

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 208 dated 17/11/2022 Regarding NCMDR
FSCA of Surdial X from (mfr: Nipro Corporation.).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 208 / 2022


بمقدّم ثقة
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2040

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17 -11-2022

Field Safety Corrective Action of Surdial X from Nipro Corporation.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17314
Product	Surdial X.
Description	Haemodialysis system, institutional.
Manufacturer	Nipro Corporation.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	All lot numbers.
Reason	Nipro has identified the potential for UF inaccuracies exceeding its acceptable range during in-vitro testing with devices used under specific operating conditions.
Action	<ol style="list-style-type: none">1. Nipro is currently preparing a software which will mitigate against the effect that certain treatment conditions have on UF performance. This is anticipated to be released Q4 2022.2. In the interim, users are advised to implement the workaround outlined in "Immediate Actions" in the attached FSN.3. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General





Field Safety Corrective Action

Ultrafiltration settings verification and software upgrade on a dialysis machine

Published On:20/10/2022

NIPRO CORPORATION

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

Dear Sir/Madam

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.

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

1. Immediate Actions

- 1) The setting of "TC3" should be lowered from 25 mmHg to 22 mmHg
- 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 Operatin. 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).	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

2. Corrective action

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

Target timeline for software release: Q4-2022.

If you have questions regarding the implementation of these corrective actions, please contact.

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

Sincerely,

Nipro Middle East