

Urgent Field Safety Notice

Software upgrade on a dialysis machine

NIPRO CORPORATION

- **FSCA number:** FSCA 2021/07/30
 - **Product:** Surdial X
 - **Type of action:** Software update
-

Dear Valued Customers,

NIPRO CORPORATION has a continuous commitment to patient safety and regularly monitors product performance 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 problem:

NIPRO CORPORATION became aware of a potential issue with Surdial X devices, where there is the possibility of inaccuracies in the Ultra-Filtration (UF) volume, visible at the end of the treatment.

Nipro Medical Europe was notified of the issue by one single customer, and immediately registered the event and informed NIPRO CORPORATION which started an investigation.

The event has been reviewed and it has been determined that, although there are no other events reported to NIPRO and the issue seems restricted to a single customer, there is a potential risk to patients due to the possible gradual erosion and abrasion of the Ultra Filtration Pump (UFP), with consequent possibility of UF inaccuracies leading to events of hypotension.

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

The Software 1.485 or higher has an additional sequence within the start-up test to verify the performance of the UFP. Therefore, devices operating with lower software versions should be updated to version 1.485 or higher to ensure the correct operation of the device and to mitigate potential risks.

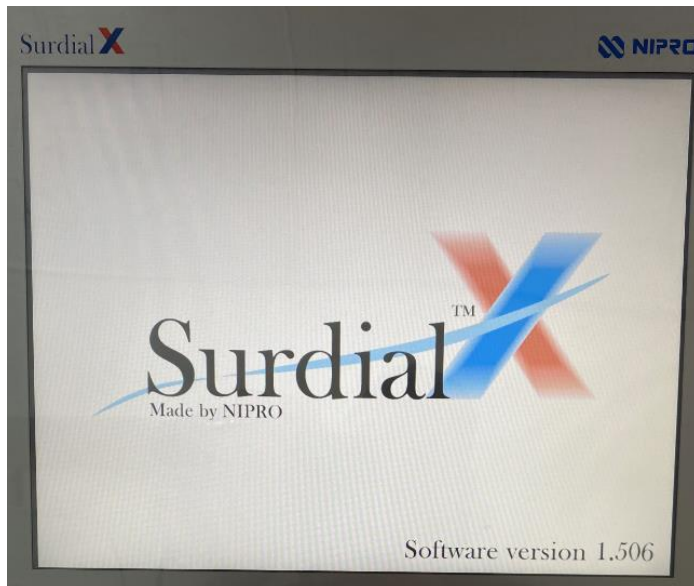
The software is available from Nipro Medical Europe. Our technical service team will contact you to support the update.

NIPRO MEDICAL EUROPE

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At machine start-up, the model name and Software version are displayed.



Until the software on the machines has been updated to version 1.485 or higher, the risk of UF inaccuracies can be minimized by:

1. Ensuring that the closed-circuit leak check during treatment is set to: ON (60 min).
2. Applying the best clinical practices in line with the international KDOQI guidelines.
3. Focus particularly on:
 - Monitoring the status of the patients during the treatment.
 - Accurately weighing the patient before and after the dialysis treatment.
 - Utilise the tools that monitor the status of the patient, such as the Blood Pressure Monitor (BPM) available on Surdial X.

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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 August 2021** 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.

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

