PatientOnLine

Instructions for Use

FRESENIUS MEDICAL CARE

Table of contents

1   Important information

1.1   How to use the Instructions for Use

Purpose

The Instructions for Use include information necessary for installing and operating the PatientOnLine application.

This manual is intended for:

➢ First studies

➢ Reference purposes

Identification

The document can be identified by the following information on the title page and on any label:

➢ Software version

➢ Edition of the Instructions for Use

➢ Part number of the Instructions for Use

Footer

The footer contains the following information:
– Company name, e.g Fresenius Medical Care
– Device type
– The English abbreviation for the document type and the international abbreviation for the document language, for example: IFU-EN refers to Instructions for Use in English.
– The editorial information, for example 09A-2022, refers to edition 09A released in 2022.

Organization of the chapters

To facilitate the use of documents from Fresenius Medical Care, the organization of the chapters has been standardized in all manuals. There may therefore be chapters within this document without any content. Chapters without content are marked accordingly.

Illustrations

The illustrations used in the documents (e.g. screenshots, photos, etc.) may differ from the original if this does not have any influence on the function.

Importance of the Instructions for Use

These Instructions for Use are part of the accompanying documents and thus an integral part of PatientOnLine. They include information necessary for the use of PatientOnLine.
The Instructions for Use must be carefully studied before attempting to use PatientOnLine.

Before the responsible organization may start operating PatientOnLine, the person responsible for the operation must have been instructed by the manufacturer on how to use the application and must be thoroughly familiar with the contents of the Instructions for Use.

PatientOnLine may only be operated by individuals who have been trained and certified in the proper operation and handling of the application.

Changes   Changes to the Instructions for Use will be released as new editions or supplements. The following applies in general: this document is subject to change without notice.

Reproduction   Reproduction, even in part, may only be performed with written approval.

1.2   Significance of warnings

Warning

Advises the user about

– a hazard for the patient and the possible cause(s) of the hazard

– the consequences of the hazard

and provides guidance (instructions) on how to prevent the hazardous situation.

1.3   Significance of notes

Note

Advises the user that failure to observe this information may have the following results:
– Damage to the device
– Desired functions will not be executed at all or will be executed incorrectly

1.4   Significance of tips

Tip

Information providing useful tips for easy handling.

1.5   Identification label
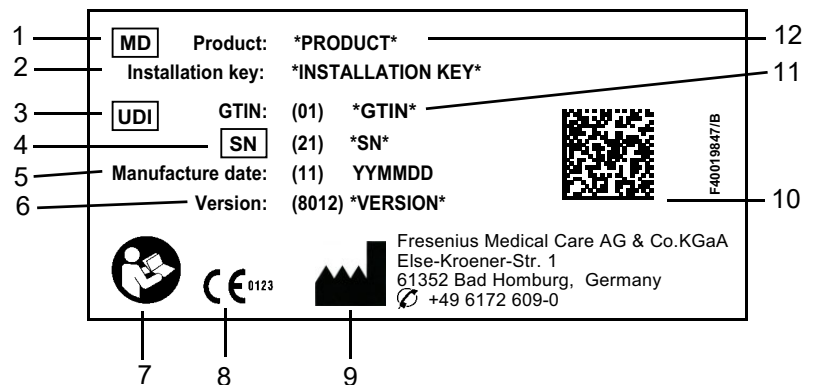
1. Medical Device

2. Installation key

3. Unique Device Identification

4. Serial Number

5. Manufacture date (build date of the software product)

6. Version

7. Follow Instructions for Use

8. CE mark

9. Manufacturer's address

10. Data matrix code with UDI information

11. Global Trade Item Number

12. Product

1.6   Program description

The main objective of the **PatientOnLine** application is to support the FME PD product range and to act as a PD Therapy Manager.

1.7   Intended purpose and related definitions

1.7.1   Intended purpose

Acquire, calculate, model, save, display and transfer parameters of dialysis treatments

1.7.2 Medical indication

Renal insufficiency requiring renal replacement therapy

1.7.3 Intended patient population

For CAPD and APD patients.

1.7.4 Intended user group and intended environment

– PatientOnLine is used by medical personnel (nurses, physicians, doctors) with the appropriate training, knowledge and experience.

– PatientOnLine is not intended to be used by patients.

– PatientOnLine is developed for the usage within dialysis centers, clinical environments and doctor´s offices.

1.8 Side effects

None

1.9 Contraindications

None

1.10 Interaction with other systems

– APD cyclers: The Patient Card is intended to be the means of transport for the electronic prescription between PatientOnLine and an APD cycler.

– BCM - Body Composition Monitor: The BCM Patient Card is intended to be the means of transport between PatientOnLine and the BCM - Body Composition Monitor.

– External Database Management System (EDBMS): The PatientOnLine Data Exchange function allows data import and export from/to External Database Management Systems.

– Telemedicine Services: PatientOnLine is able to connect to dedicated Telemedicine Services that allow remote data exchange.

1.11 Therapy restrictions

None

1.12 IT Environment

PatientOnLine is a complex medical software application. The client-server edition works within a hospital IT network that includes application 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.

Details of the IT environment required for the PatientOnLine can be found in the PatientOnLine 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 EN 60601-1-1.

1.13 Duties of the responsible organization

The responsible organization assumes the following responsibilities:

– Compliance with the national or local regulations for installation, operation and use.
– Correct and safe condition of the software.
– Permanent availability of the Instructions for Use.
– Operational IT security:
  • Regular check of the events log for suspicious activities
  • Keeping the host system, MS SQL servers, and .Net Framework up to date, including security-related patches
  • Applying state-of-the-art standards regarding security for the host system, MS SQL servers, .Net Framework, and, if applicable, LDAP servers.
  • Ensuring a secure network and host system environment, including access management to POL-related databases and FIS.
  • If necessary: The integrity and authenticity of installation files as well as installed files can be verified via digital signatures issued by Fresenius Medical Care.

Note

Data corruption or loss caused by the host system cannot be excluded. This can lead to malfunctions.

➢ The system installer must ensure that software data is processed securely, e.g. in third-party PC software applications.

➢ The network operator must ensure that any data transferred without encryption is protected.

1.14 Responsibility of the user

The following must be observed when entering parameters:

The parameters entered must be verified by the user, i.e. the user must check that the values entered are correct. If the check reveals a deviation between the desired parameters and the parameters displayed in PatientOnLine or on the device, the setting must be corrected before activating the function.
The actual values displayed must be compared to the desired values specified.

1.15 Disclaimer of liability

PatientOnLine was developed for the functions described in the Instructions for Use.

When installing, operating and using PatientOnLine, the applicable legal regulations must be complied with (e.g. in Germany the Medical Device Regulation (MDR 2017/745) and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the software or the device resulting from incorrect use of PatientOnLine.

1.16 Guarantee/warranty

Guarantee   The extent of the guarantee is stipulated in the respective sales contracts.

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

Any use of the device which is not in accordance with its intended use will void any liability and warranty.

1.17 Warnings

1.17.1 Operation

Note

PatientOnLine may exclusively be used by qualified, skilled staff. Fresenius Medical Care does not assume any responsibility for any further use of the PatientOnLine data.

Note

The parameters entered must be verified by the user, i.e. the user must check that the values entered are correct.

PatientOnLine is available in various versions.

1.18 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 labeling (	) and the competent authority of the EU member state in which the treatment is performed.

1.19 Certificates

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

The current version of the EU Declaration of Conformity will be provided by your local service support organization on request.

1.20 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

1.21 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.

1.22 Addresses

Please address any inquiries to:

Manufacturer

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY
Phone: +49 6172 609-0
www.freseniusmedicalcare.com

International Service

Fresenius Medical Care Deutschland GmbH
Digital Services Operations
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY
Phone: +49 6172 609-7000
Fax: +49 6172 609-7106
E-mail: digital-operations@fmc-ag.com

1.23 General Data Protection Regulation (GDPR)

1.23.1 GDPR-related product features

GDPR (General Data Protection Regulation) is a law imposed in the European Union. The following GDPR-related features are implemented in **PatientOnLine**:

– Personal patient data is encrypted in the **PatientOnLine** database. Personal patient data refers to the following information:
  – Name of the patient (first name, last name, and maiden name)
  – Date of birth
  – Sex
  – Picture of the patient
  – Personal identification number
  – Addresses of the patient
  – Phone numbers of the patient
  – E-mail
  – Language

– Personal user data is encrypted in the **FME User Management** database (for client-server edition). Personal user data refers to the following information:

- – Account name
- – Full name
- – Password
- – Phone numbers of the user
- – E-mail
- – PIN

– Communication between client applications like **PatientOnLine Client** or **FME User Management Tool** and the FIS server is encrypted.

– Integrity of all communication is achieved by means of specific technical features, such as cyclic redundancy check.

– Integrity of **PatientOnLine** database records is achieved by means of specific technical features, such as cyclic redundancy check at record level.

– Personal data is used only if strictly needed, for example in cases when it is mandatory and vital to correctly identify the patient.

– Patients can request that their personal data is anonymized/deleted in **PatientOnLine**. This is achieved by a **GDPR**-specific menu item that can anonymize personal patient data or fully delete patient data in/from the **PatientOnLine** database.

– Patients can request a printed report of all their personal and medical data that was processed by **PatientOnLine**, over any given time. This is achieved by a specific **GDPR** menu that extracts data from PatientOnLine database and exports it to a printable format (PDF).

– Patients can request a copy of their personal and medical data from **PatientOnLine**, over any given time, in a machine-readable format. This is achieved by a **GDPR**-specific menu item that extracts data from the PatientOnLine database and exports it to XML format.

– Patients can request the rectification of their personal data in the **PatientOnLine** database.

– User actions performed in **PatientOnLine** and in **FME User Management Tool** are logged. The user logs can be filtered by time, user or patient, and can be viewed, printed and exported to a machine-readable format.

– **PatientOnLine Client** and **FME User Management Tool** define a complex system of user access management that includes user authentication, user authorization, user roles, user permissions, etc. Only users with the respective permission can have access to a certain function.

– **PatientOnLine** defines a special right that allows only dedicated users to modify or delete information created by other users.

1.23.2 Processing of personal patient data in PatientOnLine

PatientOnLine can be delivered in various editions: stand-alone, client-server, client-server connected to a distinct clinical software application (like Euclid, TSS, etc., generically called **EDBMS** – **E**xternal **D**ata**b**ase **M**anagement **S**ystem), or client-server connected to a cloud repository (generically called **Connected Home**), with or without EDBMS connection.

In case of stand-alone edition, all personal patient data is created in **PatientOnLine**. In case of the client-server edition connected to **EDBMS**, basic personal data (first name, last name, name at birth, date of birth, gender, PIN and institution ID) is imported into **PatientOnLine** from **EDBMS**. All other personal data (see below) is created in **PatientOnLine**. The **Connected Home** cloud repository does not store any personal patient data.

The personal patient data processed in **PatientOnLine** is the following:

– First name, last name, name at birth, date of birth and gender

– Home/office/next of kin addresses (country, city, street, number, zip code)

– Phone numbers (home/office/next of kin)

– Personal identification number (PIN)

– Institution ID (only in case of EDBMS)

– Nationality, language and ethnicity

The rationale for using this personal data is the following:

Patient names and date of birth are used for patient identification. Peritoneal dialysis devices communicate with **PatientOnLine** by means of patient cards and display the first name, last name, name at birth and date of birth of the patient on the device screen. The patient or the nurse (in case of treatment performed in the clinic) must confirm the identity of the patient before starting the treatment.

Patient addresses and phone numbers are mainly used for organizing the transport of the patient from/to the dialysis clinic and for scheduling nurse home visits. Phone numbers and email address are also used to get in contact with the patient to provide medical support. Next of kin data is needed for the notification of the patient status.

Patient PIN and institution ID are usually required by the local medical insurance institutions.

Patient nationality and language are useful for adequate medical personnel to assist the patient in case the patient does not speak the local language. The ethnicity of the patient may be needed for medical purposes (dialysis prescription).

1.23.3 GDPR-specific menu item

The dedicated menu item GDPR Actions can be found in the Communication menu. Only users with a dedicated GDPR user right can access this menu item. The menu item provides the following GDPR-related actions:

– Anonymizing the personal data of any given patient.

– Deleting all data of any given patient of any given time.

– Exporting personal and medical data of any given patient and any given time to an external file in a machine-readable format (XML).

– Exporting personal and medical data of any given patient and any given time 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, in case of client-server editions connected to EDBMS.

For a detailed description of menu item GDPR Actions (see chapter 3.14.5, page 200).

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2   Installation

2.1   Hardware and software requirements

See the PatientOnLine Service Manual for minimum hardware and software requirements.

2.2   Installation

Note

PatientOnLine may be installed and started up only by authorized Fresenius Medical Care service personnel or by service technicians approved by Fresenius Medical Care.

If an earlier PatientOnLine version is installed on your computer, first back up your data before installing the new version.

Note

If you are running Windows, administrator rights on the PC are required to be able to install new software. Prior to the installation of PatientOnLine, it must be ensured that the appropriate user rights have been assigned.

The installation procedures are described in the **PatientOnLine** Service Manual.

After installation, **PatientOnLine** can be used as trial version with full functionality for a period of 60 days. In order to use the application after the trial period, **PatientOnLine** must be registered. Details about registration are described in the Service Manual.

Registration ensures the traceability of each installation, as required by the Medical Device Regulation (MDR 2017/745).

PatientOnLine is a CE-certified class IIa medical device.

3   Operation

Note

The following basic knowledge is a prerequisite for operating **PatientOnLine**:

– At least basic knowledge of Microsoft Windows.

– Knowledge in the handling and functioning of a computer mouse.

Note

General function of the **Cancel** button:

By clicking on the **Cancel** button, the current editing process is cancelled. Changes that might have been completed will be lost.

Subsequently, the function of this button will **not** be mentioned separately any more.

3.1   Opening PatientOnLine

PatientOnLine is a **Client-Server** or a **Stand-Alone** application. In both cases, the user is running the **PatientOnLine Client**.

In case of a **Client-Server** installation, several users are able to start the **PatientOnLine Client** on several workstations and to connect to the same database. Data modified from one workstation is instantly available on all other workstations connected to the same database, based on a reliable refresh mechanism.

Most of the **PatientOnLine** system administration settings (see **Setup**, page 207) are global settings, applicable to all **PatientOnLine Client** instances:

– **General Settings**: QA formulae and various options used in QA tests

– **Lab Data Settings**: units of measurement for QA and lab data

– **Limits**: height and weight limits for children and adults

– **Transport Characteristics**: classification data of PET and PFT graphs

– **Medical Lists**: management of medical lists of the application

– **Medical Lists Translation**: support for translating medical lists

– **Resource Files**: management of resource files of an APD cycler

Certain system administration settings are local settings, specific to each **PatientOnLine Client** instance: current language, view settings, data export paths.

Note

The main difference between the two editions is that for **Client-Server**, there is a global unique database for all users sharing the same data, while for **Stand-Alone**, there is only one single user of the application and of the database.

Note

In case of a **Client-Server** installation, a reliable refresh mechanism is implemented, ensuring that data modified from one **PatientOnLine Client** is instantly available on all other **PatientOnLine Client** applications connected to the same database.

Note

Regardless of whether it is a **Client-Server** or a **Stand-Alone** installation, the functionality of the **PatientOnLine Client** is the same.

Note

The **PatientOnLine Client-Server** can be configured to work connected to an external database management system (EDBMS), such as EuCliD. In this case, the patient list and certain other data categories are imported from the external system and cannot be changed in PatientOnLine (see chapter 3.14.4.1, page 191).

The installation procedure will place an icon on the desktop. Double-clicking this icon starts the application. Alternatively, you can select **Start/Programs/Fresenius Medical Care/PatientOnLine Client**. A splash screen is displayed and a login dialog box opens, requesting a user name and a password.

The **PatientOnLine** application assumes that application users and passwords have been defined. To distinguish this user level from the Windows user level, these users will be referred to as **PatientOnLine** users.

Note

If upon opening the **PatientOnLine** application its database is in an inconsistent state (for example a wrong version), an error message is issued and the application will close. It is strongly recommended to contact the technical support in such cases.

PatientOnLine is a fully internationalized software. For changing the current application language, see **Language** tab from **Administration/Setup** menu. Once a language is set, it will be used as default language at the next program start.

3.2 Closing PatientOnLine

To close the application, click on the [X] in the upper right corner of the **PatientOnLine** window.

After confirming the safety prompt, the application will close.
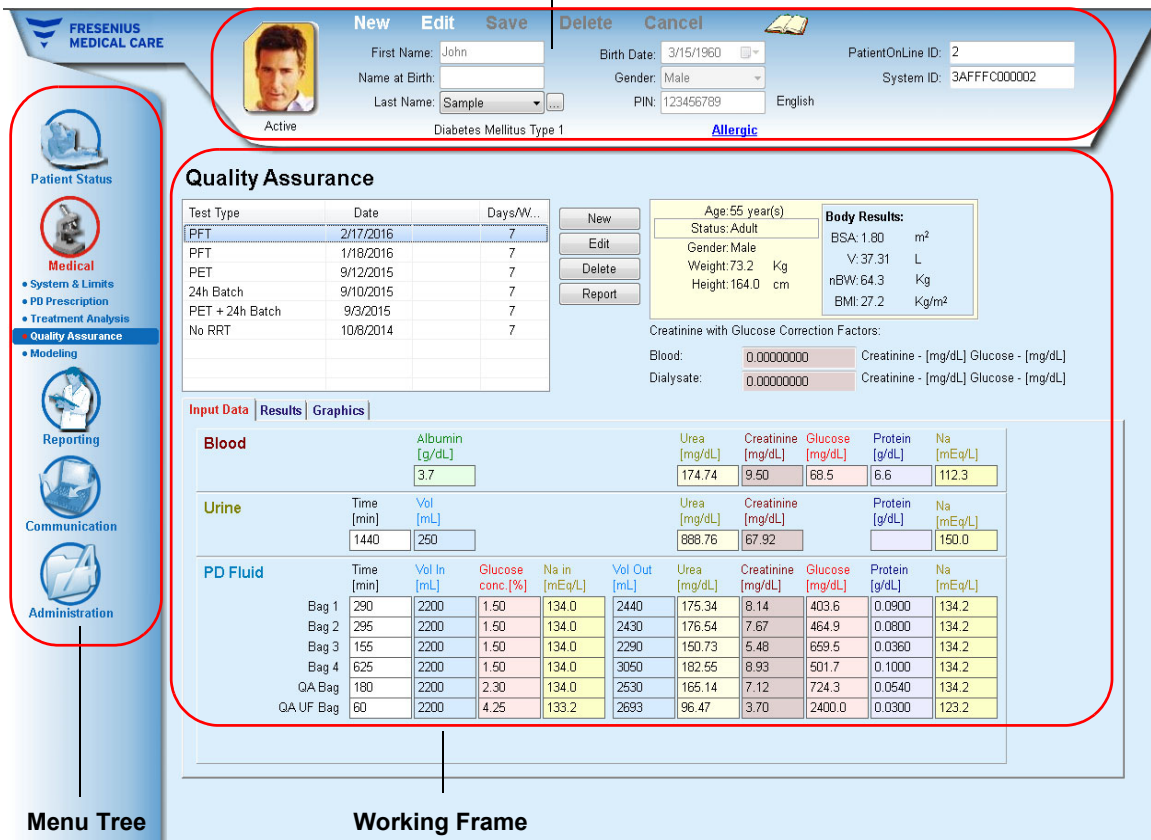
You can explicitly log off by selecting **Administration/Users/Log off**.

After confirming, another user is required to log in with their user name and password.

3.3 Main functions and features of the PatientOnLine application

3.3.1 Application window layout

Patient Frame

Menu Tree

Working Frame

The application window layout has 3 main frames:

Patient Frame
in the upper part of the application window

Menu Tree
on the left-hand side of the application window

Working Frame
in the center of the application window

Patient Frame

Contains the management module for patient basic data and is always visible. The data of the currently selected patient is displayed in this area. Its main functions are:

Creating a patient record,

Editing, **updating** and **deleting** a patient record,

Searching for patients,

How to use the **PatientOnLine Instructions for Use**,

Quick switch to **English**.

Menu Tree

There are 5 main menus in the **Menu Tree**:

Patient Status,

Medical,

Reporting,

Communication,

Administration.

Each of these five menus contains several submenus.

Working Frame

Once a menu item is selected, the **Working Frame** is refreshed with the data of the selected patient. The same applies if a different patient is selected. With a few exceptions (**Reporting/Statistics/Group of Patients, Reporting/Dashboard, Communication/Data Exchange, Administration**), all menu items require a patient to be selected in the **Patient Frame**. If no patient is selected, the **Working Frame** will display an information message and the menu item has no effect.

There are special interactions between the 3 main frames in case the **Patient Frame** or the **Working Frame** is in **Edit** mode. A frame enters the **Edit** mode when creating a new record - by clicking the **New** button, or when updating an existing record - by clicking the **Edit** button. A frame exits the **Edit** mode when saving the record - by clicking the **Save** button, or when canceling the current operation - by clicking the **Cancel** button.

The interactions are as follows:

If the **Patient Frame** is in **Edit** mode, the **Menu Tree** becomes inactive - you can no longer navigate in the tree, and the **Working Frame** becomes invisible.

If the **Working Frame** is in **Edit** mode, the **Menu Tree** becomes inactive - you can no longer navigate in the tree, and the **Patient Frame** becomes inactive - you can no longer select/edit/delete patients.

This ensures that edited but not yet saved data is not lost by changing the current menu item or by selecting a different patient.

The same approach is used when trying to close **PatientOnLine**. If the user tries to close the application while either the **patient frame** or the **working frame** is in **Edit** mode, a warning message is displayed.
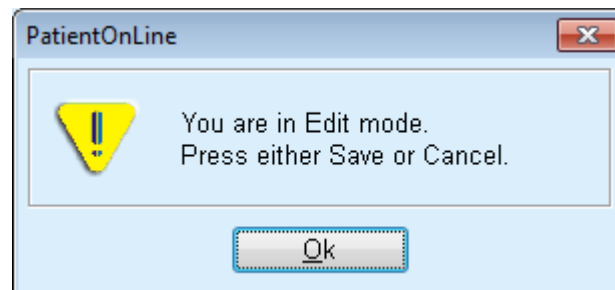
Fig. 3.1 Warning message on closing the application while in Edit mode

The **PatientOnLine** database is protected by a **CRC** mechanism that ensures the data integrity of all database tables against both hardware read/write errors and possible unauthorized access. The CRC technology can be regarded as a special signature that guarantees the correctness of data. Whenever a piece of information is read from the database, the CRC signature is checked. If any problem is detected, an error message is displayed, indicating the location of the error.
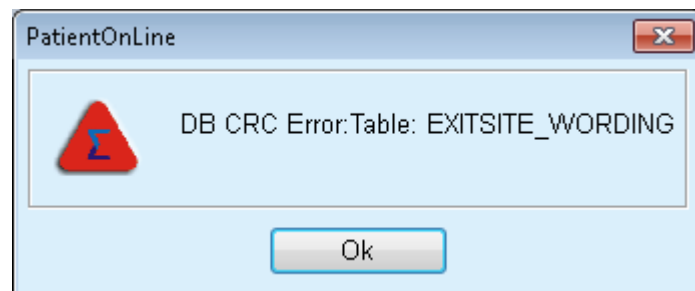
Fig. 3.2 Error message on database CRC error

If the **CRC** impairs certain critical resources, the application will stop before asking for the user login.
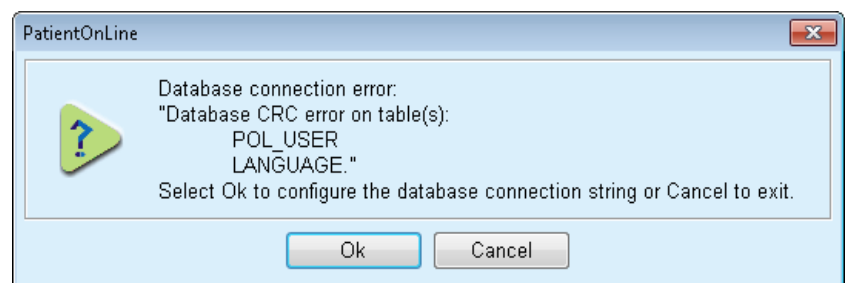
Fig. 3.3 Critical database CRC error

If the error is not critical, the application will continue to work, but certain functions may be limited or inactive.

In any case, you should contact the technical support.

3.4 Patient Status (Overview)

Demographics

The **Demographics** submenu manages the primary demographics and medical data of the patient. You can specify the patient's addresses and telephone numbers here. Other important data such as **Visual Ability**, **Fine Hand Manipulation**, **Training**, **Professional Status** etc. can also be recorded.

Diagnosis & Therapy

The **Diagnosis & Therapy** submenu allows the user to specify the primary renal disease as well as a number of comorbidity factors for the patient, the **RRT (Renal Replacement Therapy)**, the **Catheter**, the **Regular Medication**, **Allergies** as well as certain **Additional Information** such as the active/inactive status.

Tunnel & Peritonitis

The **Tunnel & Peritonitis** submenu offers management support for **Exit Site / Tunnel Infection** incidents, **Peritonitis** incidents and **Exit Site Classification**. The infection data includes associated germs, therapies (one or several), drugs and dosages for each therapy and a fully translatable exit site classification description - in both text and graphics - exists.

Assessment Methods

The **Assessment Methods** submenu offers support for the standard medical parameters that are supposed to be recorded during a patient's regular visit to the clinic. Here, the user can input and view current and past data about the patient's **weight**, **height**, **blood pressure, volume balance, BCM measurements**, **amputation**, **nasal carriage status** and **additional lab data**. The weight, blood pressure and volume balance menus allow the definition of patient-related notification limits. The measurement units for each lab parameter are fully customizable. There is also a **Comment** section for recording any data the physician or nurse finds appropriate, such as **recommended nutrition**.

Hospitalization

The **Hospitalization** submenu offers support for recording data about the patient's hospitalization: **hospital**, **department**, **ward**, **staff**, **admission** and **discharge** dates, **diagnoses**, **comments** on patient's status and development etc.

3.5 Medical (Overview)

Systems & Limits

The **Systems & Limits** submenu manages PD-specific data. The **System** and **Limits** tabs can provide data about the patient's current APD and/or CAPD system as well as certain treatment limits in case of APD systems, such as *sleep•safe*, *sleep•safe harmony*, **SILENCIA**, **etc**.

PD Prescription

The **PD Prescription** submenu offers valuable means for creating, updating, and printing PD prescriptions, depending on the selected PD system(s). Data about each exchange or cycle phase, like inflow and outflow volumes, dwell time, glucose concentration etc. can easily be managed.

Treatment Analysis	The **Treatment Analysis** submenu offers data support for analyzing the treatment protocols recorded by the APD cyclers in an electronic format. This allows the physician to follow up on the treatments that took place at thepatient's home. The treatment protocols can be downloaded from electronic media during the patient's visit to the clinic.
Quality Assurance	The **Quality Assurance** submenu offers complex management for PD-specific QA tests, like the Peritoneal Functional Test (PFT), the Peritoneal Equilibration Test (PET), 24 hours Batch Collection Test, PET+24 hours Batch Collection Test, and No Renal Replacement Therapy Test. PET tests are available as both short and extended versions.
	Data is entered easily using a wizard-like approach. Medical results are presented in text form and in well-known graphical formats, such as Twardowski PET graphs. The PFT test computes more than 50 medical parameters. Data input can be made in **Conventional** and **International** (S.I.) measurement system units, which in turn are fully configurable. For certain computed results, the user can input their own data. Various algorithms for computing Body Surface Area, Total Body Water (Urea Distribution Volume), and Protein Catabolic Rate can be selected.
	The **Quality Assurance** submenu has sophisticated algorithms for checking input limits on each parameter, as well as for dealing with missing data.
Modeling	The **Modeling** submenu offers means for estimating the outcome of a given PD prescription, taking into account patient data assessed by a QA test. It also allows the user to specify QA targets and restrictions and to obtain a list of PD prescriptions that meet both the targets and the restrictions.

3.6   Reporting (Overview)

Reports	The **Reports** submenu manages printable reports. It allows creating various flexible reports using all data available for the selectet patient. Besides printing, reports can be saved in external formats such as **PDF**, **RTF** and **MS Excel** for further usage or for archiving.
Statistics	The **Statistics** submenu manages both patient-based statistics, such as trend analyses of various parameters and infections, and group statistics, such as histograms, cross-correlations and infection rates. **PatientOnLine** offers sophisticated ways for defining patient groups by integrating various selection and range criteria.
Custom Overview	The **Custom Overview** submenu allows a synthetic view over a single CAPD or APD treatment protocol, together with blood pressure data and exit-site pictures of the same day for the selected patient. It is also possible to navigate through the list of available treatment protocols.
Dashboard	The **Dashboard** submenu allows a quick view of the treatment protocol status for all patients. The status refers to meeting certain criteria e.g. if blood pressure or volume balance are within prescribed limits etc. and is highlighted by a color code.

3.7   Communication (Overview)

Patient Card

The **Patient Card** submenu offers functions for exporting PD prescriptions and patient data on electronic media, like a Patient Card to be used on the APD cycler, as well as for importing treatment protocols from such media.

Patient Card Plus

The **Patient Card Plus** submenu offers functions for creating and reading data from FME patient cards, such as *sleep•safe harmony* and **SILENCIA** cards.

BCM Card

The **BCM Card** submenu offers functions for personalizing BCM (simple or 5008) cards with patient basic data and medical data, for importing BCM measurements and for erasing such cards.

Data Exchange

The **Data Exchange** submenu allows data to be imported and/or exported from/to other FME software applications, external database management systems and other **PatientOnLine** applications. The import of treatment protocols from a **Connected Home** cloud is also possible.

GDPR Actions

The **GDPR Actions** submenu allows the user to anonymize, delete, and export the personal patient data to a printable/machine-readable format over any given time.

3.8   Administration (Overview)

Administration

The **Administration** submenu offers support for data management concerning users, hospitals and staff, as well as the management of the application itself.

User Administration Module

The **Users** submenu offers an overview on users, groups, and rights. You can also log off from the application here. In case of **PatientOnLine Stand-Alone**, the user can change their password using this menu option.

Hospitals/Staff

The **Hospitals** and/or **Staff** submenus allow the definition of hospitals (including departments and wards) as well as staff personal data. Users can be linked to staff members on a one-to-one basis.

Setup

The **System Setup** submenu is dedicated to application management. Many settings can be configured, as follows.

Current adults and children formulae for computing Body Surface Area, Total Body Water (Urea Distribution Volume) and Protein Catabolic Rate can be selected from 17 alternative QA formulae that are currently implemented, including the formulae of DuBois & DuBois, Gehan & George, Gotch, Mosteller, Chertow, Watson, Hume-Weyers, Bergstrom, Randerson etc. The user can also define their own classification values for certain QA graphs, e.g., for urea, creatinine and glucose.

The following selections can be made for units of measurement:

➢ Measurement units for weight and height (Metric or Imperial)

➢ Measurement units for temperature (Celsius or Fahrenheit)

➢ Ureor urea nitrogen as measured solute

Units of measurement systems can be fully configured with respect to any of the measured parameters from blood, urine and dialysate. A shortcut to set default conventional or S.I. units of measurement is available.

Visibility options for treatment analysis as well as the infection rate calculation method can be set in a dedicated **Setup** submenu. The user can set weight and height limits for adults and children and can configure the transport characteristics for both adults and children.

PatientOnLine is a multi-language application. The **Administration/System Setup/Language** menu allows the user to switch the application language while **PatientOnLine** is running.

All changes above can be made without stopping the application.

The **Medical Lists** tab (comorbidity factors, diagnoses, germs, antibiotics, CAPD solutions etc.) allows the user to update the medical lists themselves, including visibility of items, thus offering flexibility.

The **Event Log** tab manages the records of critical application actions. Actions like editing patient data, creating or updating a prescription etc. are automatically recorded by the application, together with the user name and the time when the action took place.

Users with certain rights can view and edit the application log, and export values in common formats like MS Excel-compatible comma-separated values.

The **Custom Overview Settings** tab allows a full customization of the **Custom Overview** and **Dashboard** menus.

The **Connected Home** tab allows specific actions like enrollment or drop-out of clinic and patients.

3.9   General notes on operation

3.9.1   Editing records

The **PatientOnLine** menu bar follows a certain template for simple navigation and editing. All medical menus refer to the patient selected in the **patient frame**. There are a few exceptions which are clearly specified in section (see **Application window layout**, page 25).

A typical menu contains a list of items in the upper part, a detail section in the lower part of the window, and certain command buttons, usually at the bottom of the window. The buttons are **New**, **Edit**, **Delete**, **Save**, and **Cancel**.

The current item displayed in the detail section can be selected by clicking on a row of the list.

Not all buttons are available at all times. The menu window can be in two basic modes: **Navigation** and **Edit**. In **Navigation** mode, which is the default mode, the **New**, **Edit** and **Delete** buttons are active, and the **Save** and **Cancel** buttons are inactive. In this mode, you can navigate through the items by selecting rows in the item list. Fields in the detail section can not be modified.

By clicking on **New** or **Edit**, the program will enter the **Edit** mode. In this mode, you can no longer navigate in the item list, the **New**, **Edit** and **Delete** buttons are inactive, and the **Save** and **Cancel** buttons are active. The detail section is editable and you can modify the fields. By clicking on the **Save** button, the edited item will be modified according to the changes in the detail section. By clicking on the **Cancel** button, the changes will be lost and the edited item is reverted to its previous value. If it was a newly created item, it will be discarded. In both cases, the application will exit the **Edit** mode and will revert to **Navigation** mode. The item list will be refreshed.

To delete an item, it must first be selected, then the **Delete** button must be clicked. A warning message is displayed and the user must confirm the operation by selecting the **Yes** button.

Each saving or deleting operation is confirmed by an information message. In case the operation could not be properly performed, an error message is issued.

For every **New** and/or **Edit** operation, the program automatically records the user name that created the data item and the creation time, and/or the user name that last updated the data item and the last update time. This data is generically called **Created by, Creation time, Last updated by** and **Last update time**.

Note

Only users that have a special right (**Edit/delete data created by other users**) can update/delete a data item for which the **Last updated by** field is different from the current user name. If the current user does not have the respective right, the update/delete operation does not take place and a warning message appears with the following content: **You do not have permission to create/delete data created by other users. The item that you are trying to edit/delete was created by user: <user>**.

3.9.2 Getting help

PatientOnLine has a comprehensive off-line and on-line help system. The present Instructions for Use are available in PDF format at **Start/Programs/Fresenius Medical Care/PatientOnLine Client/Manual/PatientOnLine User Manual**. In order to open the manual, a PDF viewer application such as **Acrobat Reader** from **Adobe Systems Inc** is required.

The Instructions for Use can also be opened by clicking on the **book symbol** in the **Patient Frame** (see **Patient Frame**, page 36).

The usual features like **Table of contents**, **search**, **bookmarks** (expand and collapse) etc. are available.
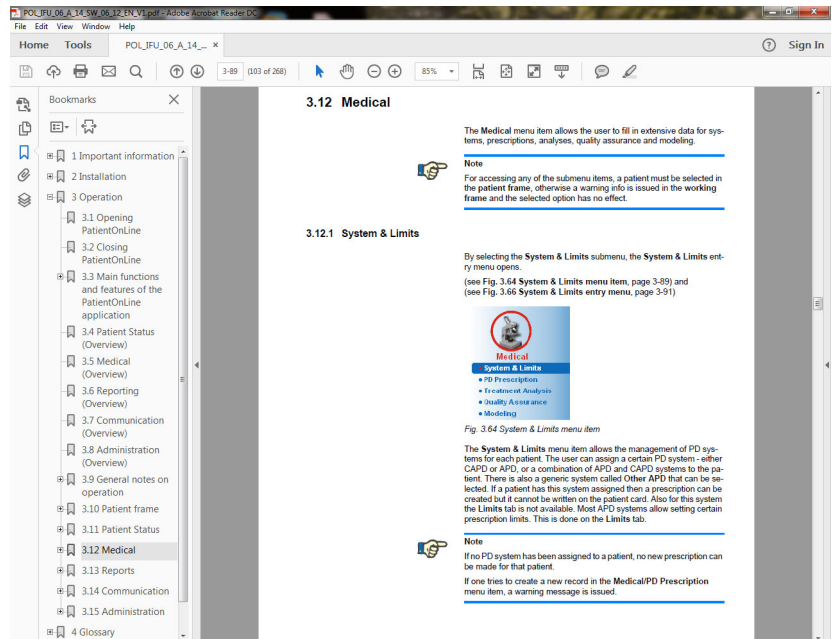
*Fig. 3.4 **PatientOnLine** help*

The **Instructions for Use** will open in any screen of the **PatientOnLine** application by pressing the **F1** key.

3.9.3   Typographic conventions

This document uses the following conventions:

Click on the **Save** button	Buttons and other control elements of the graphical user interface are written in **bold**.
Typed in by user	Data typed in with a keyboard is written in **bold**.
What is displayed	Messages displayed by the application are written in **bold**.
TAB, **SHIFT**, **CTRL + S**	Keyboard keys are written in **bold**.

Tip

Comments, suggestions and operating tips are written in **bold**.

3.10 Patient Frame

The **Patient Frame** in the upper section of the **PatientOnLine** applica-tion window allows the user to specify the basic data: **First Name**, **Name at Birth**, **Last Name**, **Birth Date**, **Gender**, **Diabetic**, **Allergic** and **Active** status; **PatientOnLine** ID (ID of patient in **PatientOnLine** database), System ID (ID of patient written on Patient Card - 5008 and BCM - and on Patient Card Plus) and the **PIN** (Patient Identification Number), as well as the patient's picture.

By clicking on the **English** label on the right-hand side of the **Patient Frame**, you can quickly switch the current language of the application to English.

Clicking on the [...] button allows the user to search for patients. In the **Search Patients** window, a **Report** option is available allowing the user to generate reports with a complete list of patients or based on various patient search criteria.

The **Patient Frame** has its own menu for the following possible actions:

– **New** - creating a patient record;

– **Edit** - editing a patient record;

– **Save** - saving a patient record;

– **Delete** - deleting a patient record;

– **Cancel** - canceling the current operation (new or edit) on a patient record;

– **Search** [...] - searching for a patient record.

Note

Upon starting the **PatientOnLine** application, only the **New** menu item of the **Patient Frame** is active (colored in white) and no data is display-ed in the text boxes.

On the left side of the **Patient Frame**, there is an image frame, which can display the picture of the current patient.

Note

Upon starting the **PatientOnLine** application, no patient is selected in the **Patient Frame** and consequently the image frame is empty.

For loading/changing a patient picture, you must:

➢ Select the desired patient in the **Patient Frame**;

➢ Double-click on the **image frame**;

The **Select patient image** window opens.

➢ Select the **drive**, **path**, **folder** and **file name** containing the picture;

➢ Select the **Open** button of the dialog window;

➢ Select the **Save** menu item. A warning message is displayed, stating the success or error of the updating operation.

Note

Only ***.bmp** and ***.jpg** image formats are supported by the **PatientOnLine** application.

3.10.1 Menu item New

Creating a new patient record

➢ Clicking the **New** menu item alllows the user to create a new patient record.

The following patient data must be entered:

➢ Patient's **first name** - maximum 30 characters;

➢ Patient's **name at birth** - maximum 40 characters;

➢ Patient's **last name** - maximum 40 characters;

➢ Patient's **birth date**.

Note

It is not allowed to select a date equal to or after the current date as a patient's birth date. A warning message is issued and the user must select a valid date.

Warning

Risk for the patient as a result of insufficient detoxification

Wrong birth date format.

The patient age at the date of a QA test cannot be computed without the birth date, and therefore the urea distribution volume (V) cannot be evaluated. As a consequence the Kt/V cannot be calculated.

➢ Calendar control does not allow invalid dates.

➢ Patient's **gender**;

➢ Filling in the patient's **PIN** number - only for users with a specific right.

Note

Only certain users, depending on their corresponding group rights, can edit the **PIN**.

Note

Two patients cannot have the same **PIN**. On saving the patient record, the patient's **PIN** is checked for duplicates in the database. If a **PIN** is found that has been assigned twice, an error message will be displayed and the user must enter a valid **PIN**.

➢ Patient image in the image area as described above.

There are two options to proceed:

➣ By clicking on the **Save** menu item, all data is saved in the database. The new patient data is displayed in the **Patient Frame**.

or

➣ By clicking on the **Cancel** button, the process is canceled.

The last selected patient record is displayed in the **patient frame**.

3.10.2 Menu item Edit

Editing a patient record

The **Edit** menu item in the **patient frame** allows the user to edit the basic data for the currently selected patient. The desired patient can be selected from the **Last Name** drop-down menu.

Tip

When the **Last Name** drop-down menu is open, moving the mouse over the patients' last names will display a yellow tip box containing **last name**, **first name**, **name at birth** and **birth date** of the highlighted patient, allowing quick and better identification of the patient. This feature is very useful in case of patient with the same last name (see Fig. 3.5, Patient Frame, page 36).

After selecting the **Edit** menu item, all text fields are available for data entry for the current patient. The **Save**, **Delete** and **Cancel** menu items become active. This allows for the following:

Menu item Save

Editing the patient's data from the corresponding text boxes and updating the patient record by selecting the **Save** menu item, updating the patient record.

Menu item Cancel

Canceling the current editing procedure by selecting the **Cancel** menu item

Menu item Delete

Deleting the patient's record by selecting the **Delete** menu item.

When not in **Edit** mode, you can only select patients using the **Last Name** drop-down menu, as described above.
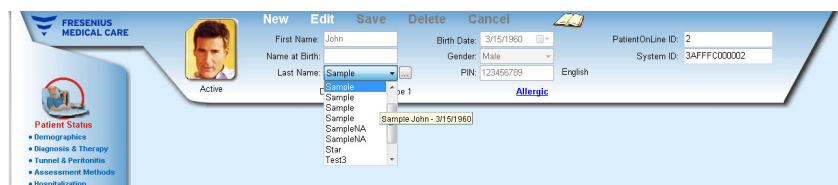
Fig. 3.5 Patient Frame

When trying to delete a patient, the following confirmation message is displayed:
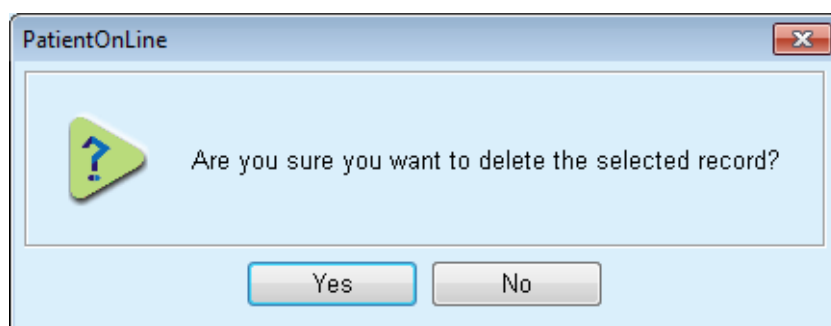
Fig. 3.6 Confirmation upon trying to delete a patient record

➢ Click the **Yes** button,

All entries for this patient will be deleted.

➢ Click the **No** button;

The operation will be canceled.

3.10.2.1 Selection Button

Searching for a patient record

The [...] button located near the **Last Name** drop-down menu allows the user to search for a specific patient. Upon selecting this button, a **Search Patients** pop-up window will be displayed.

The **Search Patients by** drop-down menu offers various search criteria, like **ID** (internal identification in the database), **First Name**, **Name at Birth**, **Gender**, **Language**, **Birth Date**, **PIN** etc. Depending on the currently selected criteria, specific controls will be displayed. The lower part contains by default a list of all available patients.

For all text-based criteria, there will be an edit box named **Search for** and a check box named **Exact match**. The specified text will be searched for. If the **Exact match** option is unchecked, all items that contain the input will be found, and text comparison will not be case-sensitive. If the **Exact match** option is checked, only items that are identical with the searched input will be found, and text comparison will be case-sensitive.

For selection criteria like **Gender** or **Language**, another drop-down menu with the possible selections is displayed.

For the **Birth Date**, 2 calendar controls are displayed, allowing to specify a time-frame.

Selecting the **Search** button will display the number of patients that meet the criteria and the list of found patients. Selecting the **Clear** button resets the patient list to the default status.

If you select a row in the patient list and click the **OK** button, the **Search Patients** window will close and the selected patient will become the current patient in the **Patient Frame**. This is a useful way of selecting a patient, especially when a large number of patients exists.

Clicking on the **Cancel** button will close the window and the **Patient Frame** will remain unchanged.

Selecting the **Report** button will generate a report with all patients matching the selection criteria. Their names, birth date, gender, language, PIN, nationality and working status as well as the ID and index are displayed. This is a flexible and quick way of generating reports for all patients in the database or for certain groups of patients, based on the selection criteria.

3.10.3 Patient Frame in case of EDBMS

The PatientOnLine client-server edition can work in combination with an external database management system (EDBMS) such as EuCliD. In this case, the patient list is imported from EDBMS and patients can no longer be created and edited in PatientOnLine. In addition, two new fields are displayed: the External DB ID (ID of the patient in EDBMS) and the Institution ID (customer-defined).

Fig. 3.7 Patient Frame in case of EDBMS

Data synchronization between PatientOnLine client-server and EDBMS takes place upon each server re-start, but the user can launch specific import-export commands, either from the Patient Frame or from the Communication/Data Exchange menu.

Upon clicking the ⟳ icon, a context menu appears with four options.

The options are:

– Import current patient

– Export current patient

– Import all patients

– Export all patients

Depending on server-side and EDBMS configurations, certain options may be unavailable.

Note

Regardless of the server configuration, patient enrollment and patient data editing can be performed only at EDBMS level.

3.11 Patient Status

The **Patient Status** menu item allows the user to fill in extensive data for the patient, from both a demographic and a medical point of view. The available options are described below.

Note

For accessing any of the submenu items, a patient must be selected in the **Patient Frame**, otherwise an information message is issued in the **Working Frame** and the selected menu item has no effect.

3.11.1 Demographics

By selecting the **Demographics** submenu, the **Patient Demographics & Details** input mask opens.
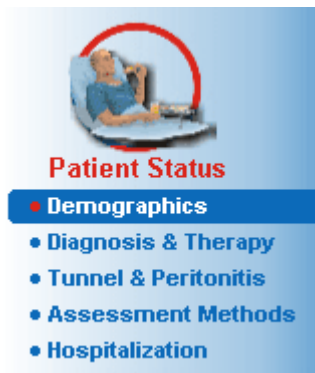
Fig. 3.8 Selecting the Demographics submenu item

The **Patient Demographics & Details** input mask will be displayed.

The **Patient Demographics & Details** input mask is organized on several tabs, namely **Demographics**, **Addresses**, **Professional Status**, **Private Environment**, **Mobility**, **Visual Ability**, **Fine Hand Manipulation**, **Helper**, **Training** and **Home Visits**.

3.11.1.1 Demographics tab

The **Demographics** tab allows the user to specify the **Nationality**, the **Language**, the **Education** status and the Ethnic group of the patient. All items are selectable from drop-down menus.

The **Education** status is assessed according to ISCED - International Standard Classification of Education, an official classification issued by UNESCO.

The drop-down menus **Nationality**, **Education**, and **Ethnic group** are set to **Unknown** by default.

To specify the demographics record for a patient, proceed as follows:

➢ Select the desired patient in the **Patient Frame**;

➢ Click the **Edit** button;

➢ Select one item from each drop-down menu;

➢ Click the **Save** button.

The record is created and saved.

By clicking on the **Cancel** button, the process is canceled.

3.11.1.2 Addresses tab

The **Addresses** tab is further structured on four tabs, namely **Home**, **Office**, **Contact Address 1** and **Contact Address 2**, allowing the user to fill in several types of addresses for the patient selected in the **Patient Frame**.

The **Home** tab is the default address. Each tab is selected by clicking on it or by using the keyboard.

To specify the addresses for a patient, proceed as follows:

➢ Select the desired patient in the **Patient Frame**;

➢ Select the desired tab for entering the address;

➢ Click the **Edit** button;

The following entry fields are available:

> **Street,**
>
> **Number,**
>
> **Zip Code,**
>
> **Town,**
>
> **Country,**
>
> **Phone,**
>
> **Fax,**
>
> **Mobile,**
>
> **Modem,**
>
> **E-mail,**
>
> **Comment.**

– In the **Office** tab, you can additionally specify the following information:

> **Working** (check box checked means that the patient is working)
>
> **Company** (name)
>
> **Department** (department in which the patient works)

– In the **Contact Address 1** and **Contact Address 2** tabs, you can additionally specify the following information:

> **First Name** (first name of the contact person)
>
> **Last Name** (last name of the contact person)

Tip

None of the data described above is mandatory.

➢ Click the **Save** button.

The record is created and saved.

By clicking on the **Cancel** button, the process is canceled.

3.11.1.3 Professional Status tab

The **Professional Status** tab allows the user to specify the professional status of the patient including any changes to this status.

In the upper part of the window, there is a table listing the professional history of the patient. In the lower part, the following data can be specified:

– The **date** on which the record was created;

– The **professional status** of the patient;

– A **comment** as a note.

➢ Select the desired patient in the **Patient Frame**;

➢ Click the **New** button;

➢ Select the desired status from the **Professional Status** drop-down menu;

Tip

The **professional status** list can be customized by adding/editing new items in the **Administration/Setup/Medical Lists** module.

➢ Select the desired date or keep the current date displayed in the **Date** control;

➢ Click the **Save** button in order to create or update the patient's **professional status** record.

By clicking on the **Cancel** button, the process is canceled.

3.11.1.4 Private Environment tab

The **Private Environment** tab allows the user to specify the private environment living-in status of the patient, including any changes to this status. The organization of this **Private Environment** tab is similar to the **Professional Status** tab.

3.11.1.5 Mobility tab

The **Mobility** tab allows the user to specify the mobility status of the patient, including any changes to this status. The organization of the **Mobility** tab is similar to the **Professional Status** tab.

3.11.1.6 Visual Ability tab

The **Visual Ability** tab allows the user to specify visual ability status of the patient, including any changes to this status. The organization of the **Visual Ability** tab is similar to the **Professional Status** tab.

3.11.1.7 Fine Hand Manipulation tab

The **Fine Hand Manipulation** tab allows the user to specify the fine hand manipulation status of the patient, including any changes to this status. The organization of the **Fine Hand Manipulation** tab is similar to the **Professional Status** tab.

3.11.1.8 Helper tab

The **Helper** tab allows the user to specify the status of help needed by the patient to perform the dialysis treatment, including any changes to this status. The organization of the **Helper** tab is similar to the **Professional Status** tab.

3.11.1.9 Training tab

The **Training** tab allows the user to specify the PD training status of the patient and the training history.

For each training session, several data items can be specified, like

> **Date,**
>
> **Training Type,**
>
> **Training Aim,**
>
> **Patient PD Status,**
>
> **Training Duration,**
>
> **Training Location,**
>
> **Trainer Type,**
>
> **Training Tools.**

Each of these items can be selected from a drop-down menu. **Unknown** is the default option for each list.

In addition, the **Date** of the training and a **Comment** can be specified as free text.

3.11.1.10 Home Visits tab

The **Home Visits** tab allows the user to document the visits performed at the patient's home and the visit history. For the visit record, the visit date and optionally the next planned visit date, the name of the responsible staff for the visit (free text) and an optional comment (free text) related to the visit can be entered.

3.11.2   Diagnosis & Therapy

The **Diagnosis & Therapy** submenu allows the user to specify various diagnoses and therapy options for the current patient.

The **Diagnosis & Therapy** submenu is organized on 7 tabs:

> **ESRD,**
>
> **Comorbidity,**
>
> **RRT (Renal Replacement Therapy),**
>
> **Catheter,**
>
> **Regular Medication,**
>
> **Allergies,**
>
> **Additional Information.**

Each tab will be described below.

The **Diagnosis & Therapy** submenu is accessible by selecting **Patient Status/Diagnosis & Therapy** in the Menu Tree.

Fig. 3.9 Selecting the Diagnosis & Therapy submenu

3.11.2.1 ESRD tab

This **ESRD** tab covers the ESRD (End Stage Renal Disease) of the current patient. The lower part displays the current ICD-10 disease classification.

Fig. 3.10 ESRD submenu

To specify an **ESRD** for a patient, proceed as follows:

➢ Select the desired patient in the **Patient Frame**;

➢ Click the **Edit** button;

➢ Click the [...] button;

An ICD-10 tree window opens, allowing the user to navigate and to se-lect a disease.

➢ Click the **OK** button;

➢ The **ESRD** submenu is displayed again;

➢ Select the desired date or keep the current date displayed in the **Date** control;

➢ Alternatively, you can enter a valid ICD-10 code directly in the **ICD-10 Code** edit box. If the code is correct, the **ICD-10 Disease** box will be updated with the corresponding text. If the entered code is not va-lid, a warning message will appear.

➢ Clicking the **<<** button will open a search area in which you can search for a disease, either by code or by description. Specify the code or the description and click on **Search**. In the **Search Results** area, you can select a certain item. Clicking the **>>** button will close the search area.

Tip

The default value and format of the **Date** calendar control is the current date, corresponding to the regional settings and date/time settings of the user's computer.

➤ Click the **Save** button.

The ESRD record is saved and/or updated.

If the above-mentioned operation is successful, an information message is issued.

By clicking the **Clear** button, the currently selected disease is erased.

By clicking on the **Cancel** button, the process is canceled.

Warning

Risk for the patient as a result of insufficient detoxification.

A wrong ICD-10 tree selection might not reveal a possible diabetic status of the patient.

In such a case, an improper glucose concentration may be prescribed.

➤ The user must verify the ICD-10 tree selection after clicking the **Save** button.

Note

In case **PatientOnLine** client-server is connected to an EDBMS and the server is configured so that ESRD is editable at EDBMS level, the editing buttons in **PatientOnLine** are not visible and the ESRD menu is read-only.

3.11.2.2 Comorbidity tab

The **Comorbidity** tab covers the comorbidities of the current patient.

Fig. 3.11 Comorbidity screen

Entering new comorbidities

To specify a new comorbidity for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Click the **New** button;

➢ Click the ... button;

An ICD-10 tree window will be displayed with the same functionality as described in section 3.11.2.1.

➢ Select the corresponding comorbidity from the tree;

➢ Click the **Ok** button.

➢ Select the desired date or keep the current date displayed in the **Start Date** calender control;

➢ Click the **Save** button.

The patient's comorbidity record is saved.

If the operation was successful, a message is issued and the comorbidity is displayed in the **Comorbidity List**.

Warning

Risk for the patient as a result of insufficient detoxification.

A wrong ICD-10 tree selection might not reveal a possible diabetic status of the patient.

In such a case, an improper glucose concentration may be prescribed.

➢ The user must verify the ICD-10 tree selection after clicking the **Save** button.

By clicking on the **Cancel** button, the process is canceled.

While a patient can have only one primary renal disease, there can be several comorbidities. To specify another comorbidity for the same patient, follow the same procedure.

Editing a comorbidity

To edit a comorbidity for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Mark the comorbidity to be changed in the **Comorbidity List**;

➢ Click the **Edit** button;

➢ Click the ... button;

The ICD-10 tree window will be displayed.

➢ Make the changes in the corresponding entry fields;

➢ Click the **Yes** button,

➢ Select the desired date or keep the current date displayed in the **Start Date** calender control;

➢ Click the **Save** button.

The patient's comorbidity record is updated.

If the operation was successful, a message is issued and the **Comorbidity List** is updated.

Warning

Risk for the patient as a result of insufficient detoxification.

A wrong ICD-10 tree selection might not reveal a possible diabetic status of the patient.

In such a case, an improper glucose concentration may be prescribed.

➢ The user must verify the ICD-10 tree selection after clicking the **Save** button.

By clicking on the **Cancel** button, the process is canceled.

Deleting a comorbidity

To delete a comorbidity for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the comorbidity to be deleted in the **Comorbidity List**;

➢ Click the **Delete** button;

The record is deleted after a safety prompt.

If the operation was successful, a message is issued and the **Comorbidity List** is updated.

Tip

If by selecting either ESRD or Comorbidity, the Diabetes Mellitus status of the patient is activated, this status is displayed in the **Patient Frame**.

If there is no ESRD record and no comorbidity record, **"Diabetes not assessed"** is displayed in the **Patient Frame**.

Note

In case **PatientOnLine** client-server is connected to an EDBMS and the server is configured so that Comorbidity is editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Comorbidity menu is read-only.

3.11.2.3 RRT (Renal Replacement Therapy) tab

To create/edit a **Renal Replacement Therapy** record for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **RRT** tab.

➢ Click the **New** or **Edit** button;

➢ Select the desired renal replacement therapy from the **RRT** dropdown menu;

➢ Select the **Start Date** in the calendar control or keep the current date displayed in the calendar control;

➢ Select the **Stop Date** in the calendar control;

Tip

It is not mandatory to enter a **Stop Date.**

Note

If the **Stop Date** occurs before the **Start Date**, a warning message is issued and the user must enter a correct date.

➢ In the **Comment** field, a note can be entered (optional);

➢ Click the **Cancel** button;

The operation will be canceled.

or

➢ Click the **Save** button in order to create or update the patient's **RRT** record.

By clicking on the **Delete** button, the record will be deleted after a safety prompt.

3.11.2.4 Catheter tab

The **Catheter** tab allows catheter and catheter extension management, providing means for creating, editing and deleting such records. Catheter and catheter extension records are interconnected, meaning that deleting a catheter record will also delete all catheter extension records associated with it. The records can, however, be created and edited independently.

Fig. 3.12 Catheter screen

Creating/editing a catheter record

To create/edit a catheter record for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Catheter** tab;

➢ Click the **New** or **Edit** button;

➢ Select the **Catheter** from the drop-down menu;

➢ Select the **Implantation Mode**, **Implantation Device**, **Verification Mode**, **Tunnel Direction** and **Exchange Reason** from the corresponding drop-down menus;

Tip

All drop-down menus above can be edited in the **Administration/Setup** input masks.

➢ Select the **Implant Date** in the calendar control or keep the current date from the calendar control;

➢ Select the **Start of Dialysis Treatment** in the calendar control or leave it blank;

Tip

It is not mandatory to enter the **Start of the Dialysis Treatment** and the **Remove Date**. The user can leave those fields blank and update them later. The **Exchange Reason** can be set to **None**, if appropriate.

➢ Select the **Remove Date** in the calendar control or leave it blank;

Note

If the **Remove Date** occurs before the **Implant Date**, any attempt to save the record will fail and a warning message will be issued. Click the **Ok** button of the warning message and return to the **Catheter** tab to correct the date fields.

➢ In the **Comment** field, a note can be entered (optional);

➢ Click on the **Save** button to create a **new catheter record** or click on the **Cancel** button to cancel the process.

● **Managing catheter extensions**

➢ Select the **Manage Extensions >** button;

The extended **Catheter Extension** screen opens;

Note

If the current record has not been saved yet, a dialog window opens and asks the user to save the data.

Note

It is not allowed to create different catheter records with the same **Implant Date**. A warning message is issued in this case and the operation is canceled.

➢ Click the **Cancel** button;

The operation will be canceled.

Or

➢ Click the **Yes** button.

The current catheter record is saved and the extended **Catheter Extension** screen opens.

Deleting a catheter record

To delete a catheter record for a patient, proceed as follows:

➢ Select the desired patient in the **Patient Frame**;

➢ Select the **Catheter** tab;

➢ Mark the record to be deleted in the **Catheter List**;

➢ Click the **Delete** button;

➢ A safety prompt opens;

➢ Click the **Yes** button;

The selected record is deleted.

Or

➢ Click the **No** button;

The operation will be canceled, the safety prompt will be closed.

Navigating between Catheter and Catheter Extension

To navigate between the **Catheter** main tab and the extended **Catheter Extension** screen, proceed as follows:

➢ Click the **Manage Extensions >** button to switch to the **Catheter Extension** screen;

➢ Click the **< Back To Catheters** button in order to switch back to the **Catheter** main tab;

Creating/editing a catheter extension record

➢ Select the patient from the **Patient Frame**;

Select the **Catheter** tab (see Fig. 3.12, Catheter screen, page 48);

➢ From the **Catheter List**, select the catheter record for which a **Catheter Extension** record is to be created/edited;

➢ Select the **Manage Extensions >** button;

The extended **Catheter Extension** screen opens;
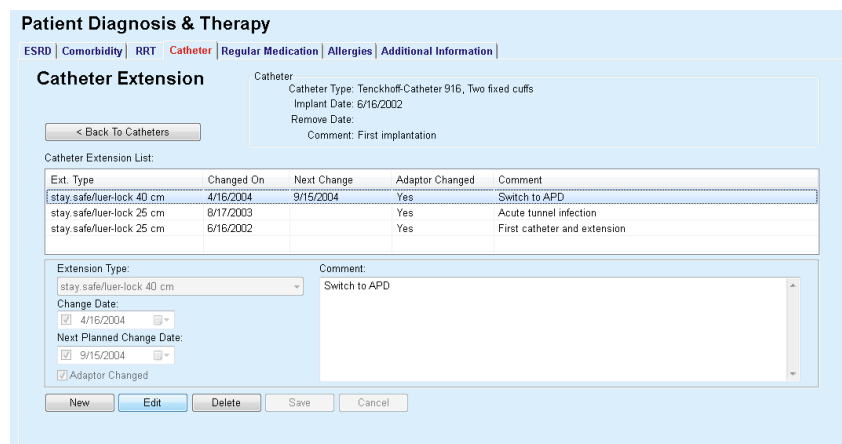
Fig. 3.13 Extended *Catheter Extension screen*

➢ Click the **New** button to add a new catheter extension record or the **Edit** button to modify the highlighted catheter extension record;

➢ Select the catheter extension from the **Extension Type** drop-down menu;

Note

The **extension type** is mandatory data; if it is not specified, a warning message will be issued

➢ Select the date from the **Change Date** calendar control;

Note

It is mandatory to enter **Change Date**. Moreover, the **Change Date** must lie between the **Implant Date** and the **Remove Date**; otherwise, a warning message will be issued and the operation will be canceled.

➢ Optionally, select a date for the **Next Planned Change Date** of the catheter extension or leave it blank by unchecking the check box of the date field. The default date is the current date;

➢ If the adapter was changed as well, the **Adapter Changed** check box must also be checked;

➢ In the Comment field, a note can be entered (optional);

➢ Click the **Save** button to save the record or click the **Cancel** button to cancel the process.

If the editing operation was successful, a message is issued and the updated catheter extension is displayed in the **Catheter Extension List**.

3.11.2.5 Regular Medication tab

The **Regular Medication** tab allows the management of a patient's regular medication, providing means for creating, editing and deleting such records.

One record may contain several drugs, which can be selected from a tree control.

Fig. 3.14 Regular Medication screen

Creating a regular medication record

To create a regular medication record for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Regular Medication** tab;

➢ Click the **New** button;

➢ Select the **Start Date** from the calendar control or keep the current date;

➢ Select the **Stop Date** from the calendar control, keep the current date or leave the entry field blank;

Note

If the **Stop Date** occurs before the **Start Date**, any attempt to save the record will fail and a warning message will be issued. Click the **Ok** button of the warning message and return to the **Regular Medication** screen to correct the date fields.

➢ In the Comment field, a note can be entered (optional);

➢ Click the **Save** button to save the record or click the **Cancel** button to cancel the process.

or

➢ Select the **Manage Drugs >** button to create a new regular medication record and to switch to the extended **Drugs** screen;

➢ In the safety prompt, select the **Ok** button to create the new regular medication record and proceed to the next window;

➢ Select the **Cancel** button to return to the **Regular Medication** screen without saving. In this case, either select the **Save** or the **Cancel** button of the **Regular Medication** tab;

If the operation of creating a new **Regular Medication** record was successful, the new record is displayed in the **Medication List**.

To specify another regular medication for the same patient, follow the same procedure.

Editing a regular medication record

To edit a regular medication record for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Regular Medication** tab (see **Regular Medication screen**, page 51);

➢ Select the medication record to be edited from the **Medication List**;

➢ Click the **Edit** button;

The **Save** and **Cancel** buttons become active.
The **New**, **Edit** and **Delete** buttons become inactive;

➢ Edit any data necessary as described in the section above;

➢ Click the **Save** button to save the record or click the **Cancel** button to cancel the process.

If the editing operation was successful, a message is issued and the updated medication record is displayed in the **Medication List**.

**Deleting a regular
medication record**

To delete a regular medication record for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Regular Medication** tab (see Fig. 3.14, Regular Medication screen, page 51);

➢ Select the medication record to be deleted from the **Medication List**;

➢ Click the **Delete** button;

➢ Confirm the safety prompt;

➢ Click the **Yes** button to delete the medication record;

➢ Click the **No** button to cancel the process;

To navigate between the **Regular Medication** main tab and the extended **Drugs** screen, proceed as follows:

➢ Select the **Manage Drugs >** button;

The extended **Drugs** screen is displayed.

➢ Select the **< Back To Medication** button;

The **Regular Medication** main tab is shown.

**Creating/editing a
medication record**

In order to create a new or edit an existing medication record for a certain medication associated with a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Regular Medication** tab;

➢ From the **Medication List**, select the medication record for which the corresponding drugs are to be created/edited;

➢ Select the **Manage Drugs >** button;

➢ The extended **Drugs** screen is displayed. Click the **New** button to create a new record;

➢ Click the **Edit** button to edit an existing record;

The **Save** and **Cancel** buttons become active.
The **New**, **Edit** and **Delete** buttons become inactive.

➢ Click the ... button;

A drugs tree pop-up window will open. See figure below.
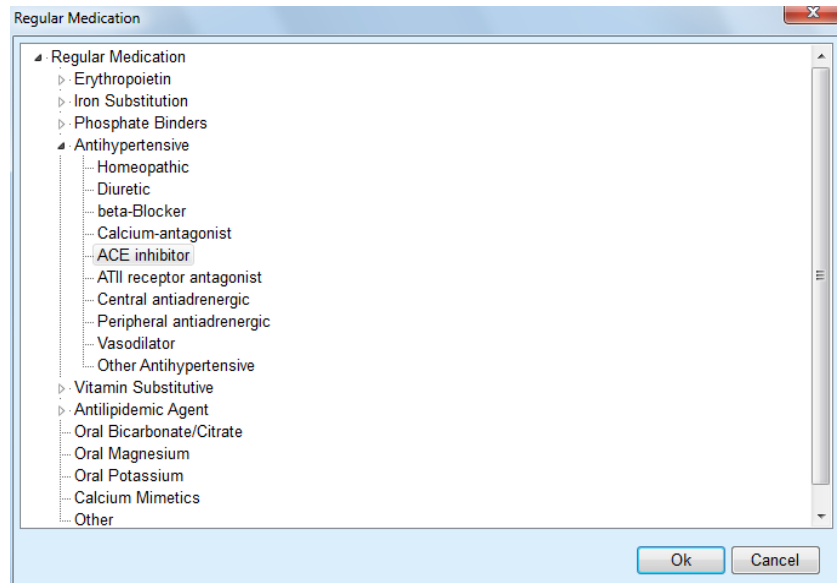
Fig. 3.15 Medication Drugs tree pop-up window

In the drugs tree, the user can navigate in a similar form as in the **Windows Explorer** and select a drug.

➢ Click on the selected drug;

➢ Click the **Yes** button to return to the **Drugs** screen;

The selected drug appears in the **Drug** entry field.

In the **Administration Mode** field, details on the drug, like commercial name, administration dose or a comment, can be entered.

➢ Click on the **Save** button to create/update the medication record or select the **Cancel** button to cancel the current process.

If the editing operation was successful, a message is issued and the updated drug is displayed in the **Drug List**.

Tip

If the patient is allergic, an additional warning icon and a label (link) is displayed in the **Drugs** window. Clicking on the **Allergic** link will open the **Allergies** tab and display the allergic status of the patient.

3.11.2.6 Allergies tab

The **Allergies** tab allows the management of a patient's allergies, providing means for creating, editing and deleting such records. A record contains the allergic status (**Yes**/**No**), a date and an optional comment.

Creating/editing an allergy record

To create/edit an allergy record for a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Allergies** tab;

➢ Click the **New** or **Edit** button;

➢ Select the **Date** from the calendar control or keep the current date;

➢ Select the allergic status **Yes**/**No** in the Allergy field;

➢ Enter a comment in the **Comment** field (mandatory if the allergic status is **Yes**);

➢ Click the **Save** button to save the record or click the **Cancel** button to cancel the process.

Deleting an allergy record

➢ Click on the allergy concerned in the Allergy List;

➢ Click the **Delete** button;

The record is deleted after a safety prompt.

A pop-up window appears to show that the delete operation has been successful.

Tip

If the current patient has at least one Allergy record with status **Yes**, the allergic condition is displayed in the **patient frame**.

If there is no Allergy record, **"Allergy not assessed"** is displayed in the **Patient Frame**.

Note

In case PatientOnLine client-server is connected to EDBMS and the server is configured so that Allergies are editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Allergies menu is read-only.

3.11.2.7 Additional Information tab

The **Additional Information** tab manages several important attributes of a patient:

➢ **Active**/**Inactive** status;

➢ **Adult**/**Child** status;

➢ **Blood Group** and **Rh Factor**.

(see Fig. 3.16, Additional Information screen, page 57)

Active/Inactive status

Examples of Inactive:

➢ Switching of the current therapy to HD;

➢ Transfer of the patient to a different dialysis center;

The **Administration/Setup/View Settings** menu item allows various options related to a patient's **Active**/**Inactive** status, such as including inactive patients in statistics.

By default, a patient is considered **Active**.

Adult/Child status

The **Adult/Child** status is relevant for choosing the appropriate QA formulae for body surface area, total body water etc. **PatientOnLine** automatically switches between Adult and Children formulae according to this status. By default, a patient's **Adult/Child** status is determined by the patient's age.

The **Administration/Setup** menu item defines an editable age threshold (default 16 years) that determines whether the patient is considered a child or an adult.

However, a nephrologist may decide in special cases that a certain patient may fit to a different profile than the one dictated by patient age. For example, a 15-year-old obese patient may weigh 120 kg and thus qualify for adult QA formulae. For these cases, a manual change of the **Adult/Child** status is possible.

In order to change the **Active/Inactive** and/or the **Adult/Child status** of a patient, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Additional Information** tab (see **Additional Information screen**, page 57);

➢ Click the **Edit** button;

➢ Select the **Active/Inactive** status in the option field;

and/or

➢ Check the **Force status manually** check box;

The Adult/Child option field is opened.

➢ Select the **Adult/Child** status in the option field;

➢ Click the **Save** button to save the record or click the **Cancel** button to cancel the process;

Blood Group and Rh Factor

The blood group and the Rh factor are important data for any person. In case of blood transfusions, for example, knowing the blood group of the patient is essential. Defining the **blood group** and **Rh factor** of a patient is simple and straightforward:

➢ Click the **Edit** button;

➢ Select the appropriate blood group (**O**, **A**, **B** or **AB**) from the corresponding drop-down menu;

➢ Select the appropriate Rh factor (**Positive**, **Negative** or **Unknown**) from the corresponding drop-down menu;

➢ Click the **Save** button to save the record or click the **Cancel** button to cancel the process.

The current **Adult/Child** status, **Active/Inactive** status, **Blood Group** and **Rh Factor** are displayed in the corresponding box of the **Additional Information** window.

Fig. 3.16 Additional Information screen

Note

In case PatientOnLine client-server is connected to EDBMS, the Adult / Child status, the Blood Group and the Rh Factor are provided by the EDBMS and cannot be edited in PatientOnLine.

3.11.3 Tunnel & Peritonitis

The **Tunnel & Peritonitis** menu item allows the management of information related to **Exit Site / Tunnel Infection** and **Peritonitis** incidents as well as to the **Exit Site Classification**.

Note

To access this information, a patient must be selected in the **Patient Frame**.

3.11.3.1 Exit Site / Tunnel Infection tab

On the **Exit Site / Tunnel Infection** tab, the user can manage all information related to **Exit Site / Tunnel Infection** incidents for a patient.

The **Exit Site / Tunnel Infection** tab can be accessed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Exit Site / Tunnel Infection** tab;

Fig. 3.17 Exit Site / Tunnel Infection tab

Different therapies can be associated with a certain incident. In the same manner, different drugs can be associated with a certain therapy. These records are interconnected, meaning that deleting an exit site / tunnel infection incident record will also delete all records of the therapies and drugs associated with that incident, on the user's confirmation. In the same manner, deleting a therapy record will also delete all the drugs associated with that therapy, on the user's confirmation. The records can, however, be created and edited independently.

An exit site / tunnel infection incident may be associated with an exit site graphical classification or even with an actual picture of the patient's exit site.

To create/edit an exit site / tunnel infection incident record, proceed as follows:

Enter the new infection incident

➢ Select the patient from the **Patient Frame**;

➢ Select the **Tunnel & Peritonitis** menu item from the Menu Tree;

➢ Select the **Exit Site / Tunnel Infection**;

➢ Click the **New** or **Edit** button;

The first window of the input wizard opens.

The following infection types can be selected:

> **Tunnel only**;

> **Exit Site only**;

> **Both Tunnel and Exit Site**.

➢ Make the corresponding selection;

➢ Click the **Next >** button to continue or click the **Close** button to cancel the process.

The second window of the input wizard opens.

Explanation regarding the **Use in statistics** check box:

If the box is checked, the current incident will be taken into account in the **Statistics** section.

If the box is **not** checked, the current incident will not be taken into account in the **Statistics** section.

	➢ Make the selection for **Use in statistics**;
	➢ Select the **Set Date** from the calendar control or keep the current date;
	➢ Select the **Swab Date** from the calendar control or keep the current date;
	➢ Enter a note in the **Comment** text field (optional).
Adding a germ	➢ Click the **Add** button to add a **germ** to the current tunnel incident (optional);
	The **Add Germs** pop-up window is displayed.
	➢ Select the respective germ from the **Add Germs** list;
	➢ Click the **Add** button;
	The selected germ is entered in the **Germs** text field.
Deleting a germ	➢ Mark an entry in the **Germs** text field;
	➢ Click the **Delete** button;
	➢ The selected entry is deleted without inquiry;
Continuing with Exit Site Classification	➢ Check the **With Exit Site Classification** check box to attach a graphical exit site classification to the infection incident;
	➢ Click the **Next >** button to go to the graphical classification;
	➢ Proceed as described in section (see **Exit Site Classification tab**, page 64).
Continuing without Exit Site Classification	➢ If the **With Exit Site Classification** check box has not been checked, click the **Finish** button or cancel the process without saving by clicking on the **Close** button.
Deleting an infection incident	To delete an exit site / tunnel infection incident record, proceed as follows:
	➢ Select the patient from the **Patient Frame**;
	➢ Select the **Tunnel & Peritonitis** menu item from the Menu Tree;
	➢ Select the **Exit Site / Tunnel Infection** tab;
	➢ Select the respective record in the **Incidents** table
	➢ Click the **Delete** button;
	➢ A safety prompt opens and shows the information that all linked records like therapies and drugs will be deleted as well.
	➢ Click the **Yes** button;
	The record will be deleted.
	A pop-up window appears to show that the delete operation has been successful.
	By clicking the **No** button, the process is canceled without deleting the record.

Creating a therapy

Once an incident record has been created, you can create/edit one or more therapies for that incident.

The **Exit Site / Tunnel Infection** tab is structured as follows:

> **Incidents** (main tab);

> **Therapies** (First extended tab);

> **Drugs** (Second extended tab).

Navigating between the linked screens

To navigate between the linked screens **Incidents**,**Therapies** and **Drugs** proceed as follows:

➢ Click the **Manage Therapies >** button to go to the **Therapies** screen;

➢ Click the **Manage Drugs >** button to go to the **Drugs** screen;

➢ Using the **< Back To ...** button, you can always switch back to the previous screen.

Creating a new therapy record

Several therapies can be associated with a certain infection incident. To add a therapy record to a tunnel infection incident, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the tunnel infection incident from the **Incidents** table;

➢ Click the **Manage Therapies >** button;

The extended **Therapies** tab opens:
(see Fig. 3.18, Therapies for a certain Exit Site / Tunnel Infection Incident, page 61)

➢ Click the **New** button;

➢ Select the **Start Date** for the selected therapy from the calendar control or keep the current date;

➢ Select the **Stop Date** for the selected therapy from the calendar control or keep the current date;

Tip

The default value and format of the **Start Date** and **Stop Date** calendar control is the current date, corresponding to the regional settings and date / time settings of the user's computer.

Note

If the **Stop Date** occurs before the **Start Date**, any attempt to save the record will fail and a warning message will be issued. Click the **Ok** button of the warning message and return to the **Therapies** screen to correct the dates in the highlighted fields.

➢ Enter a note in the **Comment** text field (optional).

➢ Click the **Save** button.

Fig. 3.18 Therapies for a certain Exit Site / Tunnel Infection Incident

The saved record is displayed in the **Incidents** main tab in the **Therapies** table.

or

➢ Click the **Cancel** button to cancel the process.

Editing a therapy record is performed in the same manner.

To delete a therapy record, proceed as follows:

Deleting a therapy record

➢ Select the therapy record to be deleted from the **Therapies** table;

➢ Click the **Delete** button;

➢ A pop-up window with a safety prompt opens;

➢ Click the **Yes** button.

The record will be deleted.

A pop-up window appears to show that the delete operation has been successful.

By clicking the **No** button, the process is canceled without deleting the record.

Note

Deleting a therapy record will also delete all **Drugs** records linked to it.

Different and multiple drugs can be associated with a certain therapy. The **Manage Drugs>** button allows this operation in a separate window. Editing drug records is similar to editing therapy records.

Tip

The drugs list can be customized by adding/editing new items from the **Administration/Setup/Medical Lists** module.

Tip

If the patient is allergic, an additional warning icon and a label (link) is displayed in the **Drugs** window. Clicking on the **Allergic** link will open the **Allergies** tab and display the allergic status of the patient.

Note

All **Drugs** windows of the application (corresponding to **Exit Site / Tunnel Infection** and **Peritonitis**) use the same approach related to **Allergies**.

3.11.3.2 Peritonitis tab

On the **Peritonitis** tab, all information related to Peritonitis incidents like Peritonitis Therapies and different Drugs can be managed.

Similar to the **Exit Site / Tunnel Infection** module, different **Therapies** can be associated with a Peritonitis incident. In the same manner, different **drugs** can be associated with a certain **therapy**. These records - **Incidents**, **Therapies** and **Drugs** - are interconnected, meaning that deleting a peritonitis incident record will also delete all records of the therapies and drugs associated with that peritonitis incident, on the user's confirmation. In the same manner, deleting a therapy record will also delete all the drugs associated with that therapy, on the user's confirmation. The records can, however, be created and edited independently.

Creating a new Peritonitis Incident record

To create a new peritonitis incident record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Tunnel & Peritonitis** menu item from the Menu Tree;

➢ Select the **Peritonitis** tab;

➢ Click the **New** button.

The **Save** and **Cancel** buttons become active.
The **New**, **Edit** and **Delete** buttons become inactive.

Explanation regarding the "Use in statistics" checkbox

If the checkbox is checked, the current incident will be taken into account in the **Statistics** section.

If the checkbox is not checked, the current incident will not be taken into account in the **Statistics** section.

➢ Make the selection for **Use in statistics**;

➢ Select the **Set Date** from the calendar control or keep the current date;

➢ Select the **Dialysate Sample Date** from the calendar control or keep the current date;

➢ Enter a note in the **Comment** text field (optional).

Adding a germ

➢ Click the **Add** button to add a **germ** to the current Peritonitis incident (optional);

The **Add Germs** pop-up window is displayed.

➢ Select the respective germ from the **Add Germs** list;

➢ Click the **Add** button;

The selected germ is entered in the **Germs** text field.

Deleting a germ

➢ Mark an entry in the **Germs** text field;

➢ Click the **Delete** button;

➢ The selected entry is deleted without inquiry;

Saving a Peritonitis Incident record

➢ Click on the **Save** button to save the record **or** select the **Cancel** button to cancel the process without saving;

Successful saving is indicated by a pop-up window.

or

➢ Select the **Manage Therapies >** button;

A pop-up window with 2 options opens:

➢ Click the **Yes** button,

The newly created record is saved; the **Therapies** screen is displayed.

or

Click the **Cancel** buttonto return to the **Incidents** tab that can be further edited.

➢ On the **Incidents** tab, click on the **Save** button to save the peritonitis incident record **or** select the **Cancel** button to cancel the process without saving;

If the operation was successful, a message is issued and the new record is displayed in the **Incidents** table.

Editing a Peritonitis Incident record

To create a peritonitis incident record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Tunnel & Peritonitis** menu item from the Menu Tree;

➢ Select the **Peritonitis** tab;

➢ Select the record to be edited in the **Incidents** table;

– Click the **Edit** button;

The **Save** and **Cancel** buttons become active.
The **New**, **Edit** and **Delete** buttons become inactive.

➢ Change any data required;

Complete the further procedure as described in (see **Creating a new Peritonitis Incident record**, page 62).

If the editing operation was successful, a message is issued and the updated record is displayed in the **Incidents** table.

Deleting a Peritonitis Incident record

To delete a **Peritonitis** incident record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Tunnel & Peritonitis** menu item from the Menu Tree;

➢ Select the **Peritonitis** tab;

➢ Select the **Peritonitis** incident record to be deleted in the **Incidents** table;

➢ Click the **Delete** button;

A pop-up window with 2 options opens:

➢ Click the **Yes** button,

The record and the associated extensions are deleted.

Or

➢ Click the **No** button;

The record will **not** be deleted. The **Incidents** tab is shown again.

Navigating between the linked screens	To navigate between the linked screens **Incidents**,**Therapies** and **Drugs**, proceed as follows:

➢ Click the **Manage Therapies >** button to go to the **Therapies** screen;

➢ Click the **Manage Drugs >** button to go to the **Drugs** screen;

➢ Using the **< Back To ...** button, you can always switch back to the previous screen;

Adding a therapy record to a Peritonitis Incident

Several therapies can be associated with a certain infection incident. To add a therapy record to a peritonitis infection incident, follow the same procedure as described in the section for adding a therapy record to an **Exit Site / Tunnel Infection** incident.

Editing a therapy record of a Peritonitis Incident

To edit a therapy record, proceed as follows:

➢ Select the therapy record from the **Incidents** table;

➢ Click the **Edit** button;

➢ Change any data required;

➢ Click the **Save** button.

Deleting a therapy record of a Peritonitis Incident

To delete a therapy record, follow the same procedure as described in the section **Exit Site / Tunnel Infection**.

Adding a drug record to a Peritonitis Incident

Different and multiple drugs can be associated with a certain therapy. To create/edit a drug record for a certain therapy associated with a patient, follow the same procedure as described in the section **Exit Site / Tunnel Infection**.

Deleting a drug record of a Peritonitis Incident

To delete a drug record, proceed as follows:

➢ Select the drug record from the **Drugs** table;

➢ Click the **Delete** button;

➢ The record is deleted after a safety prompt.

3.11.3.3 Exit Site Classification tab

The **Exit Site Classification** tab can be accessed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Tunnel & Peritonitis** menu item from the Menu Tree;

➢ Select the **Exit Site Classification** tab;

➢ Select the **Classification** or **Diagnostic Table** tab.

(see Fig. 3.19, Exit Site Classification tab, page 65)

Classification

Modified by Teixido & Arias, the Twardowski's exit site classification can be accessed on the **Classification** tab of **PatientOnLine**.
This classification allows a very accurate determination of the patient's exit site status by choosing a grade for each of the eight categories available.

The same classification can be accessed from the **Exit Site / Tunnel Infection** tab if the **With Exit Site Classification** check box is checked.

Follow the same procedure as described below to create a new **Exit Site Classification** record.

An **Exit Site Classification** can either be associated with an exit site / tunnel infection incident (see section **Exit Site / Tunnel Infection**) or it can be defined independently, using the **Exit Site Classification** tab, in case of a regular medical check-up.

If the **Exit Site Classification** is recorded when creating an **Exit Site / Tunnel Infection** incident, the record is displayed in the **Exit Site List** table in red on yellow background. The source of the record is displayed. The source can be: **Manually stored** or **Infection**.

Note

Exit Site Classification records associated with an **Exit Site / Tunnel Infection** can neither be edited nor deleted on the **Exit Site Classification** tab (**Edit**, **Delete**, **Save** and **Delete**). Editing and deleting is only allowed for records created from **Exit Site Classification**.

Fig. 3.19 Exit Site Classification tab

Creating an Exit Site Classification record

To create an **Exit Site Classification** record for the selected patient, proceed as follows:

➢ Click the **New** button;

The **Save** and **Cancel** buttons become active.
The **New**, **Edit** and **Delete** buttons become inactive.

➢ Select the desired date or keep the current date displayed in the **Start Date** calendar control;

➢ Enter a note in the **Comment** text field (optional).

If available, a digital photograph of the actual exit site can be added by double-clicking on the **Snapshot Image** area and by selecting the desired image file;

For each of the 8 exit site categories, a grade can be selected from a drop-down menu.

➢ Repeat the selection for all 8 categories;

➢ Click on the **Save** button to create the **Exit Site Classification** record or select the **Cancel** button to cancel the current process.

Editing an Exit Site Classification record

To edit an **Exit Site Classification** record for the selected patient, proceed as follows:

➢ Mark the record to be edited in the **Exit Site List** table;

➢ Click the **Edit** button;

➢ The data to be changed can now be changed;

➢ Click on the **Save** button to create the **Exit Site Classification** record or select the **Cancel** button to cancel the current process.

Deleting an Exit Site Classification record

To delete an **Exit Site Classification** record for the selected patient, proceed as follows:

➢ Mark the record to be deleted in the **Exit Site List** table;

➢ Click the **Delete** button;

➢ The record is deleted after a safety prompt.

A pop-up window appears to show that the delete operation has been successful.

Fig. 3.20 Diagnostic Table

A description of the Teixido & Arias exit site table can be found on the **Diagnostic Table** tab:

➢ Select the **Diagnostic Table** tab;

➢ Click on the corresponding picture;

A pop-up window containing a full description of the selected picture will be displayed.

To close the pop-up window:

➢ Click the [X] button;

3.11.4 Assessment Methods

The **Assessment Methods** menu item is structured on nine tabs:

> **Weight**,
>
> **Height**,
>
> **Blood pressure**,
>
> **Volume balance**,
>
> **BCM,**
>
> **Amputation**,
>
> **Nasal Carriage Status**,
>
> **Additional Lab Data**,
>
> **Comment**.

The user may **display**, **enter**, **edit** and **delete** some basic medical data for the patient selected in the patient frame.

3.11.4.1 Weight tab

The **Weight** tab (see **Weight tab**, page 69) allows the user to specify the weight of a patient and to thus create a new weight record or to edit and delete the existing weight record of a patient.

In addition, the user may define weight notification limits (min/max) with a certain date for each limit. A weight value that is highlighted in red when the value is outside of the defined limits for the specific affecting date range.

Note

A weight record is added whenever a new Quality Assurance record is created or a BCM Card is personalized with a new weight value entered in the **Personalize BCM Card** menu item. The Weight list in (see **Weight tab**, page 69) displays these weight records as well, but in a different color scheme. Weight records can also be imported from EDBMS or from CAPD treatments. The source of the record is displayed in the list. In the **Weight** tab, records that do not have **Manually stored** as source can neither be edited nor deleted.

On the **Weight** tab, the following data fields are available:

> **Weight** (Kg or Pounds),

> **With Fluid** (check box),

> **Prescribed Dry Weight (**Kg or Pounds**),**

> **Date.**

Creating a new weight record

To create a new weight record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Weight** tab;

➢ Click the **New** button;

➢ Enter the corresponding numerical values in the **Weight** and **Prescribed Dry Weight** data fields;

➢ Check the **With Fluid** check box (optional);

➢ Select the **Date** from the calendar control or keep the current date;

Tip

As soon as the mouse pointer is positioned on the **Weight** and **Prescribed Dry Weight** entry fields, a quick info with the admissible minimum and maximum limits appears. The user can change the weight limits under **Administration/Setup/Limits** at any time.

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Editing the weight record

To edit a weight record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Weight** tab;

➢ Select the record to be edited in the **Weight List**;

Note

Only records written in black can be changed. Records written in red are generated by other data sources and can thus **not** be edited.

– Click the **Edit** button;

– The **Weight** and **Prescribed Dry Weight** data fields can be changed/corrected;

– Check the **With Fluid** check box (optional);

– Select the **Date** from the calendar control or keep the current date;

– Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Fig. 3.21 Weight tab

Tip

The measurement units for the weight depend upon the settings available in **Administration/Setup/Lab Data Settings/Weight & Height Units**. You can at any moment choose between kg & cm and pounds & inches.

Deleting a weight record

➢ To delete a weight record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Weight** tab;

➢ Select the record to be deleted in the **Weight List**;

Note

Only records written in black can be deleted. Records written in red are generated by other data sources and can thus **not** be deleted.

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled and the **Weight** tab remains unchanged.

The **Limits** sub-tab allows the definition of weight notification limits by using the buttons **New**, **Edit**, **Delete**, **Save** and **Cancel**.

In order to define such a limit record, click on **New**, then set a date, a minimum value and a maximum value, and then click on **Save**.

It is possible to define multiple limit records, each with its own date. A limit record acts from its definition date until the next limit record or until the present date if no subsequent record exists.

Note

It is highly recommended that at least one set of limits is defined for each patient, with an appropriate date. Be aware that the limits will apply only to records that have a date after the limits' date.

Note

Weight values that are outside the limits that correspond to the date of the weight record are highlighted in red.

Note

In case PatientOnLine client-server is connected to EDBMS and the server is configured so that Weight is editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Weight menu is read-only.

3.11.4.2 Height tab

The **Height** tab (see **Height tab**, page 72) allows the user to specify the height of a patient and to thus create a new height record or to edit and delete the existing height record of the patient.

Note

A height record is added whenever a new Quality Assurance record is created or a BCM Card is personalized with a new height value entered in the **Personalize BCM Card** menu item. The **Height List** in (see **Height tab**, page 72) displays these height records as well, but in a different color scheme. Height records can be imported from EDBMS as well. The source of the record is displayed in the list. In the **Height** tab, records that do not have **Manually stored** as source can neither be edited nor deleted.

On the **Height** tab, the following data fields are available:

> **Height** (cm or inches),

> **Date.**

Creating a new height record

To create a new height record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Height** tab;

➢ Click the **New** button;

➢ Enter the corresponding numerical value in the **Height** data field;

➢ Select the **Date** from the calendar control or keep the current date;

Tip

As soon as the mouse pointer is positioned on the **Height** entry field, a quick info with the admissible minimum and maximum limits appears. The user can change the height limits under **Administration/Setup/Limits** at any time.

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Editing a height record

To edit a height record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Height** tab;

➢ Select the record to be edited in the **Height List**;

Note

Only records written in black can be changed. Records written in red are generated by other data sources and can thus **not** be edited.

➢ Click the **Edit** button;

➢ The **Height** data field can now be changed;

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Tip

The measurement units for the height depend upon the settings available in **Administration/Setup/Lab Data Settings/Weight & Height Units**. You can at any moment choose between kg & cm and pounds & inches.

Deleting a height record

To delete a height record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Height** tab;

➢ Select the record to be deleted in the **Height List**;

Note

Only records written in black can be deleted. Records written in red are generated by other data sources and can thus **not** be deleted.

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled.

Fig. 3.22 Height tab

The **Limits** sub-tab allows the definition of height notification limits by using the buttons **New**, **Edit**, **Delete**, **Save** and **Cancel**.

In order to define such a limit record, click on **New**, then set a date, a minimum value and a maximum value, and then click on **Save**.

It is possible to define multiple limit records, each with its own date. A limit record acts from its definition date until the next limit record or until the present date if no subsequent record exists.

Note

Height values that are outside the limits that correspond to the date of the height record are highlighted in red.

Note

In case PatientOnLine client-server is connected to EDBMS and the server is configured so that Height is editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Height menu is read-only.

3.11.4.3 Blood pressure tab

The **Blood Pressure** tab (see **Blood Pressure tab**, page 75) allows the user to document the blood pressure and body temperature of a patient.

On the **Blood Pressure** tab, the following data fields are available:

> **Systolic** (mmHg),

> **Diastolic** (mmHg),

> **Body Position**,

> **Heart Rate** (1/min),

> **Body Temperature** (degrees Celsius or Fahrenheit)**,**

> **Date**.

Note

A blood pressure record is added whenever a new CAPD treatment is created. The **Blood Pressure List** displays these records as well, but in a different color scheme. Blood pressure records can be imported from EDBMS as well. The source of the record is displayed in the list. In the **Blood Pressure tab**, records that do not have **Manually stored** as source can neither be edited nor deleted.

Creating a new blood pressure record

To create a new blood pressure record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Blood Pressure** tab;

➢ Click the **New** button;

➢ Enter the corresponding numerical values in the **Systolic**, **Diastolic**, **Body Postion** and **Heart Rate** data fields;

➢ Select the **Date** from the calendar control or keep the current date;

➢ Enter the **Body Temperature** in the corresponding field;

Tip

As soon as the mouse pointer is positioned on the **Systolic**, **Diastolic**, **Heart Rate** or **Body Temperature** entry fields, a quick info with the admissible minimum and maximum limits is displayed. Entering values outside the predefined ranges is not allowed.

Tip

The measurement units for the body temperature depend upon the settings available in **Administration/Setup/Lab Data Settings/Temperature Units**. You can at any moment choose between degrees Celsius and Fahrenheit.

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Editing the blood pressure record

To edit a blood pressure record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Blood Pressure** tab;

➢ Select the record to be edited in the **Blood Pressure List**;

➢ Click the **Edit** button;

➢ The **Systolic**, **Diastolic, Body Position**, **Heart Rate** and **Body Temperature** data fields can be changed/corrected;

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Deleting the blood pressure record

To delete a blood pressure record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Blood Pressure** tab;

➢ Select the record to be deleted in the **Blood Pressure List**;

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled and no changes are performed.

Fig. 3.23 Blood Pressure tab

The **Limits** sub-tab allows the definition of blood pressure and temperature notification limits by using the buttons **New**, **Edit**, **Delete**, **Save** and **Cancel**.

In order to define such a limit record, click on **New**, then set a date, a minimum value and a maximum value for systolic, diastolic, heart rate and temperature, and then click on **Save**.

It is possible to define multiple limit records, each with its own date. A limit record acts from its definition date until the next limit record or until the present date if no subsequent record exists.

Note

It is highly recommended that at least one set of limits is defined for each patient, with an appropriate date. Be aware that the limits will apply only to records that have a date after the limits' date.

Note

Blood pressure / temperature values that are outside the limits that correspond to the date of the blood pressure / temperature record are highlighted in red.

Note

In case PatientOnLine client-server is connected to EDBMS and the server is configured so that Blood Pressure is editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Blood Pressure menu is read-only.

3.11.4.4 Volume Balance tab

The **Volume Balance** tab *(see Fig. 3.24, Volume Balance tab, page 76)* allows the user to view the volume balance values from APD/CAPD treatment protocols. This menu is read-only.

Fig. 3.24 Volume Balance tab

By double-clicking on a row in the **Volume Balance** grid, the control will jump to the **Treatment Analysis** menu, on the respective treatment protocol. In this way you can have immediate access to the full treatment data.

The **Limits** sub-tab allows the definition of volume balance limits, by using the buttons **New**, **Edit**, **Delete**, **Save** and **Cancel**.

In order to define such a limit record, click on **New**, then set a date, a minimum value and a maximum value, then click on **Save**.

It is possible to define multiple limits records, each with its own date. A limits record acts from its definition date up until the next limit record or up until the present date if no subsequent record exists.

Note

It is highly recommended that at least one set of limits is defined for each patient, with an appropriate date. Be aware that the limits will apply only to records that have a date after the limits' date.

Note

Volume balance values that are outside the limits that correspond to the date of the volume balance record date are highlighted in red, regardless of the menu in which they are displayed.

Note

In case PatientOnLine client-server is connected to EDBMS and the server is configured so that Volume Balance Limits are editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Volume Balance Limits menu is read-only.

3.11.4.5 BCM tab

The **BCM** tab allows the user to analyze BCM measurements on a patient basis. The BCM measurements are available in both numerical format - **Results** tab, and graphical format - **Graphics** tab. For each BCM measurement, data concerning measurement input parameters, body composition, Cole parameters, raw data and measurement quality are displayed.

Fig. 3.25 BCM tab

In the upper-left part of the BCM window, there is a table with the stored BCM measurements (as provided by the BCM device) for the selected patient. The measurement date and quality are displayed. Selecting a table row will refresh all BCM data in the window.

On the upper-right side, there is an area describing the measurement's **Input Data**, referring to patient age, gender, weight, height, average systolic and diastolic blood pressure, and the BCM measurement **Body Results** in terms of Urea distribution volume (**V**), Lean tissue mass (**LTM**) and Body mass index (**BMI**).

In the lower part of the screen, there is a working area with 2 tabs - **Results** and **Graphics**. The **Results** tab comprises **Body Composition** results, **Cole-Cole Graphic** and **Raw Data**.

Body Composition

Body composition data refers to: total body water, extra-cellular water, intracellular water, extra/intra cellular water ratio, urea distribution volume, overhydration, relative overhydration, normalized hydration weight, body mass index, lean tissue index, fat tissue index, lean tissue mass, relative lean tissue mass, fat mass, relative fat mass, body cell mass, adipose tissue mass. Corresponding reference classes are displayed in graphical format (the same as the BCM device) when available (see the symbols → and **=** displayed in **(see BCM tab**, page 77)**)**.

Cole-Cole Graphic

This option displays the impedance graphic of the BCM measurement raw data. Raw data refers to the phase and amplitude (AC reactance and resistance) values measured by the BCM device for 50 different frequencies. The raw data curve gives an indication of the quality of the measurement. The BCM also computes a quality value for each measurement displayed in this screen. A quality value above 90 indicates good raw data quality.
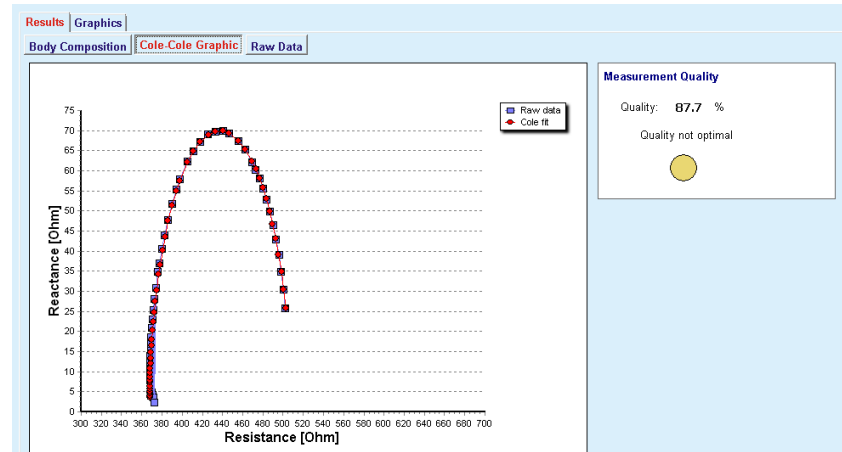

Fig. 3.26 Cole-Cole Graphic

Raw Data

This option displays all numerical values of the BCM measurement raw data, as well as the Cole parameters: extracellular resistance, intracellular resistance, alpha, time delay, capacity, and error.

Raw data can be exported in a text file in tab separated values format **(*.tsv)** by clicking the **Export raw data** button. This export feature allows further analysis and processing of raw data.

The **Graphics** tab comprises **Body Composition, Overhydration** and **Hydration Reference** graphics for all BCM measurements available in the upper left table of the working area for the selected patient.

For body composition graphics, overhydration, lean tissue mass, adipose tissue mass, systolic blood pressure, and weight are represented on the same graphics. For overhydration, only the overhydration parameter evolution is displayed. The hydration reference displays the systolic blood pressure vs. overhydration.
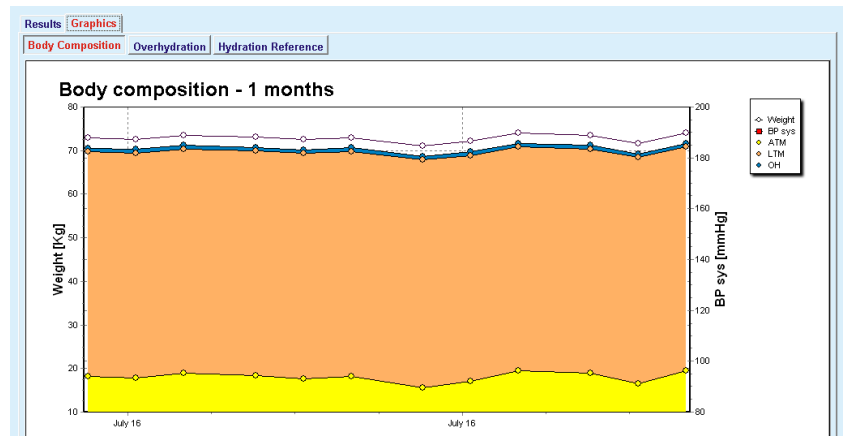
Fig. 3.27 Body Composition Graphic

All data displayed for a BCM measurement can be printed in a dedicated report by selecting the desired BCM measurement from the list and clicking the **Report** button. As a result, the corresponding input data and the results of the BCM measurement, in text and graphical format, as well as the associated (history) graphics are included in the report.

Clicking the **Delete** button will delete the currently selected BCM measurement, on user confirmation only.

Note

BCM measurements can be imported using the menu item **Import BCM Card** in **Communication/BCM Card**, as described in the corresponding section of these Instructions for Use.

3.11.4.6 Amputation tab

The **Amputation** tab (see **Amputation tab**, page 80) allows the user to specify the amputation status of a patient and to thus create a new amputation record of a patient or to edit or delete the existing amputation record of the patient.

There are four categories of amputations: for the left/right side of the body and for the upper/lower part of the body (arm/foot).

For the upper part of the body, the amputations can be:

Hand,

Arm below elbow,

Arm above elbow,

Arm at shoulder.

For the lower part of the body, the amputations can be:

Foot,

Leg below knee,

Leg above knee,

Leg at hip.

Note

The amputation record always reflects the current amputation status of the patient. Once a body part is missing, it will be missing at any future moment and it will be mentioned as missing repeatedly in every future amputation record.

You can specify an amputation status by checking the appropriate left and right-side check boxes.

Fig. 3.28 Amputation tab

Note

Regardless of the side, for both the upper and the lower part of the body, the amputation status is cumulative. Checking a check box for a higher level of amputation will automatically determine the checking of all lower levels. The descending lower levels are grayed out and impossible to uncheck. Unchecking at a higher level will - on a step-by-step basis - lead to the activation of the next lower level (not grayed out).

Note

It is not allowed to create two amputation status records with the same date. A warning message is issued in this case and the operation is canceled.

Note

The amputation status must be progressive in time. Any attempt to save an amputation status less severe than the previous registered ones will fail and a warning message is issued.
The user must click on the **Ok** button of the warning window and return to the Amputation screen in order to specify a valid amputation status.

Note

It is not allowed to register the very same amputation status on different Dates. A warning message is issued in this case and the operation is canceled.

Note

In case PatientOnLine client-server is connected to EDBMS and the server is configured so that Amputation is editable at EDBMS level, the editing buttons in PatientOnLine are not visible and the Amputation menu is read-only.

3.11.4.7 Nasal Carriage Status tab

The **Nasal Carriage Status** tab allows the user to specify the nasal carriage status.

On the **Nasal Carriage Status** tab, you can specify the following information:

> **Nasal Carriage Status Negative**

> **Nasal Carriage Status Positive**

> **Comment** (free text field)

> **Date**

Creating a new nasal carriage status record

To create a new nasal carriage status record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Nasal Carriage Status** tab;

➢ Click the **New** button;

➢ In the **Nasal Carriage Status** option field, the status of the nasal carriage can be selected;

➢ In the Comment field, a note can be entered (optional);

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Editing a nasal carriage status record

To edit a nasal carriage status record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Nasal Carriage Status** tab;

➢ Select the record to be edited in the **Nasal Status List**;

➢ Click the **Edit** button;

➢ The **Nasal Carriage Status** option field can now be changed;

➢ The Comment field can now be changed;

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Deleting a nasal carriage status record

To delete a nasal carriage status record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Nasal Carriage Status** tab;

➢ Select the record to be deleted in the **Nasal Carriage List**;

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled, the **Nasal Carriage Status** tab remains unchanged.

3.11.4.8 Additional Lab Data tab

The **Additional Lab Data** tab (see **Additional Lab Data tab**, page 84) allows the user to manage the laboratory data of the blood laboratory analysis and to document the Hepatitis B, C, and HIV infective status for a patient. Only certain users can, in addition, specify Hepatitis B, C, and HIV markers. The term **Additional** means in addition to QA tests (see section **Quality Assurance**).

● **General Lab Tests tab**

The user can record the following lab data:

urea
or

urea nitrogen, depending on the values specified by the local laboratory,

creatinine,

sodium,

potassium,

glucose,

albumin,

protein,

venous bicarbonate,

calcium (total),

phosphorus (phosphate),

parathyroid hormone (intact, biointact and total),

alkaline phosphatase,

C-reactive protein,

hemoglobin,

glycosylated hemoglobin (HbA1c),

ferritin,

transferrin saturation,

CA 125 marker

Note

While the system is running, the user can switch between **urea** and **urea nitrogen** - according to the local laboratory settings - by selecting the desired option under **Administration/Setup/Lab Data Settings**.

PatientOnLine offers a sophisticated way of specifying the units of measurement for each of the lab data in the **Administration/Setup/Lab Data Settings** section. For each type of lab data, the user can specify any possible unit.

The user can easily set/restore the default **Conventional** or **International** (S.I.) units of measurement at the click of a button.

The **Lab Data Settings** tab uses smart edit controls, which have well-established ranges for each type of data. The value ranges are automatically updated when the user re-defines the measurement units.

Note

A lab data record is added whenever a new Quality Assurance test is created. The **Additional Lab Data** list displays these QA lab data records as well, but in a different color scheme. In the **Additional Lab Data** tab, QA lab data can neither be edited nor deleted.

Creating a new additional lab data record

To create a lab data record for a patient, proceed as follows:

Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Additional Lab Data** tab;
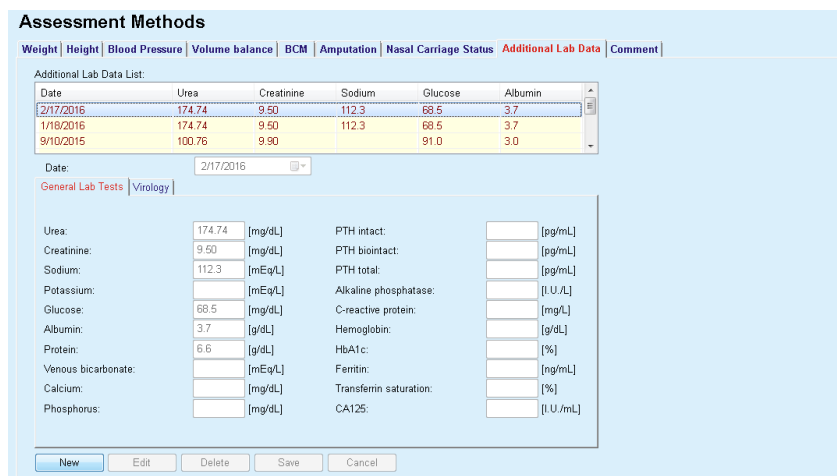
Fig. 3.29 Additional Lab Data tab

➢ Click the **New** button;

➢ Select the **Date** from the calendar control or keep the current date;

➢ Enter the lab value(s) in the corresponding entry field(s);

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

The newly created record appears in the **Additional Lab Data** list.

Note

None of the lab data is mandatory. To create a new record, at least one piece of data must be entered.

Editing an additional lab data record

To edit an **additional lab data** record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Additional Lab Data** tab;

➢ Select the record to be edited in the **Additional Lab Data List**;

➢ Click the **Edit** button;

All data fields are released for editing.

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

All changes are saved in the record.

Deleting an additional lab data record

To delete an additional lab data record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Additional Lab Data** tab;

➢ Select the record to be deleted in the **Additional Lab Data List**;

➢ Click the **Delete** button;

➢ The record is deleted after a safety prompt;

The successful deletion is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

● **Virology tab**

Infective Status tab

This option allows the user to document the **Infective Status** of a patient related to Hepatitis B, Hepatitis C, and HIV. Upon clicking the **New** button, you can select one of three options (**Negative**, **Unknown**, **Positive**) from the corresponding drop-down menus for Hepatitis B, Hepatitis C, and HIV. The date of recording the infective status should be specified in the **Date** field. To edit a record, select the desired item from the **Additional Lab Data List**, click the **Edit** button and make the desired changes. Then click the **Save** button to save the data or the **Cancel** button to cancel the process (see **Infective Status tab**, page 85). To delete a record, select the desired item from the **Additional Lab Data List**, click the **Delete** button and confirm the deleting operation.

Fig. 3.30 Infective Status tab

Laboratory tab

Only users belonging to the **Full Medical** group or having View + Edit + Make Prescription + Delete right can view and access the **Laboratory** tab offering the possibility to record the status of several blood parameters for Hepatitis B, Hepatitis C and HIV viruses (see **Laboratory tab**, page 86). The following parameters are available:

Hepatitis B virus (HBV)	Hepatitis C virus (HCV)	HIV
HBsAg	Anti-HCV	HIV
Anti-HBs	HCV-RNA	Anti-HIV ELISA
HBcAg	–	Anti-HIV Western Blot
Anti-HBc	–	P24-antigen
Anti-HBc-IgM	–	HIV-RNA
HBeAg	–	–
Anti-HBe	–	–
HBV-DNA	–	–

Creating new **Laboratory** records, editing and deleting such records should be performed in the usual way (see **Infective Status** tab description above).
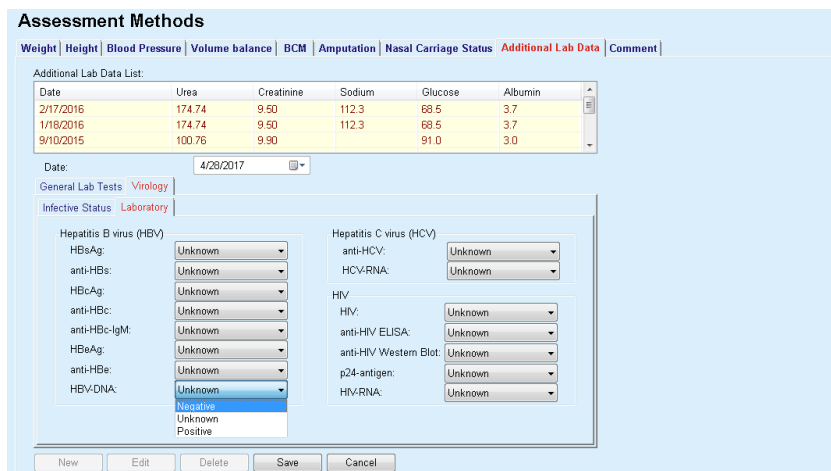

Fig. 3.31 Laboratory tab

Note

Each **Additional Lab Data** record consists of **General Lab Tests** data (like Urea N., Creatinine, Sodium, Glucose, …CA125) and **Virology** data (such as Hepatitis B, Hepatitis C and HIV infective status), including **Laboratory** data (such as HBsAg, Anti-HBs, …, HBV-DNA, Anti-HCV, HCV-RNA, HIV, …, HIV-RNA). Creating a new record is dealing with the whole bunch of parameters. Editing an existing record also deals with all parameters that may be changed. Deleting such a record will delete all data (General, Virology, Laboratory).

3.11.4.9 Comment tab

The **Comment** tab allows the user to specify a comment regarding a patient and to thus create a new comment record or to edit or delete an existing, general comment concerning a patient.

On the **Comment** tab, you can specify the following information:

> **Recommended Nutrition** (free text field),

> **General Comments** (free text field),

> **Date.**

Creating a new comment record

To create a new comment record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Comment** tab;

➢ Click the **New** button;

➢ Free text can in each case be entered in the **Recommended Nutrition** and **General Comments** text fields.

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Editing a comment record

To edit a comment record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Comment** tab;

➢ Select the record to be edited in the **Comment List**;

➢ Click the **Edit** button;

➢ The **Recommended Nutrition** and **General Comments** text fields can be edited.

➢ Select the **Date** from the calendar control or keep the current date;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Deleting a comment record   To delete a comment record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Assessment Methods** menu item from the Menu Tree;

➢ Select the **Comment** tab;

➢ Select the record to be deleted in the **Comment List**;

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled, the **Comment** tab remains unchanged.

3.11.5 Hospitalization

The **Hospitalization** submenu allows the user to manage all data related to the hospitalization of a patient:

Hospital (description, name),

Department (description, name),

Ward (description, name),

Staff in charge of the patient,

Admission Date,

Discharge date,

In Hospital ID,

Diagnosis.

By selecting the **Hospitalization** submenu, the **Hospitalization** entry menu opens.

Fig. 3.32 Hospitalization menu item

Fig. 3.33 Hospitalization screen

Creating a new hospitalization record

To create a new hospitalization record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Hospitalization** menu item from the Menu Tree;

➢ Click the **New** button;

➢ Click the **Select Staff** button;

The **Select Hospital, Department, Ward and Staff** pop-up window opens.

➢ Select the desired hospital from the **Hospital** drop-down menu;

➢ Select the desired department from the **Department** drop-down menu;

➢ Select the desired ward from the **Ward** drop-down menu;

➢ Mark the staff in charge in the **Staff** list using the mouse;

Note

The **Staff** list changes according to the selection criteria of the preceding drop-down menus.

➢ Select the **Assign** button in the pop-up window;

The selection is accepted and appears in the entry menu.

Note

The **Select Staff** operation is mandatory. If it is missing, any attempt to save the hospitalization record will fail and a warning message will be issued. Click the **Ok** button of the warning window to return to the **Hospitalization** entry menu to provide the necessary data.

➢ Select the **Admission Date** from the calendar control or keep the current date;

Note

The **Admission Date** is a mandatory data. If it is missing, any attempt to save the hospitalization record will fail and a warning message will be issued. Click the **Ok** button of the warning window to return to the **Hospitalization** entry menu to provide the necessary data. Select the **Discharge Date** from the calendar control or leave it blank.

➢ Enter the **Discharge Date** by means of the calendar control (optional);

Tip

The **Discharge Date** is not mandatory.

You can leave it blank and update it later. If the **Discharge Date** entry field is filled in, the number of hospitalization days is automatically computed and displayed.

➢ Enter the hospital ID in the **In Hospital ID** entry field;

Note

The **In Hospital ID** is a mandatory data, however it is no unique number. If it is missing, any attempt to save the hospitalization record will fail and a warning message will be issued. Click the **Ok** button of the warning window and return to the **Hospitalization** entry menu to provide the necessary data.

➢ Enter a note in the **Comment** text field (optional).

Enter the applicable diagnosis for the patient:

➢ Click the ⬚ button;

The **ICD 10** pop-up window opens;

➢ Select the applicable diagnosis from the Menu Tree;

Description, **Category**, and **Code** are displayed in the **Selected Disease** field.

➢ Click the **Yes** button,

The selection is accepted in the entry menu.

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Alternatively, you can enter a valid ICD-10 code directly in the **ICD-10 Code** edit box. If the code is correct, the **ICD-10 Disease** box will be updated with the corresponding text. If the entered code is not valid, a warning message will appear.

Warning

Risk for the patient as a result of insufficient detoxification.

A wrong ICD-10 tree selection might not reveal a possible diabetic status of the patient.

In such a case, an improper glucose concentration may be prescribed.

➢ The user must verify the ICD-10 tree selection after clicking the **Save** button.

Editing a hospitalization record

To edit a hospitalization record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Hospitalization** menu item from the Menu Tree;

➢ Select the record to be edited in the **Hospitalization List**;

➢ Click the **Edit** button;

For information for editing a record, (see **Creating a new hospitalization record**, page 89).

The following entry fields can be edited directly in the entry menu:

Admission Date,

Discharge Date,

In Hospital ID.

The following entry fields can only be edited via the **Select Staff** button:

Hospital,

Department,

Ward,

Staff.

The following entry fields can only be edited via the [...] button:

ICD-10 Code,

ICD-10 Disease.

You can enter a valid ICD-10 code directly in the **ICD-10 Code** edit box. If the code is correct, the **ICD-10 Disease** box will be updated with the corresponding text. If the entered code is not valid, a warning message will appear.

Saving the edited data

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Warning

Risk for the patient as a result of insufficient detoxification.

A wrong ICD-10 tree selection might not reveal a possible diabetic status of the patient.

In such a case, an improper glucose concentration may be prescribed.

➢ The user must verify the ICD-10 tree selection after clicking the **Save** button.

Deleting a hospitalization record

To delete a hospitalization record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Hospitalization** menu item from the Menu Tree;

➢ Select the record to be edited in the **Hospitalization List**;

➢ Click the **Delete** button;

The selected record will be deleted after a safety prompt by clicking on the **Yes** button.

3.12 Medical

The **Medical** menu item allows the user to fill in extensive data for systems, prescriptions, analyses, quality assurance, and modeling.

Note

For accessing any of the submenu items, a patient must be selected in the **Patient Frame**, otherwise an information message is issued in the **Working Frame** and the selected menu item has no effect.

3.12.1 System & Limits

By selecting the **System & Limits** submenu, the **System & Limits** entry menu opens.

(see Fig. 3.34, System & Limits menu item, page 93)
(see Fig. 3.35, System & Limits entry menu, page 94)

Fig. 3.34 System & Limits menu item

The **System & Limits** menu item allows the management of PD systems for each patient. The user can assign a certain PD system - either CAPD or APD, or a combination of APD and CAPD systems to the patient. There is also a generic system called **Other APD** that can be selected. If a patient has this system assigned, a prescription can be created but cannot be written on the patient card. Also for this system the **Limits** tab is not available. Most APD systems allow setting certain prescription limits. This is done on the **Limits** tab.

Note

If no PD system has been assigned to a patient, no new prescription can be made for that patient.

The creation of a new record in the Medical/PD Prescription menu item issues a warning message which informs the user that no PD system is selected.

This module is structured on 2 tabs, namely **System** and **Limits**, which are described below.

3.12.1.1 System tab

On the **System** tab, the patient is assigned to a certain PD system (see Fig. 3.35, System & Limits entry menu, page 94).

The following entry fields are available:

> APD System Type;
>
> Set Date;
>
> CAPD System Type;
>
> Language;
>
> Comment.

For certain systems, like *sleep·safe*, you must also select the display language of the APD system in the **Language** drop-down menu.

Normally, a PD patient always uses the same PD system. Any change in the system is entered in the **System List**.

Note

If the PD system itself is changed, all existing prescriptions need to be converted to the new PD system to make sure that they are still compatible. This needs to be done whenever a new option is selected from the **APD System Type** drop-down list, regardless of whether the device type changes or only the device version.

Converting prescriptions is done via the editing prescriptions task. For further information about editing PD prescriptions, (see chapter 3.12.2, page 99).

The PD systems used are listed in chronological order. The currently used system is displayed at the top of the list.
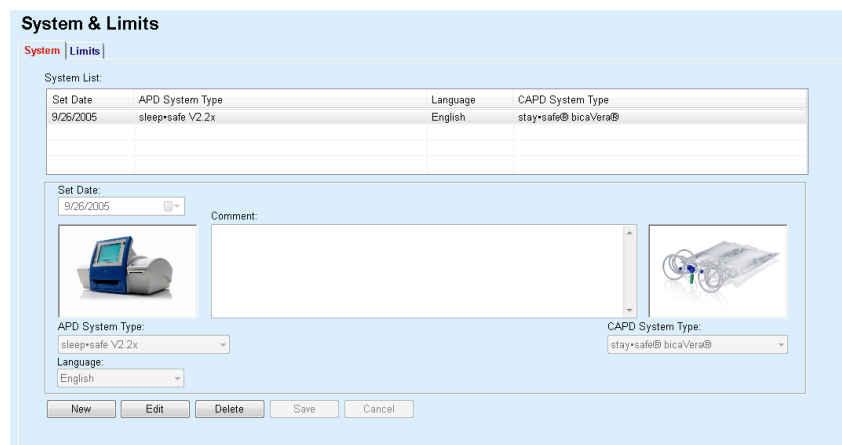
Fig. 3.35 System & Limits entry menu

By clicking on a record in the **System List**, all details including an image of the PD system will be displayed in the entry menu.

Creating a PD System record

To create a PD System record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **System & Limits** menu item from the Menu Tree;

➢ Select the **System** tab;

➢ Click the **New** button;

➢ Select the APD System from the **APD System Type** drop-down menu;

Note

If there is an image of the selected APD System, it will be displayed in the entry menu.

Note

If *sleep•safe* is selected as APD system, the available languages will be displayed in the **Language** drop-down menu. In case another APD system is selected, the **Language** drop-down menu remains empty.

➢ Select the display language of the APD system in the **Language** drop-down menu (if available);

➢ Select the **Set Date** from the calendar control or keep the current date;

➢ Select the CAPD System from the **CAPD System Type** drop-down menu;

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button. The pop-up window displays the current PD system and a reminder to set the patient system limits.

Editing a PD System record

To edit a PD System record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **System & Limits** menu item from the Menu Tree;

➢ Select the **System** tab;

➢ Select the record to be edited in the **System List**;

➢ Click the **Edit** button;

All data fields can be edited as described under (see **Creating a PD System record**, page 94).

➢ Click the **Save** button.

All changes are saved in the record.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button. The pop-up window displays the current PD system and a reminder to set the patient system limits.

Deleting a PD System record

To delete a PD System record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **System & Limits** menu item from the Menu Tree;

➢ Select the **System** tab;

➢ Select the record to be deleted in the **System** List;

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled, and the **System** tab remains unchanged. The pop-up window displays the current PD system (if any) and a reminder to set the patient system limits.

Note

For a patient that is no longer treated by PD (temporary or permanently) both APD and CAPD systems can be set to **None**.

3.12.1.2 Limits tab

The **Limits** tab allows the user to specify some constraint parameters to be taken into account when performing the treatment with an APD cycler for a patient.

Each patient can have their own parameters specified. Setting limits is available only if the current PD system supports this feature.

Different types of cycler parameters are managed:

Preselected/maximum values within the absolute min/max values imposed by the cycler;

➢ Range, with predefined values;

➢ Option (such as yes or no);

➢ Single value.

The possible actions allowed in the **Limits** window are the common ones. The **Default** button allows reverting to a predefined set of limits.

Note

The limits specified in the **Limits** tab are only available for the current combined PD system (the topmost record in the **System List** table of the **System** tab).

For the *sleep·safe* cycler, upon changing from the adult to the pediatric set, it is possible that the current adult limits may become invalid for a pediatric patient and thus they will be highlighted red. In this case, clicking the **Default** button will force the default pediatric limits.

*Fig. 3.36 Limits and options for **sleep·safe** V2.2x - adult set*

Tip

When the pediatric set is selected for *sleep•safe*, a bitmap of the Paeddy Bear will be displayed.

The specific limits and options for *sleep•safe harmony* are illustrated below.

Fig. 3.37 Limits and options for the sleep•safe harmony - adult therapy mode

The **Recommended catheter performance** is calculated by **Patient-OnLine** based on the last 7 treatment protocols, by comparing the calculated durations of outflow phases from the prescription to the actual durations of outflow phases from the treatment protocol. The recommended value, if set as **Catheter performance** in the **System & Limits/Limits** tab, will adapt the calculated duration of outflow phases to better fit the actual durations.

Note

The therapy mode of the *sleep•safe harmony* system version >V2.3 can also be changed to the pediatric therapy mode (see Fig. 3.38, Limits and options for sleep•safe harmony version >V2.3 - pediatric therapy mode, page 98).

Upon changing from adult to pediatric set, it is possible that the current adult limits may become invalid for a pediatric patient and thus they will appear in red color. In this case, pressing the **Default** button will force the default pediatric limits.
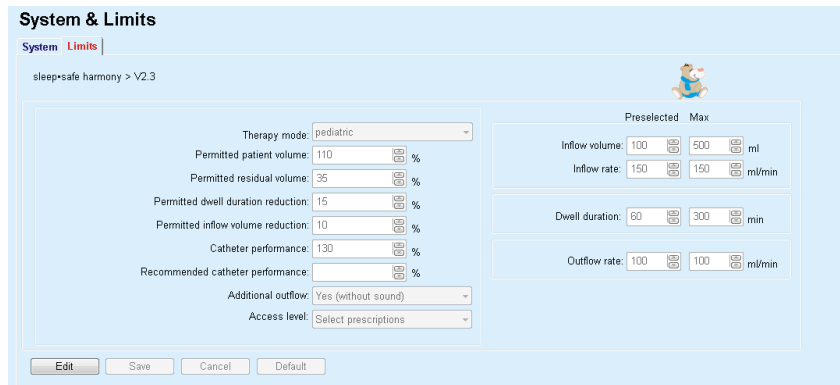
*Fig. 3.38 Limits and options for **sleep•safe harmony** version >V2.3 - pediatric therapy mode*

Note

For detailed information about the **sleep•safe harmony** limits and options in this section, refer to the **sleep•safe harmony** cycler Instructions for Use.

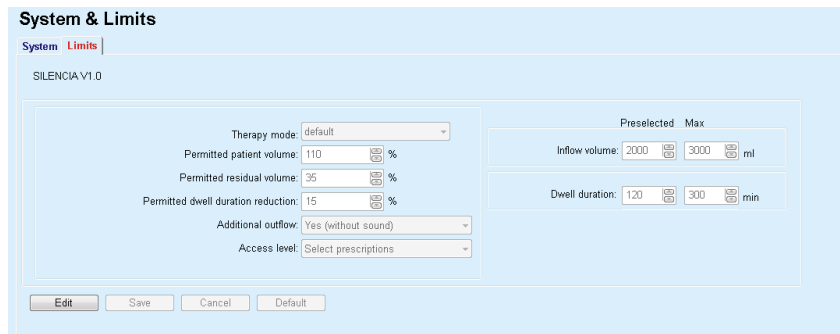The specific limits and options for **SILENCIA** are illustrated below.

*Fig. 3.39 Limits and options for **SILENCIA***

Note

For detailed information about the **SILENCIA** limits and options in this section, refer to the **SILENCIA** cycler Instructions for Use.

Note

The limits set for a cycler are patient-oriented (different for each patient).

For details about the meaning of each parameter in the Limits screens, refer to the specific Instructions for Use.

3.12.2 PD Prescription

The PD Prescriptions menu allows the user to make prescriptions for a patient depending on the PD system assigned and, if relevant, on the limits for that system.

Note

If no PD system has been assigned to a patient, no new prescription can be made for that patient.

The **PD Prescription** menu is structured differently depending on the combined system type, **APD (*sleep·safe*, *sleep•safe harmony*, SI-LENCIA** etc.) and/or **CAPD**. Consequently, the prescription can have an APD part and/or a CAPD one. Combined prescriptions are displayed in two tabs - **APD** and **CAPD** - while single-system ones are displayed in a single tab - **APD** or **CAPD**. A prescription consisting of both APD and CAPD parts is shown in the following figure.
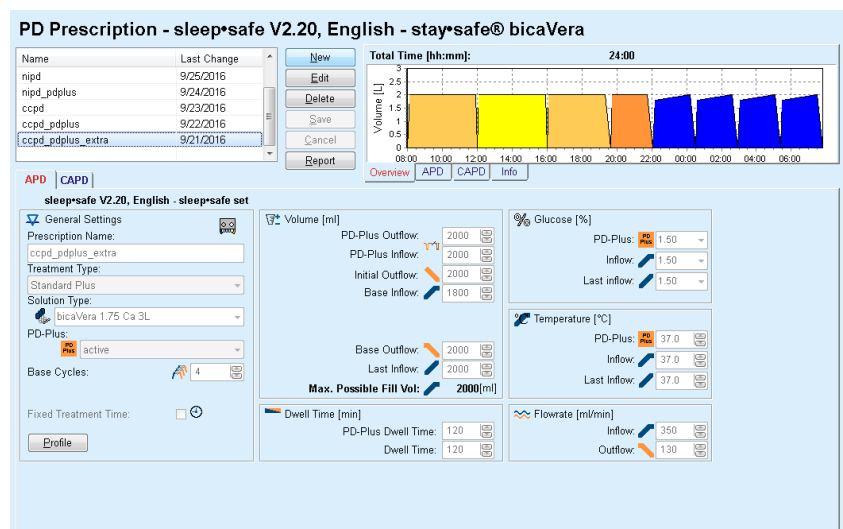

*Fig. 3.40 PD Prescription window for the **sleep·safe** APD system*

The **PD Prescription** module is divided in the following sections:

- **Prescription List** in the upper left corner;
- **Command buttons** in the upper center part;
- **Overview pane** in the upper right corner;
- **Prescription settings** with the **APD** and **CAPD** tabs in the lower part.

The **Prescription list** displays the prescription names and the date of the last change, providing the means to select and thus to edit/delete/preview prescriptions.

The Command buttons allow the following actions:

> **New** - Creating a new prescription;
>
> **Edit** - Editing an existing prescription;
>
> **Delete** - Removing a selected prescription from the database;
>
> **Save** - Saving the prescription in the database;
>
> **Cancel** - Canceling the edit operation, thus rejecting the changes;
>
> **Report** - Creating an associated report.

Adapted APD Prescription

Adapted **APD** (aAPD) is a concept introduced by Prof. M. Fischbach. In his study (see reference 10 from Chapter 5.1). Patients were treated with a sequence of short-dwell, small-volume exchanges to promote ultrafiltration, followed by longer-dwells, larger-volume exchanges to favor removal of uremic toxins. Adult **APD** patients with a mean D/P creatinine of 0.68 (range 0.58 – 0.80) initially received 2 times a small fill volume of 1500 mL with an exchange cycle of 45 minutes. The fill volume was then changed to 3000 mL (1480 – 1650 mL/m²), which was given 3 times with an exchange cycle of 150 minutes. Total nightly APD treatment was 9 hours.

Since *sleep•safe*, *sleep•safe harmony* and **SILENCIA** cyclers have the unique feature of profiling each single cycle they enable the aAPD prescription by Fischbach as well. The prescription of large fill volumes should be managed using intra peritoneal pressure (IPP) measurements to avoid the risk of a too high IPP.

If the **APD** system is *sleep•safe*, *sleep•safe harmony* or **SILENCIA**, the option "Adapted **APD**" is available upon creating a new prescription:
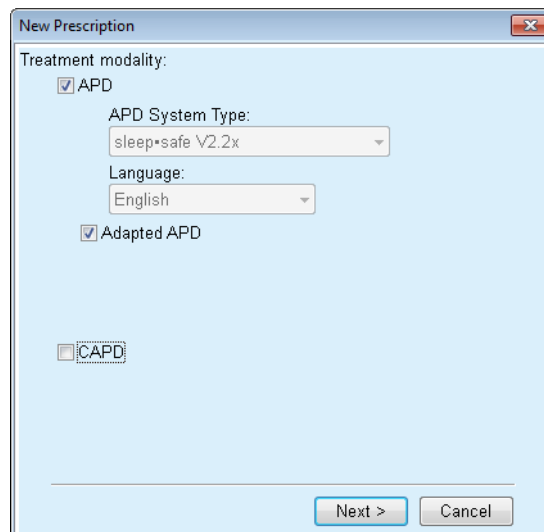

Fig. 3.41 Adapted APD option

In case the patient's age is less than 2 years, the Adapted APD option is not available (see Fig. 3.41, Adapted APD option, page 100).
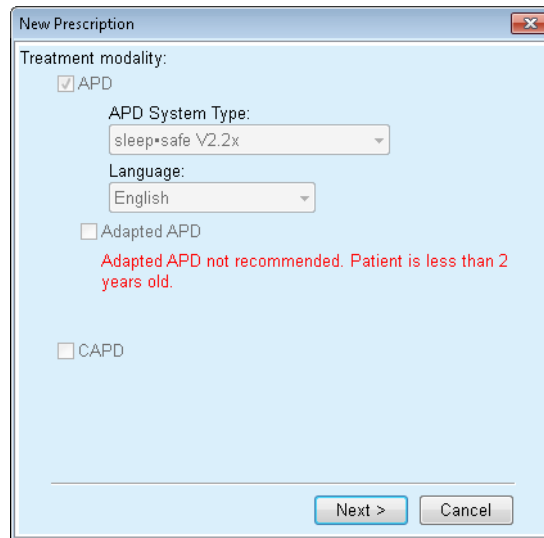
Fig. 3.42 Adapted APD option not available for children less than 2 years old

If this option is selected, the next page will offer the possibility to edit the aAPD parameters:
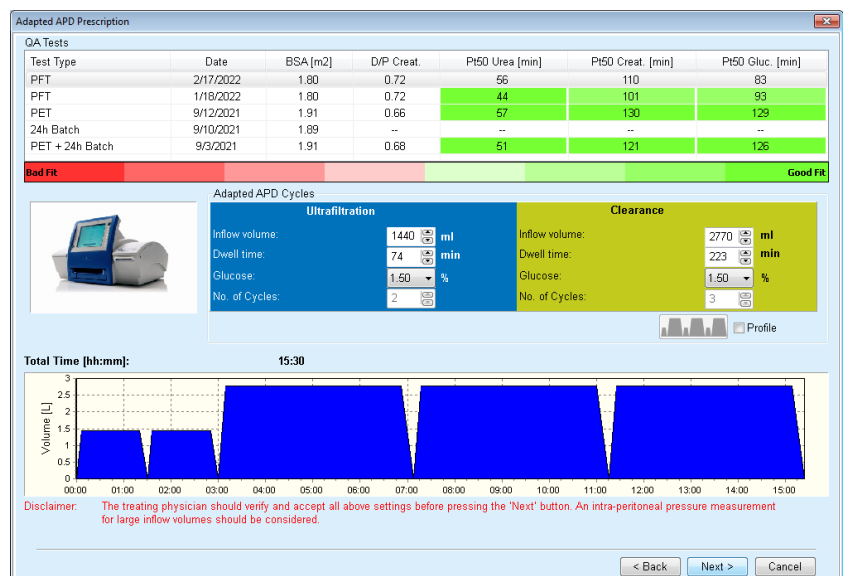

Fig. 3.43 Adapted APD prescription window

In the upper part of the window, you can view a list of available QA tests. The list contains by default the latest 6 non-draft QA tests, but none older than 25 months. The list can be extended up until a PET/PFT/PET+24h batch test is included, but not older than 25 months. In the Adapted APD Cycles area, the inflow volumes and dwell times can be edited within the current patient limits. Depending on cycler capabilities, glucose concentrations can be edited as well. The lower part is the graphical representation of the prescription.

If the APD system is *sleep•safe* or *sleep•safe harmony*, a **Profile** check box is available. Checking this option allows you to further edit the number of cycles. If **Profile** is checked, the order of cycles of the adapted APD prescription can be toggled by clicking the icon located on the left side of the **Profile**. This option is not available for **SILENCIA**.

Note

By clicking the **Next** button, the prescription will be passed on to the specific editor and prescription model (*sleep•safe*, *sleep•safe harmony* or **SILENCIA**), where you can further change it and then save it.

Creating a new PD Prescription

To create a new **PD Prescription** record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Medical** menu item from the Menu Tree;

➢ Select the **PD Prescription** submenu item.

The **PD Prescription** entry menu is opened.

➢ In the entry menu, click the **New** button;

➢ Select **APD** and/or **CAPD** for the Treatment Type;

➢ Click the **Next >** button.

Note

Depending on the selected **Treatment Type**, different tabs **APD** and/or **CAPD** will be displayed in the prescription editor.

The prescription is accepted in the entry menu.

Entries on the APD tab

➢ Enter a name for the prescription in the **Prescription Name** entry field;

➢ Select the **Treatment Type** using the drop-down menu;

Note

Depending on the selected **Treatment Type**, different entry fields for the treatment parameters will be available for changes.

Entries on the CAPD tab

➢ Enter a name for the prescription in the **Prescription Name** entry field;

➢ Select the **Number of Manual Exchanges** using the drop-down menu;

The CAPD cycles are shown in a table.

All editable cells can be changed by double-clicking them. If limits are exceeded, the exceeded value is shown in red.

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Editing PD Prescriptions

To edit a **PD Prescription** record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Medical** menu item from the Menu Tree;

➢ Select the **PD Prescription** submenu item.

The **PD Prescription** entry menu is opened.

➢ Select the record to be edited in the list (top left corner);

➢ Click the **Edit** button;

If the PD system has been changed: A dialog box is opened to convert the prescription to the new system.

➢ Click the **Ok** button;

The **Edit Prescription** dialog box is opened.

The selected Treatment Type can be accepted or changed.

➢ Click the **Next >** button.

➢ If the PD system has been changed: Check the parameters in the **APD** tab and the **APD/APD Info** tab. Any parameters displayed in red are no longer compatible with the PD system.

➢ If necessary: Adapt the parameters.

Entries on the APD tab

The following entry fields can be changed:

Treatment type

Solution Type

PD-Plus

Base cycles

Tidal cycles

The treatment parameters can be changed, if necessary.

Note

The **maximum possible fill volume** is always displayed for a prescription and is automatically updated each time the value for inflow volume (basic, last, PD Plus) is changed.

Entries on the CAPD tab

The following entry fields can be changed:

Prescription Name

Number of Manual Exchanges

The number of cycles is shown in a table.

All editable cells can be changed by double-clicking them. If limits are exceeded, the exceeded value is shown in red.

➢ Click the **Save** button.

The successful saving operation is shown as a pop-up window and must be confirmed by selecting the **Yes** button.

Note

After saving or editing an APD prescription, do not forget to update the prescription on the patient card. This reminder is also shown after successfully saving an APD prescription.

Deleting a PD Prescription

To delete a **PD Prescription** record, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Medical** menu item from the Menu Tree;

➢ Select the **PD Prescription** submenu item.

The **PD Prescription** entry menu is opened.

➢ Select the record to be deleted in the list (top left corner);

➢ Click the **Delete** button;

A pop-up window with a safety prompt opens.

By clicking on the **Yes** button, the selected record is deleted; by clicking on the **No** button, the process is canceled.

The successful deletion is shown as pop-up menu and must be confirmed by selecting the **OK** button.

Creating a report for the prescription

To create a report for a **PD Prescription**, proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Medical** menu item from the Menu Tree;

➢ Select the **PD Prescription** submenu item.

The **PD Prescription** entry menu is opened.

➢ Select the record from the list (top left corner) for which a report will be created;

➢ Click the **Report** button;

After a short generating period, the report is displayed in print format.

Click the **Printer** symbol;

➢ The report is printed on the default printer;

➢ Click the **Close Report** button.

The print view is closed.

The Overview Pane

The Overview pane shows information on the current prescription, for the APD or/and the CAPD part, together with a graphical overview. This area is divided into four tabs:

> **Overview**,
>
> **APD**,
>
> **CAPD**,
>
> **Info**.

3.12.2.1 Overview tab

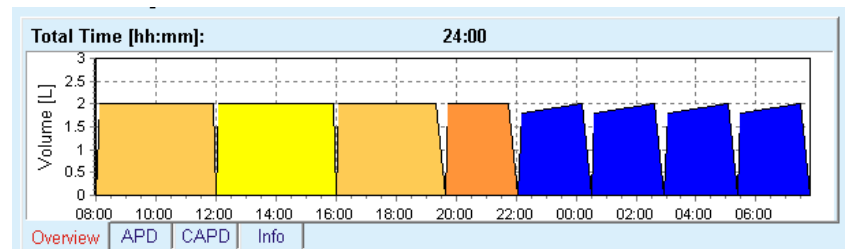The **Overview** tab shows the graphical representation of the prescription.

Fig. 3.44 Overview tab of the Overview pane

The orange cycle represents the PD-Plus cycle.

The dark yellow cycles represent the daily cycles.

The blue cycles represent the APD basic or tidal cycles.

Each cycle also has an associated quick info.

3.12.2.2 APD tab with sub-tab APD Info

The **APD** tab shows a summary of the prescription (total time, total volumes and the necessary solution bags). This information is different for each APD system. For *sleep•safe*, the tab is divided in two sub-tabs:

> **APD Info**
> **Bags**

(see Fig. 3.45, APD Info tab of the Overview pane of APD sleep·safe, page 105) and (see Fig. 3.46, Bags tab of the Overview pane of APD sleep·safe, page 106);
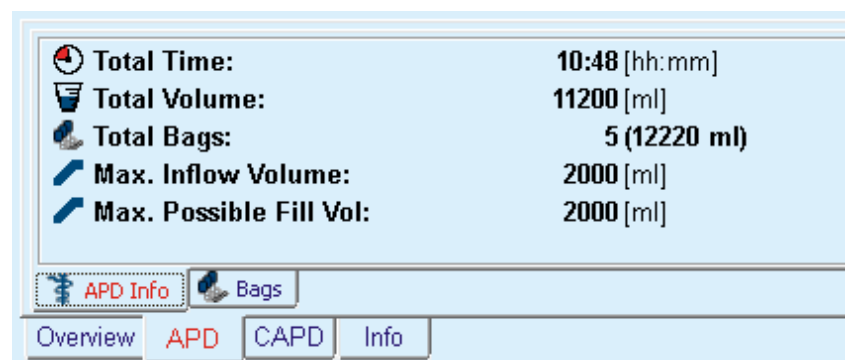
*Fig. 3.45 APD Info tab of the Overview pane of APD **sleep·safe***

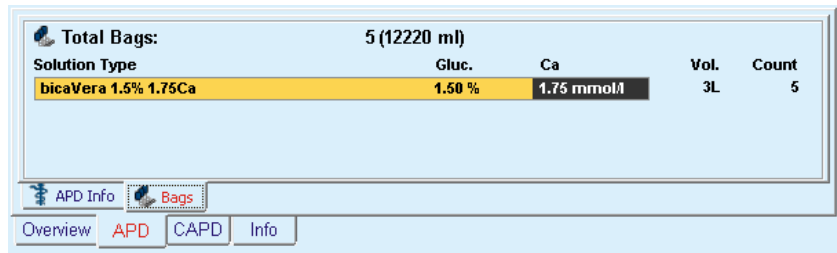### 3.12.2.3 APD tab with sub-tab Bags

*Fig. 3.46 Bags tab of the Overview pane of APD **sleep·safe***

The total volume and the total number of bags may be displayed in red, in case the total volume limit (see Limits) is exceeded.

3.12.2.4 CAPD tab

The **CAPD** tab shows a summary of the prescription (total time, total volume, number and type of bags).

The **CAPD** tab has two sub-tabs:

> **CAPD Info**,

> **Bags**.

The **CAPD** Info tab of the Overview pane of CAPD. The **Bags** tab is similar to the APD one.
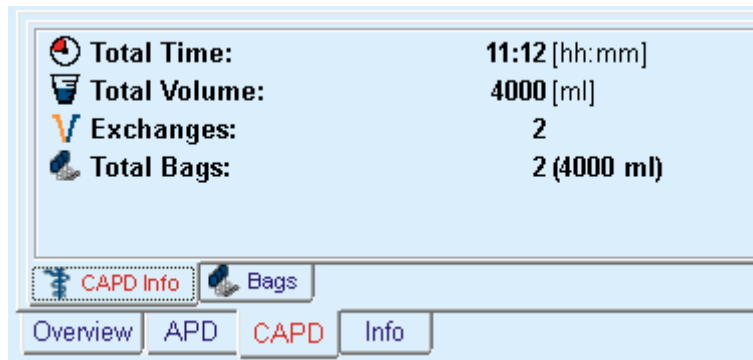
Fig. 3.47 CAPD Info tab of the Overview pane of CAPD

3.12.2.5 Info tab

The **Info** tab gives a short description of the prescription, displaying the prescription name and the combined PD system used.

In the **Prescription settings** section, the **APD**/**CAPD** tabs describe the **APD** and the **CAPD** part of the prescription. The CAPD part consists of the day exchanges, while the APD part (if any) consists of the night cycles, performed with a cycler.

Each tab contains the current APD/CAPD system assigned to the prescription. This is not necessarily the same as the APD/CAPD system assigned to the patient. For example, a patient on PD-NIGHT Patient-Card and bicaVera can have a *sleep•safe* prescription as well. In this case, the system label will be displayed in red, informing the user that a different system is assigned to the patient. By editing such a prescription, a conversion to the current system can be enforced.

● **APD Prescription -** *sleep•safe harmony*

The **APD** tab for *sleep•safe harmony* is structured in two sections: **General Settings**, on the left-hand side for the prescription name and type, and the prescription data, on the right hand side, with different parameters depending on the prescription type. The following prescription types are available for *sleep•safe harmony*, selectable from the corresponding drop-down menu: Basic, Standard, PD-plus standard, Tidal and Adapted APD.

Note

Input parameter values for all prescription types are restricted by their limits, as specified in the **System&Limits/Limits** menu. The values for these limits are provided as quick infos for each entry field in the corresponding prescription editor.

The **Overview** pane in the upper right side is providing the graphic of the prescription, summary information for the APD prescription in terms of Treatment duration, Treatment volume, Number of bags, Permitted patient volume and Permitted residual volume, the Solutions (using color code) with type, glucose and calcium concentrations, volume and necessary number of bags, data about the CAPD prescription (if any) and brief information about the PD prescription (name, used APD and CAPD systems).

A: Basic prescription

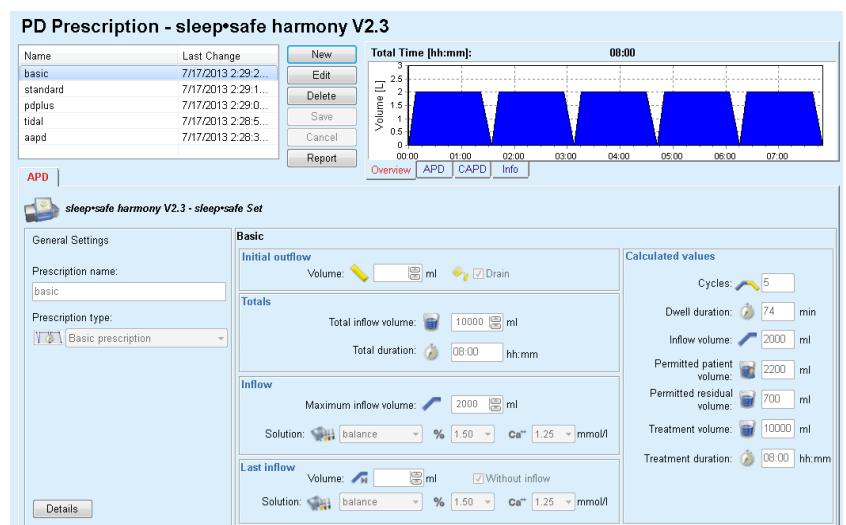A basic prescription for *sleep•safe harmony* is illustrated below.

Fig. 3.48 Basic prescription - ***sleep•safe harmony***

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow, which is pressure-driven.

➢ Total inflow volume.

➢ Total duration (of the treatment).

➢ Maximum inflow volume.

➢ Solution for the treatment, together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists.

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last cycle will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists.

On the right-hand side the **Calculated values** are provided, in terms of number of Cycles, Dwell duration, Inflow volume, Permitted patient volume, Permitted residual volume, Treatment volume and Treatment duration.

The **Details** button will open a pop-up window with information related to each cycle of the prescribed treatment in terms of Inflow Volume, Solution (name, glucose and calcium concentrations), Dwell Duration, Outflow Volume and Cycle duration. None of these parameters are editable.

Note

Profiling is not allowed for both Basic and Adapted APD prescriptions.

B: Standard prescription

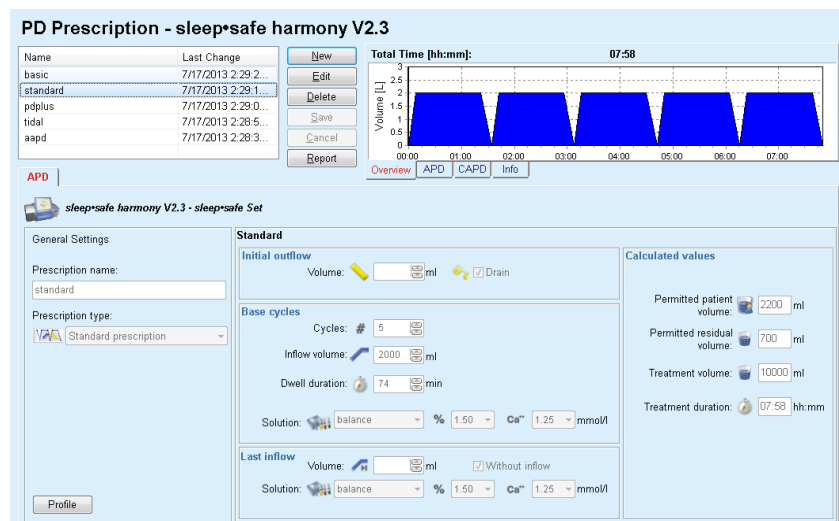A standard prescription for *sleep•safe harmony* is illustrated below.

Fig. 3.49 Standard prescription - *sleep•safe harmony*

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow, which is pressure-driven.

➢ Base cycles data, in terms of Number of cycles, Inflow volume, Dwell duration and Solution for the treatment (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last cycle will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists.

On the right-hand side the **Calculated values** are provided, in terms of Permitted patient volume, Permitted residual volume, Treatment volume and Treatment duration.

The **Profile** button will open a pop-up window allowing to profile the Inflow volume, the Solution (type, glucose and calcium concentrations), and the Dwell Duration for each prescribed cycle, upon checking the corresponding Profile check box for the corresponding parameter.

Tip

Profiled parameters will be marked in the prescription editor with a **Profile** label

C: PD-Plus standard prescription

This prescription type is similar to the Standard prescription but has some additional input data related to the PD-Plus cycle:

➢ Inflow volume.

➢ PD-Plus pause duration.

➢ Solution for the PD-Plus cycle (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

All details mentioned in item B are applicable to the PD-Plus standard prescription as well.

D: Tidal prescription

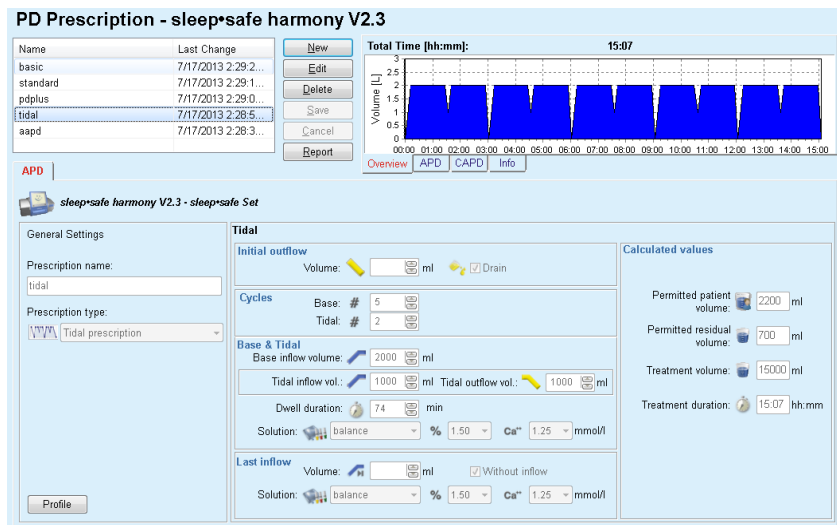A Tidal prescription for *sleep•safe harmony* is illustrated below.

*Fig. 3.50 Tidal prescription - **sleep•safe harmony***

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow, which is pressure-driven.

➢ Number of Base and Tidal cycles.

➢ Base inflow volume, Tidal inflow and outflow volumes.

➢ Dwell duration.

➢ Solution for the Base and Tidal cycles (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last cycle will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists.

The **Calculated values** and the **Profile** option are the same as for Standard and PD-Plus Standard prescriptions, described above.

E: Adapted APD prescription

An Adapted APD prescription for ***sleep•safe harmony*** is illustrated below.
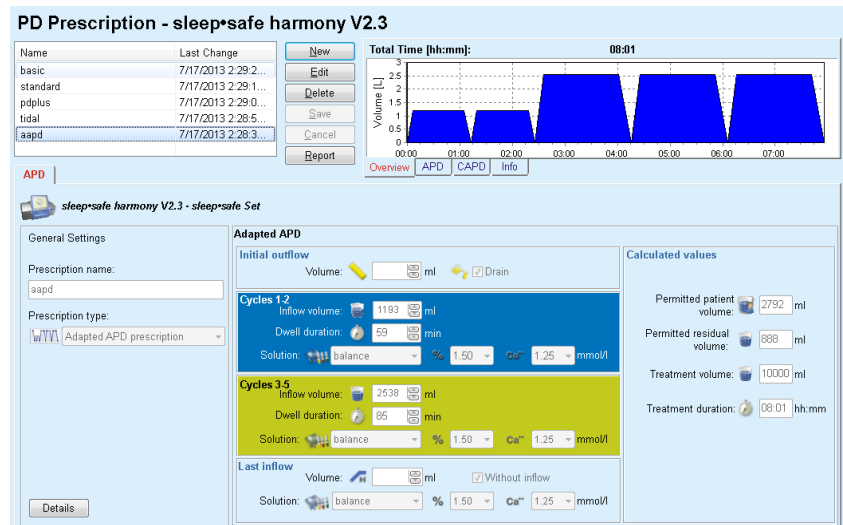
*Fig. 3.51 Adapted APD prescription - **sleep•safe harmony***

The "adapted APD" therapy concept according to Prof. M. Fischbach consists of a standard prescription of 5 cycles, with 2 cycles of short dwell time and small inflow volume and 3 cycles of long dwell time and large inflow volume. The first 2 cycles aim to achieve ultrafiltration and the last 3 ones to promote proper clearance of uremic toxins with longer diffusion times such as creatinine and phosphate.

In case the patient's age is less than 2 years, the Adapted APD therapy is not available.

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow, which is pressure-driven.

➢ Cycles 1-2 data, in terms of Inflow volume, Dwell duration and Solution (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Cycles 3-5 data, in terms of Inflow volume, Dwell duration and Solution (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last cycle will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists.

The **Calculated values** are the same as for Standard, PD-Plus Standard and Tidal prescriptions, described above.

The **Details** button will open a pop-up window with information related to each cycle of the prescribed treatment as described in case of Basic prescription.

Note

Profiling is not allowed for both Basic and Adapted APD prescriptions.

Note

For detailed information about the prescription parameters in this section, please refer to the **sleep•safe harmony** cycler Instructions for Use.

● **APD Prescription - *sleep•safe***

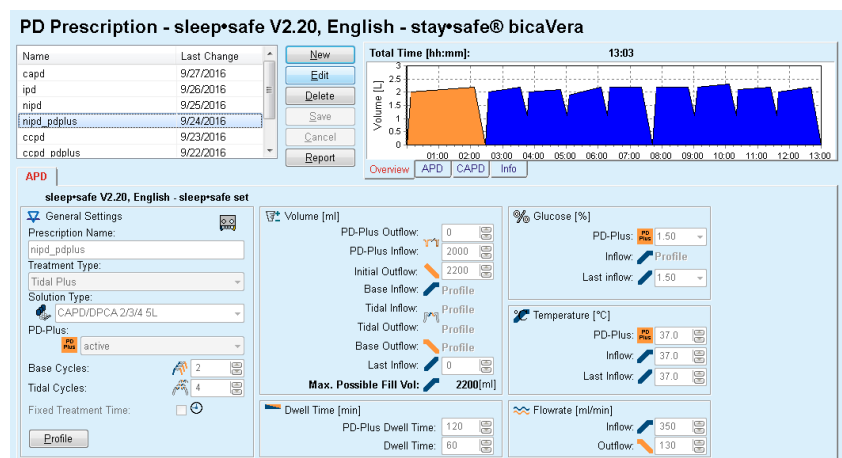The APD tab for **sleep•safe** consists of the following sections:

*Fig. 3.52 APD Prescription - **sleep•safe***

General Settings (left),

Cycle (center to the right),

Profile (button at the bottom).

In the **General Settings** section, you can make the following entries/settings:

Prescription Name,

Treatment Type,

Solution Type,

PD-Plus option (**active**/**inactive**),

Base Cycles (Number),

Tidal Cycles (Number).

Note

The name of the prescription is shown on the **sleep·safe** cycler display. It is recommended to use expressive names.

The **Cycle** section offers the possibility to optimize the following values:

Volume,

Dwell time,

Glucose,

Temperature,

Flowrate.

Note

If the treatment type excludes certain options, the related fields will be either invisible or inactive.

Example:
In a standard treatment all tidal-related fields will be invisible.

Note

Some of the phase values (e.g. outflow volume) may be automatically corrected if they fall outside the limits specified in the **System & Limits** module.

Please check all the settings carefully after a change.

The **Profile** button lets you individualize each phase of the treatment.

Cycle	Inflow			Dwell	Outflow	Cycle Time
	Volume	Temp.	Glucose	Time	Volume	
	[ml]	[°C]	[%]	[min]	[ml]	[min]
	☑ Profile	☐ Profile	☑ Profile	☐ Profile	☑ Profile	
PD-Plus Outflow	-	-	-	-	0	0
PD-Plus Inflow	2000	37.0	1.50	-	-	7
Initial Outflow	-	-	-	-	2200	20
Cycle #1/#1	2000	37.0	1.50	60	1100	79
Cycle #1/#2	900	37.0	2.30	60	1000	75
Cycle #1/#3	800	37.0	1.50	60	1100	76
Cycle #1/#4	1100	37.0	1.50	60	2200	85
Cycle #2/#1	2200	37.0	2.30	60	1100	80
Cycle #2/#2	1100	37.0	1.50	60	1200	78
Cycle #2/#3	1000	37.0	1.50	60	1100	76

Fig. 3.53 Profile pop-up window

Check the **Profile** check box in each column header to activate the profile in that particular column.

Tip

If the **Profile** in a certain column is active, **Profile** will be displayed instead of a numerical value.

Tip

The **Cycle** section and the **Profile** window are connected; changes made in one of the two are reflected in the other.

👉 **Note**

Please refer to the *sleep·safe* Instructions for Use for definitions and prescription parameters.

● **APD Prescription - SILENCIA**

The **APD** tab for **SILENCIA** is structured in two sections:
General Settings, on the left-hand side for the prescription name and type, and the prescription data, on the right-hand side, with different parameters depending on the prescription type. The following prescription types are available for **SILENCIA**, selectable from the corresponding drop-down list: Standard, Tidal and Adapted APD.

👉 **Note**

Input parameter values for all prescription types are restricted by their limits, as specified in the **System&Limits/Limits** menu. The values for these limits are provided as quick infos for each entry field in the corresponding prescription editor.

The **Overview** pane in the upper right side is providing the prescription graphic, summary information for the APD prescription in terms of Treatment duration, Treatment volume, Number of bags, Permitted patient volume and Permitted residual volume, the Solutions (using color code) with type, glucose and calcium concentrations, volume and necessary number of bags, data about the CAPD prescription (if any) and brief information about the PD prescription (name, used APD and CAPD systems).

A: Standard prescription   A standard prescription for **SILENCIA** is illustrated below.
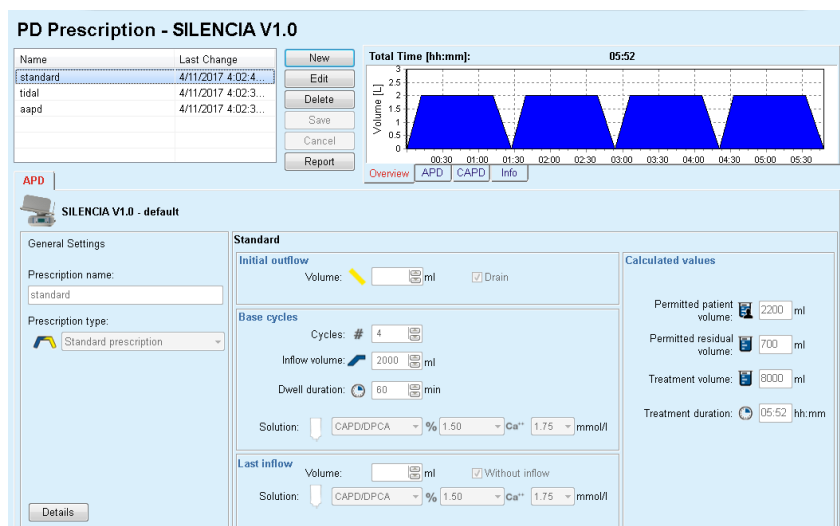
Fig. 3.54 Standard prescription - SILENCIA

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow.

➢ Base cycles data, in terms of Number of cycles, Inflow volume, Dwell duration and Solution for the treatment (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last inflow will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists. The **Bags** sub-tab of the **Overview/APD** tab shows the total number of solution bags, according to user selection.

In the right-hand side the **Calculated values** are provided, in terms of Permitted patient volume, Permitted residual volume, Treatment volume and Treatment duration.

The **Details** button will open a pop-up window with detailed values for each cycle.

Note

The selection for solution glucose allows mixed glucoses like "1.5% + 2.3%" or "2.3% + 4.25%" or "1.5% + 4.25%". Using a mixed glucose means that two distinct solution bags with different glucoses are connected to the cycler. A mixed glucose is allowed for the last inflow only if the same mixed glucose is used for the base cycles as well.

B: Tidal prescription

A tidal prescription for **SILENCIA** is illustrated below.

Fig. 3.55 Tidal prescription SILENCIA

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow, which is pressure-driven.

➢ Number of Base and Tidal cycles.

➢ Base inflow volume, Tidal inflow and outflow volumes.

➢ Dwell duration.

➢ Solution for the Base and Tidal cycles (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last inflow will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists.

Note

The selection for solution glucose allows mixing glucose concentrations like "1.5% + 2.3%" or "2.3% + 4.25%" or "1.5% + 4.25%". Using mixed glucose means that two separate solution bags with different glucose concentrations are connected to the cycler. Mixed glucose is allowed for the last inflow only if the same mixed glucose is used for the base cycles as well.

The **Calculated values** and the **Details** options are the same for standard prescriptions, described above.

C: Adapted APD prescription

An Adapted APD prescription for **SILENCIA** is illustrated below.

*Fig. 3.56 Adapted APD prescription - **SILENCIA***

The "adapted APD" therapy concept according to Prof. M. Fischbach consists of a standard prescription of 5 cycles, with 2 cycles of short dwell time and small inflow volume and 3 cycles of long dwell time and large inflow volume. The first 2 cycles aim to achieve ultrafiltration and the last 3 ones to promote proper clearance of uremic toxins with longer diffusion times such as creatinine and phosphate.

In case the patient's age is less than 2 years, the Adapted APD therapy is not available.

Input data for this prescription type are:

➢ Initial outflow volume - optional parameter. If the **Drain** option is checked, the cycler will perform an automatic initial outflow, which is pressure-driven.

➢ Cycles 1-2 data, in terms of Inflow volume and Dwell duration.

➢ Cycles 3-5 data, in terms of Inflow volume and Dwell duration

➢ Cycles 1-5 Solution (together with the Glucose and Calcium concentrations, all selectable from corresponding drop-down lists).

➢ Last inflow volume - optional parameter. In case the **Without inflow** option is checked, this last cycle will not be performed. If not checked, the last inflow volume value should be provided. The solution for this last inflow should be put in, in terms of name, glucose and calcium concentrations, all selectable from the corresponding drop-down lists.

Note

The selection for solution glucose allows mixing glucose concentrations like "1.5% + 2.3%" or "2.3% + 4.25%" or "1.5% + 4.25%". Using mixed glucose means that two separate solution bags with different glucose concentrations are connected to the cycler. Mixed glucose is allowed for the last inflow only if the same mixed glucose is used for the base cycles as well.

The **Calculated values** and **Details** sections are the same for standard and tidal prescriptions, described above.

● **APD Prescription - Other APD**

For the APD System **Other APD**, the tab will look as follows.
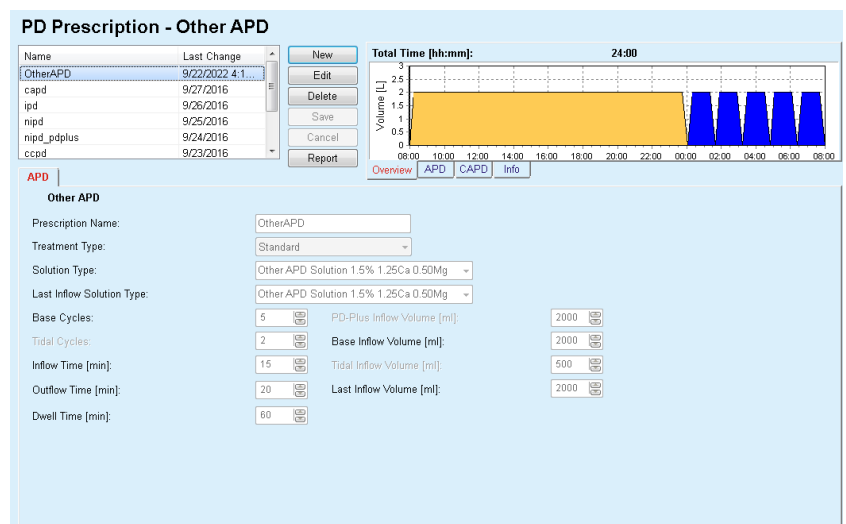
Fig. 3.57 PD Prescription window for Other APD system

The **PD Prescription Other APD** window is structured as follows:
General Settings upper part;
Prescription settings, the rest of the window;

In the **General Settings section**, the following entry fields are available:

> **Prescription Name** (enter);
> **Treatment Type** (select);
> **Solution Type** (select);
> **Last Inflow Solution Type** (select).

In the **Prescription Settings** section, you can change the following prescription parameters:

> **Number of base cycles;**
> **Number of tidal cycles;**
> **Inflow time;**
> **Outflow time;**
> **Dwell time;**
> **PD-Plus inflow volume;**
> **Base inflow volume;**
> **Tidall inflow volume;**
> **Last inflow volume.**

Note

The Other APD prescription cannot be written on the patient card.

● **CAPD Prescription**

If there is a CAPD part in a prescription, the CAPD window will look like the one illustrated in Fig. 3.58.

This window is divided in the following sections:

> **General settings** in the upper left corner,

> **Overview** pane in the upper right corner,

> **Exchange settings** at the bottom.
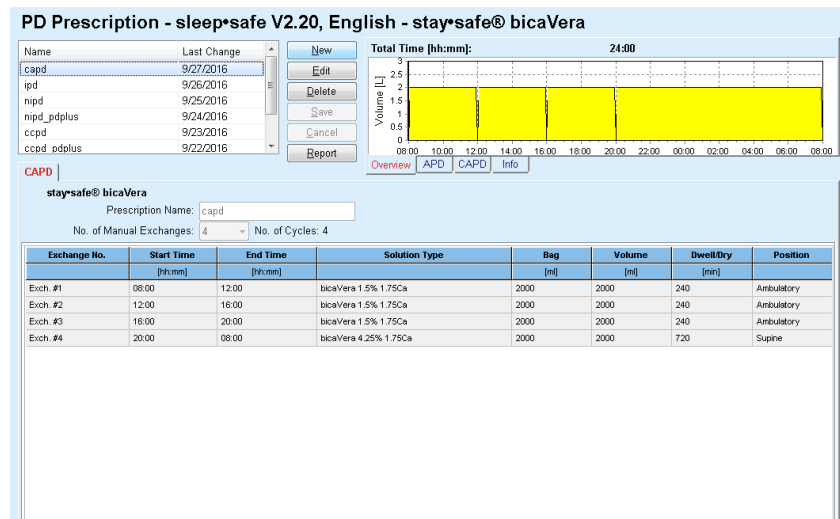
Fig. 3.58 CAPD Prescription window

In the **General settings** section, you can set the name of the prescription and select the number of exchanges. The **Overview** pane organization is similar to the one of the *sleep·safe* window.

The **Exchange settings** section allows the user to prescribe the desired values for **Start Time**, **End Time**, **Solution Type**, **Bag Volume**, **Volume**, **Dwell/Dry** and **Position** for each exchange of the treatment. You can do so by typing, selecting or using the arrow keys.

Tip

The quick-type philosophy of the Time Controls for editing the **Start Time** and **End Time** together with the cycle synchronization mechanism offers a fast and user-friendly tool for easier prescription of a CAPD treatment.

Tip

You can increase/decrease the hours by using the **PgUp**/**PgDown** keys, and increase/decrease the minutes by using the **Up**/**Down** keys. You can also directly type the desired value (see 4.2).

Tip

When editing the **Start**/**End Time** for an exchange, the cycle synchronization mechanism automatically shifts up/down the following exchanges to obtain a continuous 24-hour treatment.

Tip

To prescribe a **Dry Abdomen** interval, select the **Dry Abdomen** option in the **Solution Type** drop-down menu and set the **Start Time** and **End Time**.

Tip

The Dwell Time is automatically calculated for each cycle based on the **Start Time** and the **End Time**.

Note

If a prescription has both an **APD** and a **CAPD** part, the **Exchange settings** of the **CAPD** tab can have some restrictions (see Fig. 3.59, CAPD section of a combined PD prescription, page 120). The volume of the first CAPD cycle in the CAPD section of a combined PD prescription (see Fig. 3.59, CAPD section of a combined PD prescription, page 120) is imposed by the Last Inflow Volume of the **APD** part. Generally speaking, inflows and outflows that are performed by the cycler are controlled from the **APD** tab.

The **Position** can be **Ambulatory** or **Supine**, corresponding to the body position. For a night CAPD exchange, the position will usually be **Supine**.

The dark-yellow rows are related to the APD part (see Fig. 3.39, Limits and options for SILENCIA, page 98) and therefore certain values can not be modified from within the CAPD tab, but only from the APD one.

👉 **Note**

The total time for an APD-CAPD prescription is a multiple of **24 hours**. The dwell time of the last CAPD exchange is calculated so that a total time of 24 hours is reached. If the APD duration plus the CAPD duration exceeds 24 hours, the last CAPD dwell time will be adjusted so that the total time equals 48 hours.
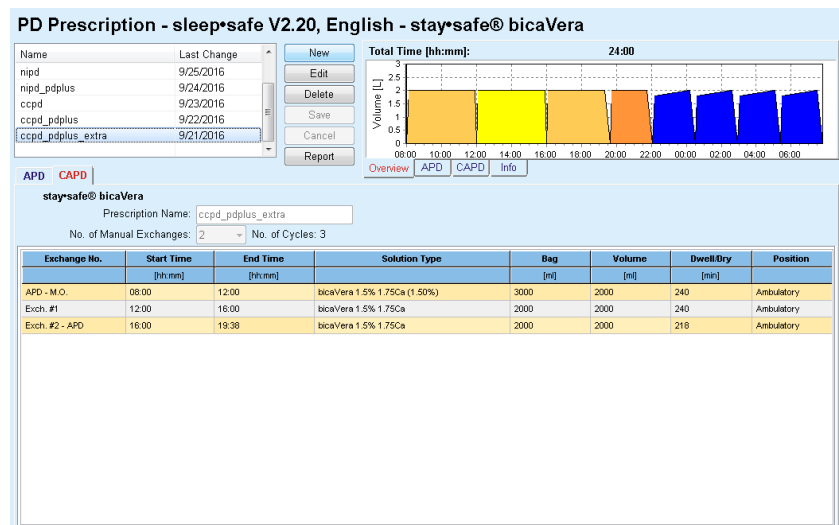
Fig. 3.59 CAPD section of a combined PD prescription

The first CAPD exchange has the same solution type and volume as the Last Inflow of the APD part. The inflow is performed by the cycler - **Last Inflow** of the APD part, while its outflow is performed manually - hence the name **APD - M.O.** (manual outflow) in the first column.

👉 **Note**

Usually, all APD prescriptions start with an **Initial Outflow**. However, for *sleep·safe* and **PD-NIGHT**, the APD prescription starts with **PD-Plus Outflow** if **PD-Plus** is active.

The last CAPD exchange has the maximum volume equal to the volume of the first outflow performed by the cycler (prescribed in the APD part). The inflow is performed manually, so the volume and the solution type are editable on the CAPD tab, while the outflow is performed by the cycler - **PD-Plus Outflow** or **Initial Outflow**, hence the name **Exch. #2-APD**.

In between the above mentioned two exchanges, there are purely manual ones, in which both the inflow and the outflow are performed manually. The number of exchanges counts only the manual inflows. There are two such manual inflows, namely **Exch #1** and **Exch. #2-APD**, in (see Fig. 3.59, CAPD section of a combined PD prescription, page 120).

This approach offers a great flexibility of day/night exchanges, which covers all the well-known PD treatments.

> **Note**
>
> The **Bag Volume** for the last CAPD exchange is selected so that it is greater than the inflow volume. The inflow volume is editable and it can exceed the first outflow volume (PD-Plus Outflow/Initial Outflow Volume) of the APD part. The **End Time** is imposed by the above mentioned total time calculation.

> **Note**
>
> The **Solution Type** for the first CAPD exchange is imposed by the APD part - Last Inflow Glucose.

● **Editing/Creating a PD prescription**

To create or edit a prescription for a given PD system, proceed as follows:

Select the patient from the **Patient Frame**;

➢ Check the patient's PD System;

> **Note**
>
> The user must ensure that APD/CAPD systems are assigned according to the medical needs.

➢ Select the **PD Prescription** menu item;

Fig. 3.60 PD Prescription menu item

➢ Select the **New** button to create a new prescription **or** the **Edit** button to update an existing prescription;

A treatment modality selection window will appear (see Fig. 3.61, Treatment modality selection window, page 122).

➢ Select the desired APD/CAPD combination;

In case the **Edit** button was clicked and the edited prescription does not have the same PD system as the one assigned to the patient, the user will be asked to confirm the conversion to the patient system.

In case the **Edit** button was clicked, the selection window will contain a check box labeled **Copy Prescription**. This is useful in case you want a new prescription with the initial content from an existing one. The check box is checked by default when a system conversion takes place;
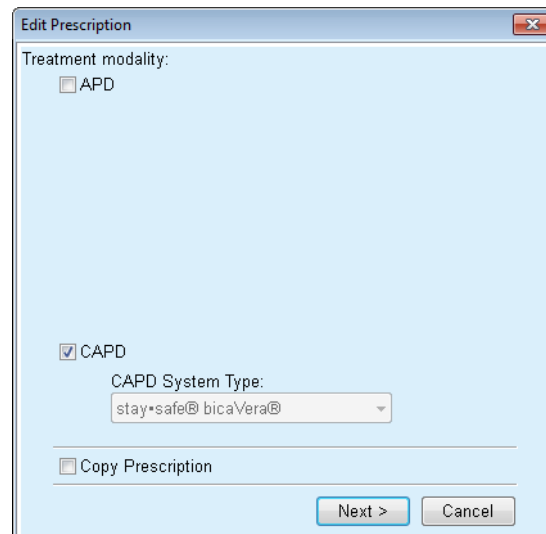
Fig. 3.61 Treatment modality selection window

➢ Click the **Next** button.

The initial screen of the APD or CAPD part appears, according to the previous selection. The **Save** and **Cancel** buttons are active, while the **New**, **Edit** and **Delete** buttons are inactive;

Edit the prescription according to the APD and/or CAPD part;

➢ Click the **Save** button.

The prescription will be saved. By clicking on the **Cancel** button, the process is canceled.

Note

If the APD settings of the prescription are somehow wrong, an error message is issued when the **Save** button is clicked. Select the **Ok** button and correct the errors or cancel the operation.

The same applies to the CAPD part.

If the editing operation was successful, a message is issued and the prescription record is updated in the **Prescription List**.

3.12.3 Treatment Analysis

3.12.3.1 General notes

This menu item offers the opportunity to analyze APD treatments based on treatment protocols recorded by *sleep•safe*, *sleep•safe harmony*, **PD-NIGHT PatientCard** and **SILENCIA** cyclers. Treatment protocols can be imported in **PatientOnLine** by using the **Communication** menu item. Selecting the **Medical/Treatment Analysis** menu item will display the Treatment Analysis window.

.

*Fig. 3.62 Treatment Analysis window - **sleep·safe***

The upper part of the window contains a table with summary data for all treatment protocols currently stored in the **PatientOnLine** database. Treatment protocols are sorted by treatment date: the most recent one is at the top. The most relevant data for the treatment (treatment status, volume balance, number of alarms, duration etc.) are displayed for each protocol. The user can also customize the appearance of the table columns to display or not display certain data for the treatment. For more information, see **Administration/Setup/View Settings**. A volume balance value that is outside limits is displayed in red. The Source column indicates the data source of the treatment protocol (e.g. Patient Card, Manually stored).

The table allows both single and multiple row selection. If multiple rows are selected, the currently displayed protocol will be the top one. On the bottom side of the window, there is a group of buttons that act on the currently selected treatment: **Report**, **Export**, **Delete**, **Summary** and **Statistics**.

In case the patient is assigned to a CAPD system, there is also a **New** button that allows documentation of CAPD treatment protocols, and an **Edit** button to modify them.

Clicking on the **Report** button opens a ready-to-print report for the currently selected protocol that contains all the available data.

PatientOnLine Report

Treatment Analysis
3/12/2001 2:16:49 PM

John Sample

3/15/1960

Allergic   Active   Diabetes Mellitus Type 1

Patient General Information

Patient Name:	John Sample				
Birth Date:	3/15/1960	PIN:	123456789		
Gender:	Male	External DB ID:			
System ID:	3AFFFC000002	PatientOnLine ID:	2	Institution ID:	
Language:	English	Blood group:	Unknown	Rh factor:	Unknown

Treatment Analysis - sleep•safe IR 77

General Information

Protocol Date:	3/12/2001 2:16:49 PM		
Protocol file:	TR200103.12A	Version:	V1.00 beta 4
Prescription:	----	Device ID:	98PEY1884
Treatment type:	Tidal Plus	Changed by patient:	No
Source:	Patient Card		

Prescribed Treatment

Number of base cycles:	1	Temperature: [°C]	37
Number of tidal cycles:	9	Safety volume: [ml]	150
Add. outflow screen:	Yes	Last bag alarm screen:	Yes

Cycle	Inflow			Dwell time	Outflow	
	Inflow volume	Inflow flow rate	Inflow solution		Outflow volume	Outflow flow rate
PD-Plus Outflow	--	--	--	--	3000	200
PD-Plus Inflow	2500	350	CAPD/DPCA 2 (1.50%)	--	--	--
Initial Outflow	--	--	--	--	2500	200
#1 / #1	2900	350	CAPD/DPCA 2 (1.50%)	35	1550	200
#1 / #2	1400	350	CAPD/DPCA 3 (4.25%)	35	1550	200
#1 / #3	1400	350	CAPD/DPCA 2 (1.50%)	35	1550	200
#1 / #4	1400	350	CAPD/DPCA 3 (4.25%)	35	1550	200
#1 / #5	1400	350	CAPD/DPCA 2 (1.50%)	35	1550	200
#1 / #6	1400	350	CAPD/DPCA 3 (4.25%)	35	1550	200
#1 / #7	1400	350	CAPD/DPCA 2 (1.50%)	35	1550	200
#1 / #8	1400	350	CAPD/DPCA 2 (1.50%)	35	1550	200
#1 / #9	1400	350	CAPD/DPCA 2 (1.50%)	35	3500	200
Last Inflow	0	350	CAPD/DPCA 2 (1.50%)	--	--	--

PatientOnLine 6.4

9/22/2022   6:44:19AM   1/4

Fig. 3.63 Treatment protocol report window

Clicking the **Export** button saves all selected treatment protocols as bi-nary file in the original format of the Patient Card. A **Browse for Folder** dialog is opened to specify the folder where these files are to be stored. The file names are the original ones, as they were on the Patient Card.

Clicking the **Delete** button will delete all selected treatment protocols. A confirmation message will be displayed for each protocol. You can apply the **Yes**/**No** option to all selected protocols by checking the **Apply all** check box.

Clicking the **Summary** button displays a ready-to-print report that contains the same data as the table in the **Treatment Analysis** window. Selecting this button opens the **Treatments Selection** pop-up window.

The following selection can be made:

> **All** or **From >>> Till** (option),
>
> **Start Date** (via calendar control),
>
> **Stop Date** (via calendar control).

➢ Click the **Yes** button.

The selection is accepted.

Selecting the **Statistics** button opens a pop-up window that allows complex graphical analysis of the treatment data. This window is described in the **Treatment Statistics** section.

In the lower part of the window, there are several tab controls offering a wide range of data in table format about the currently selected treatment protocol (see Fig. 3.62, Treatment Analysis window - sleep·safe, page 123).

The content and the name of these tabs depend on the cycler type.

The available tabs for the *sleep·safe* cycler are: **General Information**, **Prescribed Treatment**, **Performed Treatment**, **Results**, **Alarms**, **Comment**, **Graphics** and **Modified by Patient**.

3.12.3.2 CAPD Treatment Protocol

For patients assigned to CAPD systems or APD and CAPD systems, it is possible to document (create and edit) the CAPD treatment protocol. For such patients, in the **Treatment Analysis** menu, the following input data can be specified in the Treatment CAPD Wizard by selecting the **New** button:

➢ Number of exchanges.

➢ Dry weight - optional parameter.

➢ Systolic and diastolic blood pressure - optional parameters.

➢ For each exchange, the following parameters can be specified: inflow time, inflow volume, outflow time, solution type (selectable from a list of corresponding solutions for the patient's specific CAPD system) and an indication of medication administered during treatment (yes or no).

Click the **Save** button to save the CAPD treatment protocol or the **Cancel** button to cancel the operation.
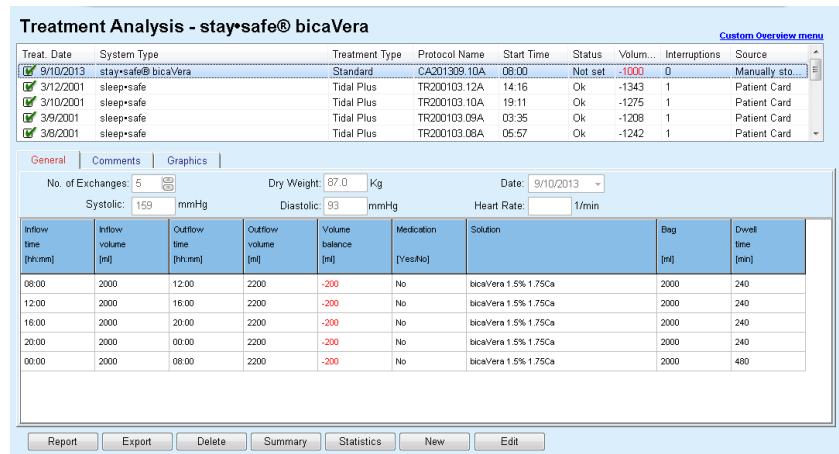
Fig. 3.64 CAPD treatment protocol window

The CAPD treatment protocols are listed in the treatment list located in the upper part of the Treatment Analysis window, together with some relevant data.

Once a CAPD treatment protocol is created, it can be edited at any time by selecting the desired CAPD treatment protocol from the list and clicking on the **Edit** button.

The **Comments** tab has the same functionality and can be operated as described in the corresponding section (see chapter 3.12.3.8, page 128).

The **Report, Export, Delete, Summary, Statistics** buttons have the same functionality as described before and can be operated in the same way as described in section Treatment Analysis (see chapter 3.12.3, page 123).

3.12.3.3 General Information tab (*sleep•safe*)

The **General Information** tab displays general data related to the currently selected treatment protocol, such as:

Protocol file
Name,

Prescription
Prescription name,

Treatment Type,

Version
Cycler software version

Device ID
Cycler device ID,

Modified by patient
Changes performed by the patient.

3.12.3.4 Prescribed Treatment tab (*sleep•safe*)

The **Prescribed Treatment** tab displays the prescription based on which the cycler performed the treatment. The prescription is taken directly from the treatment protocol and it may differ from the prescription that was originally prescribed for that particular date and stored on the Patient Card, because the patient may have changed the prescription and/or its content. The prescription is described on a cycle-basis, with relevant inflow/dwell/outflow data.

3.12.3.5 Performed Treatment tab (*sleep•safe*)

The **Performed Treatment** tab describes the treatment actually performed by the cycler. The same inflow/dwell/outflow approach is used, but in addition, the start time of each cycle and the duration of each phase are displayed.

Time [hh:mm:ss]	Cycle	Inflow volume [ml]	Inflow solution	Inflow duration [min]	Dwell time [min]	Outflow volume [ml]	Outflow duration [min]
14:32:07	PD-Plus Outflow	--	--	--	--	-3	3
14:35:18	PD-Plus Inflow	2501	--	9	--	--	--
16:50:57	Initial Outflow	--	--	--	--	2512	18
17:09:10	#1 / #1	2901	--	13	35	1550	11
18:07:28	#1 / #2	1401	--	6	35	1550	12
18:59:47	#1 / #3	1400	--	6	35	1550	11
19:51:15	#1 / #4	1400	--	6	35	1550	11
20:42:42	#1 / #5	1401	--	6	35	1550	11
21:34:08	#1 / #6	1400	--	6	35	1550	11
22:25:35	#1 / #7	1401	--	8	35	1550	11
23:19:31	#1 / #8	1401	--	6	35	1550	12

Report Export Delete Summary Statistics New Edit

*Fig. 3.65 Performed Treatment - **sleep·safe***

3.12.3.6 Results tab (*sleep·safe*)

The **Results** tab displays a significant amount of data extracted from the treatment protocol. The performed and prescribed (where appropriate) values are displayed for each item. For several parameters, relevant average (mean) values are calculated and displayed.

	Performed	Prescribed
Base cycle count	1	1
Tidal cycle count	9	9
Volume, PD-Plus outflow [ml]	-3	3000
Volume, PD-Plus inflow [ml]	2501	2500
Volume, initial outflow [ml]	2512	2500
Volume, last inflow [ml]	0	0
Volume, base/tidal inflows [ml]	14105	14100
Volume, base/tidal outflows [ml]	15448	15900
Volume balance, base/tidal cycles [ml]	-1343	-1800
Volume, total in [ml]	16606	16600
Volume, total out [ml]	17957	21400
Treatment duration [hh:mm]	08:21	08:48
Total dwell time [min]	316	315

Report Export Delete Summary Statistics New Edit

*Fig. 3.66 Results - **sleep·safe***

3.12.3.7 Alarms tab (*sleep·safe*)

The **Alarms** tab displays the alarms that occurred during the treatment in table format.

For *sleep·safe*, the following data is displayed regarding the pending alarm:

> Time of the alarm;
>
> Cycle and phase during which the alarm occurred;
>
> Current inflow/outflow volume of that phase;
>
> Current fluid volume inside patient;
>
> Alarm source code and the action that cleared the alarm, as well as the time when the alarm was acknowledge.

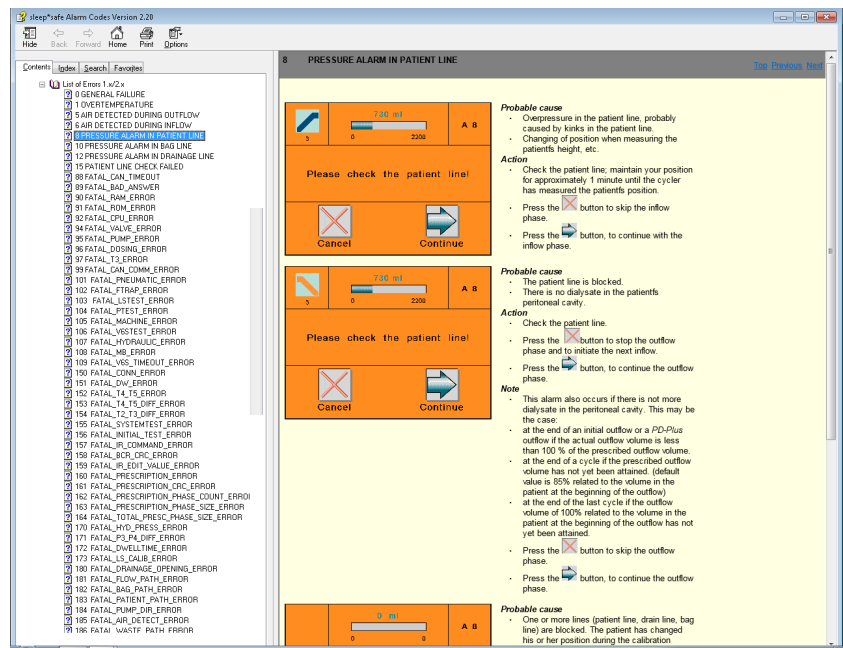If the user double-clicks on the alarm source-code table cell, a help window with a description of that particular alarm code is displayed.

*Fig. 3.67 Alarm codes help window - **sleep·safe***

For PD-NIGHT PatientCard, the number and type of alarms are displayed for each phase.

3.12.3.8 Comments tab (all devices)

The **Comments** tab allows the user to enter a specific comment for the selected treatment protocol. A check box named **Use in statistics** is provided for including/excluding the current treatment in/from the Statistics (see Treatment Statistics). To edit the comment and/or the statistics flag, select the **Edit** button. Clicking the **Save** button will finish the operation, while clicking the **Cancel** button will cancel it.

3.12.3.9 Graphics tab (*sleep·safe*)

The **Graphics** tab offers a graphical overview of both the prescribed and the performed treatment. The horizontal axis represents the time in hours. The vertical axis represents the volume inside patient in liters. In the lower part of the window, there is a horizontal time bar with the start and end time of the treatment.

If the treatment contains a PD-Plus cycle, the Prescribed graphic is synchronized with the Performed one, so that the PD-Plus outflow phases start at the same time. This approach is used because the PD-Plus duration depends on the patient and is not taken into account by the cycler.
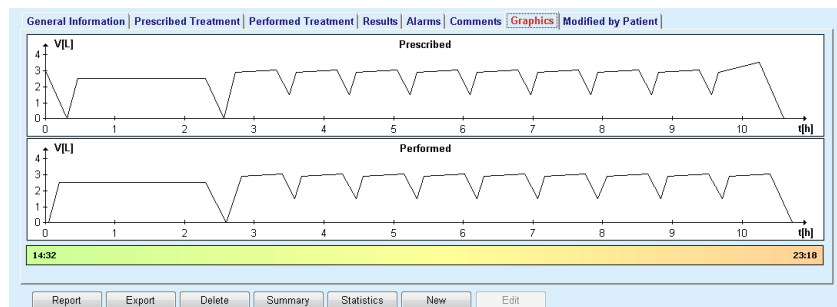
*Fig. 3.68 Graphics - **sleep·safe***

3.12.3.10 Treatment Statistics

The Treatment Statistics window is a pop-up window that is opened by clicking the **Statistics** button (see Fig. 3.69, Treatment Statistics window, page 130).

The Treatment Statistics module offers a complete graphical overview of the patient's outcome, based on some of the parameters of the performed treatments that are available for statistics.

The graphics are displayed in the lower part of the window while the upper part contains controls allowing the customization of the graphics.
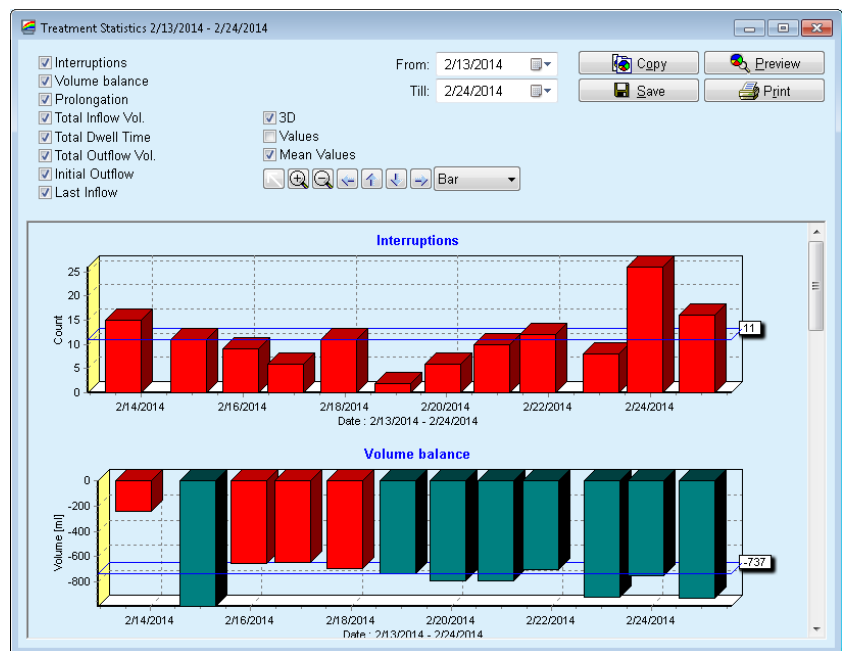
Fig. 3.69 Treatment Statistics window

By using the check boxes in the upper left corner, you can choose what type of information is of interest (alarms, volume balance, prolongation, total inflow volume, total dwell time, total outflow volume, initial outflow, last inflow).

The graphics are on a scrollable panel in the lower part of the window. Each one contains two axes: the horizontal axis (time axis) is located on the bottom of the graphic; the vertical axis (value axis) is located on the left side.

Each graphic has a title and an axis caption.

The graphics are available two-dimensionally or three-dimensionally, depending on the 3D check box selection.

By checking the **Values** check box in the upper part, the values will be displayed in the graphics.

The mean values can be shown/hidden by checking/unchecking the **Mean Values** check box in the upper part.
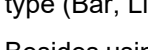
The graphics are correlated on the time axis and you can enlarge or reduce the visible period of time by using the **From**/**Till** calendar controls.

The graphics are flexible and can be customized using the tool-bar in the upper part. These tool-bar buttons have the following effects on all graphics:

Fig. 3.70 Graphics tool-bar

Reset button - reverts all changes;

Zoom In button - magnifies the graphics;

Zoom Out button - shrinks the graphics;

Left button - moves the graphics to the left;

Up button - moves the graphics up;

Down button - moves the graphics down;

Right button - moves the graphics to the right;

Bar ▾ Graphics type drop-down menu - for selecting the graphic type (Bar, Line, Point).

Besides using the tool bar buttons, you can also zoom in on the graphic using the mouse:

➢ Keeping the **left** mouse button pressed, select the area to be enlarged;

➢ Release the mouse button.

The selected area is zoomed in over the entire grid.

Tip

Keeping the **right** mouse button pressed, the selected area can be moved in the time axis (X axis).

By moving upwards/downwards (Y axis), the scale of the bar height can be changed.

The control buttons are in the upper left corner of the window (see Fig. 3.69, Treatment Statistics window, page 130).

The **Copy** button copies the graphics to the Windows clipboard so that it can be pasted and used in other applications (presentations, documents etc.).

The **Save** button allows saving the graphics to a bitmap file (*.bmp) on the hard disk.

The **Preview** button generates a report containing the patient's data and the treatment graphics for viewing and printing.

The **Print** button generates the same report and directly sends it to the default printer.

3.12.3.11 Treatment Analysis - *sleep•safe harmony*

The Treatment Analysis menu for the ***sleep•safe harmony*** cycler is illustrated in Fig. 3.71.

*Fig. 3.71 Treatment Analysis menu - **sleep•safe harmony***

The **Treatment Summary** tab displays the synthesized results of the treatment, such as total volumes, volume balance, number of cycles, treatment duration etc.

The **Prescribed Treatment** tab describes the prescription used to perform the treatment. The **Expand/Collapse** button shows or hides limits and safety parameters like the permitted patient volume.

The **Treatment Details** tab displays information about the performed treatment, at cycle level and also at phase level, on the two sub-tabs **Cycles** and **Phases**. Data such as timestamps, duration, volumes, and flow-rates are available here. The Number of interruptions column is also a link to the Interruptions tab.

Fig. 3.72 Treatment Details

The **Interruptions** tab displays the Cautions and the Alarms that occurred during the treatment. Information such as timestamp, cycle, phase, reason of the interruption, patient action and volume in patient is available. The Clear time column contains the time when the interruption was acknowledged.

Fig. 3.73 Interruptions

The **Graphics** tab illustrates the prescribed and performed treatment in graphical format. The maximum permitted volume and the minimum volume in patient are highlighted on the chart. The ultrafiltration (UF) is displayed in yellow.

Fig. 3.74 Graphics
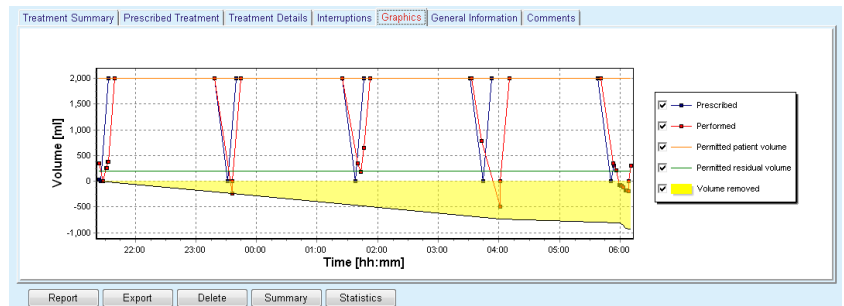
The **General Information** tab displays administrative data, such as treatment start and stop times, device serial number and software version etc. The Comments tab is identical to all other cycler types.

3.12.3.12 Treatment Analysis - SILENCIA

The **Treatment Analysis** menu for the **SILENCIA** cycler is illustrated below.

*Fig. 3.75 Treatment Analysis menu - **SILENCIA***

The **Treatment Summary** tab displays the synthesized results of the treatment, such as total volumes, volume balance, number of cycles, treatment duration etc.

The **Prescribed Treatment** describes the prescription used to perform the treatment. The **Expand/Collapse** button shows or hides limits and safety parameters like the permitted patient volume.

The **Treatment Details** tab displays information about the performed treatment, at cycle level and also at phase level, on the two sub-tabs **Cycles** and **Phases**. Data such as timestamps, duration, volumes, and flow-rates are available here. The **Number of interruptions** column is also a link to the **Interruptions** tab.

Fig. 3.76 Treatment Details

The **Interruptions** tab describes the **Cautions** and the **Alarms** that occurred during the treatment. Information such as time, cycle, phase, reason, and volume in patient is available. The **Clear time** column contains the time when the interruption was acknowledged.

– For **SILENCIA** devices with software version 2.0 only:
In the **Treatment Analysis** menu, the number of "cautions not requiring operator action on the device" will be shown in parentheses next to the number of interruptions or the number of cautions, respectively.
In the **Interruptions** tab, these cautions will be described as **Low flow notification**. There will be no entries in the columns **Result** and **Volume in patient**. If such cautions result in "cautions requiring operator action on the device", they will appear as new entry in the next line.
"Cautions not requiring operator action on the device" will not be included in the interruptions count of the treatment statistics.

Fig. 3.77 Interruptions

The **Graphics** tab illustrates the prescribed and performed treatment in graphical format. The **Permitted patient volume** and the **Permitted residual volume** in patient are highlighted on the chart. The volume balance is displayed in yellow. The graphic is similar to the one in Fig. 3.74.

The **General Information** tab displays administrative data, such as treatment start and stop times, device serial number and software version etc. The **Comments** tab is identical to all other cycler types.

3.12.4 Quality Assurance

3.12.4.1 Medical Background

The **Quality Assurance** menu item offers a wide range of tests for the physician to obtain an estimation of the patient's PD adequacy. The available tests are:

PFT (Peritoneal Functional Test),

24 hour Batch Collection;

PET (Peritoneal Equilibration Test),

PET + 24 hour Batch Collection;

No RRT (No Renal Replacement Therapy).

Data and results are structured in **Input data**, **Results** and **Graphics**.

● **Peritoneal Functional Test**

The PFT test documents many important peritoneal and patient characteristics. It requires measurement of urea, creatinine, glucose, total protein, sodium and volume for each individual exchange during a specific period of time. This test allows the calculation of important peritoneal transport characteristics, while providing useful information about protein nutrition, glucose absorption and a measure of adequacy of the peritoneal dialysis prescription.

The test consists of a 24-hour sample of individual, drained exchanges before a scheduled clinic visit, a daily urine collection when urine exceeds 100 ml/24 hours, and one or two blood samples obtained in the clinic, where the patient outflows the last dialysate exchange and performs special QA exchanges. Each individual exchange sample and the blood sample are analyzed for urea, creatinine, glucose, and protein. The urine sample is analyzed for urea, creatinine and protein.

● **Peritoneal Equilibration Test**

The PET test is designed to measure peritoneal transport for urea, creatinine and glucose under controlled clinical conditions. A standard exchange is used, and specific dialysate samples are taken at periodic intervals. A blood sample is taken at a predefined point in time. The only calculated parameters are the peritoneal transport characteristics for urea, creatinine and glucose.

● **24 hour Batch Collection Test**

The 24 hour Batch Collection test assumes that all drained dialysate exchanges during 24 hours are collected and mixed. The total drained volume is recorded and urea and creatinine are measured for the collection. Urine is also collected for 24 hours and a blood sample is taken. Urea, creatinine and protein are measured for dialysate, urine and blood. This test will calculate the amount of therapy received by the patient, but will not allow calculation of energy absorption from glucose. Peritoneal transport characteristics are not calculated either.

● **PET + 24 Hour Batch Collection Test**

This test combines the advantages of the PET and 24 hour Batch Collection tests, although it requires input data from both tests. It can calculate almost the same results as the PFT test (except for glucose absorption).

● **No Renal Replacement Therapy Test**

This test is dedicated to patients that are not receiving dialysis therapy. It requires a blood sample and a urine collection. The main purpose of this test is to calculate the renal function and the renal clearance of the patient.

● **QA Input Data**

QA tests require several types of samples and input data. The number of parameters that are actually measured may vary from test to test. For example, protein measurement is optional in all tests.

When entering data, measurement units can be fully customized for each parameter. **PatientOnLine** can deal with both Conventional and S.I. measurement units. In **Administration/Setup/Lab Data Settings** menu item, you can choose the desired measurement unit for each input parameter. Urea or Urea Nitrogen can be selected as input for blood, urine and dialysate samples (see **Lab Data Settings**, page 211).

Besides the above sample parameters, QA tests require certain patient data like gender, age, weight, and height. Weight and height can be entered either in **kg & cm** or in **pounds & inches**. The same menu item, **Administration/Setup/Lab Data Settings** allows the switching from one system to another (see **Lab Data Settings**).

Other input data, like sample time, blood volume, urine volume and dialysate inflow and outflow volumes and solution glucose concentrations are required in QA tests.

The solution glucose concentration can be input either as a percent value restricted by some limits or as special values, like PG - Polyglucose, AA - Amino Acid, NN - No name or any other non-glucose value. In case of such special non-glucose values, the dialysate sample is not taken into consideration for computing glucose-related results.

Note

In case certain dialysate glucose concentrations have special values, like "**AA**", "**PG**" or "**NN**", the **Pt50** glucose result is calculated without those dialysate samples.

● **QA Results**

QA Results are grouped by their functionality and are listed below.

Body Results - Anthropometric results: BSA, VSA, nBW, BMI.

Renal Function - Urea and creatinine renal clearances: KrU, KrCr, GFR, nGFR;

Urea Results - Parameters of peritoneal dialysis therapy calculated from urea kinetic analysis: KpT/V, KrT/V, KprT/V, KprTw/V;

Creatinine Results - Results of analysis of the level of creatinine clearance provided by the current peritoneal dialysis therapy: KpT/V, KrT/V, KprT/V;

Fluid Removed Results - This section provides an overview of fluid loss via peritoneal or renal removal per day;

Peritoneal Function Results - This section gives the calculated Pt50 values for urea, creatinine and glucose, as well as the D/P for creatinine at 4 hours, the max. UF, small pore UF and the free water transport.

Glucose Results - Results concerning the amount of glucose absorbed by peritoneal dialysis: TGA, TCal, nCal;

Protein Nutrition Results - This section summarizes the indices of protein nutrition: PCR, nPCR, DPL, nDPL, UPL, nUPL, TPL, nTPL, DPR, nDPR;

Creatinine Generation Results - Predicted GCr, Calculated GCr, Variance;

Lean Body Mass Results - Predicted LBM, Calculated LBM, Variance;

Energy Metabolism Results - EREE, nEREE, GA/EREE;

Na Removed Results - Dialysis, Renal, Total, Total Salt (NaCl)

Note

The parameters Max. UF, SPUF and FWT derive from studies by La Milia et al. (see references 23 and 24 from Chapter 5.1).

The Maximum UF (**Max. UF**) represents the ultrafiltration obtained with the QA UF sample, that uses a hypertonic solution (4.25% glucose), measured at one hour after instillation.

The small pore UF (**SPUF**) represents the ultrafiltration due to transport of water through the small pores. This **SPUF** is estimated from the ratio of sodium removal during the QA UF sample to plasma sodium.

The free water transport (**FWT**) represents the transport of water through ultra-small pores (aquaporin). It is calculated as the difference between **Max. UF and SPUF.** This calculation may produce a slight overestimation of **FWT** (less than 3%) since it is not corrected for sodium diffusion.

Note

QA results depend on the current QA formulae for adults/children and also on other QA settings (see chapter 3.15.4, page 207).

In case PatientOnLine client-server is connected to EDBMS, the QA formulae and QA settings are provided by the EDBMS.

Upon first data synchronization with EDBMS, previous existing QA test results may be recalculated according to the QA formulae and QA settings provided by the EDBMS. For example, a result like Kt/V may slightly differ because the formula for V (total body water) may have been changed.

● **QA Graphics**

Besides numerical results expressed as such, **PatientOnLine** offers a number of QA Graphics in order to provide better interpretation.

Peritoneal Function Graphics (Pt50 Graphics, PET Graphics) - These graphs are drawn in **PFT**, **PET** and **PET+24 hour Batch Collection tests for urea**, **creatinine** and **glucose**. The graphs express the peritoneum transport dynamical characteristic or the transition from one steady state to another (see Fig. 3.78, PET Urea Graphic, page 139), (see Fig. 3.79, PFT Pt50 Creatinine Graphic, page 139).

For urea and creatinine, the dialysate/plasma concentration ratio is calculated and drawn corresponding to the sample time. For glucose, the current/initial concentration ratio is drawn. These graphs allow an immediate evaluation of the Pt50 values for urea, creatinine and glucose, as well as the transport classification (high, high-average, average, low-average or low). The background of the graphic is based on Twardowski's transport classification in case of adults, and on Warady's classification in case of children. The background graphs are automatically switched for adults/children, depending on the adulthood status of the patient.
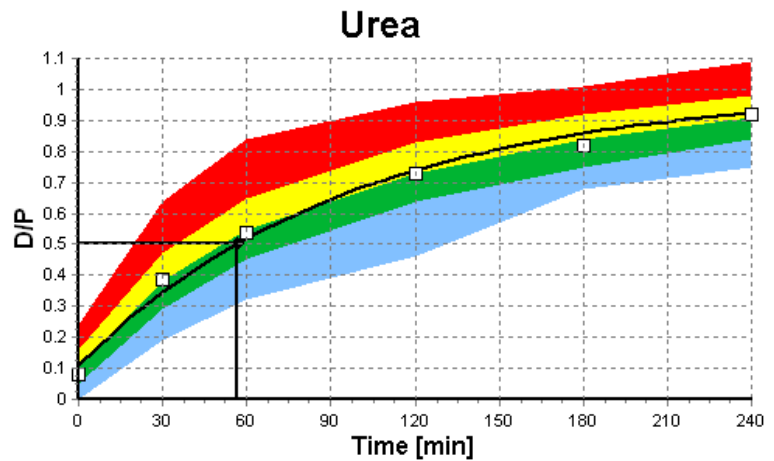
Fig. 3.78 PET Urea Graphic
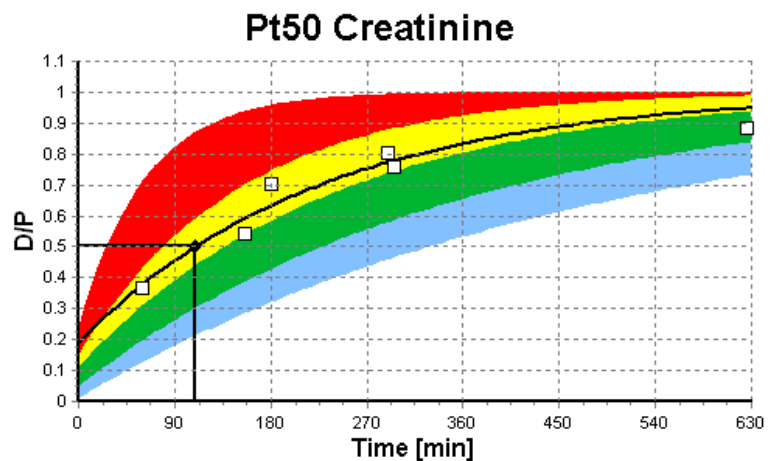
Fig. 3.79 PFT Pt50 Creatinine Graphic

QA Graph

This graph is drawn in the **PFT**, **24 hour Batch Collection**, **PET+24 hour Batch Collection** and **No RRT** tests. It expresses BUN related to nPCR at specific levels of KprTw/V (total weekly urea clearance), depicted over a range of 0.70 to 3.36. The heavy lines represent by default KprTw/V values of 1.4 and 2.0, (daily KprT/V of 0.2 and 0.285). These values can also be changed in the **Administration/Setup/General Settings** menu.
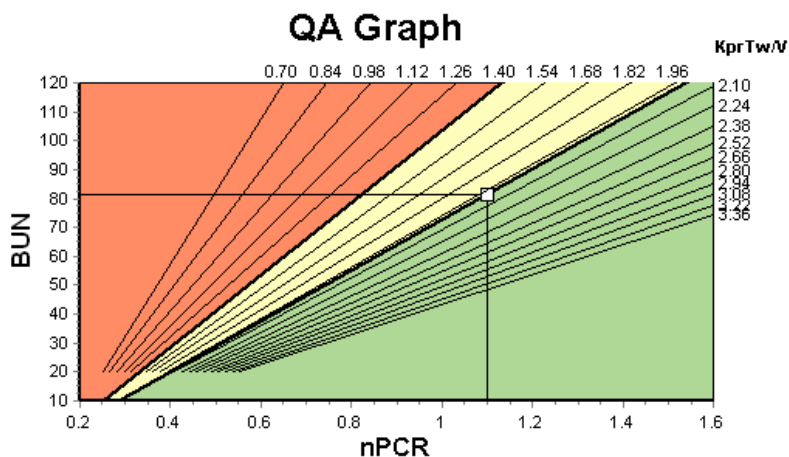
Fig. 3.80 QA Graph

Minimum Therapy Graph

This graph is based on the minimum criteria for an adequate peritoneal dialysis prescription. The ordinate is weekly creatinine KprT [L/1.73 m2/Week] while the abscissa is the weekly KprTw/V for urea. The vertical reference line is defaulted at urea KprTw/V of 2.0, while the horizontal reference line is defaulted at creatinine KprT of 50 L/1.73 m2/Week. These values can also be changed in the **Administration/Setup/General Settings** menu. Adequate peritoneal dialysis therapy by both these criteria will occur only in the right upper quadrant of the graph. The patient is considered to fail both criteria if the value falls in the lower left sector of this graph.
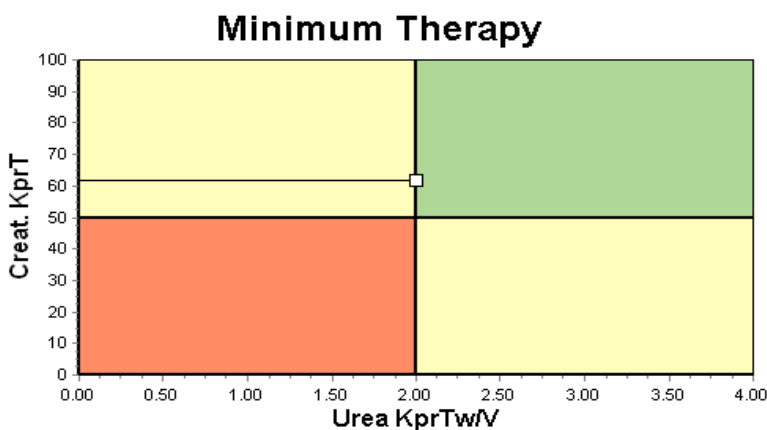
Fig. 3.81 Minimum Therapy Graph

3.12.4.2 Quality Assurance Menu

The Quality Assurance menu is displayed by clicking on **Quality Assurance** in the Menu Tree. The window content is displayed in (see Fig. 3.82, QA PFT Input Data, page 141).

In the upper-left part of the window there is a table with the stored QA tests for the current patient. The type of test and the test date are displayed. Selecting a table row will refresh all the QA data in the window. On the upper-right side there is an area describing the QA-relevant patient data (age, gender, weight, height, the notification Amputated if the patient was amputated at date of the test - see Amputation) and the Body Results for the selected test. If the patient is amputated, the body results are calculated according to the amputation status at the date of the test, which will influence all the results of the performed test.

In the lower part of the screen there is a working area with three tabs - **Input Data**, **Results** and **Graphics**. The content of each tab depends on the test type, but all the data and graphics follow the description in the Medical **Background** section.

Input Data tab

The PFT test assumes the following data:

A blood sample, for which albumin, urea/urea nitrogen, creatinine, glucose and protein concentrations are recorded;

An urine sample for which collection time, collected volume, urea/urea nitrogen, creatinine and protein concentrations are recorded;

Several (1 to 6) dialysate samples and optional QA and QA UF dialysate ones, for which the dwell time, the inflow and outflow volumes, the initial glucose concentration (in %), urea/urea nitrogen, creatinine, glucose and protein concentrations are recorded. For the QA UF sample, the glucose concentration is fixed at 4.25% and the dwell time is fixed at 1 hour.

	Time [min]		Albumin [g/dL]	Glucose conc.[%]	Na in [mEq/L]	Vol Out [mL]	Urea [mg/dL]	Creatinine [mg/dL]	Glucose [mg/dL]	Protein [g/dL]	Na [mEq/L]
Blood			3.7				174.74	9.50	68.5	6.6	112.3
Urine	1440	250					888.76	67.92			150.0
PD Fluid											
Bag 1	290	2200	1.50		134.0	2440	175.34	8.14	403.6	0.0900	134.2
Bag 2	295	2200	1.50		134.0	2430	176.54	7.67	464.9	0.0800	134.2
Bag 3	155	2200	1.50		134.0	2290	150.73	5.48	659.5	0.0360	134.2
Bag 4	625	2200	1.50		134.0	3050	182.55	8.93	501.7	0.1000	134.2
QA Bag	180	2200	2.30		134.0	2530	165.14	7.12	724.3	0.0540	134.2
QA UF Bag	60	2200	4.25		133.2	2693	96.47	3.70	2400.0	0.0300	123.2

Fig. 3.82 QA PFT Input Data

The inputs are not all mandatory. Some may be missing, but certain results may be affected by the missing values or may be missing entirely. In certain cases, **PatientOnLine** will estimate/replace the missing value. A missing value field will have a hint "**Missing value**". A missing value that was estimated by **PatientOnLine** will have a hint "Missing value - Estimated to: xxx".

Creatinine with Glucose Correction Factors for blood and dialysate may be set on a QA test basis, in addition to the global settings from **Administration/Setup/General Settings**. The default values are the global settings ones, but are editable in any QA test.

Results tab

The PFT test calculates all the results described in the QA Results section. If there is missing input data, then there will be missing results. If, for example, the urine protein value is not available, there will be no UPL and nUPL results, which will affect TPL, nTPL, DPR and nDPR also. Results that are calculated based on missing and/or estimated input data are displayed in boldface.
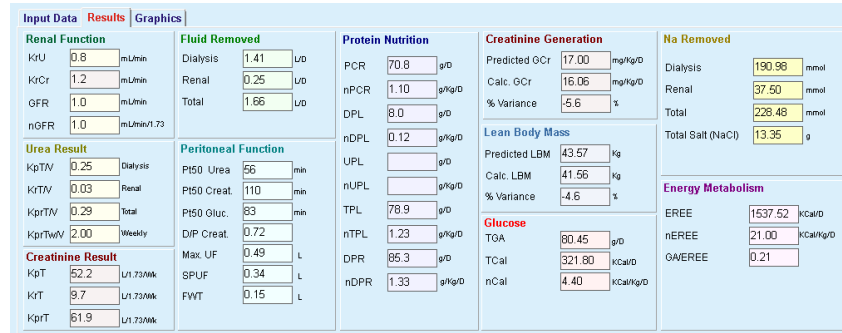
Fig. 3.83 QA PFT Results

Graphics tab

The PFT test can display all graphics described in the QA Graphics section: Pt50 for urea, creatinine and glucose, QA Graph and Minimum Therapy Graph. If there is missing input data, then there will be missing graphics. If, for example, the blood urea nitrogen value is not available, there will be no Pt50 graphic for urea.

Fig. 3.84 QA PFT Graphics

PET Input Data

The PET test assumes the following data:

> A blood sample, for which albumin, urea/urea nitrogen, creatinine, glucose and protein concentrations are recorded;

Fig. 3.85 QA PET Window

3 (Short PET) or 5 (PET) dialysate samples with fixed time values (0, 30, 60, 120, 240 min) are defined, as well as the bag inflow volume, and the initial glucose concentration. For each sample, urea/urea nitrogen, creatinine, glucose, protein and sodium concentrations are recorded. Optionally, there may be an extra 180 min sample record, set from Administration/Setup/General Settings menu item. There is also an optional Overnight Bag.

PET Results

The PET test calculates only the D/P values for urea, creatinine and glucose, as well as D/P for creatinine at 4 hours.
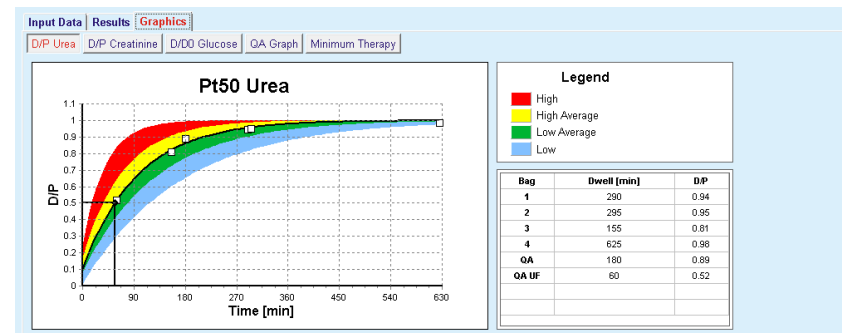
PET Graphics

The PET test displays the PET graphics (described in QA Graphics) for urea, creatinine and glucose. If there is missing input data (see Creating and Editing a QA Test), then there will be missing graphics. If, for example, the blood creatinine value is not available, there will be no PET graphic for creatinine.

24 hour Batch Collection Input Data

The 24 hour Batch Collection test assumes the following data:

A blood sample, for which albumin, urea/urea nitrogen, creatinine, glucose, protein and sodium concentrations are recorded;

A urine sample for which collection time, collected volume, urea/urea nitrogen, creatinine, protein and sodium concentrations are recorded.

A dialysate collection for which collection time, total inflow and outflow volumes and urea/urea nitrogen, creatinine, glucose, protein and sodium concentrations are recorded.

24 hour Batch Collection Results

The 24 hour Batch Collection test calculates the same results as the PFT test, except Peritoneal Function and Glucose results.

24 hours Batch Collection Graphics

The 24 hours Batch Collection test displays only the QA Graph and the Minimum Therapy Graph (described in the QA Graphics section).

PET + 24 hour Batch Collection Input Data

The PET + 24 hour Batch Collection test is a true combination of PET and 24 hour Batch Collection tests. The input data is a combination of both tests.

The missing values in a PET+24 hour Batch Collection follow the description of missing data in each of the components. In addition, missing values for one of the two blood samples are replaced by default with corresponding values from the other one.

PET + 24 hour Batch Collection Results	The PET + 24 hour Batch Collection test calculates the same results as the PFT test, except for the Glucose results.
PET + 24 hour Batch Collection Graphics	The PET + 24 hour Batch Collection test displays both PET Graphics and QA Graphics.
No RRT Input Data	The No RRT test is similar to the 24 hour Batch Collection one, but without the dialysate collection. It assumes the following data:

> A blood sample, for which albumin, urea/urea nitrogen, creatinine, glucose, protein and sodium concentrations are recorded;

> A urine sample for which collection time, collected volume, urea/urea nitrogen, creatinine, protein and sodium concentrations are recorded.

No RRT Results	The No RRT test calculates the renal function and renal clearances, as well as nutrition results.
No RRT Graphics	The No RRT Results tab displays only the QA Graph and the Minimum Therapy Graph (described in the QA Graphics section).

● **Creating and Editing a QA Test**

To create a QA test for a certain patient, one has to proceed as follows:

➢ Select the patient from the **Patient Frame**;

➢ Select the **Quality Assurance** menu item from the Menu Tree;

➢ Click the **New** button;

The Add QA Test dialog box opens;
(see Fig. 3.86, The QA Test wizard (first page), page 145);

➢ Select the desired date in the **Date** control or preserve the current date displayed;

The age of the patient at the time of test will be automatically refreshed;

➢ Enter the patient's weight in the **Weight** field.

➢ Enter the patient's height in the **Height** field.

Note

– If there are height records for the patient, the most recent height will be displayed as default. Weight values must always be entered in order to provide the weight on the date of the test;

Fig. 3.86 The QA Test wizard (first page)

➢ Select the type of test using the radio button group.

According to the selection, the following additional selection possibility may be available:

> PFT - number of bags;
>
> QA bag; QA UF bag;
>
> Number of treatments/week;
>
> PET - short/extended test;
>
> Overnight bag.

➢ Click the **Next** button.

The second dialog box of the wizard is opened, specific for each type of test.

The number of treatments/week influences the calculation of weekly clearances for urea and creatinine.

Warning

Risk for the patient as a result of insufficient detoxification

It may be the case that the PD treatment is not performed every day of the week. If the number of treatments/week is less than 7, the weekly clearances may be over-estimated.

➢ The attending physician should be aware of this possible over-estimation of the weekly clearances when assessing the adequacy of dialysis for the patient.

In the second dialog box of the wizard one has to fill in all the mandatory data (see Quality Assurance Window for a description of input data specific to each type of test). All input controls are Smart Edit controls, without the small buttons on the right side. Each control has an associated hint indicating the value range. The value range for certain parameters (like inflow volume) depends on the adulthood status of the patient. After filling in all Smart Edit Controls, one has to select the **Next** button to go to the next dialog box of the wizard.

On the second page one can also save the test as draft, by selecting the **Save as Draft** button.

This is useful in case the user is called in for an emergency and he/she didn't have the chance to fill in all data.

A draft test is marked with a brown color in the third column of the tests table (see Fig. 3.82, QA PFT Input Data, page 141).
For such a test one can view neither the results nor the graphics. The only allowed actions are **Edit** and **Delete**. A draft test can not be used in the Modeling section (see Modeling), nor can it be printed by using the **Report** button.

Fig. 3.87 The QA Test wizard (second dialog box)

Note

When selecting the **Next** button, a validation of input data is performed. If the data entered on the second page does not comply with the test requirements described in the Quality Assurance Window section, a warning message will be issued.

One has to select the **Ok** button and correct the values before the process can be continued.

The third dialog box of the wizard allows the user to bypass the computation of V, LBM, nPCR and KrT/V results and enter these values by hand. This is useful if one uses special devices/algorithms for measuring/computing these four parameters.

Fig. 3.88 The QA Test wizard (third dialog box - PFT test)

To enter user defined values on the third dialog box of the wizard one has to check first the corresponding radio button in order to enable the **Previously Stored** text field. Afterwards, the desired value can be entered.

BCM values for urea distribution volume and lean tissue mass are available on this page. Values are by default taken from the latest BCM measurement of the patient but one may select particular measurement as well. Only BCM measurements within the past 180 days are available. There are two buttons that can be used to set BCM values as **Previously stored** values for **V** and respectively **LBM.**

Clicking on the **Finish** button will save the whole test. One can cancel the editing process by selecting - on any page of the wizard - the **Cancel** button.

Note

The data entered by hand on the third (final) page of the wizard may affect the further computation of the results. The result values that are affected will be highlighted on the Results page, using a light yellow color and in the Report.

Fig. 3.89 Highlighted Results data

➢ Select the **Quality Assurance** menu in order to edit a QA test (see Fig. 3.82, QA PFT Input Data, page 141).

➢ Select the desired row in the test table;

➢ Click the **Edit** button.

The wizard is opened, in which one can edit all the values except the test type.

The **Delete** button allows for an entire deletion of a QA test while the **Report** button displays/prints a comprehensive report that includes all input data and results, both in text and graphical format, together with the formulae used for computing the results.

3.12.5 Modeling

3.12.5.1 Medical background

The Modeling item is one of the most powerful features of **PatientOnLine**. It is a valuable tool that can assist the physician - without substituting his/her medical judgment - in evaluating and predicting a PD treatment, in terms of dialysis outcome, as well as in searching for the best PD treatment that meets certain dialysis targets.

Modeling assumes that knowledge about the renal and the peritoneal function of the patient is available, by means of a QA test. The more comprehensive a test is, the better the accuracy of modeling. The patient data that is relevant for the modeling are the residual renal function, the renal fluid balance and the peritoneal function.

For patients that are not yet on a dialysis treatment, one can use the **No RRT** test which calculates renal function and renal clearances. Peritoneal function characteristics, can be set to average values.

There are two modeling methods:

By choosing the PD prescription

By choosing the dialysis targets.

The first method assumes a QA test and a PD prescription (CAPD, APD, APD+CAPD) as primary input data. The user can freely change the prescription and the patient's renal parameters. The Prescribed Therapy Outcomes are calculated in terms of total clearances, total removed fluid and total glucose absorption. The outcomes can be viewed for each cycle/exchange as well as for the entire prescription.

The second method assumes a QA test, a list of dialysis targets that must be achieved and a list of dialysis restrictions as primary input data. Targets are expressed in terms of minimum clearances and volume balance. The restrictions depend on the selected treatment modality (APD, CAPD, APD+CAPD) and are expressed in terms of maximum values for certain parameters like inflow volume, number of cycles, total prescription time etc.

Note

– The displayed modeling results are based on a mathematical model and should only be regarded as a guide. Therapeutic decisions must never be made solely on the basis of these calculations. The deployment of any PD treatment regimen remains the responsibility of the attending physician.

– The prediction accuracy of modeling has been validated in three studies (see References 21, 23, and 39 in Appendix 5.2) for 'standard PD treatments'. In APD Treatment regimens involving 'mixed cycles' (i.e. a sequence of cycles with different glucose composition or varying dwell periods and varying volumes), the same mathematical model is applied to each cycle as in the case of a 'standard APD treatment' regimen. Evidence regarding the prediction accuracy of 'mixed cycle' APD Treatment regimens is lacking currently. The same is true for treatments including 'tidal cycles'. Therefore the discrepancy between predicted and actual toxin removal may be greater than the limits of agreement determined in the existing studies referenced above.

PatientOnLine will determine a list of prescriptions that meet all the restrictions and achieve the specified targets. Each prescription can be analyzed for details and saved. Moreover, a prescription can be fine-tuned using the first modeling method, by means of an Optimize feature.

Note

Be aware that when the attending physician requires profiled cycles (a sequence of cycles with changes in fill volume, glucose concentration or dwell duration), the capabilities of the mathematical models on which the POL modeling functions are based, are challenged. While useful in gaining an impression of the direction in which clearance is likely to be modified, precise values cannot be guaranteed. The treatment program remains the responsibility of the physician. The efficacy of any program involving profiled cycles can be verified by measurements according to the quality assurance procedures.

3.12.5.2 Starting a Modeling session

The Modeling menu item is available in the Medical section of the Menu Tree.

Fig. 3.90 Modeling menu item

The Modeling menu includes the following sections:
(see Fig. 3.91, Modeling: By choosing the prescription, page 150)

> Select the Modeling method in the upper part;

> Modeling General area in the middle;

> Start Modeling in the lower part.

This module allows the user to model PD prescriptions for a certain patient, with one of the two possible modeling methods described in the Modeling - Medical background section.

3.12.5.3 Modeling: By choosing the prescription

This modeling method allows the user to edit an existing prescription, using the same editors as in the PD Prescription section, but with an instant view of the prescribed therapy outcomes.

By selecting this radio button in **Select Modeling Method**, the lower area will look like in Fig. 3.91.
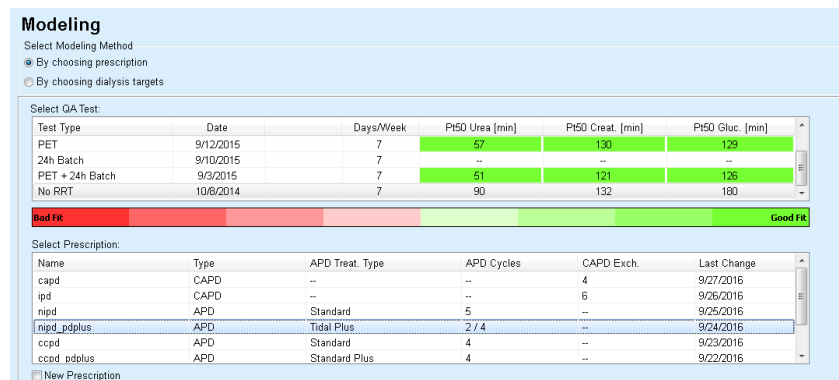
Fig. 3.91 Modeling: **By choosing the prescription**

The **Modeling General area** for this method is divided into the following sections:

> **Select QA Test** in the upper part;

> **Select Prescription** in the middle;

> **New Prescription** in the lower part.

The **Select QA Test** list displays all the QA tests performed by the patient. The test type and date are displayed, together with the Pt50 values for urea, creatinine and glucose. Each Pt50 value is displayed on a colored background that illustrates the accuracy of the Pt50 value, described as the fitting degree of the D/P or D/D0 points onto the QA graphs (see Quality Assurance - Peritoneal Function Graphics). On the bottom of the list there is a color legend, with several colors ranging from Red - Bad Fit to Green - Good fit. A green color means accuracy of more than 90%, while a red one means accuracy below 50%.

The **Select Prescription** list displays all available prescriptions. In both, the **Select QA** Test and in the **Select Prescription** list, the first row is selected be default.

A non-draft QA test must be selected. One must either select an existing prescription or check the **New Prescription** check box in order to start modeling.
(see Fig. 3.91, Modeling: By choosing the prescription, page 150)

Note

A warning message will appear if no QA test or no prescription is selected.

In order to start the modeling session one must press the **Start Modeling...** button. If a PD Prescription was selected, a window similar to the one illustrated in Fig. 3.92 will be displayed.

Fig. 3.92 Prescription modeling by choosing the prescription - sleep·safe

If **New Prescription** was selected in (see Fig. 3.91, Modeling: By choosing the prescription, page 150), the user will be asked to choose a PD system for the new prescription. No restrictions apply, even if the patient does not have a PD system assigned. This is particularly useful in case of new patients, for which a therapy was not yet set. The PD system is selected by means of an intermediate window.

See in Fig. 3.93 which APD and/or CAPD systems can be chosen. If the patient has a PD system assigned, the system components - APD and/or CAPD - will be used as default for the two selection lists. Still, the user is allowed to freely change the system.
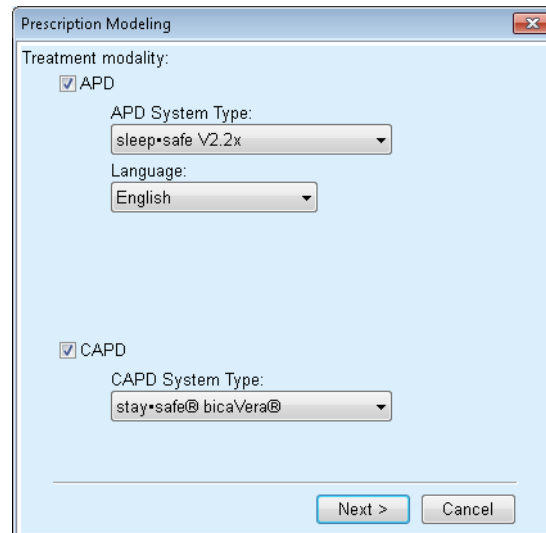
Fig. 3.93 Selecting a PD System for a new prescription

The Modeling window includes the following sections (see Fig. 3.92, Prescription modeling by choosing the prescription - sleep·safe, page 151).

> **Patient Parameters** in the upper left corner,

> **Prescribed Therapy Outcomes** in the upper right corner,

> **Modeled Prescription** in the middle,

> **Command** buttons at the bottom.

The **Modeled Prescription** area depends on the PD system attached to the prescription.

The same entry masks are used for the **Modeling** and **PD Prescription** sections.

3.12.5.4 Patient Parameters area

The **Patient Parameters** area has three panels: **Renal Function**, **Peritoneal Function** and **Fluid Removed** which contain the patient's renal data. This data is editable.

Note

The **Patient Parameters** values depend on the selected QA test type. For example, a **24 hour Batch Collection** test will have no **Peritoneal Function** data by default, but instead the most recent values from a previous PET/PFT/PET+24h Batch Collection will be displayed.

The **Prescribed Therapy Outcomes** area displays the results and is divided into several tabs:

3.12.5.5 Prescribed Therapy Outcomes area

● **Summary tab**

The **Summary** tab shows the results for the entire prescription.
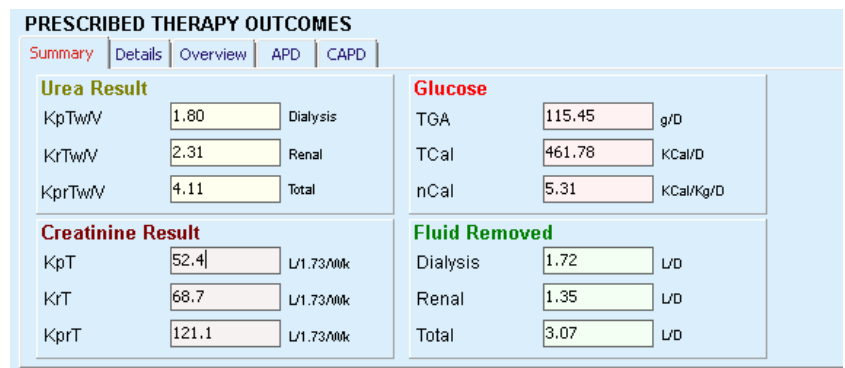
*Fig. 3.94 The **Summary** tab of the Prescribed Therapy Outcomes*

● **Details tab**

The **Details** tab shows the results per exchange or cycle as well as totals for Ambulatory/Supine positions and for Renal/Peritoneal contributions.
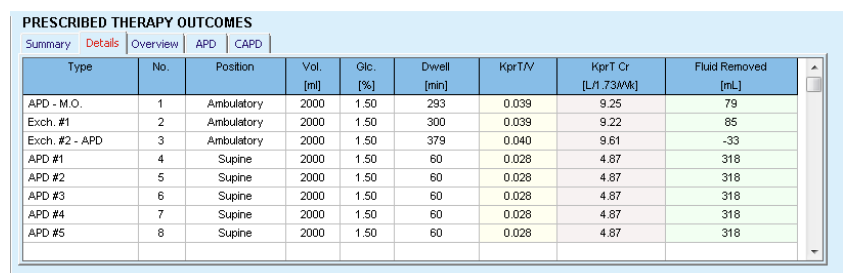
Fig. 3.95 The Details tab of the Prescribed Therapy Outcomes

● **Overview tab**

The **Overview** tab shows the graphical representation of the prescription. This is the same graph as in the **PD Prescription** section (see Fig. 3.91, Modeling: By choosing the prescription, page 150).

● **APD tab**

The **APD** tab shows certain data on the APD part of the Modeling prescription. The total time and the number of solution bags are amongst the data provided by this tab (see Fig. 3.45, APD Info tab of the Overview pane of APD sleep·safe, page 105).

● **CAPD tab**

The **CAPD** tab shows certain data on the CAPD part of the Modeling prescription. This is the same tab as in the **PD Prescription** section (see Fig. 3.47, CAPD Info tab of the Overview pane of CAPD, page 106).

3.12.5.6 Modeled Prescription area

● **APD/CAPD tabs**

The **Modeled Prescription** area with **APD** and/or **CAPD** tab is an editor that is operated in a similar form as described in the PD Prescription section.

● **Button functions**

The command buttons allow for the following actions:

The **Report** button creates a comprehensive report for the Modeling prescription and the QA test;

The **Reset Patient Parameters** button reverts the data in the Patient Parameters area to the original patient data. If the patient data was modified, this button has to be pressed before saving the prescription;

The **Finish** button saves the Modeling prescription, always as a new prescription. A new name must be provided.
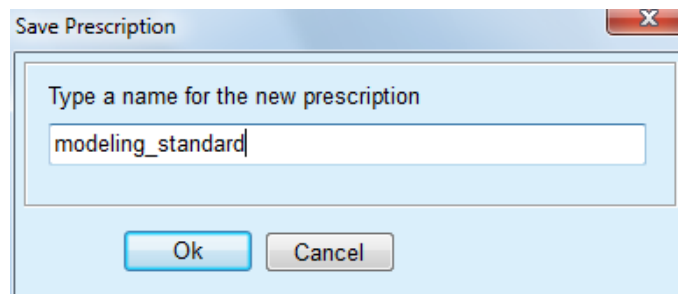
Fig. 3.96 **Save Prescription** *dialog for Modeling*

👉 **Note**

When selecting the **Finish** or **Report** buttons the user will be asked to revert the data to the original patient data if this was manually modified.

The **Close** button closes the Prescription Modeling window.
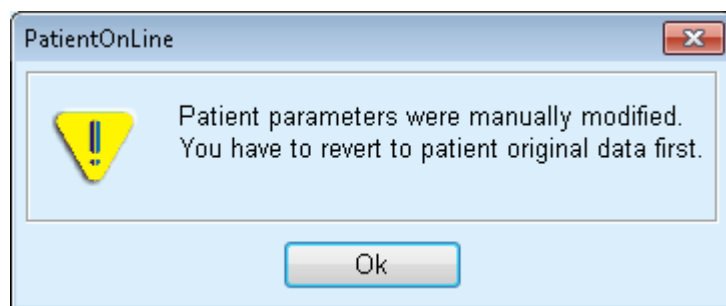
3.12.5.7 Modeling: By choosing the dialysis targets

The **By choosing dialysis targets** method allows the user to specify certain values for dialysis therapy outcomes as modeling targets and certain prescription restrictions (see Modeling - Medical background). Based on a selected QA test, **PatientOnLine** will try to generate a list of possible prescriptions that meet all the requirements and satisfy all targets.

The modeling window for the **By choosing the dialysis targets** method is illustrated in Fig. 3.97.
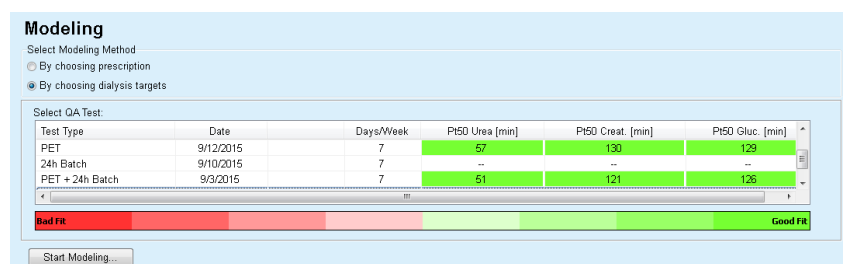
Fig. 3.97 Modeling: **By choosing the dialysis targets**

The Modeling General area has only one **Select QA Test** list by means of which Modeling is started.
To start Modeling, one must proceed as follows:

– Select a QA test from the **Select QA Test** list. PET tests are not allowed because they provide insufficient data for modeling;

– Click the **Start Modeling**... button.

The **Prescription Modeling** dialog box is opened.

– Select the **Treatment Type** using the check box and the pull-down menu.

Any PD system combination with the current PD system (if any) as default system is allowed.

(see Fig. 3.93, Selecting a PD System for a new prescription, page 152)

Click the **Next >** button.

The Prescription Modeling entry menu is opened that shows the target definitions and restrictions.

Fig. 3.98 Specifying targets and restriction

The entry menu is divided into the following sections:

Patient Parameters left side
Here, there are the **Renal Function**, **Peritoneal Function** and **Fluid Removed** entry fields;

Set targets and restrictions right side
Here, the dialysis targets and the restrictions for **CAPD/APD** are defined.
The targets and restrictions are described in the section **Modeling** (see **Medical background**, page 148);

Continuing modeling:

➢ Click the **Next >** button.

The pop-up window opens providing the number of prescriptions obtained.

➢ Click the **Ok** button.

The second dialog window **Prescription Modeling** is opened.

Fig. 3.99 Resulting Prescriptions window

The **Prescription Modeling** window consists of three sections:

> **Prescription List**
> top,

> **Prescribed Therapy Outcomes**
> tab center

> **Buttons**
> bottom.

Prescription List

The **Prescription List** contains all prescriptions meeting the targets and restrictions. The list displays the APD/CAPD type, APD treatment type, the number of APD cycles and the number of CAPD exchanges.

Prescribed Therapy Outcomes

The tabs under **Prescribed Therapy Outcomes** are identical with the tabs of the first modeling method (**By choosing the prescription**).

The results refer to the **Prescription List**.

Buttons

< Back button to return to the previous entry menu.
(see Fig. 3.99, Resulting Prescriptions window, page 157)

Optimize button to change to the entry menu of the first modeling method for fine tuning.
In addition, the entry menu of the first modeling method contains a **< Back** button by means of which you can again return to the **Prescribed Therapy Outcomes** entry menu;

Selecting the **Finish** button opens a pop-up window asking you to enter a name for the prescription.

– Enter the name for the prescription;

– Click the **Yes** button.

The operation will be finished.

After completion of the entry, the initial **Modeling** screen will be displayed again and a new prescription can be started.

If no prescription is found that meets all the targets and restrictions, a warning message will be displayed.

If the specified targets are met by the patient's renal function only, a warning message will be displayed and no prescription will be generated.

3.13 Reports

3.13.1 Reports

General notes

The **Reports** menu item allows the user to generate, view and print reports concerning demographics and/or medical data for a certain patient.

Fig. 3.100 Reporting menu item

When selecting the **Reports** menu item from the menu tree, the **working frame** will display a window with seven tabs: **Demographics**, **Diagnosis & Therapy**, **Tunnel & Peritonitis**, **Assessment Methods**, **Hospitalization**, **Hospitals' Staff** and **Input Forms**.

Fig. 3.101 Reports window

Tip

The first tab, **Demogrophics**, is selected by default.

Each tab contains a **Preview** tab located in the bottom right corner. This button is used to obtain the desired Report Preview.

Creating a report

In order to create a certain report, one must proceed as follows:

Select the patient from the **Patient Frame**;

➢ Select the tab from the Reports window;

➢ Select the desired data by checking and/or unchecking the corresponding check boxes.

Initially, all the check boxes are checked.

Note

If none of the check boxes is selected, the **Preview** button will be deactivated.

– Click the **Preview** button;

The report is generated with the selections made.
The progress of the report generation is signaled in an info window.

The report is generated as print preview at the display.

A Print Preview window will then be opened with a standard menu bar on top of it.

A section with no data will not be present in the generated report. Moreover, if any of the checked sections has no data, the generated report will contain a blank page.

Printing a report

By clicking on the **left printer symbol**, the created report will be printed completely on the default printer.

By clicking on the **right printer symbol**, one of the installed printers can be selected. In addition, the following selection can be made:

Selecting the print area;

Selecting the number of copies.

Saving a report

In order to save a report as a file on the hard disk, one has to proceed as follows:

➢ Click the [icon] button.

The **Export** dialog box is opened.

➢ Select the export format in the pull-down menu;

The following export formats are possible:

*.pdf (Adobe Acrobat),

*.rft (Microsoft Word),

*.xls (Microsoft Excel),

➢ Select the **Page Range**;

➢ Click the **Export** button;

➢ A "**Save as**" dialog window is opened;

➢ Select the export location;

➢ Click the **Save** button.

➢ The report is exported according to the selection;

Close the Print Preview

➢ Click the **Close Report** button.

The print preview is closed.

3.13.1.1 Demographics tab

The following data can be included in the **Demographics** report:

Demographics,

Addresses,

Professional Status,

Private Environment,

Mobility,

Visual Ability,

Fine Hand Manipulation,

Helper,

Training

The first page of the report contains the **Patient General Information** and **Demographics Addresses** sections. The **Patient General Information** data is always present in the report and cannot be removed.

3.13.1.2 Diagnosis & Therapy tab

The following data can be included in the **Diagnosis & Therapy** report:

ESRD & Comorbidity,

Renal Replacement History,

Catheter,

Allergies,

Regular Medication

3.13.1.3 Tunnel & Peritonitis tab

The following data can be included in the **Tunnel & Peritonitis** report:

Exit Site / Tunnel Infection,

Peritonitis,

Exit Site Classification

This report contains all data from the **Patient Status/Tunnel & Peritonitis** menu.

3.13.1.4 Assessment Methods tab

The following data can be included in the **Assessment Methods** report:

Weight,

Height,

Blood pressure,

Volume balance,

Amputation,

Nasal Carriage Status,

Additional Lab Data,

Comment

This report contains all data from the **Patient Status/Assessment Methods** menu.

3.13.1.5 Hospitalization tab

The **Hospitalization** tab contains a single check box allowing report generation for all hospitalizations of the current patient (see **Patient Status/Hospitalization**). This check box cannot be deselected.

3.13.1.6 Hospital's Staff tab

The **Hospital's Staff** tab contains a single check box allowing report generation for all hospitalizations of the current patient (see **Patient Status/Hospital's Staff**). This check box cannot be deselected.

3.13.1.7 Input Forms tab

The following data can be included in the **Input Forms** report:

> PFT,
>
> 24 hour Batch Collection,
>
> PET,
>
> PET + 24 hour Batch Collection,
>
> No RRT

For each selected QA test, the generated report contains the necessary data fields, but with no data at all.

Tip

For all the available types of QA tests, the Input Forms have the same graphical layout and data fields as on the Medical/QA/Input Data tab.

In this way, the Input Forms option is very useful as the selected report, with all fields empty, can be used in printed format as a basis for manual data collection. The staff members can use the printed report for writing down the patients' personal data, their age and gender, weight and height, as well as for inputting the data of the QA test manually. Also after having been filled in, the paper reports can be easily archived.

3.13.1.8 Home Visits

The **Home Visits** tab contains the following sections:

➢ A list containing all the available patients;

➢ Option to select the date of next visit.

In order to generate the report, first of all one should choose the patients for which the home visits will be displayed. Then the user must specify an interval for the date of next visit or choose an option from the already defined intervals in the combo box.

Available options are **Next day, Next week, This month, This year.**

The result will be a report containing the home visit records that have the **Date of next visit** between **From** and **Till** dates for the selected patients.

3.13.2 Statistics

3.13.2.1 General notes

The **Statistics** menu item allows both single patient-based statistics, such as trend analysis of various parameters, and group statistics such as histograms, cross-correlations and infection rates.

Upon selecting this item from the Menu Tree, the **working frame** will display two tabs:

> Current Patient
>
> Patient Group

(see Fig. 3.102, Statistics for the current patient - Trend Analysis, page 164)

The **Current Patient** tab allows the user to graphically analyze the evolution of several key parameters such as renal function, clearances etc. for a single patient in time - also called trend analysis or history graph. Certain graphical representation may contain several related parameters. A second option allows calculation of individual infection rates.

The **Patient Group** tab allows statistical analysis, such as histograms, cross-correlations and infection rates on patient lots. There is a comprehensive way of defining patient lots based on several criteria.

3.13.2.2 Current Patient tab

The **Current Patient** tab requires a patient to be selected in the **patient frame**. The tab has two sub-tabs, namely **Trend Analysis** and **Infections** (see **Statistics for the current patient - Trend Analysis**, page 164).

Trend Analysis

The **Trend Analysis** tab contains the following controls:

> **Select Parameter**,
> Allows the user to specify the desired parameter from a list of 20 possible selections, mainly from the **QA** and **Additional Lab Data** sections;
>
> **Last** x **years/From** - **Till**,
> Allows the user to specify the time frame, in other words - the horizontal axis of the graph. Selecting the Last x years radio button will activate the smart edit box nearby, with a default value of 2 years. Selecting the **From** - **Till** radio button will activate the two calendar controls nearby, which allow direct setting of both ends of the time-interval. Either selection will update the horizontal axis of the graph.
>
> **Values**,
> Displays the numerical value on top of each graph element;
>
> The **graphics toolbar**,
> which allows for the control of the layout;
>
> The **Report** button,
> which creates an associated report.

For certain selections, several parameters are displayed. The Creatinine Clearance selection, for example, will display the renal, the peritoneal and the total creatinine clearance.
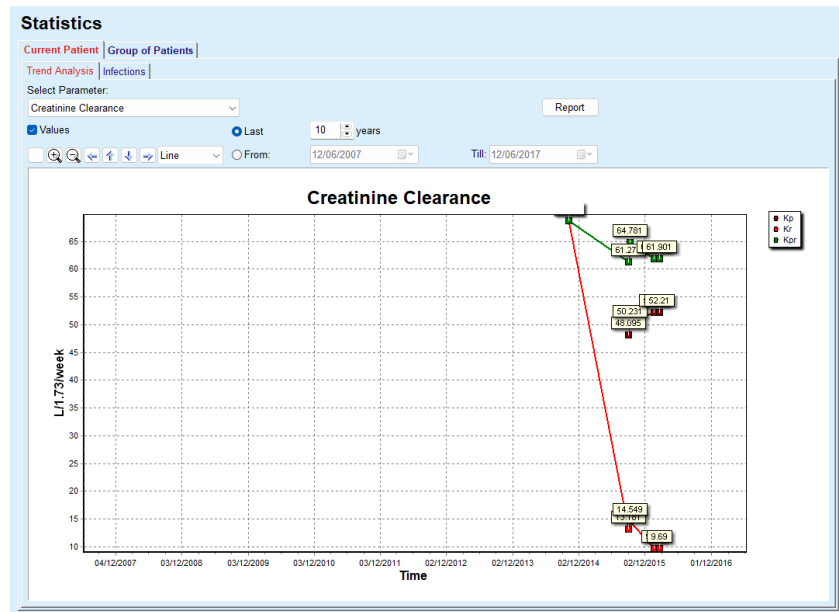
Fig. 3.102 Statistics for the current patient - Trend Analysis

Upon clicking on the **Report** button, a Parameter window is firstly displayed, allowing the selection of the parameters that will be included in the report. Selecting the **Report** button will generate the report, while selecting **Cancel** will close the Parameters window.

If several parameters are selected, all the graphs in the report will have the same settings for the horizontal time axis.

Infection Rates (single patient)

The **Infections** tab allows the user to obtain the infection rates for the current patient. The following control elements are available:

➢ The **Infection Rates Report** panel with three check boxes that control the infection types included in the report and the **Report** button which creates the report;

➢ Three sub-tabs for:

> **Peritonitis Rate**,

> **Tunnel Infection Rate,**

> **Exit Site Infection Rate**.

➢ **Last** x **years**/**From** - **Till** allowing the user to specify the time frame for which the infection rates are computed. By default, the **From Date** is set to the **PD Start Date** and the **Till Date** to the current date or the **PD Exit Date**. Selecting the **Last** x **years** radio button will activate the smart edit box nearby, with a default value of 2 years. Selecting the **From** - **Till** radio button will activate the two calendar controls nearby, which allow direct setting of both ends of the time-interval. By clicking on the **Default** button, the controls are reset to default values.

Each sub-tab displays the patient's PD time frame, incident count and infection rates or germs distribution. In this way, the user may also see the germs distribution for peritonitis, tunnel infection and exit site infection in a graphical representation.

3.13.2.3 Group of Patients tab

For the creation of statistics with a **Group of Patients**, a group of patients has to be defined and activated, based on a certain criteria.

The Group of Patients tab is divided into the following sub-tabs:

Criteria

Histograms

Cross-Correlations

Infections

PatientOnLine allows the user to edit, save and delete several such criteria, each defining a patient group. Only one criterion can be active at a certain moment. There is a default criterion named All which selects all the patients in the database. This criterion can not be edited or deleted. Criteria are defined on a user basis, thus allowing each physician to develop his/her own statistics.

For example, one criterion could define male patients older than 45, having Diabetes Mellitus as primary renal disease and hypertension as comorbidity, treated by CAPD with bicaVera solution. Once such a criterion is defined, one can set it as the active criterion and germs distribution.

When a criterion is defined, the user may specify the patient lot either by using **Subcriteria** or by **Explicit** inclusion of the desired patients in the lot.

Criteria

The Criteria section allows the user to manage selection criteria for defining patient groups.

Fig. 3.103 Statistics for Group of Patients - Criteria

In the upper part of the screen there is the **Criteria List** table which holds all the available criteria, following the order in which they were defined. Criteria are stored and viewed on a user-basis. The All criterion, which selects all the patients, is always available for all users.

In the middle part of the screen, there are five tab controls that describe various possible components of a criterion such as **Common Criteria**, **Discrete Criteria**, **Range Criteria**, **Criteria Overview** and **Selected Patient Lot** resulting from the application of the criterion.

The lower part of the screen contains the buttons **New**, **Edit**, **Delete** and **Set Active**. The first three buttons are used to create, edit and delete a certain criterion.

Although several criteria can be defined and stored, only one can be active at a certain moment. The user can set a certain criterion as the active one by selecting the corresponding row in the **Criteria List** table and by pressing the **Set Active** button. The active criterion is displayed with the ☑ sign near it, while the inactive ones are displayed with a ☒ sign. By default, the **All** criterion is the active one. A criterion has a name and, possibly, an associated comment. It can also have a time frame, defined by the **From** and **Till** calendar controls.

In order to create/edit a new/existing criterion, one must select the **New** and/or **Edit** button. This will open an **Edit Criteria** wizard which will guide the user through the **Common Criteria**, **Discrete Criteria** and **Range Criteria** settings. Upon selecting **New** and/or **Edit**, the first page of the wizard will open.

In this dialog box one can edit the **Name** of the criteria, the time frame (**Date From, Till)**, an optional **Comment** and the modality of obtaining the patient lot. The patients included in the patient lot can be specified either **Explicitly** or can be obtained as a result of the **Subcriteria**.

It is possible to define specific criteria to be used in the **Dashboard/My Patients** menu by checking the **For Dashboard** check box. In this case, the **Range Criteria** settings will not be available.

Except for the name, all settings are optional.

There are two status options or the **Patient Active Status** field:

> **Active patients**

> **All**

The setting can be changed under **Administration/Setup/View Settings/Options for active/inactive patients**.

A criteria defined for the **Dashboard** menu will not allow the specification of the **From/Till** dates and will include only active patients, regardless of the settings in the **Administration/Setup/View Settings** menu.

If under **Administration/Setup/View Settings/Options for active/inactive Patients** the **View inactive patient** check box is checked, all patients will be displayed, regardless of their active status.

See **Additional Information** under **Patient Status/Diagnosis & Therapy** and **Administration/View Settings** for details.

The **Default** button will set the **From** and **Till** dates to empty values, meaning that global or most recent medical parameters are taken into account in order to establish the patient lot.

The **Close** button will cancel the editing process without saving.

When the definition of the patient lot is based on **Explicit** option, moving to the **Next** window will display the **Include Patients** page.
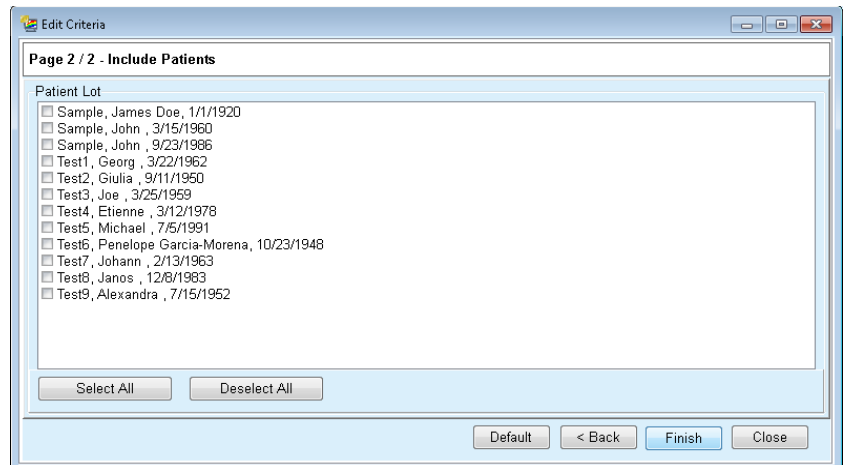
Fig. 3.104 Edit Criteria Wizard - Include Patients

The **Include Patients** page contains a list with all the available patients. From this list the user can choose the patients he is interested in and thus resulting the patient lot corresponding to this criterion.

When the user selects **Finish** the wizard is completed and the criterion is saved.

When the definition of the patient lot is based on **Subcriteria** option, moving to the **Next** window will display the **Discrete Criteria** page (see **Edit Criteria Wizard - Discrete Criteria**, page 168).

The **Discrete Criteria** page allows the user to define sub-criteria that can be expressed as selections from pre-defined lists. The name "discrete" comes from the opposite of continuous.

The current sub-criteria include **Gender**, **Working**, **Diabetic**, **ESRD**, **Comorbidity**, **PD System Type**, **APD Solutions** and **CAPD Solutions**. The default value for each of the selections is **All**, meaning that all the patients are considered. This value can be globally set by pressing the **Default** button.

For **ESRD** and **Comorbidity** the same **ICD-10 tree controls** are available as in the **Patient Status/Diagnosis & Therapy** menu item. For statistical purposes, one can select both ICD-10 categories and diseases.
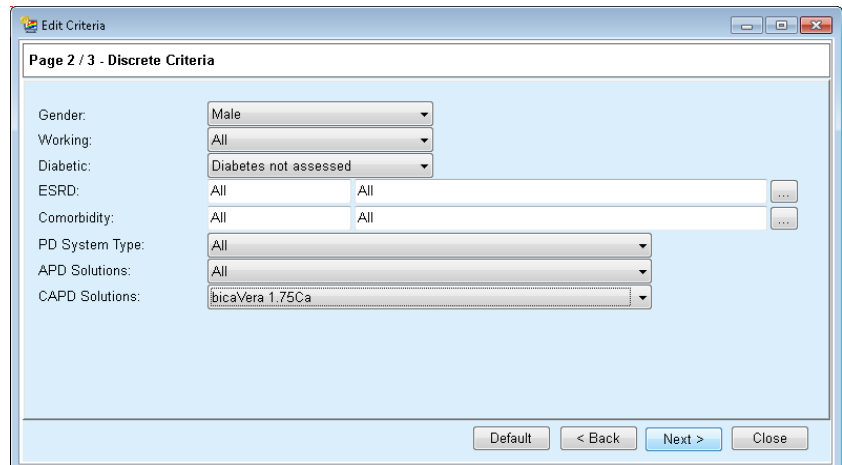
Fig. 3.105 Edit Criteria Wizard - Discrete Criteria

The **Next** button will get the user to the third and last page of the wizard.

On the third page one can specify various range sub-criteria. For each parameter, one can define a range with lower and upper limit by using the smart edit pairs.

The criteria described in the following figure will filter all patients with age greater or equal than 45 years, weighing more than 70 kg, and with a daily urine volume of less than 0.5 liters. These sub-criteria will be combined with the ones described in Fig. 3.105 - diabetic male patients treated with bicaVera 1.75Ca CAPD solution.
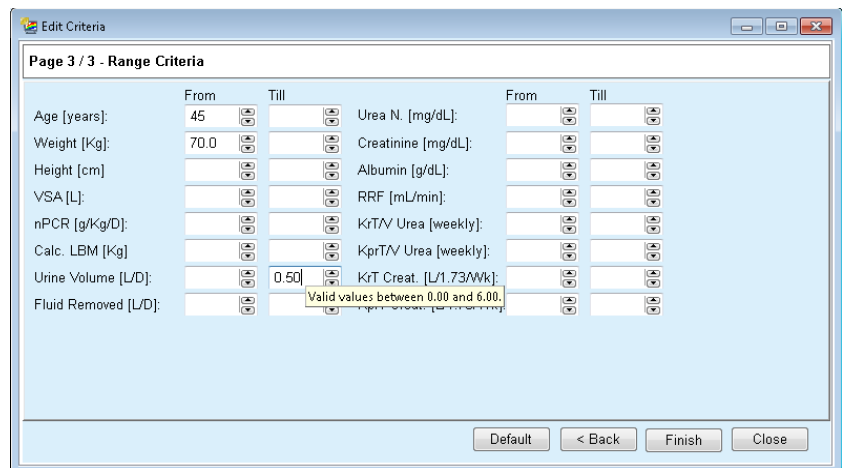
Fig. 3.106 Edit Criteria Wizard - Range Criteria

The **Finish** button will close the wizard thus saving the edited criterion. If the edited criterion was a newly created one, a confirmation window will be displayed, asking if this criterion should become the active one.

The **Criteria Overview** tab offers a text description of the selected criterion. The **Selected Patient Lot** tab lists the patients that matched the currently active criterion. This tab is available only for the active criterion. The patients are listed with their basic demographics data.

The **Selected Patient Lot** tab contains a highly customizable report that includes all the patients in the patient lot.

When the **Report** button is pressed a pop-up menu appears, allowing the user to choose which parameters should be displayed for each patient. The maximum number of parameters that can be selected and displayed on the report at a certain moment are nine.

In this pop-up press **Report** button to display the report.

Histograms

The **Histograms** tab allows the user to analyze various histograms for the selected patient lot.

The name of the active criterion is displayed in the upper-left corner of the page. The **Select Parameter** drop-down menu serves the selection of the histogram. There are 23 types of histograms available, mainly from the QA results area, but also from lab data.
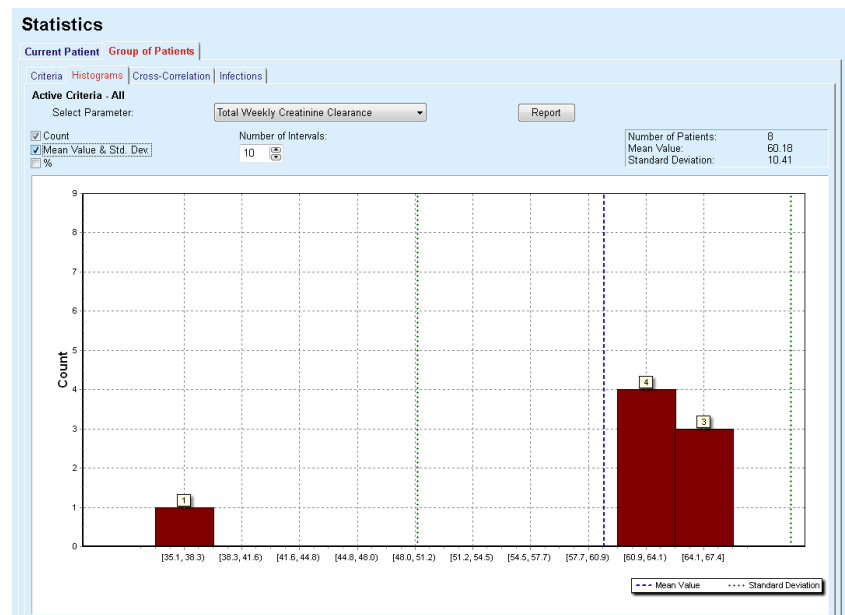
Fig. 3.107 Statistics for Group of Patients - Histograms

Certain statistical parameters like the **Number of Patients** in the lot, **Mean Value** and **Standard Deviation** of the histogram are displayed in the upper-right corner of the page.

Three check-boxes are present in the left part of the screen:

> **Count**
> displays the numerical values on top of each bar of the histogram;
>
> **Mean Value & Std. Dev**
> displays three vertical dot lines corresponding to the mean value (blue) and mean value ± standard deviation (green), together with an attached legend;
>
> **%**
> displays percentages instead of counts on top of each bar.

The **Number of Intervals** smart edit control allows you to narrow/enlarge the horizontal intervals of the histogram.

If the user moves the mouse over any histogram bar, a tooltip will appear displaying the patients belonging to that interval along with the value of the parameter of the histogram.

The **Report** button will create an associated report.

Cross-Correlation

The **Cross-Correlation** tab allows the user to analyze the statistical correlation between two medical parameters in the selected patient lot.

The name of the active criterion is displayed in the upper-left corner of the page.
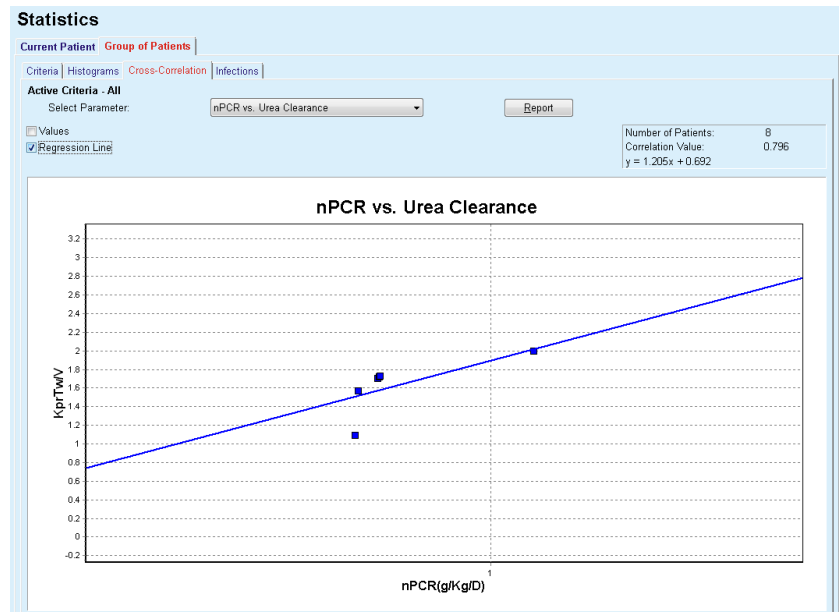
Fig. 3.108 Statistics for Group of Patients - Cross-Correlations

The **Select Parameter** drop-down menu allows the user to choose the type of correlation. There are 13 types of predefined parameter pairs, mainly from the QA results area.

Certain statistical parameters like the **Number of Patients** in the lot, **Correlation Value** and the **Regression Line Equation** are displayed in the upper-right corner of the page.

Two check boxes are present in the left part of the screen:

– **Values**
displays the numerical values (x, y) on top of each point of the chart;

– **Regression Line**
displays the regression line in the chart.

The **Report** button will create an associated report.

Infection Rates (group of patients)

The **Infections** tab displays the **Peritonitis Rate**, the **Tunnel Infection Rate** and the **Exit Site Infection Rate** for the selected patient lot.

The calculation method can be selected in the **Administration/Set-up/View Settings** section.

Fig. 3.109 Statistics for Group of Patients - Infections

There are the following control elements:

➢ The **Infections** tab with three check boxes for selecting the infection types included in the report and the **Report** button which creates the report;

➢ Three sub-tabs for **Peritonitis Rate**, **Tunnel Infection Rate** and **Exit Site Infection Rate**.

Each of the **Peritonitis**, **Tunnel Infection** and **Exit Site Infection** sub-tabs contains a patient list in which certain data is displayed.

The **Rate** section contains the following data:

> **ID**
> The patient ID from the **PatientOnLine** database;

> **Name**
> the patient's first and last name;

> **Start Date**
> the patient's PD Start Date or the From Date as specified in Criteria;

> **End Date**
> the current date or the PD Stop Date or the Till Date as specified in Criteria;

> **Incidents**
> the number of incidents within the interval (Start Date, End Date);

> **Rate (incidents per years)**
> the infection rate of the single patient in incidents/year;

> **Rate (months between incidents)**
> the infection rate of the single patient in months between incidents.

In the lower part of the screen, the **Rates** are calculated and the current **Calculation Method** is displayed with the units of measurement and a short description of the calculation method.

The **Germs** section contains the distribution of germs for each of the Peritonitis, Tunnel Infection and Exit Site Infection in a graphical representation. The user can observe from the pie chart which germs are the most frequent and in which percentage.

3.13.3 Custom Overview

The **Custom Overview** menu is patient-oriented and shows a series of synthetic treatment data about the current patient.

In the upper part there is a navigation section that shows the status of the last 7 treatment days, by means of a graphical symbol for each day. The symbol may be:

– a blue cross, signifying missing data;

– a green check box, signifying that all customized data is within defined limits;

– a red exclamation mark, signifying that certain customized data is outside defined limits;

– a grey equal sign, signifying that certain customized data is outside defined limits, but the respective data has been acknowledged by a medical staff.

Fig. 3.110 Custom Overview

Note

For certain vital parameters like weight, blood pressure and volume balance, you can define patient-dependent notification limits. See respective sections (see chapter 3.11.4.1, page 68), (see chapter 3.11.4.3, page 73) and (see chapter 3.11.4.4, page 75).

Clicking on a graphical symbol will refresh the menu with data from the respective day.

The navigation section has two navigation arrows (left-side, right-side) and a calendar control that you can use to quickly navigate to a certain date.

Below the navigation section, there is a **Blood Pressure List** section that shows the blood pressure measurements of the selected day, exactly like in the **Blood Pressure** menu (see chapter 3.11.4.3, page 73). A link allows you to quickly go to that menu for viewing details. On the right side, there is an **Exit Site** section that shows exit site images from the current date, together with a link to the respective menu.

The **Treatments** section shows certain customized data from the current treatment protocol of the day. In case there are several of such protocols (e.g. an APD one and a CAPD one), each protocol is shown in a separate tab. The **Treatment Summary** table shows a series of prescribed and performed data. This data can be configured via the **Setup** menu (see chapter 3.15.4.10, page 220). If the performed data exceeds the prescribed data with a certain configurable threshold, the respective performed data is shown in red. The **General Information** section shows a few basic data for the current treatment protocol. A link to the treatment analysis menu is also available.

The **Statistics** button opens the treatment statistics chart (see Fig. 3.69, Treatment Statistics window, page 130). The **Graphics** button opens the graphics chart of the current treatment (see Fig. 3.74, Graphics, page 133).

The **Review** button allows you to review the current treatment. If the status symbol was "red", signalizing that certain data were outside defined limits, it will turn "grey" after being reviewed. The user name and date of the review operation is displayed.

3.13.4 Dashboard

The **Dashboard** menu reflects the synthetic treatment status for all active patients or for a configurable group of patients. It has two tabs: **All patients** (showing all active patients) and **My patients** showing the active patients defined according to certain criteria – (see chapter 3.13.2.3, page 165).

Each tab displays a series of boxes, one for each patient, with the treatment status of the last 7 days, using the same symbols as in the Custom Overview menu (see chapter 3.13.3, page 172). Boxes can be displayed in a collapsed or expanded form. The button **Expand/Collapse overview** allows you to switch between the two display modes.

In the expanded mode, up to 4 configurable treatment parameters can be displayed. The parameters can be configured via the **Setup** menu (see chapter 3.15.4.10, page 220). In the lower part of the expanded box, a list of colored vertical bar graphs describes the blood pressure measurements of the day. A green/red red color signifies that the measurement is within/outside defined limits, while a grey color signifies that a measurement outside the limits has been checked by a medical staff.
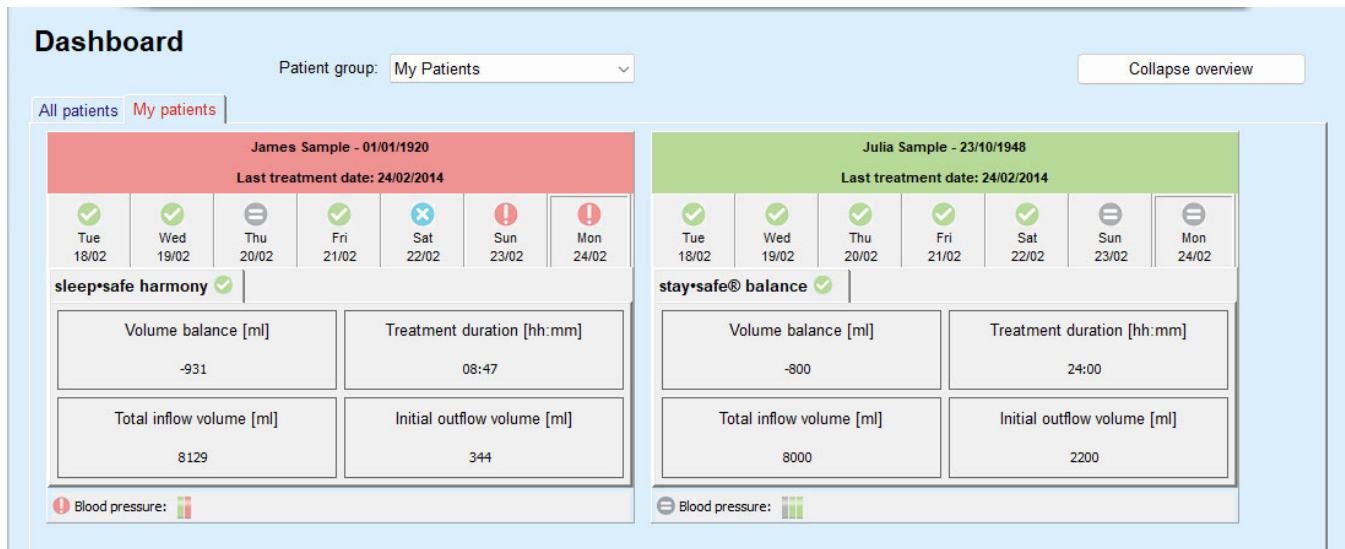
Fig. 3.111 Dashboard

Double-clicking a certain patient cell will transfer the control to the **Custom Overview** menu for the respective patient.

If there are several treatment protocols for the same day, data from each protocol will be shown in a separate tab within the respective box.

The **My patients** tab has a selection box in which you can specify a patient criterion. Patient selection criteria are user-based.

3.14 Communication

3.14.1 Patient Card

3.14.1.1 General notes

The **Patient Card** menu item is the communication support between the **PatientOnLine** application and an APD cycler, allowing APD prescriptions to be exported to the cycler and treatment protocols to be imported into the application. The communication is done by means of a patient card, which is an external memory device that can store data files. Patient cards can be read/written by personal computers and laptops.

After selection of the **Patient Card** menu item Fig. 3.112 the **working frame** of the application will display a screen as illustrated in (see Fig. 3.113, Import Patient Card - sleep·safe, page 175).

Fig. 3.112 Patient Card menu item

The **Patient Card** menu contains two tabs, namely:

> **Import Patient Card**
> for importing patient cards;

> **Create Patient Card**
> for creating patient cards.

The functionality of each tab is the same regardless of the APD system of the patient or on the patient card and will be described accordingly in the following sections.

3.14.1.2 Import Patient Card tab

In order to import a patient card one has to select the **Import Patient Card** tab in the **Patient Card** screen (see Fig. 3.113).

Select the [...] button in order to choose the path to the patient card or directly type the path into the **Select Patient Card folder** field.
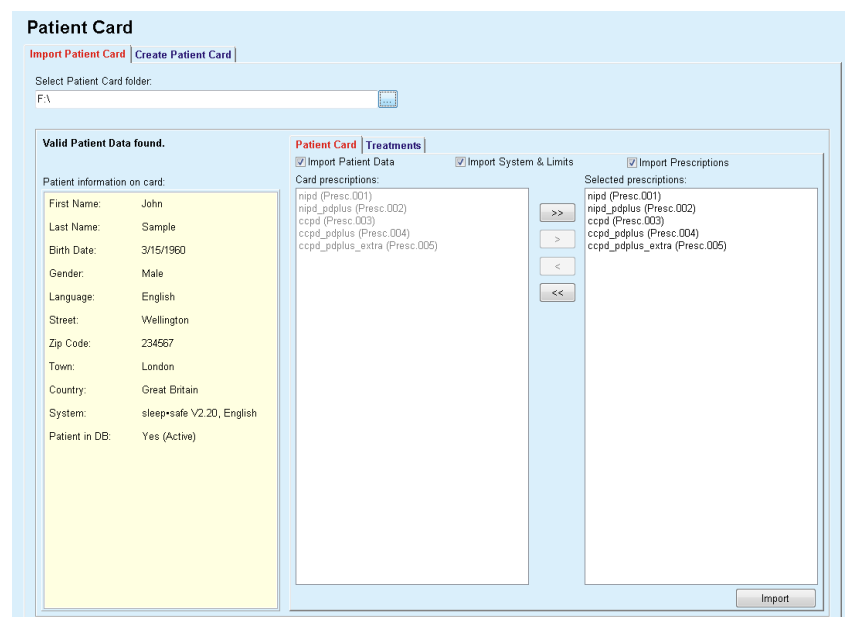
*Fig. 3.113 Import Patient Card - **sleep·safe***

If a valid patient card folder is selected, the patient data from the card will be listed in the **Patient information on card** panel together with the type of the APD cycler. In addition, the patient data is searched for in the **PatientOnLine** database and the result is listed as Patient in DB: Yes/No.

The right-hand side contains two sub-tabs:

Patient Card

Treatments.

The **Patient Card** sub-tab handles all contents on the card, except for the treatment protocols.

The user can select which data is to be imported by means of the following check boxes:

Import Patient Data,

Import System & Limits,

Import Prescriptions.

The patient data is mandatory.

If the **Import Prescriptions** check box is checked, the prescription(s) on the card can be selected in order to be imported. Only the selected prescriptions transferred into the **Selected prescriptions** list will be imported along with the patient information, PD System and limits.

One can use several navigational buttons (**>>**, **>**, **<**, **<<**) to move prescriptions between the two lists.

Tip

Once a prescription is in the right list it will appear grayed out in the left list; thus, double selection of the prescription is avoided.

The **Import** button saves the content of the patient card together with the selected prescriptions in the database in two steps.

In the first step the patient data (personal data, PD system and limits) and the selected prescriptions are directly saved if the patient on the card is a new one.

If the patient is identified in the database, a confirmation window will be displayed asking whether to update the patient data or not. The APD system and its associated limits are updated along with the patient data. The same applies to prescriptions. At the end of this first step, a summary window will be displayed.

If a selected prescription is invalid with respect to the PD system of the imported/updated patient, this prescription is no longer imported.

If a selected prescription does not match the limits of the PD system, the prescription will be saved nevertheless, but a warning message advises the user to change the associated limits afterwards.

If a selected prescription is already in the database, an overwrite confirmation message will be issued.

In the overwrite confirmation window, one can check the **Apply all** check box, thus applying the selection to all following prescriptions. In the end a window containing the save results will appear.

As a result of the Import Patient Card operation, the imported/updated patient will become the current one in the **patient frame**.

A valid patient card may also contain treatment protocols. These protocols are available on the **Treatments** tab.

In order to import treatment protocols, one must proceed as follows:

➢ Select the desired treatment protocols from the **Card treatments** list using the mouse.

➢ Use the navigational buttons (**>>**, **>**, **<**, **<<**) to move the treatments between **Card treatments** and **Selected treatments** lists.

Tip

If several treatment protocols should be imported at the same time, one can proceed as follows:

➢ Keep the Ctrl key pressed;

➢ Select the desired treatments using the mouse.

➢ If the treatment protocols are to be deleted from the patient card after storing, the **Delete imported treatment files from Patient Card** check box must be checked;

➢ Select the **Import** button to store the **selected treatments** in the database (right field).

Note

In case a valid patient card folder exists and the patient on the card is not found in the database (the left-hand panel displays No for Patient in DB), selecting the **Import** button for treatments will lead to a warning message. One must select the Patient Card tab and import the patient first.

At the end of the import process, a window containing a summary of the imported treatment protocols will be displayed.

If the selected path does not contain a valid patient card structure, and there is a patient selected in the **patient frame**, a warning message will be displayed in the active window.

The search for the treatments for the selected patient must be confirmed with **Ok**.

Only protocols compatible with the current PD system of the patient will be searched for.

If you select **Ok** and the path contains compatible treatment protocols, a window for the import of treatments will appear, but without the patient data section.
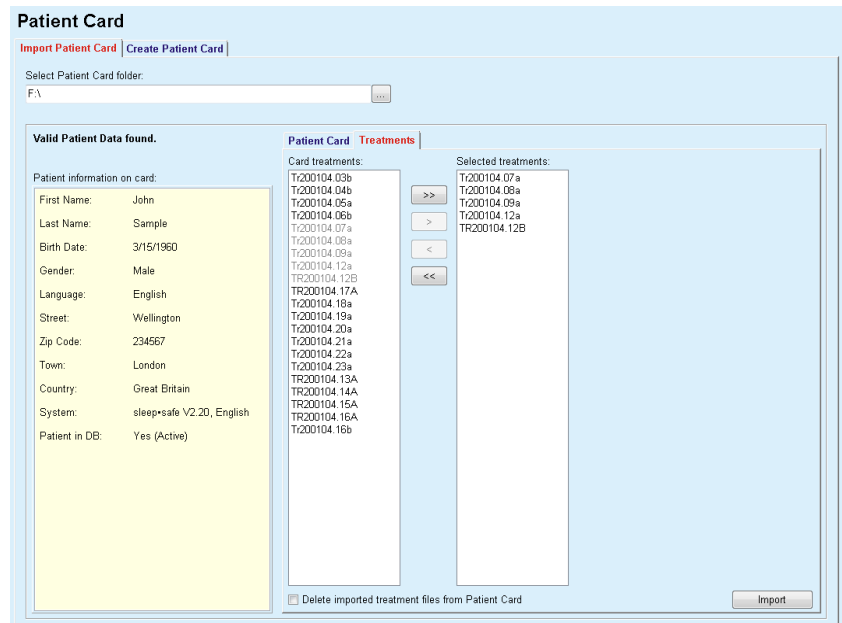
*Fig. 3.114 Importing treatment protocols only - **sleep·safe***

By clicking on the **Import** button, the selected treatment protocols will be attached to the current patient.

Although the normal procedure is to operate with full valid cards, the above functionality allows the user to import treatment protocols from a generic path/folder.

Regardless of the import procedure, the user is asked to confirm the import operation if the patient's identification number from any of the protocol files differs from the patient's identification number in the **PatientOnLine** database.

This may happen when a patient card created by another software application or a default factory card has been used on the cycler.

Note

If the patient card is replaced between various steps of the the import procedures, and another patient identity exists on the new card, a warning message appears. Click **Ok** to confirm and the patient information will be refreshed.
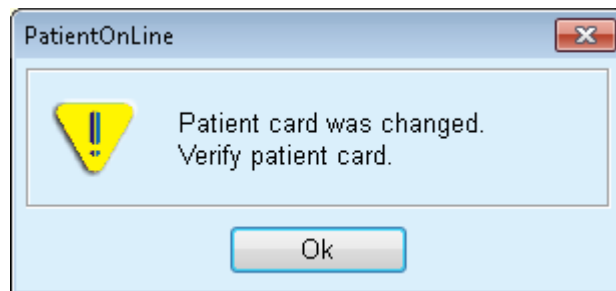
Fig. 3.115 Warning on import when changing card

3.14.1.3 Create Patient Card tab

In order to create a new patient card, one must proceed as follows:

➢ Select a patient who has an APD system as part of the current PD system;

➢ Select the **Create Patient Card** tab.

As a result, all available valid prescriptions will be displayed in the **Card treatments** list.

Note

For cyclers that support multiple prescriptions, a maximum of 10 prescriptions can be written to the patient card;
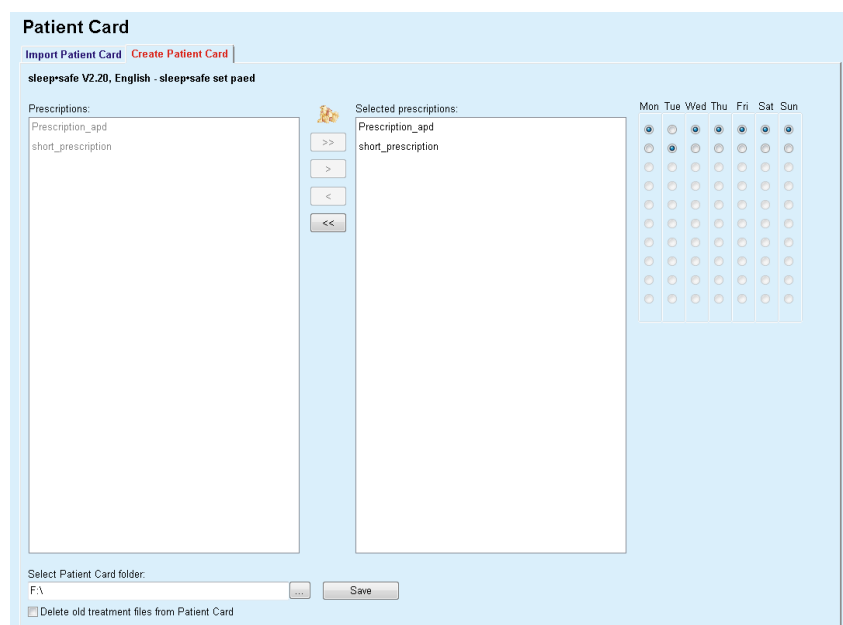
*Fig. 3.116 Create Patient Card window - **sleep·safe***

Note

Prescriptions may become invalid with respect to the current PD system and/or associated limits by subsequent editing operations. In such cases, the invalid prescriptions are displayed in red color in the left list and cannot be selected for storing on the patient card.

➢ Select the prescriptions to be written to the patient card;

➢ If the cycler supports prescription calendars, it must be specified by means of the radio buttons (right) on which days of the week the prescriptions are to be performed; In addition, there is a quick way of setting a default prescription for all days by clicking the **Select as default** button, available when a prescription in the **Selected prescription** list is selected.

➢ Enter the path for the patient card folder in the **Select Patient Card folder** field or click on the ... button.

Note

If the specified folder does not exist, a confirmation window will be issued.

By clicking on the **Yes** button, you can specify a new directory.

➢ If you want to free space on the card, the **Delete old treatment files from Patient Card** check box must be checked (see **Create Patient Card window - sleep·safe**, page 179).

➢ Click on the **Save** button to create the patient card.

All relevant files on the card will be deleted. Treatment protocol files will only be deleted if the above-mentioned check box was checked. A warning message is displayed that must be confirmed by the user;

The patient card will be created.

All the stored information is read back from the card and displayed in a confirmation window.

*Fig. 3.117 Create Patient Card confirmation window - **sleep·safe***

➢ In order to be able to confirm the card content, the user should click on the **Confirm** button which is enabled only if the list is scrolled down to the bottom;

➢ Click the **Confirm** button if the information is correct.

An information message is displayed informing the user about the operation's success.

A ready-to-print report with the content of the card that has just been written will be displayed if the check-box **Print** is checked.

> **Note**
>
> If the **Reject** button is selected, all the information written to the patient card folder will be erased.

3.14.2 Patient Card Plus

The **Patient Card Plus** menu item is the communication support between the **PatientOnLine** application and *sleep•safe harmony* or **SILENCIA** devices, allowing prescriptions to be exported to the cycler and treatment protocols to be imported into the application. The communication is done by means of a patient chip-card, which is an external memory device that can store data. Patient cards can be read/written by personal computers and laptops.
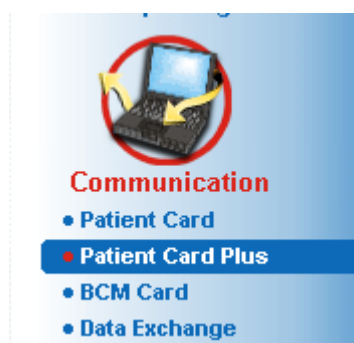
Fig. 3.118 Patient Card Plus menu item

The Patient Card menu contains two tabs, namely:

➢ **Import Patient Card Plus** for importing patient cards;

➢ **Create Patient Card Plus** for creating patient cards.

After the selection of the Patient Card Plus menu item the **working frame** of the application will display a screen as illustrated below.

3.14.2.1 Import Patient Card Plus

The menu is similar to the **Import Patient Card** one, but it contains in addition a graphical control that displays the card status (inserted in the reader or not).

After a valid card is inserted, the card content is displayed:
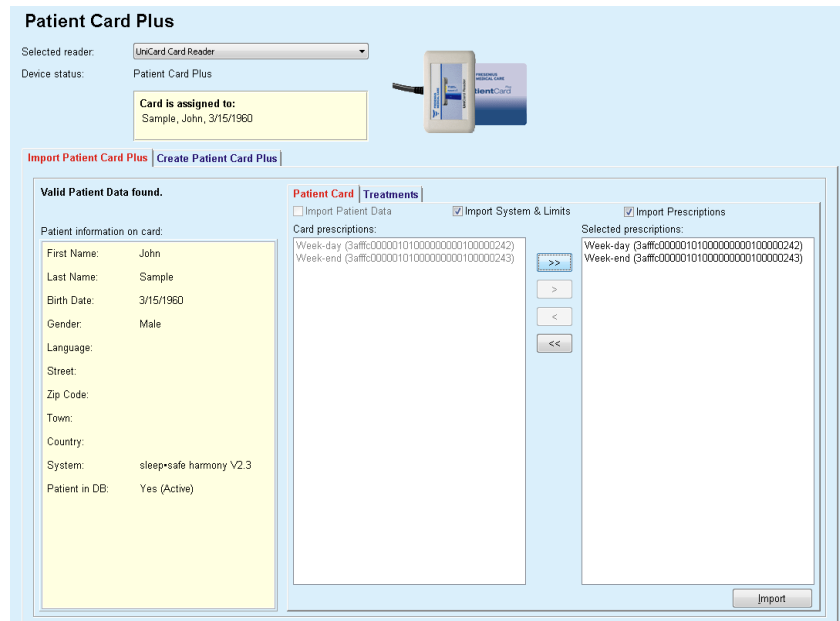
Fig. 3.119 Patient Card Plus - Import data

You can check the data categories to import (including the list of pre-scriptions) and then click on the Import tab.

The **Import** button saves the content of the patient card together with the selected prescriptions in the database in two steps.

In the first step the patient data (personal data, system and limits) and the selected prescriptions are directly saved if the patient on the card is a new one.

– For **SILENCIA** devices only:
  A dialog is shown where the user has to select the device version.

If the patient is identified in the database, a confirmation window will be displayed asking whether to update the patient data or not. Depending on the card content, the *sleep•safe harmony* or **SILENCIA** system and its associated limits are updated along with the patient data.

The same applies to prescriptions. At the end of this first step, a summary window will be displayed.

If a selected prescription is invalid with respect to the PD system of the imported/updated patient, this prescription is no longer imported. If a selected prescription is already in the database, an overwrite confirmation message will be issued.

As a result of the Import Patient Card operation, the imported/updated patient will become the current one in the **patient frame**.

A valid patient card may also contain treatment protocols. These protocols are available on the **Treatments** tab.
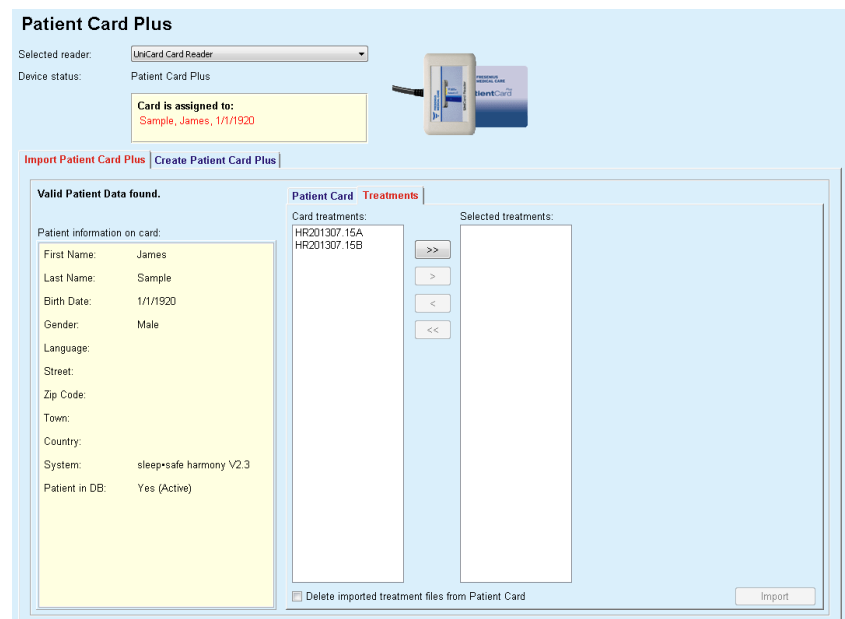
Fig. 3.120 Patient Card Plus - Import treatments

Select the desired treatments and then click on the **Import** button to store the **selected treatments** in the database.

Note

If the treatment protocols are to be deleted from the patient card after storing, the **Delete imported treatment files from Patient Card** check box must be checked.

At the end of the import process, a window containing a summary of the imported treatment protocols will be displayed.

Note

In case a valid patient card folder exists and the patient on the card is not found in the database (the left-hand panel displays No for Patient in DB), selecting the **Import** button for treatments will lead to a warning message. One must select the **Patient Card Plus** tab and import the patient first.

3.14.2.2 Create Patient Card Plus

In order to create a new patient card, one must proceed as follows:

➢ Select a patient who has a ***sleep•safe harmony*** or a **SILENCIA** system as part of the current PD system;

➢ Select the **Create Patient Card Plus** tab

As a result, all available valid prescriptions will be displayed in the **Card treatments** list:
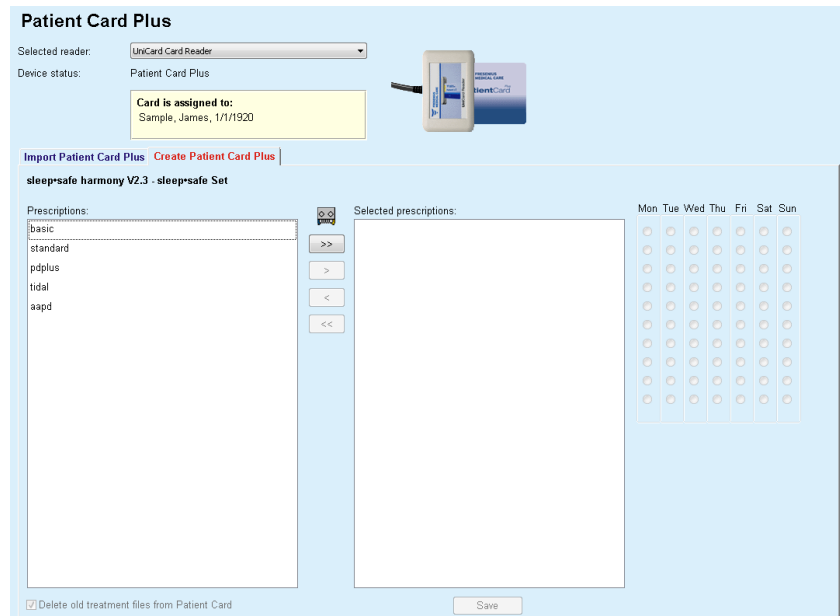
Fig. 3.121 Create Patient Card Plus

👉 **Note**

A maximum of 9 prescriptions can be written to the
sleep•safe harmony or **SILENCIA** card.

➢ Select the prescriptions to be written to the patient card;

➢ Specify in which days of the week the prescriptions are to be performed by means of means of the radio buttons in the right-side calendar; In addition, there is a quick way of setting a default prescription for all days by clicking the **Select for all week** button, available when a prescription in the **Selected prescription** list is selected;

➢ Both *sleep•safe harmony* and **SILENCIA** cyclers requires one of the prescriptions to be declared as default prescription. A default prescription is used instead of a scheduled prescription that was deleted on the cycler. The first prescription in the **Selected prescription** list is automatically set as default (the name is in bold print) but you can explicitly set this attribute by right-clicking on a prescription and choosing the option **Set as default prescription**;

– If you want to free space on the card, the **Delete old treatment files from Patient Card** check box must be checked.

👉 **Note**

If the patient card is re-initialized with a new patient, this checkbox is automatically checked and cannot be unchecked. This is to prevent that treatment protocols for one patient are assigned to another patient.

– Click on the **Save** button to create the patient card.

All relevant files on the card will be deleted. Treatment protocol files will only be deleted if the above-mentioned check box was checked. A warning message is displayed that must be confirmed by the user;

Note

Prescriptions may become invalid with respect to the current PD system and/or associated limits by subsequent editing operations. In such cases, the invalid prescriptions are displayed in red color in the left list and cannot be selected for storing on the patient card.

The patient card will be created.

All the stored information is read back from the card and displayed in a confirmation window:

Fig. 3.122 Patient Card Content

➢ In order to be able to confirm the card content, the user should click on the **Confirm** button which is enabled only if the list is scrolled down to the bottom;

➢ Click the **Confirm** button if the information is correct.

An information message is displayed informing the user about the operation's success.

A ready-to-print report with the content of the card that has just been written will be displayed if the check-box **Print** is checked.

Note

If the **Reject** button is selected, all the information written to the patient card will be erased.

3.14.3 BCM Card

3.14.3.1 General notes

The BCM Card menu provides communication support between **PatientOnLine** and the **Body Composition Monitor** device (BCM device). The communication is done by means of a chip-card that stores the identity and the BCM measurements of the patient. There are three chip-card types currently supported by PatientOnLine: BCM card, 5008 card and Patient Card Plus. The identity of the patient can be written on the chip-card from the **BCM Card** menu. BCM measurement values are saved on the chip-card by the BCM device and can be then imported from the **BCM Card** menu. In order to read/write the chip-card a compatible card reader must be connected to the computer or laptop. There are several types of card readers currently supported by PatientOnLine: OMNIKEY 3121, SCR 3311 and UniCard Reader.

After selection of the **BCM Card** menu item the working frame of the application will display the **BCM Card** window illustrated in Fig. 3.123, provided there is no patient selected in the patient frame and no BCM card is inserted in the card reader.

Fig. 3.123 BCM Card menu item

The selected card reader device, the status of the card reader and the status of the BCM card is displayed in the upper part of the **BCM Card** window.

In the lower part of the **BCM Card** menu there are three tabs, namely:

Personalize BCM Card for creating BCM cards;

Import BCM Card for importing patient identity and measurements from the card;

Erase BCM Card for erasing BCM cards.
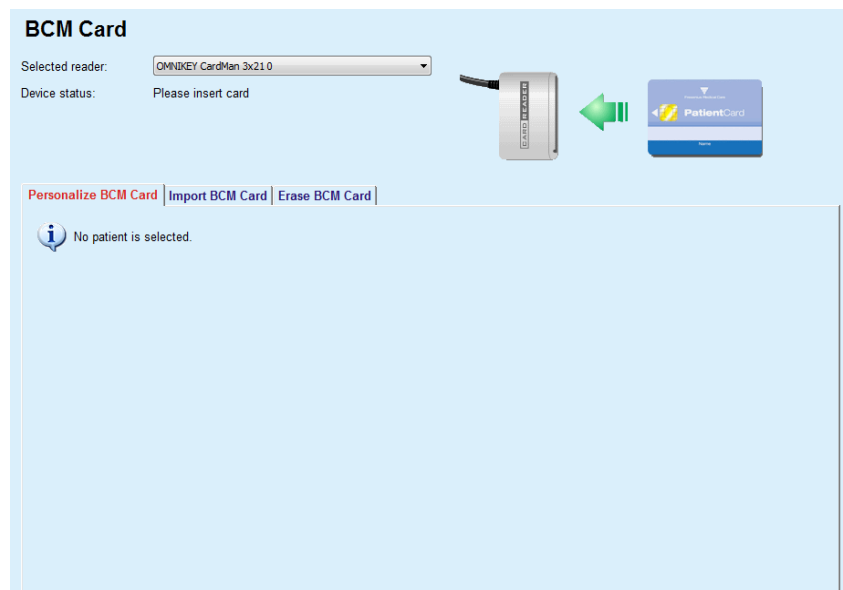
Fig. 3.124 BCM Card window

The functionality of each tab page and of the card reader selector region will be described accordingly in the following sections.

3.14.3.2 BCM Card status

When entering the **BCM Card** the first card reader in the list of all connected card readers will be automatically selected and monitored. Current card reader can be changed from the **Selected reader** drop–down list.

The card reader region shows the status of the card reader device and of the card in both text and graphical format.

This section describes the possible status. If a valid card is recognized, the type of the card is displayed. In case the patient identity is missing on the card, or the patient cannot be identified in the database, the BCM card must be personalized. The status description can also indicate a device connection error, an unknown card reader, or an unknown status.

The card status region also displays patient information read from the card (last name, first name and birthday) with black or red colored text. Text color is red when BCM identity is missing or corrupted or when selected **PatientOnLine** patient is not the same with the patient on card.

When a BCM card with identity is available the patient data is searched for in the **PatientOnLine** database. If a patient with the same name, birthday and gender is found then the patient from card is automatically selected as the current one in the **patient frame.**

If more patients are found in the database then a **Patient Selection** window appears, enabling the user to select just one patient from the multiple possible patients.

Press the **OK** button to set the selected patient as the current patient.

3.14.3.3 Personalize BCM Card tab

The **Personalize BCM Card** tab allows the user to write patient identity (last name, first name and birthday) and BCM input data on the chip-card.

Fig. 3.125 Personalize BCM Card tab

Possible actions when personalizing a card are:

– **Preserve medical data on card and assign it to the current patient** that overwrites input data only, and preserves other existing medical data;

– **Erase all data on card and assign the card to the current patient** that erases all card content first and then writes identity and input data.

Both actions are not always available. When current patient is not the same with patient on card or the card is corrupted or unknown, preserving medical data on card is not allowed. The recommended action is automatically checked. When available, the user may change the recommended action.

Input data:

➢ refers to patient gender, age, weight, height, average systolic blood pressure and average diastolic blood pressure. Weight and height are mandatory, average blood pressure values are optional (can be left empty).

Average blood pressure values are computed over the last 4 weeks. If blood pressure values are missing then the last average values written on card are displayed. Weight and height are the last values for weight and respectively height entered in **PatientOnLine** (via **Assement Method**s or **Quality Assurance** or **BCM Card** menus).

The user may edit input data. If **Reset Patient Parameters** button is pressed then the original input values from the database are displayed.

Personalize Card button writes identity and input data on card depending on the selected action.

If option **Erase all data on card and assign the card to the current patient** was checked, all card content will be erased. A warning message is displayed that must be confirmed by the user.

The BCM device is able to display only a limited set of characters. In case the patient name contains unsupported characters, a warning message will be issued.

You are required to specify/confirm a displayed name that will be written on the card. If a name was displayed for the patient before, that name will be automatically proposed for confirmation.

Note

The chip-card must not be removed from the card reader during read/write operations. Removing the chip-card during read/write operations may damage card data, making the card invalid.

3.14.3.4 Import BCM Card tab

From the **Import BCM Card** tab the user can import the patient identity and the BCM measurements from a BCM card.

The patient data from the card will be listed in the **Patient information on card** panel. In addition, the patient data is searched for in the **PatientOnLine** database and the result is listed as Patient in DB: Yes/No.

If patient on card does not exists in **PatientOnLine** database in respect to last name, first name, birthday and gender, then the user can import patient data by pressing the **Import Patient** button. The imported patient will become the current one in the **patient frame**. Because some BCM cards may be missing gender information, a gender selector is available.

BCM measurements cannot be imported until patient identity is imported.

Fig. 3.126 Import BCM Patient

If patient on card already exists in **PatientOnLine** database then the patient import region (**Gender** drop-down box and **Import Patient** button) is not visible.
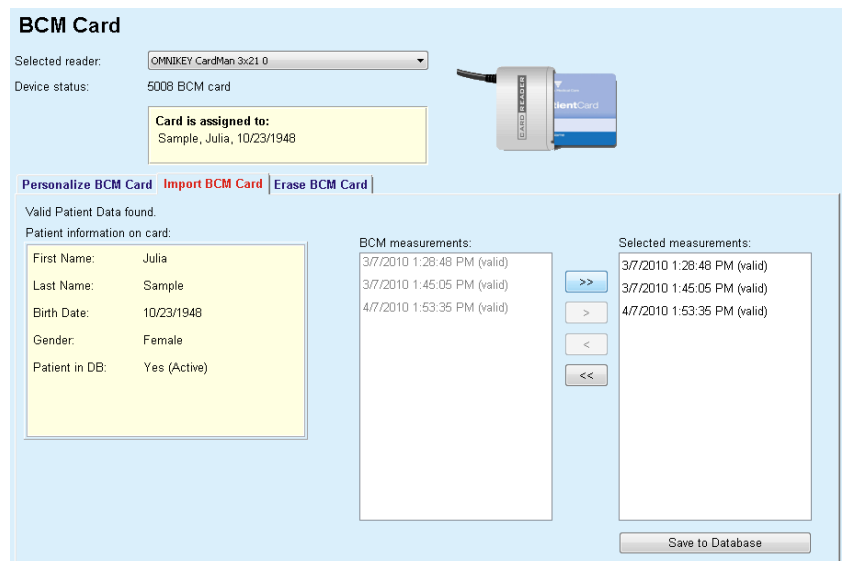
Fig. 3.127 Import BCM Measurements

The **BCM measurements** on card can be selected in order to be imported. Only the selected measurements transferred into the **Selected measurements** list will be imported. Corrupted measurements are marked as invalid and cannot be selected for import.

Tip

Once a BCM measurement is in the right list it will appear grayed out in the left list; thus, double selection of the BCM measurement is avoided.

One can use several buttons to move measurements between the two lists.

The **Save to database** button imports selected BCM measurements in the database.

Note

The chip-card must not be removed from the card reader during read/write operations. Removing the chip-card during read/write operations may damage card data, making the card invalid.

3.14.3.5 Erase BCM Card tab

The **Erase BCM Card** tab allows the user to erase data from a BCM card.

Erasing the BCM card is done by pressing the **Erase Card** button. All medical data on card will be lost, including patient identity.

3.14.4 Data Exchange

The **Data Exchange** menu is the communication support between **PatientOnLine** and other software applications, allowing data to be imported and/or exported.

After selection of the **Data Exchange** menu item the working frame of the application will display the Data Exchange window illustrated (see **Import from Other Applications**, page 193).

Fig. 3.128 Data Exchange menu item

The Data Exchange window is organized on several tabs:

– **External Database** - This tab is visible only when **PatientOnLine client-server** is connected to an External Database Management System (**EDBMS**).

– **Import from Other Applications**

– **Export to Other Applications**

3.14.4.1 External Database

This tab is visible only when **PatientOnLine client-server** is connected to an External Database Management System (**EDBMS**). It contains a journal of all the import/export import/export operations from/to EDBMS and the same commands (available as clickable links) that are available in the Patient Frame:

– Import all patients

– Export all patients

– Import current patient

– Export current patient
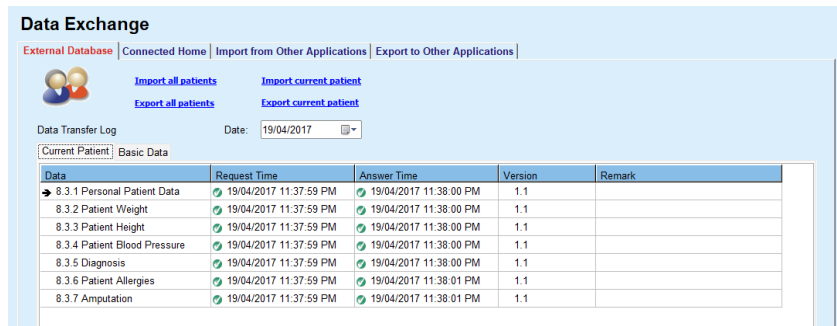
Fig. 3.129 Data Exchange with External Database - Current Patient

The Data Transfer log has two tabs: **Current Patient** and **Basic Data**. The Data is filtered by date from the **Date** calendar control.

The **Current Patient** tab displays the import/export operations for the current patient, organized on data categories. Import operations are numbered as 8.3.* and export ones as 8.4.*. The time when the request to **EDBMS** was made and the time when the answer from **EDBMS** was received are displayed.

Note

The import/export operations categories depend on the **EDBMS** and server configurations.

The **Basic Data** tab displays a record of the patient-independent data import, such as EDBMS identification, patient list, and QA settings. Basic data categories are numbered as 8.2.*.

The 4 link buttons performs the import/export operations for the current patient or for all the patients. By default a full import/export operation takes place whenever the server is restarted. Usually the server is scheduled to re-start automatically every night so **PatientOnLine** data is automatically synchronized every day with the **EDBMS**. However, the 4 link buttons allows you to perform import/export operations at any moment.

Depending on server-side and EDBMS configurations, certain options may be unavailable. For example, if the server is configured so that all medical data is editable in **PatientOnLine**, the link buttons will be as follows:

Regardless the server configuration, patient enrollment and patient data editing can be performed only at EDBMS level.

Upon clicking on a link button, a confirmation message appears informing about the start of the operation:

After a short time, the **Data Transfer** log tabs will be refreshed with the new import/export operations that were triggered by the link buttons.

3.14.4.2 Import from Other Applications tab

The **Import from Other Applications** tab allows the user to directly import data from other Fresenius application databases, including from other PatientOnLine application. Depending on the selected product range, the following applications will be available in separate tabs:
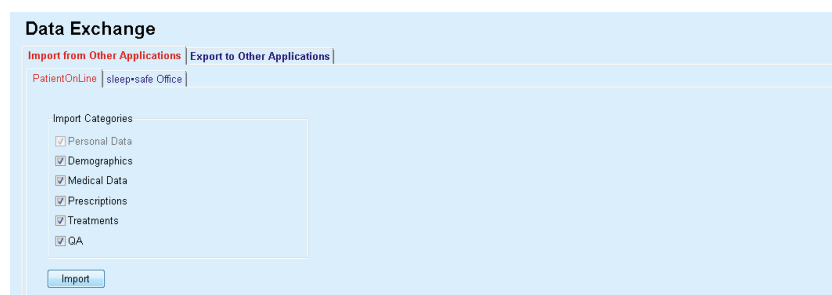
Fig. 3.130 Import from Other Applications

PatientOnLine

This option allows the user to import data from another **PatientOnLine** application. This feature is very useful for handling data between two **PatientOnLine** instances. The import operation is file oriented based on a proprietary file format and the file is encrypted. The name of such files contains the suffix **POL** and a time stamp, for quick identification.

To import data from another PatientOnLine application, one must proceed as follows:

➢ Select the **Import from Other Applications** tab from **Communication/Data Exchange**;

➢ Select the desired import category from the **Import Categories** list;

The following categories are available:

- **Demographics,**

- **Medical Data,**

- **Prescriptions,**

- **Treatments,**

- **QA.**

Tip

By default, when the **Import from Other Applications/PatientOnLine** tab is selected for the first time, all import categories are selected. Patients' basic personal data is **always** selected.

➢ Click the **Import** button;

An **Open** dialog window similar to the ones in Windows is opened allowing for the navigation to the storage location and selection of the data files to be imported.

Tip

By default, the **Open** dialog window is positioned in the **Data Exchange** folder.

➢ Click the **Open** button

If a patient is found in the **PatientOnLine** database, a confirmation window will be displayed, asking the user whether the patient's data should be overwritten.

Note

Overwriting the data for one patient by importing a data file may change the data associated to that patient.

Tip

Checking the **Apply all** check box will apply the selection to all subsequent patients when clicking on the **Yes** and/or **No** button.

By clicking on the **Cancel** button, the entire import operation including all prior selections will be canceled.

During the import operation, a progress bar is displayed, illustrating the status of the operation.

After the import, an **Import Results** pop-up window is displayed, summarizing the personal patient data and the number of items imported for each category of data. The text within the window can be saved in a text file by means of the **Export as Text** button. If no patients have been imported, the **No Patient Imported** message will be shown.

If a patient from the external file is found in the **PatientOnLine** database, a confirmation window will be displayed, asking the user whether the patient's data should be overwritten. Checking the **Apply all** check box will apply the selection to all subsequent patients when clicking on the **Yes** and/or **No** button.

By clicking on the **Cancel** button, the entire import operation including all prior selections will be canceled.

During the import operation, a progress bar is displayed, illustrating the status of the operation. Instead of the **Import** button, a **Cancel** button is available by means of which one can interrupt the import operation at any time.

After the import operation is completed, a summary window is displayed, describing the status of each imported patient. For a quick identification the patients's name and birth date are also listed. The text within the window can be saved in a text file by means of the **Export as Text** button.

3.14.4.3 Export to Other Applications tab

The **Export to Other Applications** option is a very useful feature of **PatientOnLine** that increases the application's flexibility and strengthens its open character. This option is file oriented, allowing the user to export data from **PatientOnLine**:

– to another **PatientOnLine** application, using a proprietary file format. This file is by default stored in a predefined folder - Data Exchange. This file is located under:

%SystemDrive%:\Users\<User>\My Documents\PatientOnLine\ Data Exchange
whereas **<User>** is the name of the current Windows user and **%SystemDrive%** is the drive where the operating system is installed (usually C:);

and/or

– to another software application, using XML format. The resulting XML data file is self-descriptive. The generated data file is by default stored in the same **Data Exchange** folder as mentioned above.

In both cases, the generated data files can be stored at any place that the user specifies.

Moreover, these generated data files have standard names, like **POL_20190620_120642** or **POL_20190620_120642.xml**. The file name contains a time stamp for quick identification.

Selecting **Communication/Data Exchange/Export** will display the window illustrated in Fig. 3.131.
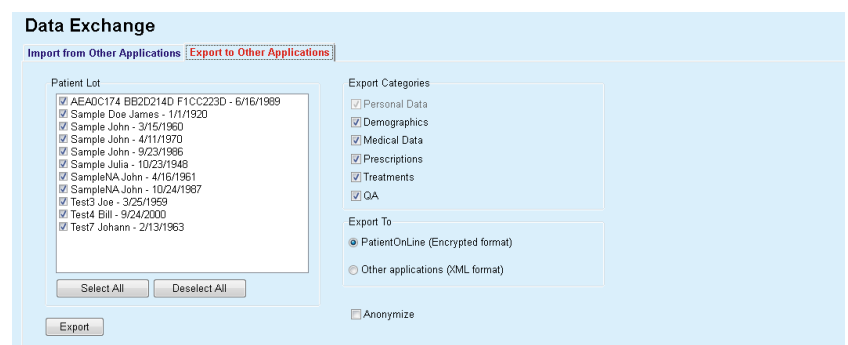
Fig. 3.131 Export tab window

To export data from the **PatientOnLine** application, one must proceed as follows:

– Select the **Export** tab;

– Select the patient by checking the corresponding check box.

Tip

By clicking on the **Select All** or **Deselect All** buttons, all patients can be selected and/or deselected quickly.

Tip

By default, when selecting the Export option for the first time, all patients in the lot are selected.

Tip

The Patient Lot list is displaying the name and birth date of each patient in the application's database, for an easy identification.

– Select the export categories:

Demographics,

Medical Data,

Prescriptions,

Treatments,

QA.

Tip

By default, when selecting the Export option for the first time, all export categories are selected. Patients' basic personal data is **always** exported.

Tip

Treatments are exported in a binary format to another **PatientOnLine** application.

– Select an export format in the **Export To** field.

PatientOnLine (Encrypted format)

or

Other applications (XML format)

– Click the **Export** button.

The export operation is launched, the progress of the operation is displayed.

If the export operation has been successful, a confirmation message is issued indicating the location (full path) of the generated data file.

Note

If the export operation has failed, a warning message is issued, indicating the cause of the failure.

Note

If the Patient Lot is empty, no export is performed, consequently no data file is generated, and a warning message is issued.

Note

Besides the patient data, a hospital list and a staff list will be added at the end of the XML file, containing all hospitals and staff that were associated to the selected Patient Lot by means of hospitalization episodes.

Note

All medical lists are also exported, with text description in the current **PatientOnLine** language.

Note

It is possible to export anonymous data from **PatientOnLine** with respect to patient names (only initials are exported) and birth date (only the year is exported). Patient addresses, contact information and PIN are not exported either.

To do this, simply check **Anonymize** check box in the **Export to Other Applications** window.

3.14.4.4 Connected Home

This tab is visible only when the **PatientOnLine** client-server is connected to a remote PD treatment cloud (generically named **Connected Home**). The tab contains a journal of all the import/export operations from/to **Connected Home** and the command (available as a clickable link) for importing patient data.

Note

Only users that have the **Connected Home** user right are able to access the **Connected Home** tab.

The Connected Home concept is dedicated to home dialysis patients that are under CAPD or APD therapies. In PatientOnLine there are clear data entities like:

– CAPD treatment protocols (see chapter 3.12.3.2, page 125)

– APD treatment protocols for *sleep•safe harmony* treatment protocols (see chapter 3.12.2.3, page 106)

– Blood pressure measurements (see chapter 3.11.4.3, page 73)

– Exit site images (see chapter 3.11.3.3, page 64)

For APD patients, a special device located at the patient's home can read the patient card, pack and encrypt treatment protocols from the patient card and send the data to the the **Connected Home** cloud.

The data is encrypted by the gateway and can only be decrypted by the **PatientOnLine** at the clinic. The encryption algorithm is based on the so-called asymmetric (public key) cryptography. The **PatientOnLine** in the clinic generates a pair of encryption keys (one public and one private). The public key is sent to the **Connected Home** cloud which in turn sends it to the gateway located at the patient's home. The public key allows only the encryption of data, while decryption is possible only by using the private key, which is located within **PatientOnLine** in the clinic.

Each clinic has distinct encryption keys. This means that nobody outside the clinic where **PatientOnLine** is installed can decrypt the transferred files. From this perspective, the **Connected Home** cloud is a simple repository of files, and no entity at the cloud level can decrypt the files.

A patient must be enrolled to **Connected Home** before any communication can take place. An enrolled patient can be dropped-out from Connected Home at any time. For details about patient enrollment and drop-out operations (see chapter 3.15.4.10, page 220). The clinic must also be enrolled to **Connected Home**.

PatientOnLine queries the **Connected Home** cloud periodically, requesting a list of available encrypted files. If the cloud delivers such a list, a sequence of reading (downloading) operations follows. Once a file is successfully read from the cloud, the respective file will not be downloaded again, unless this is explicitly required. Only enrolled patients are considered in the communication between **PatientOnLine** and **Connected Home**.

The **Connected Home** menu has two tabs: **Current Patient** and **Basic Data**. The data is filtered by date from the Date calendar control. By default, the calendar is set to the current date.

The link **Import all patients** triggers a full import operation of all files available for all enrolled patients.

The **Current Patient** tab displays the communication operations for the current patient, organized by data categories. Operations are numbered as 8.2.* and can be patient enrollment, patient drop-out, read file, and delete file. The time when the request to **Connected Home** was made and the time when the answer from **Connected Home** was received are displayed. The **Remark** column may contain error or warning messages in case the respective operation was not successful.

Fig. 3.132 Data Exchange -Connected Home - Current Patient

The **Basic Data** tab displays a record of the patient-independent data import, such as **Connected Home** identification, export of public encryption key and request for the list of files. The **Remark** column may contain error or warning messages in case the respective operation was not successful.

Fig. 3.133 Data Exchange - Connected Home - Basic Data

3.14.5 GDPR Actions

This menu item opens a dialogue in which you can apply GDPR actions like anonymize, delete or export data for the currently selected patient. If needed, you can check the check box "View inactive patients" (see chapter 3.15.4.3, page 212), so that GDPR actions are applied to inactive patients.

Fig. 3.134 GDPR Actions

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 allow to specify 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** perform the GDPR-specific actions: anonymize personal patient 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 workstation where the exported files should be saved. For XML export, a unique XML file will be created, having the name POL_<patient ID>_<from>_<till>.xml. For PDF export, several PDF files will be created for various data entities, having the generic name POL_<patient ID>_<category>_<name>_<from>_<till>.pdf, where <category> is the data category and <name> is an optional name of the respective data record.

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 data records 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 **Cancel** button.

3.15 Administration

3.15.1 User Administration Module

The **Users** menu item offers an overview on users, groups and rights. It also allows logging off from the application. In case of **PatientOnLine Stand-Alone**, the user may change its password using this menu option. After selecting the **Administration/Users** menu item, the User Administration Module window is displayed.

(see Fig. 3.135, Fig. 3.136 and Fig. 3.137)

Fig. 3.135 The **Administration/Users** *menu item*
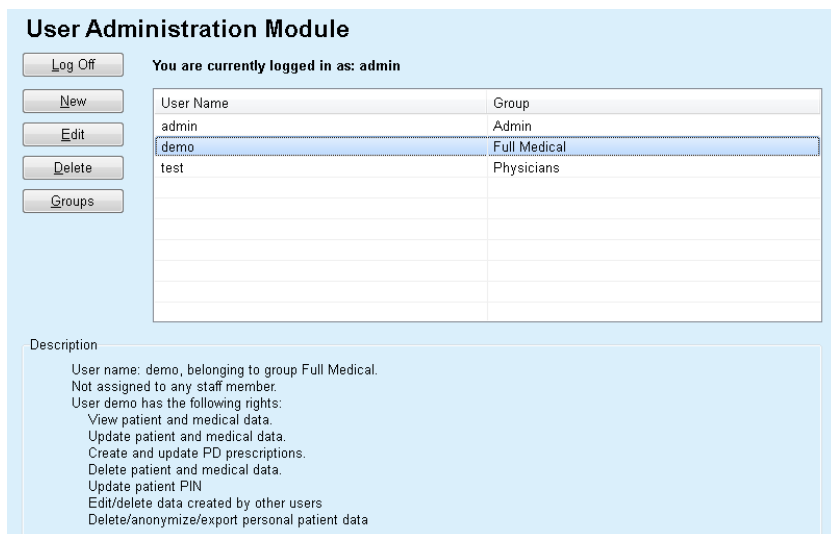
Fig. 3.136 The Users Administration Module window in case of Stand-Alone installation
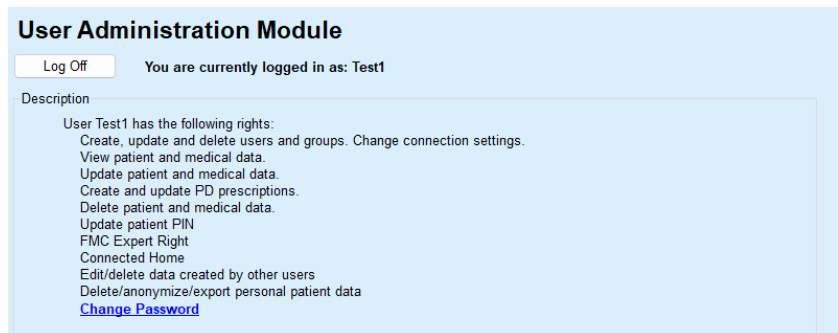
Fig. 3.137 The Users Administration Module window in case of Client-Server installation

A group is a category of users, having certain rights and a name for identification. Each user must be assigned to a group and consequently will benefit from the group rights. The **PatientOnLine** application provides several default rights, having the following meaning:

Admin
the right to create, update and delete users and groups, as well as to change the connection string to the database;

View
the right to view patient data and medical data;

Edit
the right to update patient data and medical data;

Make Prescriptions
the right to create and update APD and CAPD prescriptions as well as the right to create patient cards;

Delete
the right to delete patient data and medical data

Update Patient PIN
the right to update personal patient identification number;

Edit/delete data created by other users
the right to change or delete data that was created or updated by other users;

Delete/anonymize/export personal patient data
the right to perform GDPR-related actions like deleting or anonymizing personal patient data, or exporting of patient data to machine-readable/printable format.

Based on these rights, the **PatientOnLine** application provides also several default groups, namely:

Admin
only having the **Admin** right;

Viewers
only having the **View** right;

Nurses
having the **View** + **Edit** right;

Physicians
having the **View** + **Edit** + **Make Prescriptions** right;

Full Medical
having the **View** + **Edit** + **Make Prescriptions** + **Delete** + **Edit/delete data created by other users** + **Delete/anonymize/export personal patient data** right.

Tip

After installing **PatientOnLine** an Admin user is provided by the **PatientOnLine** application.

After selection of a certain user in the **User** menu item, a description of the rights assigned to that user is displayed in the **Description** field (see **The Users Administration Module window in case of Stand-Alone installation**, page 201), (see **The Users Administration Module window in case of Client-Server installation**, page 202).

The **Log Off** button allows the user to log off from the application. A confirmation window is displayed and the user is asked to log in again, following the procedure described in the section Opening and closing the **PatientOnLine** application.

In case of a **PatientOnLine** Stand-Alone installation, depending on the password rights set for each user, it is possible for the user to change its own password by pressing the **Edit** button and typing the old and new password, as well as the password confirmation.

3.15.2 Hospitals

The **Hospitals** menu item allows for the management of the **Hospitals** and the **Departments**, **Wards** and the **Staff**, providing means for creating, editing and deleting such records. It is to be mentioned that these records are interconnected meaning that deleting a **Hospital record** will also delete all the records of the departments and wards of that hospital, and all the staff records assigned to that hospital, after a confirmation from the user. Such records can, however, be created and edited independently.

3.15.2.1 Hospitals management

After selecting the **Administration/Hospitals** menu item, the Hospitals menu is opened.

See Fig. 3.138 and Fig. 3.139

Fig. 3.138 The Administration/Hospitals menu item

Creating/editing a hospital record

In order to create a **Hospital** record, one has to proceed as follows:

➢ Click the **New** and/or **Edit** button.

The records existing in the table are greyed out. The input form will be available with empty input fields.
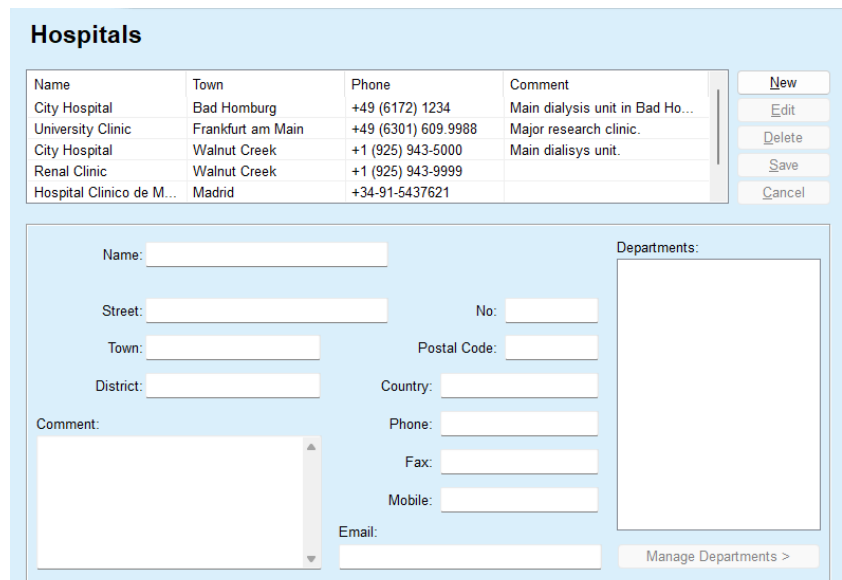
Fig. 3.139 The Hospitals window

– Type in the data in the corresponding text fields. (Name, Street, Town, Number, etc.)

The only mandatory data to fill in is the Hospital Name. In case this piece of data is not provided, a warning message is issued.

➢ Click the **Save** button.

The record is saved, the successful saving operation is displayed in a pop-up window.

If the saving operation fails, this is also displayed in a pop-up window.

Deleting a Hospital record

To delete a **Hospital record**, one must proceed as follows:

➢ Mark the record to be deleted in the list;

➢ Click the **Delete** button;

A safety prompt is opened.

➢ Confirm the delete operation with **Yes**;

A pop-up window appears to show that the delete operation has been successful.

➢ Click the **Yes** button.

The delete operation is finished.

Note

Deleting a **Hospital record** for which there is a hospitalization record is forbidden. In this case a warning message is issued and the delete operation is canceled.

3.15.2.2 Departments management

As departments records are associated to a **Hospital record**, they can only be created, edited or deleted if the corresponding **Hospital record** is selected.

Creating/editing/deleting a department record

Department records are **created**/**edited**/**deleted** in the same way as described under (see **Hospitals management**, page 203).

➢ By clicking on the **< Back to Hospitals** button, you can change back to the previous menu.

➢ Click on the **Manage Departments >** button to go to the **Departments** menu.

Note

A **Hospital record** that might not have been saved will be saved after a safety prompt. A pop-up window appears to show that the save operation has been successful.
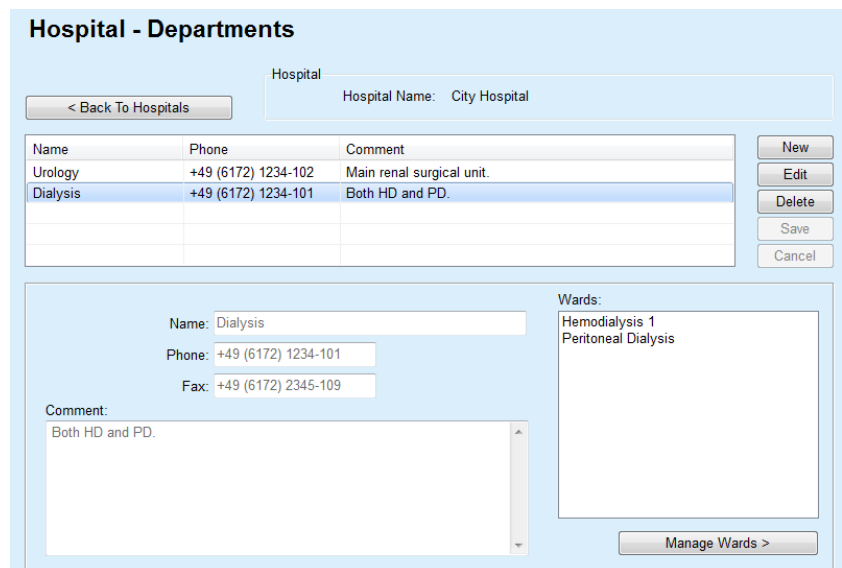
Fig. 3.140 The Hospital - Departments window

3.15.2.3 Wards management

Creating/editing/deleting a ward record

Ward records are **created**/**edited**/**deleted** in the same way as described under (see **Hospitals management**, page 203).

➢ By clicking on the **< Back to Hospitals** button, you can change back to the previous menu.

As **Wards** records are associated to a **Departments** record, they can only be created, edited or deleted if a **Departments** record is selected.
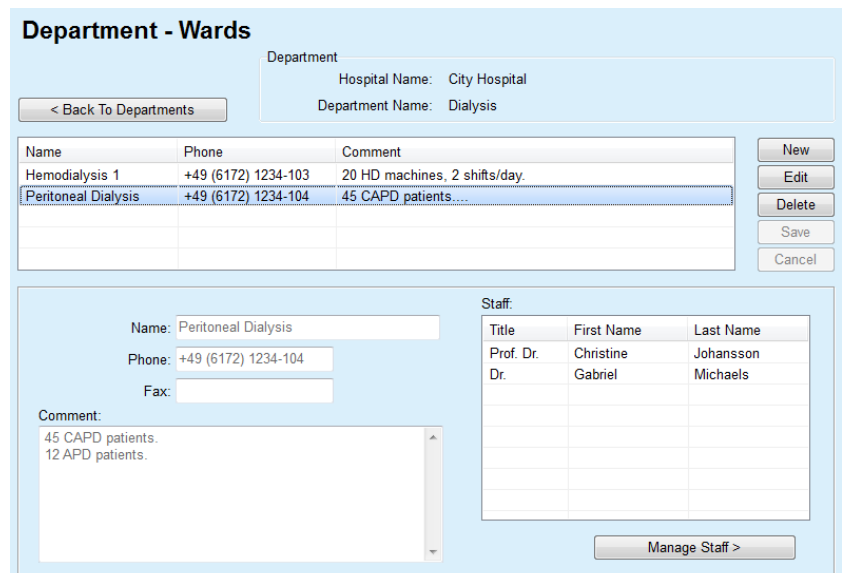
Fig. 3.141 The Department - Wards window

3.15.2.4 Staff management

Creating/editing/deleting a staff record

Staff records are **created/edited/deleted** in the same way as described under (see **Hospitals management**, page 203).

➢ By clicking on the **< Back to Hospitals** button, you can change back to the previous menu.

The **Staff** submenu item allows the user to create and to assign a certain staff member (record) to a certain **Hospital**, **Department** and **Ward**, as well as to edit and delete the data associated to this staff member.

Note

The staff members can be assigned to the **Hospital**, **Department**, **Ward** records under **Administration/Staff**

Creating/**Editing** a staff member record is straightforward.

Fig. 3.142 The Staff window

3.15.3 Staff

The **Staff** menu item allows for the management of **Staff records**, providing means for creating, editing and deleting staff records. It is to be mentioned that one can also access this item from the **Hospitals/Departments/Wards/Staff** menu. The functionality is described in chapter (see **Hospitals**, page 203).

3.15.4 Setup

The **Setup** menu item allows for the configuration of the application itself. Selecting this menu item from the menu tree as illustrated in Fig. 3.143 will display the Setup window, illustrated in Fig. 3.144.

Fig. 3.143 The Administration/Setup menu item

General Settings
for selection of QA formulae and various options used in QA tests;

Lab Data Settings
for setting the system of units of measurement for weight & height values, for temperature values and for urea input data, for setting the default conventional or S.I. system of measurement and for setting specific units of measurement for each lab data;

View Settings
for setting the visible columns in the Treatment Analysis menu, as well as other visibility options;

Limits
used to define height and weight limits for children and adults;

Transport Characteristics
for setting classification data of PET graphs, for both adults and children;

Medical Lists
used to manage all kinds of application medical lists;

Language
for selecting the **PatientOnLine** run-time language;

Custom Overview Settings
used to define the content of **Custom Overview** and **Dashboard** menus;

Connected Home
enables management of clinics and patients (enroll, drop-out) with respected to **Connected Home** cloud;

Events Log
enables access to the history of users' critical actions;

About
provides information about the **PatientOnLine** user license.

> **Note**
>
> Almost all of the settings available in the **Administration/Setup** menu are **global** settings, applicable for all **PatientOnLine Clients**, in case of a Client-Server installation. If a **PatientOnLine Client** is changing options of **General Settings**, **Lab Data Settings**, **Limits**, **Medical Lists**, **Events Log,** that change will apply to all of the **PatientOnLine Clients** in the network.

> **Note**
>
> Only **View Settings** and **Language** are local ones, so that each **PatientOnLine Client** may set these options independently one from another.

Fig. 3.144 The Administration/Setup/General Settings menu

3.15.4.1 General Settings screen

The **General Settings** tab allows several options to be specified, thus offering a great degree of flexibility.

1st section

In the first section of the **General Settings** tab, you can make the following selection/setting:

> **QA Body Surface Formulae**,
>
> **QA Body Water Formulae**,
>
> **QA nPCR Formulae**.

In this section, you can also distinguish between **Adults** and **Children**.

2nd section

In the second section of the **General Settings** tab, you can make the following selection/setting:

Use 3h Sample in PET
Also includes a 3-hour sample in the PET test.

Use free water clearances
Considers the plasma protein concentrations (if measured) in the equivalent urea/creatinine/glucose dialysate concentrations.

Use GFR for Creatinine clearance calculation

Calculates the renal creatinine clearance considering the glomerular filtration rate (GFR).

These options ensure the compatibility of **PatientOnLine** with other software packages that may use these features.

3rd section

In the third section of the **General Settings** tab, you can make the **settings for the** Graphs Values:

> QA Graph K1
> QA Graph K2
> QA Min Therapy Cr
> QA Min Therapy KprT/V

This section manages the QA Graphics constants section definitions in the QA Graph and the Minimum Therapy Graph (see **Quality Assurance**, page 135).

4th section

In the fourth section of the **General Settings** tab, you can make the **settings related to** Creatinine Correction factors, as follows:

> Blood Creatinine Correction Factor
> Dialysate Creatinine Correction Factor

This section manages the blood creatinine and dialysate creatinine correction factors. The correction factors can be defined according to the glucose concentration. This correction factor adapts the dialysate and blood creatinine concentration according to the glucose concentration (see **Quality Assurance**, page 135). The value of this factor is converted according to the current QA measurement system and to the current creatinine and glucose units of measurement. The input limits are also converted. These correction factors may be set individually for each QA test, as described in section 3.14.4.3 (see **Export to Other Applications tab**, page 195).

Note

Most laboratories perform this correction automatically, in which case the correction factor must be set to 0.

Changes on the General Settings tab:

In order to change the **General Settings** tab, one has to proceed as follows:

➢ Click the **Edit** button;

The **Save**, **Default** and **Cancel** buttons become active;

➢ Complete the changes on the tab;

➢ Click the **Save** button.

A pop-up window appears to show that the save operation has been successful.

Tip

Clicking on the **Default** button will bring all the settings to predefined values.

Note

In case PatientOnLine client-server is connected to EDBMS, the **QA formulae** for adults and children, as well as the **Use free water clearances** and **Use GFR for Creatinine clearance calculation** settings are provided by the EDBMS and can not be edited in PatientOnLine.

3.15.4.2 Lab Data Settings

The **Lab Data Settings** tab allows the user to change the units of measurement of the application.

The following settings can be made, upon pressing the **Edit** button:

> **Weight & Height Units**
> Kg & cm
> Pounds & inches

> **Usage of Urea input data in QA and Additional Lab Data**
> Use Urea Nitrogen
> Use Urea

> **Temperature Units**
> Celsius
> Fahrenheit

Selection of Default **Conventional Units**/Default **S.I. Units** applies to both, the menu item (see **Quality Assurance**, page 135) and (see **Additional Lab Data tab**, page 82) upon a mouse click on the **Default conventional** or **Default S.I.** buttons.

Depending on local country or hospital practice, Urea or Urea Nitrogen can be measured in blood, urine or dialysate.

In **PatientOnLine**, you can choose between Urea and Urea Nitrogen. The default settings are Urea Nitrogen in Conventional system and Urea in S.I. system. All QA and lab data will be automatically updated accordingly. An indication about the normal range of each of the two parameters is also displayed, to help the user to decide.

Note

In case PatientOnLine client-server is connected to EDBMS, the usage of **Urea Nitrogen** or **Urea** is provided by the EDBMS and can not be edited in PatientOnLine.

The **Lab Data Settings** tab allows also the user to define two sets of measurement units (one for the conventional system and one for the international system) for the Additional Lab Data and for the QA (see **Additional Lab Data tab**, page 82) and (see **Quality Assurance**, page 135). The lab data parameters are grouped in three tabs:

> **Blood**,

> **Urine**,

> **Dialysate**.

For each individual parameter, one can define a specific unit of measurement by selecting a nominator unit and a denominator one from the corresponding drop-down menus. The content of the single drop-down menus is chosen so that all possible combinations of units that may be encountered in hospitals and labs should be possible.
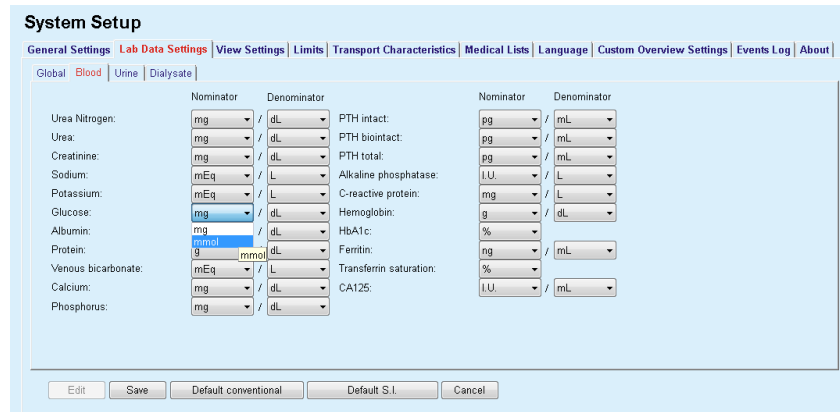
Fig. 3.145 Lab Data Settings tab

Changing the settings for the units of measurement for the lab data will be instantly reflected on the (see **Additional Lab Data tab**, page 82) and in the (see **Quality Assurance**, page 135) menu (see sections Additional Lab Data and Quality Assurance).

3.15.4.3 View Settings tab

On the **View Settings** tab, the visible columns of the treatment lists can be changed (see **Additional Information tab**, page 55). There is a total of 16 list items tied to 16 check boxes. The first 2 items are grayed out and cannot be unchecked. From the other 14, one can check 7 items at most.
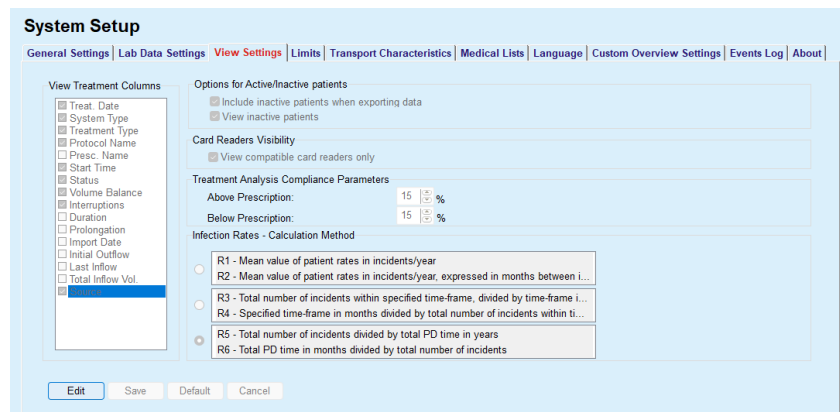
Fig. 3.146 View Settings tab

There are two **Options for Active/Inactive Patients**. The first one controls whether inactive patients will be included in data exports, and the second one controls the visibility of inactive patients in the **patient frame**. Checking the **View inactive patients** check box will include inactive patients in statistics criteria as well.

The **Card Readers Visibility** option allows the user to filter only the compatible card readers.

The **Treatment Analysis Compliance Parameters** defines the thresholds used in the **Custom Overview** and **Dashboard** menus to notify about differences between prescribed and performed treatment parameters.

The **Infection Rates - Calculation Method** section allows the user to specify which statistics methods will be used for group of patients' infection rates. The default methods are (R_5, R_6).

In order to make any changes press the **Edit** button, make the desired settings on the check boxes and/or radio buttons, or press the **Default** button (will restore the default view settings and options values), then press the **Save** button to save the configurations or the **Cancel** button to abandon the whole operation.

3.15.4.4 Limits tab

The **Limits** tab is used to customize the height and weight limits for children and adults. These values are used in the program in the **Assessment Methods** and in other frames. By default, the Smart Edit Controls contain the minimal and the maximal values that can be imposed.

The **Adulthood age** smart edit control defines the threshold for considering a patient as adult or child.

This is relevant for choosing adult/child QA formulae. Also (see **Additional Information tab**, page 55).

Note

In case PatientOnLine client-server is connected to EDBMS, the **Adulthood age** is provided by the EDBMS and can not be edited in PatientOnLine.

3.15.4.5 Transport Characteristics tab

The **Transport Characteristics** tab allows for the point-by-point definition of the standard PET graphics for adults (Twardowski graphics) and for children for urea, creatinine and glucose. In order to edit the values, for both Adults and Children, for Urea, Creatinine or Glucose, one should press the **Edit** button, make the changes or revert to default values, then press the **Save** button to actually save the record or press the **Cancel** button to abandon the operation. For urea and creatinine, the values should increase from left to right and decrease downwards. For glucose, the values should decrease from left to right and decrease downwards. If these requirements are not met, an error message appears when pressing the **Save** button. One can always revert to the original values by selecting the **Default** button, when in edit mode (after pressing the **Edit** button).
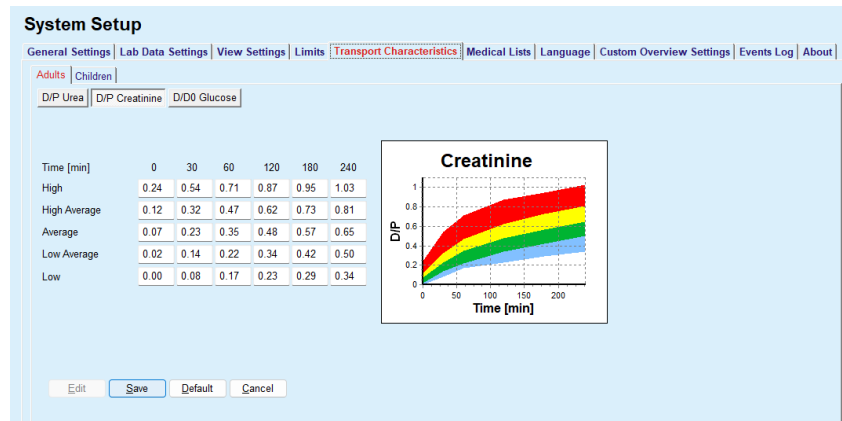
Fig. 3.147 Transport Characteristics tab

3.15.4.6 Medical Lists tab

The **Medical Lists** tab is used to manage the medical lists in **PatientOnLine**. These lists are used in different other frames. The tab looks differently according to the selected type of the medical list for Catheters List and for CAPD Solutions List).
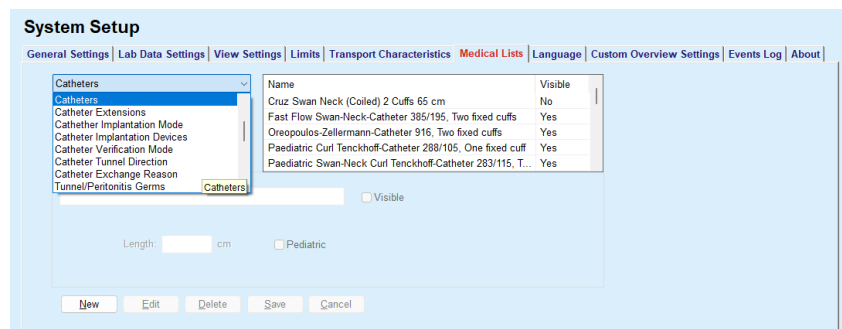
Fig. 3.148 Medical Lists tab - Catheters
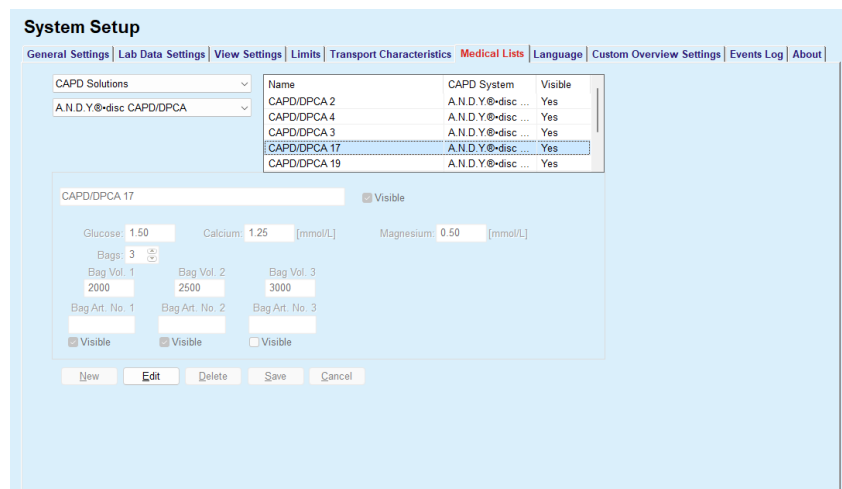
Fig. 3.149 Medical Lists tab - CAPD Solutions

The most important controls are the drop-down menu and the table.

The drop-down menu is used to select the target list where the user wants to add, delete or modify one item. The table presents the selected medical list elements. These elements can be managed using the buttons located at the bottom of the window (**New**, **Edit**, **Delete**, **Save** and **Cancel**).

Each item of the medical list has an attribute **Yes** and/or **No** in the **Visible** column. The status (**Yes** or **No**) of this list item is set by checking the **Visible** check box.

If this attribute is set to **No** this means that the corresponding element is invisible in the associated drop-down list.

Upon selecting the **CAPD Solutions** list, another **CAPD systems** drop-down menu is displayed in the left side. Selecting a certain CAPD system will refresh and display the corresponding available CAPD solutions (for the selected system only) in the table located in the right side of the window. The user should select a certain CAPD solution from the table and may only edit it in terms of **Visibility**. The same applies to the **APD Solutions** medical list, related to the **APD systems** drop-down menu and the **Visibility** edit option. By checking the "Global" check box, the visibility of the solution can be set for all versions of the selected cycler. By unchecking the "Global" check box, the visibility of the solution can be set only for the version of the selected cycler. This checkbook is visible only for *sleep•safe harmony*.

For the CAPD Solutions list, there are other types of controls, namely the **Bags** smart edit control, the **Glucose**, **Calcium** and **Magnesium** smart edit control and the **Bag Vol. 1**, **Bag Vol. 2**, **Bag Vol. 3** up to **Bag Vol. 6** smart edit controls. The **Bag Vol.** smart edit controls are available depending on the number of the **Bags** value. Also, one may specify the bag article number for each solution bag. Only in case of **Other CAPD** system, one can set the number of bags for the CAPD solution in the Bags control, the concentration of glucose, calcium and magnesium in the corresponding fields and the volume for each solution bag in the **Bag Vol.** x control, whereas x is the number of the bag. The same applies to **APD Solutions** list and the associated **Other APD** system as explained above for **CAPD Solutions** and **Other CAPD** system related to the fields available and editing options.

Upon pressing the **New** button, the user should specify the name of the new solution for the **Other CAPD** system, the number of bags, the associated **Glucose**, **Calcium** and **Magnesium** concentrations, and the **Volume** for each bag. The same applies in case of creating new **Other APD** solutions items. Also, one may specify the bag article number for each solution bag.

Note

One may add a new **CAPD Solution** item only for the **Other CAPD** system. For **all** the CAPD systems except **Other CAPD** system, the user may only edit the visibility of the item. The same applies to the **APD Solutions**: one may add a new **APD Solution** item only for the **Other APD** system. For **all** the APD systems except **Other APD** system, the user may only edit the visibility and bag article number of the item.

Note

The **Visible** check box is checked by default, so the new item appears visible in all frames.

Tip

When creating a new element of a medical list, the corresponding **Visible** attribute is set to "Yes". To change it to "No", one has to later edit the element (press the **Edit** button, uncheck the corresponding check box and press the **Save** button).

Note

One cannot delete an element of a medical list that is used by at least one patient.

Note

The default elements of the medical lists cannot be deleted. For these elements the user can only modify the **Visible** attribute by means of the **Edit** button. Elements that are used by at least one patient can not be hidden by clearing the Visible flag and cannot be edited (changed) either.

Note

If **PatientOnLine** is running in any other language than English, creating and editing an element of a medical list follows the same procedures as described above, except that one must also provide the English name. The English name is necessary for keeping the consistency of the database. If the item is used by at least one patient, the English name cannot be changed. This restriction applies in addition to general delete or edit restrictions described above.

Note

Changing the visibility of a PD System may also affect the visibility of Import from Other Applications sub-tabs.

3.15.4.7 Language tab

The **Language** tab contains information about the application's current language, namely language name, code page, decimal separator and short date format and a button that allows you to change the application language.

Note

Language Code Page, Decimal Separator and Short Date Format depend on the current Windows Regional Settings. The System Code Page represents the current Windows code page.

PatientOnLine is a multi-language application, fully translated in more than 30 languages. The list of available languages that appears when you click the **Language** button depends on the resources that are currently installed on the client computer:
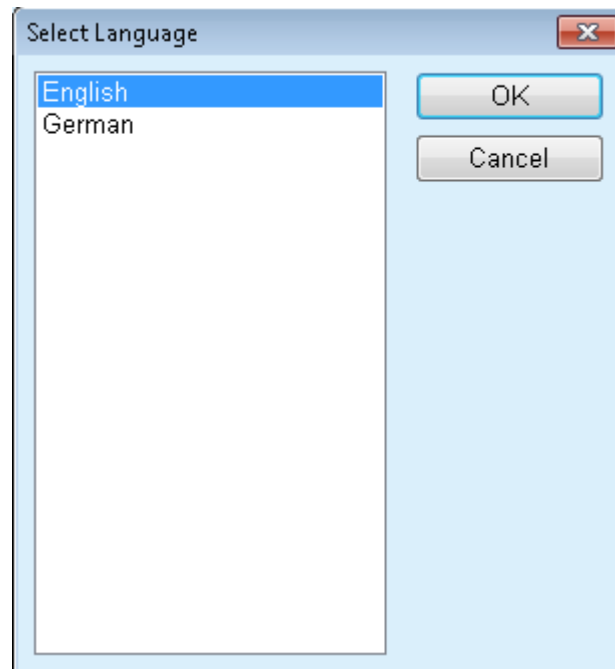
Fig. 3.150 Select Language option

Tip

After a language change, all **PatientOnLine** windows will be translated. This operation may take a few moments, depending on the computer speed.

Note

If the selected language is not compatible with the current Windows code page, a warning will appear and the language change will not take place.
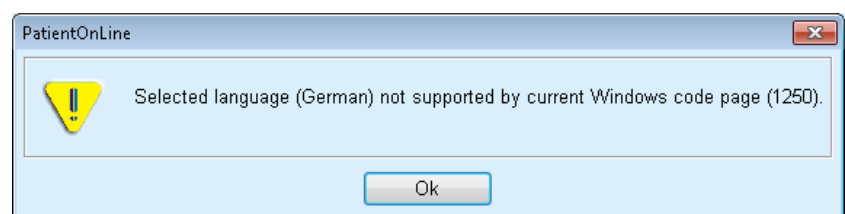
Fig. 3.151 Select Language Information window

3.15.4.8 Events Log tab

The **Events Log** tab displays the history of user actions. The following user actions are logged:

– Creating, updating, and deleting patient records

– Login and logout

– If a patient is selected: reading
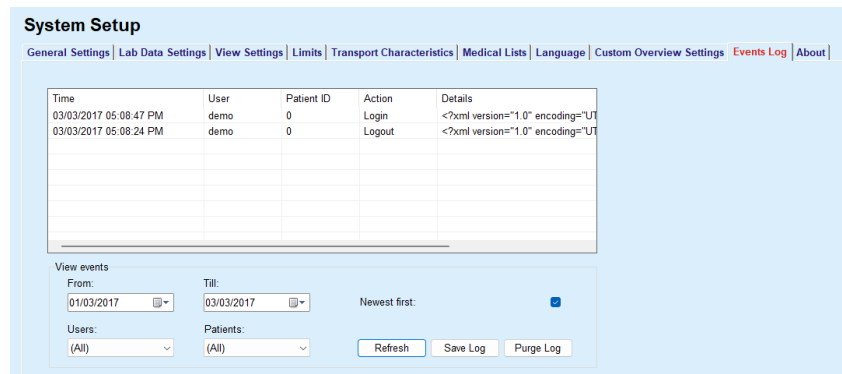
Fig. 3.152 The Events Log tab

The main element of this frame is the event table. Each row represents a single action. The columns of the table are:

Time
Represents the date and the time when that action was performed;

User
Contains the name of the user who performed the action;

Patient ID
The ID of the patient in the database

Action
Short description of the action;

Description
Action main parameters;

Details
Some detailed information about the action, if available.

Tip

If not all rows or columns are visible the user can navigate using the horizontal and vertical scroll bars.

In the **View events** section, the user can:

> Set the time interval for displaying the events by selecting the dates in the From and Till calendar controls;

> Filter the events for a particular user, using the **Users** drop-down list;

> Filter the events for a specific patient, using the **Patients** drop-down list.

Tip

By default, the **Users** drop-down menu is set to **(All)**; this option is always available. This list includes only the names of users that performed one or more **actions**. By default, the **Patients** drop-down menu is set to **(All)**; this option is always available.

> Set the criteria for **View events** ascending or descending, based on the time stamp of the event, using the **Newest first** check box;

Tip

Whenever some changes are made to these controls (**From**, **Till**, **Users** and **Newest first**), the **Refresh** button must be selected in order to update events table according to the new settings.

> Save the events list in a file on the hard disk in a predefined format (csv format) by selecting the **Save Log** button;

> Completely erase the events list by selecting the **Purge Log** button.

Note

Before the events list is deleted, the user has the possibility to save the events list in *.csv format.

The events list will only be deleted after a safety prompt.

Note

After a Purge Log operation is performed, all listed events will be deleted. It is recommended to perform a Save Log operation first.

A pop-up window appears to show that the delete operation has been successful.

3.15.4.9 Connected Home

This tab is visible only when PatientOnLine is connected to a **Connected Home** cloud and only if the current user has the **Connected Home** user right.

The **Clinic** tab allows you to set the status of the clinic with respect to **Connected Home**, by means of the **Edit**, **Save** and **Cancel** buttons. The **Status** list-box allows you to specify the current status as **Active** or **Inactive**.

Clinic address (street, city, country etc.) can also be edited.

The **Patients** tab allows you to enroll patients to or drop out patients from **Connected Home**, by means of the **Enroll patient** and **Drop out patient** buttons. The **Patient selection** drop-down list allows you to view all patients, only enrolled patients or only dropped-out patients. This can be helpful in case of large patient lists.

The patient list presents the patient enrollment status in the column **Status** and the active status in the column **Active**. Only active patients can be enrolled to **Connected Home**.

The **Enroll patient** button is enabled only if the selected patient from the list is active and is not already enrolled. The **Drop out patient** button is enabled only if the selected patient from the list is enrolled.
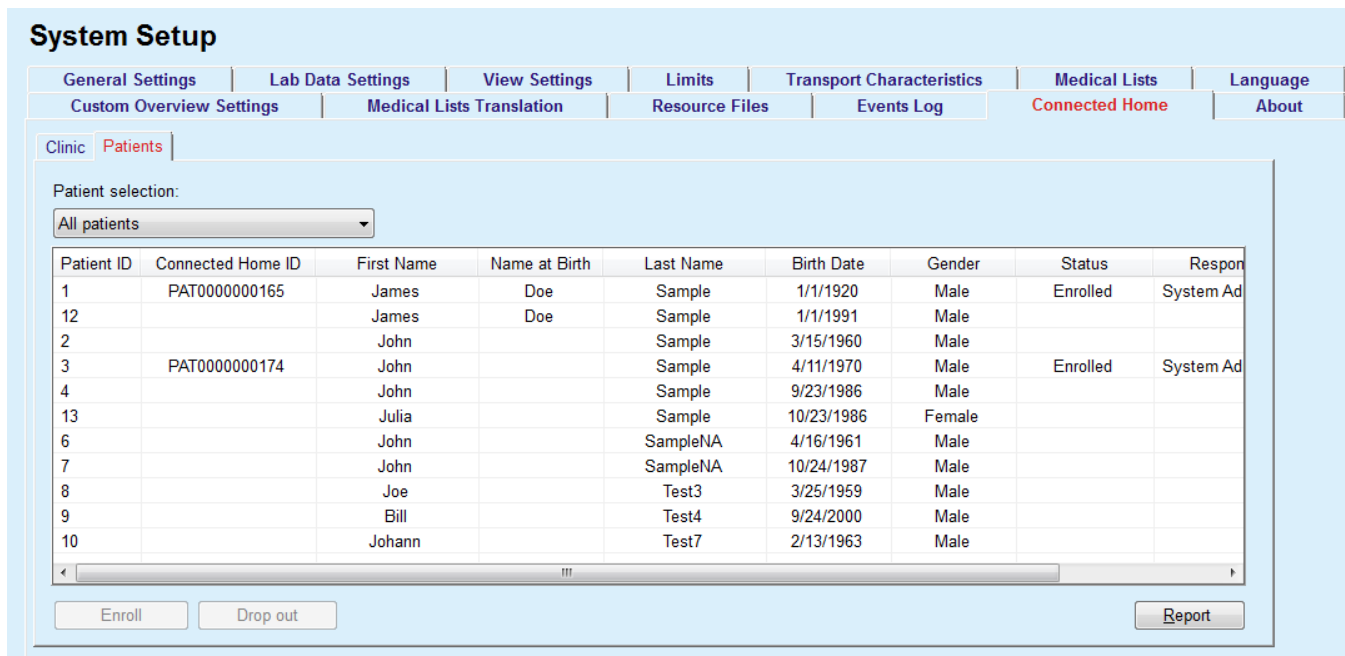
Fig. 3.153 System Setup - Connected Home

The **Report** button allows you to print a report with the same content as the patient list.

3.15.4.10 Custom Overview Settings

The **Custom Overview Settings** tab allows you to define the content of the **Custom Overview** and **Dashboard** menus.

Click on the **Edit** button to edit the settings, then click on **Save** or **Cancel** to finalize the operation. The **Default** button defines certain default settings.

Fig. 3.154 System Setup - Custom Overview Settings

In the **Overview Settings** panel, you can select the treatment parameters to be displayed in the **Custom Overview** menu and the compliance range (above/below prescribed percentages) that will trigger a status notification in case a selected treatment parameter's performed value differs too much from the prescribed one.

> **Note**
>
> For certain vital parameters like weight, blood pressure and volume balance, you can define patient-dependent notification limits. See sections (see chapter 3.11.4.1, page 68), (see chapter 3.11.4.3, page 73) and (see chapter 3.11.4.5, page 77).

In the **Dashboard Settings** panel you can select 4 treatment parameters to be displayed in the **Dashboard** menu. The parameters are displayed as a list or as tiled boxes, depending on the **Display boxes**/**Display list** radio-button. Right-click on a box/list item to select a certain treatment parameter. You cannot select the same parameter more than once. In addition, you can leave a cell empty by selecting <Empty>.

3.15.4.11 About tab

The **About** tab provides information about the licensing and registration of the PatientOnLine product. Depending on the stand-alone or client-server editions, certain settings like FIS address and port, or database connection string are available. On stand-alone editions, clicking the **Manage Registration** link allows you to register the product.

The available license agreement is displayed by clicking on the **Show License Agreement** link.

By clicking the **About** link, a regulatory information page is displayed that provides for example product logo, version, manufacturer, manufacture date, manufacturer address, information on the UDI. If required by local legislation, additional information about local representatives of the manufacturer or importer can be displayed.
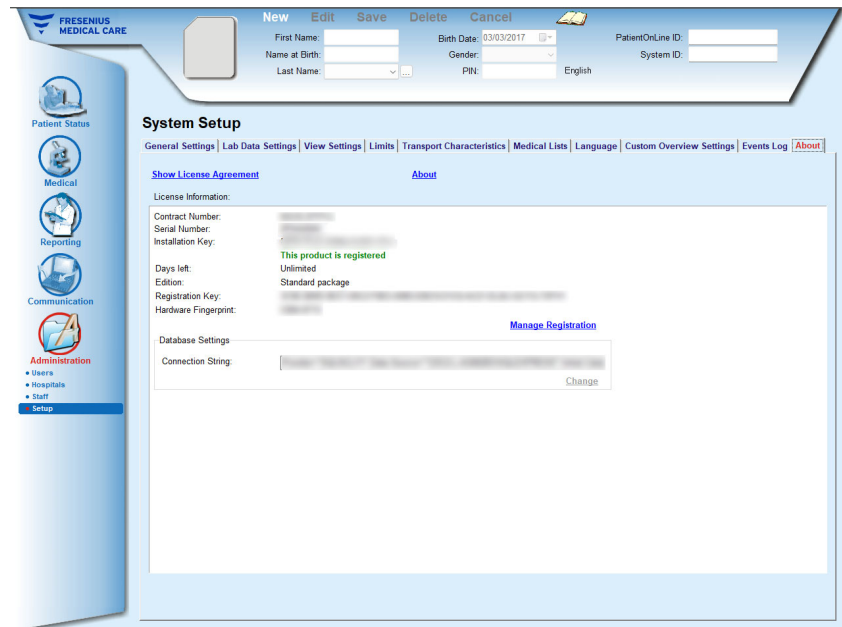
Fig. 3.155 About tab

Fig. 3.156 About page

4 Glossary

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

4.1 Abbreviations commonly used in quality assurance

● **Body Results**

    BSA   Body Surface Area

    V   Urea distribution volume or total body water

    nBW   Normalized body weight from total body water (V/0.58)

    BMI   Body Mass Index

● **Renal function**

    KrU   Residual renal urea clearance

    KrCr   Residual renal creatinine clearance

    GFR   Glomerular Filtration Rate

    RRF   Residual Renal Function

● **Urea result**

    KpT/V   Total peritoneal urea clearance per urea distribution volume

    KrT/V   Residual renal urea clearance per day per urea distribution volume

    KprT/V   Sum of peritoneal and renal urea clearance per urea distribution volume

    KprTw/V   Total weekly peritoneal urea clearance per urea distribution volume

● **Creatinine Result**

    KpT   Weekly peritoneal creatinine clearance per 1.73 m² BSA

    KrT   Weekly residual renal creatinine clearance per 1.73 m² BSA

    KprT   Sum of peritoneal and renal clearances per week per 1.73 m² BSA

- **Peritoneal Function**

  Pt50 Urea   Time to reach 50% of steady-state value for dialysate urea

  Pt50 Creat   Time to reach 50% of steady-state value for dialysate creatinine

  Pt50 Gluc   Time to reach 50% of steady-state value for dialysate glucose

  D/P Creatinine   The dialysate/plasma ratio for creatinine, measured at 4 hours after ins-
                           tillation

  Max. UF   The ultrafiltration obtained with a hyper-tonic solution (4.25% glucose)
                           measured at one hour after instillation

  FWT   Free Water Transport - the difference between Max. UF and the UF
                           across small pores, obtained with a hyper-tonic solution (4.25% gluco-
                           se) measured at one hour after instillation

  SPUF   Ultrafiltration due to transport of water through small pores

- **Fluid Removed**

  Volume balance   **Volume balance** is used throughout the Fresenius Medical Care PD
                           product portfolio currently. It describes the amount of fluid the patient
                           has lost by the dialysis session. It is calculated by the inflow volumes
                           minus outflow volumes of the treatment session. See Appendix for fur-
                           ther details (see chapter 5.3 , page 236).

  UF   **Ultrafiltration volume (UF)** describes the amount of fluid which has
                           been removed within dialysis treatment from the patient. **UF** is related
                           to the **Volume balance** by a change of sign. See Appendix for further
                           details (see chapter 5.2, page 233).

  Total volume removed **Daily (24 h) total volume removed** captures the volume contributions
                           from each section of a **PD treatment modality** undertaken by the pati-
                           ent and the 24 hr **Urine volume**. See Appendix for further details (see
                           chapter 5.2, page 233).

- **Glucose**

  TGA   Total glucose absorption per day

  Tcal   Calories absorbed from glucose per day

  nCal   Calories absorbed per kg of body weight per day

- **Na Removed**

  Na   Natrium (Sodium)

  NaCl   Salt

- **Protein Nutrition**

  PCR   Protein Catabolic Rate

  nPCR   Normalized Protein Catabolic Rate (PCR/nBW)

  DPL   Dialysate Protein Loss

  nDPL   Normalized dialysate protein loss (DPL/nBW)

  UPL   Urine Protein Loss

  nUPL   Normalized urine protein loss (UPL/nBW)

  TPL   Total Protein Loss

  nTPL   Normalized total protein loss (TPL/nBW)

  DPR   Dietary Protein Requirement

  nDPR   Normalized dietary protein requirement (DPR/nBW)

- **Creatinine Generation**

  GCr   Creatinine generation rate

  Predicted GCr   Predicted Gcr based on published data relating Gcr to age and sex. This represents the rate of creatinine generation as a function of muscle mass.

  Calculated GCr   Determined from the total (peritoneal and renal) creatinine clearances plus estimated gut creatinine clearance times the serum creatinine divided by body weight.

  % Variance   ((Calculated GCr - Predicted GCr)/Predicted GCr) * 100

                             A value higher than + 40% suggests that the patient may not regularly perform all the prescribed exchanges/cycles.

- **Lean Body Mass**

  LBM   Lean Body Mass

  Predicted LBM   Determined directly from the predicted Gcr, based on reported correlations of whole body potassium content to Gcr.

  Calculated LBM   Determined directly from the calculated Gcr, based on reported correlations of whole body potassium content to Gcr.

  % Variance   ((Calculated LBM - Predicted LBM)/Predicted LBM) * 100

                             A positive variance in LBM raises the question of compliance with the PD prescription.

● **Energy Metabolism**

EREE   Estimated Resting Energy Expenditure

nEREE   Normalized estimated resting energy expenditure (per body weight)

GA/EREE   Ratio of the energy-equivalent of total glucose absorption (in kilocal./day) and the estimated resting energy expenditure (in kilocal./day)

4.2   Abbreviations used

Abbreviation	Significance
APD	Automatic Peritoneal Dialysis
ACE	Angiotensin Converting Enzyme
ATII	Angiotensin II
BMI	Body Mass Index
BSA	Body Surface Area
BUN	Blood Urea Nitrogen
CAPD	Continuous Ambulatory Peritoneal Dialysis
CA	Cancer Antigen
CKD	Chronic Kidney Disease
CRC	Cyclic Redundancy Check
CRP	C-Reactive Protein
DB	Database
DOQI	Dialysis Outcome Quality Initiative
DPL	Dialysate protein loss
DPR	Dietary Protein Requirement
EDBMS	External Database Management System
EDTA	European Dialysis and Transplant Association
EREE	Estimated Resting Energy Expenditure
ESRD	End Stage Renal Disease
FME	Fresenius Medical Care
FWT	Free Water Transport
GDPR	General Data Protection Regulation
GFR	Glomerular Filtration Rate

Abbreviation	Significance
GUI	Graphical User Interface
HMG-CoA	3-Hidroxy-3-MethylGlutaryl coenzyme A
ICD	International Classification of Diseases
ISCED	International Standard Classification of Education
K/DOQI	Kidney Disease Outcomes Quality Initiative
LAN	Local Area Network
LBM	Lean Body Mass
NBW	Normalized Body Weight
NPCR	Normalized Protein Catabolic Rate
PC	Personal Computer
PCR	Protein Catabolic Rate
PD	Peritoneal Dialysis
PDF	Portable Data Format
PET	Peritoneal Equilibration Test
PFT	Peritoneal Functional Test
PIN	Personal Identification Number
POL	**PatientOnLine**
PTH	Parathyroid Hormone
QA	Quality Assurance
RRF	Residual Renal Function
RRT	Renal Replacement Therapy
RTF	Rich Text Format
SPUF	Small Pore Ultrafiltration
TBW	Total Body Water
TGA	Total Glucose Absorbed
TPL	Total Protein Loss
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPL	Urine Protein Loss
WCCF	Waste Concentration Factor
XML	Extended Markup Language

5 Appendix

5.1 Further Explanation of Volume Terminology

● **Volume Balance**

The term **volume balance** is used currently in several systems in the Fresenius Medical Care PD product portfolio. This term refers to the patient standpoint. Consequently, net fluid (ultrafiltrate) **removed** by the PD treatment process is regarded in the sense of a **decrease** in the patient's body weight. **Volume balance** in the Fresenius PD product portfolio is defined as:

Volume balance = Total inflow volume – Total outflow volume

Total inflow volume and **Total outflow volume** are determined for a given PD treatment modality. It is the sum inflow and outflow volumes contributed by each cycle/exchange of the treatment within a specific period of the PD treatment.

1. CAPD

2. APD

3. Manual exchanges

4. Renal function

5. APD & Manual exchanges

6. CAPD & Renal function

7. APD, Manual exchanges & Renal function

8. Treatment period (24 hrs)

9. Reporting period (24 hrs)

10. Flowsheet -> POL

11. APD cycler -> POL

12. Initial outflow (cycler assisted)

13. Last Inflow (cycler assisted)

14. CAPD UF

15. APD UF

16. Manual exchanges UF

17. Urine volume

18. Daily (24 hrs) total volume removed
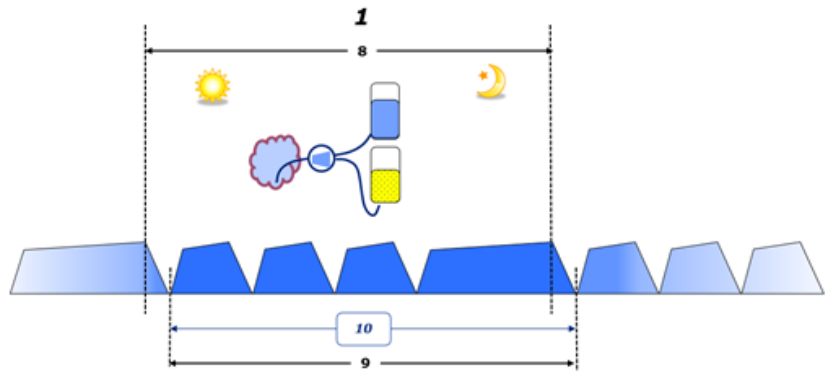
– In CAPD, the inflow and outflow volumes are reported in the patient's paper flowsheet. When the flowsheet data are entered manually into POL further analysis is possible such as calculation of the Volume balance.
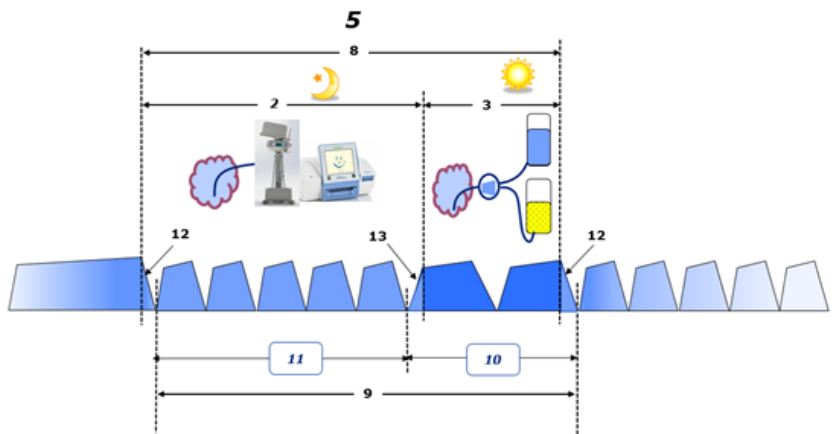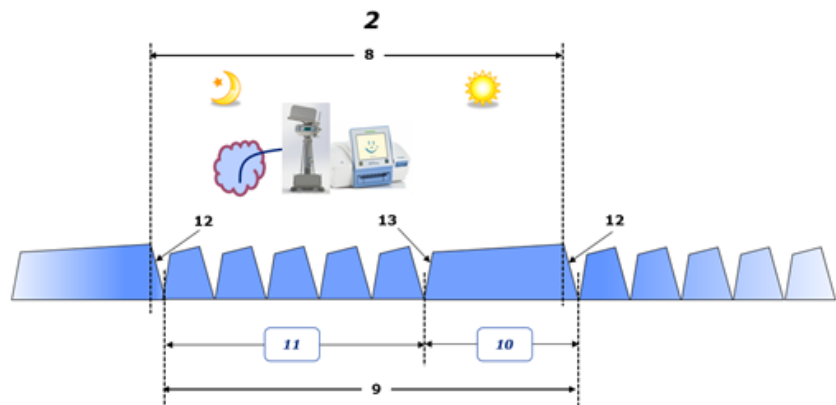
– In PD treatments performed only by an APD cycler such as CCPD or in PD treatments where combinations of APD and manual exchanges are involved such as PD-Plus:
   – The **Volume balance** for the period between the end of the Initial outflow and the beginning of the Last inflow is reported by the APD cycler.

– The **Volume balance** for the period between the beginning of the Last inflow and the end of the Initial Outflow is captured by the patient's flowsheet.

– The **Volume balance** reported by the APD cycler and captured on the patient's flowsheet may be aggregated in POL for further analysis.

At the end of a **PD treatment modality** when it is determined that a net volume of fluid has been **removed** from the patient, the **volume balance** reported is negatively signed, e.g. -1357 mL.

At the end of a **PD treatment modality** when it is determined that a net volume of fluid has been **gained** by the patient, the **volume balance** is positively signed, e.g. +308 mL.

● **Ultrafiltration Volume**

Ultrafiltration volume (UF) is the clinical term used widely within all forms of renal replacement therapy in the management of a patient's fluid status. UF is defined as:

UF = Total outflow volume – Total inflow volume

Total inflow volume and **Total outflow volume** are determined as the sum of inflow and outflow volumes contributed by each cycle of the treatment within a period of 24 hours.

At the end of a **PD treatment modality** when it is determined that a net volume of fluid (ultrafiltrate) **removed** from the patient, the **UF** is **positively signed** e.g. 1357 mL,

At the end of a **PD treatment modality** where it is determined that a net volume fluid has been **gained** by the patient, the UF is **negatively signed**, e.g. -308 mL. Of the fluid **gained**, some of this fluid may continue to reside in the peritoneal cavity (residual volume in the peritoneal cavity) while the remainder is **absorbed** into the circulatory system via the lymphatic system and peritoneal capillaries.

Ultrafiltration volume (UF) and **Volume balance** are related by a change of sign. Therefore

UF = - Volume balance

For example, if **Volume balance = -1357 mL** then **UF = +1357 mL**

● **Daily (24 hrs) total volume removed**

Daily (24 hrs) total volume removed captures the volume contributions from each section of a **PD treatment modality** undertaken by the patient and the 24 hr **Urine volume** as per the figures below.
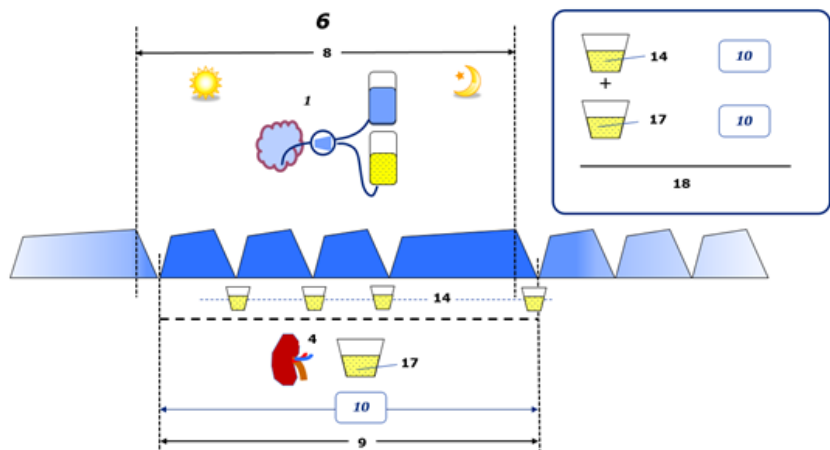
See the diagram legend on page 230.

In CAPD, **Daily (24 hrs) total volume removed** is calculated as:

Daily (24 hrs) total volume removed = CAPD UF + Urine volume

For example, if CAPD **UF = 1428 mL** and **Urine volume = 327 mL**, then **Daily (24 hrs) total volume removed = 1755 mL**.
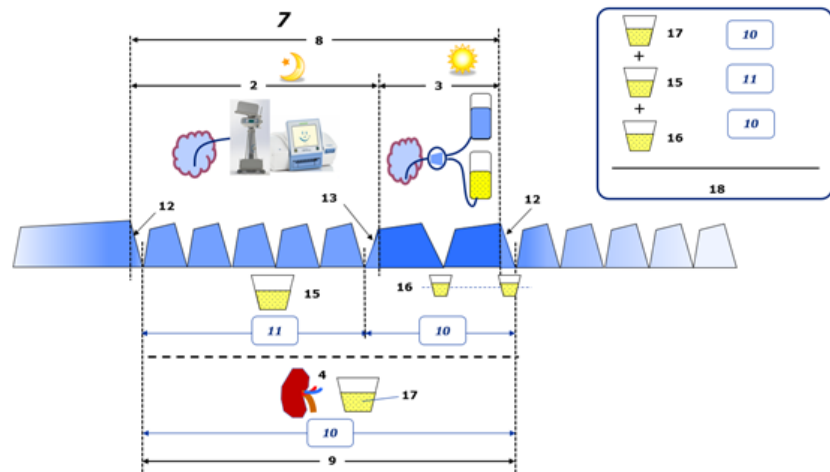
See the diagram legend on page 230.

In PD treatments involving APD only such as CCPD, **Daily (24 hrs) total volume removed** is calculated as:

Daily (24 hrs) total volume removed = APD UF + Urine volume

For example, if APD **UF = 1406 mL** and **Urine volume = 327 mL**, then **Daily (24 hrs) total volume removed = 1733 mL**.

In PD treatments involving APD AND Manual exchanges, **Daily (24 hrs) total volume removed** is calculated as:

Daily (24 hrs) total volume removed = APD UF + Manual exchanges UF + Urine volume

For example, if APD **UF = 1406 mL**, Manual exchanges **UF = 423 mL** and **Urine volume = 131 mL**, then **Daily (24 hrs) total volume removed = 1960 mL**.

● **Clinical usage of terms Volume balance and Fluid balance**

In everyday clinical practice, terms such as volume balance or fluid balance usually refer to the difference between total fluid intake and total fluid loss over a given period, often 24 hours. The patient is considered in steady state if the total fluid intake and loss are in 'balance'.

Total fluid intake is generally difficult to measure whereas it is possible to account for the total fluid loss with reasonable accuracy. Most of the Total fluid loss is represented by the Daily (24 hrs) total volume removed as described above, but insensible losses (respiration & perspiration) and fluid content of the stool are not included.

In the interests of further clarification, it is emphasised that the use of the term **Volume balance** in the context of the Fresenius Medical Care PD product portfolio applies **only to the PD treatment process**. The clinical usage of the term **volume balance** refers to an overall holistic view of the patient and therefore has a different meaning to **Volume balance** as used in the Fresenius Medical Care PD product portfolio.

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5.3   Symbols

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

Symbol	Description
	Follow Instructions for Use
$C\epsilon$ 0123	CE mark
	Manufacturer

Symbol	Description
SN	Serial number
MD	Medical device
UDI	Unique Device Identification

5.4 Instructions on the use of "Free software"

Contents

A. **Medical software application – "Free software"**

B. **Note required according to Regulation (EU) 2017/745 on Medical Devices**

C. **Information and remarks on the free software contained in the PatientOnLine device**

A. Medical software application device – "Free software"

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C. Information and remarks on the free software contained in the PatientOnLine device

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zlib
Zlib
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2. zlib

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