

To our customers of
Resuscitaire & Birthing Room Warmers with Scale option

April 2023

Important Safety Notice

Important safety notice regarding potential inaccurate weight measurement

Only the following products are affected:

Resuscitaire – MU20503, with scale

Birthing Room Warmer – MU20512, with scale

Dear Valued Customer,

During the course of our global market surveillance activities, we have become aware of cases in which the Resuscitaire Infant Radiant Warmer with the optional scale could display inaccurate weight values. We have determined that there is a potential for the mattress cover material to slightly interfere with the corner brackets and/or side panels of the bassinet. When this condition is present, the scale may not “zero” correctly during a “weigh” function, which may lead to an inaccurate weight measurement of the infant. There have been no reported injuries or impact to patient care.

Technical Information

The scale weight specification at the center mattress location is:

± 5 grams from 0 to 5000 grams

± 10 grams from 5001 to 8000 grams

Actions to be taken:

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information. Users can mitigate this risk by performing the visual check, test procedure and take appropriate actions based on the Attachment provided in this notice.

Complete and return the enclosed “Customer Acknowledgement and Response Form”.

We are continuing to evaluate this issue and will advise the affected customers when have an alternative solution.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, you have received Resuscitaire(s) and/or Birthing Room Warmer(s) **with Scale** [Model(s): RW82VHA-1, RW82VHA-1C, RW82VHA-1D, RW82-1, RW82-1C, RW82-1D, WBR82-1 and WBR82-1C] manufactured by Dräger Medical Systems Inc. that may be affected by this issue.

Unique Device Identifier (UDI)

MU20503 (Resuscitaire) UDI - 04049098000215

MU20512 (Birthing Room Warmer – BRW) UDI - 04049098058001

ESRN: Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. [USA]

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative. We apologize for any inconvenience caused by this measure.

We thank you for your support.

With kind regards

A redacted signature area consisting of three horizontal black bars of varying lengths, completely obscuring the name and any handwritten notes.

Dräger Medical Systems Inc.

ATTACHMENT:

Background

Scale measurements which are inaccurate may occur due to the mattress cover contacting and interfering with the corner blocks or side panels of the Resuscitaire. See photos in Figure 1.

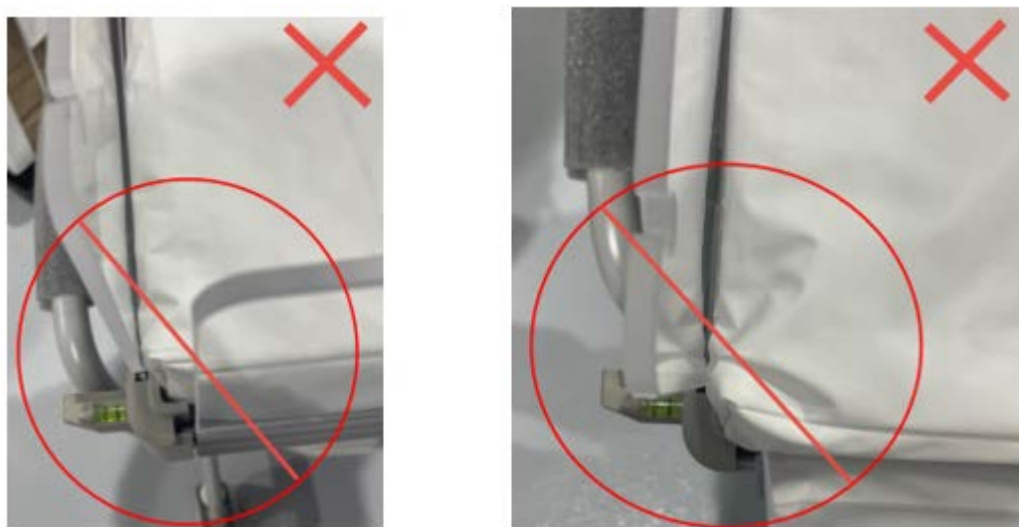


Figure 1: Examples of mattress contacting corner blocks.

Visual Check for Correct Mattress Placement:

To ensure proper operation of the scale, please check to confirm there is a clearance between the mattress cover and the corner blocks and side panels of the Resuscitaire.

1. Ensure mattress with cover is installed in the Resuscitaire bassinets.
2. Observe edges of mattress for clearance with corner blocks and side panels, see Figure 2.
3. If there is interference, then the scale may not provide accurate weight measurements.
 - It is recommended to use an independent scale for therapeutic decisions and treatment

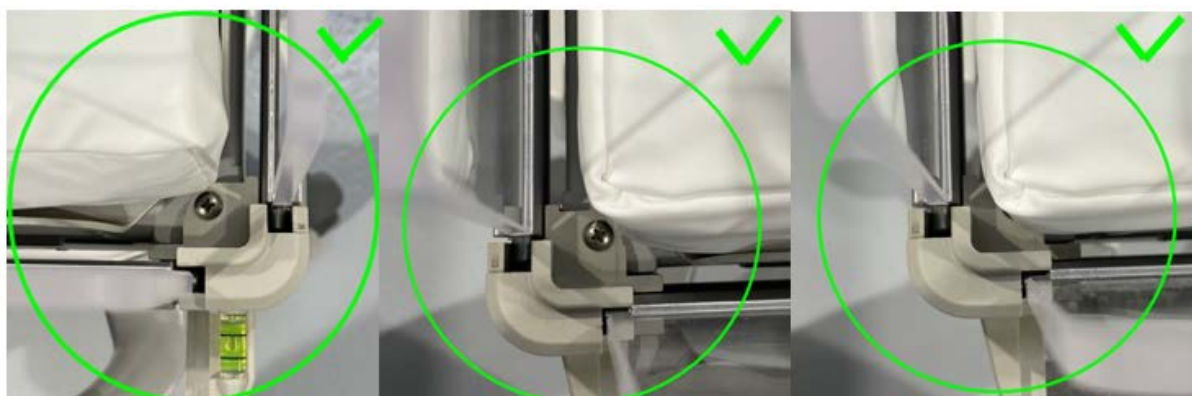


Figure 2: Photos show no interference of the mattress cover with corner blocks or side panels

Test Procedure

If it is unclear from the visual check if the mattress cover interferes with the corner blocks and/or side panels, impacting scale function, please perform the following test:

- a. Place a known calibrated weight on the center mattress (with mattress cover installed). *A 5kg weight is recommended in the instructions for use.*
- b. Execute weighing procedure and record weight.
- c. Repeat weighing procedure 5-10 times.
- d. Compare measurements.
 - i. If measurements are within 5 grams of calibrated 5kg weight, mattress assembly is acceptable.
 - ii. If measurements deviate more than +/- 5 grams from the calibrated 5kg weight, it is recommended to use an alternate weighing scale