User’s guide

Neo*ICU*

KOHJ-H-13-EN1-1.0-24052021

Table of contents

1 Description of symbols used

1.1 Device and packaging symbols

Manufacturer

Do not use if the packaging is damaged or has been opened

Product code

Date of manufacture (yymmdd)

Store away from heat

Serial number

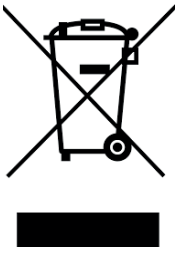
Double insulated device

See user's guide

Warning

Class 1 medical device under the EU Medical Device Regulation 2017/745 (MDR)

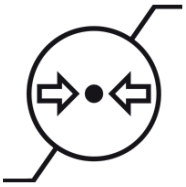
Type BF device



The device must be disposed of in accordance with EU directive 2002/96/EC (WEEE Directive).

Main fuse information

Permitted air humidity limits



Allowable air pressure limits

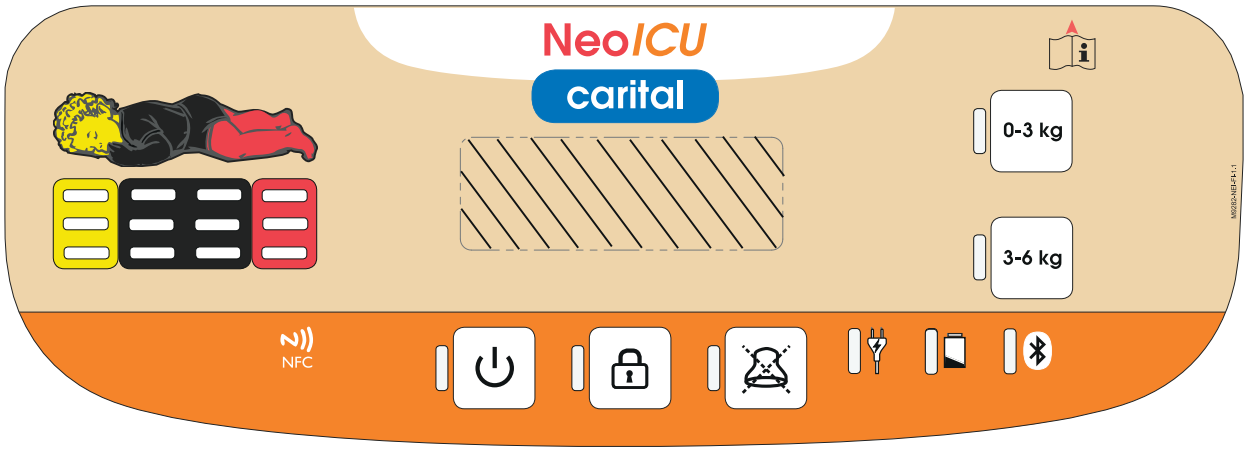
Keep protected from rain

Device IP class

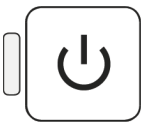
Allowable temperature limits

Fragile, handle with care

1.2 Symbols on the controller's operating panel

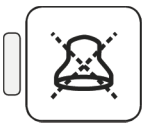


General functions



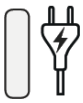
Device standby button

Keypad lock



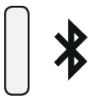
Acknowledgement of information signal

LED lights



Mains connected

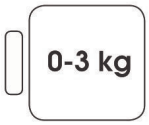
Battery usage



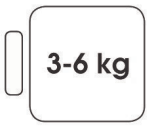
Bluetooth connection established *(note: this feature is not yet implemented)*

LED lights indicating information signals and the adjustment of different adjustment regions

Operating modes



0-3 kg



3-6 kg

Other

NFC tag location in device *(note: this feature is not yet implemented)*

2 Introduction

2.1 Intended purpose and target patients

Carital® Neo*ICU* is a specialty mattress for prevention of pressure ulcers in high-risk and extreme-high-risk prematurely born children (> 500 g) or in neonates i.e. a full term infants under 28 days of age and older children up to the weight of 6 kg.

2.2 Operating environment and user profile

The Carital® Neo*ICU* is intended for healthcare environments (regular wards and intensive care).

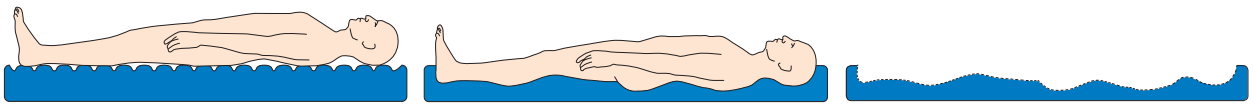
The user can be a healthcare professional that has read the user's guide and understands the basic operating principle and use of the mattress system.

2.3 Contraindications

No known contraindications.

2.4 System description

The Carital® Neo*ICU* mattress system has tunnel-shaped cells that adjust to the patient's body. The cells form three separate adjustment regions (head, torso, feet). All cells respond to the weight, profile and position of the body, distributing the load evenly across all cells.



1. Initial situation
2. Adjusted mattress
3. The shape of an adjusted mattress without the patient.

The Carital® principle: Maximizes contact area, minimizes contact pressure and tissue deformation.

2.5 Products whose use is described in this guide

- Neo*ICU* controller and cells
- Medicase® hygiene cover

This guide applies only to second-generation Carital® controllers. A second-generation controller can be identified with its serial number beginning with the PC identifier.

Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Read this guide carefully before starting to use the mattress system. Persons who have not read this user's guide or cannot understand its content may not operate the mattress system independently.

Keep this guide.

2.6 Warnings

- This guide applies only to second-generation Carital® controllers. A second-generation controller can be identified with its serial number beginning with the PC identifier.
- Only healthcare professionals can assess the need for and suitability of a mattress system in the treatment situation.
- Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the competent authority of the Member or Sovereign State in which the user and/or patient is established.
- If you have any questions regarding the commissioning, use or maintenance of the mattress system or if you notice that the device works in an unanticipated way or a way not described in this guide, contact the mattress system's reseller.
- Contact the mattress system's reseller if any part of the mattress system is damaged or works in an unusual way. Do not attempt to repair damage before contacting the reseller.
- Do not use the device if the configuration is incomplete or any of its components is broken, worn or contaminated. Worn, missing and broken parts must be replaced and contaminated once cleaned.

- Do not modify the mattress system and do not connect the mattress system to other devices without the manufacturer's permission. Unauthorised modifications and connections may pose a danger to the user of the mattress system.

- The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

- Use only original Carital® spare parts and accessories.

- The temperature of the controller may have decreased or increased during transport beyond the limits of the allowable operating temperatures. Do not use the controller before it has been at room temperature (~ +20°C) for at least two hours. This time is required for all components of the controller to reach the normal recommended operating temperature of +10 – +35°C.

- Ensure that the settings of the device do not change unintentionally, for example because of children or pets. If necessary and the operating environment poses a risk of inadvertent changes of control operating modes, use the keypad lock in the controller.

- A twisted air tube or controller power cable around the neck or head may result in suffocation. Make sure that the air tubes and the controller's power cable cannot twist around the head or neck.

- Place the controller's power cable in such a way that it cannot be clamped in any situation, for example by the folding parts of the incubator.

- Make sure there is no risk of tripping over the connected power cable.

- The power cable of the controller must always be plugged into the outlet, excluding short patient transports or similar situations.

- To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

- Always place the controller in such a way that it can easily be disconnected from the mains. Ensure that the control panel and connectors of the controller are always accessible.

- If the Sixtube connector of the air tube system is disconnected from the controller, the cells will deflate.

- Never use the mattress system without a cover on the cells.

- Do not use extra bed sheets, pillows or heavy positioning pillows on the mattress system.

- The placement of WSS in a treatment situation must be done according to a separate assessment by a health care professional.

- Before placing the patient on the mattress, start the device as described in section 5.1, and allow the mattress system to adjust to the selected weight class successfully, so that all green LEDs are lit in the centre of the LED light bar.
- The dimensions of the mattress should always fit to the size of the patient, such that the pressure in all the adjustment sections are optimally placed to be regulated by the controller in correspondence to the patient's body parts.
- Before evacuation, disconnect the controller's power cable from the mains.
- When resuscitating, turn off the device from the standby button and start CPR immediately without deflating the cells.
- Do not immerse the controller in liquid.
- Do not cover the controller while in operation.
- Be sure to put the quick guide caddy back in place after examination.
- Do not lift the mattress by holding the cells or the cover.
- Sharp objects may puncture the cells.
- If the cover or cells are exposed to urea (sweat and urine) for a prolonged period, the molecular structure of polyurethane may break down, damaging the cover or the cells. Clean the cover and/or cells immediately if exposed to urea.
- Do not clean the plastic parts of the mattress system using solvents, phenols or clean alcohols.
- Ensure that the cover is entirely dry before commissioning it.
- Do not wash the foam inserts.
- If the mattress is used in violation of the instructions specified in the user's guide, or it is not cleaned of body secretions containing urea in particular, or the mattress system is used by a prominently sweating or mobile patient, the estimated life cycle of the cover and the cells may be shortened.
- Do not store anything on top of the mattress system.
- Do not place sharp or heavy objects on or near the mattress system.
- Keep the controller away from heat sources.
- Avoid using the controller in the proximity of other electric devices or in a stacked configuration, as this may interfere with the controller's operation. If the above use is necessary, ensure the normal operation of the controller by monitoring it.
- Using accessories, transformers or cables other than those specified by the manufacturer or supplied with the device may result in elevated electromagnetic emissions or reduced electromagnetic immunity and have adverse effect on the performance of the controller for its intended purpose.

- The distance of portable devices communicating using radio frequencies (including antenna cables and external antennas) to the controller and its cables should be at least 30 cm so as to ensure the performance specified in the technical files of the controller.

- The controller is intended for long-term use. However, it contains components that may break if the product is dropped or subjected to impact or vibration exceeding design standards. The limited manufacturer warranty does not apply to situations where the product has been mishandled.

- The batteries may only be replaced by Carital® service. Incorrect battery replacement may result in a situation where the device will not work correctly.

- Contaminated components must be cleaned before disposal or, if cleaning is not possible, disposed of in accordance with official regulations pertaining to contaminated healthcare waste.

- If the controller has encountered a significant mechanical strain (dropped, hard collision or similar), check the mechanical condition of the control port's connection gates and ensure that the seals between the operator panel/frame and the connection port/base plastic parts and the body are in place. If you notice any damage to the device, contact Carital® service.

- Maintenance and repair must always be carried out by Carital® service. The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

- If the mattress system behaves contrary to the functions and situations described in this user’s manual, disconnect the air tubing from the cell’s tube system and the power cable from the controller, turn off the controller, and contact Carital® service.

- The mattress system must always be serviced according to the service programme described in this guide. A device that has not been serviced in accordance with the service programme must not be used but must be sent to Carital® service, instead. The user is responsible for any and all consequences resulting from neglecting service.

- Scheduled maintenance may only be carried out by Carital® service.

3 Covers and support surfaces

This section presents the cover and support surfaces available for the Carital® Neo*ICU* mattress system as well as how to take off and put on the cover.

3.1 Medicase® hygiene cover

The Medicase® hygiene cover protects the mattress system's cells from liquids and body fluids. The surface of the cover is polyurethane and the lower layer is polyester. The cover can be removed using zippers.

The cover has an integrated pouch for an x-ray plate. The patient can be x-rayed on the mattress.

The Medicase® hygiene cover for NeoICU

3.2 Giraffe support surface

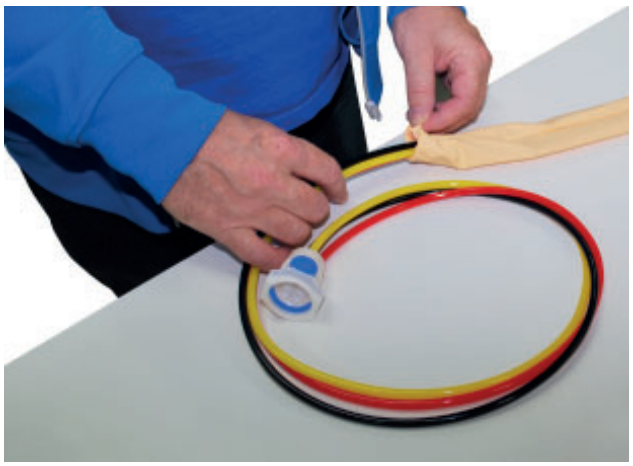
The dimensions of the Giraffe support surface is designed to fit into GE Giraffe Omnibed carestation and similar sized incubators. This is done by cell size and integrated foam inserts in the Medicase® cover.

NeoICU with Giraffe support surface inside the GE Giraffe Omnibed carestation

3.3 Taking off the cover

1. *Remove the mattress from the controller by disconnecting the air tube system and power cable. Disconnect the power cable from the electrical outlet.*

2. *Pull the protective tube sleeve back to re veal the tube connectors. Disconnect the air tubing from the cell's tube system.*



3. *Remove the protective tube sleeve.*

4. *Open the zippers on the sides of the support surface and remove the four integrated foam inserts from the cover.*

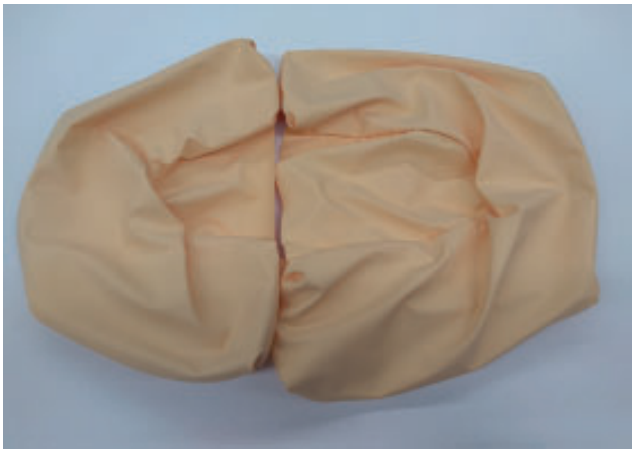
5. *Turn the mattress system upside down and open the zipper to reveal the cell system.*

6. *Pass the air tubes out of their hole.*

7. Remove the cell system.

8. Open the velcro on the womb substitute system WSS and remove the cell system carefully.

3.4 Putting on the cover



1. *Check that the necessary components are readily available: cover, WSS cells and their covers, foam inserts, air tubes with their protective tube sleeve.*

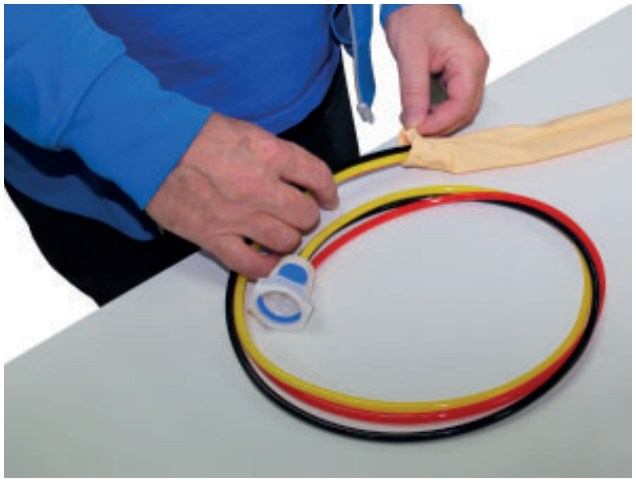
2. *Insert the four foam inserts into their designated compartments in the cover.*

3. *Insert the cell system into place. Ensure that the label in the foot section indicating the direction is faced correctly.*

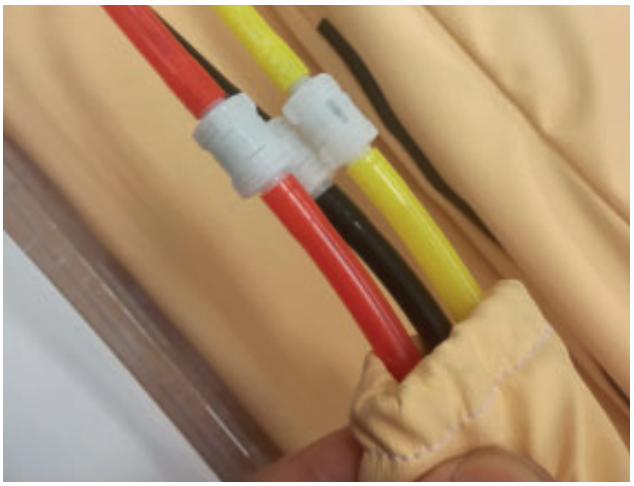
4. *Pass the cell air tubes out of their hole.*

5. *Close the cover zipper.*

6. *Insert the womb substitute system (WSS) into its cover. Repeat for both parts.*



7. *Pass the protective tube sleeve as far up as possible towards the white and blue CPC-quick release button.*



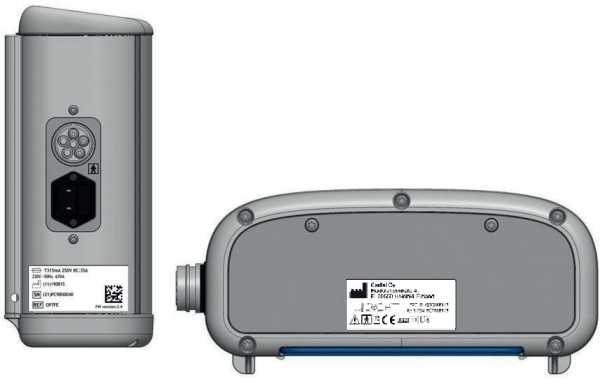
8. *To connect the three colour-coded tubes of the air tube system to their counterpieces, push and turn them clockwise.*

4 Commissioning

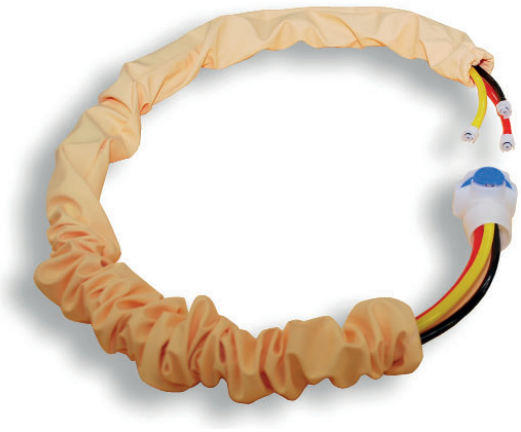
4.1 Components of the mattress system

Controller

Controller



Type labels on the side and at the bottom of the controller contain the device identification information.



Air tube system between the controller and cells, including connectors. The air tube system is delivered with the tube sleeve on.

The lockable power cable (5 m). The power cable is delivered pre-installed in its designated conduit in the cover.

Cells

NeoGiraffe cells without cover. The cells are delivered with the cover on. The size and serial number of the cells are marked on the bottom mat.

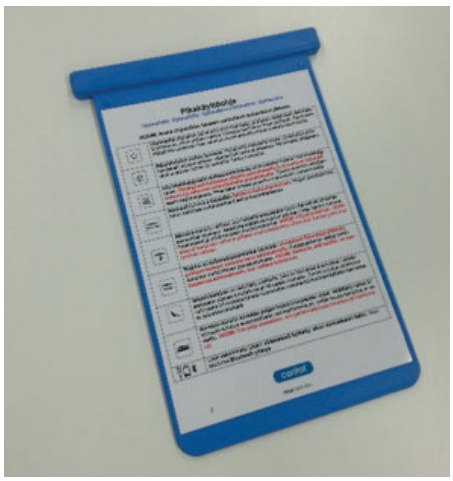
Neo womb substitute system (WSS).

Covers

The covers are delivered pre-installed on the cells. The cover is equipped with a label that indicates the size, type, time of manufacture, manufacturer data, and washing and cleaning instructions for the cover. The label also indicates the correct direction of installation of the mattress system.

Other

The controller has an integrated two-sided quick guide that describes the functions of the device and provides an example of troubleshooting.



Te double-sided quick guide is found on the back of the controller and is released for viewing by raising it upwards.

Be sure to put the quick guide caddy back in place after examination.

The delivery also includes this long-form user's guide.

If the delivery set is damaged or incomplete, do not commission the device. Immediately contact the mattress system's reseller.

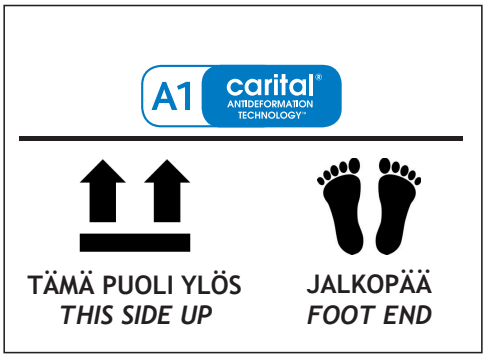
The temperature of the controller may have decreased or increased during transport beyond the limits of the allowable operating temperatures. Do not use the controller before it has been at room temperature (~ +20°C) for at least two hours. This time is required for all components of the controller to reach the normal recommended operating temperature of +10°C - +35°C.

4.2 Placing the mattress system onto the incubator

The air tubes of the cells are routed out at the left or right corner of the cover. **NOTE! The outlet of the tubes is interchangeable according to the incubator.**

The Medicase® hygiene cover for NeoICU

Place the support surface on the incubator. Ensure that the label indicating the correct direction of installation of the mattress system is located at the foot end and facing upward.



Label indicating the correct direction of installation of the mattress system.

Neo*ICU* mattress system contains a womb substitute system (WSS) that can be used to support the patient on the mattress. Place the WSS on the mattress and attach it with straps under the Neo*ICU* support surface.

Womb substitute system (WSS)

The placement of WSS in a treatment situation must be done according to a separate assessment by a health care professional.

Do not use extra bed sheets, pillows or heavy positioning pillows on the mattress.

4.3 Commissioning the controller

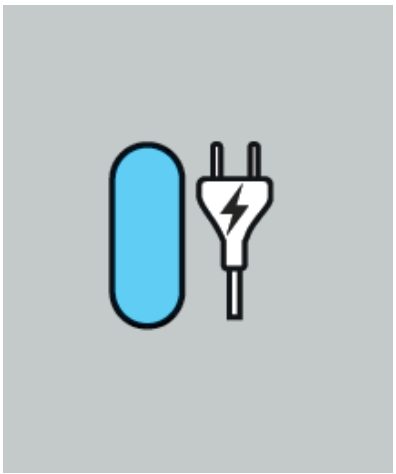
1. *Suspend the controller firmly on the incubator's load-bearing structure of at least 10 kg (e.g. side rail) so that the controller is not disturbing care or is not exposed to falling. Ensure that the hanger is attached firmly.*

2. *To connect the three colour-coded tubes of the air tube system to their counterpieces, push and turn them clockwise.*

3. *Connect the power cable to the mains controller.*

4. *Connect the Sixtube connector of the controller with the blue release button facing up and make sure the connector snaps when locking into place.*

5. *Pass the protective tube sleeve as far up as possible towards the controller.*



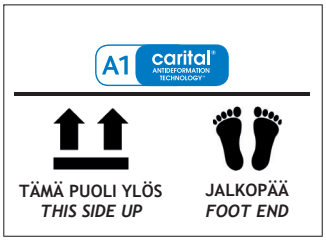
6. *Plug the power cable into an electrical outlet. The LED indicating a connected mains cable lights up.*

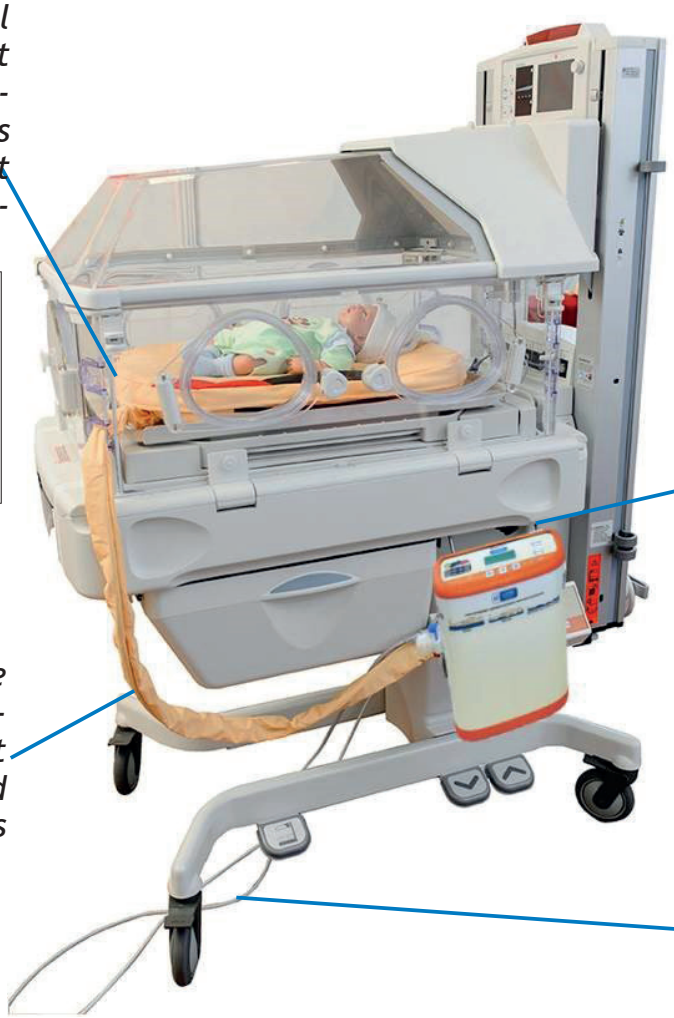
4.4 Lifting the controller

As a general rule, lift and handle the controller using two hands on both sides of the body or according to the instructions with the attached suspender.

4.5 Things to do check before use

Ensure that the label indicating the correct direction of installation of the mattress system is located at the foot end and facing upward.





Ensure that the controller has been suspended firmly. Ensure that there is sufficient space around the controller for operation and unobstructed disconnection.

Make sure the tube sleeve has been routed in such a way that it cannot be clamped by the folding parts of the incubator.

Make sure there is no risk of tripping over the connected power cable.

To guarantee fault-free operation of the controller, the power cable must always be connected to the mains, with the exception of short patient transports and power outages.

Always place the controller in such a way that it can easily be disconnected from the mains and that the controller's switches are unobstructed.

Make sure there is no risk of tripping over the connected power cable.

5 Operation

5.1 Turning on the controller and activating the weight class

Weight class 0-3 kg is intended for patients with very high or high risk of pressure ulcer who weigh 0-3 kg.

Weight class 3-6 kg is intended for patients with very high or high risk of pressure ulcer who weigh 3-6 kg.

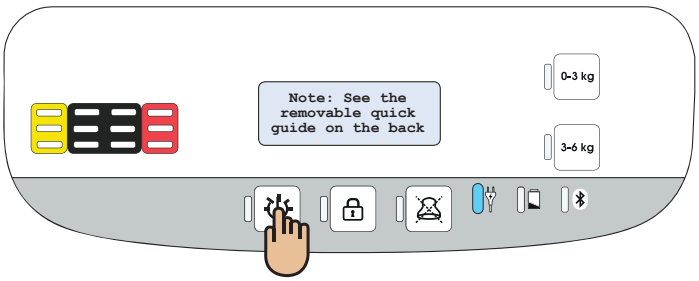
Before placing the patient on the mattress, start the device as described in section 5.1, and allow the mattress system to adjust to the selected weight class successfully, so that all green LEDs are lit in the centre of the LED light bar.

The dimensions of the mattress should always fit to the size of the patient, such that the pressure in all the adjustment sections are optimally placed to be regulated by the controller in correspondence to the patient's body parts.

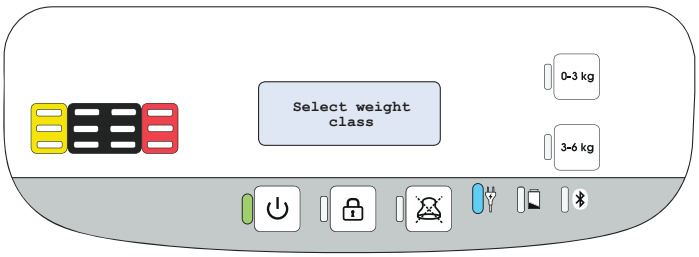
Make sure that the controller is connected according to the instructions in the section 4.3 Commissioning the controller, and check the required things before use.

To turn on the controller, press down the device standby button briefly.

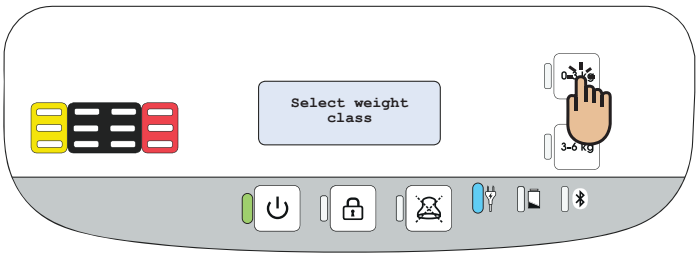
The device prompts you to consult the quick guide that can be found on the removable tray behind the device.



The device prompts you to select the weight class of the patient.



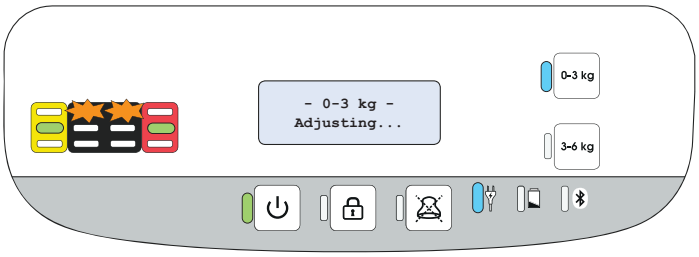
Select the patient's weight class by pressing the operation button.



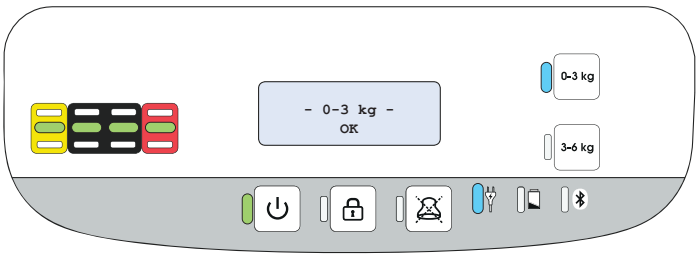
The device will switch to the selected operation.

The device will first adjust the torso, then the foot region and finally the head.

The selected operation LED is lit and the LED light bars for the cells will rise up or fall down with the adjustment of the cells.



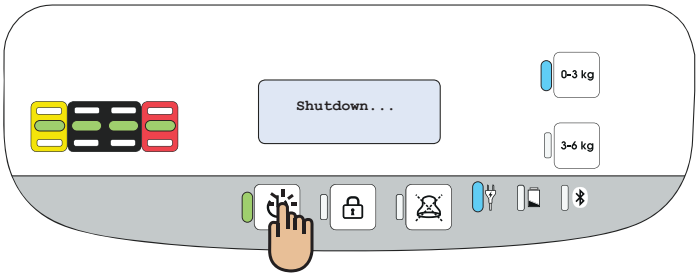
When the mattress system has successfully activated the selected operation, green LED indicators will light up in the centre of the LED light bar.



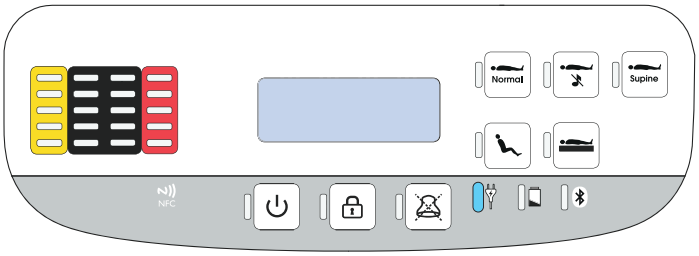
5.2 Turning off the controller

To turn off the controller in any operating mode, press the device's standby button.

The controller can be turned off in any operating mode by pressing the device's standby button.



The device remains connected to the mains and the power connection LED will stay lit until the device is disconnected from the mains.

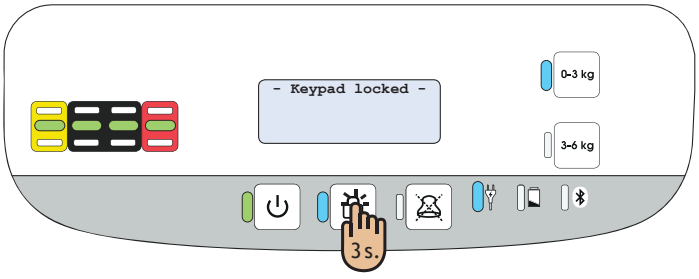


5.3 Keypad lock

The controller's keypad can be locked if deemed necessary considering the conditions of the operating environment.

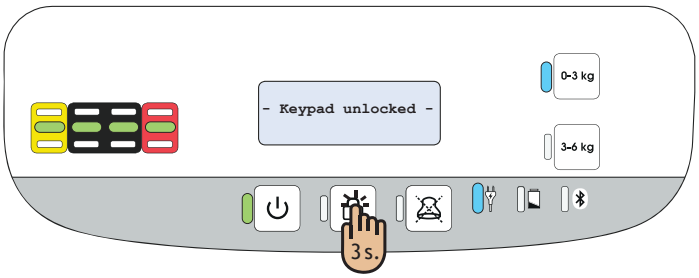
To lock the keys of the controller, press and hold down the keypad lock button for three (3) seconds while the device is running.

Keypad locking is indicated on the device screen. The LED on the keypad lock turns on.



To deactivate the keypad lock, press and hold down the keypad lock button for three (3) seconds until the display reads “Keypad unlocked.”

The LED on the keypad lock turns off.



5.4 Operating the controller using battery power

The controller must be connected to the mains by a power cable whenever possible. In exceptional cases, the controller can be operated for a short time using battery power. Allow the controller to be running and connected to the cells during transport. The mattress system will then run on the internal battery of the device.

Under normal operating conditions, a fully charged battery will suffice for at least 30 minutes of continuous pumping of the cells. The battery will charge from empty to full in approximately 12 hours.

When transporting patients: Disconnect the device’s power cable from the mains and make sure that the cable cannot be run over by the bed wheels, for instance, during transport. Once the patient transport is finished, connect the controller back to the mains by connecting the power cable to an electrical outlet. The cells will not deflate during transport.

The controller must be connected to the mains whenever possible. In exceptional cases, the controller can be operated for a short time using battery power.

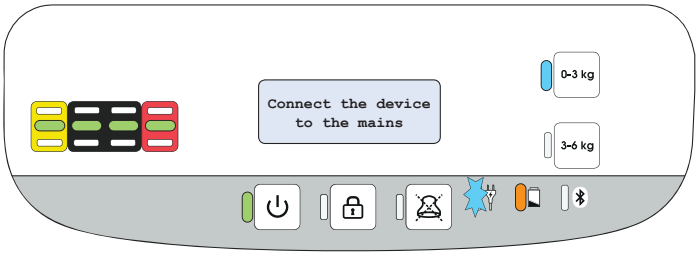
If the Sixtube connector of the air tube system is disconnected from the controller, the cells will deflate.

To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

If the device is disconnected from the mains while running, it will automatically continue running powered by its internal battery.

The device indicates the battery usage by flashing the LED light on the network interface and by lighting up the battery usage LED. In addition, the device notifies you to disconnect the mains cable by beeping five times and prompts you to connect the device to mains.

The device reminds of connecting to the mains with a simple beep, if the function keys of the device are pressed during battery usage.



For instructions on what to do if battery charge falls below the level required for normal operation, see section 6.9 (Information signals - Battery charge falls low).

5.5 Resuscitation situations

WHEN RESUSCITATING:
Turn off the device from the standby button and begin CPR immediately without deflating the cells.

When resuscitating, turn off the device from the standby button and start CPR immediately without deflating the cells. Do not use *Firm* operation when resuscitating.

5.6 Fault situations

The identified fault situations of the mattress system and detecting them is described in the sections 6. and 7.2.

If the mattress system behaves contrary to the functions and situations described in this user's manual, disconnect the air tubing from the cell's tube system and the power cable from the controller, turn off the controller, and contact Carital® service.

6 Information signals

If the controller detects a failure or wishes to inform the user, it will provide audible and visual indication using the display, information signal LED and LED bars. This section describes how the information signals must be interpreted and what action they require from users.

Below is a list of information signals in the LED display and references to more detailed troubleshooting guides:

6.1 Pressure sensor function error

6.2 Check the air tubes (leak in tube or cells)
- potential leak in the torso section

6.2 Check the air tubes (leak in tube or cells)
- potential leak in the head section

6.2 Check the air tubes (leak in tube or cells)
- potential leak in the foot section

6.3 Pressure target value invalid

6.4 SD card operating error

6.5 Scheduled maintenance notices

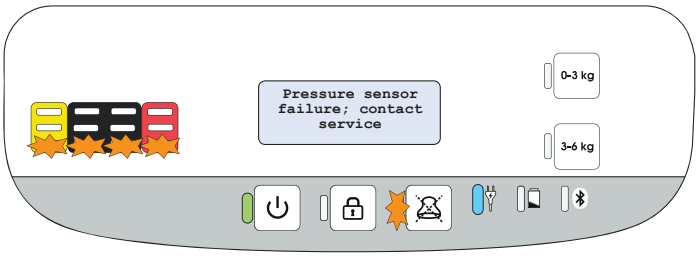
6.7 Battery operating error

6.8 Battery charge falls low

6.9 Device internal error

6.1 Pressure sensor function error

The LED row will light up as shown in the figure. The LED for the information signal reset button blinks and the display indicates failure.

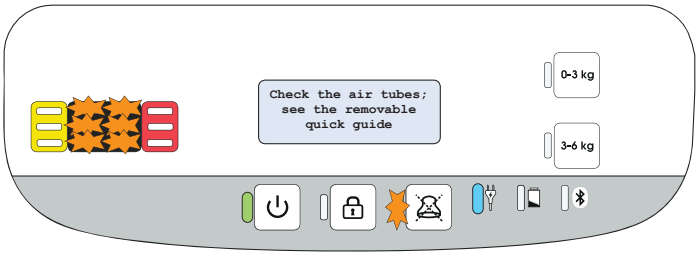


To acknowledge the failure indication signal, press the information signal reset button. Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

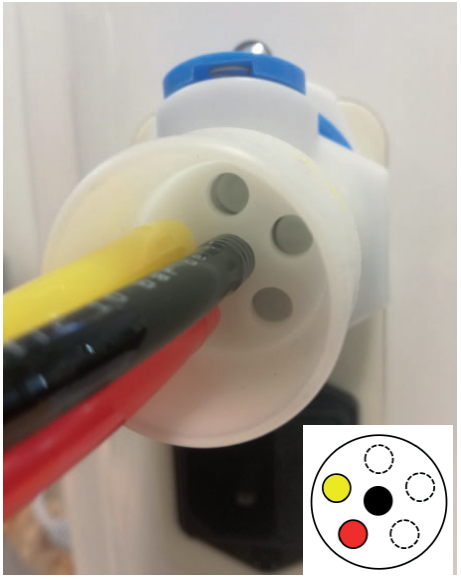
6.2 Check the air tubes (leak in tube or cells)

The information signal reset button blinks and the display reads, “Check the air tubes; see the removable quick guide”.



This information signal is displayed if the device does not achieve the desired function of the active operation within 45 minutes. This may be due to a disconnected tube or a leak in the inner cell or tube system, among other causes.

The LED display is lit for that area of operation where the controller has failed to achieve the target pressure value for the function. In this example, the issue has been detected in the torso section of the cell.



Perform the following tasks:

First check whether the Sixtube connector connected to the controller is locked in place and whether its attached tubes are in their holders.

Open the tube sleeve until the tube connectors are revealed: check whether the tubes between the cells and controller are connected to their connectors. Also check that the colours match (for example, black on black). Check whether there is any clearly visible damage to the cells or leaks in them.

If you notice any loose tubes, connect them to each other as appropriate. Close the tube sleeve.

When you have checked the above, acknowledge the information signal by pressing and holding down the information signal reset button for three seconds.

If the information signal persists or you detect a leak in the mattress system, contact Carital® service.

6.3 Pressure target value invalid

The LED row will light up as shown in the figure and the display will read, “Incorrect target pressure value; contact service”.

To acknowledge the failure indication signal, press the information signal reset button.

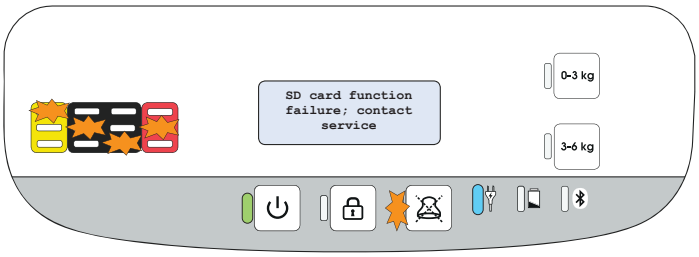
Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

The audible information signal will start again if the device is restarted.

Immediately contact Carital® service.

6.4 SD card operating error

The LED row will light up as shown in the figure and the display will read, “SD card function failure; contact service”.

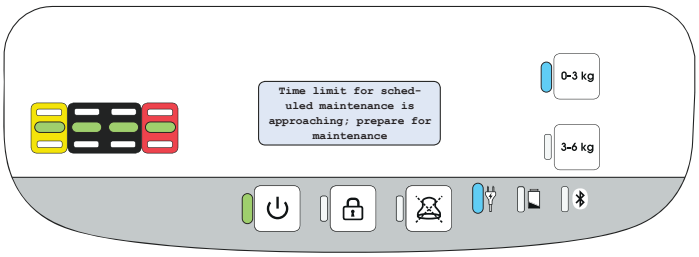


To acknowledge the failure indication signal, press the information signal reset button. Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

6.5 Scheduled maintenance notices

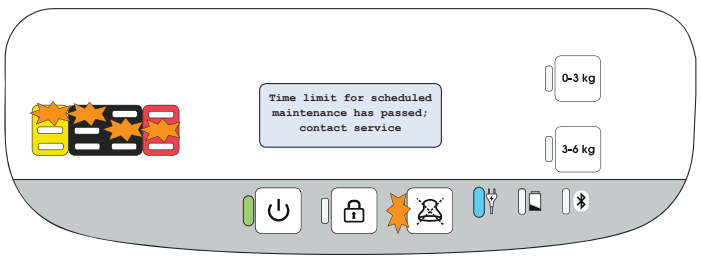
The display will read, “Time limit for scheduled maintenance is approaching; prepare for maintenance”.



Prepare to send the controller in for scheduled maintenance after one (1) month.

After this, the device will display a reminder for 5 seconds whenever a function button is pressed or the device is turned on.

The LED row will light up as shown in the figure and the display will read, “The time limit for scheduled maintenance has passed; contact service”.



Immediately contact Carital® service and send the controller in for scheduled maintenance.

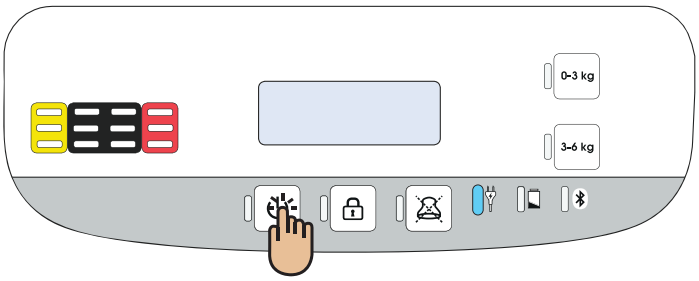
To acknowledge the indication signal, press the information signal reset button. The LED will stop blinking and remain on continuously.

Press and hold down the information signal reset button for three (3) seconds to turn off the LED and remove the visual signal from the display. After this, the device will display a reminder for 5 seconds whenever a function button is pressed and provide a new information signal when the device is turned on.

6.6 Electromagnetic interference and display information fault situations

1)
If the device display is exposed to an unexpected electrostatic discharge, the display information and letters may be shown in an illogical way.

Turn the controller off and on with the standby button shown in the figure. The device will resume normal operation after restarting.



If the device does not resume normal operation, discontinue using the device and **contact Carital® service**.

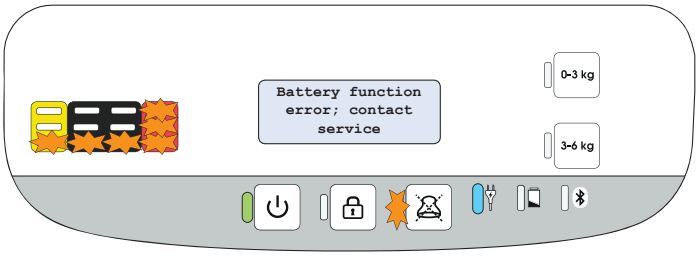
2)
If the device is exposed to significant electromagnetic interference in excess of the thresholds specified in Appendix 1, a situation may result where the device's mode of operation will randomly change without user action.

Move the device further from the source of the electromagnetic interference to eliminate the interference and restart the device if necessary.

If the device does not resume *Normal* operation, discontinue using the device and **contact Carital® service**.

6.7 Battery operating error

If the battery temperature of the device rises too high, and the charging is interrupted or the battery does not charge as expected and the charger times out, the device will report a malfunction with the information signal.



The LED row will light up as shown in the figure. The LED for the information signal reset button blinks and the display indicates operating error.

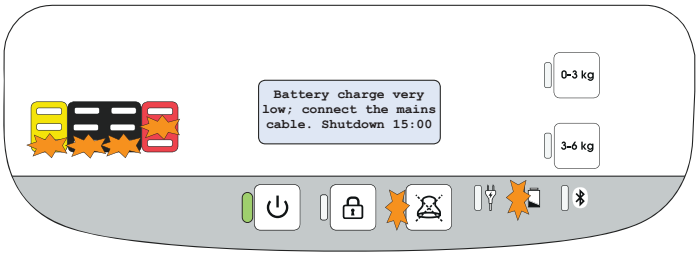
To acknowledge the failure indication signal, press the information signal reset button. Only the audible part of the information signal is acknowledged.

The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

6.8 Battery charge falls low

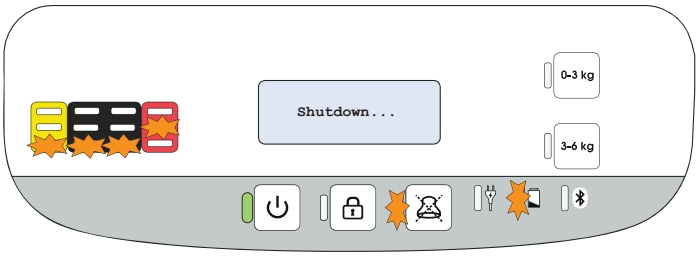
When the charge of the internal battery falls to a very low level (7.2V–7.0V), the controller will provide an information signal.



Despite acknowledging the indication signal, the visual signals will remain on and the adjustment of the mattress system will cease until the device is connected back to the mains.

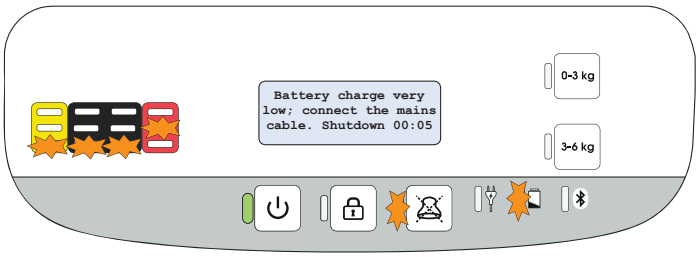
The 15-minute timer for the self-shutdown of the controller will start running. The device will indicate the decreasing time on the display.

After 15 minutes, the device will turn off completely and indicate this with a sound and on the device screen.



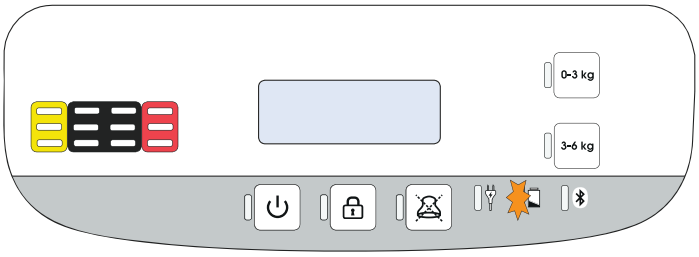
When the device is connected back to the mains, restart it by pressing the standby button.

If the device shuts down after the counter process, and it is restarted, the device turns off after 5 seconds from booting.



The battery indicator flashes for 20 seconds after the restart attempt begins.

If the internal charge of the battery reaches the critical low point (< 7.0V), the device turns off immediately and flashes the battery light for 20 seconds.



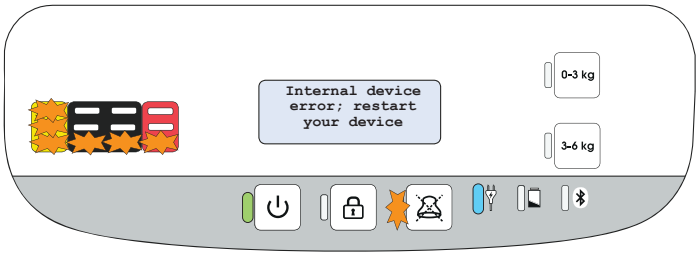
Restart attempts from now on will only generate the battery indicator light (20 sec.) until the device is connected to mains again.

NOTE:
When the levels of very low or critical voltage are reached, the battery operation cannot be resumed, but the device must be plugged into the mains. Normal battery usage is possible once the device has been charging for approx. 5 to 6 hours (depending on the condition of the battery). If the device is disconnected from the mains before an adequate charge level has been reached, the device will shut down itself after 5 seconds after booting.

To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

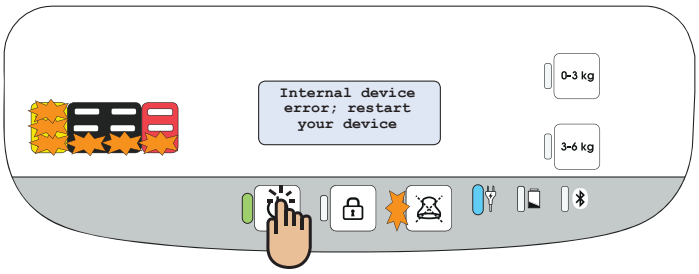
6.9 Device internal error

The LED row lights up as shown in the figure and the display shows "Internal device error; restart your device".



The indication signal of this one-time malfunction failure state can be acknowledged by pressing the acknowledgement button of the indication signal. The indication signal is acknowledged only for sound, visual information signals remain on.

The device will no longer return to the previous operation and will require a restart. Press the standby button to restart the device.



If the indication signal is not removed after restarting, contact Carital® service immediately.

NOTE:
Check your Carital® service contact information on the last page of the user's guide.

If the controller has encountered a significant mechanical strain (dropped, hard collision or similar), check the mechanical condition of the control port's connection gates and ensure that the seals between the operator panel/frame and the connection port/base plastic parts and the body are in place. If you notice any damage to the device, contact Carital® service.

Do not use the device if the configuration is incomplete or any of its components is broken, worn or contaminated. Worn, missing and broken parts must be replaced and contaminated ones cleaned.

Maintenance and repair must always be carried out by Carital® service. The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

If the mattress system behaves contrary to the functions and situations described in this user’s manual, disconnect the air tubing from the cell’s tube system and the power cable from the controller, turn off the controller, and contact Carital® service.

The mattress system must always be serviced according to the service programme described in this guide. A device that has not been serviced in accordance with the service programme must not be used but must be sent to Carital® service, instead. The user is responsible for any and all consequences resulting from neglecting service.

Any serious incident that has occurred in relation to the device described in the user’s guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health, (c) a serious public health threat; should be reported to the manufacturer and the competent authority of the Member or Sovereign State in which the user and/or patient is established.

7 Maintenance and storage

7.1 Cleaning

The mattress system must be cleaned in accordance with these instructions whenever

- there is suspicion that any part of the mattress system is contaminated
- there is visible dirt or secretions on the cover
- the patient using the mattress system changes
- before maintenance and repair

Do not clean the plastic parts of the mattress system using solvents, phenols or clean alcohols.

If the cover or cells are exposed to urea (sweat and urine) for a prolonged period, the molecular structure of polyurethane may break down, damaging the cover or the cells. Clean the cover and/or cells immediately if exposed to urea.

7.1.1 Controller and tube system

Disinfect by wiping using regular cleaning and disinfection agents (including ethanol solutions 60–80%, chlorine solutions max. 1,000 ppm).

Dry at room temperature.

Do not immerse the controller in liquid.

7.1.2 Cells

Disinfect by wiping using regular cleaning and disinfection agents (including ethanol solutions 60–80%, chlorine solutions max. 1,000ppm).

The cells can also be disinfected by washing them at a temperature of 70°C.

Dry at room temperature.

7.1.3 Medicase® cover

Primary cleaning recommendation

- Wipe the cover with a cleaning and, if necessary, disinfecting cleaning agent
- Maximum chlorine content 2,000 ppm, in occasional use max. 5,000 ppm, ethanol solutions max. 60-80% (pH≈10)
- Avoid corrosive agents
- When using corrosive agents, rinse by wiping with clean water and then dry

Machine wash

Ensure that the cover is entirely dry before commissioning it.

7.1.4 Foam inserts

Remove the integrated foam inserts from the cover. After washing and drying the cover, place back the foam inserts in their compartments. Close the zippers.

Do not wash the foam inserts.

7.2 Checking the operability of the mattress system

To maintain the operational reliability of the mattress system, you need to monitor its condition throughout its lifetime as follows.

7.2.1 Controller

The condition of the controller must be checked as follows:

- When commissioning the controller
- When moving the controller
- When cleaning
- Whenever there is reason to believe the device has had an accident

The controller should be visually inspected for the condition of the power cable and the air tube connections, and that the seals of the plastic parts and the body between the operator panel/frame and the connection port/base are in place. In addition, any surface damage to the operating panel and the body, the hanger mounting of the controller, and the readability of technical type plate markings should be checked.

If you notice any damaged components or surfaces, contact Carital® service.

7.2.2 Cover

The condition of the cover must be checked as follows:

- When cleaning
- If you suspect that the cover is broken or the interior is contaminated
- When the patient changes or weekly in long-term care

Check the cover's seams, zipper and velcro operation, condition of the surface of the cover and any darkening or stains on the interior of the cover.

If you notice any damages, contact Carital® service.

7.2.3 Cells

The condition of cells must be inspected:

- When cleaning
- If you suspect that the cover is broken or the interior is contaminated
- When the patient changes or weekly in long-term care

Strip the cover from the cells and check the overall condition of the cells visually (stretches, deterioration, thinning) and any punctured cells.

Leaks in the cells can be detected by the information signal displayed while the controller is used (see 6.2). In the event of a leak in the cells, the controller will not achieve the desired pressure values and the information signal is displayed automatically. Leaks can be detected visually by looking for cell sections that are empty.

If you notice any damaged components or surfaces, contact Carital® service.

7.2.4 Life cycle of the mattress system

The estimated life cycle of the mattress system, when properly cleaned and maintained under its normal intended purpose, has been assessed to be as follows:

- Controller and hanger: eight (8) years
- Cells and tube system: six (6) years
- Covers: five (5) years

If the mattress is used in violation of the instructions specified in the user's guide, or it is not cleaned of body secretions containing urea in particular, or the mattress system is used by a prominently sweating or mobile patient, the estimated life cycle of the cover and the cells may be shortened.

7.3 Scheduled maintenance

7.3.1 Scheduled maintenance interval

Scheduled maintenance must be performed on the mattress system's controller every three (3) years. Scheduled maintenance includes the technical inspection of the controller and the replacement of wearing parts.

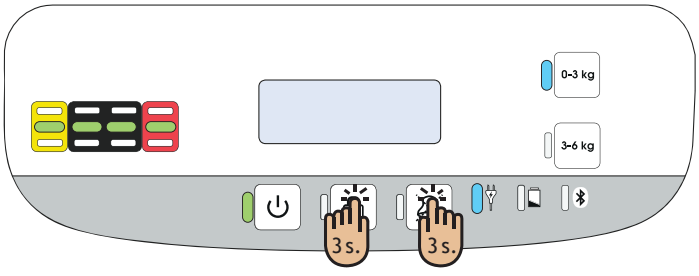
The controller will alert you to the need of scheduled maintenance one month before the deadline for the scheduled maintenance is reached.

See your Carital® service contact information on the last page of this user's guide.

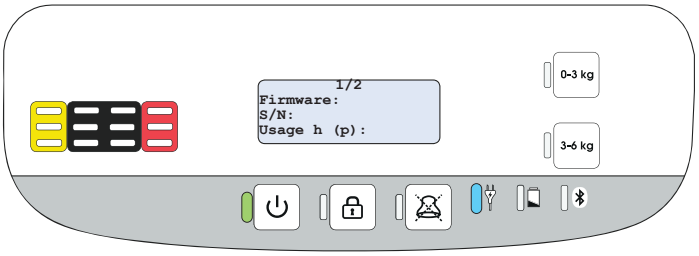
Scheduled maintenance may only be carried out by Carital® service.

7.3.2 Checking the maintenance data in the controller's maintenance view

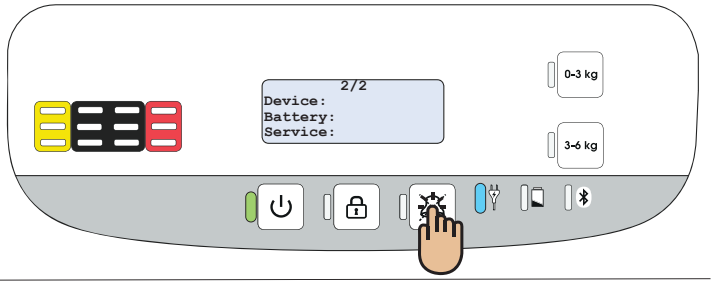
With the device running, press and hold down the lock and information signal reset button for three (3) seconds to access the maintenance view.



In the view, you can check the device software version, (*Firmware*), serial number (*S/N*), pump operation hours (*Usage h (p)*), date of device commissioning (*Device*), date of battery commissioning (*Battery*) and the date of the following scheduled maintenance (*Service*).

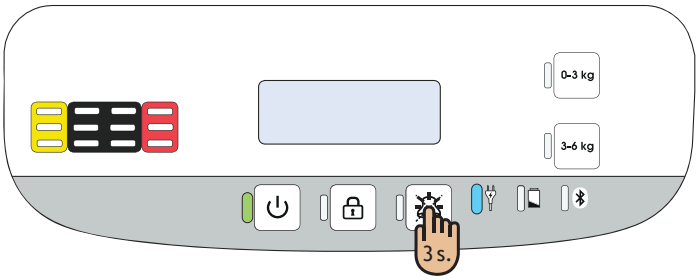


To change from one tab to another in the maintenance view, press the information signal reset button.



To return from the maintenance view to the normal operating mode, press and hold down the information signal reset button for three (3) seconds.

After returning from the maintenance view, the device checks the pressure values of the mattress system.



7.4 Storage and transport

Decommissioning the mattress system

1. *Press the standby button to stop the device operation and then disconnect the device's power plug from the mains.*

2. *Disconnect the power cable by pressing the yellow button and pulling the cable out.*

3. Disconnect the air tube system's Sixtube connector by pressing the blue CPC button and pulling the connector out.

The cells and the cover can be emptied for transport or storage by removing the air tubes from the controller and allowing the cells to deflate by themselves. You can expedite the deflation by carefully folding the cells inward.

Storage and transport conditions for the mattress system

	Temperature	-25°C to +50°C > +35°C to +70°C with vapour pressure 50 hPa
	Air humidity	max. 90%

- Store in a clean and dry place, horizontally.
- Do not store anything on top of the mattress system.
- Do not place sharp or heavy objects on or near the mattress system.
- Keep heat sources away from the mattress system.

To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.8 Disposal

Contaminated components must be cleaned before disposal or, if cleaning is not possible, disposed of in accordance with official regulations pertaining to contaminated healthcare waste.

8 Disposal

8.1 Controller

The device must be decommissioned in accordance with waste electrical and electronic equipment regulations. The user's guide can be recycled with paper.

The device must be disposed of in accordance with EU directive 2002/96/EC (WEEE Directive).

8.2 Cells and cover

The cells and cover can be disposed of as burnable matter or in mixed waste.

8.3 Packaging

The cardboard part of the mattress system packaging can be recycled with cardboard. The styrofoam packaging supports and packaging plastic can be recycled with plastic packaging.

9 Warranty

The Carital® Neo*ICU* mattress system has three-year warranty (36 months) from the date of purchase. The warranty covers all faults resulting from defects in materials or workmanship.

Repair will be carried free of charge at Carital® service on the basis of the warranty.

For warranty questions, please contact the mattress system's seller, always citing the device and subcomponent (controller/cells/cover) serial number or identifier.

The controller is intended for long-term use. However, it contains components that may break if the product is dropped or subjected to impact or vibration exceeding design standards. The limited manufacturer warranty does not apply to situations where the product has been mishandled.

10 Technical specifications

Essential performance of the medical device		Measures, adjusts and maintains the function-specific pressure values in the mattress system, specified in the software for each program.
Permissible weight of the patient		0-6 kg
REF code of the adjusting device		NEIxyz, where x=language (F=Finnish, S=Swedish, E=English, D=German, R=French, P=Spanish, J=Japanese, N=Dutch, O=Norwegian, T=Danish, G=Portuguese), y=voltage range (E=230 V, S=120 V), z=hanger type
Controller dimensions (W x L x H)		26 x 26 x 11.5 cm
Mattress dimensions (W x L x H)		35 x 65 x 4 cm, 48 x 66 x 4 cm (Giraffe)
Weight (controller/mattress)		5 kg/2 kg (depending on cell dimensions)
Controller decibel level		26,41 LAeq (24-hour operating time, 1 m)
Flammability (mattress)		EN 597-1:2015; EN 597-2:2015; IMO 2010 FTP Code, Annex 1, Part 9
Operating voltage		230V 50HZ (voltage range E) **or** 120V 50/60HZ (voltage range S)
Nominal input power		max. 35W
Battery type		Lithium-ion, 7.26V, capacity 2,650mAh, manufacturer: Cell-tech Oy / Varta Storage GmbH
Non-rechargeable battery type		CR2032, lithium-ion, 3.0V, capacity 230mAh, manufacturer: Varta Microbattery GmbH
Fuses		F1 & F2 - T 2.5A/250V 5X20 mm; F3 - T5A/250V 5X20 mm; F4 - T 2.0A/250V 5X20 mm; pump/motor fuse - T 1.6A/250V; main fuse: (voltage range E) - T315mA/250V 5X20 mm, breaking capacity (BC) 35A or (voltage range S) - T500mA/250V 5X20 mm, breaking capacity (BC) 35A
Separating device		Power cable - EU/UK/AU (voltage range E): C13, 1 mm^2, 10A/250 VAC; 50 Hz or US (voltage range S): C13, SJT 3x16 AWG, 13 A / 125 VAC; 50/60 Hz
Electromagnetic compatibility		See Appendix 1: Carital Controllers - Guidance and Manufacturer's Declarations - EMC
	**Applied part** **Applied part type**	Mattress (cover and cells) BF
IP22	**IP class**	IP22 (protected against particles with a diameter of 12.5mm or greater and from water falling vertically or at an angle not exceeding 15°)
	**Protection class**	II, insulated
	**Operating environment temperature range**	+10°C - +35°C
	**Operating environment air humidity**	15% - 90%
	**Operating environment atmospheric pressure**	700 hPa - 1,060 hPa
CE	MD	Class 1 medical device under the EU Medical Device Regulation 2017/745 (MDR)

	Design standards	IEC 60601-1:2005 & IEC 60601-1:2005/AMD1:2012 except for clause 11.7 IEC 60601-2:2014 IEC 60601-1-6:2010 & IEC 60601-1-6:2010/AMD1:2013 IEC 60601-1-11:2015 IEC 62304:2006 & IEC 62304:2006/AMD1:2015 IEC 62366:2007 & IEC 62366:2007/AMD1:2014 EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 15223-1:2016 EN ISO 3758:2012 EN 597-1:2015 & EN 597-2:2015 EN 12182:2012

11 Contact details of the manufacturer and service

Manufactured by:

Carital Ltd
Haukilahdenkatu 4
FI-00550 HELSINKI

Service:

add local
service here

Appendices

Appendix 1: Carital Controllers - Guidance and Manufacturer's Declarations – EMC

Electromagnetic Emissions (IEC 60601-1-2)			
Emission Test		**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11		Group 1, Class B	Carital mattress systems are suitable for use in all establishments including domestic establishments
Harmonic Emissions: IEC 61000-3-2		Complies	
Voltage fluctuations/flicker emissions: IEC 61000-3-3		Complies	
Electromagnetic Immunity (IEC 60601-1-2)			
Emission Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines, ±1kV for input/output lines	±2kV for power supply lines, ±1kV for input/output lines	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Surge 61000-4-5	±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±0.5 kV, ±1 kV, ±2 kV Line-to-ground	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the Carital mattress system requires continued operation during power mains interruption, it is recommended that the Carital controller is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: Ur is the A.C. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz), 6 Vrms in ISM bands between 150 kHz to 80 MHz (80 % AM at 1 kHz)		Portable and mobile RF communications equipment should not be used closer than 30cm (12 inch) of Carital controller, including cables. Using portable and mobile RF communications equipment too close may result Carital controller in not functioning properly. Interference may occur in the vicinity of equipment marked with the following symbol 
Radiated RF IEC 61000-4-3	10V/m (80 MHz to 2,7 GHz) and 20 V/m (800 MHz to 2,5 GHz)	10V/m (80 MHz to 2,7 GHz) and 20 V/m (800 MHz to 2,5 GHz)	
Proximity fields from RF wireless communications EQUIPMENT IEC 61000-4-3	9V/m 710MHz, 745MHz, 780MHz, 5,240MHz, 5,500MHz and 5,785MHz 27V/m 385MHz 28V/m 450MHz, 810MHz, 870MHz, 930MHz, 1,720MHz, 1,845MHz, 1,970MHz and 2,450MHz	9V/m 710MHz, 745MHz, 780MHz, 5,240MHz, 5,500MHz and 5,785MHz 27V/m 385MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz	