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.

NIPRO MEDICAL EUROPE
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VAT: BE0 444 276 727

Number of devices affected by this FSN:

Country	Number of machines
Switzerland	3

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
+32 15 263 584

Confidential

Field Safety Notice
Response Form

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

Dear Sir or Madam,

Please complete and sign this Response Form no later than 21 December 2018.

Dialysis Unit name: Click or tap here to enter text.
Serial number of Surdial X machines affected by FSCA 2018/12/05: Click or tap here to enter text.
Contact person 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:

- We hereby acknowledge the receipt, distribution, and implementation of this important information. The preventative actions have been/will be implemented by our institution. ☐

Please check one of the two:

- We have a trained an authorized Engineer who will perform the update and we will report the evidence to Nipro Medical Europe no later than 29 March 2019. Nipro Medical Europe must provide the new software. ☐
- We do not have a trained or authorized Engineer who can perform the update, therefore we will require Nipro Medical Europe to perform the update and it will be scheduled for no later than 29 March 2019. ☐

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Please be informed that this Response Form must be sent by 21 December 2018, but an action plan (one of the two options checked above) is due by 29 March 2019.

First scan and email this signed form:
quality@nipro-europe.com no later than 21 December 2018.

Then mail by post the original signed copy to:

Nipro Medical Europe
Rossella Sindona
Complaint Manager
Blokhuisstraat 42, 2800 Mechelen

Date, Location

Signature or stamp of Dialysis Unit

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