Mr / Mrs …..
Company
Street
Postcode, Town, Country

Geschwenda, 06.07.2018

Urgent safety information

Updated warning
about the
Geratherm® UniqueTemp°
(manufactured between 2009 and 2013)
Amendment to 3442-WSYS

Dear Sir or Madam,

In February 2018 we informed you about an important change to the intervals we have set for the performance of safety inspections for all types of warming blankets of the models UniqueTemp° and UniqueResc of the manufacturing period 2009 – 2013. We would like to amend this information and give you a more precise instruction which allows you a better understanding when the safety checks need to be performed for your warming systems:

	In addition, for all components of Geratherm Patient Warming Systems that are more than 4 years old, it is necessary to perform the safety inspections every 12 months. **For example:** 05/2013 installation of warming system 05/2015 first safety inspection (at the latest) 05/2017 second safety inspection (24 months after the first safety inspection) 05/2018 third safety inspection (12 months after the second safety inspection) 05/2019 fourth safety inspection (12 months after third safety inspection)

No patients have so far come to any harm.

What action should I take?
Forward this information to all users of the patient warming system, and ensure that the safery inspections are performed according to the intervals and instructions given by the manufacturer.
Keep this letter together with the instruction manual for the product.

Please return the enclosed confirmation form to us by 20.07.2018.

Forwarding this information to others:
Please ensure that all operators of the above products within your organisation are made aware of this urgent safety warning, as well as anyone else there who requires this information. If you have passed on the products to a third party, please forward a copy of this information to them, or notify the contact person named below.

The Federal Institute for Drugs and Medical Devices has received a copy of this 'Urgent safety information'.

Contact person:

Geratherm Medical AG
Mr Denny Holland-Moritz
Safety Officer pursuant to Art. 30 Medical Devices Act (MPG)
Fahrenheitstrasse 1
D-98716 Geschwenda
Email: d.holland-moritz@geratherm.com
Tel.: +49 (0) 36205-980
Fax: +49 (0) 36205-98115

Yours faithfully,

D. Holland-Moritz
Safety Officer pursuant to Art. 30 MPG

A. Langen
Head of Quality Management

C.Richter
Head of Marketing (Warming Systems)

Encl.
Confirmation form

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Confirmation form

☐ We have identified the products affected. They are undergoing safety inspections at the newly specified intervals in accordance with the manufacturer's service instructions. This information has been appended to the product documentation.

☐ We no longer have any of the affected products in use.

Customer / Customer No.: _____

Name / Job title _____

Tel. No.: _____

Email address: _____

Date / Signature _____

Please return this confirmation form to one of the addresses given below:

Fax No.: +49 (0) 36205-98115
Email address: info@geratherm.com
Postal address: Geratherm Medical AG
Fahrenheitstrasse 1
D-98716 Geschwenda