



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 114 dated 29/5/23 Regarding NCMDR Field Safety Notice of Infant Radiant Warmer from (mfr: Draeger Medical Systems Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 114 / 2023

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29 -05-2023

نتقدم بـ  
Moving Forward  
with Confidence



### Field Safety Notice of Infant Radiant Warmer from Draeger Medical Systems Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=19536">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=19536</a>
Product	Resuscitaire – MU20503, with scale, Birthing Room Warmer – MU20512, with scale.
Description	Infant Radiant Warmer.
Manufacturer	Draeger Medical Systems Inc.
Local agent	Waleed Pharmacy & Stores.
The affected products	Model(s): RW82VHA-1, RW82VHA-1C, RW82VHA-1D, RW82-1, RW82-1C, RW82-1D, WBR82-1 and WBR82-1C Unique Device Identifier (UDI): MU20503 (Resuscitaire) UDI – 04049098000215 MU20512 (Birthing Room Warmer – BRW) UDI - 04049098058001
Reason	Could display inaccurate weight values.
Action	1. Users can mitigate this risk by performing the visual check, test procedure and take appropriate actions based on provided instructions in the attached FSN. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General



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

*D. Marshall*

*Dan Marshall*

*Senior Product Manager - Neonatal Care*

*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.

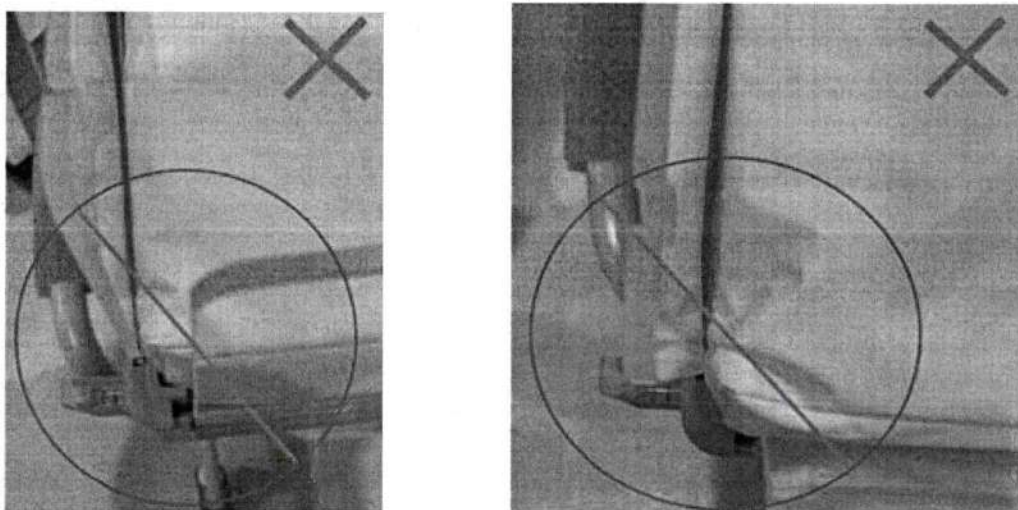
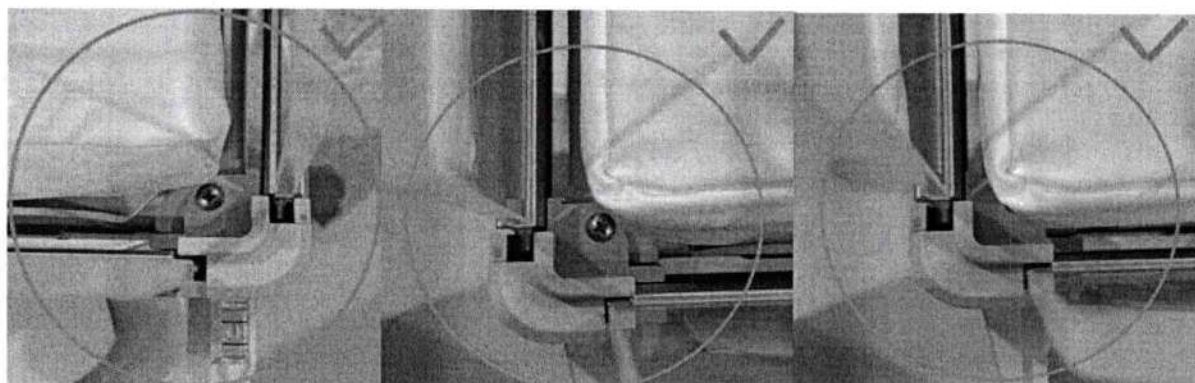


Figure 1: Examples of mattress contacting corner blocks.

### 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