Field Safety Corrective Action for Master vacuum pumps

20. November 2023

FSN: FSN_2023-01

Attention: Distributors and users of the Master vacuum pumps

Dear customer,
With this letter we would like to inform you about a Field Safety Corrective Action (FSCA) of Ardo medical AG. This is a Field Safety Corrective Action that requires testing of the affected devices series at the distributors or at the end users site.

1 Information on affected devices:

Article no.	Description	Serial number
30.00.33	Master, 230V, Swiss plug	2315233

2 Reason for the Field Safety Corrective Action (FSCA)

2.1 Description of the product problem

Some devices (Master) can overheat due to an incorrectly assembled circuit board and as a result therefore switches off. This error only occurs if the device is switched off after a running time of approximately 60 minutes and immediately switched on again. When the device overheats and then switches off, it will take up to 6 minutes before it can be used again. This can lead to a delay in treatment.

2.2 Hazard giving rise to the FSCA

In rare cases, this error can lead to a delay in suction, which prolongs the treatment.

2.3 Probability of problem arising

From the inventory inspection of the circuit boards that can cause the problem, we conclude that every second device can be affected by this malfunction. From the field (Complaints) we have feedback from a device in which a spare part from the affected batch was installed and did not pass the test. We are talking here about a probability of 0.2% of all devices ever delivered.

2.4 Predicted risk to patient/users

It can lead to an interruption of the suction, hence prolonging the intervention. A second device must always be close by during operations, and the risk for the patient can be classified as a non-serious deterioration in the patient's health condition.

2.5 Further information to help characterise the problem

N/A

2.6 Background on Issue

It was found during internal end testing procedure and was then confirmed from another tested device at our subsidiary in Germany. They had a replacement part from the affected delivery built in a device which was at their site for repair.

3 Type of Action to mitigate the risk

3.1 Action To Be Taken by the Distributor

☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device

☒ On-site device modification/inspection

Check your stocks for relevant products. Immediately carry out a complete physical inventory to identify the affected products and withdraw them from circulation due to the detected error.

If any of the products concerned have been passed on to other persons or organisations, a copy of this FSCA with the FSN_2023-01_Reply-Form_Switzerland_V01 answer document must be forwarded to these end-users.

3.2 Action To Be Taken by the End-User

As we are not in direct contact with the end users, this communication must be done by the distributor.

☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device

☒ On-site device modification/inspection

All users of the affected products must have read and follow all instructions and information in this FSCA and following the instruction how to test the devices on the form FSN_2023-01_Reply-Form_Switzerland_V01.

3.3 By when should the action be completed?

The planned deadline for the FSCA / FSN is by the 31st of January 2024

4 Communication and Information

The communication for the FSCA / FSN must be done to the following E-Mail address qmb@ardo.ch

4.1 Which information must be provided

1. Confirmation of receipt of the FSCA / FSN
2. Information about the contact to the end users, with information date
3. How to test the devices is described in the document "FSN_2023-01_Reply-Form_Switzerland"
4. Returning of the test outcomes for each serial number separately
    a. How to proceed with affected devices
5. Information about the status of the FSCA / FSN repair of affected devices

For this, you must use the document "FSN_2023-01_Reply-Form_Switzerland_V01".

5 General Information

FSN Type*	New
For updated FSN, reference number and date of previous FSN	n/a
For Updated FSN, key new information as follows:	n/a
Further advice or information already expected in follow-up FSN? *	Not planned yet
If follow-up FSN expected, what is the further advice expected to relate to:	n/a
Anticipated timescale for follow-up FSN:	For provision of updated advice.

Manufacturer information

Ardo medical AG
Gewerbestrasse 19
CH – 6314 Unteraegeri
www.ardomedical.com

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
swissmedic (Vk_20231108_33)
List of attachments/appendices: **FSN_2023-01_Reply-Form_Switzerland**
Name/Signa[redacted]

Marcel Bühler
Director of QM&RA
Ardo medical AG

Customer Reply Form

1 Field Safety Notice (FSN) information

FSN Reference number	FSN_2023-01
FSN Date	20. Nov. 2023
Affected Product / Device name	Master
Article No.(s)	30.00.33
Serial Number(s)	2315233

2 Customer Details

Company Name	[redacted]
Address	[redacted]
Postal Code / City	[redacted]
Country	Switzerland
Name of Contact	[redacted]
Function	Owner
Department	n/a
Telephone Number	n/a
Email address	[redacted]

3 Customer action undertaken on behalf of manufacturer

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have a query please contact me (e.g. need for replace-ment of the product).	

4 Information how to test

1. Switch on the unit, set it to maximum vacuum and let it run at no load for 60 minutes.

2. Switch off the unit and switch it on again immediately, again at maximum vacuum and at no load. Let the unit run again for 60 minutes.

3. If the unit continues to pump after this time (motor noise perceptible?), the unit can continue to be operated without restrictions.
Please document the result accordingly on the ***Information about devices***

4. If the unit stops pumping during this time, the push-start print must be replaced. This may only be done by authorised persons.
Please contact your sales partner for contact information of the responsible service partners.
Please document the result accordingly on the List of affected devices

5 Information about devices

	Testing result			
SN	Passed	Failed	Replaced part	Sending in to
2315233	x	n/a	Print Push-start Ticket 185367	n/a

5.1 Information about replaced parts

☐	I have returned affected parts	
☐	I have destroyed affected parts according local law	

6 Return acknowledgement to sender

Company Name	Ardo medical AG
Address	Gewerbestrasse 19
Postal Code / City	6314 Unteraegeri
Country	Switzerland
Name of Contact	Marcel Bühler
Function	Director QM&RA
Department	QM&RA
Telephone Number	n/a
Email address	qmb@ardo.ch

7 Deadline for returning the customer reply

31. Jan. 2024

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 we need to monitor the progress of the corrective actions.

8 Confirmation

We have performed all the mentioned points outlined in the FSN and the devices in our country are safe for further use.

Place / Date:_____ Signature:_____