

URGENT – Field Safety Notice

To:

Title: Revised Cleaning and Disinfection procedure for the Paratherm water heater / cooler

FSN Number: 2017-06-23

Date of Issue: 23rd June 2017

Product Codes: 54-00-16

Serial Numbers: All Serial numbers

Type of Action: Customer Notification

Description

Further to FSN No: 2017-02-10 issued 17th February 2017, Chalice have now completed the validation work required, and can provide a revised cleaning and disinfection procedure to all customers / users of the Paratherm water heater / cooler. The validation confirms that the NTM (*Mycobacterium chimera*) is effectively removed with this updated cleaning procedure.

Corrective Action

All versions of the Paratherm Operating and cleaning instructions prior to Revision 13 are to be destroyed and replaced with the attached instructions and Appendix 1 (cleaning and disinfection procedure)

Advice or Action to be Taken by the User

Complete and Return the attached acknowledgement form as soon as possible.

Replace all current versions of the Paratherm manual and replace with the enclosed operating instructions (Revision 13) and Appendix 1 (cleaning and disinfection).

Contact Details

Chalice Medical Ltd
Unit 1 Drayton Court
Manton Wood Enterprise Park
Worksop
UK
S80 2RS

Please contact your individual Sales Manager for further details.

Referenced Attachment

Paratherm Operating Instructions (Revision 13) including Appendix 1 - Cleaning and Disinfection
FSN Acknowledgement

Transmission of this Field Safety Notice

All personnel who are involved in the maintenance and cleaning of the Paratherm units should be made aware of these updated cleaning instructions.

All relevant National Competent Authorities have been advised of this Field Safety Notice.

Sincerely



Carol Middleton
Quality Manager

FSN Acknowledgment

FSN Reference Number: 2017-06-23

Please complete this acknowledgment form confirming receipt of the revised cleaning and disinfection information and send back to cmiddleton@chalicemedical.com at Chalice Medical immediately.

Hospital	
Address	
Form Completed By	
Title / Role	
Date	