


Mr / Mrs
Company
Street
Postcode, Town, Country

Geschwenda, 19.06.2018

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:

	<p>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.</p> <p>For example:</p> <p>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)</p>
---	--

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 safety 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 30.06.2018.

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*

[Redacted Signature]

[Redacted Signature]

Encl.
Confirmation form

Urgent safety information

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

Confirmation form

- ☐ We have identified the products affected. They will be stored in accordance with the updated safety warning. 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

Geratherm Medical AG • Fahrenheitstraße 1 • D-98716 Geschwenda

Address


Geschwenda, 13 February 2018

Customer information regarding a corrective action

Dear Customers,

We should like to inform you about an important change to the intervals we have set for the performance of safety inspections:

“In order to ensure the safety of the appliance, Geratherm requires that safety inspections, including device-specific checks, must be performed as set out in the Geratherm Service Handbook *for all components* of the Geratherm UniqueTemp[®] Patient Warming Systems every 24 months.

	In addition, for all components of Geratherm Patient Warming Systems that are five or more years old, it is necessary to perform the safety inspections every 12 months.
---	--

The Service Handbook can be obtained from the manufacturer free of charge upon request.”

Geratherm Medical AG • Fahrenheitstraße 1 • D-98716 Geschwenda

In the course of analysing an incident involving a Geratherm UniqueTemp[®] warming blanket for nursing (year of manufacture: 2012), we have ascertained that high levels of mechanical stress for a longer period can, under unfavourable circumstances, cause damage to the warming blankets. Through the evaluation of this incident we have come to the conclusion that such damage could have been detected at an early stage during a safety inspection and that the incident thereby could have been avoided. The warming blanket concerned has been in use since 2013 without any further safety inspections.

In order to ensure electrical and fire safety, safety inspections are necessary at the intervals demanded by us. We also explicitly point out that the requirement for safety inspections as set out in our Service Handbook applies to *all components* of the Geratherm UniqueTemp[®] Patient Warming Systems.

Please do not hesitate to contact us if you have any queries or would like further information.

With kind regards,

Geratherm Medical AG

