July 14, 2021 via FEDEX

Urgent Medical Device Recall
HEATER-COOLER UNIT (HCU 30)
DISCONTINUE USE OF HEATER-COOLER UNITS

All Product Distributed Since December 30, 2004

PLEASE FORWARD THIS INFORMATION TO ALL USERS, PERFUSIONISTS, AND STAFF WHO MAY USE AND/OR MAINTAIN MAQUET HEATER-COOLER UNITS.

Dear Risk Manager,

The purpose of this letter is to advise our customers that if your facility still has any Heater Cooler Unit HCU 30 units, users should discontinue the use of and dispose of these devices. In 2014, Maquet Cardiopulmonary ("MCP") had sent a letter notifying all customers of the Heater Cooler Unit HCU 30 that the end of service life for all units was December 31, 2017. At that time, all service and maintenance activities would cease support from Maquet Cardiopulmonary.

Description of the problem:

The use of heater-cooler devices has been associated with Nontuberculous mycobacteria (NTM) infections in patients. There is a potential for bacterial growth in the water systems.

Maquet Cardiopulmonary has received isolated reports indicating bacterial contamination in the system water of HCU 30 including mycobacterial counts. Maquet Cardiopulmonary has not received any reports that a mycobacterial infection or any other bacterial infection has been caused by a HCU 30 Heater-Cooler Unit in the United States.

Actions to be taken by the Device User:

MCP has not developed a cleaning protocol that meets current concerns and expectations of the FDA. If your facility still has any HCU 30 Units in operation, users should take the unit out of operation at the earliest opportunity and decommission the unit. This action impacts customers in the United States.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Please acknowledge receipt of the Urgent Medical Device Recall by completing and returning the **online form with digital signature**, or by completing and returning the enclosed response form. Please either fax the completed form to (866) 571-5830 or send via email to MCPHCU30.qrc@getinge.com.

This recall is being made with the knowledge of the U.S Food and Drug Administration.

We apologize for any inconvenience that this may cause to you or your patients. For any questions, please contact your Getinge sales representative or Getinge Technical Support at (888) 9GETUSA / (888) 943–8872 (option 4, 2) Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. EST.

Thank you for your cooperation and immediate assistance.

Sincerely,

Rachana Patel
Regulatory Affairs and Field Action Compliance Specialist
Getinge
45 Barbour Pond Drive
Wayne, NJ 07470
Telephone Number: (973) 709 7412

July 14, 2021

URGENT MEDICAL DEVICE RECALL - Response Form
EMAIL TO: MCPHCU30.qrc@getinge.com
or FAX BACK TO: (866) 571-5830

ADD ACCOUNT#
[Customer NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

☐ **Please check this box to confirm:**

- **You will take action as soon as possible according to instructions, and you will ensure that all users of the Maquet Heater-Cooler unit(s) (HCU 30) at this facility have been notified accordingly.**
- **I acknowledge that I have reviewed and understand the Urgent Medical Device Recall for the Maquet Heater-Cooler unit(s) (HCU 30) at this facility.**
- **I confirm that Maquet Heater-Cooler unit(s) (HCU 30) will be dispositioned accordingly.**

Please provide the required information and signature below and return this form to Getinge even if you no longer have the affected device at your facility.

List of Affected Maquet Heater-Cooler unit(s) (HCU 30) at your facility

Item description/Serial #	Device on site? Yes/No:

Facility Representative Information:

Signature:_____ **Date:**_____

Name:_____ **Phone:**_____
E-Mail Address:_____
Title:_____ **Department:**_____
Hospital Name:_____
Address, City and State: _____
_____
We have sold/moved our Maquet Heater-Cooler unit(s) (HCU 30) to another facility:
Circle one YES NO
If you answered YES above: please provide new facility information below.
New Facility Name and Address:_____
_____
New Facility Contact Name:_____ **New Facility Phone #:** _____

Return the completed form by FAX to (866) 571-5830 or email address;
MCPHCU30.qrc@getinge.com