

2019-11-14

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2019-11-11 ROTAFLOW Drive – Loose ODU plug connection of coaxial cable

Affected Product:

- 70101.0875 ROTAFLOW Drive Unit, blue
- 70102.2161 ROTAFLOW Drive Unit, blue
- 70105.1427 ROTAFLOW Drive Unit, blue
- MCP0.0952291 ROTAFLOW Drive Unit, blue right

Affected Serial No.: S/N are listed in the attached Annex I list of affected units

Unique Device Identifier:

- 04037691258997 for 70102.2161 ROTAFLOW Drive Unit, blue

Dear valued customers,

Maquet Cardiopulmonary GmbH has determined during a flow measurement test that the ROTAFLOW Drive Units listed in Annex I have been equipped with a coaxial cable which may contain a loose ODU plug connection. The coaxial cable of the ROTAFLOW Drive (RFD) connects the RFD with the ROTAFLOW Console.

The loose plug connection may result in poor contact of the pins which are responsible for the data transmission of the flow measurements. This may lead to fluctuating flow values which are displayed on the ROTAFLOW Console. The displayed flow values can change up to two liters per minute, either in positive or negative direction, and can remain at the new value without returning back to the original value. The malfunction may be triggered if the cable of the RFD unit is moved or touched.

The real pump speed and blood flow are directly affected if the ROTAFLOW Console is operated in LPM (liters per minute) mode. In LPM mode the user can set the flow setpoint. The system operates the pump in such a way that the set flow is maintained. The speed is varied according to the resistance of the extracorporeal circulation. In this mode the flow measurement erroneous display has a direct impact on the operation of the ROTAFLOW System and therefore on the patient's blood supply. If the flow measurement deviates downwards, i.e. the measured value is lower than the actual value, the ROTAFLOW Console automatically increases the speed specification of the RFD until the measured flow returns to the originally set value. This means an actual blood delivery above the set value. If the flow measurement deviates upwards, the speed is correspondingly reduced, resulting in reduced blood delivery. An increased or reduced blood delivery can potentially lead to severe harm of the affected patients.

In RPM mode (revolutions per minute) the pump speed and blood flow are not directly affected by the loose plug connection. In RPM mode the user can set the pump's speed setpoint. The system operates the pump constantly at the set speed. As a result the flow can vary according to the resistance of the extracorporeal circulation.

In case treatment is being performed by an affected RFD unit in LPM mode (liters per minute), switch to RPM mode. After switching into RPM mode check your inventory for an unaffected RFD unit which is not listed on Annex I and replace the affected RFD unit.

In case you do not have an unaffected RFD unit, look for an independent external flow measurement system to measure the actual flow. Only use a reliable external flow measurement that is gauged and zeroed. Use that measurement system in conjunction with the RPM mode. If necessary adjust the RPM according to the flow reading as obtained with the independent external flow measurement system. A continuous control of the patient vital signs monitoring is indicated. Keep the Bubble Sensor intervention of the inbuilt Flow/Bubble Sensor active in order to detect air bubbles.

In case no external flow measurement system is available stay on RPM mode and continuously control vital signs monitoring. It is indicated to closely monitor the blood gases of the respective patient. The assessment of the vital sign monitoring and the blood gas analysis in conjunction with the indicated pump speed (RPM) is required. Keep the Bubble Sensor intervention of the inbuilt Flow/Bubble Sensor active in order to detect air bubbles.

In case you do not have an unaffected RFD unit and cannot perform patient treatments, please contact your local Getinge representative regarding a loaner unit.

Please do not use the affected RFD units in your inventory and also do not further use the affected RFD unit after the completion of the patient's treatment until the defective cable has been exchanged.

The repair of the affected RFD units cannot be performed at the clinical site and therefore needs to be returned in the original packaging to your local Getinge representative.

Maquet Cardiopulmonary GmbH has not received any complaints with serious injuries or deaths due to the malfunction of the RFD units.

Corrective Action: Return your affected product(s) with the S/N listed in Annex I to your local Getinge representative

Advice on action to be taken by the User:

- According to our post-market surveillance documentation, your current stock may include products affected by this action.
- Duly fill out the enclosed Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning FSCA-2019-11-11 as reference.
- If you have identified an affected unit listed on Annex I in your stock: Please return the identified unit(s) in the original packaging for safe transportation to your local Getinge representative. If the original packaging is no longer available, new packaging can be requested via your local Getinge representative.

Referenced documents/ attachments:

- Letter of Acknowledgement Customer
- Annex I List of affected products

Transmission of the Field Safety Notice:

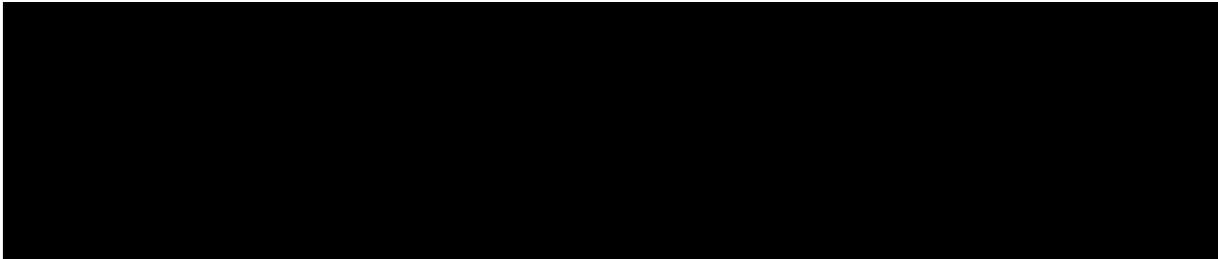
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,



Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY