2024-08-08

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	1074963 – RS232 accessory cable not conforming to IEC 60601-1
FSN Type:	New
Affected Product:	Serial interface cable (RS232) (Mat. 701075475, Type Label Mat. 701074356)
Unique Device Identifier(s) (UDI-DI):	04058863234496
Affected Batch No.:	3000142796, 3000215802, 3000243099, 3000248166, 3000249231, 3000262484, 3000263356, 3000289870, 3000294925, 3000343256
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about a recall for the serial interface cable (RS232) due to nonconformance to the IEC 60601-1 standard.

The general function of the Rotaflow II System is to drive, to control and to monitor an extracorporeal circulation. The purpose of the serial cable (RS232) (Figure 1) in the context of the Rotaflow II system is to facilitate transmission/transfer of data between the Rotaflow II console and data collection systems (e.g., electronic medical records (EMR)).

Figure 1: Picture of Serial interface cable

Problem description

Maquet Cardiopulmonary GmbH became aware of this issue through testing of the upper housing of the Rotaflow II. The test found that the RS232 cable of the Rotaflow II does not comply with the IEC 60601-1 standard as the capacitor of the respective socket is designed for 300V rather than 500V AC required by the IEC 60601-1. When the required voltage was applied, the RS232 cable was damaged as a result. In the worst-case scenario, 17 mA could flow through the user's body this way.

Hazardous situation

Through the completion of the Health Hazard Evaluation (HHE), Maquet Cardiopulmonary GmbH determined the following hazardous situation:

- Exposed to inappropriately high leakage current (patient, user, third person)

Potential harm

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following (for further information refer to Annex I):

- Electric[al] Shock (medium)

Maquet Cardiopulmonary GmbH has identified no relevant customer complaints for the same issue.

Corrective Action:

- Return of affected devices

Action to be taken by the user:

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

Details of the further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory immediately to determine, if you have any affected product in your inventory.
- Please quarantine and return immediately all affected products in your stock to your local Getinge representative.
- Upon return of the affected products, please contact your local Getinge representative for credit.
- Please **always** report any adverse events potentially related to the affected products to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative by **August 30, 2024,** the latest. Please give **FSCA-1074963** as reference in the subject line of your email.

Action to be taken by the manufacturer:

☒ Product Removal ☐ On-site device modification/ inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.

Enclosed documents:

- Customer response form
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause you and 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, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

Managing Director
(On behalf of the)

Signature: Johannes Schlenker *Electronically signed by: Johannes Schlenker Reason: I approve this document. Date: Aug 8. 2024 14:50 GMT+2*

Email: johannes.schlenker@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Alexander Bernhardt *Electronically signed by: Alexander Bernhardt Reason: I approve this document. Date: Aug 8. 2024 14:39 GMT+2*

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer

Alexander Bernhardt
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Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	1074963 – RS232 accessory cable not conforming to IEC 60601-1
Affected Product:	Serial interface cable (RS232) (Mat. 701075475, Type Label Mat. 701074356)
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Please send this form at the latest by **August 30, 2024,** to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for all affected products. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ I do not have any affected products in my inventory.
☐ I have following affected products in my inventory:

Article No.	Description	Batch No.	Quantity

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email enter local Getinge mail address or via post enter local Getinge address or FAX.

Annex I Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 1074963 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
Exposed to inappropriately high leakage current (patient, user, third person)	Electric[al] Shock	4	3	☐	☒	☐
Device replacement and / or change	User inconvenience	1	1	☒	☐	☐

Severity Definitions:

Negligible (1) Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required

Low (2) Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.

Critical (3) Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.

Catastrophic (4) Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

Probability Definitions:

Improbable (1) Harm is not likely.

Remote (2) Harm occurs infrequently

Occasional (3) Harm may occur occasionally / intermittently

Probable (4) Harm may occur often

Frequent (5) Harm will occur repeatedly