FSN Ref: CAPA 86

FSCA Ref: CAPA 86

Date: 11.04.2025

Urgent Field Safety Notice
RO Medical / RO Medical Basic

For Attention of: Responsible person for device maintenance

Contact

NIPRO Pure Water GmbH
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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	RO Medical is a water treatment system which uses the reverse osmosis principle to produce dialysis water
1.	2. Commercial name(s)
	RO Medical / RO Medical Basic
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The RO Medical and RO Medical Basic are used for the central water treatment in dialysis. The device is a water purification system that uses reverse osmosis to remove microbiological, organic, and inorganic contaminants from the potable water. The purified water is used to dilute dialysis concentrate to form dialysate for dialysis machines/dialysers used in hemodialysis therapies.
1.	5. Device Model/Catalogue/part number(s)*
	RO Medical / RO Medical Basic
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	2, 4, 12, 29, 83, 99, 104, 116, 118, 119, 129, 130, 141, 142, 144, 145, 146, 176, 177, 222, 229, 259, 395, 422, 471
1.	8. Associated devices
	N/A

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2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Capacitor of pump motor did fail and caused a stitch flame.
2.	2. Hazard giving rise to the FSCA*
	There is no direct risk for the patient. Due a malfunction of the capacitor, the water treatment system will not work, which will cause a delay of ongoing therapy.
2.	3. Probability of problem arising
	As the capacitor has already been part of yearly maintenance for replacement and based on 15 years of complaint data, which shows no further incidents, we determined the probability of occurrence is very low.
2.	4. Predicted risk to patient/users
	The risk for the patient is low as there is an indirect impact due to the delay of therapy. In the unlikely event of malfunction of the capacitor and presents of the user at the device, there is a risk of injury.
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	The capacitor must be changed yearly as the maintenance documents indicate. If the capacitor is not changed, this could lead to a malfunction, with the listed consequences.
2.	7. Other information relevant to FSCA
	As the cause could not be clearly determined, a capacitor with an overpressure disconnector was selected, which disconnects the capacitor from the mains in the event of destruction. This prevents the formation of flames and reduces the risk for the user.

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	3 Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ **Identify Device** ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ **On-site device modification/inspection** ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Please provide us the current operational status and the address of the device. After your feedback we will send the replacement capacitor to your provided address. The replacement activity is the same as the yearly exchange of the capacitor during the maintenance. If you require further instructions or support, please let us know so that we can assist you with this activity or, if necessary, carry it out for you. It is important to provide feedback after the replacement to monitor the progress of the corrective actions.	
3.	2. By when should the action be completed?	11.07.2025
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes (see 3.1 and 3.2)
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Providing the replacement capacitor and support customer with on-site modification if required.	
3	5. By when should the action be completed?	11.07.2025
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Nipro Pure Water GmbH
	b. Address	Werner-von-Siemenstr. 2-6 76646 Bruchsal, Germany
	c. Website address	https://www.nipro-group.com/en/our-company/our-locations/nipro-pure-water-germany
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * yes	
4.	9. Name/Signature	**Heiko Sutter, PRRC**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Date: 23.04.2025

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN reference number	FSN ref: CAPA 86
FSN date	23.04.2025
Product/device name	RO Medical / RO Medical Basic

We would like to take this opportunity to apologise for any inconvenience caused and thank you for your support. Please return the completed form to all listed email address below.

2. Return details	
Email address for reply form	npw-regulatory@nipro-group.com NME@nipro-group.com MIC@nipro-group.com

3. Costumer details	
Healthcare Organisation name*	
Organisation Adress*	
Adress of product / device*	
Serial number of the product*	
Contact person* (Name, Email, Telephone number)	
Shipping address for replacement*	

4. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	
☐	I requested the replacement and performed the exchange*	
☐	I require technical support for the replacement*	
☐	The information and required actions have been brought to the attention of all relevant users and executed.*	
☐	I do not have any affected devices or it is not longer operational.*	
Name*		
Signature*		

Nipro Pure Water GmbH – Werner Von Siemensstr. 2-6 – 76646 Bruchsal - Germany

Date*	

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence to monitor the progress of the corrective actions.