carital®

User's guide

Neo*ICU*
Neo*IW*

KOHJ-H-13-EN5-2.0-09082023

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 I medical device under the 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


Allowable air humidity limits


Allowable air pressure limits


Keep protected from rain

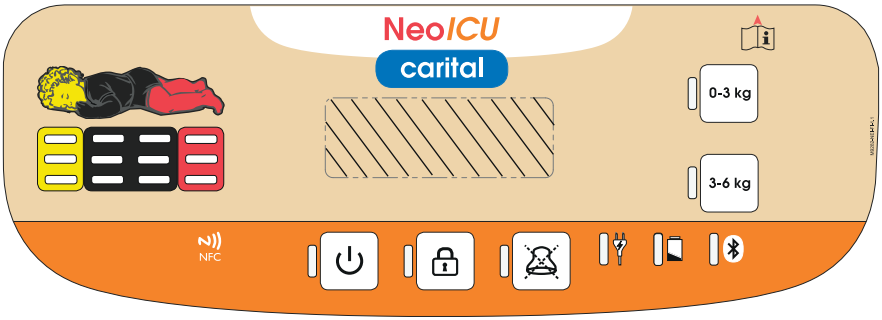
Device IP class


Allowable temperature limits


Fragile, handle with care

1.2 Symbols on the controller's operating panel

The Neo*ICU* panel used as an example.



General functions

Device standby button

Keypad lock

Information signal acknowledgement

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 use and target patients

A mattress system for the prevention and treatment of pressure ulcers in prematurely born patients (> 500 g) with high and very high risk of pressure ulcers or in newborn patients, i.e. in mature infants under 28 days of age and older children weighing up to 6 kg.

2.2 Operating environment and user profile

Intended for use in incubators (Neo*ICU*) as well as in neonate warmers and baby stations (Neo*IW*) in professional healthcare environments (standard wards and intensive care).

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

2.3 Indications

The indications include use in healthcare for the patient group mentioned in section 2.1

- in the treatment and prevention of pressure ulcers in burn patients
- in the prevention of pressure ulcers in special patient groups, such as patients who undergo extracorporeal membrane oxygenation (ECMO) or therapeutic hypothermia or who have spinal or other severe or unstable fractures
- in the treatment of pressure ulcers, regardless of the classification or stage (I–IV) of the pressure ulcer, including stage non-specific ulcers/injuries.

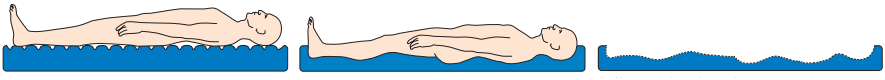
The devices are also indicated for pain management in the above-mentioned patients.

2.4 Contraindications

No known contraindications.

2.5 System description

Carital® Neo*ICU* and Neo*IW* mattress systems have tunnel-shaped cells that adjust to the body of the patient. The cells are interconnected, forming 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 a patient.

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

2.6 Products whose use is described in this guide

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

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

Serious incidents related to the medical devices described in the user's guide that directly or indirectly resulted in, could have resulted in or could result in 1) death of a patient, user or other person 2) serious or permanent deterioration in the health of a patient, user or other person 3) serious threat to public health must be immediately reported to the manufacturer and the Therapeutic Goods Administration (TGA) (AUS) or the New Zealand Medicines and Medical Devices Safety Authority (NZ).

Read this guide carefully before commissioning 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.

2.7 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 a healthcare professional can assess the need and suitability of using the mattress system in a treatment situation.
- Serious incidents related to the medical devices described in the user's guide that directly or indirectly resulted in, could have resulted in or could result in 1) death of a patient, user or other person 2) serious or permanent deterioration in the health of a patient, user or other person 3) serious threat to public health must be immediately reported to the manufacturer and the Therapeutic Goods Administration (TGA) (AUS) or the New Zealand Medicines and Medical Devices Safety Authority (NZ).
- 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 distributor.

- 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.

- 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 use 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 until it has been at room temperature (ca. +20 °C) for at least two hours. This time is required for all components of the controller to reach the normal recommended operating temperature (+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 cause suffocation. Make sure that the air tubes and the controller's power cable cannot twist around the head or neck.

- The power cable of the controller must be positioned in such a way that it cannot be clamped, for example, by the folding parts of the incubator under any circumstances.

- Ensure that the power cable is plugged into its mains outlet in such a way that it does not present a risk of stumbling.

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

- To maintain the battery's performance, keep the controller continuously connected to the mains 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 sheets, pillows or heavy position supports on the mattress system.

- A healthcare professional needs to assess the suitability of and need for the womb substitute system (WSS) separately in each treatment situation.
- Before placing the patient on the support surface, start the device as described in section 5.1, and allow the mattress system to adjust to the desired weight category successfully, so that all green LEDs are lit in the centre of the LED light bar.
- The size of the support surface should correspond to the size of the patient for the optimal adjustment of the pressure values in all parts of the support surface which correspond to different body parts.
- Before evacuation, disconnect the controller's power cable from the mains and the air tubes from the controller.
- When resuscitating, turn off the device from the standby button and start CPR immediately without deflating the cells.
- Do not immerse the controller in any 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 support surface 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.
- The foam plastic supports must not be washed.
- If the support surface 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 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 use.

- 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, the controller has components which may break if the controller is subjected to an impact, force or shake that exceeds the design standards. The limited manufacturer warranty does not apply to situations where the product has been mishandled.

- The rechargeable or non-rechargeable 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 use or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

- If the mattress system does not behave in accordance with the functions and situations described in this manual, disconnect the air tubing from the tube system of the cells 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.

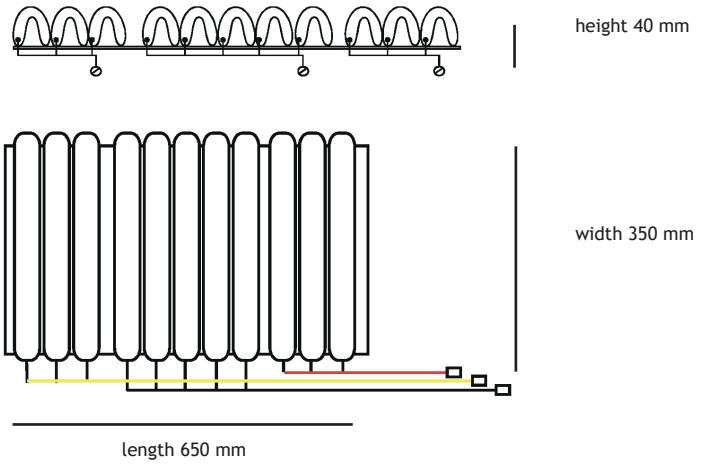
- Scheduled maintenance may only be carried out by Carital® service.

3 Support surface options and covers

This section presents the cover and support surface options available for the Carital® Neo*ICU* and Neo*IW* mattress systems and explains how to take off and put on the cover (illustrated with the Neo*ICU* Giraffe variant).

3.1 Neo*ICU* support surfaces

3.1.1 Standard

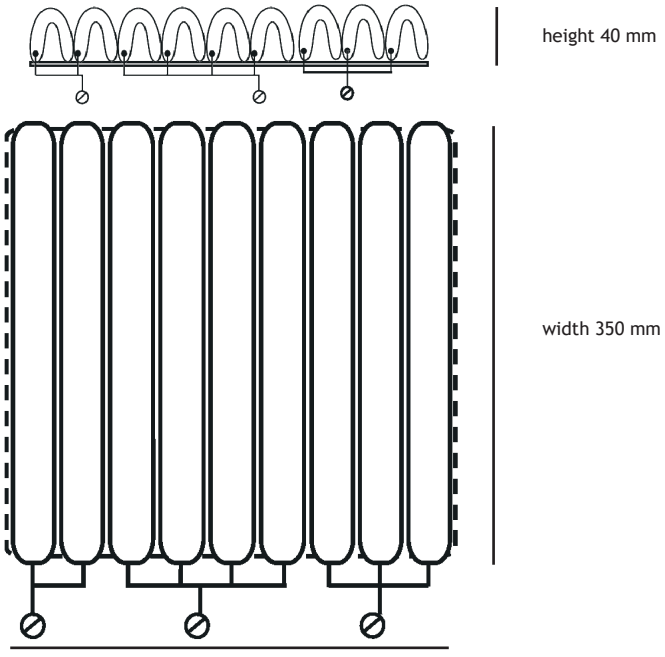


Dimensions of the NeoICU cells.

3.1.2 Giraffe

The dimensions of the Giraffe support surface are designed to fit the GE Giraffe Omnibed carestation and incubators of the same size. The fit has been achieved by paying attention to the size of the cells and with the help of the foam plastic edges integrated into the Medicase® hygiene cover.

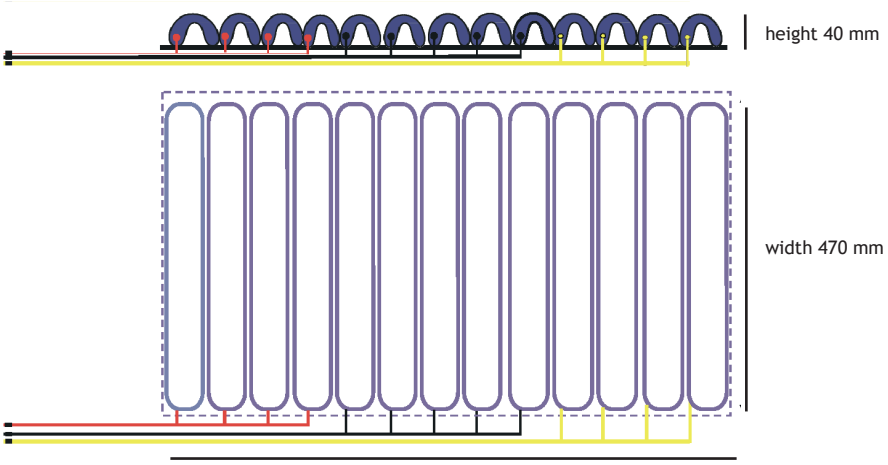
NeoICU Giraffe support surface in the GE Giraffe Omnibed carestation.



Dimensions of the NeoICU Giraffe cells.

3.2 Neo*IW* support surface

The Neo*IW* support surface is designed for use in warmers and baby stations.



Dimensions of the NeoIW cells.

3.3 Medicase® hygiene cover

The Medicase® hygiene cover protects the cells of the mattress system 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.

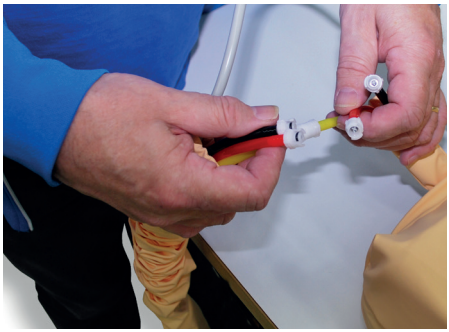
The Carital® Neo*ICU* cover has an integrated pouch for an x-ray plate. This allows for the patient to be x-rayed on the mattress.

NeoICU Medicase® hygiene cover

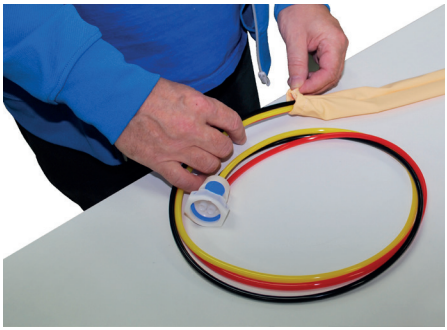
3.3.1 Removing the cover

The example illustrates the removal of the cover of the Neo*ICU* Giraffe support surface.

1. *Disconnect the support surface from the controller by first disconnecting the power cable. Then disconnect the air tube system's Sixtube connector by pressing the blue CPC button and pulling the connector out. Disconnect the power cable from the mains.*



2. *Pull the tube sleeve back to reveal the connectors. Remove the air tubing from the tube system of the cells.*

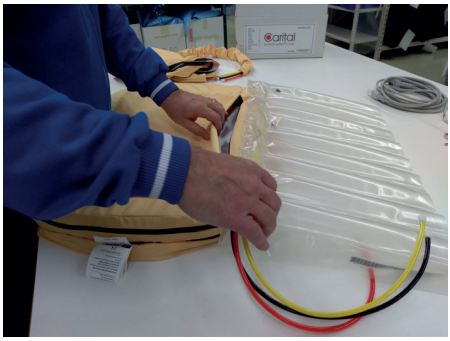


3. *Remove the tube sleeve.*

4. *Open the zippers on the sides of the support surface and remove the four foam plastic supports integrated into the cover (Note! NeoICU Giraffe only).*

5. *Turn the support surface upside down and open the zipper to reveal the cells.*

6. *Pass the air hose through its opening.*

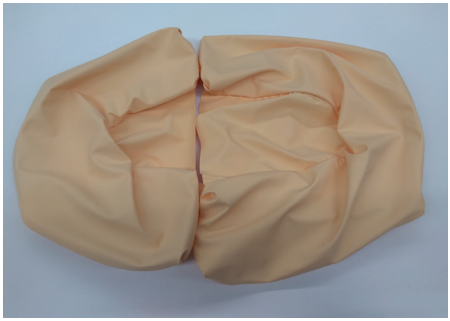


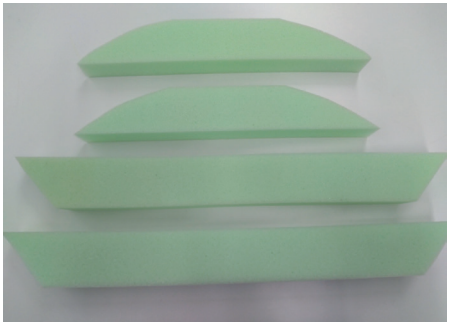
7. *Remove the air cells.*

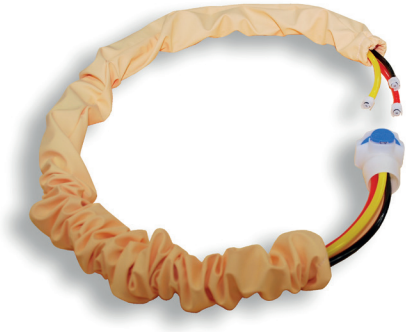
8. *Open the velcro on the womb substitute system (Note! NeoICU only) and carefully remove the cells. Repeat for both parts.*

3.3.2 Putting on the cover

The example illustrates putting on the cover of the Neo*ICU* Giraffe support surface.

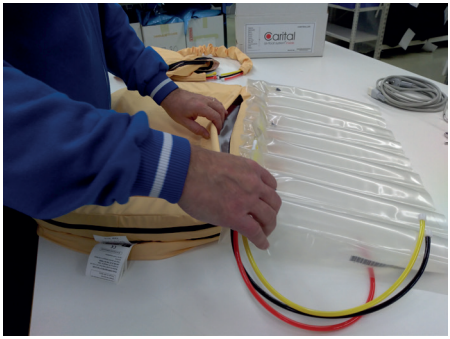






1. *Check that the necessary components are readily available: cover, WSS cells and their covers (Note! NeoICU only), foam plastic inserts (Note! NeoICU Giraffe only), air tubes and the tube sleeve.*

2. *Insert the foam plastic inserts (Note! NeoICU Giraffe only) into their compartments in the cover.*

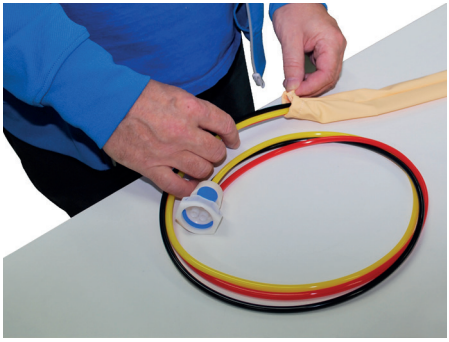


3. *Insert the cell system into place. Ensure that the label at the foot end indicating the correct direction faces the right way.*

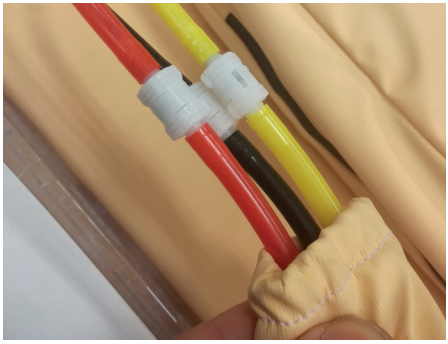
4. *Pass the cell air tubes out of their opening.*

5. *Close the cover zippers.*

6. *Insert the womb substitute system (Note! NeoICU only) into its cover. Repeat for both parts.*



7. *Pass the tube sleeve as far up as possible towards the white and blue Sixtube connector.*



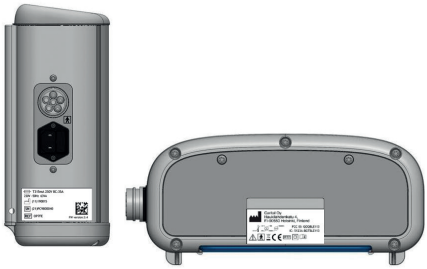
8. *To connect the three colour-coded tubes of the air tube system to their counterpieces, push and turn them clockwise.*

4 Commissioning

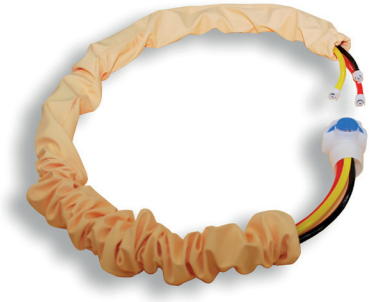
4.1 Components of the mattress system

Controller

Controller



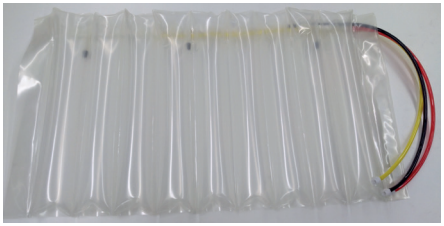
Type plate stickers on the side and at the bottom of the controller contain the device identification information.



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

The lockable power cable (5 m).

Cells



NeoICU Giraffe 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 of the cells.

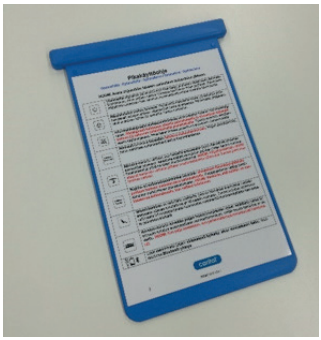
The NeoICU womb substitute system (WSS).

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

Other

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



The 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 reseller of the mattress system.

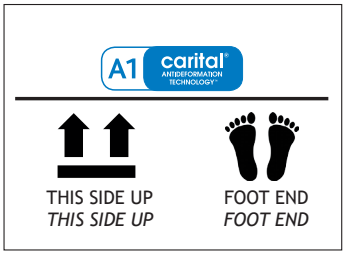
The temperature of the controller may have decreased or increased during transport beyond the limits of the allowable operating temperatures. Do not use the controller until it has been at room temperature (ca. +20 °C) for at least two (2) hours. This time is required for all the components of the controller to reach the normal recommended operating temperature (+10 °C...+35 °C).

4.2 Placing the mattress system onto the incubator

The air tubes of the cells have been routed out at the left or right corner of the leg part.
NOTE: The outlet of the tubes can be changed according to the incubator.

NeoICU Giraffe Medicase® hygiene cover

Place the support surface on the incubator ensuring that the cover label is placed at the foot end and facing upward as indicated on the label.



The label describing the correct installation direction of the mattress system.

Neo*ICU* mattress system contains a womb substitute system (WSS) that can be used to support the premature infant on the mattress. Place the WSS onto the support surface and fasten the straps under the Neo*ICU* support surface.

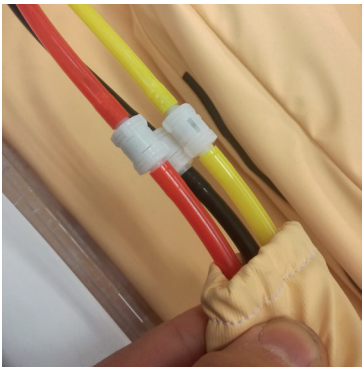
Womb substitute system (WSS)

A healthcare professional needs to assess the suitability of and need for the womb substitute system (WSS) separately in each treatment situation.

Do not use extra sheets, pillows or heavy position supports on the mattress system.

4.3 Commissioning the controller

1. *Suspend the controller firmly on an incubator structure with at least a 10-kilogram load-bearing capacity (e.g. side rail) in a way that does not prevent care or allow for the controller to accidentally fall. Ensure that the hanger is attached firmly.*

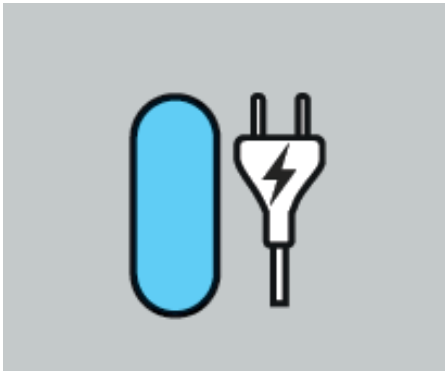


2. *To connect the three colour-coded tubes of the air tube system to their counterpieces, push and turn them clockwise.*

3. Connect the power cable to the mains connector of the controller.

4. Connect the Sixtube connector to 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 cord into an electrical outlet. The LED light indicating a connected mains cord lights up.

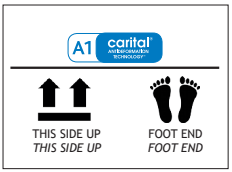
4.4 Lifting the controller

As a general rule, lift and handle the controller using two hands on both sides of the body or by using the hanger.

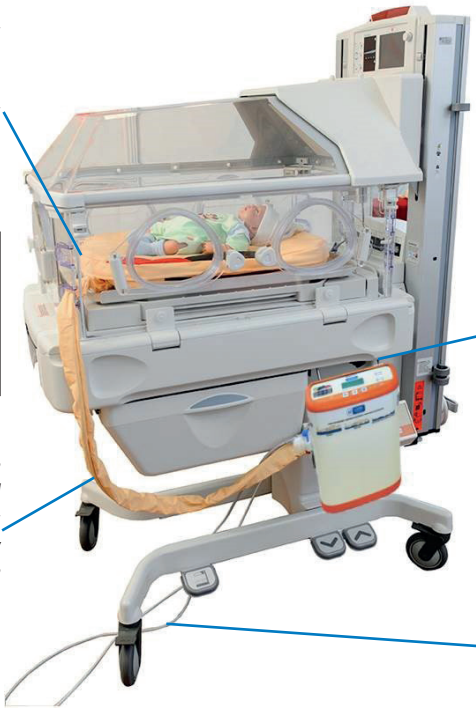
4.5 Things to check before use

The illustration in this section uses the Neo*ICU* Giraffe support surface variant.

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



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



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

Ensure that the power cable is plugged into its mains outlet in such a way that it does not present a risk of stumbling.

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. Ensure that the control panel and connectors of the controller are always accessible.

Ensure that the power cable is plugged into its mains outlet in such a way that it does not present a risk of stumbling.

5 Operation

5.1 Turning on the controller and selecting the weight category

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

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

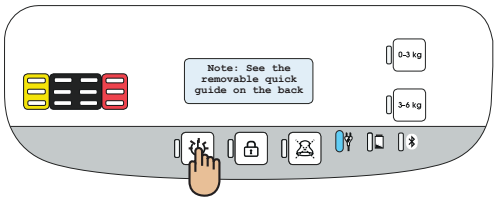
Only a healthcare professional can assess the need and suitability of using the mattress system in a treatment situation.

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

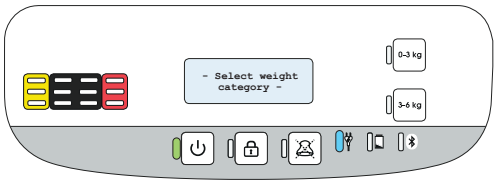
The size of the support surface should correspond to the size of the patient for the optimal adjustment of the pressure values in all parts of the support surface which correspond to different body parts.

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

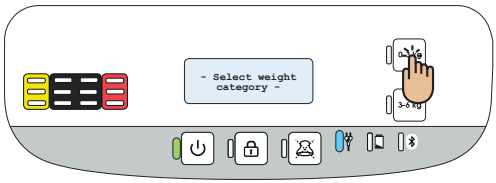
To turn on the controller, press down the device standby button briefly. The device prompts you to consult the quick guide that can be found on the removable tray behind the device.



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



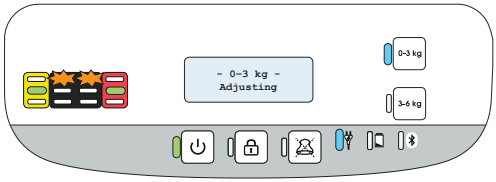
Select the patient's weight class by briefly pressing the relevant button.



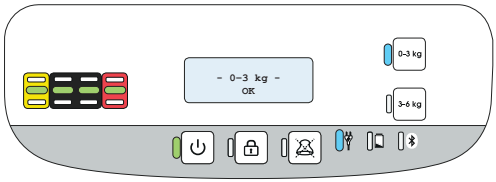
The mattress system will be set to the selected operation.

The device will first adjust the leg part, then the head and finally the torso.

The LED light bars for the cells will rise up or fall down with the adjustment of the cells.



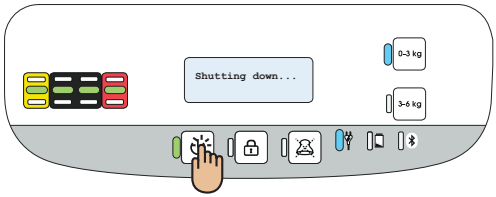
When the mattress system has successfully activated the selected operation, green LED indicators will light up at the centre of the LED light bar.



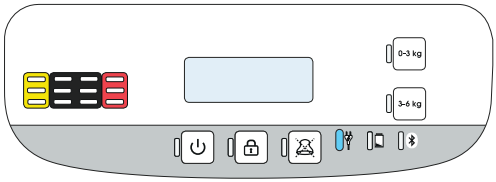
5.2 Turning off the controller

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.

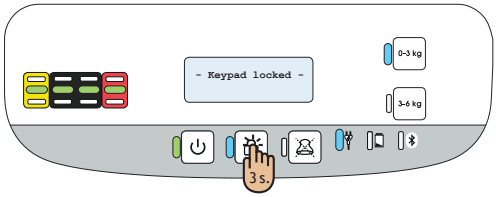


5.3 Keypad lock

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

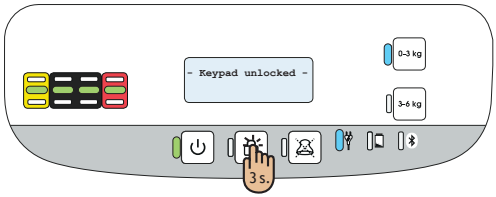
To lock the keys of the controller, press and hold down the keypad lock button for three (3) seconds while the device is running.

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



If you wish to deactivate the keypad lock, press and hold down the keypad lock button for three (3) seconds.

The LED on the keypad lock turns off.



5.4 Operating the controller using battery power

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. 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 charge 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 it cannot be run over by the incubator wheels, for instance, during transport. Once the patient transport is finished, connect the controller back to the mains. The cells will not deflate during transport.

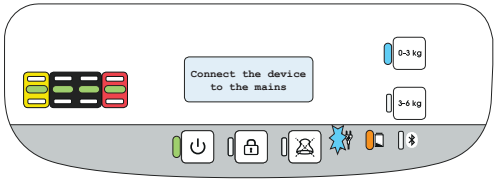
The controller must be connected to the mains whenever possible. In exceptional cases, the controller can be operated for a short time using battery power.

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

To maintain the battery's performance, keep the controller continuously connected to the mains 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 of the disconnected power cable by beeping five times.



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 6.8 (Information signals - Battery charge falls low).

5.5 Resuscitation situations

IN A RESUSCITATION SITUATION:
Turn off the device from the standby button and start CPR immediately without deflating the cells.

When resuscitating, turn off the device from the standby button and start CPR immediately without deflating the cells.

5.6 Fault situations

The identified fault situations of the mattress system and their detection are described in sections 6 and 7.2.

If the mattress system does not behave in accordance with the functions and situations described in this manual, disconnect the air tube set from the tube system of the cells and the power cable from the controller, turn off the controller and contact Carital® service.

5.7 Function during a power outage

Below you will find instructions for operating the mattress system during a power outage or during a higher risk of power outages in the operating environment.

1) Before a power outage:

- During normal circumstances the mattress system controller must always be connected to the mains for the internal battery to maintain as high charge as possible during a potential power outage. The battery will charge from empty to full in approximately 12 hours.
- As far as possible, prepare for supporting the operating environment with an emergency power supply.

To maintain the battery's performance, keep the controller continuously connected to the mains for 12 hours at least every three (3) months.

2) During a power outage:

- When the mains is cut off, the mattress system switches to running on the internal battery in accordance with chapter 5.4. The air cells will be controlled normally with the chosen function until the battery charge falls low in accordance with chapter 6.8. Under normal operating conditions, a fully charged battery will suffice for at least 30 minutes of continuous pumping of the cells.
- If the outage lasts for longer than the battery charge, the controller will shut down in accordance with chapter 6.8. When the controller shuts down, the pressure controlled by the mattress system will remain in the closed air system cells.
- Do not disconnect the Sixtube connector from the controller, as it will deflate the air cells.

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

3) After a power outage:

- If the charge of the mattress system battery has been sufficient during the power outage, the controller will continue functioning normally without further action when the power is restored.
- If the controller has shut down because of low battery (see 6.8), the controller must be restarted in accordance with chapter 5.1 when the power is restored and set to the desired function.
- In both cases mentioned above, you must ensure that after the outage the controller is continuously connected to the mains for 12 hours to regain a full battery.

6 Information signals

If the controller detects a failure or wishes to inform the user, it will provide an audible and visual signal 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.

The following includes a list of the 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 cell system)
- potential leak in the centre part

6.2 Check the air tubes (leak in tube or cell system)
- potential leak in the head part

6.2 Check the air tubes (leak in tube or cell system)
- potential leak in the leg part

6.3 Pressure target value invalid

6.4 SD card operating error

6.5 Scheduled maintenance notices

6.7 Battery operating error

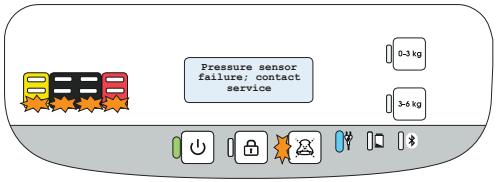
6.8 Battery charge falls low

6.9 Device internal error

6.10 Weight category not selected within time limit

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.

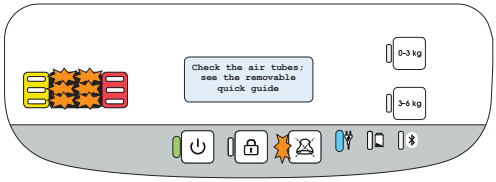


To acknowledge the failure indication signal, press the information signal reset button. Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

6.2 Check the air tubes (leak in tube or cell system)

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 operational setting within 45 minutes. This may be due to, for example, a disconnected tube or a leak in the cell or tube system.

The LED display is lit for the control area where the controller has failed to achieve the target pressure value for the setting. In this example, the issue has been detected in the torso part of the cells.

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.

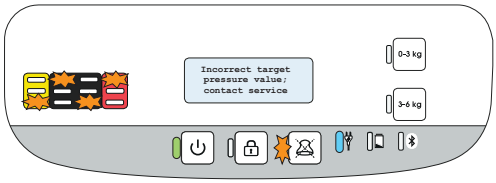
If you notice any loose tubes, connect them to each other as appropriate. Close the tube sleeve.

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”.



The fault status information signal can be acknowledged press the information signal reset button.

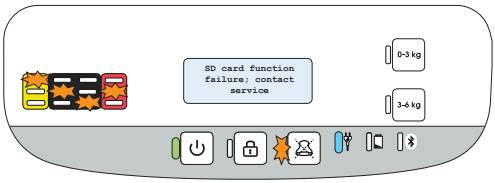
Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

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”.



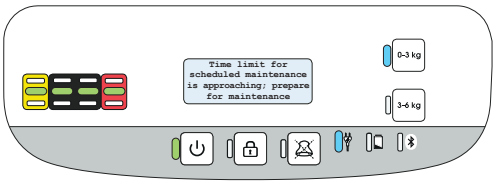
To acknowledge the failure indication signal, press the information signal reset button.

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.

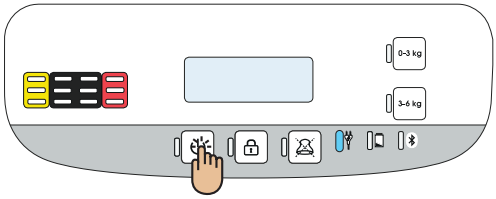
The LED will stop blinking and will be on continuously. Press and hold down the information signal reset button for three (3) seconds to turn off the LED and remove the visual signal from the display.

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 or the display refresh rate is otherwise disturbed, 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.



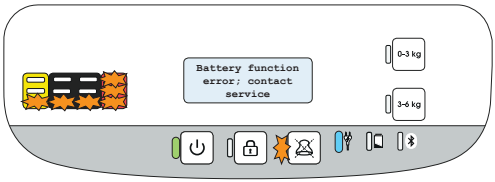
If the device does not resume normal operation, discontinue using the device and **contact Carital® service**.

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.
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.

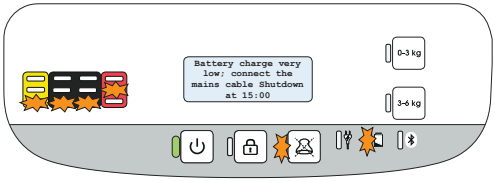
To acknowledge the failure indication signal, press the information signal reset button.

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

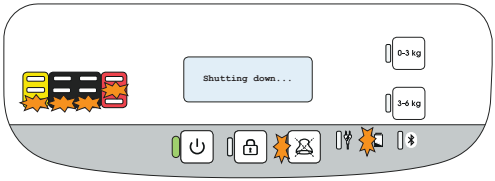
When the charge of the internal battery falls to a very low level (7.2V–7.0V), the controller will provide an information signal.



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.

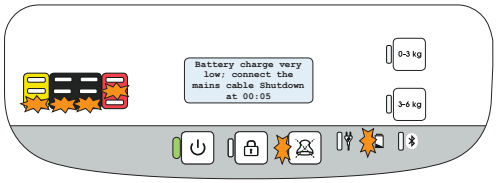
After 15 minutes, the device will turn off completely and indicate this with a sound and on the device screen.



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

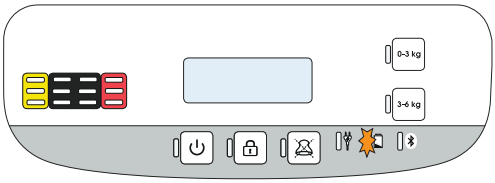
If the device shuts down after the counter process and is restarted, the device turns off after 5 seconds from booting.

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



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.

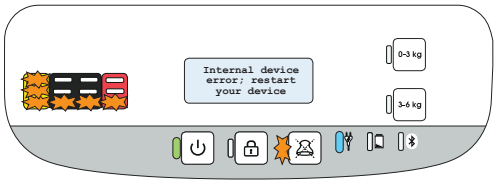
To maintain the battery's performance, keep the controller continuously connected to the mains for 12 hours at least every three (3) months.

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".

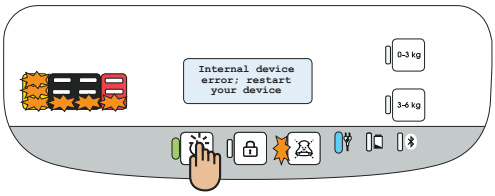
The indication signal of this one-time malfunction failure state can be acknowledged by pressing the acknowledgement button of the indication signal.

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.



6.10 Weight category not selected within time limit

If the weight category (0–3 kg / 0–6 kg) has not been selected within 15 minutes of turning on the device, the device gives an information signal.

The information signal can be acknowledged by selecting either weight category function or, alternatively, by pressing the information signal acknowledgement button for three (3) seconds. The device will start a new 15-minute waiting cycle.

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 use or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

If the mattress system does not behave in accordance with the functions and situations described in this manual, disconnect the air tubing from the tube system of the cells 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.

Serious incidents related to the medical devices described in the user's guide that directly or indirectly resulted in, could have resulted in or could result in 1) death of a patient, user or other person 2) serious or permanent deterioration in the health of a patient, user or other person 3) serious threat to public health must be immediately reported to the manufacturer and the Therapeutic Goods Administration (TGA) (AUS) or the New Zealand Medicines and Medical Devices Safety Authority (NZ).

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 any liquid.

7.1.2 Cells

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

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

Dry at room temperature.

7.1.3 Medicase® hygiene 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

- Open the zipper and turn the cover so that the textile sides are facing out
- Recommended heat disinfection 10 min at 70 °C
- Max. washing temperature 95 °C
- Hang to dry (or use 1-point tumble dry in a washing bag)
- Ensure that the cover is entirely dry before commissioning it
- Do not chlorine bleach
- Do not iron
- Do not dry wash
- Do not use conditioners

Ensure that the cover is entirely dry before commissioning it.

7.1.4 Foam plastic supports

Remove the integrated foam plastic support from the cover (Note! Neo*ICU* Giraffe only). After washing and drying the cover, the support can be placed back in their compartments. Close the zippers.

The foam plastic supports must not be washed.

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 been damaged

The controller should be visually inspected for the condition of the power cord 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 mounting of the hanger and the readability of the technical type plate markings should be checked.

If you notice any damaged components, 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
- whenever the patient using the mattress system changes or weekly in long-term care

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

If you notice any damages, contact Carital® service.

7.2.3 Cells

The condition of the cells must be checked

- when cleaning
- if you suspect that the cover is broken or the interior is contaminated
- whenever the patient using the mattress system changes or weekly in long-term care

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

If you notice any damaged cell components, 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 use, 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 support surface is used in violation of the instructions specified in the user's guide, and 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.

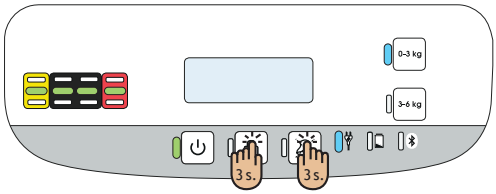
The controller will alert you to the need of scheduled maintenance one month before the deadline for the scheduled maintenance is reached.

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

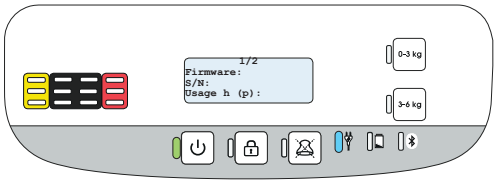
Scheduled maintenance may only be carried out by Carital® service.

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

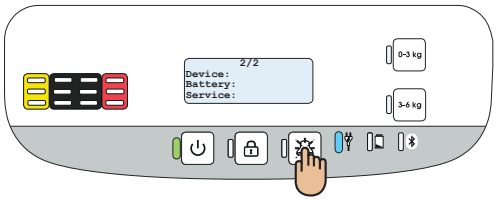
With the device running, press and hold down the lock and information signal reset buttons for three (3) seconds to access the maintenance view.



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*).

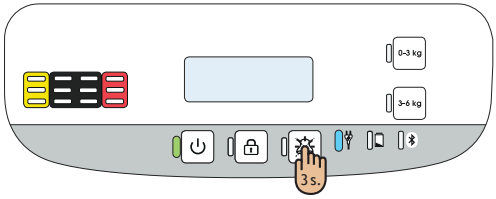


To change from one tab to another in the maintenance view, press the information signal reset button.



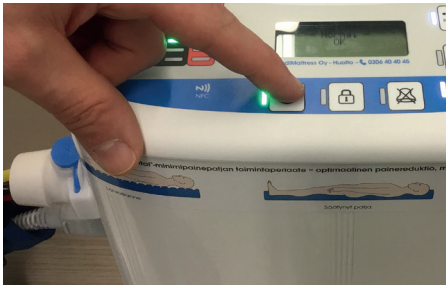
To return from the maintenance view to the normal operating mode, press and hold down the information signal reset button for three (3) seconds.

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

The cells 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...+50 °C > +35 °C...+70 °C with vapour pressure 50 hPa
Air humidity	max. 90%

- Store in a clean, dry place.
- The cells and the cover can be rolled up for storage using, for example, the transport bag (accessory).
- The cells and the cover can be hung on a bar with the bottom facing down, folded once with the bottom parts against each other or spread out flat.
- 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 the battery's performance, keep the controller continuously connected to the mains 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.

8.1 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 packaging of the mattress system can be recycled with cardboard. The styrofoam packaging supports and the plastic packaging can be sorted into plastic packaging collection.

9 Warranty

The Carital® Neo*ICU* and Neo*IW* mattress systems have a 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.

In matters related to the warranty, 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, the controller has components which may break if the controller is subjected to an impact, force or shake that exceeds the design standards. The limited manufacturer warranty does not apply to situations where the product has been mishandled.

10 Technical specifications

General description of medical device		
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
Basic UDI-DI (GMN)		Neo*ICU* - 6429810591NEID4 Neo*IW* - 629810591NEWDY
REF code (total product)		Neo*ICU* – NEIAEC*a6bccddde* Neo*IW* – NEWAEC*a6bccddde* *a* = tube set type, *b* = possible controller add-on, *cc* = cell type, *ddd* = cover type, *e* = possible mattress system accessory
Controller		
REF code (controller)		Neo*ICU* - NEIAEC Neo*IW* - NEWAEC
Controller dimensions (W x L x D)		26 x 26 x 11.5 cm
Weight		5 kg
Sound level		26,41 dB LAeq (operating time 24 hours, distance 1 m)
Operating voltage		230V 50HZ
Nominal input power		max. 35W
Battery type		Lithium-ion, 7.26V, capacity 2,650mAh, manufacturer: Celltech 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
Separating device		Power cable - AS/NZS 3112/C17, 5 m
Electromagnetic compatibility		See Appendix 1: Carital Controllers - Guidance and Manufacturer's Declarations – EMC
	**Applied part** **Applied part type**	Support surface (cover and cells) BF
IP22	**IP class**	IP22 (protected against particles with a diameter of 12.5 mm 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

Mattress & air tube system	
Mattress dimensions (W x L x H)	35 x 65 x 4 cm (Neo*ICU*), 48 x 66 x 4 cm (Neo*ICU* Giraffe) 47 x 74 x 4 cm (Neo*IW*)
Weight (support surface)	1-1,5 kg (depending on cell dimensions)
Materials	**Cells:** TPU (cells, bottom mat & cell nipples); PBT (base adapters); POM (CPC adapters) **Air tube system:** TPU (air tubes); POM (CPC adapters) **Covers:** PU/PES (Medicase) **Foam plastic supports (Note! Neo*ICU* with Giraffe cells variant only):** PU/PES (cover); viscoelastic foam plastic - 50 kg/m^3 - 1,6 kPa CLD 40 % (foam insert composition)
Flammability (support surface)	EN 597-1:2015; EN 597-2:2015; IMO 2010 FTP Code, Annex 1, Part 9
Applied legislation	
CE MD	Class 1 medical device under the EU Medical Device Regulation 2017/745 (MDR) (Rule 1 - Non-invasive devices / Rule 13 - All other active devices).
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 IMO 2010 FTP Code, Annex 1	

11 Contact details of the manufacturer, distributors and service

Manufacturer:

MediMattress Ltd.
Haukilahdenkatu 4
FI-00550 Helsinki
tel. +358 306 40 40 40
info@medimattress.fi

Distributors and Service:

Australia

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PO Box 562
Wembley
6193
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T: +61 (0) 423 852 810
E: info@directhealthcareservices.com.au

HospEquip Pty Ltd.
Canning Vale
Western Australia
6155
T: +61 (08) 9456 166

New Zealand

USL Medical
494 Rosebank Road,
Avondale,
Auckland 1026,
New Zealand
T: +64 9 551 2010
customerservices@uslmedical.co.nz

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	±0.5kV, ±1kV, ±2kV Line-to-ground	±0.5kV, ±1kV, ±2kV 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	