Field Safety Corrective Action

Ultrafiltration settings verification and software upgrade on a dialysis machine

NIPRO CORPORATION

- **FSCA number**: FSCA 20220913
- **Product**: Surdial X
- **Type of actions**:
    1. Immediate action: Ultrafiltration settings verification
    2. Corrective action: Software update upon availability (Q4-2022)

Dear Valued Customer,

NIPRO CORPORATION is committed to patient safety. We regularly monitor product performance and quality to ensure the highest standards of customer satisfaction and patient safety.

We always strive for product excellence and would like to provide you with this important update regarding product compliance.

Description of the issue:

While UF variations are expected in all dialysis treatments, Nipro has identified the potential for UF inaccuracies exceeding its acceptable range during in-vitro testing with devices used under specific operating conditions. This has led to the issuing of this FSN.

The settings that could lead to increased wear of the UF pump causing UF inaccuracies under specific operating conditions are as follows:

- a high dialysate flow (Qd) where Qd is higher than 700ml/min
- a high venous pressure (PV) where the average PV is higher than 200mmHg

This may result in a higher fluid removal than prescribed, potentially adversely impacting the patient in terms of fluid management and increasing the risk of hypotensive events. There is a risk to patients who are unable to tolerate excess fluid removal for e.g., patients with poor cardiac function, body weight below 55 kg, or sepsis and diabetic patients with autonomic neuropathy.

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Affected machine population:

Both the following immediate and corrective actions are applicable to **all Surdial X devices**.

Action to be taken by the recipients of this Field Safety Notice

1. Immediate Actions

Upon receipt of this communication, the local technical responsible is requested to perform verifications and, if necessary, implement a series of modifications on the machine's parameters to avoid the occurrence of UF inaccuracies. Should technical personnel not be available, the customer should notify Nipro or the local distributor by ticking the appropriate box in the response form.

1) The setting of "TC3" should be lowered from 25 mmHg to 22 mmHg (please refer to MM3408_Setting of TC3 Value) by a trained technician.

2) Check and record the TC3 test result value of each Surdial X and report the value to your local Nipro contact using an Excel spreadsheet indicating Serial Number/Date of reading/TC3 value.

3) Check the runtime of the UF pump (please refer to MM3407_Check of UFP Operating time). If the number is lower than 3,500 working hours, no further action is needed.

4) If the runtime of the pump is higher than 3,500 working hours, please refer to the following reference table.

Reference Table

TC3 (mmHg)	Action	Health Care Team (Practitioner)
0 - 10	No compensation required. The user should check TC3 (User Guide MM3406_Check of TC3) once a month.	Instruction for trained clinical professionals, healthcare providers, and service engineers / technicians
11 - 21	Apply -50 ml/h UF Offset setting (User Guide MM3409_Setting of UFP Offset) and a restriction on available Qd* allowed to be set only between 300 - 700 ml/min.	Instruction for trained clinical professionals, healthcare providers, and service engineers / technicians
22 - 25	Notify technical service. If no local technical service is available, contact Nipro or the local distributor	Instruction for trained service engineers / technicians only

* Restrict the total Qd to 700 ml/min, in Nipro Surdial X total Qd is Qd + Sub flow

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All users should apply the best clinical practices in line with international KDOQI guidelines.

Nipro would like to remind you about focusing particularly on accurately weighing the patient before and after the dialysis treatment, and to make sure that the priming stage is fully completed before starting the treatment in order to avoid air infusion into the patient's circulatory system.

2. Corrective action

Nipro is currently preparing a software which will mitigate against the effect that certain treatment conditions have on UF performance.

Until your machine is equipped with this new software version, the limitations described in this FSN should be applied.

Target timeline for software release: beginning Q4-2022.

Transmission of this Field Safety Notice:

This notice should be distributed to the technical and nurse manager of your facility.

Please complete and return the Response letter within 10 working days and no later than 30.09.2022 to Damiano Cani (Complaint and PMS manager) at quality@nipro-europe.com.

Please act immediately so we are assured that you have received and distributed this important communication.

Nipro requests that close attention is maintained regarding these actions until your machine is equipped with the new software version. We also request that all related incidents are reported to Nipro in a timely manner.

If you have questions regarding the implementation of these corrective actions, please contact quality@nipro-europe.com.

We would like to take this opportunity to express our sincere appreciation for your continued business and support.

Sincerely,

Damiano Cani
Complaint & PMS Manager

Confidential

Field Safety Notice
Response Form

NIPRO CORPORATION
Product code: Surdial™ X
FSCA 20220913
Type of action: Ultrafiltration settings verification and software upgrade on a dialysis machine

Dear Sir or Madam,

Please complete, sign, and return this Response Form no later than 30.09.2022.

Dialysis Unit name: Click or tap here to enter text.

Contact person first name, surname: Click or tap here to enter text.

Contact person job title: Click or tap here to enter text.

Contact person email/tel. details: Click or tap here to enter text.

Response required (please tick):

- We hereby acknowledge the receipt, distribution, and implementation of this important information. ☐
- The immediate actions were/will be implemented, and the software as corrective action will be installed without undue delays upon availability.

Please tick one of the two statements below:

- We have a trained and authorized Engineer who can be contacted by us to implement the changes on the machine's parameters. ☐
- We do not have a trained or authorized Engineer who can implement the changes on the machine's parameters. Therefore, we will require support from Nipro Medical Europe to perform the modifications. ☐

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Please be informed that this Response Form must be sent by 30.09.2022.

All the safety measures indicated in the Field Safety Notice will need to be implemented at your institution.

Please return the form completed and signed to quality@nipro-europe.com.

Date, Location

Signature or stamp of Dialysis Unit

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To whom it might concern,

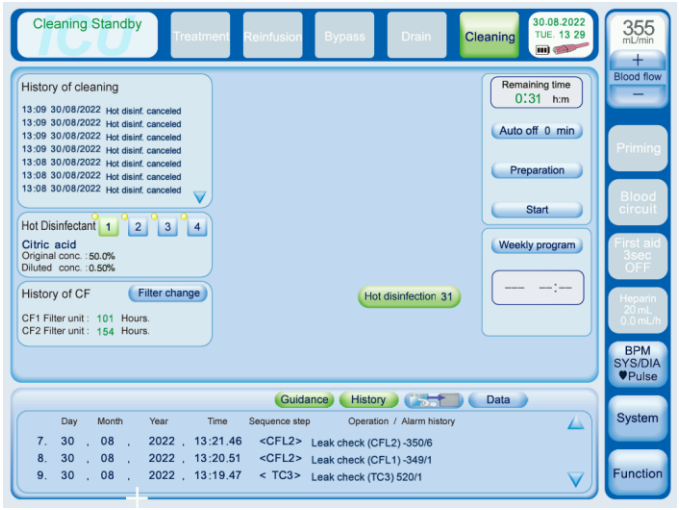
How to set the TC3 Test Value on the Surdial X dialysis machine

Change the TC3 Value from 25 mmHg to 22 mmHg

Instruction for trained service engineers / technicians only

For references, please refer to Service Manual: DN2123-2010-ENG0. Please perform the following actions to change the TC3 value in the Surdial X device:

1. Go to [**System**]:



2. Select [**Maker**] and select [**5. Parameter Setting**]:

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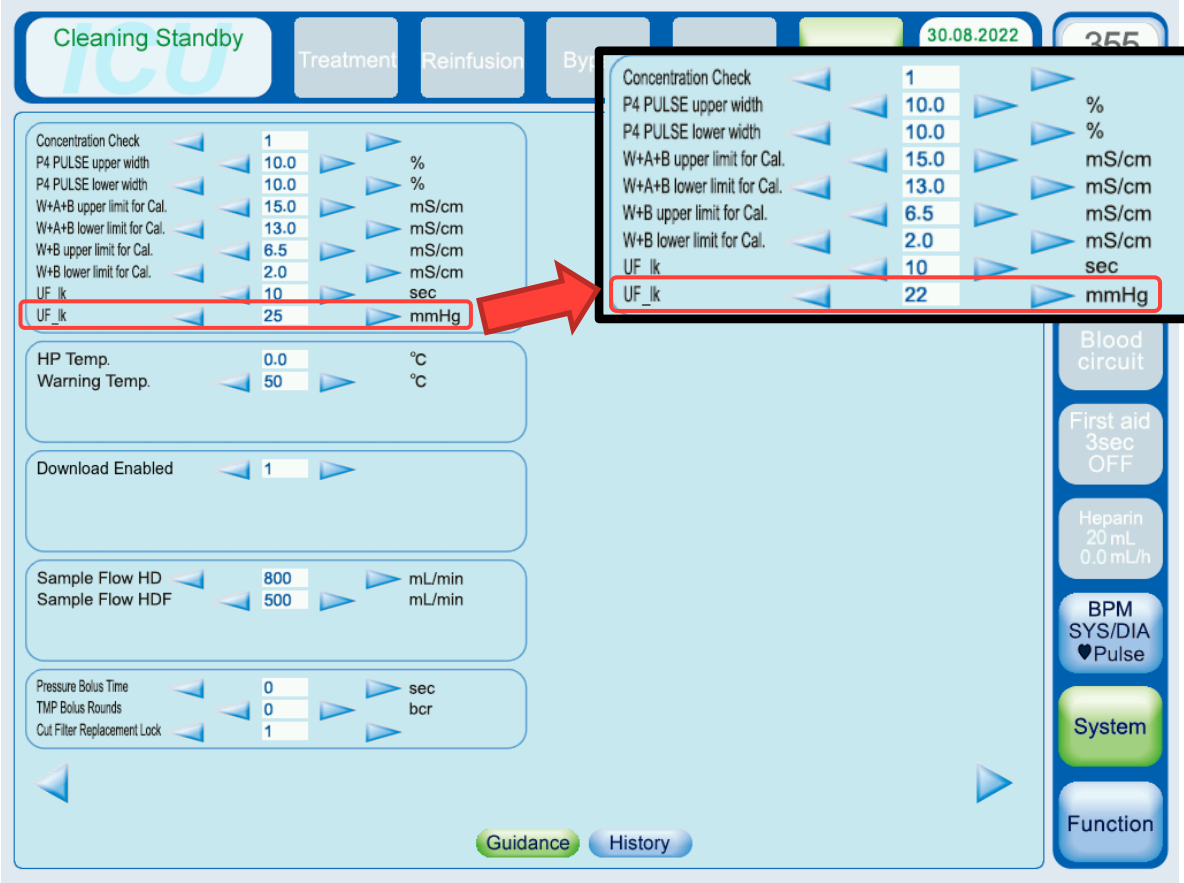
USt-Id: DE296484338

3. Input the password

4. To change the TC3 value navigate to **page 5** of the Parameter setting screens and set the new value for **UF_lk** [**22 mmHg**] by using [◀] or [▶]:



!! **CAUTION** !!
Do not change the value for UF_lk [10 sec]!

Push **[System]** to leave all menus.

For any question or concern please contact surdialquality@nipro-europe.com

Sören Blum
Head of European Technical Service

Damiano Cani
Complaint & PMS Manager

To whom it might concern,

How to check the TC3 value on the Surdial X dialysis machine

Verify if TC3 is equal or greater than 11mmHg

Instruction for trained clinical professionals, healthcare providers and service engineers / technicians

For reference, please refer to Operator Manual: DN1138-2004-ENG0. Please perform the following actions to check the TC3 value on the Surdial X device. Kindly note, that there are two ways to check the TC3 value in Nipro Surdial X.

How to identify the TC3 Value

1. Check the numerical value indicating the TC3 test results next to the brackets "(TC3)"
2. In the Example under Figure 1, the TC3 Value is **2 mmHg**

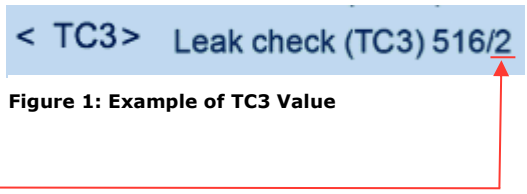
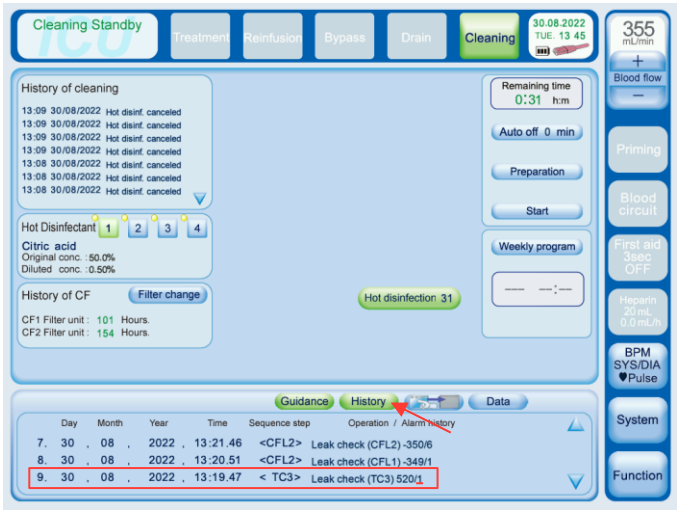


Figure 1: Example of TC3 Value

Via the Main Screen: Message Display - History

1. Go to the **Message Display screen section** and select [**History**] navigate to the most recent TC3 results by using [▲] or [▼] and record the value:



**the message display screen can be reached at any time*

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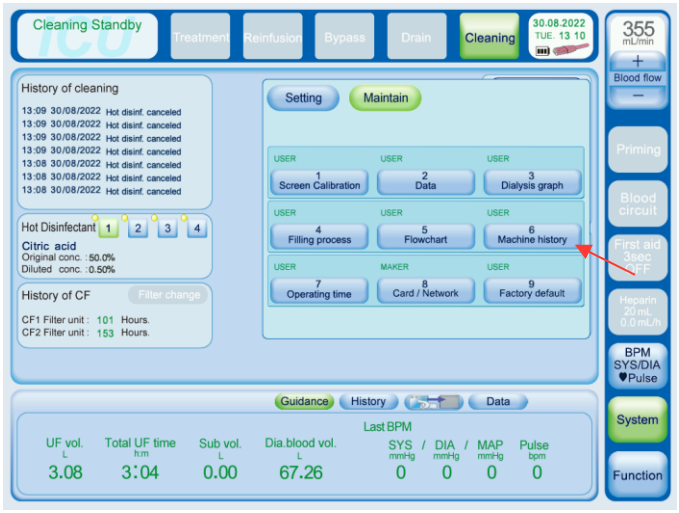
Via the System Menu: Machine history Screen

1. Go to the Machine Menu on the right and select [**System**]

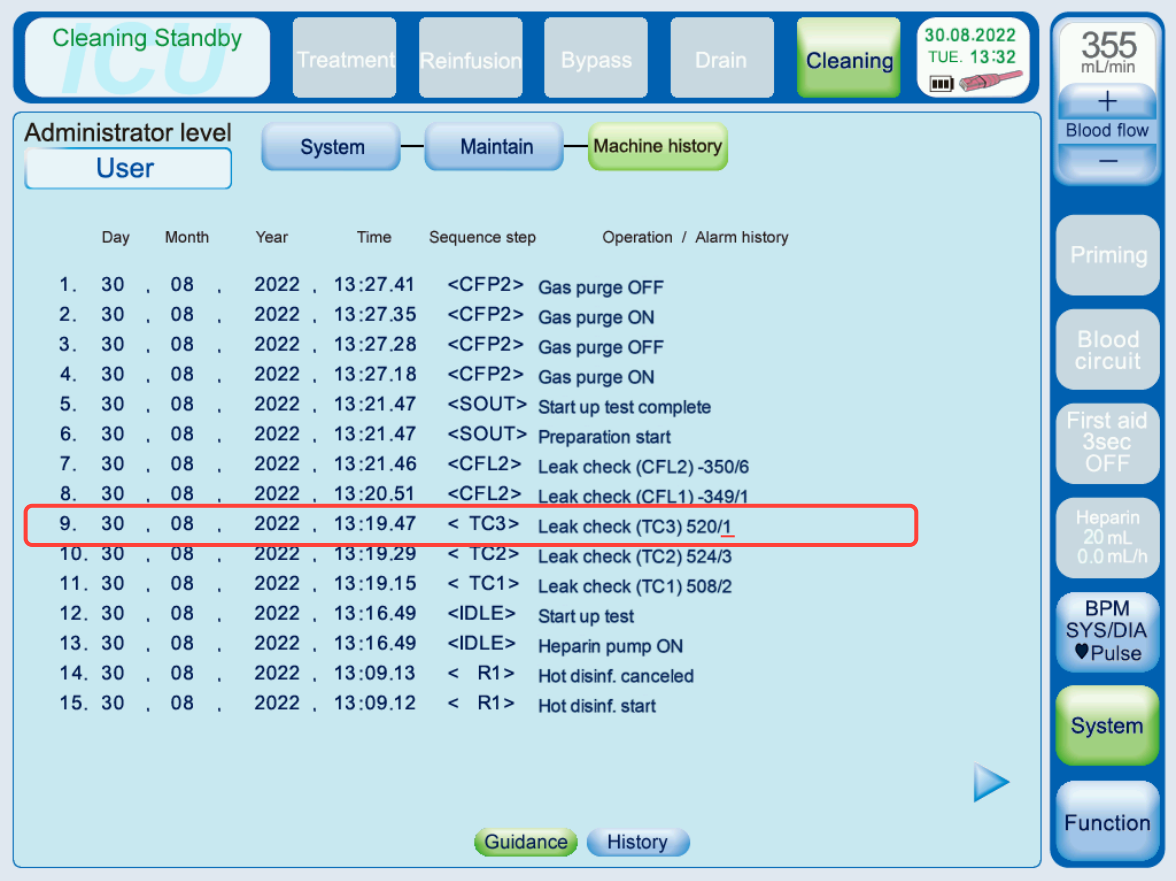
**the System – Machine History screen can be reached at any time*

2. Navigate to [**Maintain**] and select [**6. Machine history**]:



3. Enter the password.

4. To check the TC3 value, navigate to the most recent TC3 results by using [◄] or [►] and <u>record the value</u>:



Push **[System]** to leave all menus.

Should you have any questions or concerns, please contact quality@nipro-europe.com.

Sören Blum
Head of European Technical Service

Damiano Cani
Complaint & PMS Manager

To whom it might concern,

How to check the UF Pump (UFP) operating time on the Surdial X dialysis machine

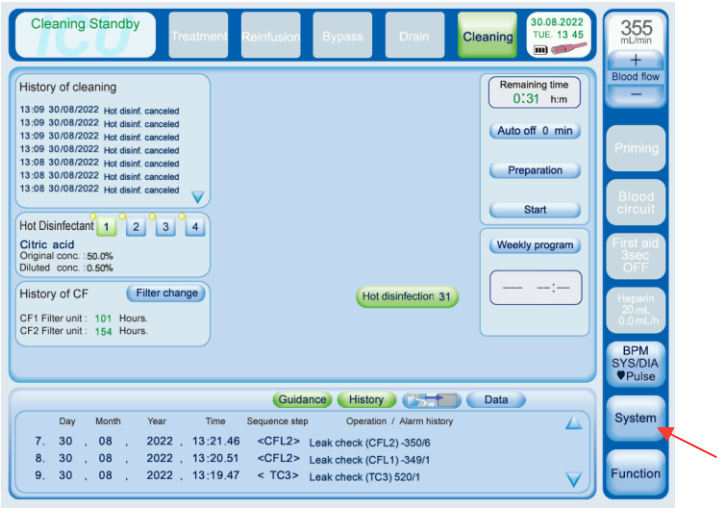
Verify if UFP operating time is equal to or greater than 3500 hours

Instruction for trained service engineers / technicians only

For reference, please refer to Operator Manual: DN1138-2004-ENG0. Please perform the following actions to check the UFP operating time on the Surdial X device. Kindly note, that depending on the condition of your Nipro Surdial X / UF Pump, there is a two-factor verification required for the UF operating time.

Initial Verification of Operating time

1. Go to the Machine Menu on the right and select [**System**]



**the System – Machine History screen can be reached at any time*

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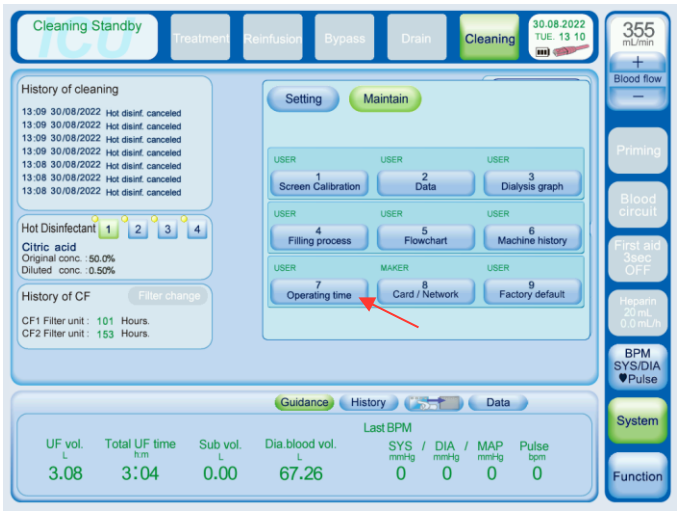
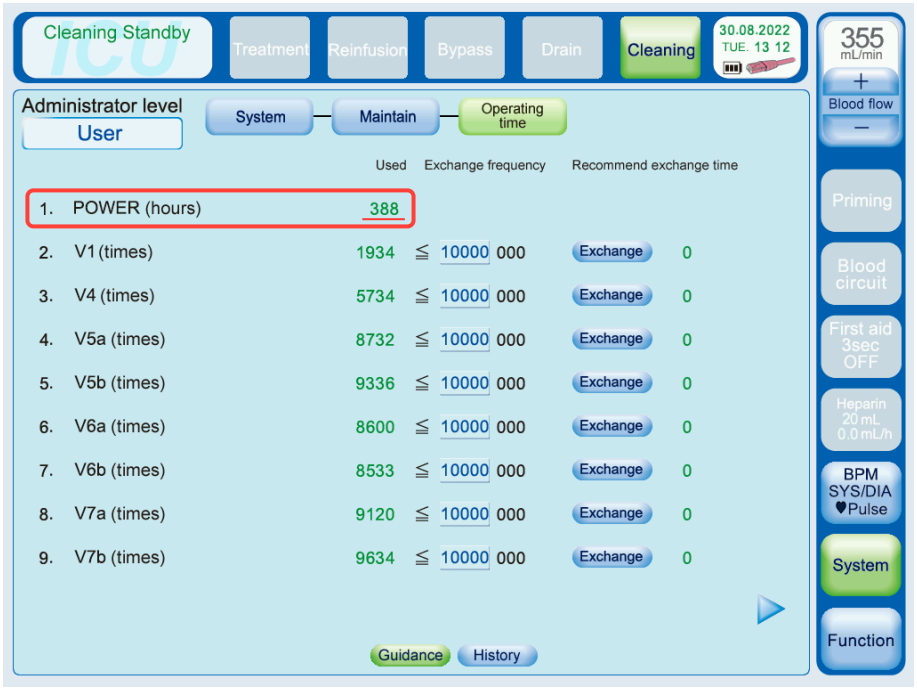
2. Navigate to [**Maintain**] and select [**7. Operating time**]:



3. Enter the password.

4. To view the Operating time of your machine (UFP operating time), check the value under **1. POWER (hours)** and record the value:



5. If the Operating time is lower than or equal to 3500 hours there are no further actions required. Please push [**System**] to leave all menus. If the Operating time is higher than 3500 hours, please perform Step 6.

Service Documentation of your Nipro Surdial X Device

6. If the UFP operating time is higher than 3500 hours, please verify, if the UF Pump has been replaced recently. Please check the UF Pump operating time by verifying the delta of the current Operating time (1. POWER (hours) (see Step 4.)) and the Operating Hours during at the time of replacement of the UF Pump / Pump Head Assy.

   [Delta = current Operating time (1. POWER (hours) – Operating time at time of replacement]

   ***Example**:*

   - current Operating time (1. POWER (hours) = 14000
   - Operating time during replacement of UFP / Pump Head Assy = 12500

   Delta = 14000 – 12500 = 1500 → the UF Pump Operating time is less than 3500 hours.

!! **CAUTION** !!

If you are not able to confirm the UF Operating time, please refer to the TC3 Value as an indication, by using the User Guide MM3406_Check of TC3

Should you have any questions or concerns, please contact quality@nipro-europe.com.

Sören Blum
Head of European Technical Service

Damiano Cani
Complaint & PMS Manager

To whom it might concern,

How to set the UF offset on the Surdial X dialysis machine

Set the UF offset to -50ml/h when TC3 is equal or greater than 11mmHg

Instruction for trained clinical professionals, healthcare providers and service engineers / technicians

For reference, please refer to Operator Manual: DN1138-2004-ENG0. Please perform the following actions to change the UF offset on the Surdial X device:

1. Go to **Cleaning Standby** and select [**System**]:

2. Select [**3. Characteristics**]:

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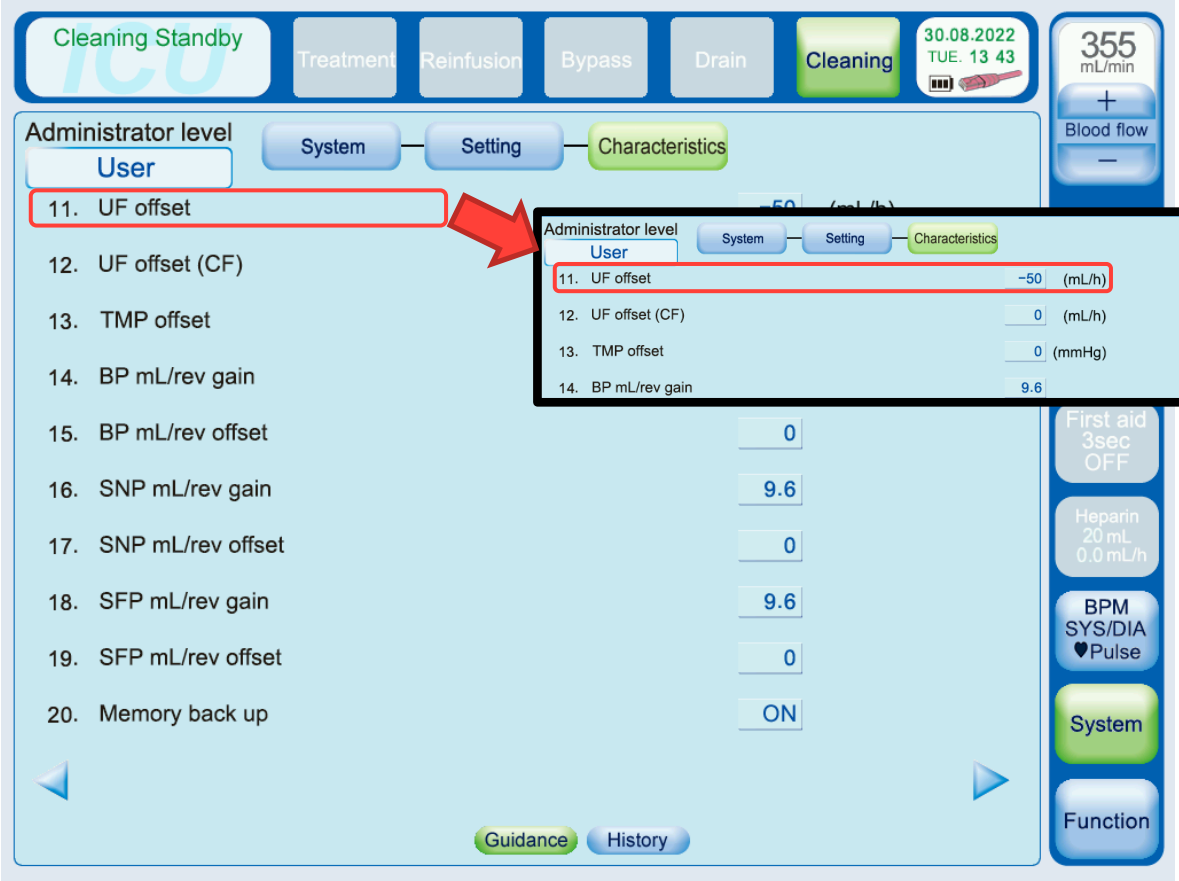
3. Enter the password.

4. To change the **11. UF offset**, navigate to **page 2** of the Characteristics screens and set the value to [**- 50 ml/h**] by using [◄] or [►]:



!! **CAUTION** !!

Do not apply a positive (50ml/h) UF offset!
Do not change the value for UF offset (CF)!

Push **[System]** to leave all menus.

Should you have any questions or concerns, please contact quality@nipro-europe.com.

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