


URGENT FIELD SAFETY NOTICE UniqueTemp° Patient Warming System	
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Geratal/Germany, 2020-11-13

For attention of Geratherm Medical AG distribution partners and end users.

Dear Sir, dear Madam,

This is a follow-up Field Safety Notice to the ones issued on 13 February 2018 and on 15 April 2020. This is for all users of the Geratherm Medical AG UniqueTemp° patient warming system.

Our previous safety notice stressed the need for regular standard safety inspections including in particular the current value check. This safety inspection establishes the continuing safe operation of the blankets. It specifically tests the integrity of the heating foil.

The reason for this follow-up is because there has recently been a burn in a blanket. This blanket had not had the mandatory inspection done in spite of our previous notice. In this case, there was no harm done to a patient, as this fault showed itself in the first few minutes of switching on.

The heating foil can occasionally after long-term use or poor and inappropriate physical treatment suffer damage which may lead to the occurrence of a hot-spot where the heating material has been damaged and cause a small localized burn. Whilst temperature sensors are used across the recovery blanket, these are designed to control, regulate and monitor warming and the temperature of the blanket as set by the user via the control interface. A small localized burn resulting from localized damage to the heating material may not set off the over temperature alarm.


Changed maintenance instruction:

Servicing and safety inspection for UniqueTemp° patient warming systems including accessories **must be carried out every 12 months.**

Blankets which require testing are:

Blanket	Article Number
Arm/shoulder	8001140202
Torso	8001140301
Leg left	8001140409
Leg right	8001140408
Arm/Shoulder ECG plus	8001160202
Torso ECG plus	8001160301
Leg left ECG plus	8001160409

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Blanket	Article Number
Leg right ECG plus	8001160408
Jelly	8001140600 8001140602
Jelly ECG plus	8001160600 8001160602
Arm/shoulder small	8001240202
Torso small	8001240301
Leg left small	8001240409
Leg right small	8001240408

The UniqueTemp° control unit is also required to be visually and operationally inspected and electrically checked to be within the mandated parameters. This is standard practice for all products with the article number 800114800.


Users of the UniqueTemp° patient warming system must be immediately check when their blanket/s was/were last inspected. If 12 months have passed since the last safety inspection, then the UniqueTemp° patient warming system must be tested, and the manufacturer or the local Geratherm Medical AG distributor must be contacted to arrange the safety inspection.

Another possibility is that Geratherm Medical AG provides the service manual, the test box, the test instructions and the test protocols for the control unit and the blankets on request.

Once the safety inspection is successfully completed the blankets will be compliant and safe to continue to use for the next year until the next inspection is due.

UniqueTemp° patient warming systems older than 5 years may require an upgrade of the heating foil which can be carried out with the assistance of Geratherm Medical AG and the regional local distributor.

Please confirm by filling and signing the attached FSN Attachment that you have received this Field Safety Notice and forwarded it to all relevant customers. Please return the filled and signed confirmation to Geratherm Medical AG within 14 days after receipt to the e-mail below.

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E-mail: m.kaufmann@geratherm.com

or

Fax: +49 (0) 36205 98 115

Should you have questions regarding this Field Safety Notice or need more information, please contact:

Mr. Mihir Vyas

E-Mail: m.vyas@geratherm.com

Phone: +49 (0) 36205 98 210

Best regards,
Geratherm Medical AG

Denny Holland-Moritz
Safety officer

Attachment: FSN Attachm_2020-11-13


History:

02	
01	First Edition

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Date	Name	Signature	Date	Name	Signature
13.11.2020	M. Abe	gez. Abe	13.11.2020	D. Holland-Moritz	gez. Holland-Moritz

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Return to: Geratherm Medical AG, Fahrenheitstraße 1, 99331 Geratal/ Germany

Fax no.: +49 (0) 36205 98 255

E-mail: m.kaufmann@geratherm.com

URGENT FIELD SAFETY NOTICE ATTACHMENT 2020-11-13
UniqueTemp°

I hereby confirm that I've received the above mentioned Field Safety Notice dated 2020-11-13, and that I will forward this Field Safety Notice immediately to my relevant customers.

Name: _____


Company name: _____

Company address: _____

Date and Signature: _____

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