2026-08-05

Urgent Field Safety Notice	
Manufacturer:	Maquet Cardiopulmonary GmbH (SRN: DE-MF-000020091)
Manufacturer's Reference Number:	1618466 - Rotaflow – battery charging interruption
Notification Type:	New

Product or Trade Name	**Reference or Model Number (s)**	**UDI-DI**	**Model Name**
Rotaflow Console	Please see Annex I – List of affected Products		

Manufacturing Dates:	All products currently on the market are affected. Asia*: 2005 through 2024-09-05 Rest of World: 2005 through 2020-12-31
Distribution Dates:	Asia*: 2005 through 2024-10-02 Rest of World: 2005 through 2020-12-31 *Japan, China, Thailand, South Korea

Dear valued Customer,

The purpose of this letter is to advise you that Maquet Cardiopulmonary GmbH (MCP), a subsidiary of Getinge, is voluntarily notifying users of ROTAFLOW System due to battery charging interruption.

The ROTAFLOW Centrifugal Pump System, which is a device that uses a non-revolving roller method to pump the blood through an extracorporeal circuit for the purpose of providing either:

- Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
- Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

The ROTAFLOW System can be used as a stand-alone device or as part of the HL 20 heart-lung machine.

The ROTAFLOW Console automatically switches to battery operation if the external power supply (mains voltage or console of the HL 20) is interrupted. Once external power returns, the system will automatically switch back to the external power supply. The batteries are charged automatically when the ROTAFLOW Console is connected to the external power supply.



Figure 1 Picture of ROTAFLOW Console with framed charging indicator (red box)

Issue Description

During internal validation of new replacement batteries, MCP identified an issue on the ROTAFLOW Console. This issue can cause the device to stop battery charging after the battery operation mode has been utilized.

The issue can be recognized by users as follows:

The charging indicator turns off approximately 3 minutes after switching from battery operation mode to external power supply mode (i.e., recharge mode). (Position of charging indicator: see Figure 1, red box)

Interim solution (**Amendment** pending software update):

- During patient support:
  When connecting the device to mains power following battery operation:
  - ☐ Check the charging indicator after 3 minutes (Position of charging indicator: see Figure 1, red box)
    - ✓ Indicator is illuminated - no action is required.
    - × Indicator is off - reconnect the mains power and repeat the check after 3 minutes.
- Charging the device when not used for patient support:
  To ensure uninterrupted battery charging, switch the Rotaflow Console off and disconnect it from the mains power. Wait for 30 seconds and reconnect it to the mains power. Verify the charging indicator is illuminated.

No patient injuries and/or deaths were reported to MCP connected to this issue.

Further investigation identified a software problem as root cause. Because of this, all devices on the market are considered affected by this issue.

Potential Hazards

Maquet Cardiopulmonary GmbH determined the following hazardous situations and harms that may arise (for further information please refer to Annex II):

Potential Hazardous Situation	Potential Harm
• Exposed to too low blood flow (Patient)	• Ischemia • Hemodynamic instability

Actions To Be Taken by User

☒	Identify Device	☐	Quarantine Device	☐	Return Device	☐	Destroy Device
☐	On-site Modification/inspection	☒	Take note of amendment/reinforcement of instructions for use	☐	Patient follow-up	☐	Review of patients' previous results

Actions To Be Taken by Manufacturer

☐	Product Removal	☒	On-site modification/ inspection	☒	Software Upgrade
☐	IFU or Labeling Change	☐	Other _____	☐	Customer Information Only

Patient Management Recommendations

Patients should be monitored as appropriate according to your facility's standard of care.

Recommended Mitigations

Interim solution (pending software update):

- During patient support:
  When connecting the device to mains power following battery operation:
  - Check the charging indicator after 3 minutes (Position of charging indicator: see Figure 1, red box)
    - ✓ Indicator is illuminated - no action is required.
    - × Indicator is off - reconnect the mains power and repeat the check after 3 minutes.
- Charging the device when not used for patient support:
  To ensure uninterrupted battery charging, switch the Rotaflow Console off and disconnect it from the mains power. Wait for 30 seconds and reconnect it to the mains power. Verify the charging indicator is illuminated.

Customer Actions

Our records indicate that you have received one or more units of the device affected by this recall. As a result, Getinge requests that you take the following actions:

1. Please check your inventory to properly identify affected devices.
2. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred, including any third-party organizations that need awareness.
3. Always report any adverse events potentially related to the affected products to your Getinge representative.
4. Until availability of a software update, please follow the provided interim solution when using a Rotaflow console for application on patients.
5. Complete and return the enclosed Letter of Acknowledgement and return it to your local Getinge representative as soon as possible, latest by 2026-12-11. Include "FSCA 1618466" as reference in the subject line of your mail.
6. Please maintain awareness on the notice and the interim solution for an appropriate period to ensure effectiveness.

Contact Details of Local Representative

<insert local SSU or distributor contact details with name/address/phone/email>

We regret any inconvenience this may cause and remain committed to patient safety. Getinge is communicating this information to regulatory authorities as required. We appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative.

Sincerely,

Contact details of manufacturer
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

Enclosed documents:

- Customer Response Form
- Annex I: List of affected products
- Annex II: Further information regarding Hazardous situation, Harms and Risk Levels

CUSTOMER RESPONSE FORM

Manufacturer:	Maquet Cardiopulmonary GmbH (SRN: DE-MF-000020091)
Manufacturer's Reference Number:	1618466 - Rotaflow – battery charging interruption
Notification Type:	New

Product or Trade Name	**Reference or Model Number (s)**	**UDI-DI**	**Model Name**
Rotaflow Console	Please see Annex I – List of affected Products		

Manufacturing Dates:	All products manufactured; From 2005 until 2024-09-05
Distribution Dates:	From 2005 until 2024-10-02

Please send this form at the latest by **2026-12-11**, 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. 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 personnel.

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

☐ I have the following affected products in my inventory:

Reference Number	Model Name	Serial Number

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 List of affected products

This Annex I List of affected products is considered as a supplementary attachment to the 1618466 Field Safety Notice.

Reference Number	UDI-DI	Model Name
701046408	N/A	MCP00706297#RotaFlow Finnish EU-Plug
701051709	N/A	RotaFlow Norwegian EU-Plug ICU
701051707	N/A	RotaFlow Turkish EU-Plug ICU
701051706	N/A	RotaFlow Czech EU-Plug ICU
701043288	N/A	MCP00706043#RotaFlow Danish EU-Plug
701046409	N/A	MCP00706299#RotaFlow Norwegian EU-Plug
701053989	N/A	RotaFlow Portuguese/Brazilian-Plug ICU
701053967	N/A	RotaFlow English/Australia-Plug ICU
701051698	N/A	RotaFlow Danish EU-Plug ICU
701046412	N/A	MCP00706303#RotaFlow En/North Am US-Plug
701075629	N/A	RotaFlow Russian EU-Plug ICU
701075627	N/A	RotaFlow Russian EU-Plug
701043289	04037691900933	MCP00706049#RotaFlow Dutch EU-Plug
701043291	04037691517094	MCP00706041#RotaFlow English/UK UK-Plug
701043292	04037691562445	MCP00706035#RotaFlow English/US US-Plug
701043293	04037691482262	MCP00706045#RotaFlow French EU-Plug
701043296	04058863031798	MCP00706047#RotaFlow Italian EU-Plug
701043298	04058863018713	MCP00706053#RotaFlow Portuguese EU-Plug
701051697	04037691705903	RotaFlow English/UK UK-Plug ICU
701051699	04037691705910	RotaFlow French EU-Plug ICU
701051700	04058863018720	RotaFlow Italian EU-Plug ICU
701051703	04037691704456	RotaFlow Portuguese EU-Plug ICU
701051704	04058863017587	RotaFlow Spanish EU-Plug ICU
701051705	04058863179506	RotaFlow Chinese ZH-Plug ICU
701051711	04058863300870	RotaFlow Japanese US-Plug ICU
701051712	04037691679013	RotaFlow English/US US-Plug ICU
701051713	04058863018744	RotaFlow En/North Am US-Plug ICU
701043297	04037691720821	MCP00706033#RotaFlow Japanese US-Plug
701043299	04037691649962	MCP00706055#RotaFlow Spanish EU-Plug
701051710	04058863018737	RotaFlow Swedish EU-Plug ICU
701051701	04058863175324	RotaFlow Dutch EU-Plug ICU
701054401	04058863137537	RotaFlow Spanish/South Am. US-Plug ICU
701054400	04058863114118	RotaFlow Spanish/South Am. US-Plug
701053976	04058863195940	RotaFlow Portuguese/Brazilian-Plug
701053966	04058863176857	RotaFlow English/Australia-Plug
701046410	04037691565736	MCP00706301#RotaFlow Swedish EU-Plug
701046407	04037691585581	MCP00706293#RotaFlow Czech EU-Plug
701046405	04037691718910	MCP00706291#RotaFlow Chinese ZH-Plug
701043290	04037691525532	MCP00706037#RotaFlow English EU-Plug
701043294	04037691457871	MCP00706051#RotaFlow German EU-Plug
701046411	04037691761688	MCP00706295#RotaFlow Turkish EU-Plug
701051696	04037691682297	RotaFlow English EU-Plug ICU
701051702	04037691697123	RotaFlow German EU-Plug ICU

Annex II: Further information regarding Hazardous situation, Harms and Risk Levels

This Annex II Further information regarding Hazardous situation, Harms and Risk Levels is considered as a supplementary attachment to the 1618466 Field Safety Notice.

Hazardous situation	Harm	S from Medical	P from above	Risk		
				Low	Med	High
Exposed to too low blood flow (Patient)	Ischemia	4	2	☐	☒	☐
	Hemodynamic instability	4	2	☐	☒	☐
Product replacement	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 / intermittent.
Probable (4) Harm may occur often.
Frequent (5) Harm will occur repeatedly.