

To operators and users of
Dräger Infant warmers and open infant care units
Babytherm 8004/8010 and Babytherm 8000WB for newborns

August 2014

Important safety information!!!
Babytherm 8000WB, Babytherm 8004 and Babytherm 8010
Warmers for newborns

Dear Sir / Madam,

As part of our market and product monitoring we have become aware of a case in which a side panel on a Babytherm 8010 did not fully slide to the bottom in the corner guides and was not completely locked. The side panel did not open during this incident and no patient was affected.

When reviewing the locking mechanism in a number of hospitals it was possible to fully close the side panels by pushing down on them slightly. However, it cannot be guaranteed that the panel will lock into position under its own weight. In this respect, we would like to remind you to pay attention to the information provided in the Instructions for Use: "Check that the side panels lock securely into position and that they remain securely locked"



Securely locked



Not securely locked

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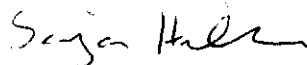
If the locking mechanism is not functioning, please contact your DrägerService representative.

Furthermore, as part of the above review, we identified that the inner 70mm panels are to be inserted pursuant to the Instructions for Use are not always used. However, the inner panels are part of the safety concept of the Babytherm 80xx. If, contrary to the information provided in the Instructions for Use, the inner panels are not inserted and if a side panel has not been fully locked into position, this may allow the baby's movements to open the side panel. It may be possible for a child to fall out!

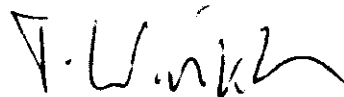
We hope that this preventive measure will help to increase patient safety.

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

With best regards,



for Frank Clanzett
Head of Postmarket Surveillance
Quality and Regulatory Affairs



Tobias Winkler
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