MHRA Device Safety Information

Reference **MDSI2202** Issued **17 Feb 2022**

Surdial X Haemodialysis machine: potential for devices to remove excess fluid outside of machine specification

Summary

The Surdial X haemodialysis machine is manufactured by Nipro Corporation. The information in this notice relates to all serial numbers of this model.

The MHRA are aware of instances of Surdial X machines removing excess fluid via ultrafiltration outside of its specification. There is a risk to patients who are unable to tolerate excess fluid removal.

Haemodialysis is a treatment given to patients whose kidneys stop working properly. The machines and associated items such as filter and tubing lines perform the function of the human kidney, to clean and filter unwanted substances and fluids from the blood.

The manufacturer has previously issued a Field Safety Notice (Nipro FSCA20210730) and are continuing to investigate this matter. The likely root cause is unexpected wear of the ultrafiltration pump.

Action

Actions for heads of Renal units and Renal nursing

1. Weigh your patients consistently before and after each treatment. If any anomalies are detected closely monitor the patient for signs of hypotension, document the machine used and notify the renal technician or Nipro technical team.
2. Identify clinically susceptible patients undergoing dialysis treatment with the Surdial X machine, considering clinical factors such as poor cardiac function and poor tolerance to ultrafiltration deviation. Consider additional monitoring of vulnerable patients for signs of excess fluid removal if the TC3 value exceeds 15 (for machines identified via the renal technicians' actions below).
3. Ensure the manufacturer's instructions for use for stopping ultrafiltration mid-treatment are followed.

Actions for Renal technicians

1. Ensure machines are running with software version 1.485 or higher.
2. Review the TC3 self-check test pressure value of the machine. If the value is higher than 15, schedule a check of the ultrafiltration performance of the machine as soon as possible to identify whether the machine is removing fluid outside of its specification.
3. The identified machines from step 2 should be highlighted to the renal nursing staff.
4. For machines identified to be removing excessive fluid outside of its specifications, perform the following:

    a) Ultrafiltration (UFP) Flow Measurement (DNAJ03-017) procedure to calculate the new UFP Flow value
    b) Ultrafiltration (UF) Accuracy checks as per section 8.4 of the Technical Safety Inspection procedure (DN2123-2010) to confirm the UF Accuracy.

    If the UF Accuracy cannot be achieved within the specification, document the TC3 pressure value and the values of the UF Accuracy tests and notify your local Nipro Technical Service representative to discuss to arrange for replacement components as necessary.
5. Schedule annual checks of Ultrafiltration performance of the machine and consider reviewing the TC3 values on a quarterly basis to monitor the performance of the Ultrafiltration pump and take the recommended actions as if TC3 value is higher than 15.

Actions for patients

The advice in this DSI is aimed at the renal healthcare team who are responsible for providing your dialysis treatment. If you have any concerns about this advice, contact your renal specialist team for assistance.

Equipment Details

The Surdial X haemodialysis machine manufactured by Nipro Corporation. The information in this notice relates to all serial numbers of this model.

Risk involved with using affected product

All Nipro Surdial X machines operating with software versions higher than 1.485 have a self-check test (TC3 test), for monitoring the ultrafiltration circuit within the limits specified in the IEC60601-2-16 guidelines. The TC3 test will not permit treatment if the fluid removal exceeds the limits specified by the IEC 60601-2-16 guidelines which is +/- 100ml per hour, or a maximum of 400 ml per treatment.

According to the specification of Nipro Surdial X the tolerance for ultrafiltration accuracy is +/-30 ml/h. Nipro have identified potential for the machines to remove fluid outside of these technical specifications. This is referred to as ultrafiltration deviation. Machines are recommended to be serviced every 24 months therefore increased levels of ultrafiltration deviation may not be obvious to the user in between servicing periods.

There is a small risk of dialysis induced hypotension to patients who are unable to tolerate excess fluid removal e.g. patients with poor cardiac function, sepsis and diabetic patients with autonomic neuropathy.

The MHRA are aware of reports of symptomatic hypotensive episodes from one site, including a small number which resulted in the patients receiving fluid resuscitation. The manufacturer is investigating possible links between these cases and excessive fluid removal.

Based on information received to date, the manufacturer considers this to be an isolated occurrence which may be linked to specific operating conditions contributing to wear of the ultrafiltration pump. The manufacturer states that they are have not received any reports since the implementation of FSCA20210730.

Manufacturer contact details

Nipro Medical Europe email: quality@nipro-europe.com

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.