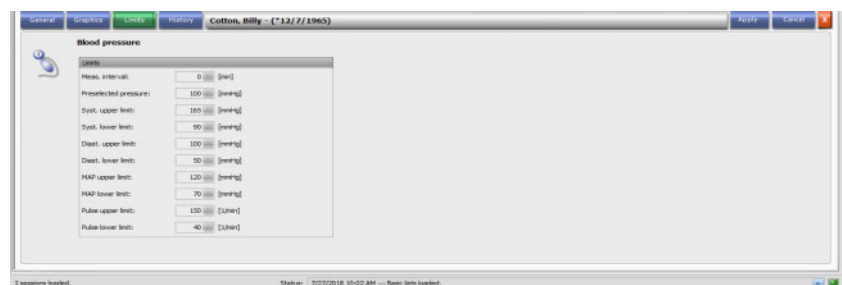
In the Blood pressure detail area you have the option to display the measurement values in a graph. Select the **Graphics** menu item.



This graphic contains the evolution of systolic/diastolic pressure and pulse. The color coding (red denotes the systolic, blue the diastolic pressure and green the pulse) provides you with a clear overview of the blood pressure evolution.

Place the mouse on a color coded symbol to display the measurement result.

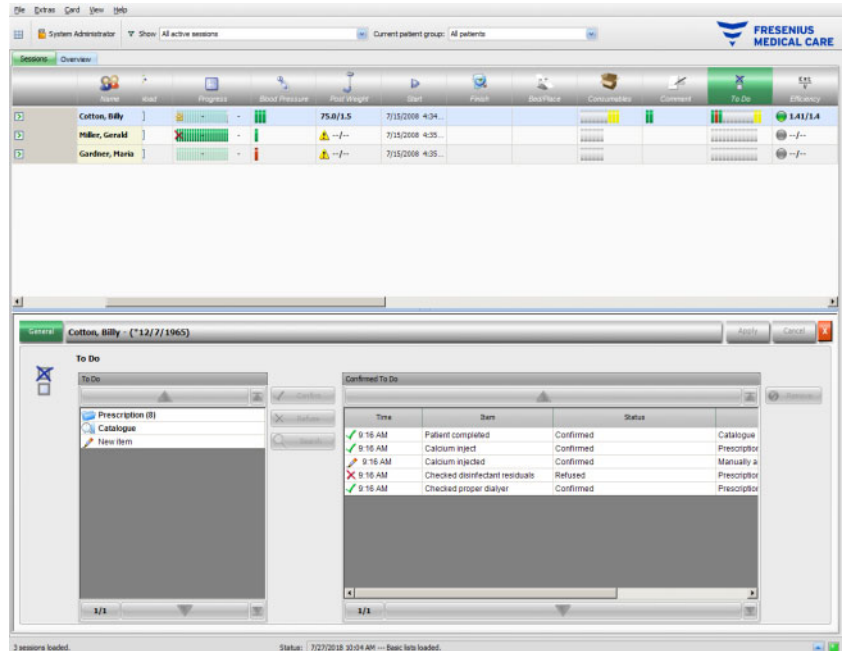
You can also view blood pressure limits for the respective patient, as provided by the EDBMS and/or by the dialysis systems. Select the **Limits** menu. The limits values are not editable.



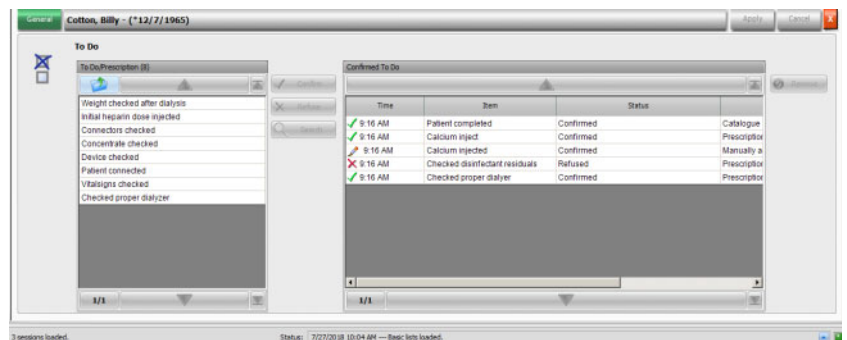
The **History** menu item displays blood pressure data from previous sessions, both in text and graphical format. The first measurement of each session is displayed (systolic, diastolic, MAP, pulse) together with the session start date.

3.4.8 To Do

When you click on the activity bar in the column below the **To Do** symbol for the respective patient, the **To Do** detail area will appear.



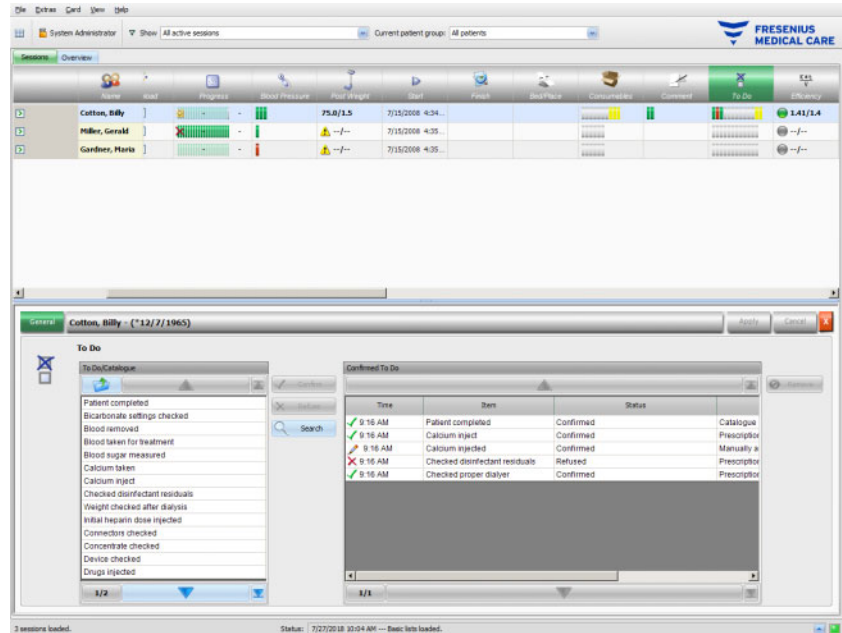
This option allows you to document routine procedures defined by the EDBMS as well as recording the name of the responsible user and the time of the check.



In the left-hand side area, click on the **Prescription** folder in order to confirm or reject a prescribed To Do item, then click on **Apply** button. The **Catalogue** folder contains all the possible To Do items. You can apply an item from the **Catalogue** as well.

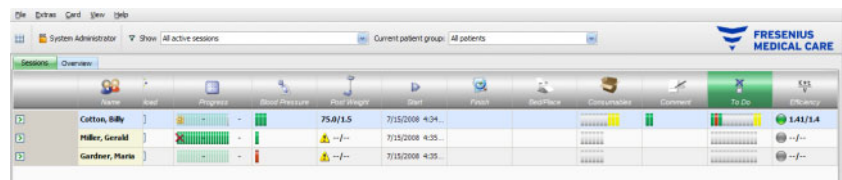
You can also confirm an item that does not exist in the catalogue by clicking on the **New Item** button and by entering the name manually.

Applied or rejected items are displayed in the right-hand side table of the detail view, together with the source and the user name. The **Time** column of the table is editable, thus allowing a more flexible documentation.

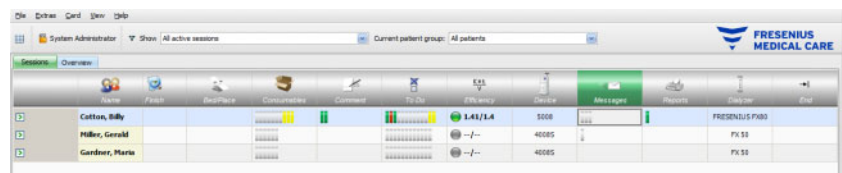


Save your entries with **Apply** and discard them with **Cancel**.

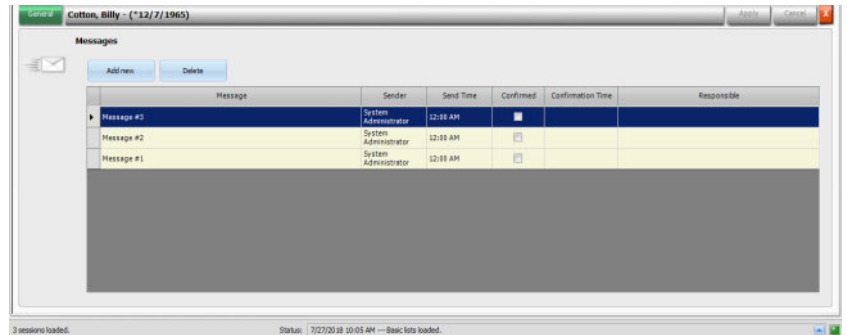
In the activity bar, below the **To Do** symbol, you can see how many gray, green, red or yellow bars are displayed. A green bar indicates a prescribed item that is confirmed; a red one indicates a rejected item, while a gray one indicates an item not yet confirmed or rejected. A yellow bar indicates an item confirmed from the catalogue or manually added.



3.4.9 Messages



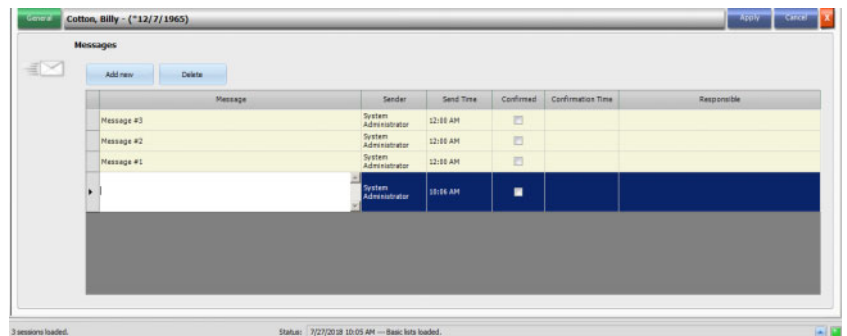
When you click on the activity bar in the column below the **Messages** symbol for the respective patient, the **Messages** detail area will appear.



This detail area contains notes and indications which have either already been performed or are still outstanding. These notes/indications either originate from an EDBMS or can be added to this detail area by inserting a new line via the **Add new** button. A new line can be removed with **Delete**.

Use the tab key to edit the individual columns.

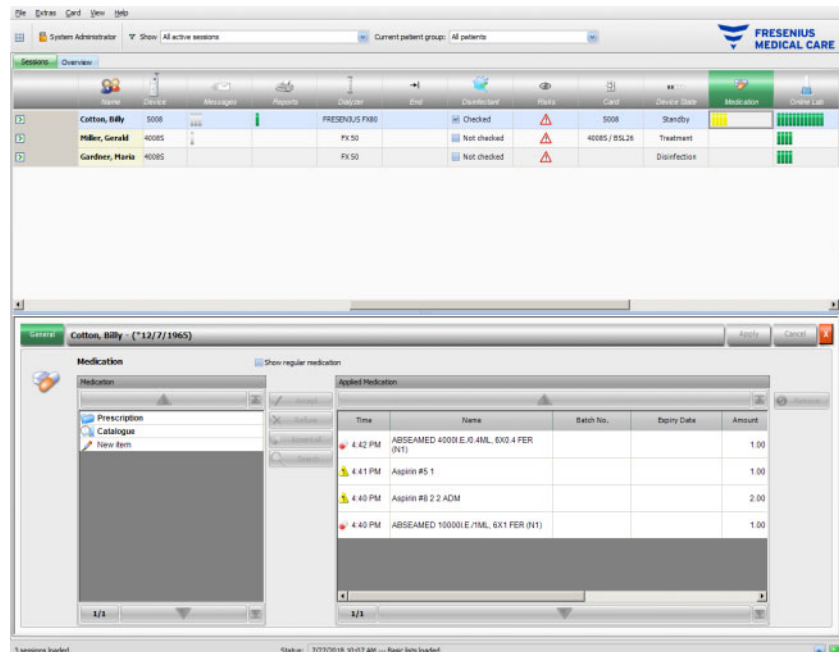
As usual, save the data with **Apply** or abandon the operation with **Cancel**.



In the activity bar below the **Messages** symbol, you can see how many green and gray bars are displayed. Each green bar represents a confirmed message and each gray bar indicates that a message has not been confirmed.

3.4.10 Medication

When you click on the activity bar in the column below the Medication symbol for the respective patient, the **Medication** detail area will appear.



The detail area contains two navigation panels. In the one on the left, you can access the prescribed medication and the medication catalogue. The check box **Show regular medication** allows you to see the patient's prescribed regular medication as well, besides the special or on-demand ones. In the panel on the right you can access the applied medication.

In the **Prescription** folder of the left panel, selecting a special or on demand medication will activate the **Accept** and **Refuse** buttons. Both actions will move the selected item to the applied panel. An applied item can be edited by changing the prescribed amount, by adding a comment or by editing the batch number and expiry date of the medication item. The confirmation of the medication item is automatically managed ('applied as prescribed', 'applied according to amount', 'refused'), as well as the user and time of the operation. Regular medication can be applied only in case a certain option ('Confirm regular medication') is active at FIS level. The amount is mandatory and cannot be null. The button **Accept all** allows you to apply all the special medication by one single click. Depending on FIS settings, regular medication can be accepted or refused. In this case the check box **Show Regular Medication** is checked and buttons Accept and Refused are active for regular items as well.

The **Therapy Monitor** system maintains a list of currently used batch numbers and expiry dates for each type of medication. By double-clicking in the batch no. cell of the applied medication, you can simply choose a batch no. from the list. This in turn will automatically select the corresponding expiry date. If the batch no. printed on the medication that you are applying is not in the list, or the list is empty, you must manually enter the batch no. and expiry date.



Note

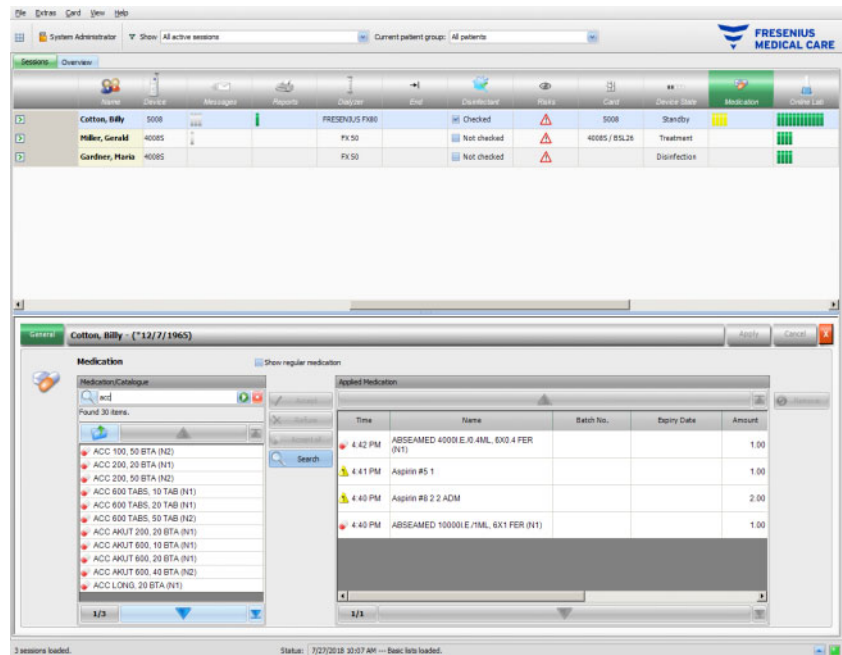
The FIS server has an option of not to use batch numbers and expiry dates at all. If this option is turned on, the corresponding columns in the applied medication panel will be visible.

In the **Catalogue** folder of the left panel, you can navigate through the entire medication list, as it is defined by the EDBMS. The items are displayed in pages and the up/down buttons move the content from one page to the other. The current and total page numbers are displayed near the down button.

Time	Name	Batch No.	Expiry Date	Amount
4:42 PM	ABSEAMED 4000 E.0.4ML. 6X0.4 FER (NT)			1.00
4:41 PM	Aspirin #5 1			1.00
4:40 PM	Aspirin #6 2 2 ADM			2.00
4:40 PM	ABSEAMED 10000 E.1ML. 6X1 FER (NT)			1.00

Selecting an item will activate the **Accept** button. By clicking this button, the catalogue item is applied with type 'on demand', amount 0 and confirmation 'applied according to amount'. You need to specify an amount in the navigation panel on the right.

You can search for particular medication items by clicking the **Search** button. Type a text in the search text box and then click on the green arrow or press Enter. This will display a filtered list of medication. By clicking the red X button you can reload the entire medication catalogue again. Clicking again on the **Search** button will also cancel the search.



By pressing **New item** in the left panel, you can apply a medication item which is neither prescribed nor present in the medication catalogue. For such an item you must provide a name and an amount.



Note

From **Prescription** or **Catalogue** you can always go one level up by pressing the folder button near the up arrow. All navigation buttons have hints like 'Next page', 'Previous page', 'Up', 'Last Page', 'First page', 'Search', and 'Close'. This functionality is common for other menus as well like Consumables, Measures, and Events.

In the applied medication panel, you can remove an applied item by selecting it and then pressing the **Remove** button.

As usual, save the applied data with **Apply** or abandon the operation with **Cancel**. If the mandatory information is missing or invalid, there will be an error message and the apply operation will not be possible.

In the activity bar, below the **Medication** symbol for the respective patient, you will find gray bars for prescribed but not yet applied items, green bars for applied as prescribed items, red bars for refused items and yellow bars from prescribed items applied according to amount and for items applied from catalogue.



Note

Display and confirmation of instructions, e.g., Medication, Prescription, are only intended as an aid and are subject to the due diligence of the user.

The entries of the prescribed medication list and of the medication catalogue are automatically available via the connected EDBMS. The automatic import of medication contents (catalogue and prescription) requires the activation of this function in the connected EDBMS.

3.4.11 Bed/Place



This entry contains information on the patient's treatment Bed/Place.

3.4.12 Comment

When you click on the activity bar in the column below the **Comment** symbol for the respective patient, the **Comments** detail area will appear. This area allows you to freely enter any number of comments for the treatment.

Click on **Add new** in order to define a new comment, then type the text in the Comment column of the grid. The time and user columns are automatically filled in. The time and comment fields are editable.

Save the data with **Apply** or abandon the operation with **Cancel**.

You can enter a comment from the **Finish** detail area as well, just before closing the session. See chapter 3.4.25.

In the activity bar, below the **Comment** symbol for the respective patient, you will find green bars for each comment.

The **History** tab displays the comments from the previous six sessions.

3.4.13 Reports



This item is used to start the print-out of treatment reports for the current session.



Warning

Risk for the patient as a result of corrupted data
Risk for the patient as a result of a wrong therapeutic decision

A software error during report generation can lead to incorrect documentation of treatment data. Based on this incorrect data, wrong therapeutic decisions can be made.

- After printing the report, the user must check its data content against the data displayed in the client program to verify its correctness.

Therapy Monitor allows the definition of custom reports, besides the default one.



Warning

Risk for the patient as a result of corrupted data
Risk for the patient as a result of a wrong therapeutic decision

Incorrect data mapping and/or labeling in custom reports can lead to a wrong judgement of the therapy and influence therapeutic decisions.

- The external report designer must ensure correct data mapping and labeling in the custom report.

3.4.14 Dialyzer



The last used dialyzer is displayed under this entry.

3.4.15 Session start

The **Start** symbol in the activity bar stands for the commencement of the patient's session, i.e., the time at which the patient was logged in to the system.

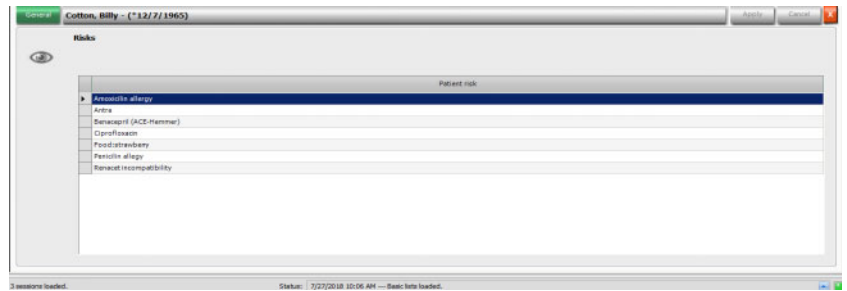
3.4.16 Session end

The **End** symbol in the activity bar stands for the end of the patient's session, i.e., the time at which the patient was logged out from the system.

3.4.17 Risks

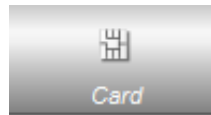
Session	Overview	Name	To Do	Efficiency	Device	Messages	Reports	Dialyzer	End	Disinfect	Make	Card	Device State
		Collins, Billy		3.41/1.4	5008			PRESENIUS P183		Checked	⚠	5508	Standby
		Hiller, Gerald		-/-	4085			PX 50		Not checked	⚠	4085 / 858.26	Treatment
		Gardner, Maria		-/-	4085			PX 50		Not checked	⚠		Disinfection

The red warning triangle in the activity bar below the Risks symbol indicates that the respective patient shows risks. Click in the column below the Risks symbol to call up the Risks detail area.



This detail area provides you with information on the patient's existing risks. The risks originate from the EDBMS.

3.4.18 Card



The card symbol in the overview screen indicates the current location of the patient card.



Warning

Risk for the patient as a result of wrong treatment parameters

In case a session is created manually in the **Therapy Monitor** client a wrong patient may be selected and the wrong patient card may be used at the dialysis device. This may result in wrong treatment with data from a different patient.

- The use of the correct patient card is the responsibility of the user.
- Each patient card must be labeled with the patient name, the patient ID and the date of birth to ensure a correct patient identification.

3.4.19 Device



Indicates the type of dialysis system used for treatment.

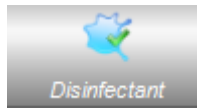
3.4.20 Device state



Displays the current device state:

- Standby
- Preparation
- Treatment
- Treatment end, reinfusion
- Disinfection

3.4.21 Disinfectant



The **Disinfectant** option documents the disinfection status of the device, as well as the status of the disinfectant residuals.

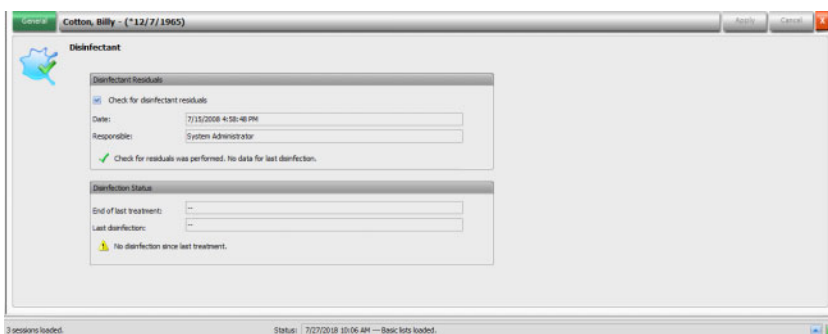
End of Last Treatment represents the date and time when the last treatment ended.

Last Disinfection represents the date and time of the last disinfection.

The status label and image represent the relation between the end of the last treatment and the last disinfection. If the last disinfection was before the end of the last treatment, a warning picture and the message 'No disinfection since last treatment' will appear. Otherwise, an OK picture and 'No treatment since last disinfection' will appear.

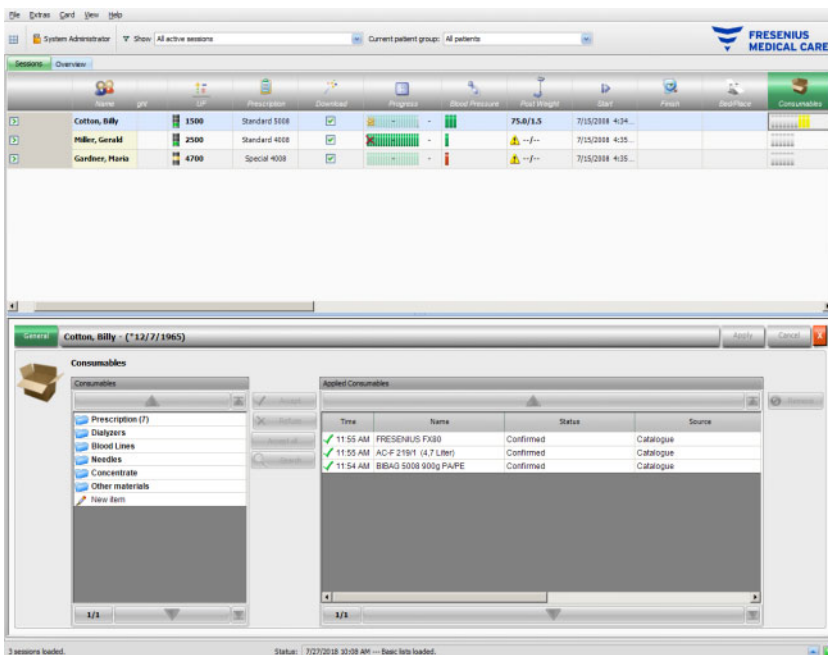
End of Last Treatment and **Last Disinfection** are available on 5008/5008S devices having software version 4.00 or later and on 6008 device.

When a user checks for residuals after the disinfection process, the **Check for disinfectant residuals** checkbox must be ticked. **Date** represents the last date and time when **Check for disinfectant residuals** was checked. **Responsible** specifies the username of the user that last checked for disinfectant residuals. On 5008/5008S devices with software version 4.50 or later and on 6008 device, the disinfectant residuals status is managed by the device itself. In this case, the **Check for disinfectant residuals** check box is no longer available. Instead, a status from the device is displayed. If the disinfectant residuals status was checked before the last disinfection, a warning picture and the message 'Check required' will appear. Otherwise, an OK image and 'Check for residuals was performed after last disinfection' will appear. Depending on the used disinfectant (for example citrate) 5008/5008S devices with software version 4.50 or later and on 6008 device. may report a status 'No check required'.



3.4.22 Consumables

When you click on the activity bar in the column below the **Consumables** symbol for the respective patient, the **Consumables** detail area will appear, menu item **General**.



The detail area contains two navigation panels. In the panel on the left, you can access the prescribed consumables and the consumable catalogues. The catalogues are **Dialyzers**, **Blood lines**, **Needles**, **Concentrate** and **Other materials**. The **Needles** and **Blood lines** catalogues have sub-catalogues for **Arterial**, **Venous**, **Single-Needle** and **AV Set**, and the **Concentrate** one for **Dialysate**, **Additional** and **Substitute**. In the panel on the right you can access the applied consumables.

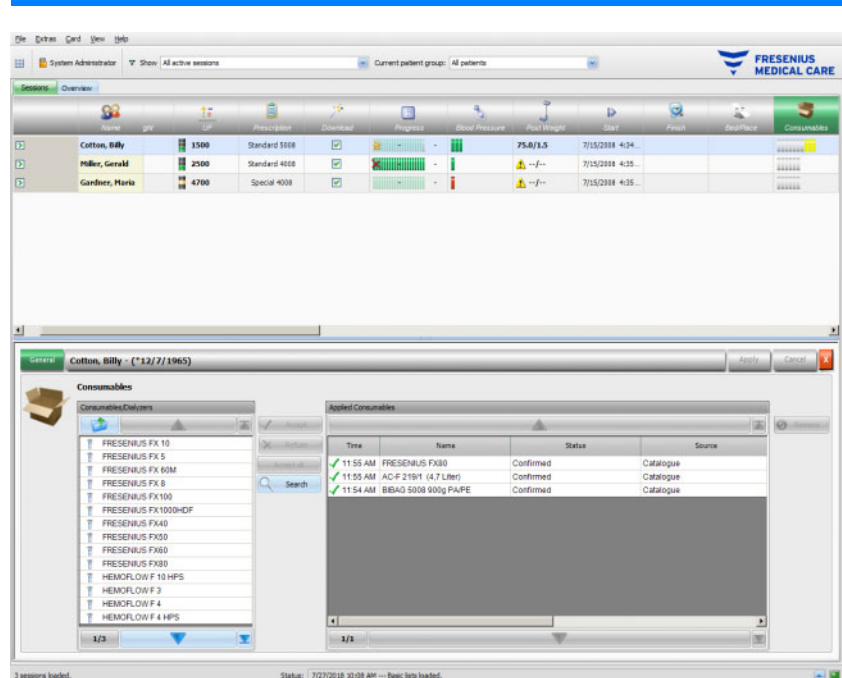
In the **Prescription** folder of the left panel, selecting a consumable item will activate the **Accept** and **Refuse** buttons. Clicking these buttons will move the selected item to the applied panel. An applied item can be edited by specifying the **Batch No.** and the **Expiry date** which are printed on each consumable. All other data like category, subcategory, user, and time are automatically provided. The button **Accept all** allows you to apply all prescribed consumables by one single click.

The **Therapy Monitor** system maintains a list of currently used batch numbers and expiry dates for each type of consumables. By double-clicking in the batch no. cell of the applied consumable, you can simply choose a batch no. from the list. This in turn will automatically select the corresponding expiry date. If the batch no. printed on the consumable that you are applying is not in the list, or the list is empty, you must manually enter the batch no. and expiry date.



Note

The FIS server has an option of not to use batch numbers and expiry dates at all. If this option is turned on, the corresponding columns in the applied consumables panel will be visible.



Selecting an item will activate the **Accept** button. By clicking this button, the catalogue item is applied. You need to specify an amount in the navigation panel on the right.

You can search for particular consumable items by clicking the **Search** button.

By pressing **New item** in the left navigation panel, you can apply a consumable item which is neither prescribed nor present in the catalogues. For such an item you must provide the missing mandatory information - name, category and subcategory, and optionally the batch no. and expiry date.

In the applied consumables panel, you can remove an applied item by selecting it and then pressing the **Remove** button.

As usual, save the applied data with **Apply** or abandon the operation with **Cancel**. If the mandatory information is missing or invalid, there will be an error message and the apply operation will not be possible.

In the activity bar, below the **Consumable** symbol for the respective patient, you will find gray bars for prescribed but not yet applied items, green bars for prescribed and applied items, and yellow bars for items applied from catalogues.



Note

Display and confirmation of instructions, e.g., Consumables, Prescription, are only intended as an aid and are subject to the due diligence of the user.

The entries of the prescribed consumable list and of the consumables catalogues are automatically available via the connected EDBMS. The automatic import of consumable contents (catalogues and prescription) requires the activation of this function in the connected EDBMS.

3.4.23 Online Lab



This option displays laboratory measurement values taken during a session. In the activity bar below the **Online Lab** symbol for the respective patient, you will find green bars for each laboratory measurement taken during the session for the respective patient.

Parameter	Date	Time	Device parameters	Source	Value	Number	Comment
	12/12/2007	10:45 AM	ImkA++	SONOMETER EH-F	132,000	4	
	12/12/2007	10:45 AM	Imk+	SONOMETER EH-F	5,880	4	
	12/12/2007	10:45 AM	ImCa++	SONOMETER EH-F	1,540	4	
	12/12/2007	10:45 AM	ImpH	SONOMETER EH-F	7,420	4	
	12/12/2007	10:45 AM	ImkA	SONOMETER EH-F	132,000	4	
	12/12/2007	10:45 AM	Imk+	SONOMETER EH-F	5,880	4	
	12/12/2007	10:45 AM	ImCa++	SONOMETER EH-F	1,540	4	
	12/12/2007	10:45 AM	ImpH	SONOMETER EH-F	7,420	4	
	3/17/2008	3:46 PM	ImkA++	SONOMETER EH-F	131,600	6	
	3/17/2008	3:46 PM	Imk+	SONOMETER EH-F	5,880	6	
	3/17/2008	3:46 PM	ImCa++	SONOMETER EH-F	1,540	6	
	3/17/2008	3:46 PM	ImpH	SONOMETER EH-F	7,380	6	

Laboratory values are displayed in the detail area.

Parameter	Date	Time	Device parameters	Source	Value	Number	Comment
Alk. Phosphatase [U/l]	12/12/2007	10:45 AM	ImkA++	SONOMETER EH-F	1,540	4	
Alveolar Arterial [mmHg]	12/12/2007	10:45 AM	ImpH	SONOMETER EH-F	7,420	4	
Arterial [U/l]	3/17/2008	3:46 PM	ImkA	SONOMETER EH-F	131,600	6	
AP-Phos [U/l]	3/17/2008	3:46 PM	Imk+	SONOMETER EH-F	5,880	6	
Arterial Arterial [U/l]	3/17/2008	3:46 PM	ImCa++	SONOMETER EH-F	1,540	6	
Bilo [mmol/l]	3/17/2008	3:46 PM	ImpH	SONOMETER EH-F	7,380	6	
	7/27/2018	10:08 AM		System Administra			

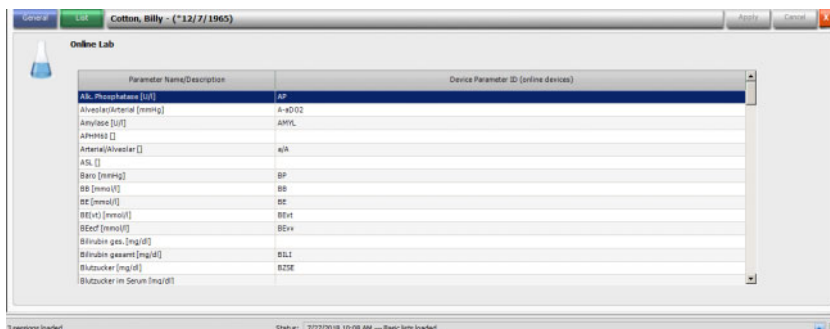
Measurement results of laboratory data originating from external analyzers are automatically saved and are available for further information in the **Online Lab** detail area, together with date and time stamps and the source of the measurement.

Manual data input is also possible. In this case the source is the user name.

A new line is created with **Add new**. Via the selection window, the user can immediately select the respective laboratory parameters to open. Finally, only the measurement result is added manually.

A quick search for the laboratory parameters is supported if you enter the first letter of the laboratory parameter. The marker in the selection box is automatically set to the selected range.

The **List** menu item displays all available laboratory parameters with the corresponding abbreviations of all online devices.

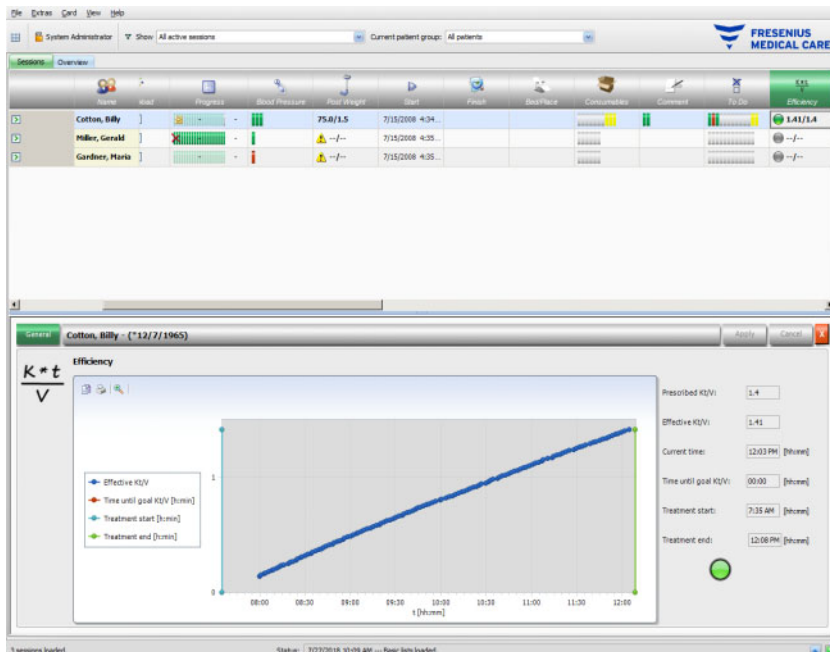


3.4.24 Efficiency



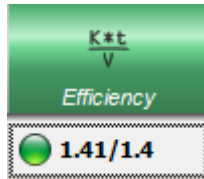
The **Efficiency** option of the activity bar will display the current effective Kt/V / goal Kt/V values, with two decimal precision. If any of the two is missing, -- will appear instead.

When you click on the activity bar in the column below the **Efficiency** symbol for the respective patient, the **Efficiency** detail area will appear. This area displays the graphical evolution of the Kt/V as sent by the device's OCM module.



In addition, the current Kt/V and the estimated time to reach the Kt/V goal are displayed, together with the estimated time for finishing the treatment. If the time to reach the Kt/V goal is below the remaining treatment time, then a green status symbol is displayed, otherwise a red one is shown.

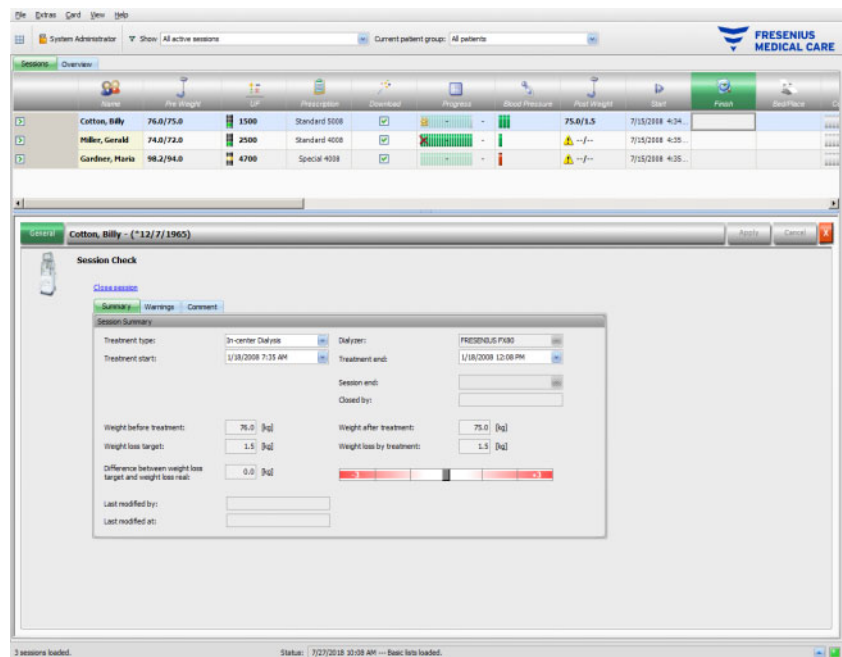
In the activity bar, a green or red symbol is displayed as well, to signal the Kt/V status. If no data is available from the OCM module then a gray symbol will be displayed.



3.4.25 Finish



The **Finish** option allows you to close the patient's current session. Upon selecting **Finish**, a **Session Check** detail view is opened, displaying a session summary, a list of warnings and a comment entry option.



The **Summary** section displays the session and treatment start and end times, the user who closed the session (for closed sessions) as well as the export status of the session. Treatment start/end is automatically documented but can also be manually edited. The user and time-stamp of the edit operation are recorded as well. Summarized weight data is also presented. Click on **Close session** in order to start closing the session. A confirmation window will appear. Click **Yes** to close the session or **No** to abandon the operation.



Note

If the session filter is set to **All active sessions**, closing an active session will remove it from the activity grid.

The **Warnings** section displays the number of unconfirmed (if any) medication items, To Do items, messages, consumables, and special situations like a missing post-weight value or the lack of any blood pressure measurement or comment during the treatment, according to the settings in menu **Options/Sessions/Multiple close options** (see Chapter 3.2.2.1 on page 3-9).

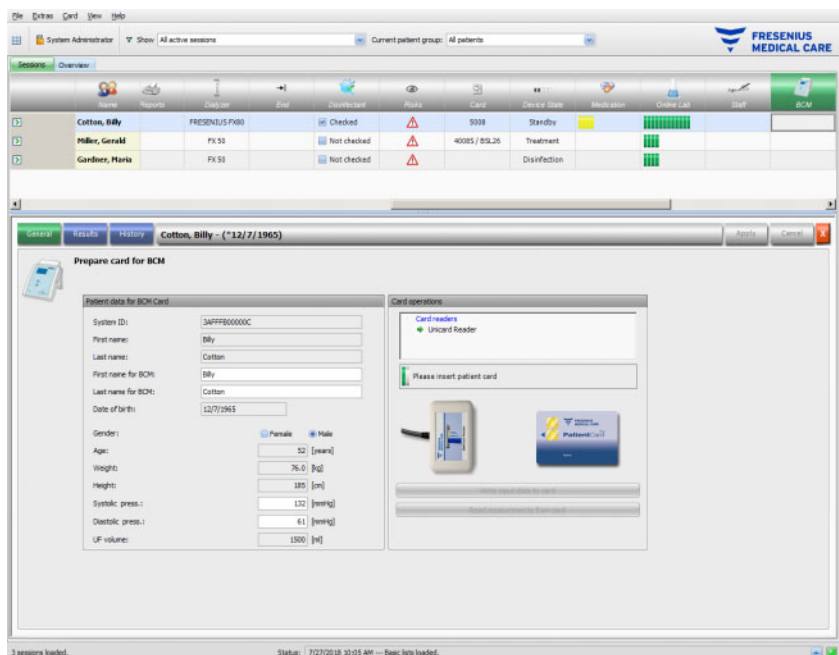
The **Comment** section allows you to save a comment. Type in the text and then click on **Apply**. The comment will be visible in the **Comments** detail area and activity.

3.4.26 BCM

When you click on the activity bar in the column below the **BCM** symbol for the respective patient, the **BCM** detail area will appear, menu item **General**. This area allows you to fully manage the Body Composition Monitor workflow for the current treatment - prepare BCM card for measurement, import and view BCM results in text and graphical format, as well as to view previous BCM measurements.

The **General** menu item contains a patient data area that is needed by the BCM device. Certain data are automatically filled in by the system (name, ID, date of birth, gender).

The **First name for BCM** and **Last name for BCM** fields are useful in case the patient name contains special characters that cannot be displayed by the BCM device. In this case, the invalid name for BCM will be displayed in red color and you should type in a name containing only Latin characters.



The weight is filled in from the **Pre Weight** detail area and is mandatory. Height is imported from the EDBMS and is mandatory as well, but it can be edited from the **Prepare patient card for BCM** menu. The systolic and diastolic pressures are optional and are filled in by the system as average values for the last 4 weeks of the first blood pressure measurement of the treatment. If missing, the blood pressure data can be filled in manually. The **UF** volume is mandatory and is automatically filled in from the UF detail area. Manually entered data must be saved by the **Apply** button or discarded by the **Cancel** one.



Note

If there is a weight plausibility warning or a UF warning, warning signs are displayed near the respective fields and the BCM patient data is considered invalid. Data must be corrected from the respective detail areas. An invalid patient data set is signaled in the activity bar, below the **BCM** symbol for the respective patient, by a red traffic light.

The area on the right of the General menu item contains a card reader control. If the patient data is valid and a valid card is inserted in the card reader, the button **Write input data to card** becomes active. Click on this button to prepare the patient card for the BCM measurement.

After the measurement is performed, insert the card in the reader. If there is a valid measurement on the card the button **Read measurements from card** becomes active. Click this button and you will obtain a pop-up window with the measurements on the card. Only measurements that were performed after the card was prepared can be selected. Select the required measurement and then click the **Import selected data** button.

The **Results** menu item displays the BCM data read from the card. If you want to delete the measurement, click on **Delete results**.

The screenshot displays the Fresenius Medical Care Therapy Monitor interface. At the top, there is a menu bar and a patient list table. The patient list table has columns for patient name, ID, status, and BCM. Below the patient list, the 'Measurement results' window is open for patient Cotton, Billy. This window is divided into several sections: 'Measurement info' (date and time), 'Patient data' (gender, weight, height, age, systolic/diastolic pressure, UF volume), 'Quality of measurement' (97.5%), and 'Body Composition' (various metrics like hydration, lean mass, fat mass). A warning message is shown at the bottom of the measurement results window, stating: 'BCM warning. The BCM measured value differs too much from the prescribed one. Confirm overwriting the BCM value with the prescribed value.' There are buttons to 'Keep BCM urea distr. volume' and 'Accept prescribed urea distr. volume'.



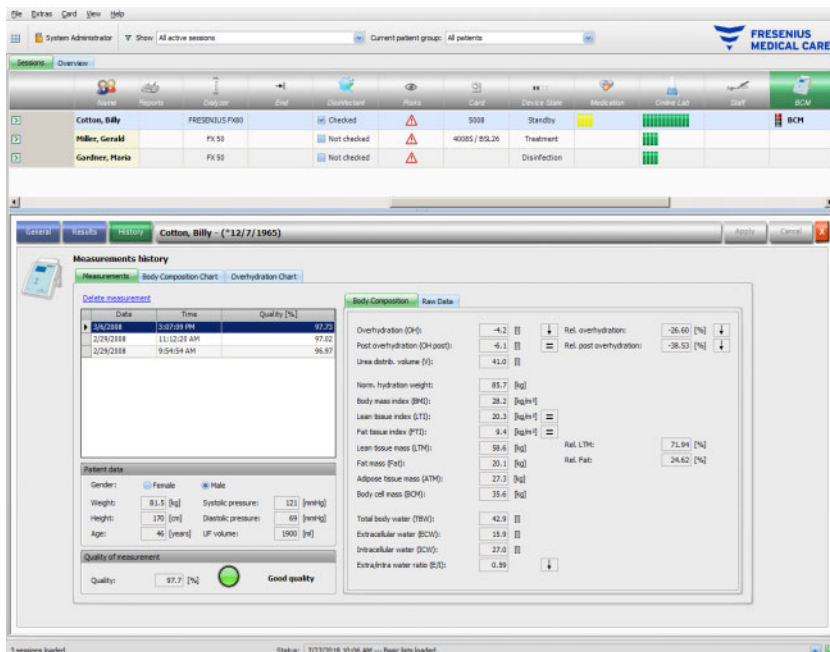
Note

Only one BCM measurement can be associated with a treatment. Historical BCM measurements can be imported from the **Card/Import BCM measurements** menu.

The **Urea distribution volumes** area allows you to specify which V value shall be downloaded to the 5008/6008 device: the prescribed one, which is imported from the EDBMS or the one measured by the BCM device (default). Click on the required button to decide which value will be used for download and then click **Apply**.

The area on the right of the **Results** menu item displays the BCM measurements data. Click on **Body Composition** to see the relevant hydration and nutrition status like over-hydration, urea distribution volume, body mass index, adipose tissue mass, etc. Click on the **Raw Data** to see the impedance raw data (amplitude and phase) and the corresponding frequencies, as well as the interpreted impedance results. Click on **Show diagram** to see the impedance chart in reactance-resistance coordinates, and on **Show data** to see the impedance values. As for other charts, data can be exported either as text or as graphics.

The **History** menu item documents BCM measurements from previous treatments. Here you can see also measurements that do not belong to treatments but where imported from BCM cards by the **Card/Import BCM measurements** menu.



In the **Measurements** tab, the area on the left contains the measurements you can select. The last 15 measurements from the session date are available for selection. Click on a measurement in order to view the respective data. The results are presented exactly in the same way as in the **Results** menu.

If the selected measurement does not belong to a particular treatment, it can be deleted by clicking on the **Delete measurement** and then on **Apply**.

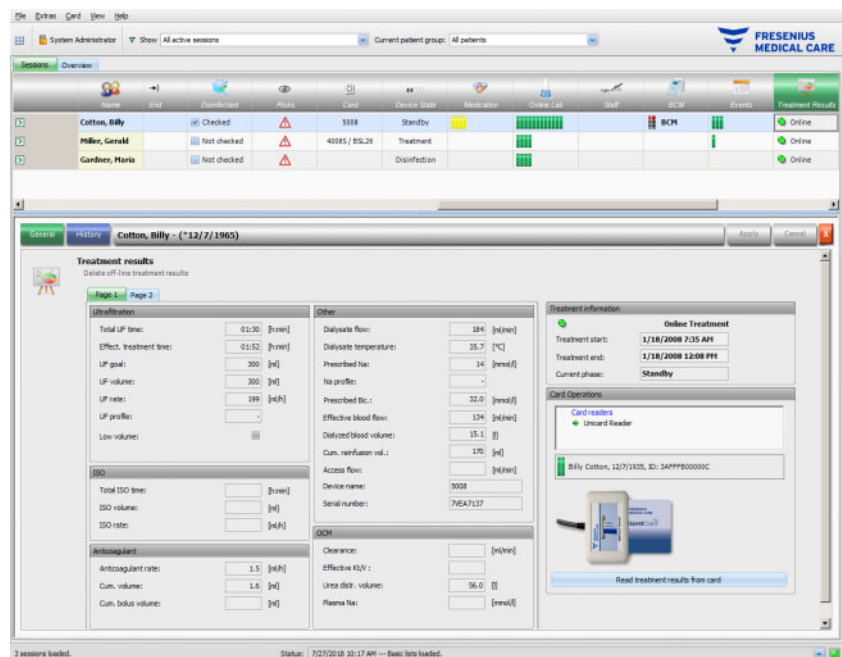
Otherwise, you can delete it from the **BCM Results** menu of the respective treatment. You can also export the raw data for a particular measurement to a tab-separated text file by clicking on the **Export raw data**.

3.4.27 Treatment Results

When you click on the activity bar in the column below the **Treatment Results** symbol for the respective patient, the **Treatment Results** detail area will appear, menu item **General**. This area documents the synthesis results of the treatment, calculated from the data sent by online dialysis devices (6008, 5008, 4008) or imported from offline results stored on the 5008/6008 patient card.

Treatment results read from the card are called offline results, as opposed to online results which are sent by the dialysis device at the end of the treatment via the network. A session with treatment results read from the card is called an offline session, as opposed to an online session which has online results.

The activity bar in the column below the **Treatment Results** symbol displays the type of the results (online or offline) together with a green or gray symbol. If no results exist, then no data is displayed.



The area on the left of the **General** menu item contains a tab control with two sub-pages that display the treatment results for the current session. The information is organized on device modules and consists of aggregated data such as cumulative or average values. For example, the UF volume and UF rate represents the cumulated UF volume and the average UF for the entire treatment.

In the upper area on the right, the treatment start and treatment end date/times are displayed, together with the current phase of the treatment.

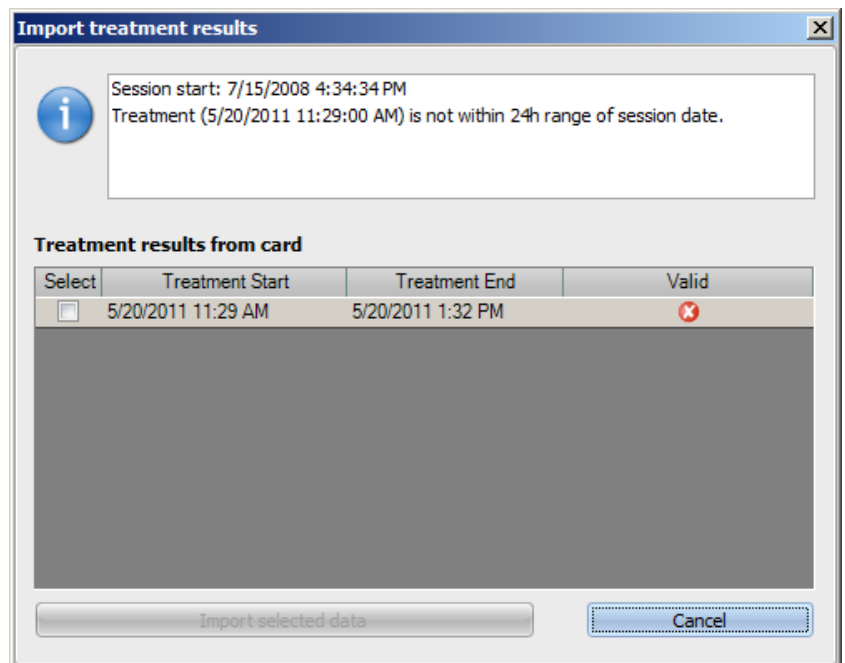


Note

For online devices, the data in the Treatment Results window is displayed during the treatment as well. However, the presented values do not represent the final results until the treatment reaches the 'Treatment End, Reinfusion' phase. Observe the current phase displayed in the upper area on the right.

The lower area on the right contains a card reader control that allows the import of offline treatment results from a 5008/6008 patient card. To import offline results, insert a patient card in the card reader. If the patient identity from the card is the same as for the current session, the button **Read treatments from the card** is active.

Click on the button to read treatment results from the card. A pop-up window will be displayed presenting the data read from the card.



For each treatment, the start and end date/time is displayed, together with the validity status. Treatments that are within a plus/minus 24 hours range from the current session start date/time can be selected for import. Only one such treatment can be selected.

After selection, you can click on **Import selected data** button to import the treatment result. If the session already holds treatment results, either online or offline, you are required to confirm the over-write operation. However, only offline results are overwritten. Online results are actually hidden by offline ones. When importing treatment results for an off-line session, the device data and blood pressure measurements stored on the patient card are imported as well. This data can be viewed in the Progress and Blood Pressure detail views.



Note

If the session is online, importing offline treatment results from the card will supersede the online results. However, offline results can be explicitly deleted by clicking on the **Delete offline treatment results** link and then on **Apply** button. In such a case, the online results are visible again. Online results cannot be deleted.



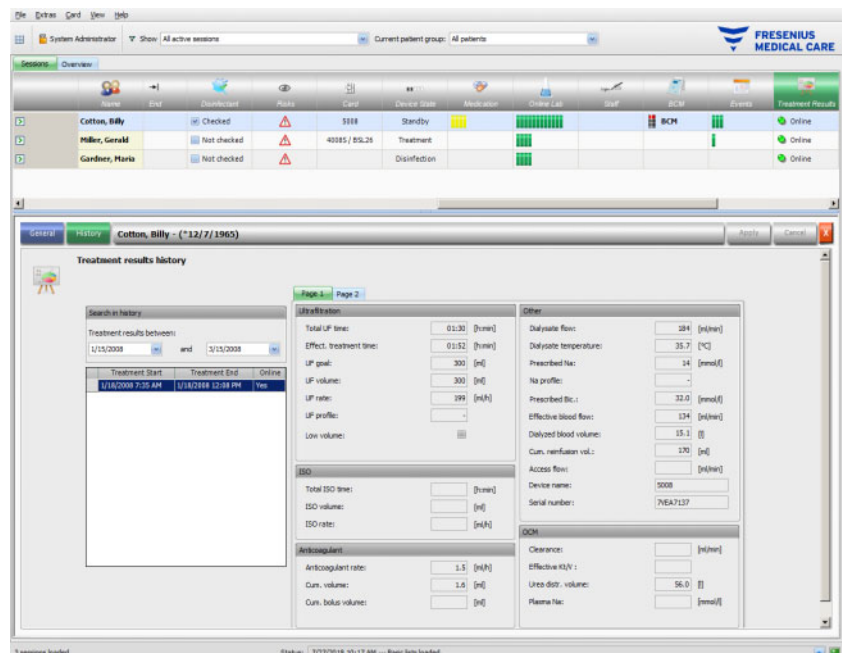
Warning

**Risk for the patient as a result of corrupted data
Risk for the patient as a result of a wrong therapeutic decision**

A software or hardware error can lead to corruption of treatment results displayed by **Therapy Monitor**. Based on this incorrect data, wrong therapeutic decisions can be made.

- The user must check the online and/or offline treatment results against the results displayed by the dialysis device.

The **History** menu item displays treatment results from previous sessions.

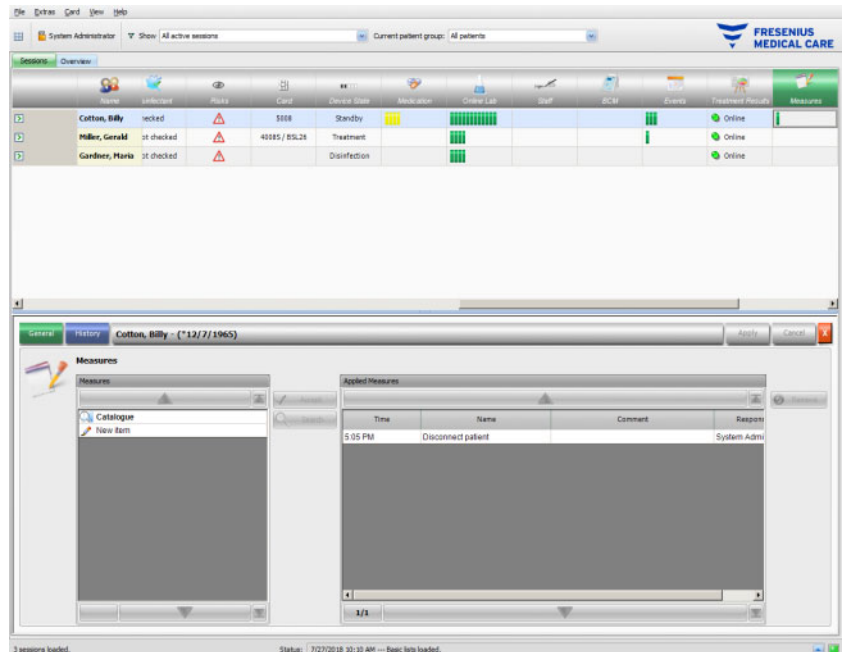


The area on the left contains two calendars, by means of which you can specify the time span you wish to view. By default, one month back from the current session start date is considered. Below the two calendars, a list with the treatments from the selected date period is displayed. Each of these treatments can be individually selected.

The area on the right displays the selected treatment in the same way (a tab control with two pages) as the **General** menu item.

3.4.28 Measures

When you click on the activity bar in the column below the **Measures** symbol for the respective patient, the **Measures** detail area will appear. This area documents the measures - others than giving a medication and applying a consumable - taken by the attending staff during the dialysis session.



The detail area contains two navigation panels. In the panel on the left, you can access the measure catalogue. In the panel on the right you can access the applied measures.

In the catalogue folder of the left panel, you can navigate through the measure list, as it is defined by the EDBMS. The items are displayed in pages and the up/down buttons move the content from one page to the other. The current and total page numbers are displayed near the down button.

Selecting an item will activate the **Accept** button. By clicking this button, the measure is applied. You may enter a comment in the navigation panel on the right.

You can search for particular measures by clicking the **Search** button.

By pressing **New item** in the left navigation panel, you can apply a measure which is not present in the catalogue. For such an item you must provide a name and optionally a comment.

In the applied measures panel, you can remove an applied measure by selecting it and then pressing the **Remove** button.

As usual, save the applied data with **Apply** or abandon the operation with **Cancel**. If the mandatory information is missing, there will be an error message and the apply operation will not be possible.

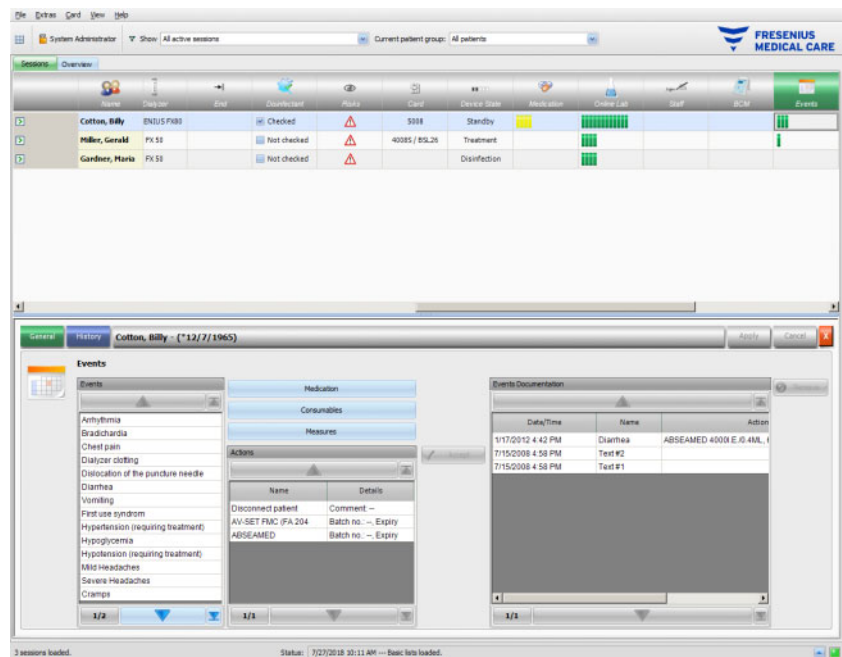
The **History** tab display the measures from the previous six sessions.

In the activity bar, below the **Measures** symbol for the respective patient, you will find green bars for applied items.

The entries of the measure list are automatically available via the connected EDBMS. The automatic import of measure list contents requires the activation of this function in the connected EDBMS.

3.4.29 Events

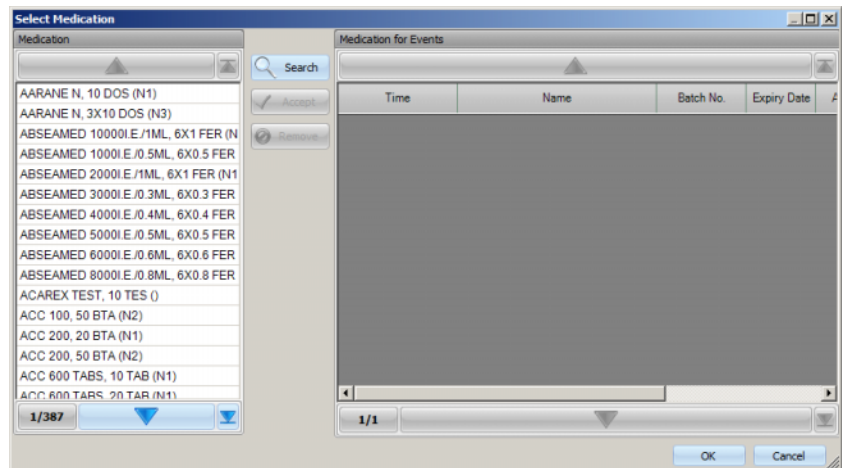
When you click on the activity bar in the column below the **Events** symbol for the respective patient, the **Events** detail area will appear, menu item **General**. This area documents patient events during treatment and the corresponding actions (medication, consumables, and/or measures) taken by the attending staff.



The detail area contains three navigation panels. In the panel on the left, you can access the **Events** catalogue. In the middle-side panel, you can access the **Medication, Consumables** and **Measures** catalogues, as well as a list of actions used so far during the current treatment. In the panel on the right you can access the events documented so far for the treatment.

In the catalogue folder of the panel on the left, you can navigate through the event list, as it is defined by the EDBMS. The items are displayed in pages and the up/down buttons move the content from one page to the other. The current and total page numbers are displayed near the down button.

By pressing the **Medication, Consumables** or **Measures** buttons from the middle panel, a pop-up window is displayed, with functionality similar to the corresponding detail areas (including search facilities).



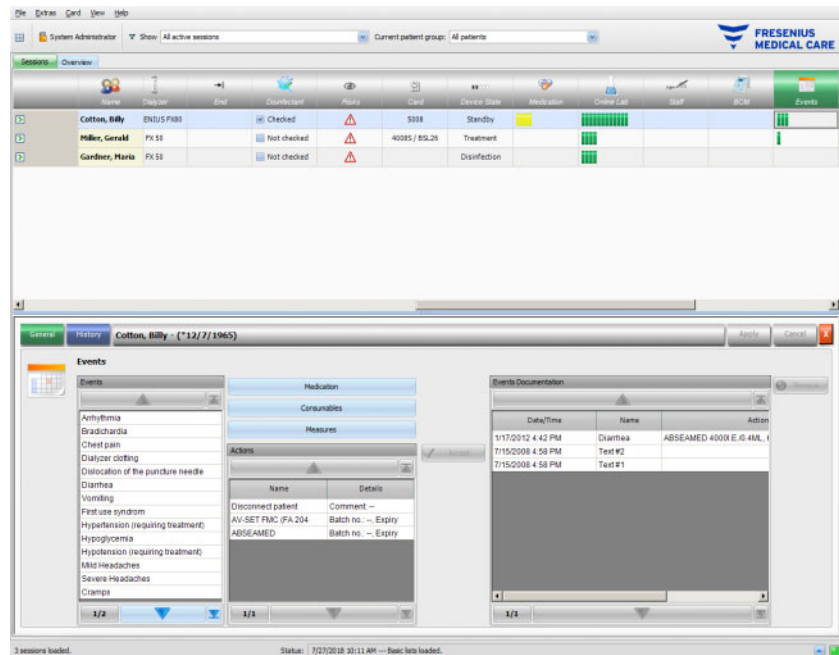
In the pop-up window, select a catalog item and then click on **Accept**, then edit the mandatory and optional data amount and comment in this case. Click on **Remove** to remove an accepted item. You can add several medication items in this way. When you are done, click on the **OK** button or abandon the operation by **Cancel**. If you click **OK**, the pop-up window is closed and the selected medication items are displayed in the middle panel, below the catalogue buttons, as an action to be used with an event.

The functionality of the **Consumables** or **Measures** buttons is similar - only the information that must be provided differs: for consumables you may provide a batch number and an expiration date, while for measures only a comment.

By double-clicking an action in the middle panel, you are able to edit the relevant information amount and comment for medication, batch number and expiry date for consumables, comment for measures.

Selecting an event item from the panel on the left will activate the **Accept** button. You can now select one or more actions from the middle panel. Clicking again a selected action in the middle panel will deselect it. By pressing the **Accept** button, the event and the associated actions are copied to the panel on the right. An event can be applied with no actions, but actions without an event cannot.

In the panel on the right you can manually edit the date and time of the event, by means of a special calendar and clock control.



By double-clicking an applied event, a pop-up is displayed with all the event details.

In the panel on the right, you can remove an applied event by selecting it and then pressing the **Remove** button.

As usual, save the applied data with **Apply** or abandon the operation with **Cancel**.



Note

When an event is saved, the associated actions are also saved in the corresponding data sections. For example, an event with an associated medication item will make that medication item to be applied in the **Medication** area. Deleting that particular medication in the **Medication** area will result in deleting it also from the event. However, the item will remain in the action list in the middle-panel of the **Events** area for future use. When an event is deleted, all associated actions are deleted as well from the corresponding data sections, but remain in the action list of the **Events** area for future use.



Note

The list of actions in the middle panel is strictly defined only for the current patient treatment. A new session always starts with an empty list.

The **History** menu item documents events for the past 12 treatments. By clicking **See details** all the events' details for a particular treatment will be displayed in a pop-up window.

In the activity bar, below the **Events** symbol for the respective patient, you will find green bars for applied events.

The entries of the events, medication, consumables and measures lists are automatically available via the connected EDBMS. The automatic import of these list contents requires the activation of this function in the connected EDBMS.

3.4.30 Staff

The activity bar in the column below the **Staff** symbol for the respective patient contains the name of the responsible staff as defined in the **Name** detail area, menu item **Session**. (see Chapter 3.3.1 on page 3-39)

3.4.31 Temperature

When you click on the activity bar in the column below the **Temperature** symbol for the respective patient, the **Temperature** detail area will appear, menu item **General**.

Time	Value	Unit of measurement	Responsible
2:27 PM	36.0	°C	Systemadministrator
12:10 PM	37.5	°C	System Administrator
12:08 PM	35.8	°C	System Administrator

This area documents the patient temperature as recorded by the attending staff during the dialysis session. Depending on a setting at FIS level, the values are presented in **Celsius** or **Fahrenheit** degrees. In the activity bar, below the **Temperature** symbol for the respective patient, you will find green bars for measurement items.

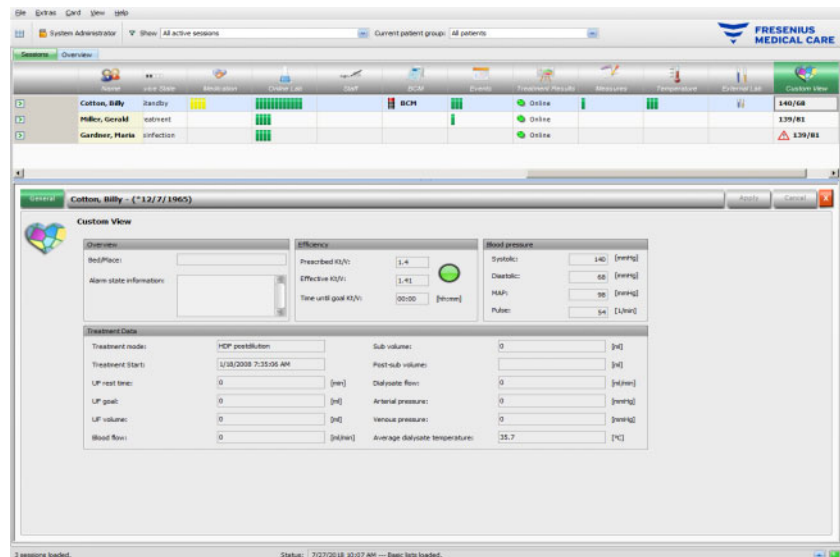
The **History** menu item displays temperature data from previous sessions in both text and graphical format. The first measurement of each session is displayed together with the session start date.

3.4.32 External Lab

When you click on the activity bar in the column below the **External Lab** symbol for the respective patient, the **External Lab** detail area will appear. This area documents the current laboratory values for the patient, as received from the EDBMS. The values cannot be changed in **Therapy Monitor**.

3.4.33 Custom View

When you click on the activity bar in the column below the **Custom View** symbol for the respective patient, the **Custom View** detail area will appear. This area documents the current data sent by the dialysis device for the session, as it was customized by the user (see Chapter 3.2.4.2 on page 3-35).



The **Overview** panel is fixed and cannot be customized. It contains information about the bed/place, the current alarm state, the Kt/V state, and the latest blood pressure. The **Treatment Data** panel contains up to 12 parameters which are fully customizable.

3.4.34 Summary

When you click on the activity bar in the column below the **Summary** symbol for the respective patient, the **Summary** detail area will appear. This area presents a few data categories like weight, UF, comments, events with associated user actions, and measures that are not linked to events, as well as treatment start and treatment end.

Depending on a certain setting at FIS level, the summary data is presented either grouped by categories, or sorted by time in ascending order.

The **History** tab presents the summary data for the previous eight sessions.

3.5 Program logic

3.5.1 FME User Management

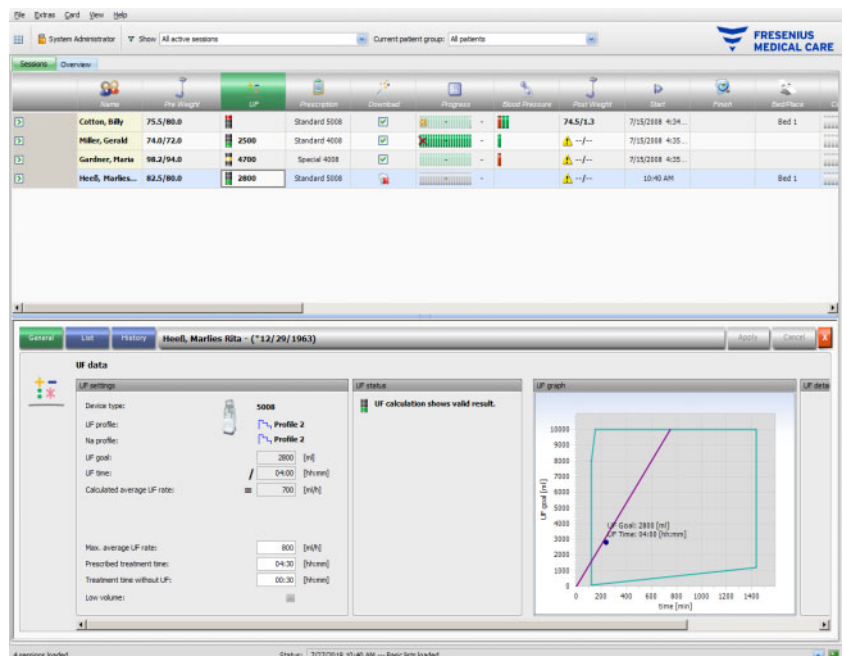
User management is configured in the FME Interface Server (FIS) and is operated via the 'FME User Management' program. For more information see FME User Management Instructions for Use.

3.5.2 External Database Management System (EDBMS)

As soon as a patient has logged in to **Therapy Monitor**, usually by inserting his patient card, the EDBMS automatically transfers the respective patient's session data to the **Therapy Monitor** (data import). If treatment data is to be changed for the current dialysis day only, this is performed by manual input in **Therapy Monitor** client. The user performs permanent changes in the EDBMS only. As long as the dialysis system is not in actual treatment mode (optical detector has not yet detected blood), data changed in the EDBMS can update the existing session data through renewed data import into the **Therapy Monitor**.

If the user closes a session or a session is automatically closed, automatic data transfer of the completed session takes place from the **Therapy Monitor** to the EDBMS.

3.5.3 UF calculation



Automatic UF calculation for the respective session is based on the pre-dialysis weight, tare (wheelchair, clothing), fluid intake during treatment, the current target weight (dry weight), maximum average UF rate, treatment time, etc. The device-specific UF restrictions (like UF/Na profiles) are also taken into account.

3.5.4 Data transfer to the dialysis system

3.5.4.1 Download

Data transferred to the dialysis systems must be confirmed by the user at the dialysis system to enable data acceptance.

Further information can be found in the Instructions for Use of the dialysis machines.

3.5.4.2 The data Xchange panel (dXp)



Warning

Risk for the patient as a result of corrupted data

Risk for the patient as a result of a wrong therapeutic decision

Data (e.g. To Do, Messages, Medication) displayed or entered in the data Xchange panel (dXp) on the dialysis machine can be compromised by network or software errors. Its correctness, completeness or plausibility can be negatively affected. Such compromised data cannot be detected by the dialysis device.

If undetected by the user, this can lead to impaired treatment planning or wrong therapeutic decisions.

- Users must check that the data displayed in the data Xchange panel (dXp) corresponds to the entered information.
 - If displayed data does not correspond to the entered information, the user has to re-enter the correct data, save it and check again.
-

3.5.5 Online data collection



Warning

Risk for the patient as a result of corrupted data

Risk for the patient as a result of a wrong therapeutic decision

Software or hardware errors can lead to the corruption of treatment data. This corrupted data can influence treatment planning or therapeutic decisions, thus leading to a wrong treatment for the patient.

- Users must check the recorded treatment data for correctness.
-



Warning

Risk for the patient as a result of unnecessary vessel punctures

Data transfer between laboratory devices and **Therapy Monitor** might be interrupted due to network problems. In this case data from laboratory devices cannot be displayed by **Therapy Monitor**. This may lead to a new blood sample measurement, which implies an additional vessel puncture.

- Before exposing the patient to additional vessel punctures, try to read out the data memory of the laboratory device and enter the sample data manually into **Therapy Monitor**.
-

4 The dataXchange panel

4.1 Introduction

The dataXchange panel (dXp) is a selection of screens on the display of the 5008/6008 dialysis device. With the dXp the medical staff can operate the **Therapy Monitor** system directly from the patient's bed side without the need of going to the computer (which is often located far away from the patient). Mainly all activities related to the patient's treatment session can be performed from the 5008/6008 screen itself.

The dXp is based on Web technology, by which a dedicated browser application within the 5008/6008 device (similar to Internet Explorer or any other PC Internet browser) navigates through the Web pages provided by the **Therapy Monitor**.

4.2 Data input controls

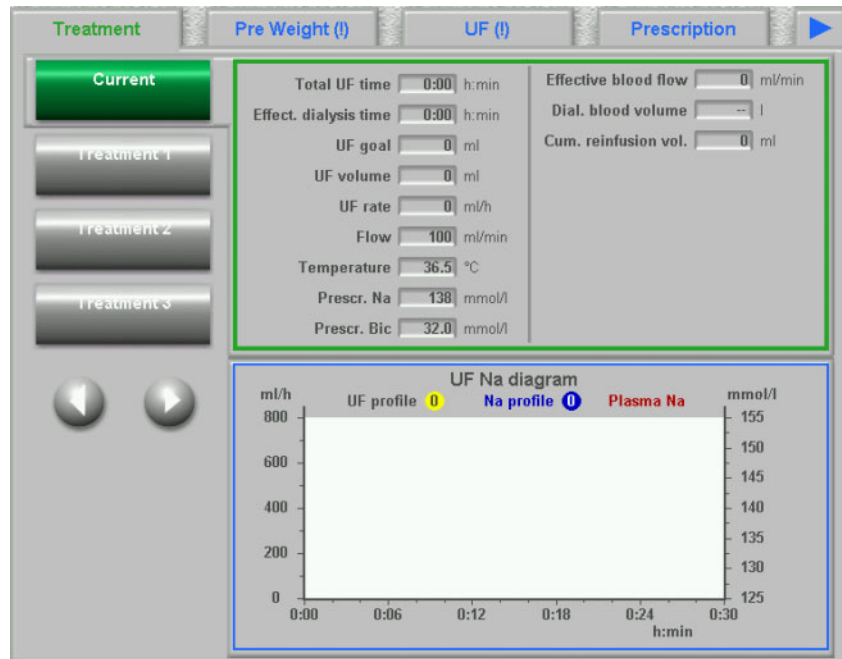
The 5008/6008 device has a touch screen – any user input must be performed by touching various controls on the screen. The color convention of the 5008 or 6008 devices applies for each control: green – selected, blue – active (selectable), gray – inactive.

4.2.1 The main controls are:

Tab menu

The tab menu allows the selection of various dXp pages. The available pages are:

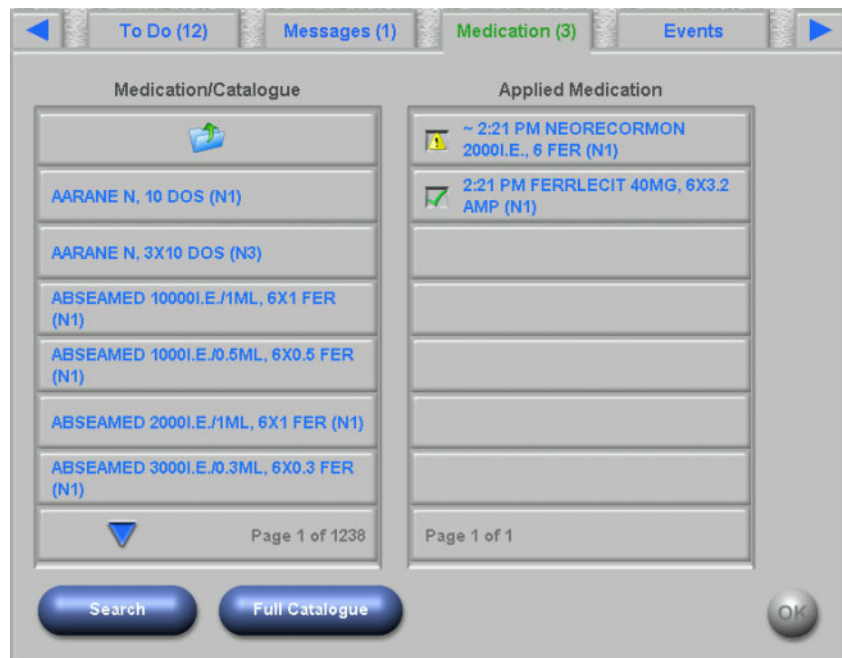
Pre-Weight, UF, Prescription, Medication, To Do, Messages, Consumables, Measures, Events, Disinfection, BCM, Risks, Temperature, Online Lab, External Lab, Post-Weight, Finish, Summary and Information. The visibility and order of these pages are configured upon dXp setup. The Treatment page is always visible from the dXp.



List box

The list box control displays a number of text items organized as a vertical list. It can have navigation buttons (Up and Down) and other options like a folder item, which allows navigating from one list box to another, the number of the current page, etc. Individual items can be selected by touching them on the 5008/6008 device screen.

Examples of list boxes are: available users, prescribed medication, medication catalogue, consumables catalogues, list of events, etc.



Text buttons

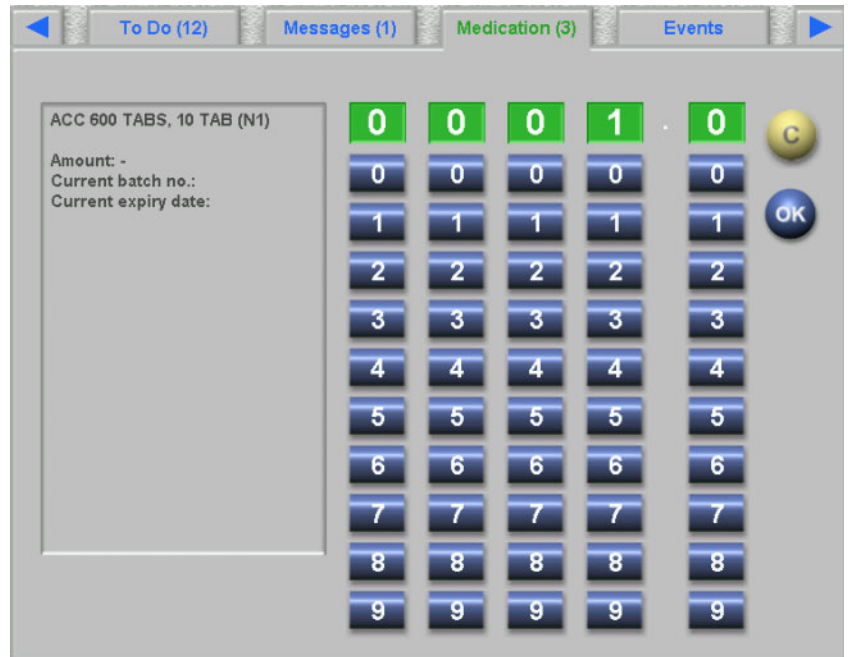
Text buttons are buttons with any text displayed on it. Functionality varies from page to page.

Control buttons

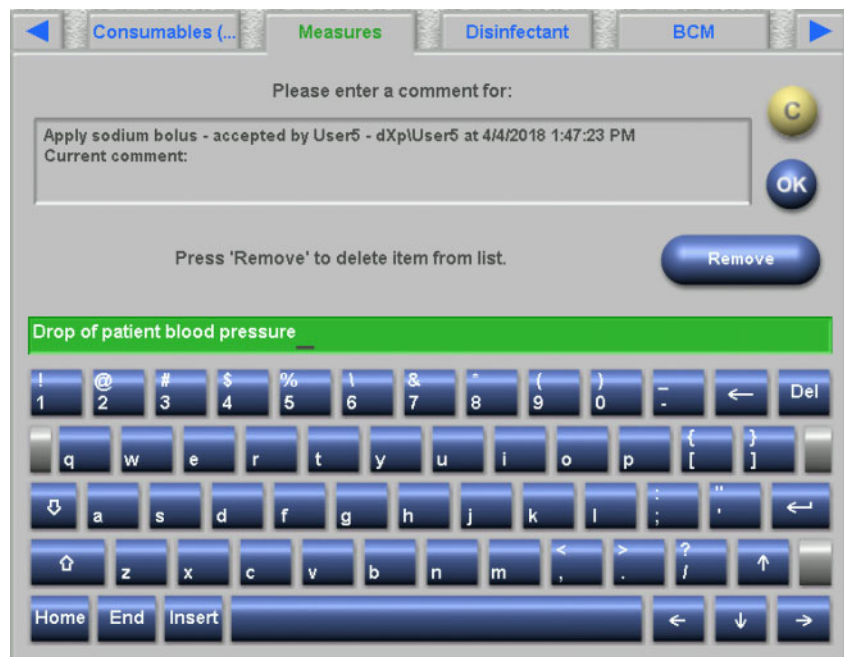
There are two control buttons **OK** and **C** (Cancel). Each user action that modified or created any piece of data must be confirmed by pressing the **OK** button or canceled by pressing the **C** button. Leaving the current page without pressing the **OK** button will abort the current operation and no data will be saved.

Value input page

This page allows the user to enter numerical values within a pre-defined range.

**Keyboard input page**

This control allows the user to enter alphanumerical values by a keyboard on the touch-screen. The keyboard has Back and Del keys that can be used for corrections. The input text is displayed on top of the page.



Time input control

This control allows the user to specify a time value in hh:mm format.

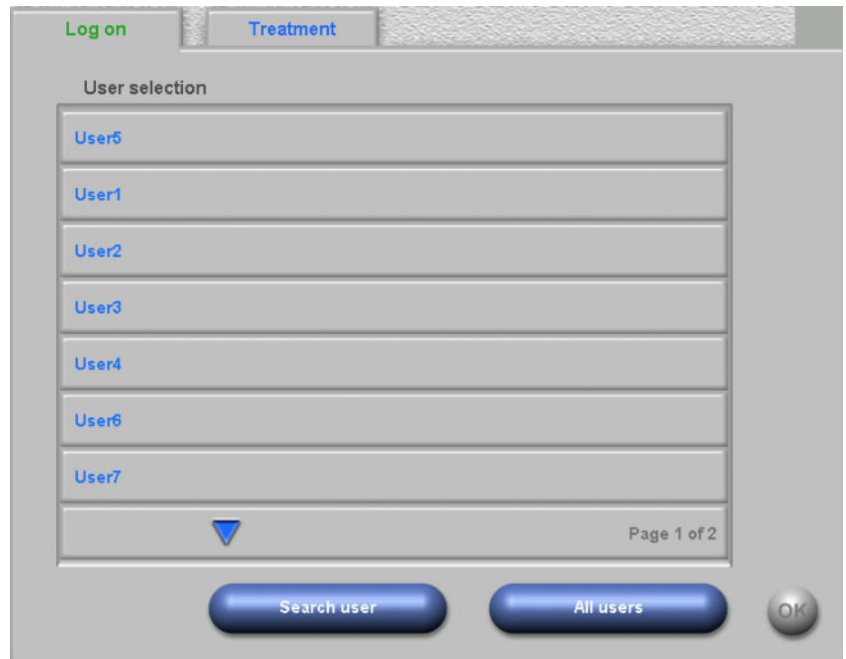


4.3 Starting and stopping the dXp

The dXp is opened by touching the patient menu item of the status bar. A patient card with a valid patient ID must be prior inserted in the 5008/6008 device.

If needed, a user login page will be displayed first, asking for the selection of a user name from a list box with the available users. The last three users that logged in successfully are on top of the list.

If the password is correct, the dXp shows the Treatment page. However, if the patient menu item is blinking, thus signaling for the user attention (Message Indicator), the user will be redirected to the page that caused the signal. You can also search for particular users: press the **Search user** button and enter a search text then press **OK**. The list of users is filtered according to the search text. You can revert to the full user list by pressing the **All users** button.



The Message Indicator is blinking if there is an UF conflict, or a weight plausibility mismatch, or a new item, not viewed so far, exists in the Medication, Messages, To Do and Risks menus. The user is re-directed to the respective page, according to the following priority: UF, Pre Weight, Risks, Messages, To Do, Medication. The visibility and order of the dXp pages is configurable using the dXp configuration application.

4.4 Pre Weight

This dXp page corresponds to the Pre Weight activity in the TMon client. The user can enter or overwrite the scale reading, the clothes/tare weight, the fluid intake goal during treatment and the current target weight. Other values like weight before treatment or weight loss target are not editable, but calculated by the system. If there is a weight mismatch between the weight before treatment and the current target weight, or a mismatch between the low volume (pediatric) option and the target weight, a plausibility warning will be displayed and the title of the page will contain an exclamation mark (!).

A prescription with a low volume (pediatric) option is highlighted by a graphical symbol (Teddy bear). The **>>After** button copies the pre-dialysis clothes/tare value to the post-dialysis one. Then press **OK** to save the changes or **C** to cancel the operation. This is useful when you know that post-dialysis value is the same with the pre-dialysis one, and there is no need to scale it again.

The History button displays a page with the pre- and post-treatment weight, as well as the target weight of the latest 8 treatment sessions.

Field	Value	Unit
Scale reading before treatment:	88.6	[kg]
Clothes / tare before treatment:	- 0.5	[kg]
Weight before treatment:	= 88.1	[kg]
Fluid/food intake during treatment (goal):	+ 0.3	[kg]
Current target weight:	- 80.0	[kg]
Weight loss target:	= 8.4	[kg]

Warning: Weight mismatch (weight before treatment differs too much from target weight)

4.5 UF

This dXp page corresponds to the UF activity in the TMon client. The user can enter or overwrite the maximum average UF rate, the prescribed treatment time or the treatment time without UF. Each modification refreshes the UF state which is displayed by a description and as a traffic light in red, yellow or green colors.

A prescription with a low volume (pediatric) option is highlighted by a graphical symbol (Teddy bear). If there is an UF conflict, the title of the page contains an exclamation mark (!) and the traffic light is red. In addition, three or four adjustment buttons are available for adjusting the UF time, the UF goal, for accepting the calculated UF rate or for disabling the UF/Na profile(s) for the current treatment. Selecting any of these buttons will change the UF status and will re-compute certain UF parameters. The traffic light will become yellow. New computed items like additional treatment time or fluid surplus will also be displayed. Press **OK** to save the changes or **C** to cancel the operation.

The **History** button displays a page with the target and total UF volume and average the UF rate for the latest 8 sessions.

UF: Profile 2
Na: Profile 2

UF warning. The current calculated UF rate is outside the admissible domain. Please choose one of these actions:

UF goal:	/	8400	[ml]	Adjust UF time
UF time:	=	04:00	[hh:mm]	Adjust UF goal
Calculated average UF rate:		2100	[ml/h]	Exceed max. UF rate
Additional treatment time:		00:00	[hh:mm]	Disable profile
Fluid surplus:		0	[ml]	History
Max. average UF rate:		800	[ml/h]	
Prescribed treatment time:		04:30	[hh:mm]	
Treatment time without UF:		00:30	[hh:mm]	

Battery icon and OK button at the bottom right.

4.6 Prescription

This page displays the current treatment prescription. If a download operation is performed, this is the prescription that will be downloaded to the 5008/6008 device.



Note

The content of this page is not necessarily the same as the content of the prescription on the device, since the user may have changed certain parameters on the device itself, after the download operation.

The page is organized in several sub-pages. The first one contains general data like prescription name, creator of the prescription, date of prescription creation/modification, remark, vascular access settings and treatment type, while the other pages contain mandatory parameters, anticoagulation data and optional parameters. Depending on the device software version, certain parameters may appear in the mandatory or in the optional sub-pages.

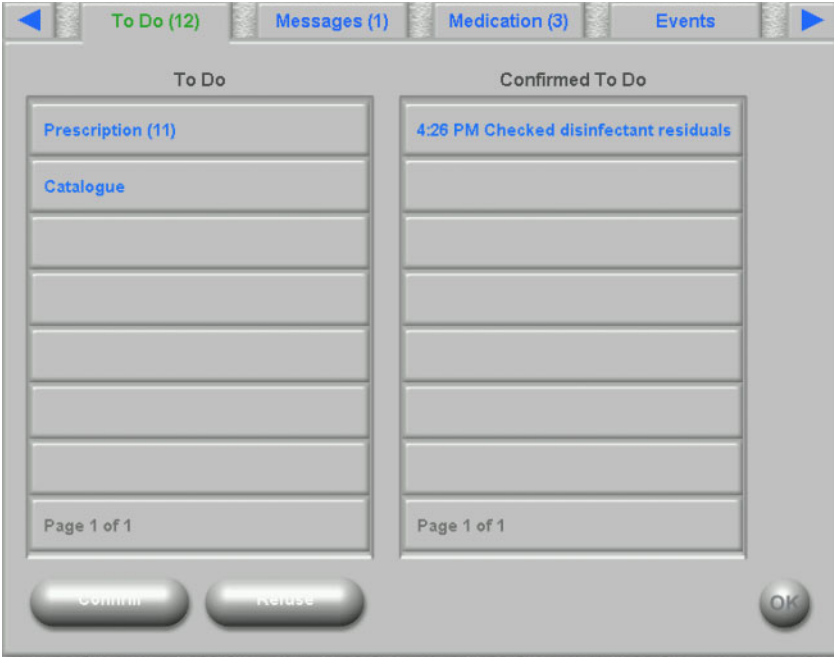
4.7 To Do

The list box on the left contains two folders: Prescription and Catalogue. The folder Prescription contains the To Do items that were prescribed but not yet confirmed. The folder Catalogue contains all To Do items that are available in the EDBMS. The list box on the right contains the To Do items that have either been confirmed or rejected.

Selecting an item from the folder Prescription on the left will activate the Confirm and Refuse buttons, which you can press to move the selected item from left to right. Items from the folder Catalogue can only be confirmed. Confirmation is necessary by means of the **OK** button.

Selecting an item in the list on the right will open a detail window that will allow you to remove (un-confirm) the item. Selecting the Remove button will move the item back from right to left.

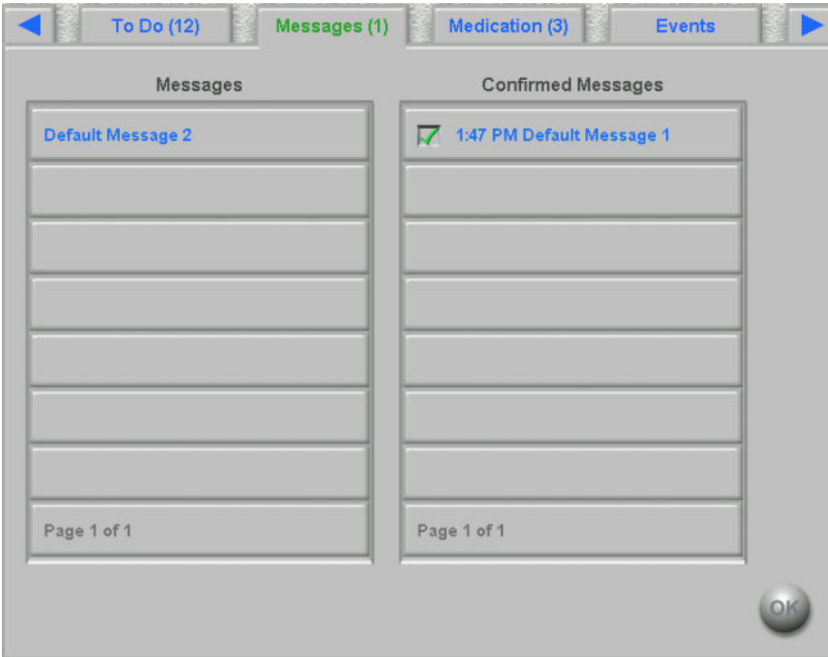
The title of the page contains the number of unconfirmed items.



4.8 Messages

The list box on the left contains the messages items that have not yet been confirmed, while the one on the right contains the ones that have been confirmed.

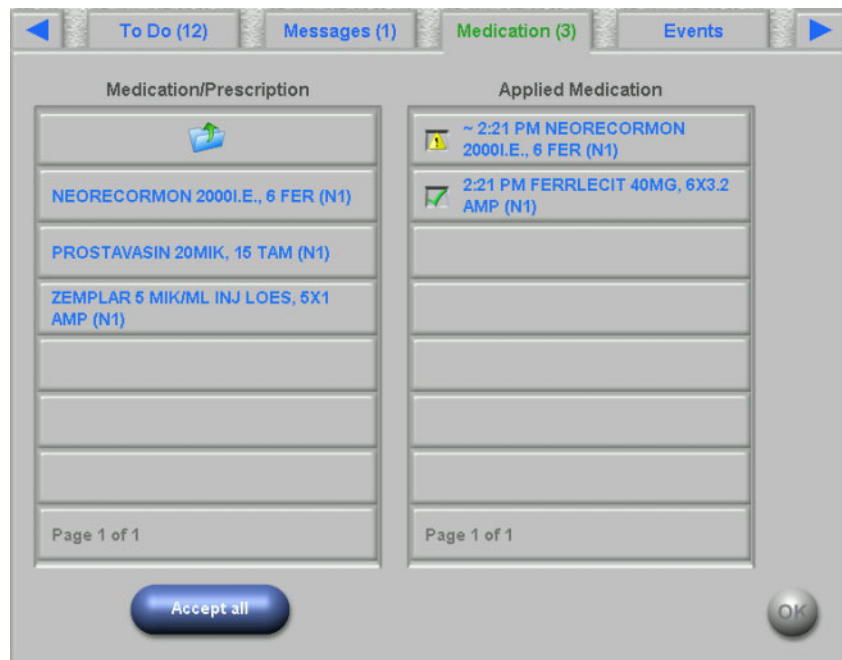
The functionality is similar to the To Do page.



4.9 Medication

This dXp page displays the medication applied during the treatment session including the regular medication, if so configured at FIS level. The list box on the left contains two folders: Prescription and Catalogue. The list box on the right contains the applied and/or rejected medication.

The Prescription folder contains the list of prescribed medication, which are not yet applied. The number of not applied items is displayed in the name of the folder and on the page title. The **Accept all** button allows the user to confirm all prescribed items. This action will move all the items from the Prescription folder to the list box on the right.



A prescribed item can be individually confirmed by selecting it from the Prescription folder. This action will open a detail window in which the user can accept or refuse a medication.



After a medication is accepted, it can be selected from the list box on the right. This action will display a detail page in which the amount can be changed, a batch number and expiry date can be input, or the item can be removed from the list on the right. Removing an applied item will move it back to the Prescription folder.



Depending on the status of an item (accepted, refused, accepted with amount changed), specific icons are displayed in the list on the right.

Medication can be selected also from the Catalogue folder. This action will open a detail page in which an amount can be provided and the item can be accepted. The **Search** button allows you to search for particular medication items. A search text will filter the medication catalogue. This is useful in case of large medication catalogues. You can cancel a search by selecting the button **Full catalogue**.

4.10 Events

This page is similar to the **Events** activity in TMon client. An event can be confirmed from a list of possible events. It can have an optional list of associated actions, which can be: applying a medication, a consumable or a measure. All confirmed events are listed in the events documentation. Actions without an event cannot be saved.

The list box on the left contains the possible events. The middle list box contains the list of available actions, ordered by their time-stamps - the most recent updated action is on the top.

In order to give the user the possibility to define new actions (medication, consumables or measures) from the Events page, three buttons are available: **Medication**, **Consumables** and **Measures**. These buttons will re-direct the user to the respective dXp page, in which medication, consumables and measures can be added from catalogues. In this case, the respective pages will contain a **Back to Events** button, so that the user can navigate back and forth between the Events page and the **Medication/Consumables/Measures** pages without losing the unconfirmed operations in the **Events** page.

Selecting an event from the list on the left will highlight it in green and activate the **OK** button. The user can also select one or more actions from the middle list. When an action is selected from the middle list, a specific detail page is opened in order to change the needed details. For a medication item, you can change the amount, for a consumable item you can change the batch no. and expiration date and for a measure item you can change the comment.

FERRLECIT 40MG, 6X3.2 AMP (N1)

Type: On demand
Amount: 1.0
Comment:

Current batch no.:
Current expiry date:

New batch no.

New expiry date

Batch no.: SFH22860, Expiry date: 3/30/2019

Cancel Amount Back to Events

Pressing the **Back to Events** button in each of the detail pages will bring back the user to the Events page in which the edited action is highlighted. Selecting again a highlighted action will deselect it.

Events Actions Events Documentation

▲

First use syndrom

Hypertension (requiring treatment)

Hypoglycemia

Hypotension (requiring treatment)

Mild Headaches

Severe Headaches

Page 2 of 4

Medication

Consumables

Measures

PARACETAMOL - CT 250MG, 10 KKS (N1)

FERRLECIT 40MG, 6X3.2 AMP (N1)

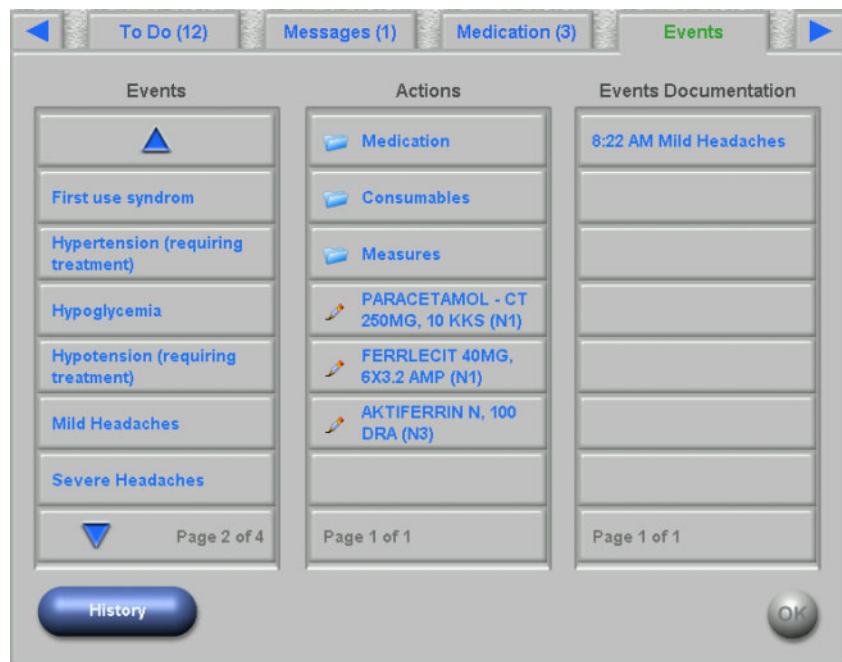
AKTIFERRIN N, 100 DRA (N3)

Page 1 of 1

Page 1 of 1

History OK

Pressing the Medication button will re-redirect the user to the **Medication/Catalogue** page. Selecting a catalogue item will open a detail page in which the amount can be specified. Press **Amount** in order to specify an amount or **Cancel** to go back to the medication catalogue. Pressing **Back to Events** will re-redirect the user to the **Events** page, in which the selected medication appears highlighted in green color in the middle list box. Press **OK** to save the event and the associated actions. The saved event appears in the **Event Documentation** list box on the right.



Selecting a saved event in the list on the right will open a detail page with all the event information. The **Remove** button will delete the event.



Note

When an event is saved, the associated actions are also saved in the corresponding data sections. For example, an event with an associated medication item will make that medication item to be applied in the **Medication** page. Deleting that particular medication in the **Medication** page will result in deleting it also from the event. However, the item will remain in the action list in the middle list of the **Events** page for future use.

When an event is deleted, all associated actions are deleted as well from the corresponding data sections, but remain in the action list of the **Events** page for future use.

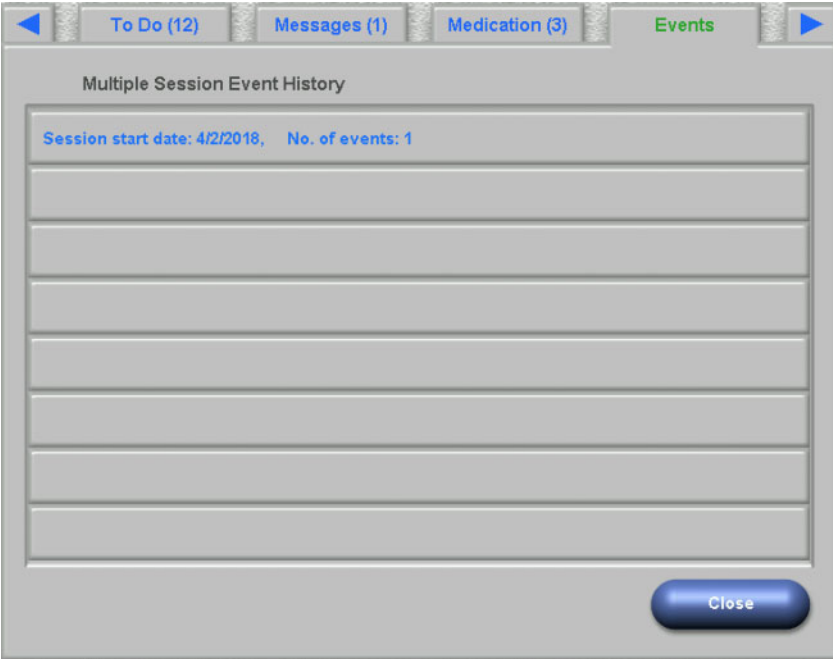


Note

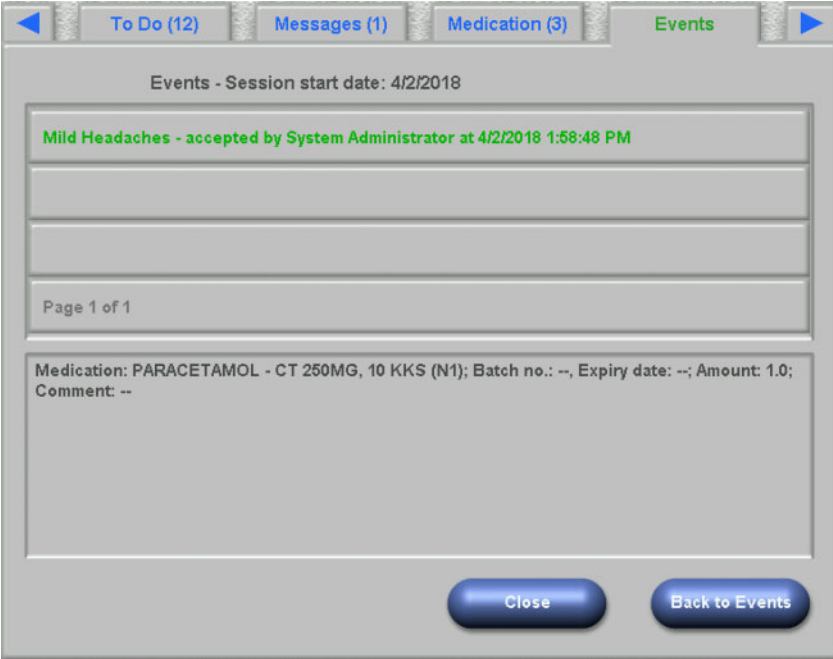
The list of actions in the middle panel is strictly defined only for the current patient treatment. A new session always starts with an empty list.

The functionality for the Consumables and Measures actions is similar. However, specific details may be entered in each case. For example, for a consumable item you can define the batch number and expiration date, while for a measure item just a comment. See chapters 4.11 and 4.12 for details.

The **History** button opens a page in which the events for the past 8 treatments are documented. A list box with the session start date and the number of events is displayed.

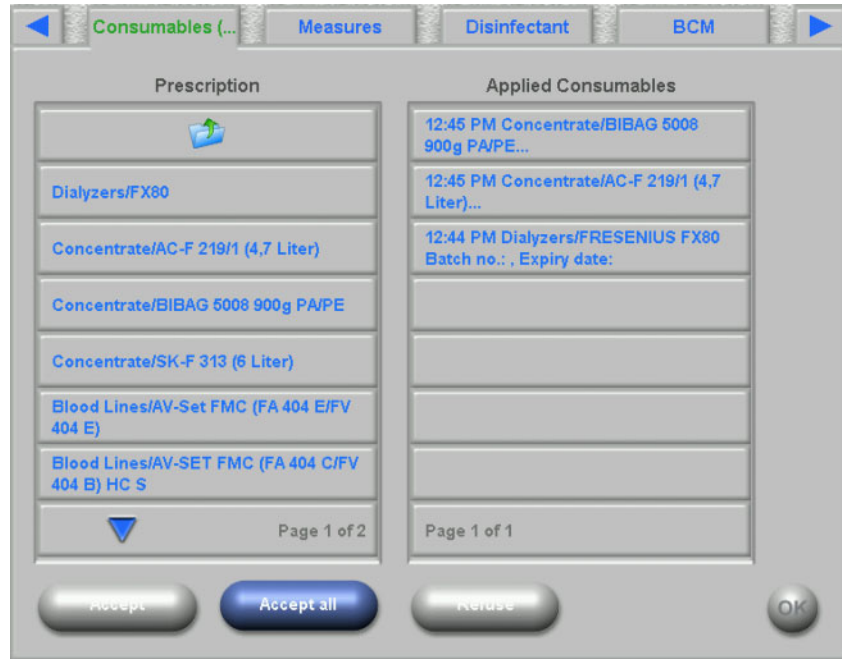


By selecting an item in the list, a detail page for that session is displayed. Selecting an event will display all the associated actions with all the details. Press **Close** to go back to the history list or **Back to Events** to go back to the **Events** page.



4.11 Consumables

The list on the left of this dXp page includes several folders: the Prescription folder contains the prescribed consumables, while all other folders are catalogues with various consumable types. Certain folders like Needles or Concentrates contain sub-folders.



The user can accept all the items from the Prescription folder or can accept or refuse one item at a time. Once an item is accepted/refused, it is listed in the applied consumables list box. An accepted/refused item can be selected, thus opening a detail window in which you can enter the batch number and expiry date of the consumables or remove the item from the applied list.

Consumables (... Measures Disinfectant BCM

Concentrate/AC-F 219/1 (4,7 Liter)

Current batch no.: SFH23768
 Current expiry date: 12/1/2019
 Catalogue - accepted by System Administrator at 4/4/2018 12:45:25 PM

You can input a new batch no. or expiry date.

You can select a batch number from the list:

Batch no.: SFH23768, Expiry date: 12/1/2019

Remove

New batch no.

New expiry date

C

OK

A list of recently used batch numbers and expiry dates is available and the user can simply select the entry from the list which matches the applied consumable. A new batch number and expiry date can be entered by selecting the appropriate buttons. Press **OK** to save your input or **C** to abandon the operation.

Removing a prescribed item will move it back to the Prescription folder. The name of this folder includes the number of prescribed items that are not yet applied.



Notes

The FIS server has an option of not to use batch numbers and expiry dates at all. If this option is turned on, the detail page will contain only the **Remove** button.

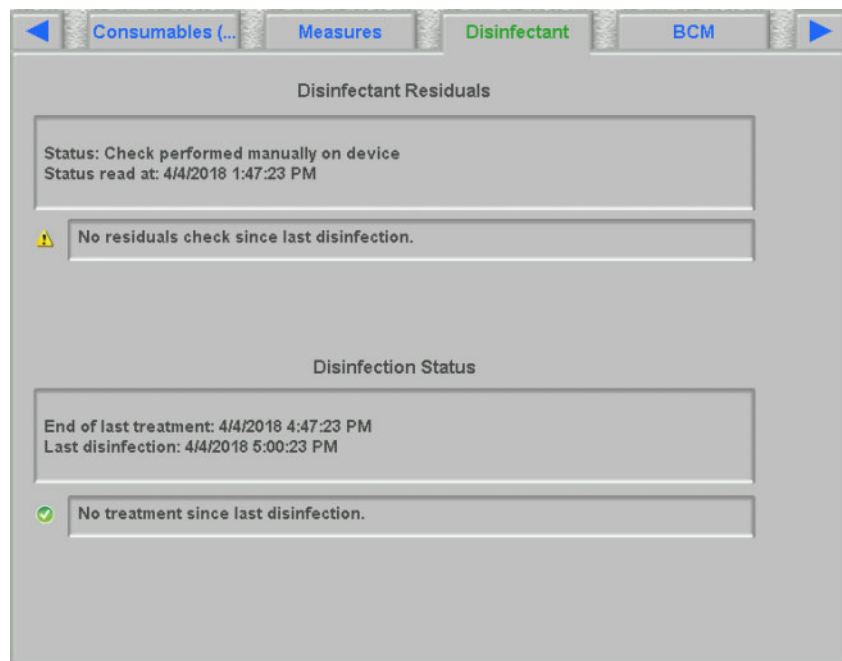
4.12 Measures

The list on the left of this dXp page includes the measures catalogue, from which the user can confirm one or several items. Confirmed items are displayed in the list of accepted measures on the right. An accepted item can be selected, thus opening a detail window in which you can enter an associated comment as free text or can remove the item from the accepted list.

4.13 Disinfectant

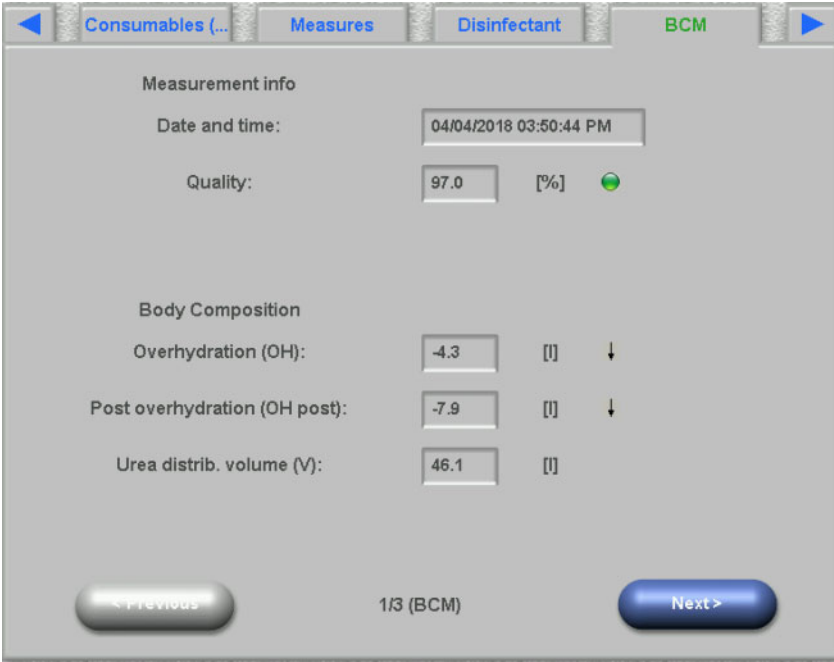
This dXp page displays the date of the last disinfection performed on the 5008/6008 device and the date of the last treatment. Depending on these two dates, a message informing about the disinfection status is displayed. The user can also document the check for the disinfection residuals.

If the 5008 device software version is 4.50 or later or the device is 6008, the check for disinfectant residuals is managed and documented by the device itself.



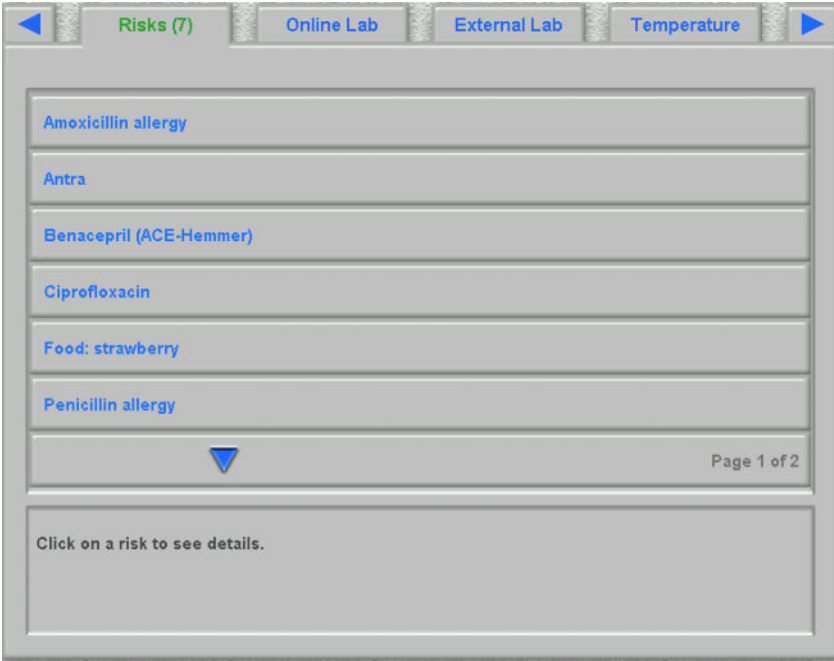
4.14 BCM

This dXp page displays the latest BCM measurement of the current patient. The page is organized in 3 sub-pages. The date and quality of the measurement is presented in the first page.



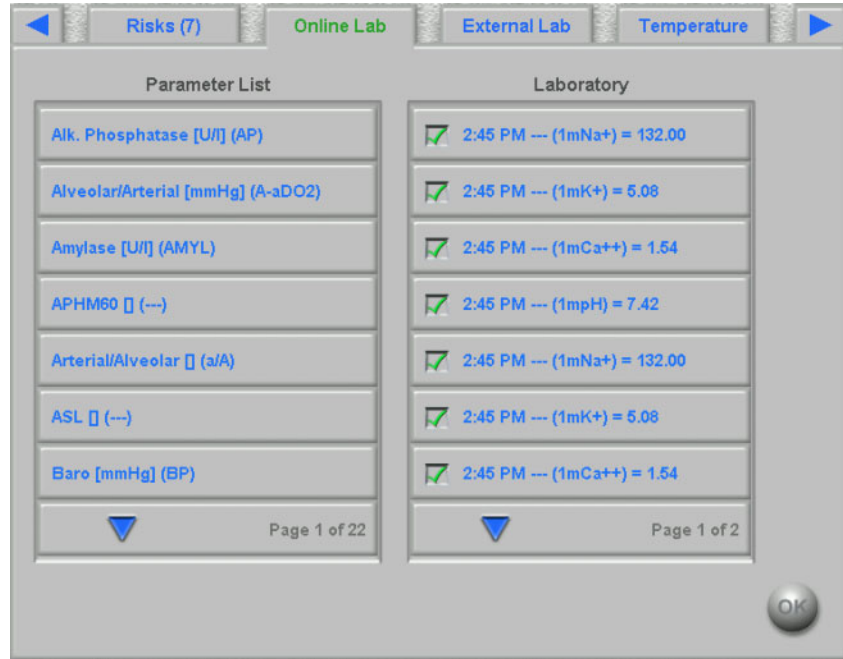
4.15 Risks

This dXp page displays the patient risks, as imported from the EDBMS. One can navigate through the risks by using the list box control.



4.16 Online Lab

The list on the left of this dXp page includes the online laboratory catalogue.



Selecting an item will open an editor page in which one can change the date and time of the measurement, enter the value and a possible comment.



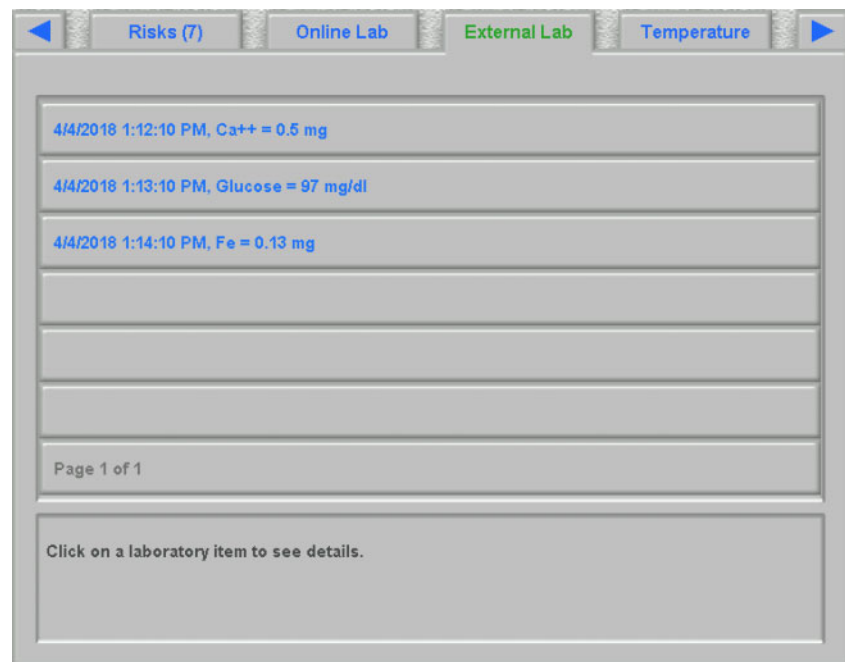
By default, the numerical editor is used for entering the **Value** field. The precision is set in the dXp configuration application, upon configuration of the dXp pages. Since the numerical editor has a limited number of digits, it can happen that certain very large or very small values cannot be entered. In this case, one can click on the **Use Text Editor** link. As a result the keyboard control will open when clicking the Value button, which allows any numerical value to be entered.

Click on **Accept** to finalize the editing or on **Close** to abandon the operation. In the main page click on **OK** to save the data or on **C** button to cancel the operation.

After saving the data, an online lab item appears in the list on the right of the page. One can click on that entry for further editing or for removing the item, by means of the **Remove** button.

4.17 External Lab

This dXp page displays the patient's current laboratory data, as imported from the EDBMS. One can navigate through the items by using the list box control.



4.18 Temperature

This dXp page allows the input of patient temperature measurement. Depending on a FIS setting, the values and editing limits are in Celsius or Fahrenheit degrees.



Click on **New Temp** button in order to input a new measurement. Type in the value and then click on **OK**. The input value appears in the list box control, together with the timestamp of the record. Clicking on an existing measurement allows further editing or removing by means of the **Remove** button.

The **History** button opens a page in which the first measurement of each treatment is displayed together with the session start date and unit of measurement, for the past 8 treatments.

4.19 Post Weight

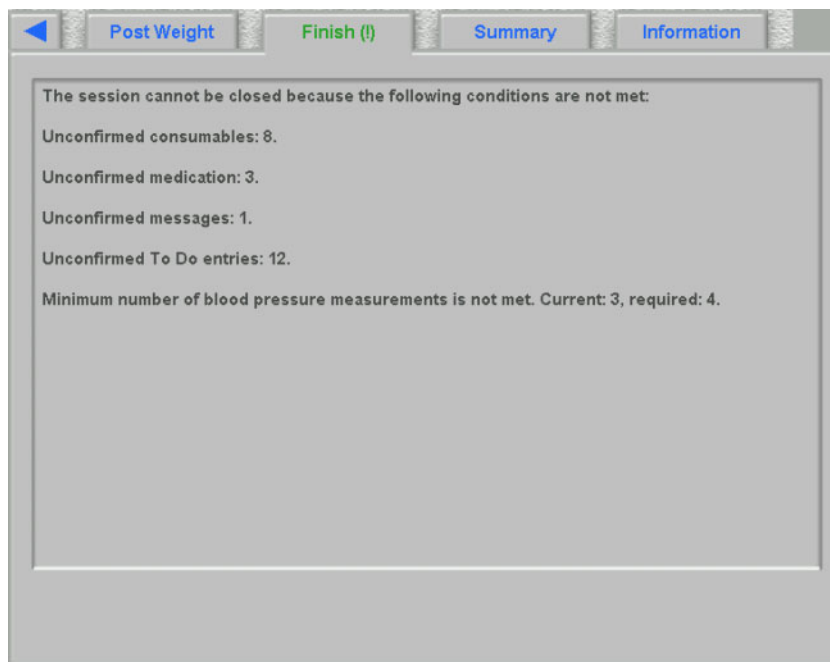
This dXp page corresponds to the Post Weight activity in the TMon client. The user can enter or overwrite the scale reading, the clothes/tare weight and the real fluid intake during treatment. Other values like weight after treatment or weight loss by treatment are not editable, but calculated by the system. If post-weight differs too much from the pre-weight or the weight is increased during the treatment, a warning will be displayed and the title of the page will contain an exclamation mark (!).

The **History** button displays a page with the pre- and post-treatment weight, as well as the target weight of the latest 8 treatment sessions.

Field	Value	Unit
Scale reading after treatment:	85.0	[kg]
Clothes / tare after treatment:	- 0.5	[kg]
Weight after treatment:	= 84.5	[kg]
Fluid/food intake during treatment (real):	- 0.3	[kg]
Weight before treatment:	- 88.1	[kg]
Weight loss by treatment:	= 3.9	[kg]

4.20 Finish

This dXp page corresponds to the Finish/Warnings activity in the TMon client. It displays conditions (if any) that prevent the session from being closed, like the number of unconfirmed medication items, To Do items, messages, consumables, and special situations like a missing post-weight value or the lack of any blood pressure measurement during the treatment, according to the settings in menu **Options/Sessions/Multiple close options** (see Chapter 3.2.2.1 on page 3-9). If any of these conditions exist, the title of the page will contain an exclamation mark (!).

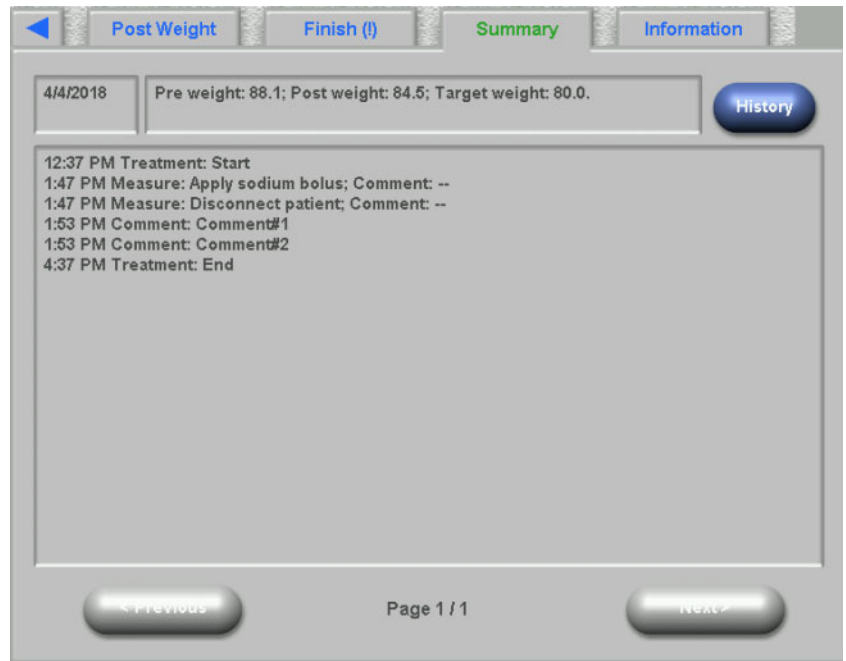


4.21 Summary

This dXp page corresponds to the **Summary** detail view in **Therapy Monitor** client. It presents a few session data categories like weight, UF, comments, events with associated user actions, measures that are not linked to events, as well as treatment start/end. Navigation buttons are included, in case the information does not fit in one page.

Depending on a certain setting at FIS level, the summary data is presented either grouped by categories, or sorted by time in ascending order.

The **History** button displays a page from which you can select synthetic data from the previous eight sessions.



4.22 Information

The Information page displays details about the current dXp user, the current patient, session ID and language, as well as certain technical details like network configuration.



5 Administration

5.1 Description of error handling

Error message, error description	Explanation	Actions to be taken	Error prevention
No connection to server	Connection symbol in the status line is red; Data is not displayed	<ul style="list-style-type: none"> – Check the physical connection to the server: Is the workstation PC connected to the network (plug-in connection PC and wall socket)? – Has the PC been correctly set up in the network by the administrator (IP address, subnet, etc.)? – Is the server PC connected to the network? – Are the required software components running on the server (Fresenius Interface Server)? – Has the required server plug-in been correctly installed and configured? 	
A session was closed but remains visible in the overview screen.	In principle, all active and inactive sessions can be displayed on the overview screen. This is influenced by the session selection.	Check the session filter referring to the session selection. If you have not selected active sessions, the recently completed session may well be included in the display criteria. If you do not wish this to happen, reselect the display of active sessions.	Should you suspect that a session which should be available is not displayed or a session is still displayed although it should not be, then please always first check the session filter to see whether it complies with your current wishes.

5.2 Behavior in exceptional situations

Under unfavorable conditions such as after a disconnected network connection to the server or after program crashes, deviations between the data on the server side and those in the client program may occur. In this case we recommend closing and restarting the program.



Warning

Risk for the patient as a result of wrong treatment parameters

Software errors can lead to a missing prescription in the **Therapy Monitor** database. In this case prescription data cannot be downloaded to the dialysis device and has to be entered manually on the device.

- Users should always have access to the treatment prescription (e.g., in written/printed form) of every patient in order to be able to enter the prescription data manually on the device.
-

5.3 Data backup



Note

We recommend regular backup measures.

The TMon system databases is constantly being edited by a MS-SQL server and can therefore not be copied as a regular file.

We therefore recommend data backups using a data backup software. The backup files thus created can be saved with any backup software or copied to any memory medium.

Users should perform a data backup at regular intervals (at least once a day) and before each software update, as needed.

6 Definitons

6.1 Symbols

In accordance with the applicable legal and normative requirements, the following symbols are used in the About menu or on the identification label:



Follow Instructions for Use



CE mark



Manufacturer



Serial number



Medical device

