

Geratal/Germany, 2020-04-15

## URGENT FIELD SAFETY NOTICE

**UniqueTemp° recovery blanket**

**REF no.: 8001150500, 8001150501**

For attention of Geratherm Medical distribution partners and end users

### Contact details of local representative

Name  
Address  
E-Mail  
Phone  
Fax

Dear Sir, dear Madam,

This is a follow-up Field Safety Notice to the one issued on 13 February 2018. This is for all users of the Geratherm UniqueTemp° patient warming system (including recovery blankets).

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 blanket. 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 localised 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 localised burn resulting from localised damage to the heating material may not set off the over temperature alarm.

### Changed maintenance instruction:

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

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Users of the UniqueTemp° warming system should immediately check when their blanket was last inspected. If more than 12 months have passed since the last safety inspection, then the UniqueTemp° warming system shall not be used, and the manufacturer or the local Geratherm distributor shall be contacted to arrange the safety inspection. Once the safety inspection is successfully completed the blankets will be safe to be used.

UniqueTemp° warming systems older than 5 years (manufactured before February 2015) should be immediately withdrawn and sent to the manufacturer for safety inspection, regardless of when the last safety inspection was performed.

Please confirm by completing and signing the attached template that you have received this Field Safety Notice and forwarded it to all relevant customers. Please return the completed and signed confirmation to Geratherm Medical AG and attach a list of the informed customers (name, address) **within 14 days** after receipt by

**E-Mail to: [m.kaufmann@geratherm.com](mailto:m.kaufmann@geratherm.com)**

or

**Fax to: +49 (0) 36205 98 115**

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

**Mr. Matthias Kaufmann**

**E-Mail: [m.kaufmann@geratherm.com](mailto:m.kaufmann@geratherm.com)**

**Phone: +49 (0) 36205 98 255**

Best regards,

Geratherm Medical AG

Denny Holland-Moritz  
Safety officer

Attachment: Confirmation letter template