

URGENT – Field Safety Notice

FAO: Perfusionists
ICU Managers
Theatre Managers
Medical Device Safety Officers
Distributors

Customer:

Title: Alarm Colour

FSN Number: 20220708

Date of Issue: 17/08/2021

Product Codes: 54-00-16
54-00-18

Serial Numbers: All Serial Numbers

Type of Action: Customer Notification

Description

The purpose of this Field Safety Notice is to make customers aware that the colour of the LED which is used to optically signal an alarm condition is to be changed from red to yellow.

This FSN is not as a result of any safety issues with the ParaTherm, but results from the alarm classification within the device being downgraded to meet the requirements of BS EN 60601-1-8. The alarm priority for the ParaTherm has changed from high priority to medium following the criteria in BS EN 60601-1-8 and has been evaluated fully as part of our risk management activities. To meet the requirements of a medium priority alarm in compliance with the BS EN 60601-1-8 the visual alarm indicator must be yellow which has resulted in our LED changing from red to yellow.

The ParaTherm is still safe to use until its scheduled service date.

Corrective Action

This has resulted in an update to the ParaTherm IFU to change the information from red to yellow.

ParaTherm units in the field, will be required to have the LED light changed during the next service.

Please note this is not a recall.

Advice or Action to be Taken by the User

Please ensure that all relevant personnel are aware of the information contained within this FSN.

This applies to all ParaTherm units. Attached to this FSN you will find the most current version of the IFU which details the correct LED light colour. Should you require any further copies please contact your sales manager directly.

No action is required by the user, ParaTherm units should be sent for servicing as per the normal scheduling.

Please complete the FSN acknowledgement form and return to regulatoryaffairs@chalicemedical.com

Contact Details

Chalice Medical Ltd
Manton Wood Enterprise Park
Worksop
S80 2RS
UK
regulatoryaffairs@chalicemedical.com

Please contact your individual Sales Manager/Distributor for further details.

Referenced Attachment

FSN Acknowledgement
Copy of revised IFU

Transmission of this Field Safety Notice

All personnel who are involved with the use of the ParaTherm should be made aware of the contents of this FSN.

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

Sincerely



Carol Middleton
Senior Regulatory Manager

APPENDIX 1

FSN Acknowledgment

FSN Reference Number:

Please complete this acknowledgment form confirming receipt of the FSN and send back to regulatoryaffairs@chalicemedical.com at Chalice Medical Ltd immediately.

Hospital	
Address	
Form Completed By	
Title / Role	
Date	