Field Safety Corrective Action for Master vacuum pumps

22 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
30.00.31	Master, 230V, Schuko (Euro-plug)
30.00.36	Master, 230V, with foot switch, Schuko-plug
30.00.39	Master, 230V, Schuko-Plug, RAL9002
30.00.40	Master, 230V, with foot switch, Schuko, RAL9002

Serial numbers: from 2315180 to 2315317

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 the 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 FSN with the FSN_2023-01_Reply-Form_(country specific) 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_(country specific).

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_(country specific)”
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_(country specific)”.

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

Persoonsgegevens

The Competent (Regulatory) EU Authority has been informed about this communication to customers.
BfArM (35007/23)

List of attachments/appendices: **FSN_2023-01_Reply-Form_(country specific)**

Name/Signature Persoonsgegevens