

To our customers and users of the:

- Babyroo TN300 Radiant Warmer

August 2023

Important Safety Notice

Dear Customer,

During the course of our global market surveillance activities, we have become aware that the TN300 Babyroo Radiant Warmer mattress tray may tilt without engaging the tilt mechanism when the mattress assembly is pushed down. The tilt mechanism may not lock/release correctly due to either loose or missing screws.

Risk to Patient Health:

This defect could result in patient or user injury if not identified prior to use.

There have been no reports of adverse patient impact relating to this issue in the field.

The issue would be apparent to users or service personnel because when pushing on the mattress tray with minimal pressure, the tilt mechanism will shift, and the mattress will rapidly tilt.

Actions to be taken:

Until the issue is corrected, if the device is impacted, remove it from service. Refer to the Getting Started section of the TN300 Instructions for Use (IfU), Section 6.1 (Checking for operational readiness), which requires users check the device to ensure it is operating correctly before being put in use and warns users not to use the device if any part of the equipment is damaged or the integrity is compromised. To check the proper function of the tilt mechanism, follow the IfU Safety Checks Section 13.3.1.1, step 2, Perform a functional test of the following functions according to the IfU (Section 4.7 covers Operating the bed-tilt):

- Proper function of bed-tilt:
 - o The bed can be tilted up to 15 degrees in the front and rear directions
 - o The bed tilt mechanism locks the bassinet in place when released

Please ensure that all users of the above-mentioned product and other persons within your organization are made aware of this Important Safety Notice. If you have provided the product to third parties, please forward a copy of this information.

The responsible authorities have been notified of this action.

Actions being taken by the Company:

We are still determining the solution for those devices experiencing the issue and will issue an updated Field Safety Notice when the solution becomes available.

Please keep this information at least until the measure has been completed. Please also complete and return the Customer Acknowledgement and Response Form provided on page 3 to confirm that you have received this information.

Identification of the affected medical devices:

According to our records, you have received a Babyroo TN300 Radiant Warmer, part number MU20300.

Contact:

If you have any questions regarding the operation of the Product, please contact your local Draeger representative.

We apologize for any inconvenience caused by this measure. We thank you for your support.

With kind regards,



Suresh Chinthakunta
Product Management, Life Support Systems
Draeger Medical Systems, Inc. - Thermoregulation

List of affected medical devices including their UDI

Product name	Unique Device Identifier (UDI)
MU20300	04049098099042



Customer Acknowledgement and Response Form

RE: Babyroo TN300 Radiant Warmer (tilt mechanism)

Customer Name/Address:

I acknowledge the receipt of the information in the safety notice and confirm that the information has been brought to the attention of all concerned users.

Completed By:

Print Name: _____

Signature/Date: _____

Thank you for sending the completed acknowledgement form to our attention per the instructions provided by your Dräger representative. Your Dräger service representative will contact you regarding options for your affected device.