

Isolette[®] 8000/8000plus/C2000/C2000e

Incubator



Information on verification of the scale

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1 Information on verification of the scale

The following document provides background information on the Isolette® scales and the proper techniques necessary to perform the verification.

This document is intended to provide information to verification agencies, local authorities, and other official bodies or persons as appropriate.

NOTE

Draeger Medical Systems Inc. (Telford, USA) performs initial verification of the scale for conformity to the requirements of **EU** Council Directive 2014/31/EU.

1.1 General information

The Isolette® 8000 Plus, Isolette® 8000, Isolette® C2000 and Isolette® C2000e are self-contained care units (incubators) for keeping premature babies and neonates thermally stable.

A weighing platform can be added as a factory installed option, and together when connected to the Isolette form a non-automatic scale for baby weighing (accuracy class III).

The scale is approved in accordance with the requirements of the regulations of EU Directive 2014/31/EU for non-automatic weighing instruments, and has the following features:

Class	III
Max	7 kg
Min	200 g
e	10 g
T	-4 kg
Operating range of the weighing module	+10 °C to +40 °C

1.2 Important instructions for verification

The scales in devices used outside Germany are adjusted to gross zero including mattress.

The scales used in Germany are adjusted to gross zero **without a mattress** on the mattress tray.

NOTE

For testing zero on scales used in Germany, and the maximum weighing capacity, the **mattress must be removed** from the bassinets.

If the verification is to be performed at a geographic location other than the intended installation site (as referenced on the label), the location information may have to be adjusted in the system configuration menu.

1.3 Important instructions for handling

These instructions must be followed to ensure correct weighing:

- The trolley casters must be locked.
- Attachments such as supply and discharge hoses must be removed.
- Make sure the scale's cable is not obstructing the scale and is not rubbing on the top of the scale.
- The side panels must be folded down.
- Make sure that exact weighing is not impaired by wind or drafts.
- The scale has been positioned horizontally using the integrated spirit level.
- The scale must be energized for at least 10 minutes before the verification starts, so that the operating temperature of the load cells and the electronics have stabilized.
- Always wear gloves when handling the test weights.
- The keys on the controller should be pressed gently in order to avoid vibration and shock.
- Do not touch the bed when lifting the weight.
- To avoid corrupting the weighing result, do not use the mattress tray as a support, or touch the mattress tray with scrubs for example.

1.4 Description of the scale function and operation

The weighing process is initiated by lifting the patient up. Actual weighing starts when the patient is placed on the bed.

The device always shows the current net weight.

1.4.1 Operation of the weighing function (semi-automatic tare function)

Procedure

1. Call up the screen menu for measuring the weight.
2. Press the ->0/T< softkey to start the weighing:
 - ⇒ The display shows a message to lift the patient and also a progress bar.
3. Lift the patient off the mattress:
 - ⇒ The taring starts. A progress bar shows the taring process.
When the taring has been completed successfully, an audible tone sounds.
The display shows "0.000" kg and a message appears, indicating that the patient should be laid down.
4. Place the patient on the mattress:
 - ⇒ The current net weight is shown.
5. Press the softkey to save the value:
 - ⇒ The patient weight is saved in the user interface for trend displays.

1.4.2 Exceeding the weighing range

The maximum weighing capacity of the scale is 7 kg. If the gross weight is more than nine parts above the maximum capacity, i.e. >7090 g, weighing is blocked. The display shows a system message indicating that the weight is too high.

If the gross weight is negative below zero range, a system message indicates that the weight is too low.

If the weight on the weighing platform after starting to weigh and lifting the test weight is higher than the maximum tare weight, taring will fail and a system message is shown.

The maximum weighing capacity relates to the total weight (gross). The weight shown is always the net weight. To weigh a test weight of 7 kg, all objects must be removed from the weighing platform (no tare weight).

For scales used in Germany also the mattress needs to be removed.

1.4.3 **Combined semi-automatic zero setting and semi-automatic tare balancing device**

The semi-automatic zero-setting device and the semi-automatic tare-balancing device are operated by the key "0/T" on the Weighing screen.

After stable equilibrium is achieved the zero-setting function is applied for negative gross weight, otherwise the semi-automatic tare-balancing function is used.

NOTE

As long as no tare operation is done after powering up of the device, the weight value displayed on the weighing screen menu represents the gross weight value (=no tare weight applied).

1.4.4 **Geographic location**

The location data (latitude and altitude) is configured in the device.

1.4.5 **Adjustment**

CAUTION

As required by OIML R76-1 and EN45501, access to the adjustment function is "sealed" and should only be carried out by authorized trained personnel.

1.5 Verification procedure

NOTE

The incubator with the scale must be energized and turned "on" for at least 10 minutes before the verification starts, so that the operating temperature of the load cells and the electronics have stabilized.

CAUTION

For verification of scales used in Germany, the mattress must be removed from the weighing platform.

NOTE

To minimize the influence of the incubator's air heater, the side panels must be folded down completely. For further information see "1.3 Important instructions for handling".

1.5.1 Weighing with taring / metrological test

NOTE

Correctness and accuracy testing of the tare function is possible according to EN 45501: 2015 A 4.6.1. Tare values between 1/3 and 2/3 of the maximum tare value (1333 g - 2666 g) should be used on scales with subtractive tare.

Procedure:

1. Call up the screen menu for measuring the weight.
2. Place the test weight(s) on the bed.
3. Press the ->0/T< softkey.
4. Without touching the bed, remove the test weight from the bed.
 - ⇒ The taring starts. A progress bar shows the taring process.
When the taring has been completed successfully, an audible tone sounds.
The display shows "0.000" kg.
5. After the indicator for placing the patient is shown, place the test weights on the bed.
 - ⇒ The weighing procedure is carried out and the current net weight is displayed.
6. This process can now be repeated with different loads according to test specifications.

1.6 Labeling

1.6.1 Device labels

The scale data (date of the initial conformity assessment, serial number and the destination with the values "geographical latitude" (Latitude) and "height above sea level" (Altitude)) is indicated on a label on the rear panel of the incubator (Fig. 1/1) and the controller (Fig. 2/1).

The device must be used at the location matching the location printed on the label on the rear of the device (see Fig. 1 and Fig. 2).

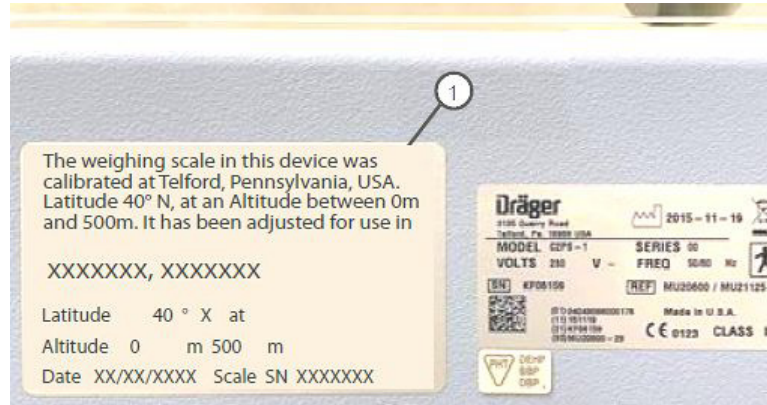


Fig. 1 Detail view of the labeling on the rear of the incubator

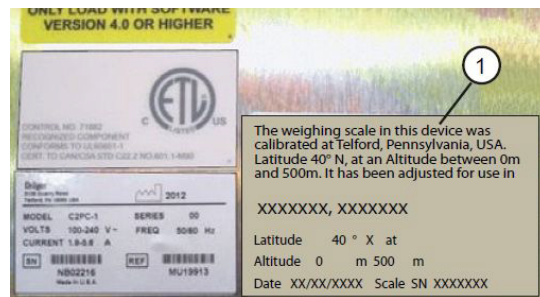


Fig. 2 Detail view of the labeling on the controller

To adjust the scale, the tamper-proof seal (Fig. 3) on the controller must be destroyed. Afterwards, a jumper must be plugged onto another plug-in contact in the controller. To prevent unauthorized opening and disassembling the device controller, service tamper-evident seal labels are placed on device controller.

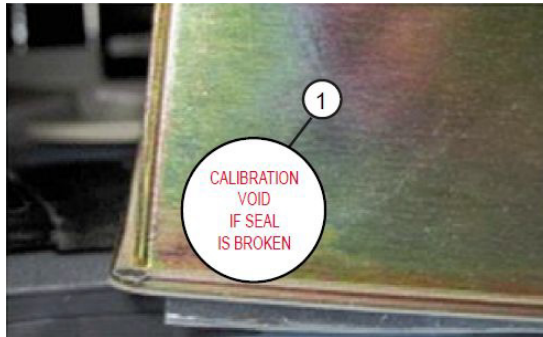


Fig. 3 Tamper evident seal on controller

For scales used in Germany an additional label documenting the scale features (accuracy class, weighing range, calibration value, maximum tare load, temperature range) is placed near the display of the device (Fig. 4/1).

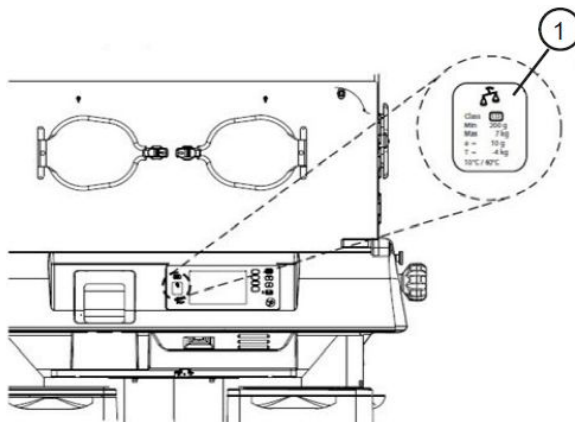


Fig. 4 Additional label with scale accuracy class/weighing range information near display – German scales only

1.6.2 Weighing platform labels

The label with manufacturer information and scale features including accuracy class, weighing range, calibration value, maximum tare load, and temperature range (Fig. 5), and the label with conformity marking and notified body information/approval number (Fig. 6) are located on the right side of the weighing platform.



Fig. 5 Label with manufacturer information and scale accuracy class/weighing range information

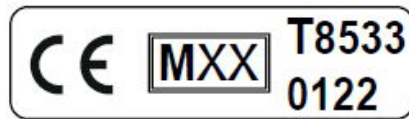


Fig. 6 Label with conformity marking and notified body information/approval number

For placement of these labels see Fig. 7/3 and Fig. 7/4.

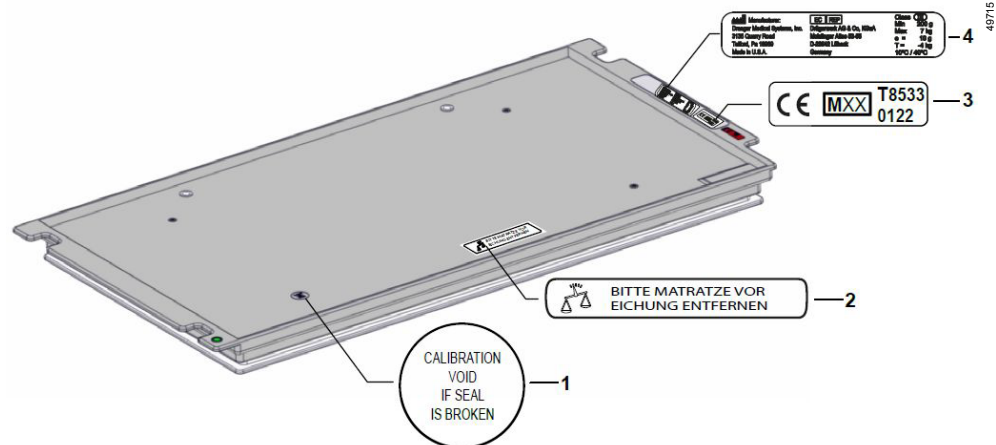


Fig. 7 Label placement on weighing platform

To prevent unauthorized opening and disassembling the weighing platform, a service tamper-evident seal label is placed on a screw of the weighing platform (Fig. 7/1).

For scales used in Germany an additional label is placed on the weighing platform as a reminder to remove the mattress for verification tests (Fig. 7/2).


The label with serial number and part number of the weighing platform (Fig. 8) is placed on the underside of the weighing platform.




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Fig. 8 Label with serial number and part number of weighing platform

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