

Urgent Field Safety Notice

Software upgrade on a dialysis machine

NIPRO CORPORATION
Product code: Surdial™ X
FSCA 2018/12/05
Type of action: Software upgrade on a dialysis machine

Dear Sir or Madam,

The purpose of this communication is to inform you that NIPRO CORPORATION is initiating Field Safety Corrective Action (FSCA) 2018/12/05 on select serial numbers of the below medical device:

- Surdial X

Details on affected devices:

All devices with model name Surdial X operating only with software version 1.453 are involved in FSCA 2018/12/05.

Reason for and details of the FSCA:

Nipro Corporation has a continuous commitment to patient safety and regularly monitors product performance in order to ensure the highest of customer satisfaction and patient safety.

Nipro Corporation identified an issue that, in specific circumstances, a dialysis treatment can be interrupted. The problem has been identified as a conflict in software version 1.453 as follows: in the event the Dose Detector function is stopped within two minutes after the initiation of the sodium bolus, the treatment can be concluded as per usual. But for the dialysis session that immediately follows, the screen will freeze.

The end result is that the touchscreen of the dialysis machine is not responsive. Treatment must then be terminated and the user is required to disconnect the patient manually.

A customer notified Nipro Medical Europe about this issue related to software version 1.453. Immediately after being informed about the issue, Nipro Medical Europe registered the event. The reported event has been reviewed and determined that there is potential risk to the patient.



Number of devices affected by this FSN:

Country	Number of machines
Croatia	6

Advice on action to be taken by the user:

The issue is corrected in software version 1.460 or higher. Therefore, devices operating with software version 1.453 should be updated to version 1.460 or higher in order to correct the issue. Software is available from Nipro Medical Europe.

Users of the involved Surdial X machines will be contacted by Nipro Medical Europe to perform the **immediate corrective actions** listed below.

In order to prevent the issue related to FSCA 2018/12/05, one of the following must be taken immediately:

1. Dose Detector Function of Surdial X must be switched **OFF** in the **OPTION** menu.
OR
2. The operator must ensure that Surdial X is switched **OFF** and **ON** between each treatment session. This can be done with the setting of an automatic program in the cleaning menu where a disinfection cycle with **AUTO OFF** is programmed.

Users of the involved Surdial X machines will be subsequently contacted by Nipro Medical Europe to perform the **final preventive action**:

- Upgrade of the Surdial X dialysis machine to software version 1.460 or higher must occur no later than 29 March 2019.

Transmission of this Field Safety Notice:

This notice should be distributed to the Technical and Nurse Manager of your facility. Please complete, sign, and return the enclosed Response Form **within 10 working days** so we are assured you have received and distributed this important communication.

Contact reference person:

Please contact Rossella Sindona, Complaint Manager Nipro Medical Europe, here undersigned.

Sincerely,

Rossella Sindona

Complaint Manager

Rossella.Sindona@nipro-group.com or quality@nipro-europe.com

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11/12/2018

