

**To all operators and users of
Babytherm 8004/8010 open care units
for premature and newborn patients**

**Important safety notice!!!
Babytherm 8004/8010
open care units for premature and newborn patients**

June 2016

Dear Madam/Sir,

As part of our market and product monitoring we have become aware of a case in which a Babytherm 8004 without patient was operated in skin temperature mode with skin temperature sensor to prepare it for use. In skin temperature mode, the radiant warmer output is controlled automatically until the set skin temperature is reached. As a result of operating the temperature sensor without patient contact, the radiant warmer was operated continuously at a high output level. During this forced continuous operation under high thermal load, the heating element aged faster. A part became detached from the heating element and fell onto the mattress tray where a towel caught fire.

Do not operate the device in skin temperature mode with temperature sensor without patient contact!

To preheat the device, you can use the manual mode up to level 3 as there is no active time limit. At level 4 or above, there will be regular alarms. If the alarm is not acknowledged, the radiant warmer will be automatically switched off. For further details, please refer to the Babytherm 8004/8010 instructions for use.

Additionally, our analyses have shown that the heating elements are not replaced at regular intervals as recommended in the Babytherm instructions for use. We attribute this to the fact that it might not be practicable to replace the heating element after 10,000 operating hours. We have therefore converted this value into a period of 2 years, which can be measured more easily.

If your heating elements have been in operation for more than 2 years, please replace them.

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Rainer Klug
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If you have any questions regarding orders, please contact your local Dräger representative. If you have concluded a service contract with us, your responsible Dräger service technician will check the age of your heating elements at the next opportunity and replace them if necessary.

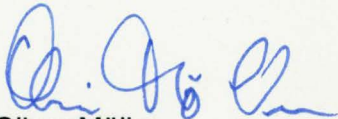
We amended our instructions for use by the attached supplement, which contains corresponding notes and warnings.

Please add the supplement to all instructions for use of the Babytherm 8004/8010 and inform any possible users in your facility about it.

We regret any inconvenience this information may cause but consider it necessary as a preventive measure to increase patient and user safety.

Please feel free to contact your local Dräger representative if you have any questions.

Yours faithfully,



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs



Inken Schroeter
Product Management Life Support Systems
Thermoregulation

Attachment:

- Supplement to the instructions for use of your Babytherm 8004/8010