multiAssist Module User Manual

Version 4.0

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Ascom UMS s.r.l. Unipersonale
Via Amilcare Ponchielli 29, 50018, Scandicci (FI), Italy
Tel. (+39) 055 0512161 – Fax (+39) 055 829030
www.ascom.com

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1. multiAssist

1.1. Introduction

This manual describes the multi**Assist** module developed for Fresenius Medical Care (henceforth "Fresenius"). The exact name of the module is multi**Assist** with the word "Assist" written in bold characters. From now on, the module will be referred to as multiAssist.

The module is intended to support the clinical workflows around critically ill patients with Acute Kidney Injury (AKI) who need continuous kidney replacement therapies (CKRT) in ICU. It is designed to facilitate prescription, preparation, monitoring, and therapy adjustments for CKRT treatment.

Among the other things, the software responds to the need of nephrologists and other clinicians to be able to remotely organize and prepare prescriptions, then visible to other doctors and nurses in charge of setting up the dialysis machines.
Any configuration change performed in DIGISTAT® multiAssist is critical and must be implemented by technicians who are officially authorized and trained by ASCOM UMS.

The module is designed to work in conjunction with the Fresenius Multifiltrate Pro device. It does not support other Hemofiltration devices. The module supports CKRT workflows, however the therapy is fully performed by the Multifiltrate Pro device and is unaffected by the presence of the multiAssist module.

For information about the Product environment, precautions, warnings and intended use see USR ENG Digistat Care (for the Digistat Suite EU) or USR ENG Digistat Suite NA (for Digistat Suite NA). The knowledge and understanding of the appropriate document are mandatory for a correct and safe configuration of the multiAssist module.

The multiAssist module configuration is performed on the Digistat web configuration tool. See the Digistat Suite configuration manual for general instructions on the Digistat web configuration tool.

For any question regarding the Configuration of the multiAssist module contact Ascom technical assistance.

1.2. The Dashboard page

To access the main dashboard, a login with registered credentials is required. Enter the credentials and click on Login button.
The main dashboard is displayed:

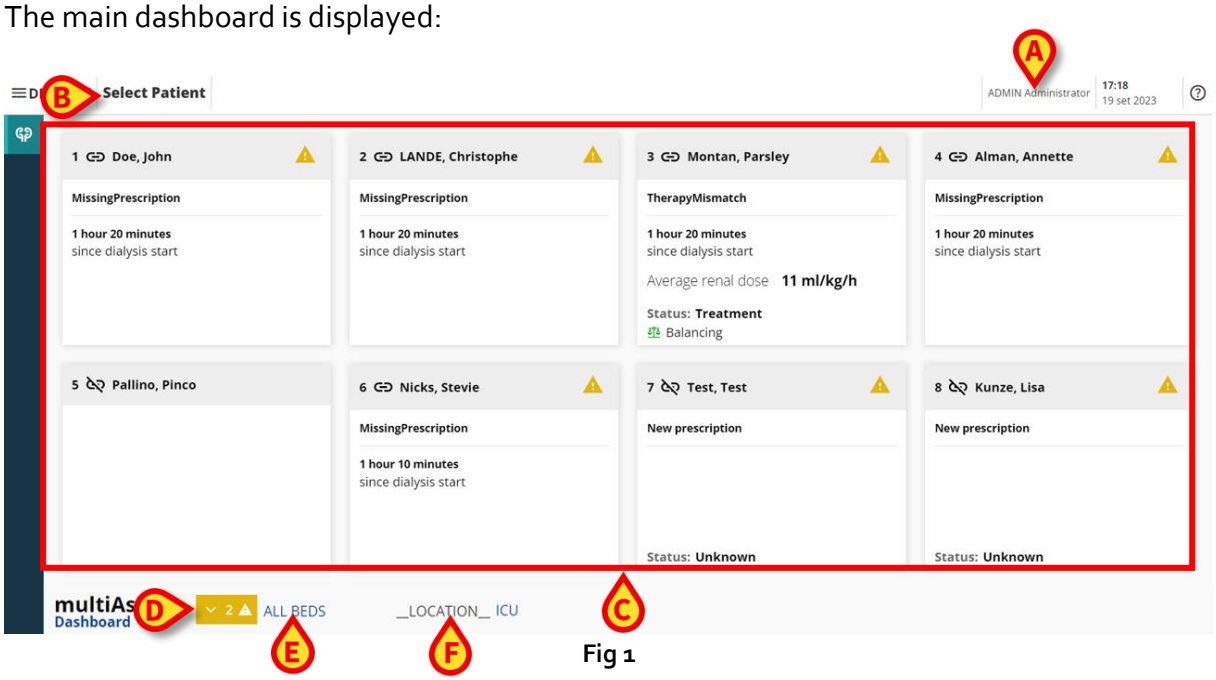


Fig 1

- At the top right there is a button with the abbreviation and the full name of the **username** who logged in and information on current date and time (Fig 1 **A**).

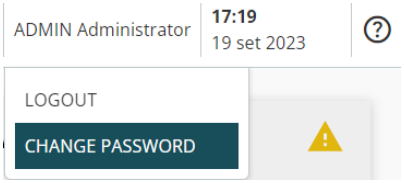


Fig 2

By clicking on the user button, a dropdown menu of two options is provided and it is possible to:

- Perform the logout of the current user clicking on **LOGOUT** button. The user is then redirected to the login page, or

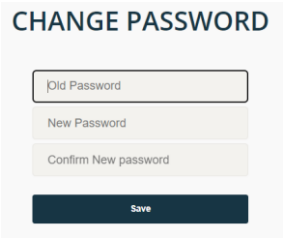


Fig 3

- Change the password clicking on **CHANGE PASSWORD** button. The user is then redirected to the "Change Password page" where they're asked to enter the Old Password and then the New Password twice.

- At the top left, the **Select Patient** button is provided (Fig 1 **B**). Clicking on it, a dialog window opens that allows the user to search among the patients registered on the application database or to create and add new ones (see Section 1.2.1.).
- In the central part, the dashboard is displayed (Fig 1 **C**), and the beds are arranged on a configurable number of rows (see Section 1.2.2.).
- If not all beds configured appear on the main page, a button with a down arrow is provided in the command bar at the bottom left of the window. Clicking on the down arrow button (Fig 1 **D**), the user can scroll the screen and view other beds.

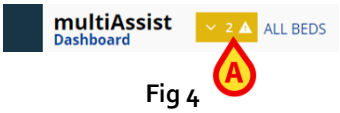


Fig 4

If a bed that is not currently displayed has at least one notification, the button appears yellow (Fig 4 **A**). Moving the cursor over the button, it is possible to display the warning message relating to the bed that is not displayed.

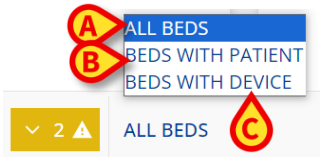


Fig 5

- A button is provided (Fig 1 **E**) and by clicking on it a menu of options to choose from is given: selecting the available buttons it is possible to show all beds (Fig 5 **A**) or only beds with associated patients (Fig 5 **B**) or beds with attached devices (Fig 5 **C**).

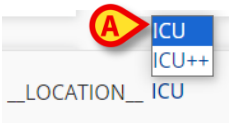


Fig 6

- Finally, the **LOCATION** button is provided (Fig 1 **F**) and by clicking on it a menu that contains all the configured locations to choose from (Fig 6 **A**) is given. Click on a location to display the associated dashboard.

1.2.1. Patient Selection and Patient creation form

Admissions, discharges and transfers of patients are generally managed through, and then all the information acquired directly from the **hospital information systems** and no particular action is required.
When the automatic import and update of information is not enabled or it is necessary to manually change patient information (or their admission status), the multiAssist module provides adequate tools.

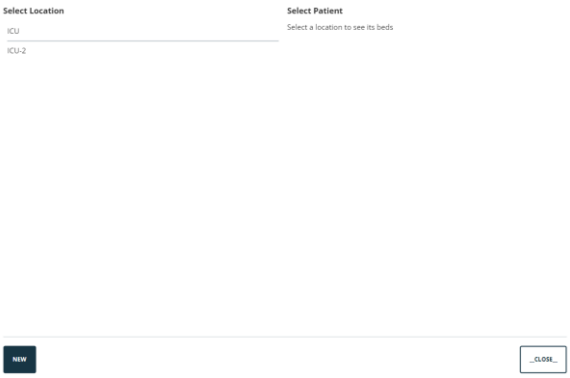


Fig 7

- As mentioned before, click on the **Select patient** button to open a new window where it is possible to select the Location.

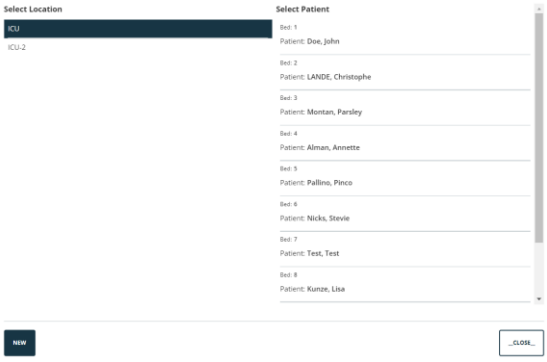


Fig 8

Once the Location has been chosen, the **Select Patient** section (Fig 8 **A**) is populated with a list of patient cards and for each patient, information on the occupied beds and their surnames and names are displayed. A **NEW** button (Fig 8 **B**) is also provided to start the creation of a new patient.

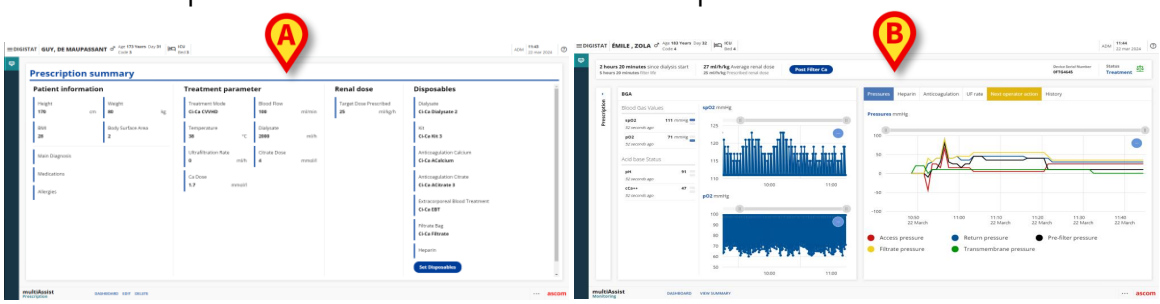


Fig 9

- Clicking on a patient card, the user is redirected to the patient detail page that could be a Prescription page (Fig 9 **A**) or a Monitoring one (Fig 9 **B**) depending on the patient's treatment stage.

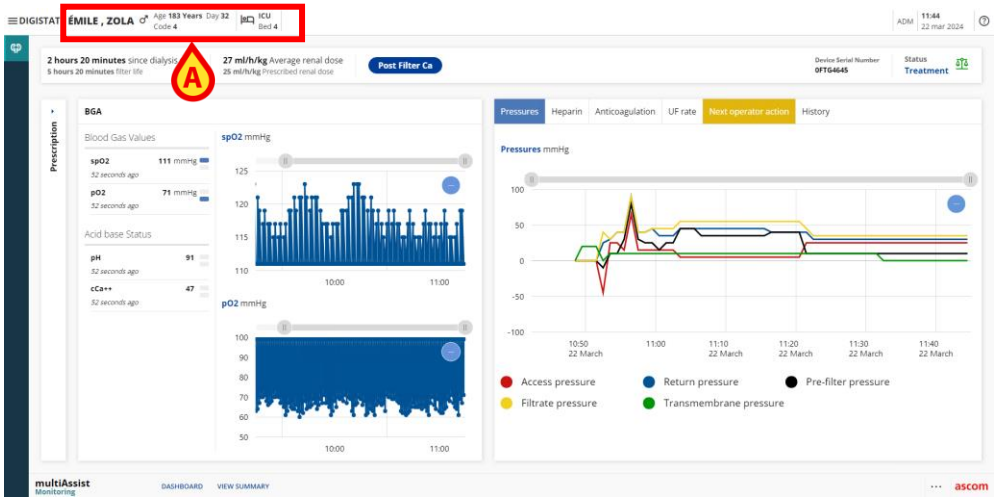


Fig 10

Fig 11

- Clicking on the **Patient** button on top of the Patient detail window (Fig 10 **A**) it is possible to come back to the Select Location/Select Patient window and from there to select one of the provided buttons:

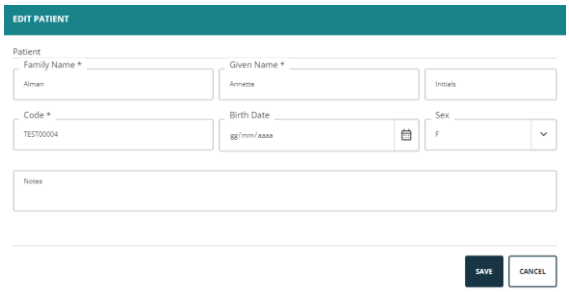


Fig 12

  - **EDIT**: to open the **EDIT PATIENT** (Fig 12) window and modify, add, or remove the originally entered patient data and information. The edit procedure can be performed both on admitted and not-admitted patients. Click on **SAVE** button to save the entered data or **CANCEL** button to abort the procedure;

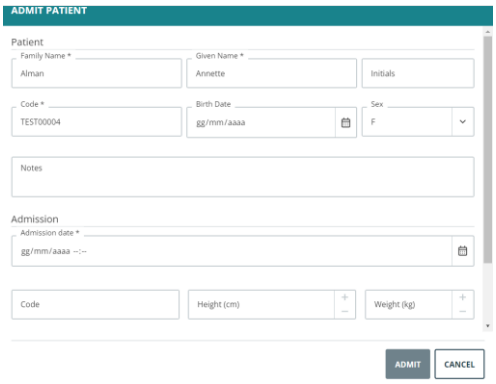


Fig 13

- **ADMIT** (Fig 11 **C**): to open the **ADMIT PATIENT** (Fig 13) window and modify, add, remove patient data, enter admission information, and associate bed to the selected patient. Click on **ADMIT** button to admit the selected patient to chosen Location and Bed;

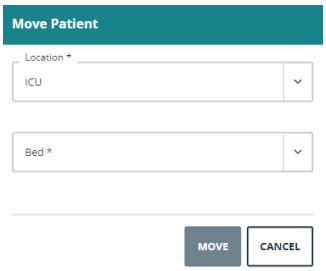


Fig 14

- **MOVE** (Fig 11 **A**): to move the selected patient to another Location and Bed;
- **DISCHARGE** (Fig 11 **B**): to discharge the selected patient. A confirmation dialog will be shown and if the user confirms, the patient is correctly discharged;
- **DELETE**: to delete the selected patient. Confirmation is needed;
- **NONE**: to deselect the patient and be redirected to the Main Dashboard page.

To create a new patient, go back to the Select Location/Select Patient page and

- click on **NEW** button provided (Fig 8 **B**). The following window opens:

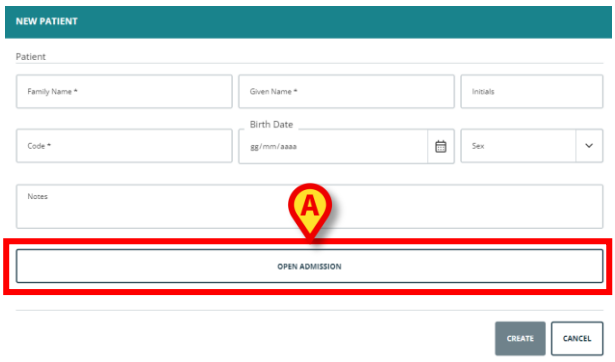


Fig 15

In the Patient section it is possible to enter patient information as Family Name, Given Name and Code (they are all mandatory fields), Initials, Birthdate, Sex and Notes.

- Enter all the necessary data;

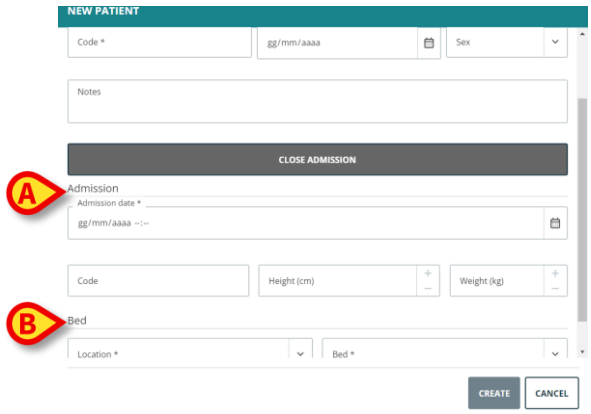


Fig 16

- Click the **OPEN ADMISSION** button (Fig 15 **A**) to expand the section and show the fields to be configured to proceed with patient admission.
- Fill in the fields provided in the **Admission** (Fig 16 **A**) section entering the **Admission date** (mandatory field), the admission **Code**, the **Height** and **Weight** of the patient at admission time.
- Fill in the fields provided in the **Bed** section (Fig 16 **B**), choosing the **Location** and **Bed** (both are mandatory fields) from the provided dropdown menus.
- Click on **CREATE** button to confirm the new patient creation or on **CANCEL** button to skip the patient creation procedure.

1.2.2. Dashboard Beds User interface

In the central section of the dashboard, the beds are displayed in rectangular boxes that can contain and display different information. They can be:

Fig 17

- **Empty**: the card appears completely white, and no data is displayed in the header of the card next to the bed number. **A crossed-out symbol is provided to indicate that no MultifiltratePro device is connected to the bed**. The empty beds can't be selected.

Fig 18

- **Occupied by patients**: patient data as name, surname, sex, age, code, location, and bed can be imported from the ADT system or they can be entered and edited from the application. Other information as weight, height, BMI, Body Surface Area, Medications and Allergies can be imported from hospital or user-entered software. The occupied beds can display different statuses:

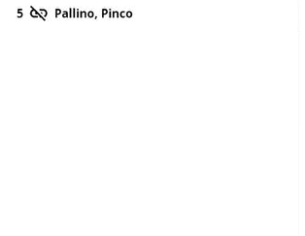


Fig 19

  - Occupied by patients**, not yet undergoing therapy**: the header displays the bed number, the crossed-out "link" symbol, the patient's name, and the card box is empty, no data appears.

Fig 20

  - Occupied by patients **undergoing therapy**, but **not connected to dialysis machine**: the card appears grey, and the warning: "**Missing connection**" is provided since no connection to a medical device is retrieved. This state is obtained in the case where the device was originally associated with the bed and then, by mistake or intentionally, was disconnected.

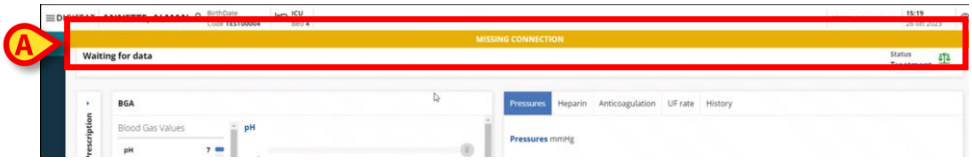


Fig 21

Clicking on the bed card, a yellow banner is displayed on the patient detail page with a "Missing Connection" warning at the top of the page, along with a "Waiting for Data" message (Fig 21 **A**).

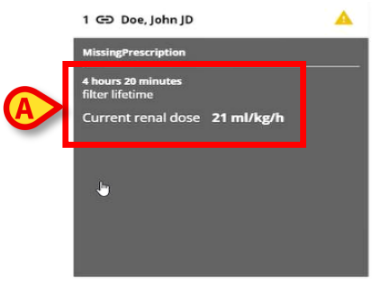


Fig 22

- **Patient connected to dialysis machine with ongoing therapy**: if a prescription has been correctly registered and the therapy is ongoing, the **link icon** is no longer barred, the **Average Renal Dose** is displayed in the body of the card along with the **elapsed time since the start of dialysis** treatment (Fig 22 **A**).

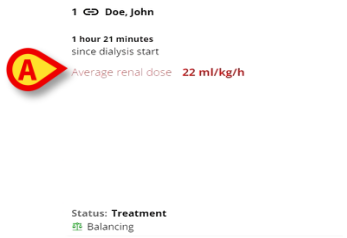


Fig 23

The Average Renal Dose message may appear in red (Fig 23 **A**), in case the average dose is below a certain threshold, lower than expected. Depending on the configuration, a grace period may be given before the red colouring of the Average Renal Dose message.

Renal dose is calculated only when all the following conditions are met: a prescription exists, a multiFiltratePro is connected, machine status is Treatment, balancing is active. At the beginning of a therapy, the renal dose calculation can be displayed a few minutes (up to 10) after the actual start of therapy.

Fig 24

The **Status** of the device is also displayed in the lower part of the bed card together with the **Balancing** label and icon (Fig 24 **A**) if the device is in balancing mode.

Some **warnings**, related to the status of the prescription and the therapy, may also appear on the card. The following warnings are available:

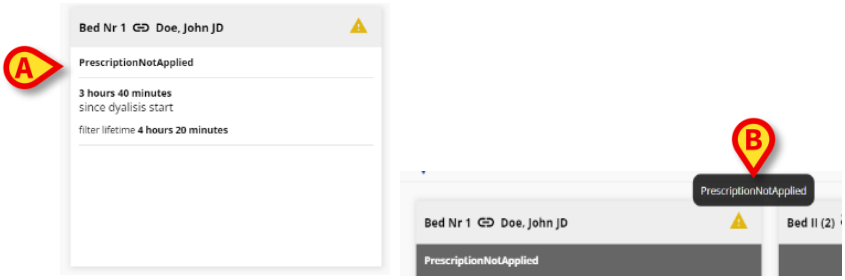


Fig 25

- **Prescription Not Applied** (Fig 25 **A**): if a misalignment is registered between the values recorded in the prescription compiled through the form and the values manually entered in the Fresenius machine. The device settings must be updated. Moving the cursor over the yellow warning symbol, a toast appears with the message "PrescriptionNotApplied" (Fig 25 **B**).
- **Prescription Settings Changed**: if the values sent from the device do not consistently align with those in the prescription. After a configurable grace period, the warning is displayed on the dashboard so that the anomaly recorded by the application can be checked and corrected. The parameter for configuring the grace period following a prescription change is the system option *AllowedTimesBeforeTherapyMismatch.*

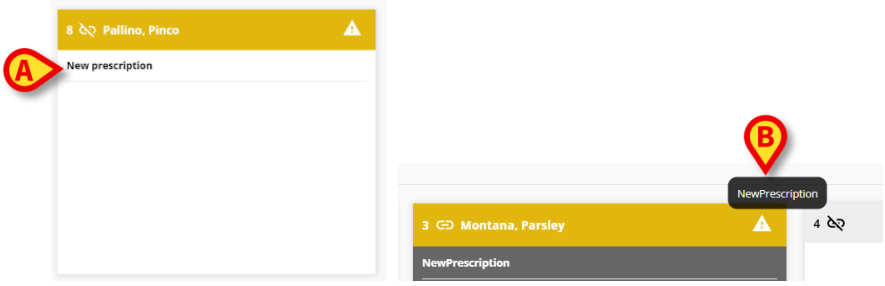


Fig 26

- **New Prescription** (Fig 26 **A**): in case a new prescription has been prepared by the doctor and needs to be viewed and then performed by the responsible nurse. No device is connected. Moving the cursor over the warning symbol, a toast appears with the message "NewPrescription" (Fig 26 **B**).

- **Missing Prescription:** in case a device with ongoing therapy has been connected but no prescription has been registered for that patient.
- **Device Settings changed:** if the settings of a device with ongoing therapy have been changed but the recorded prescription has not yet been modified accordingly.

The device IFU warnings are primary multiAssist information and warnings and do not replace the MultifiltratePro device warnings. The user should refer primarily to the MultifiltratePro device IFU.

Depending on the configuration, some **warnings** related to the **Bags changes** can be also provided. Each warning (Filter,Dialysate,Citrate/Calcium) can be active or inactive depending on the configuration.

A warning is displayed to alert the user when the fluids in the bags are about to run out. This information may not be accurate in the event of a disconnection, as the calculation is based on infusion time.
The calculation of bag change times varies depending on the type of bag considered:

- For **filter bags,** the filter bag selected during the configuration of disposables in the **Prescription** phase is considered. If no **disposables** are selected during prescription, the first filter bag configured in the system is considered. If no filter bag has been configured, the filter bag change alert will not be displayed.
- For **dialysate/replacement bags** (scale 1 and 2 on the device) the maximum load for the scales (20 Liters, 10 each) will always be considered.
- [Valid only for Ci-Ca therapies] For **Citrate** and **Calcium** bags (Pole on the device) the citrate and calcium bag selected during the configuration of disposables in the **Prescription** step is considered. If no disposables are selected during prescription, the first citrate and calcium bag configured in the system is considered. If no citrate and calcium bag has been configured, the citrate and calcium bag change alert will not be displayed. Citrate and Calcium bags warnings rely on information inserted by the user.

If different bags are used on the device, the alert may be unreliable.

- Finally, when a patient admitted to a bed has received at least one therapy in the past but is not currently receiving therapy or prescriptions, the following message is displayed:

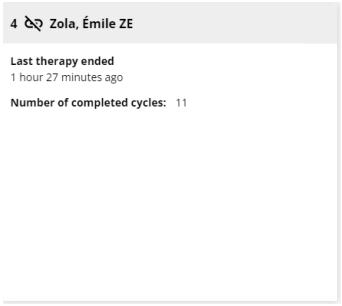


Fig 27

Two pieces of information are provided:
- when the **last therapy ended**;

- the **number of therapies** (number of completed cycles) **administered** to the patient.

1.3. Prescription Window

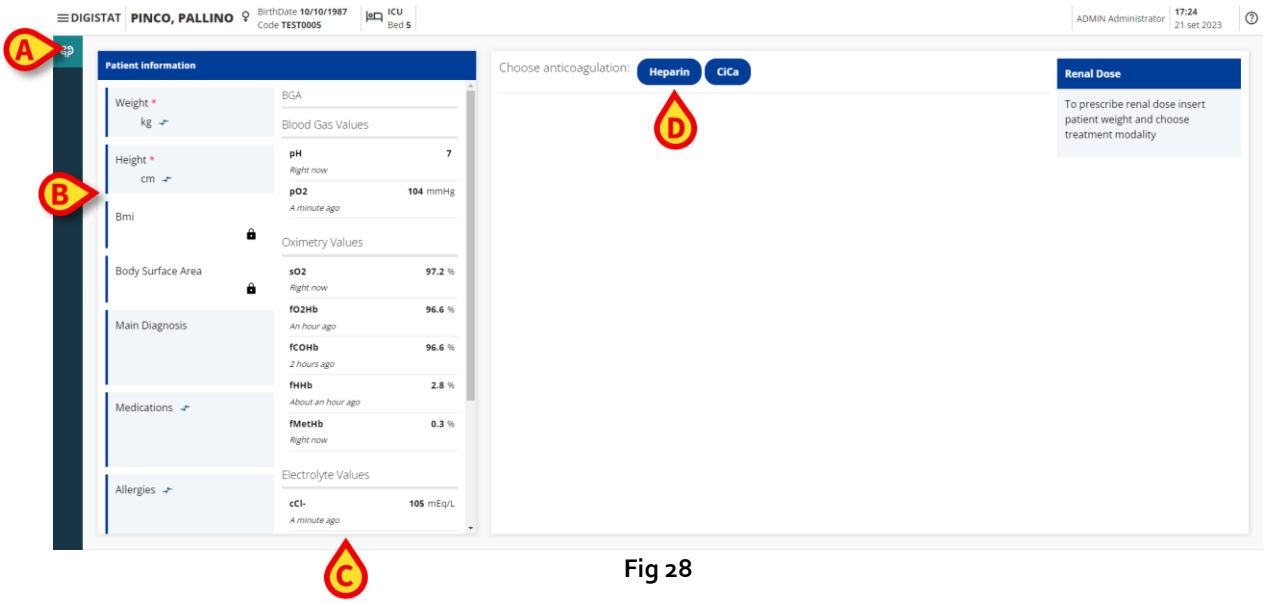


Fig 28

To start a prescription, click on a new patient card. A new window appears (Fig 28), and it is divided into 4 sections:

- On the top bar (Fig 28 **A**) the **surname** and **name**, **sex** (symbol), **age**, **patient code**, and **bed/location** couple are displayed.
- In the central body of the window, on the left (Fig 28 **B**), the patient information is gathered and displayed, such as Weight and Height (necessary for the calculation of the renal dose, they are mandatory fields to be filled in), Medications Allergies that can be imported (e.g., from ADT) or added manually by the user. The blue arrows icon means that the default data displayed or to be shown are the imported one. If the data are manually entered, the arrow symbols disappear. If both patient height and weight are imported or entered, BMI (Body Mass Index) and BSA (Body surface area) are automatically calculated. Every time the entered values for height and weight are modified, the two calculated data are updated accordingly.
- In the same section, on the right (Fig 28 **C**), **BGA data**, preconfigured and directly imported from the haemodialysis machine are shown. The data cannot be edited.
- On the right section of the page (Fig 28 **D**), the **Therapy** can be chosen and set. The first step is to choose the type of **anticoagulation** treatment between two available options: **Heparin** or **Ci-Ca**.

1.3.1. Prescription form

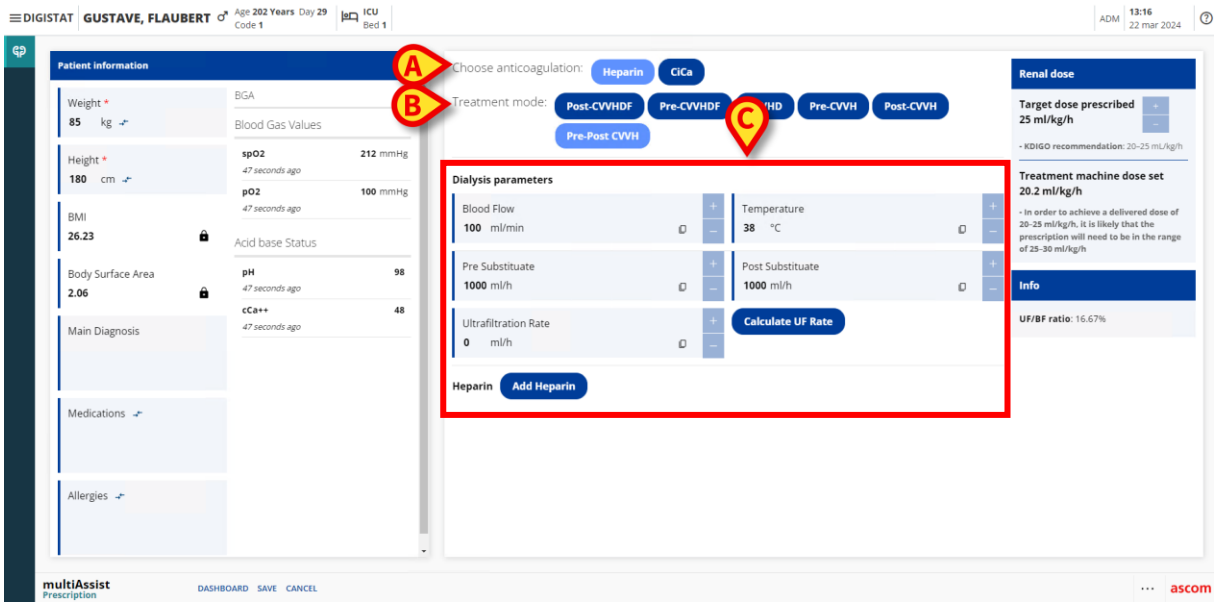


Fig 29

- Choose an anticoagulation treatment between **Heparin** and **Ci-Ca** (Fig 29 **A**). Once an option is selected, submenus consisting of different number of options are provided (Fig 29 **B**). Select the treatment and customize the therapy parameters. The available fields appear to be pre-populated with default data according to a Standard Therapy to be customized (Fig 29 **C**).

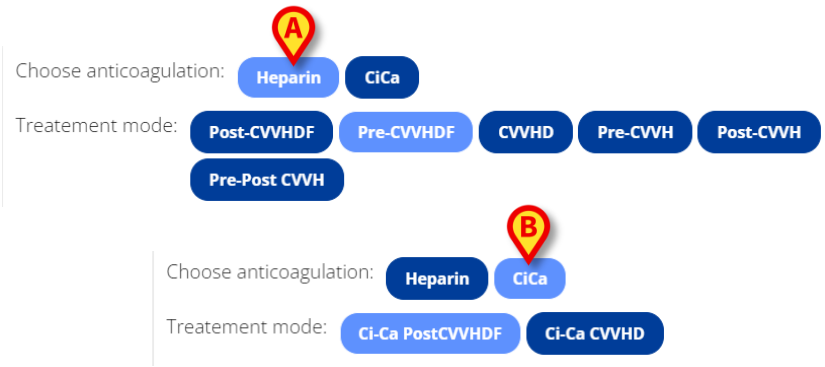


Fig 30

Depending on the therapy, different fields are provided (Fig 30 **A** and **B**).

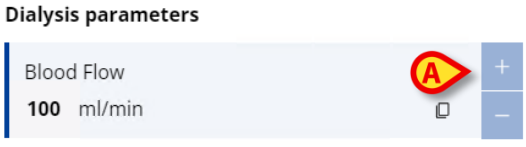


Fig 31

It is possible to edit the data clicking on the up and down arrows (Fig 31 **A**) next to each parameter field or clicking on the field and choosing a value from a menu of preconfigured discrete values.

The provided workflow and configured treatments are intended for a group of adult patients.

The lower and upper limits of the possible values of each parameter are the same as those set on the Fresenius MultiFiltrate device.

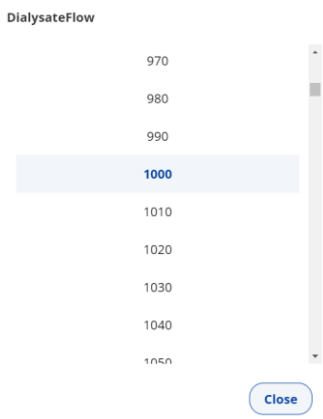


Fig 32

In the example the **DialysateFlow** parameter is shown. Just click on a value to select and customize the treatment.

Fig 33

When a value is modified, a **reminder** that contains the **default** one appears under the field (Fig 33 **A**), and a button is also provided to reset the value to the originally set value (Fig 33 **B**).

Fig 34

In case the default value is retained, a rectangular icon (Fig 34 **A**) is displayed next to it to indicate that the value displayed is indeed the default value.

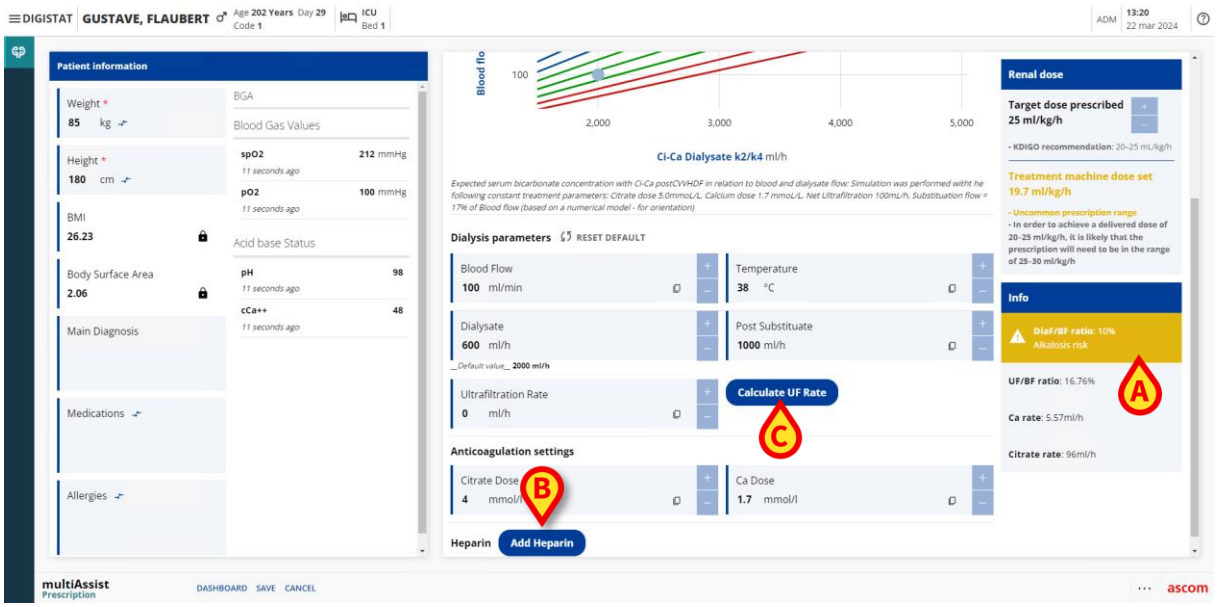


Fig 35

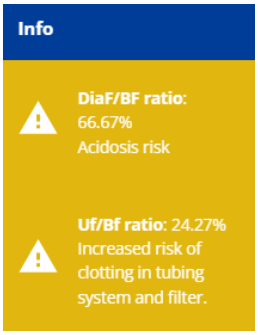


Fig 36

If an entered value of a given parameter is outside a configured range, a warning message appears in the right section of the page under the section relating to the calculation of the renal dose (Fig 35 **A**).
In the examples shown in Fig 35 **A** the risk of "alkalosis" warning is shown, while in Fig 36, the double risk of "acidosis" and "clotting in tubing system and filter" warnings are provided. The warnings are non-blocking: the clinician can confirm and save the prescription according to his/her clinical knowledge.

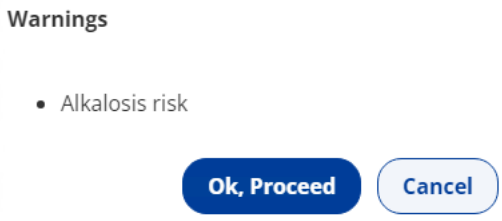


Fig 37

When the prescription is saved, a warning pop-up will appear reminding the user of the problem, asking for confirmation (Fig 37). **Ok, Proceed** and **Close** buttons are provided.

Optional fields are also available:

- Set the **Heparin** optional value by, first, clicking on the **Add Heparin** button (Fig 35 **B**) and then using the up and down arrows or selecting the value from the options provided in the **Heparin** field.

Fig 38

Once customized and set, it can eventually be removed clicking on the **Remove Heparin** button (Fig 38 **A**) that appears in place of the **Add Heparin** button.

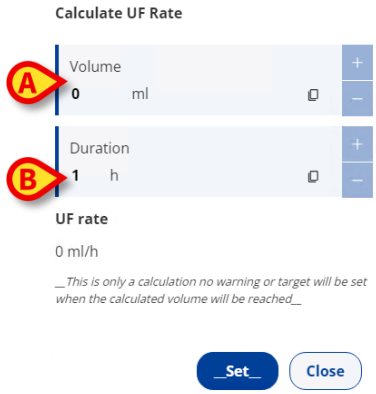


Fig 39

- Add the calculation of the Ultra Filtration Rate, clicking on the **Calculate Uf Rate** (Fig 35 **C**) button provided in the **Dialysis Parameters** section and entering the due value into the **Volume** (Fig 39 **A**) and **Duration** (Fig 39 **B**) fields provided.

As mentioned before, depending on the chosen therapy, **different fields** are available. If the **Ci-Ca** treatments has been chosen to be prescribed, a chart is also provided to calculate the **Acid Base**.

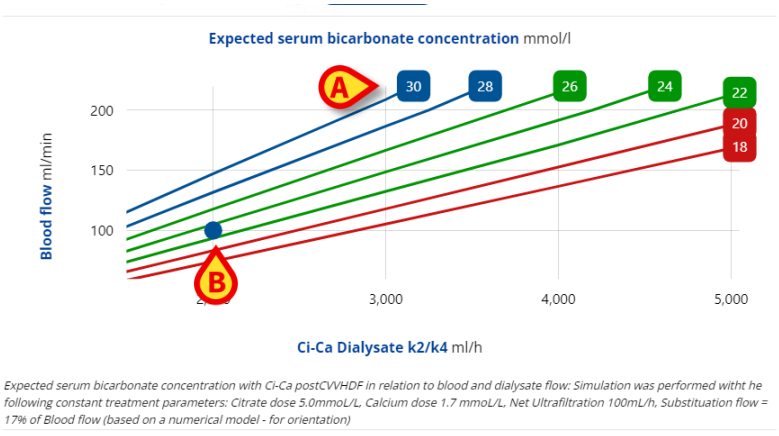


Fig 40

This shows a graphical visualization of Ci-Ca treatment protocol and its target equilibrium under standard conditions (the expected serum bicarbonate concentration, whose values,

between 18 and 30 mmol/l, are recorded and shown in coloured squares placed in the upper and right part of the graph, see Fig 40 **A**).

The graph calculating the expected bicarbonate concentration in Ci-Ca treatments is only to be used for values above the minimum values of 60 ml/min for the blood flow and 1500 ml/h for the dialysate flow.

The blue dot (Fig 40 **B**) indicates the expected bicarbonate concentration in serum according to the parameters' values set in the fields provided below the chart.
If the dot representing the actual status of the prescribed therapy is within the range drawn by the **green** slanted lines, then the therapy is correctly set. If, on the other hand, the blue dot is out of that range, the doctor or nurse can adjust the values of the **Dialysis parameters:**

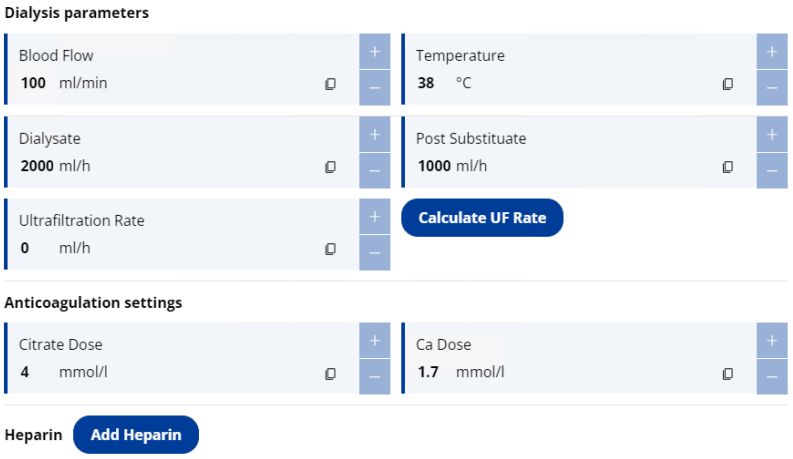
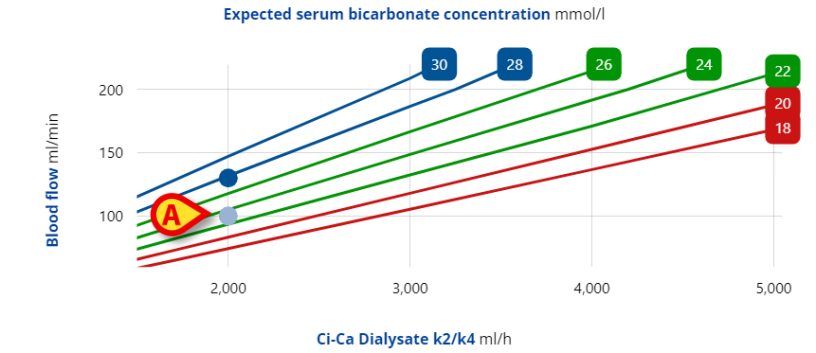


Fig 41

Fig 42

Click on the plus or minus buttons or on the fields (Fig 41) to be modified to set the value from the list provided in the pop-up window (Fig 42).



Expected serum bicarbonate concentration with Ci-Ca postCVVHDF in relation to blood and dialysate flow: Simulation was performed witht he following constant treatment parameters: Citrate dose 5.0mmoL/L, Calcium dose 1.7 mmoL/L, Net Ultrafiltration 100mL/h, Substituation flow = 17% of Blood flow (based on a numerical model - for orientation)

Fig 43

By changing the values, the dot on the graph moves accordingly and, therefore, it can be adjusted appropriately. A lighter coloured dot appears in the graph to indicate the default position, previously occupied (Fig 43 **A**). Once the new values have been set, click on **Set** button to correct the prescription with the new data.

Any registered settings, updates, or changes, must necessarily be manually reported on the dialysis machine, which is not automatically updated.

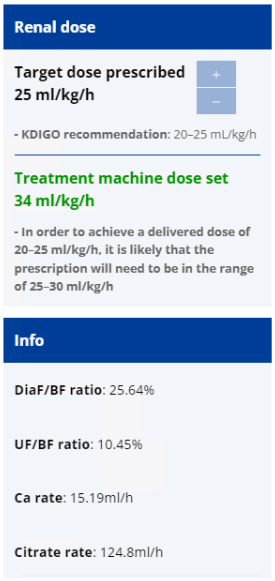


Fig 44

The calculator is only provided to facilitate the selection of a UF Rate. No warning alert is triggered as on whether the desired volume is reached or not.

On the right section of the Prescription page, the **Renal Dose** is calculated and displayed (Fig 44). It consists of two values:

- The **Target Renal Dose Prescribed**, is the Renal Dose to be reached according to clinical considerations. It can be modified by adjusting the value using the + and – buttons provided. The **KDIGO** recommendation for the renal dose is also provided;

- The **Treatment Machine Renal Dose Set**, which takes into account the patient's weight (it is expressed in ml/Kg/h), is calculated by the system based on the values entered and set in the fields relative to the Dialysis parameters and Anticoagulation settings (if Ci-Ca anticoagulation is chosen). The Treatment Machine Renal Dose Set can be modified by changing the values entered in these same fields.

Fig 45

If the value of the **Treatment machine dose** is greater than 35 ml/kg/h or less than 20 ml/kg/h, the Treatment machine dose set label is coloured yellow. A not-blocking warning is also provided to remind the user that the set range is "Uncommon prescription range".

Once everything is duly configured and set, the **SAVE** button placed in the command bar of the Prescription page is enabled. Click on the **SAVE** button to save the Prescription or click **Cancel** button to skip the Prescription procedure.

➢ Click on **Save** button. The Prescription summary window is shown.

1.3.2. Prescription Summary Page

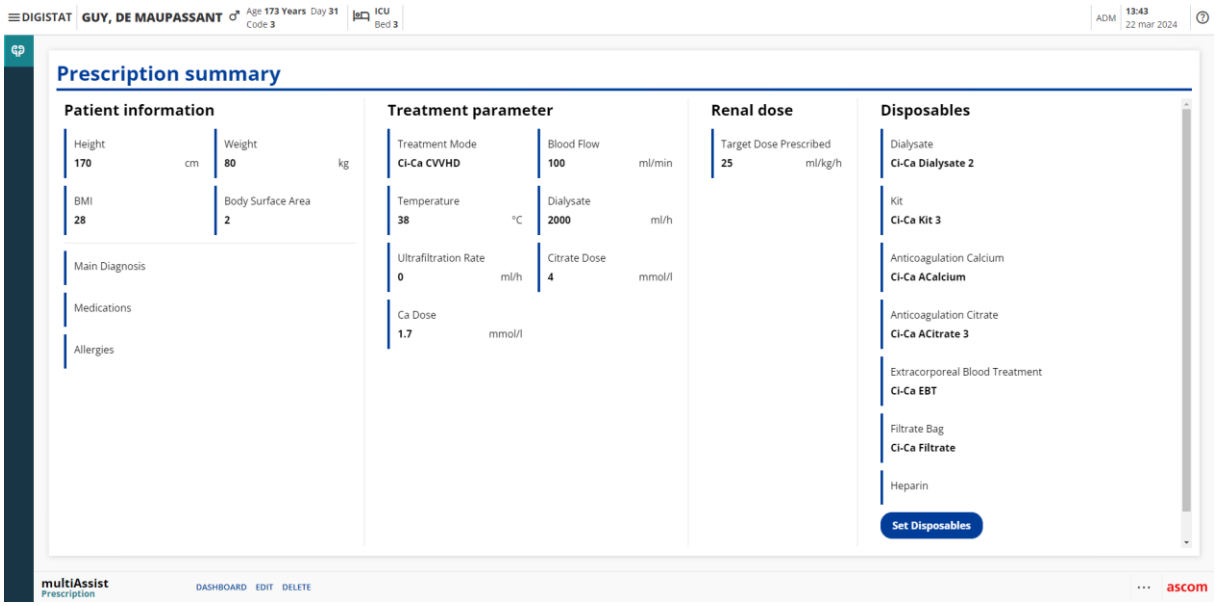


Fig 46

The page shown in Fig 46 is the Prescription summary and it is the page that the nurse will open by clicking on the bed that show the "New Prescription" message on the main Dashboard (Fig 47 **A**).

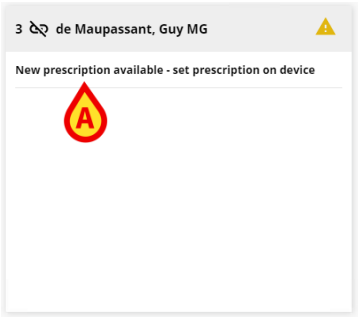


Fig 47

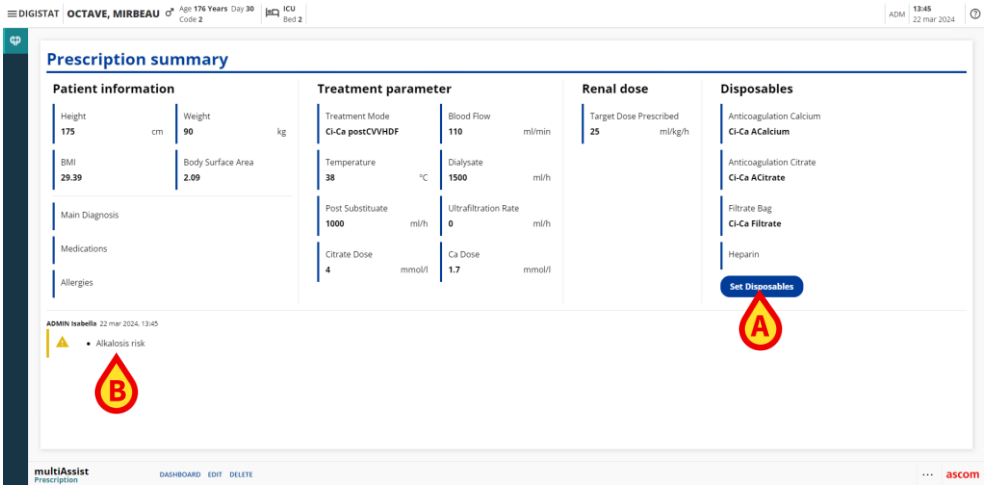


Fig 48

Patient information, the prescribed treatments (**Treatment parameter** section) and the **calculated renal dose** data are displayed in three columns. A fourth column with optional information to be specified is provided and it is about the setting of **disposables** (Fig 48 **A**).

Fig 49

- Click on the **Set disposables** button (Fig 48 **B**) to open a new window with **multiple configurable dropdown menus of configurable options** to choose from, according to the patient needs or hospital warehouse supplies availability (Fig 49).
- Choose the desired equipment and then:
- click on **Save Disposables** button to save the configuration or on **Close** button to skip the procedure.

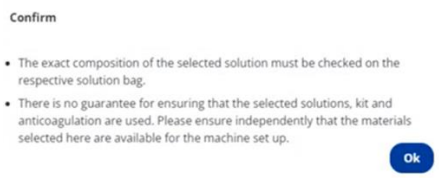


Fig 50

Once **Save** is clicked, an alert pop-up window appears asking the user to verify that the composition of the actual bags is compared with the therapy prescribed and that everything has been complied with correctly, as there is no control system for checking the bag used. By clicking the **OK** button, the **Disposables** section of the Prescription summary window is consistently updated.

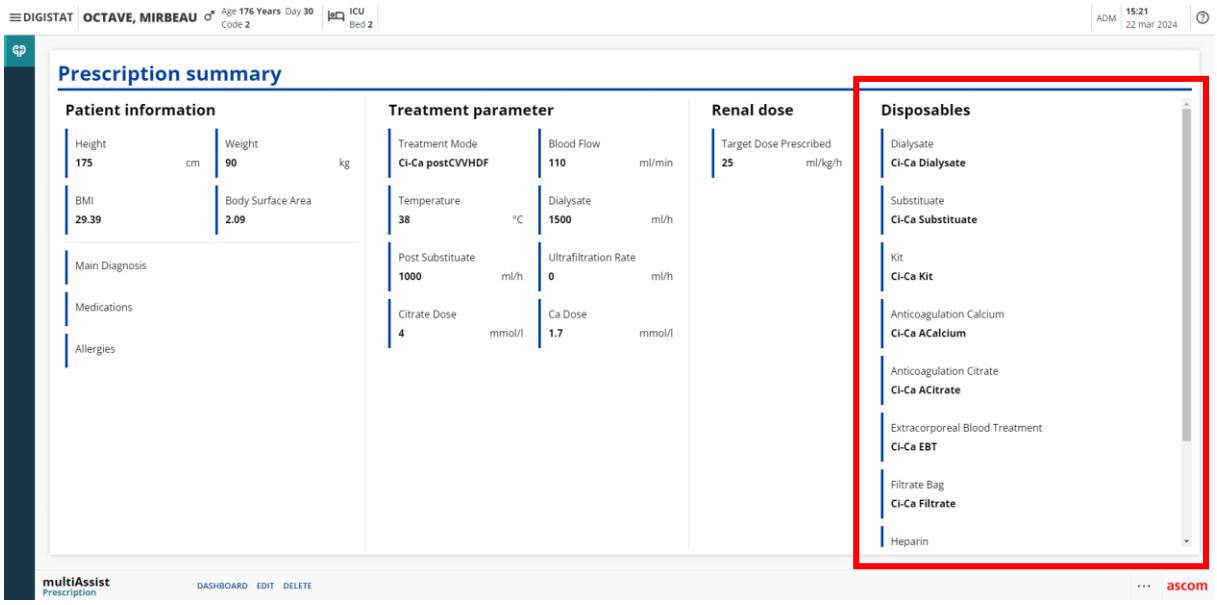


Fig 51

The warning message that appears in case of problematic prescription is displayed one more time in the lower left section of the page (Fig 48 **B**) together with the **Username** of the user that confirmed the prescription, the date and time of the confirmation.

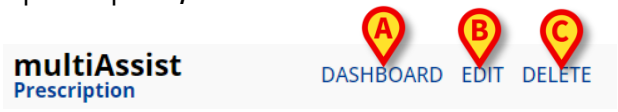


Fig 52

Finally, three buttons are provided in the command bar:

- **DASHBOARD** (Fig 52 **A**): clicking on it, the user is redirected to the main dashboard;
- **EDIT** (Fig 52 **B**): clicking on it, the user is redirected to the treatment prescription page where it is possible to modify the values entered;
- **DELETE** (Fig 52 **C**): clicking on it and confirming the cancellation, the prescription is deleted.

1.4. Monitoring Page

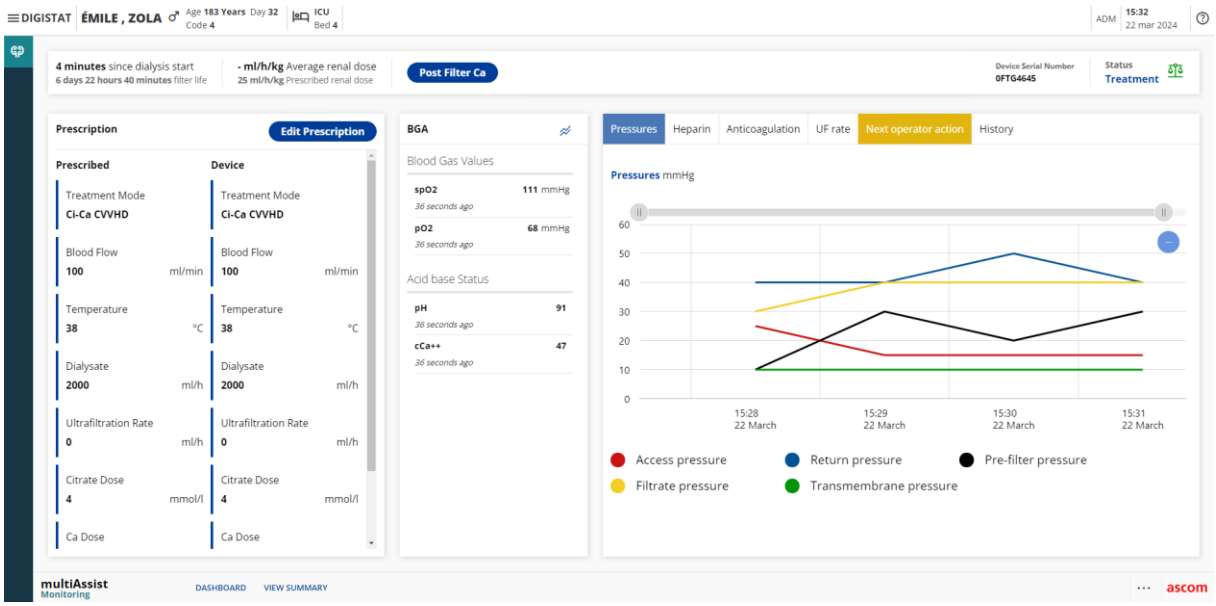


Fig 53

When the patient is connected to a dialysis machine and the treatment starts, clicking on their bed, the user access to the **Monitoring Page** (Fig 53). The top left section of the window displays the **Average Renal Dose**, obtained from the parameters with which the machine is operating, and the **Prescribed Renal Dose**, the target value chosen during the prescription. The **Average Renal Dose** values (along with the corresponding label) appear coloured if they are lower than the **Prescribed Renal Dose**, after a configured and configurable period of time (the Average Renal Dose changes over time and, in the first few minutes/hours of treatment, may not be reliable).

Fig 54

For Ci-Ca therapies, depending on the configuration, **Post Filter calcium** cannot be retrieved directly from the BGA device and must be entered manually. It such cases, the "Post Filter calcium" button will be displayed as follows:

Fig 55

Clicking on the provided button, the following dialog is displayed:

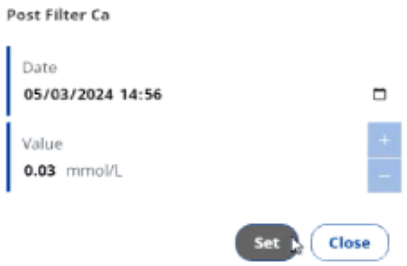


Fig 56

The user will be able to enter the date and time of the sample and the **postfilter calcium** value.
This value will be used in the **BGA** and **Anticoagulation** sections.

If the currently selected bed is already connected to a dialysis machine, next to the Renal Dose values, the **elapsed time from the start of dialysis** and the **filter lifetime** are shown. On the right part, on the same level, the **Device Serial** is provided together with the **Status** of the prescription, indicated on the upper right part of the window. In the example (Fig 54 **A**) the Status is "Treatment" since the treatment has been correctly started. If the dialysis machine is disconnected (Status: **Missing Connection**), the button END TREATMENT is provided at the bottom part of the window to terminate the therapy.

On the command bar, next to the **End Treatment** button, there is a free text field that allows the user to specify the reasons why the treatment was terminated.

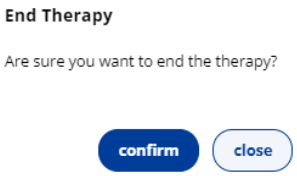


Fig 57

- Click on the **End Treatment** button and then confirm the action selecting **Confirm** or skip the procedure clicking on the **Close** button.

1.4.1. BGA section

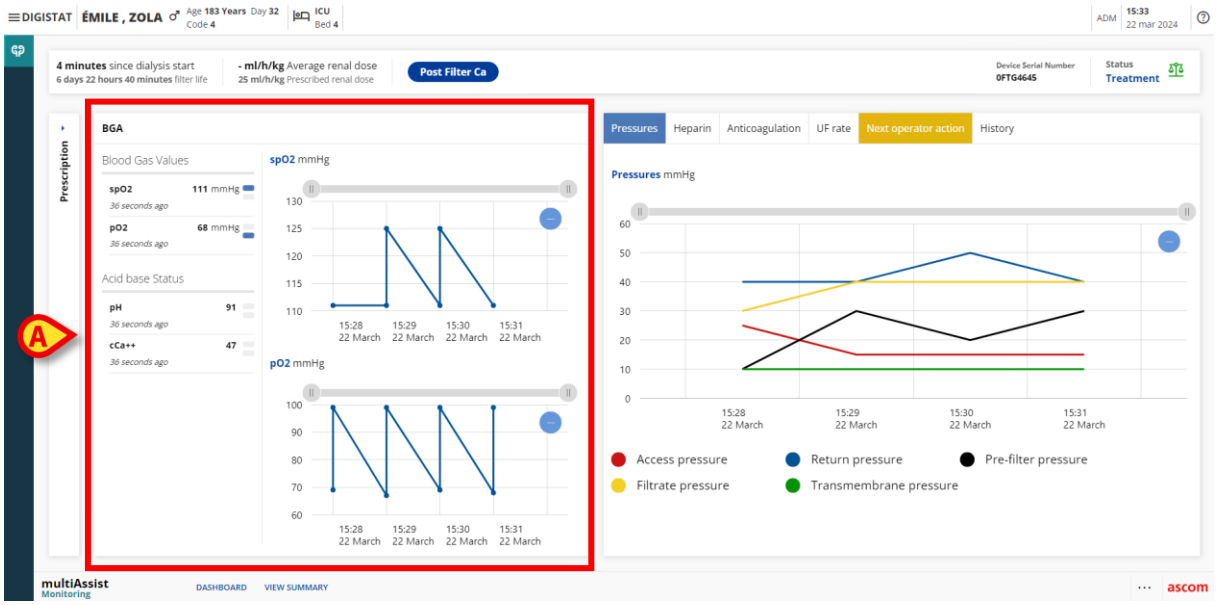


Fig 58

The first column on the left of the central section (Fig 58 **A**) shows the BGA data and values **retrieved** during the therapy.

Fig 59

Next to the list of those data, two graphs that shows their trends are drawn (Fig 59).

Fig 60

Only two graphs can be displayed at a time, so it is possible to select which parameters will be shown selecting the up or down buttons provided next to each parameter fields. If a parameter is selected the button is coloured in blue (Fig 60 **A** and **B**).

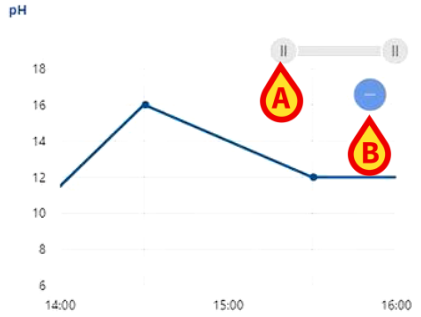


Fig 61

The last two hours are displayed by default. The displayed time interval can be extended or shortened by widening or narrowing the width of the handles button shown in Fig 61 **A**.

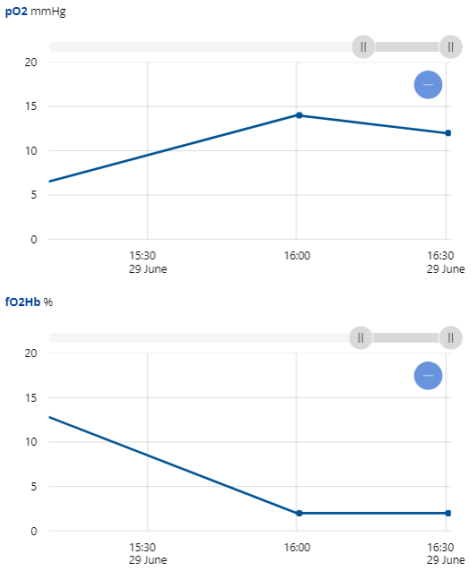


Fig 62

They can also be scrolled horizontally moving the same handles left and right. Moving and adjusting the handles of a graph, both graphs are synchronously scanned.

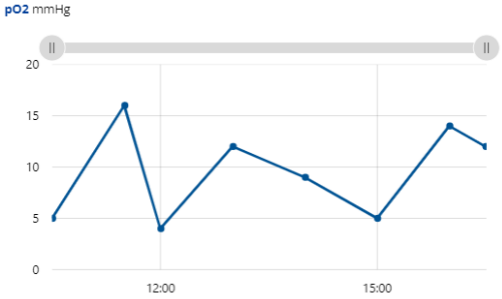


Fig 63

Click on the minus button (Fig 61 **B**) to get a complete view of the graph and all the values recorded since the beginning of the therapy.

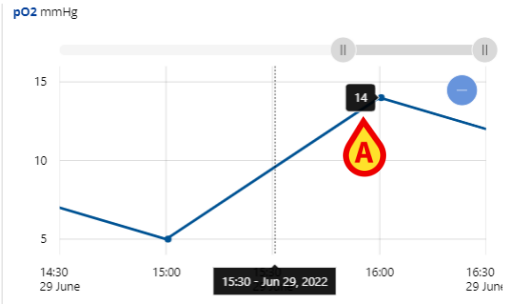


Fig 64

By passing the cursor on the graph it is possible to read the values of the parameters retrieved (Fig 64 A) and registered together with the date and time of their recording.

1.4.2. "Pressures" Tab

Fig 65

On the right part of the **Monitoring** page, a third section is provided consisting of a different number of tabs (it depends on the type of the treatment selected and its customization) that shows the data coming from the dialysis machine. The first tab, selected and displayed by default is the **Pressure** one. The machine measures and sends information on 5 different pressures (Access, Return, Prefilter, Filtrate and Transmembrane): their statuses and trends are registered and displayed in a graph, that can be moved, zoomed out and scrolled using the same handle and buttons previously described (Fig 65 **A**).

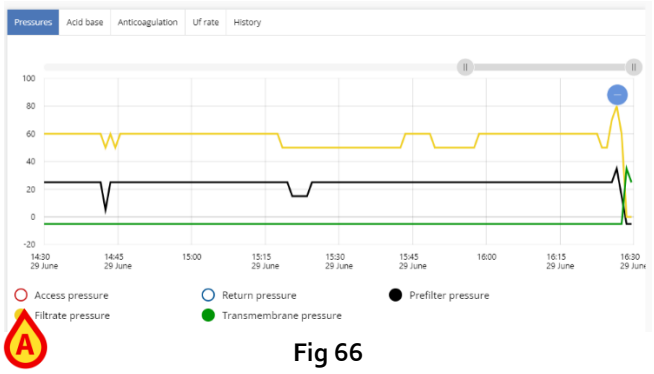


Fig 66

The graphs can also be filtered and only chosen pressures be displayed selecting them by clicking on the coloured circle button provided for each pressure (Fig 65 **B**). If the circle icon is fully coloured, the pressure is shown, while if it's empty (double click on the circle button), the corresponding pressure is no longer displayed.

1.4.3. "Heparin" Tab

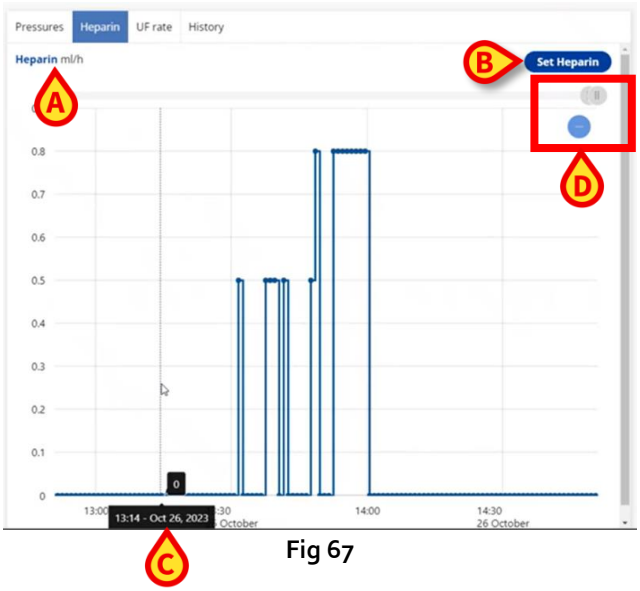


Fig 67

By selecting the **Heparin** tab, the graph showing the trend of heparin administration is displayed.
At the top left, the Heparin value measured in ml/h is retrieved and shown (in the example in Fig 67 **A**, the administration is suspended or terminated), while on the left a **Set Heparin** button is provided.

- Click on **Set Heparin** button:

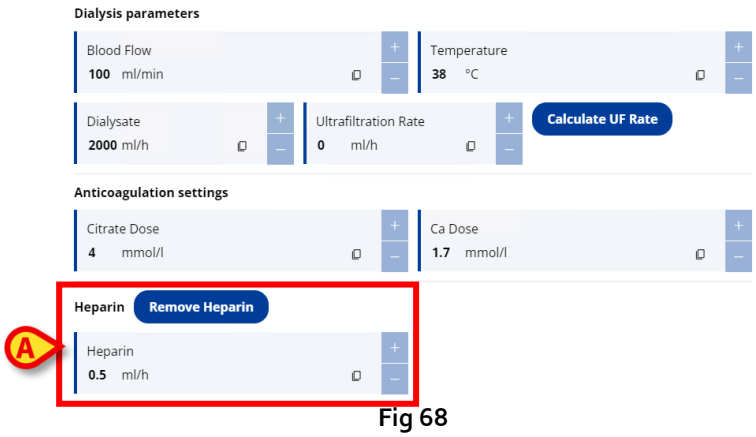


Fig 68

The user is redirected to the **Prescription** page where the **Heparin** value to be entered into the dialysis machine can be set (Fig 68 **A**).

Like the previously described graphs, the heparin trend graph shows the datetime on the abscissae and the values of the heparin expressed in ml/h on the ordinates. It can be moved, zoomed out and scrolled using the provided handle and buttons already presented (Fig 67 **D**).

By clicking anywhere on the graph, a vertical line is drawn, and a toast is displayed containing the heparin value recorded at that given time, the time and date in of administration (Fig 67 **C**).

1.4.4. "Anticoagulation" Tab (Ci-Ca therapy only)

Fig 69

If and only if a Ci-Ca treatment has been selected and prescribed, the third tab provided is the **Anticoagulation tab.**

Two graphs are given: they show two lines each (Fig 69 **A** and **B**) that represent and monitor the trend over time of, respectively, the values of **Post Filter Ionized Calcium** and **Citrate dose**, and the **Systemic Ionized Calcium** concentration and **Calcium dose**. Those values are retrieved from the **BGA** or inserted manually by the user. The blue area represents the value that the concentrations must reach and maintain (Fig 69 **C**). On the right, two sets of instructions are provided that suggest setup actions to take if the values fall within certain ranges (Fig 69 **D**). The range in which the values are currently recorded is highlighted in bold and blue.

- To correctly adjust the **Anticoagulation** values, click on **Set Citrate** and/or **Set Calcium** buttons (Fig 69 **E**).

Fig 70

The corresponding pop-up windows appears in foreground. Using the plus/minus buttons or clicking on the **CalciumDose** or **CitrateDose** fields, it is possible to set the new values.

- Click on **Set** button to save the changes or on **Close** button to skip the procedure.

1.4.5. "Uf Rate" Tab

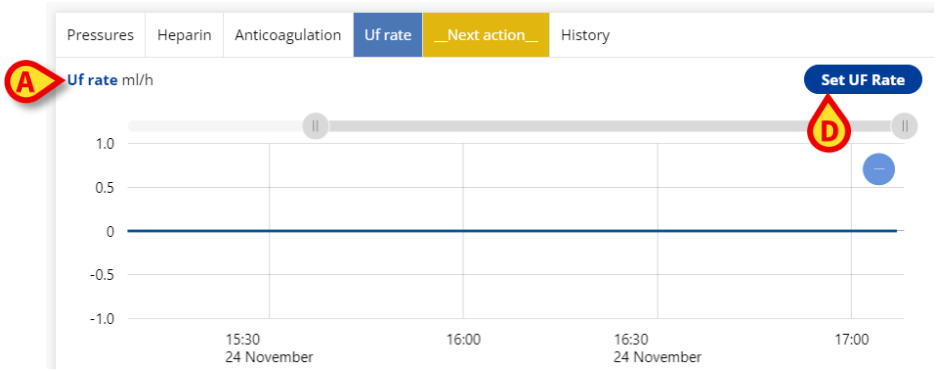


Fig 71

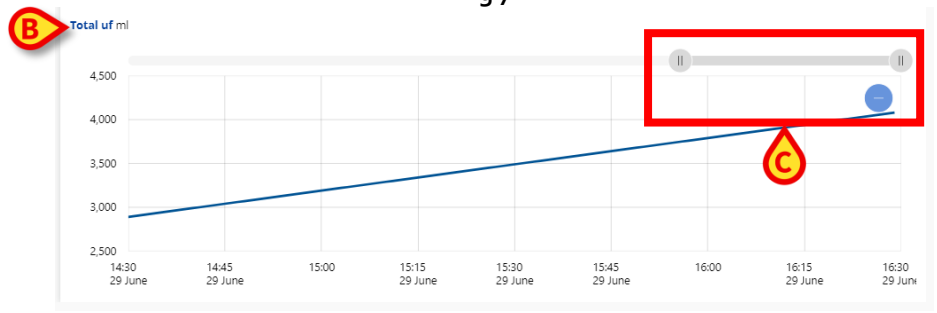


Fig 72

A tab that both the prescriptions with Ci-Ca treatment and with Heparin have in common is the **Uf rate** one, which shows the setting data of the dialysis machine. In particular, the first of the two graphs provided illustrates the **Uf rate** trend (Fig 71 **A**), while the second graph draws the **Total Uf** (Fig 72 **B**).

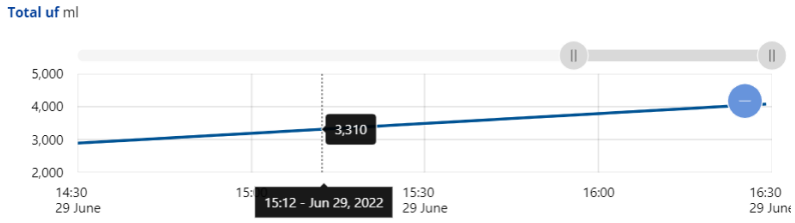


Fig 73

As for the other graphs, it is possible to read the numerical values just moving the cursor over the drawn line. Use the minus button to display the total overview of the values recorded from the beginning of the treatment. Use the grey handles to scroll the graph horizontally over time and to extend or decrease the interval (Fig 72 **C**).

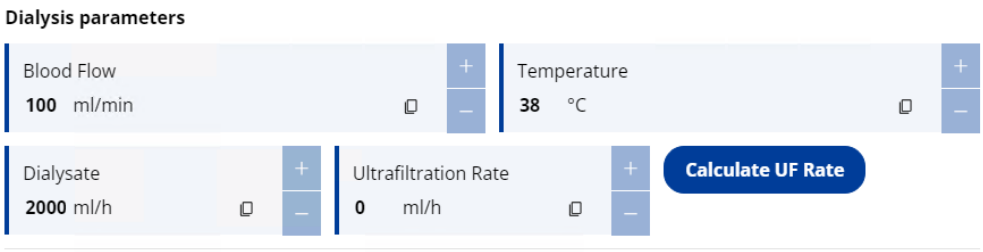


Fig 74

It is possible to set or modify an already configured Uf goal clicking on the **Set Uf Goal** button (Fig 71 **D**), then proceeding with the configuration as described in the **paragraph 1.3.1** (Fig 39). The graph will draw a new line with the data set in the Total Uf.

1.4.6. "Next Operator Action" Tab

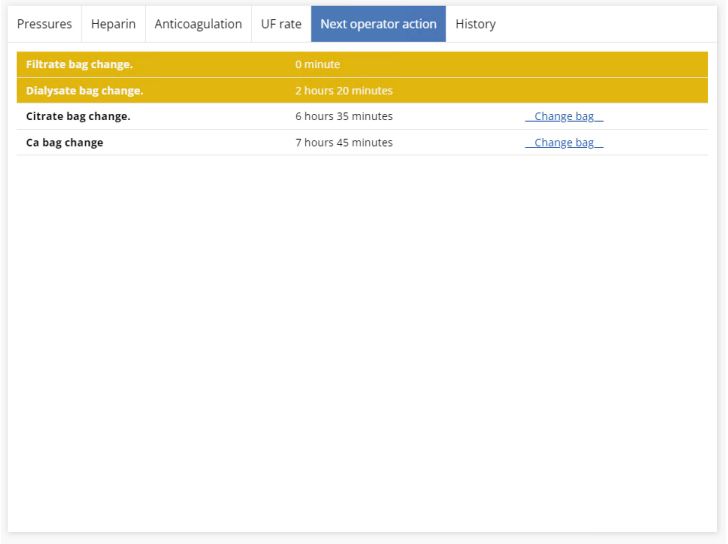


Fig 75

Depending on the configuration, the "New Operator Action" tab (Fig 75) shows how long until the bags are empty or full (depending on the type of bag). A row highlighted in yellow indicates that the bag will be empty (or full) within a configurable time. The yellow highlighted row will be also displayed on the dashboard (Fig 76).
If one or more bags are highlighted, the tab itself is highlighted.

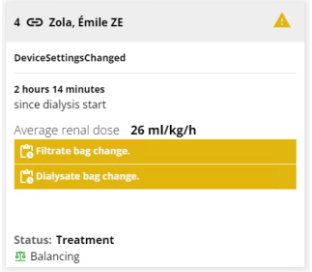


Fig 76

For Citrate and Calcium bags, a button is provided to allow the user to manually enter the date and time of the bag change.

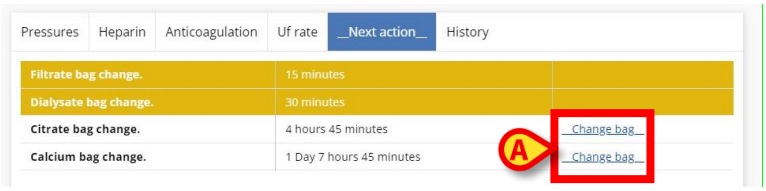


Fig 77

Clicking on "Change Bag" button, the following dialog box will be displayed:

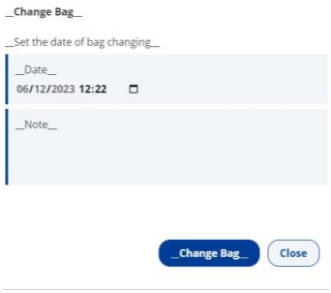


Fig 78

Estimation of citrate and calcium in empty bags must take this information into account. Missing or incorrect data entry may result in unreliable bag information.

Specifically, information on bag size assumptions, i.e., an estimate of bags change (filter bag full and dialysis/substituate bags empty) is retrieved and provided.

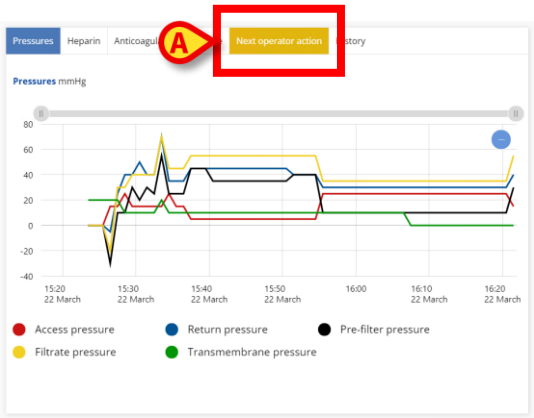


Fig 79

When a configurable threshold is exceeded, the tab is highlighted (Fig 79 **A**).

1.4.7. "History" Tab

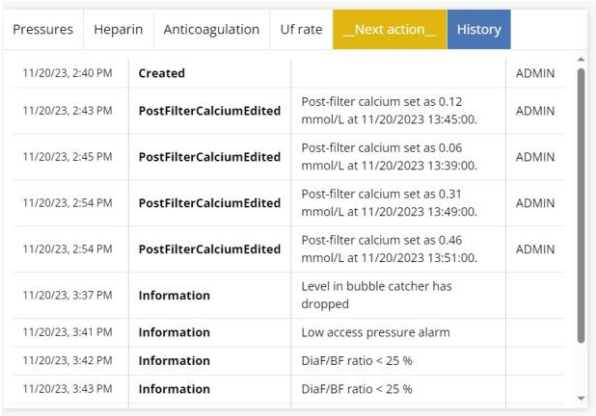


Fig 80

The last tab available is the **History** tab. As the name suggests, this section contains the logs of everything that has happened since the creation of the Prescription and the subsequent actions, such as the configuration of disposables, the starting or ending of the treatment, the modifications of the settings etc. The history section contains and shows messages and events from the dialysis machine and the **username** of the doctor who performed the actions is also registered.

1.4.8. "Prescription" Section

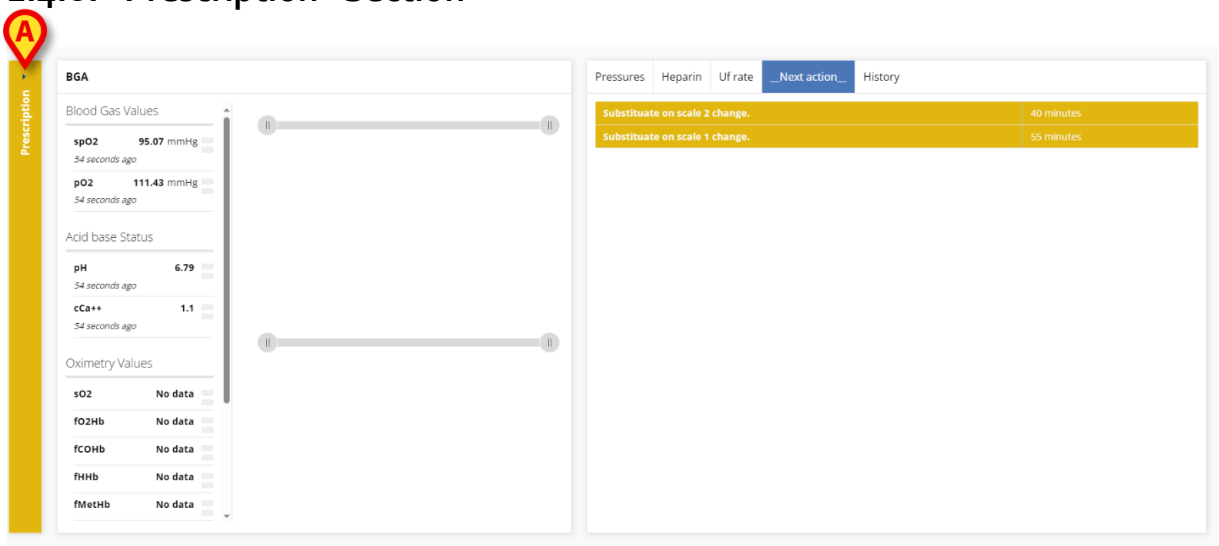


Fig 81

Clicking on the arrow indicated in Fig 81 **A** or on the bar itself (the bar displayed in the picture is yellow since no prescription has been entered yet), a section dedicated to the Prescription itself is shown while the BGA section containing the graphs previously described is compressed.

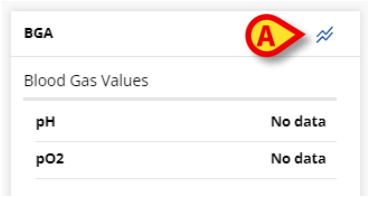


Fig 82

- To return to the original BGA graphs screen, click on the double wave icon that appears next to the BGA header (Fig 82 **A**).

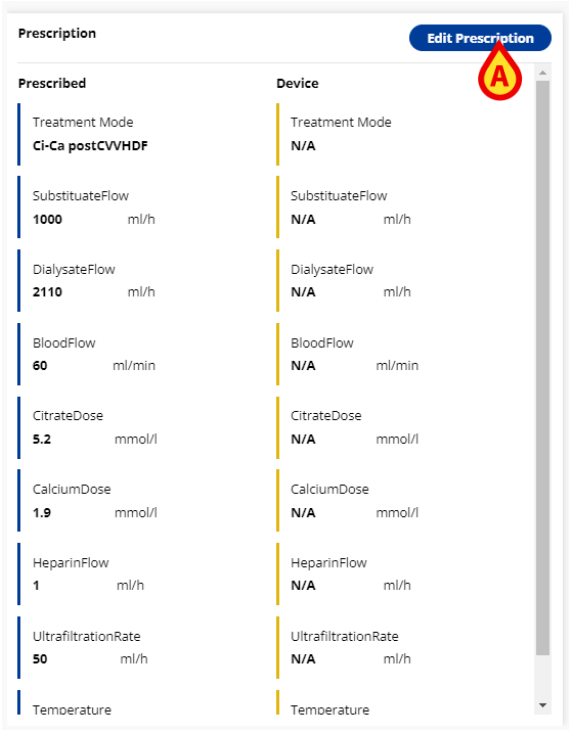


Fig 83

The section consists of two columns. The first column displays the values of the prescribed therapy, while the second column records the data sent by the connected medical device. If the dialysis machine has not been connected ("Missing connection" status is registered in the main dashboard as seen in Fig 20), no data will be shown, and a yellow highlighted bar will be placed to the left of the undetected value/values (Fig 84 **A**).

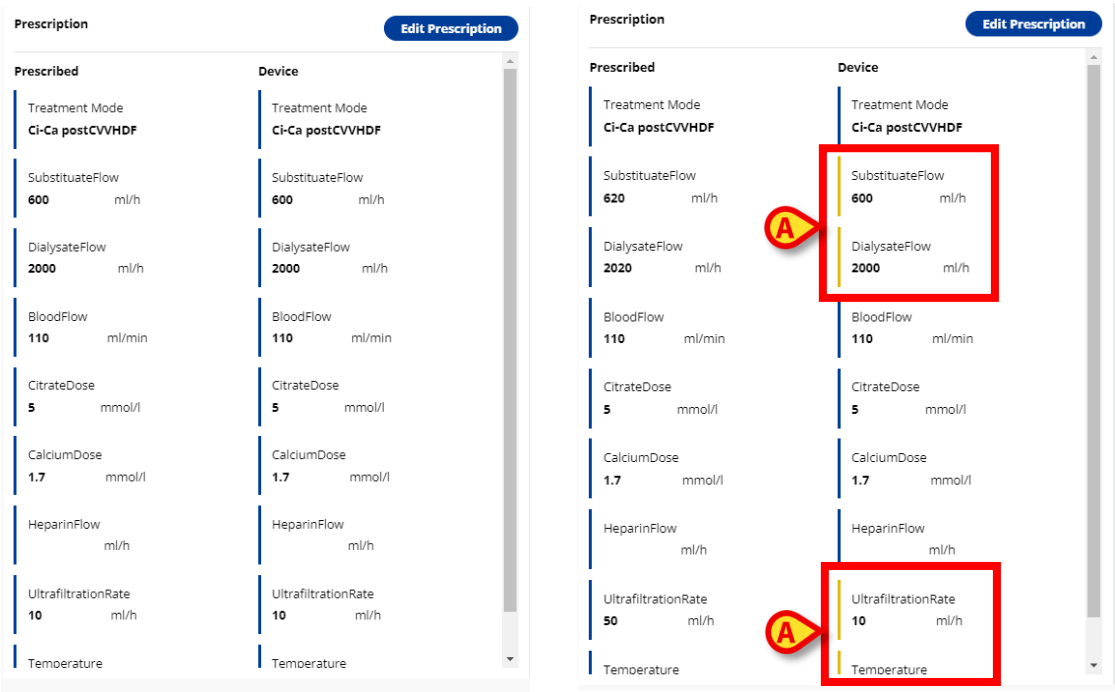


Fig 84

If the data coming from the machine are recorded correctly and match those entered in the prescription, the yellow highlighted bar will turn blue. If the values sent from the device do not align with those in the prescription, the blue bar will turn yellow again.

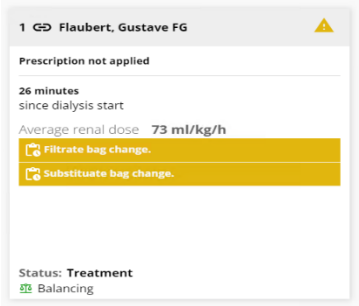


Fig 85

A **Prescription Not Applied** warning is displayed on the dashboard so that the anomaly recorded by the application can be checked and corrected. The doctor or nurse can reliably and consistently change the therapy by clicking on the **Edit Prescription** button (Fig 83 **A**) or by modifying the values on the dialysis machine.

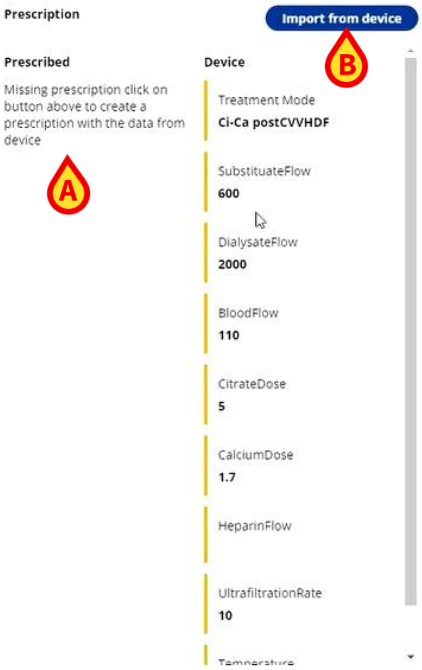


Fig 86

A fourth scenario, compatible with an emergency, is given: the machine is correctly prepared, configured with the therapy and connected to the bed, but the prescription has not yet been entered through the form. Under the **Prescribed** column, a message warns the user that the prescription has not been filled (Fig 86 **A**) and that this can be done using the data received from the machine.

Fig 87

To perform this, just click on **Import from device** button (Fig 86 **B**): the Prescription page is shown (Fig 87), the Therapy correctly selected and all the enabled fields are automatically filled with the device data. Once everything is duly configured and filled,

- click on **Save** button to save the Prescription.

1.5. Benchmarking module

The **Benchmarking** module tool allows the retrieval and analysis of historical data of CRRT treatments in support of cost estimates and epidemiological studies. The page displays a configurable number of graphs that draw the progress of therapies over time and that can be created using the filters provided, selecting and grouping machine data by years, months, weeks and comparing them with other meaningful data.

Fig 88

- Click on the three dots button at the bottom right of the command bar and
- Select the provided **Benchmarking** button to access the **Benchmarking** module page.

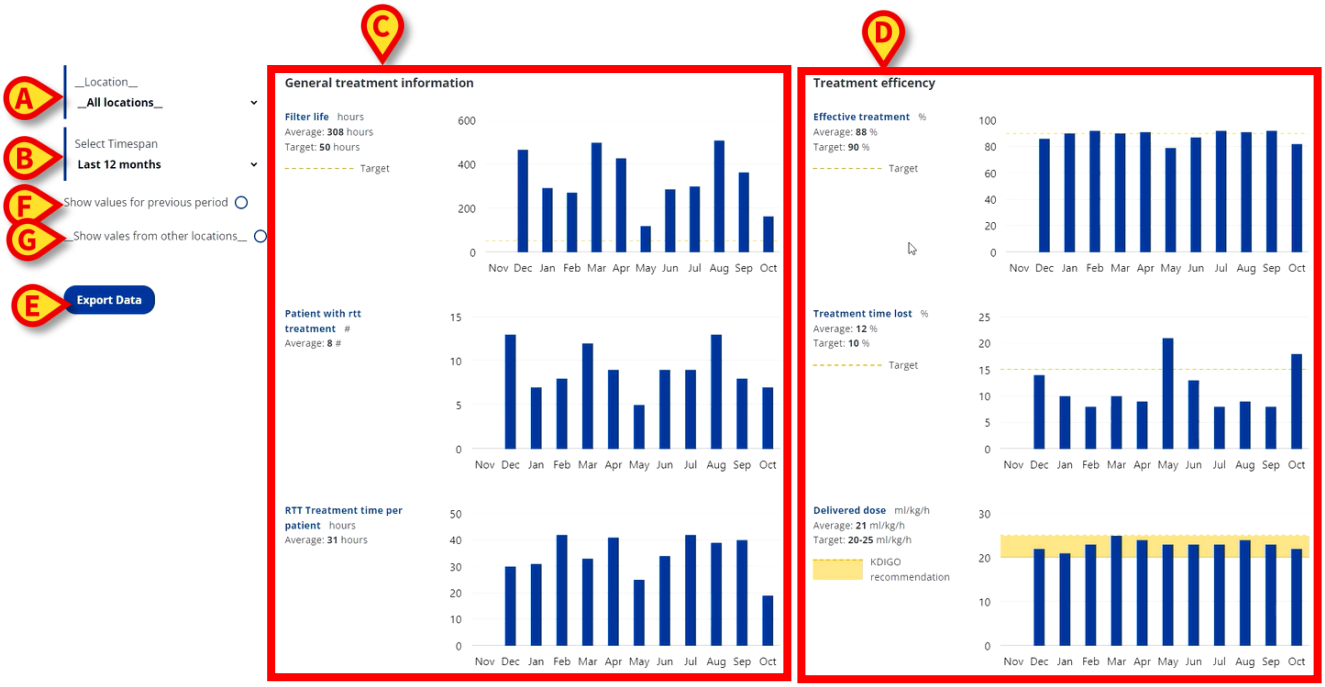


Fig 89

Aggregated data of therapies administered within the hospital (**All locations**) or a specific department over a selectable time interval are displayed.

Compared data are grouped into two sections:

- **General treatment information** (Fig 89 **C**) and
- **Treatment efficiency** (Fig 89 **D**).

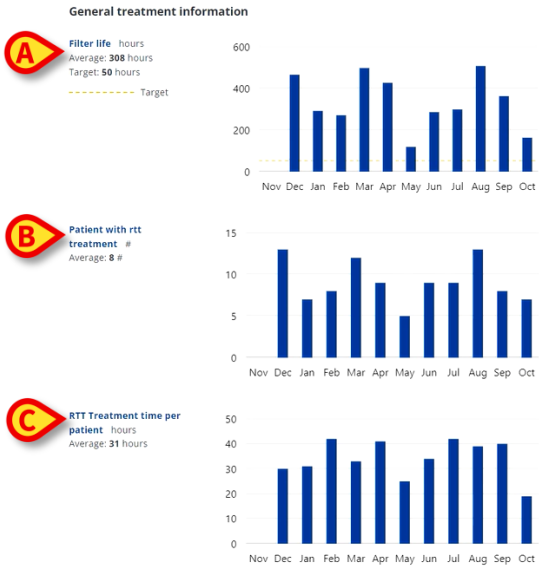


Fig 90

Under **General treatment information,** three histogram charts are given**,** and they display:

- The **Filter life in hours** (Fig 90 **A**): the chart contains information on the average lifespan of filters and the hospital-set target (indicated by a dashed yellow horizontal line) configured through the *System Option TargetHoursOfFilterLifetime*;
- The **Number of Patients with RTT treatment** (Fig 90 **B**) with the registered average value;
- The **RTT Treatment time per patient** (Fig 90 **A**) in hours, with the registered average value.

Fig 91

Under **Treatment efficiency**, three histogram charts are given, and they display:

- The **Percentage of effective treatment** (Fig 91 **A**): it shows statistics on renal dose, displaying the average value and the target value (indicated on the graph by a dashed yellow horizontal line) configured through the *System Option TargetPercentageOfEffectiveTreatmentTime*;
- The **Treatment time lost** (Fig 91 **B**) (e.g., dialysis machine stoppage during bag change or patient dressing changes) with the average value and the target value (indicated on the graph by a dashed yellow horizontal line) configured through the *System Option TargetPercentageOfTreatmentTimeLost*;
  The **Delivered dose** (Fig 91 **C**) expressed in ml/kg/h with average and target range values set and KDIGO recommendation (indicated on the graph by an orange dashed horizontal line describing a range area below, coloured in yellow) configured through the *System Option TargetRenalDosePrescribedDefaultValue*.

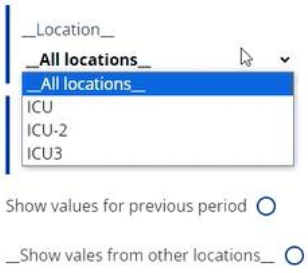


Fig 92

It is possible to select the **Location** (a single location) or **All** configured **locations** through the dropdown menu displayed in Fig 89 **A** and the **Timespan** through the dropdown menu displayed in Fig 89 **B**.

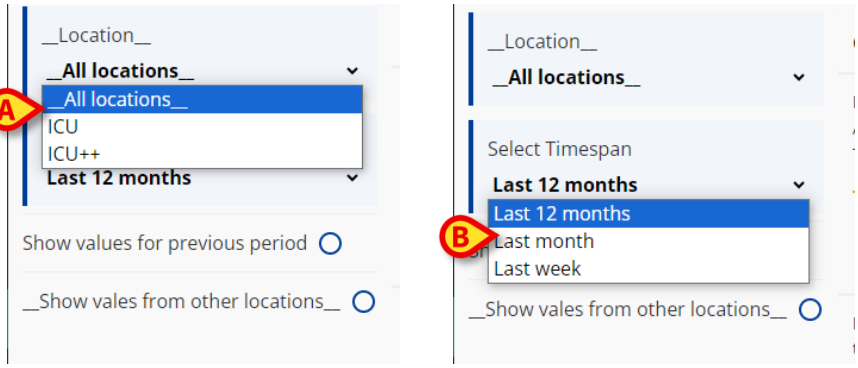


Fig 93

Changing the values (Fig 93 **A** and **B**), the charts are accordingly updated.

Additionally, it is possible to alternatively check two options that respectively allow **show**ing **values for the previous period** (Fig 89 **E**) and **show**ing **values from other locations** (Fig 89 **F**).

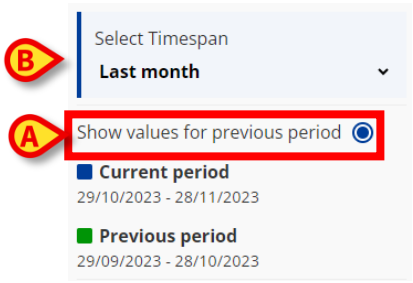


Fig 94

➢ Check the **Show values for the previous period** radio button (Fig 94 **A**).

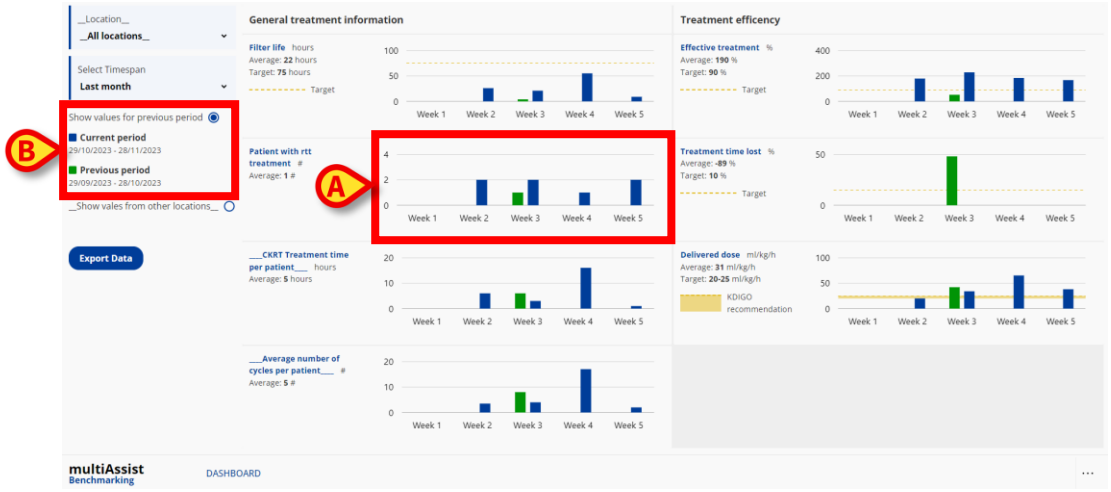


Fig 95

The charts are updated, and comparative histogram charts are provided (Fig 95 **A**). The histograms are coloured according to the colours shown in the legend provided, which indicates the colours for the **Current period** and **Previous period** with their respective time

ranges (Fig 95 **B**). The **Previous period** is calculated according to the option previously selected in the **Select Timespan** menu (Fig 94 **B**). Therefore, if, for example, the **Last Month** option was selected, the **Previous period** will contain the values recorded in the month preceding the current one.

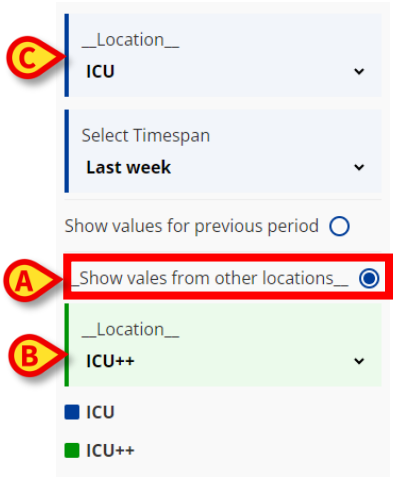


Fig 96

- Check the **Show values from other locations** radio button (Fig 96 **A**) to open a second **Location** dropdown menu (Fig 96 **B**) to choose a second configured location from;
- Choose a second location;

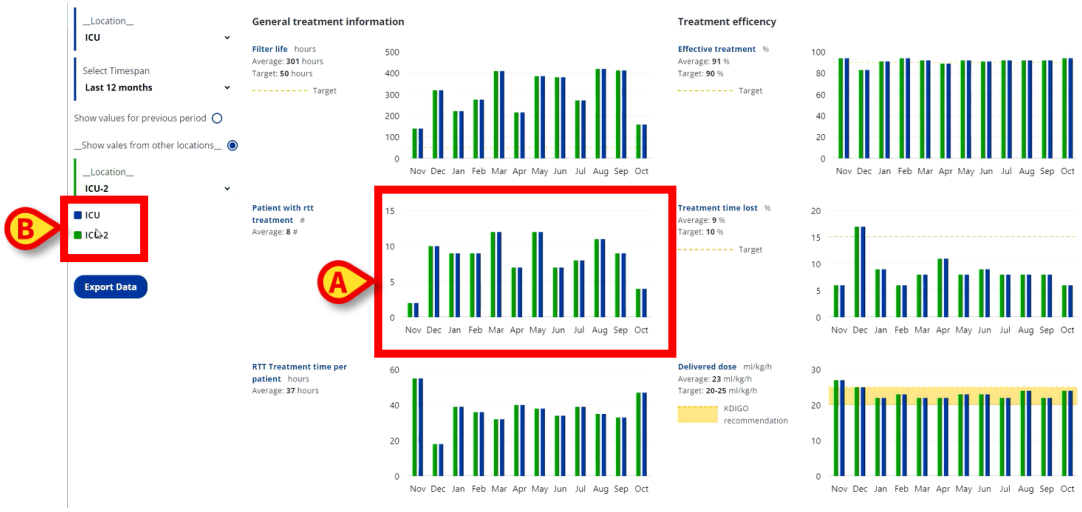


Fig 97

The charts are updated, and comparative histogram charts are provided (Fig 97 **A**). The histograms are coloured according to the colours shown in the provided legend (Fig 97 **B**) indicating the colours for the **Locations** chosen in the first (Fig 96 **C**) and second dropdown (Fig 96 **C**) menus.

Finally, an **Export Data** (Fig 89 **A**) button is provided to export the data, graphs, and target parameters entered in the configuration to an Excel spreadsheet.

1.6. Appendix

This document provides the references for data and formulas used by multi**Assist** module of Digistat Care product. The formulas have been validated by Fresenius team as detailed in the "CCTS Formulas 20231207 ACDM-585-14838" document.

1.6.1. Definitions

1.6.1.1. Parameter Definitions

Definitions of parameter applied in formulas to calculate the Treatment machine dose set. All parameters are those set by the user except where otherwise specified.

Term	Unit	Description
RD	ml/h/kg	Renal dose
UF	ml/h	Ultrafiltration rate
HF	ml/h	Heparin flow
BF	ml/min	Blood flow
DF	ml/h	Dialysate flow
preSF	ml/h	Pre-substituate flow
postSF	ml/h	Post-substituate flow
Ci_D	mmol/l	Citrate dose
Ca_D	mmol/l	Calcium dose
CiF	ml/h	Citrate Flow[4]
CaF	ml/h	Calcium flow[5]
Ci_C	mmol/l	Citrate concentration solution[1]
Ca_C	mmol/l	Calcium concentration solution[2]
CaS_C	mmol/l	Calcium substituate concentration solution[3]
W	kg	Weight of the patient

[1] **Ci_C** from system-option "CitrateConcentration"
[2] **Ca_C** from system-option "CalciumConcentration"
[3] **CaS_C** from system-option "CalciumSubstituateConcentration"
[4] **Cif** Calculated
[5] **Caf** Calculated

1.6.1.2. Machine parameters

List of parameters acquired by MultiFiltratePro. For each parameter:

- Name: name of the parameter when used into formulas
- ParID: Digistat StandardParameterID
- UomID: Digistat StandardUnitofMeasureID
- Description: a textual description of the parameter
- FMC Code: code of the parameter in the Fresenius MultifiltratePro protocol.

Name	ParID	UomID	Description	FMC Code
BF	5500	1306	Blood Flow set	QFOYSY
	5110	1306	Actual Blood Flow	QPOYSY
St	5114	99999	Treatment status code	GFZSON
	5113	36	Filter lifetime	QPZSSM
	5087	36	Treatment time, running total	QPZSGG
Ci-Ca	5532	99999	Ci-Ca Active	QFPPNP
	5104	99999	Treatment Start	GFGFGE
C	5070	99999	Therapy Type	GFZSGU
	5518	1307	Substitution rate set	QFZSNE
DF	5503	1307	Dialysate Flow set	QFZSQE
UF	5517	1307	UF rate set	QFZSRR
	5072	1307	Citrate Flow	QPZPVS
CaF	5073	1307	Calcium Flow	QPZPNS
UFr	5020	1002	Ultrafiltration Ratio	QPHSOS
UV	5079	1302	Effective total withdrawal total	QPZSRG
SV	5083	1302	Substituate-Total total	QPZSFG
DV	5077	1302	DF-Total balance total	QPZSQG
CiV	5095	1302	Citrate volume, total	QPZSVT
CaV	5093	1302	Calcium volume, total	QPZSNT
HV	5089	1302	Anticoagulation, continuous total	QPZSXG
	5508	1307	Heparin Continuous Rate set	QFURCE
	5516	22	Dialysate temperature set	QFQVGC
	5520	1642	Citrate Dose set	QFZPVQ
	5521	1642	Calcium Dose set	QFZPNQ
	5096	3	Weight of scale 1	QPZSJN
	5097	3	Weight of scale 2	QPZSJO
	5098	3	Weight of scale 3	QPZSJP
	5099	3	Weight of scale 4	QPZSJQ
	7583	99999	Device Serial number	GFFEAO
SF	5518	1307	Substitution rate setting	QFZSNE
	5107	99999	Treatment end	GFGRAQ
	5108	99999	Treatment Pause Begin	GFGCNO
Sc	5109	99999	Treatment Pause End	GFGCNR
	5533	99999	Device Status	GFZSFP
	5001	1401	Access Pressure	QPNECE
	5004	1401	Return Pressure	QPIRCE
	5006	1401	Transmembrane Pressure	QPGZCI
	5534	99999	Alarms and warnings on the device	QPZSRE
	5112	1401	Pre-Hemofilter pressure	QPZSCU
	5003	1401	Effluent Pressure	QPZSCS

1.6.2. Formulas

1.6.2.1. DF/BF ratio

Dialysate/Blood flow ratio is defined as: $$r = \frac{DF}{BF * 60}$$

Where: $$r = \frac{UF + postSF + CaF}{BF * 60}$$

BF: Blood flow as set by the user
DF: Dialysate flow as set by the user

1.6.2.2. UF/BF ratio

Ultrafiltration/Blood flow ratio is defined as:

Where:

Parameter	Unit	Description
r		ratio
UF	ml/h	Ultrafiltration rate as set by the user
BF	ml/min	Blood flow as set by the user
postSF	ml/h	Post-substituate flow as set by the user (equals to 0 if the therapy doesn't have the "Post-substituate flow" parameter)
CaF	ml/h	Calcium flow as calculated (equals to 0 if therapy is not a Ci-Ca therapy)

1.6.2.3. Calcium Flow

Calcium Flow is defined as:

$$CaF = \frac{Cad * (DF + UF + CiF + HF + postSF) - CaSc * postSF}{Cac - Cad}$$

1.6.2.4. Citrate Flow

Citrate Flow is defined as: $$CiFp = \frac{Cid * BF * 60}{Cic}$$

1.6.2.5. PreDiluitionFactor Prescription

PreDilutionFactor used in prescription is defined as:

$$Pfp = \frac{(BF * 60)}{(BF * 60) + CiF + HF + preSF}$$

1.6.2.6. Machine Renal Dose Set

Renal dose calculation depends on the therapy as follows:

- For a **Post-CVVHDF** therapy, treatment machine dose set is calculated by this formula:

$$RD = \frac{UF + HF + DF + postSF}{W}$$

- For a **Pre-CVVHDF** therapy, treatment machine dose set is calculated by this formula:

$$RD = Pfp * \frac{UF + HF + DF + preSF}{W}$$

- For a **CVVHD** therapy, treatment machine dose set is calculated by this formula:

$$RD = \frac{UF + HF + DF}{W}$$

- For a **Pre-CVVH** therapy, treatment machine dose set is calculated by this formula:

$$RD = Pfp * \frac{UF + HF + preSF}{W}$$

- For a **Post-CVVH** therapy, treatment machine dose set is calculated by this formula:

$$RD = \frac{UF + HF + postSF}{W}$$

- For a **Pre-Post-CVVH** therapy, treatment machine dose set is calculated by this formula:

$$RD = Pfp * \frac{UF + HF + preSF + postSF}{W}$$

- For a **Ci-Ca postCVVHDF** therapy, treatment machine dose set is calculated by this formula:

$$RD = Pfp * \frac{UF + HF + DF + postSF + CiF + CaF}{W}$$

- For a **Ci-Ca CVVHD** therapy, treatment machine dose set is calculated by this formula:

$$RD = Pfp * \frac{UF + HF + DF + CiF + CaF}{W}$$

1.6.2.7. Substituate Flow (SFc)

Substituate Flow (SFc) is needed to determine the current therapy ongoing on the MultiFiltratePro.

It is calculated as: $$SF_C = \frac{UF_R * BF * 60}{100} - UF - CF$$

1.6.2.8. Treatment Time (TT)

The duration of treatment [**TT**] shall be calculated after determining the start date of treatment. The start date corresponds to the start date of the blood pump, indicated by the duration of use of the filter (parameter **FLT** in minutes). This parameter is only updated every 10 minutes, so the system needs to detect the change of the value to calculate the start date. The interception must be in the interval of 1 minute.

Example 1:

Dataset time (date part is not relevant)	**Filter lifetime**	
10:33	0	
10:34	0	
…	…	
10:44	0	←Change detected.
10:45	10	
10:46	10	
…	…	

The start time of the blood pump is considered as: $10:45 - 10\text{min} = \mathbf{10:35}$

Example 2:

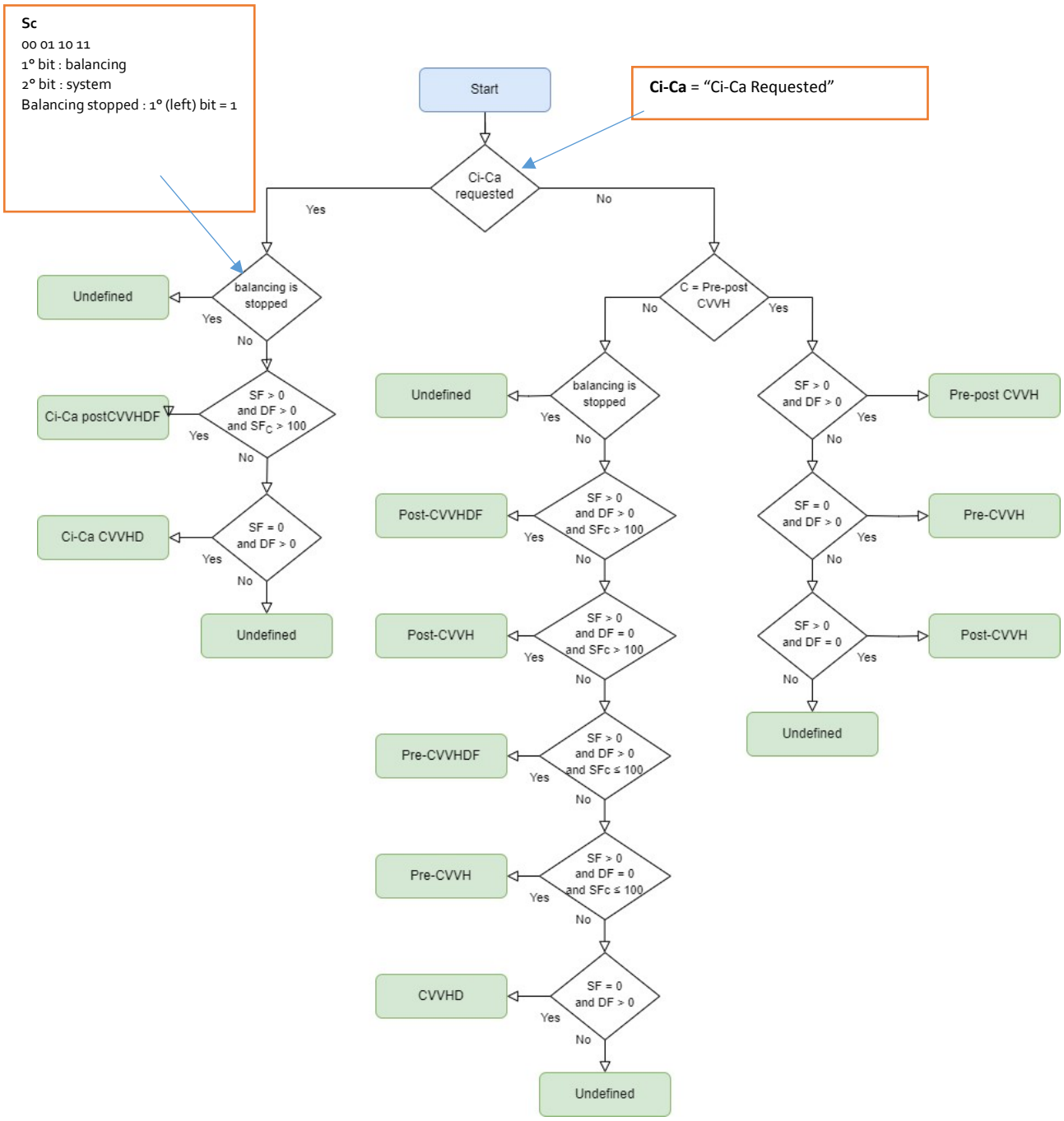
Dataset time (date part is not relevant)	Filter lifetime	
10:33	0	
10:34	0	
…	…	
10:45	0	
10:47	10	←the interval is 2 minutes: no interception
…	…	
10:54	10	←Change detected
10:55	20	
10:56	20	
…	…	

The start time of the blood pump is: $10:55 - 20\text{min} = \mathbf{10:35}$

1.6.2.9. Therapy Code (Tc)

Code of the therapy running on the device is retrieved by using the following diagram. It requires the following calculated value first:

- Substituate Flow calculation (SFc)



1.6.2.10. Prediluition Factor (Pf)

Predilution factor is used by "PRE" therapies and it's calculated as follows:

- This formula is used for all "PRE-only" therapies and Ci-Ca (Pre-CVVHDF, Pre-CVVH, Ci-Ca postCVVHDF, Ci-Ca CVVHD):

$$\frac{(BF * 60)}{(BF * 60) + CiF + HF + SF}$$

- This formula is used for "PRE-POST" therapies (Pre-Post CVVH):

$$\frac{(BF * 60)}{(BF * 60) + CiF + HF + DF}$$

1.6.2.11. Effluent Rate (ER)

The Effluent Rate is calculated only when all following occur:

- the device status is "Treatment" [**St** = "Treatment"]
- the device balance status is not stopped [**Sc** = 00 or **Sc** == 01]
- the effective treatment code is determined [**Tc**]
- Treatment time is determined [**TT**]

This formula is used for the following therapies (all "PRE" therapies and CiCa):

- Pre-CVVHDF, Pre-CVVH, Pre-Post CVVH, Ci-Ca postCVVHDF, Ci-Ca CVVHD:

$$\frac{CiV + CaV + SV + DV + UV + HV}{\frac{TT}{60}} * pf$$

- Other therapies (Post-CVVHDF, CVVHD, Post-CVVH) adopt the following:

$$\frac{CiV + CaV + SV + DV + UV + HV}{\frac{TT}{60}}$$

1.6.2.12. Average Renal Dose

Average Renal Dose [RD] calculation requires the Effluent Rate [ER] and the patient weight [W]. It's calculated as follows:

$$RD = \frac{ER}{W}$$

1.6.2.13. Bags Calculations – Filtrate bag full

Calculations to Filtrate bag full is performed as follow (Note: all calculations consider a density of 1 g/ml)

Calculation can be performed only if all the following are satisfied:

- There is a prescription saved;
- Prescription has been saved with a disposable of type "Filtrate";
- Selected disposable has a volume set;
- There is an ongoing therapy on the machine;
- The machine is in status "Treatment";
- The balancing is active (see "4.8 Therapy Code (Tc)")

Filtrate Bag Target (Fbt) is retrieved by "volume" property of selected disposable.

FbT must take into account the Tara of the bag. Tara is retrieved as described in 1.6.3.3 Bags Volume/Tara relationship.

Filtrate bag Target effective (FbTe) = FbT – Tara

Calculation of Filtrate bag Speed (FbS):
Speed is calculated taking two consecutive dataset of parameters QPZSJP + QPZSJQ (weights on scales 3 and 4)

FbW (Filtrate bag weight) = QPZSJP + QPZSJQ

Given the following:

DateTimeClinical	FbW
T1 (last before current)	FbW1
T2 (current)	FbW2

FbS (Filtrate bag speed) is calculated as:

$$FbS = \frac{FbW2 - FbW1}{T2 - T1\ (*)}$$

(*) = in minutes.

FbS must be greater than 0. If less or equal to 0, calculation cannot be performed.

Remaining time is calculated as:

$$Time = \frac{FbTe - FbW2}{FbS}$$

If resulting time is negative, it shall be considered as 0.
Resulting time is rounded with steps of 5 minutes (example: 13 minutes will become 10 minutes).

1.6.2.14. Bags Calculations – Dialysate/Substituate bags empty

Calculations to Dialysate/Substituate bag empty is performed as follow (Note: all calculations consider a density of 1 g/ml)

Calculation is performed only when all the following are met:

- There is an ongoing therapy on the machine;
- The machine status is "Treatment";
- Balancing is active (see 1.6.2.9 Therapy Code (Tc)).

There could be different calculation depending on the therapy that is running on the device retrieved as described in 1.6.2.9 Therapy Code (Tc).

For all therapies except CiCA Post CVVHDF calculation is performed on the sum of the scales 1 and 2 given by parameters QPZSJN and QPZSJO (see 1.6.3.4 Scale-Bags-Therapy relationship, as reference)

DialSub bag weight (DSbW) = QPZSJN + QPZSJO

Target weight is considered always as 900 grams (we assume that the max load of 20 kgs will apply on balances 1 and 2)

DialSub bag Target (DSbT) = 900 g

Speed is calculated taking two consecutive datasets as follows:

DateTimeClinical	DSbW
T1 (last before current)	DSbW1
T2 (current)	DSbW2

DSbS (DialSub bag speed) is calculated as:

$$DSbS = \frac{DSbW2 - DSbW1}{T2 - T1\ (*)}$$

(*) = in minutes.

Due to the nature of the calculation, DSbS is usually negative. If DSbS is equal or greater than 0, time calculation will not be performed.
Remaining time is calculated as:

$$Time = \frac{DSbW2 - DSbT}{-DSbS}$$

Resulting time is rounded with steps of 5 minutes (example: 13 minutes will become 10 minutes)

Output message shall be produced according to the running therapy type as described in 1.6.3.4 Scale-Bags-Therapy relationship. As an example, if a CVVHD therapy is running the message shall refers to the emptying of Dyalisate.

For CiCA Post CVVHDF therapy calculation is performed on each scale given by parameters QPZSJN and QPZSJO (see 1.6.3.4 Scale-Bags-Therapy relationship, as reference)

Disalysate bag weight (DbW) = QPZSJN
Substituate bag weight (SbW) = QPZSJO

Target weight is considered always as 500 grams (we assume that the max load of 10 kgs on scale 1 and another 10 Kgs on scale 2 will apply)

For Dialysate bag the following applies (for Susbstituate the calculation is exactly the same except the data source, SbW = QPZSJO, and the returned message shall refer to substitutate)

Dialysate bag Target (DbT) = 500 g

Speed is calculated taking two consecutive datasets as follows:

DateTimeClinical	DbW
T1 (last before current)	DbW1
T2 (current)	DbW2

DbS (DialSub bag speed) is calculated as:

$$DbS = \frac{DbW2 - DbW1}{T2 - T1\ (*)}$$

(*) = in minutes.
Due to the nature of the calculation, DbS is usually negative. If DbS is equal or greater than 0, time calculation will not be performed.

$$Time = \frac{DbW2 - DbT}{-DbS}$$

If resulting time is negative, it shall be considered as 0.

Resulting time is rounded with steps of 5 minutes (example: 13 minutes will become 10 minutes).

1.6.2.15. Bags Calculations – Citrate/Calcium bag empty

Calculations to Citrate and Calcium bags empty is performed as follows (Note: all calculations consider a density of 1 g/ml)

Calculation can be performed only if all the following are satisfied:

- There is a prescription saved;
- Prescription has been saved with a disposable of type "Citrate"/"Calcium";
- Selected disposable has a volume set;
- There is an ongoing therapy on the machine;
- The machine is in status "Treatment";
- The balancing is active (see 1.6.2.9 Therapy Code (Tc)).

Calculation relies on:

- Therapy treatment time (see 1.6.2.8 Treatment Time (TT));
- Manual action on multiAssist to record bag change;
- Citrate flow (QPZPVS).

Calculus

BagFlow = QPZPVS for Citrate Flow (QPZPNS for Calcium Flow) retrieved from the machine

BagVol = the volume of the Citrate bag (or Calcium Bag) as retrieved by disposable selected in prescription.

ChangeT = the most recent date/time from:

- Therapy start time (ThStart), calculated as:
  ThStart = Current date/time – Treatment Time (see 1.6.2.8 Treatment Time (TT));
- A manual action of "bag change" has been recorded in multiAssist.

Remaining time for Citrate (Calcium) bag empty is calculated as:

Given DeltaT as:

$$DeltaT = (DateTimeCurrent - ChangeT)$$

BagFlow must be greater than 0. If 0 or negative, Time calculation will not be performed.

Remaining time is calculated as:

$$Time = \frac{(BagVol - BagFlow * DeltaT)}{BagFlow}$$

If resulting time is negative, it shall be considered as 0. Resulting time is rounded with steps of 5 minutes (example: 13 minutes will become 10 minutes)

1.6.3. Tables

1.6.3.1. Prescription parameters limits and default values

The following table defines the parameter values for each therapy: the min-max values and the default value (in brackets). All the parameters with default value are required, except the heparin flow.

	Blood flow in ml/min	Temperature in °C	Dialysate flow in ml/h	Pre-substituate flow in ml/h	Post-substituate flow in ml/h	Ultrafiltration rate in ml/h	Heparin flow in ml/h	Citrate dose in mmol/l	Calcium dose in mmol/l
Resolution →	10	0,5	10	10	10	10	0,1	0,1	0,1
Pre-CVVHDF	10-500 (100)	35-39 (38)	600-4800 (1000)	600-4800 (1000)		0-990 (0)	0,5-25,0 (off:0 – on: 0,5)		
Post-CVVHDF	10-500 (100)	35-39 (38)	600-4800 (1000)		600-4800 (1000)	0-990 (0)	0,5-25,0 (0,5)		
CVVHD	10-500 (100)	35-39 (38)	600-4800 (2000)			0-990 (0)	0,5-25,0 (0,5)		
Pre-CVVH	10-500 (100)	35-39 (38)		600-4800 (1000)		0-990 (0)	0,5-25,0 (0,5)		
Post-CVVH	10-500 (100)	35-39 (38)			600-4800 (1000)	0-990 (0)	0,5-25,0 (0,5)		
Pre-post CVVH	10-500 (100)	35-39 (38)		600-4800 (1000)	600-4800 (1000)	0-990 (0)	0,5-25,0 (0,5)		
Ci-Ca postCVVHDF	10-200 (100)	35-39 (38)	600-4800 (2000)		600-2400 (1000)	0-990 (0)	0,5-25,0 (0,5)	2,0-6,0 (4,0)	0,1-3,0 (1,7)
Ci-Ca CVVHD	10-200 (100)	35-39 (38)	600-4800 (2000)			0-990 (0)	0,5-25,0 (0,5)	2,0-6,0 (4,0)	0,1-3,0 (1,7)

1.6.3.2. Prescription parameters limits and default values

For a running therapy, user can switch prescription according to the following table:

Initial therapy defined	Therapies allowed
Pre-CVVHDF	Post-CVVHDF, CVVHD, Pre-CVVH, Post-CVVH
Post-CVVHDF	Pre-CVVHDF, CVVHD, Pre-CVVH, Post-CVVH
CVVHD	Pre-CVVHDF, Post-CVVHDF, Pre-CVVH, Post-CVVH
Pre-CVVH	Pre-CVVHDF, Post-CVVHDF, Post-CVVH, CVVHD
Post-CVVH	Pre-CVVHDF, Post-CVVHDF, Pre-CVVH, CVVHD
Pre-post CVVH	Pre-CVVH, Post-CVVH
Ci-Ca postCVVHDF	Pre-CVVHDF, Post-CVVHDF
Ci-Ca CVVHD	CVVHD

1.6.3.3. Bags Volume/Tara relationship

The following table represents the relationship between the applied weight on balances and the tara:

Applied weight in g	Tara in g
0 < weight <= 7000	300
7000 < weight <= 12000	500
12000 < weight <= 17000	700
weight <=17000	900

Weight-Volume relationship is considered by applying a default density of 1 g/ml.

1.6.3.4. Scale-Bags-Therapy relationship

The following table shows the relationship between device scales, bag types and therapies.

Bag	Therapy							
	Pre-CVVHDF	Post-CVVHDF	CVVHD	Pre-CVVH	Post-CVVH	Per-Post-CVVH	CiCa post-CVVHDF	CiCa CVVHD
Dialyate			Scale 1 and 2				Scale 1	Scale 1 and 2
Substituate				Scale 1 and 2	Scale 1 and 2	Scale 1 and 2	Scale 2	
Dial/Sub	Scale 1 and 2	Scale 1 and 2						
Ca							Left pole	Left pole
Citrate							Left pole	Left pole
Filtrate	Scales 3 and 4							