

Instructions for use

2025-09-30

CuroCell® IQ, CuroCell® A4, CuroCell® M4
Air mattress systems

Instructions for use item number: 95-001436-EN0000



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Read the instructions carefully before use.
All user instructions and safety instructions must be followed.

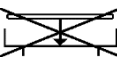
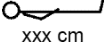
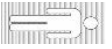
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1 Symbol key

Symbols to convey medical device information			
	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	Medical device		Distributor
	Unique device identifier		Date of manufacture
	Warning		Caution
	Catalogue number		Batch code
	Serial number		Read the instructions for use
	Consult instructions for use		
Symbols for product information – Control unit			
	Temperature limit (room temperature)		Type BF
IP__	Ingress protection class		Class II equipment (double isolated)
CPR	Cardiopulmonary resuscitation		Electrical hazard
	Indoor use		Atmospheric pressure limitation
	Humidity limitation		Keep dry
	Fragile, handle with care		

Symbols for product information - Mattress			
XXXX-XX-XX	Year-Month-Day		Foot placement
	Patient information – pressure ulcer category		Recommended patient weight
	Counteracts shear		Do not rotate
	Heel function		Do not turn around
	Place on top of existing mattress		Place on top of the bed
	Do not place directly on bed		Do not place on top of another mattress
	Minimum length		The mattress should be used with the patient lying lengthways
	Size of mattress		
Symbols for cleaning, reconditioning and recycling			
	Machine wash at 95 °C		Machine wash at 70°C
	Drip dry		Do not machine wash
	Tumble dry		Do not tumble dry
	Do not iron		Do not dry clean
	Wipe clean		Chlorine
	Do not dispose of with household waste		Recycling

2 Warnings- and safety precautions



The following points contain important information about using the product.

- The instructions in this document shall always be followed.
- The instructions for use shall always be kept together with the product.
- It is recommended to always use the original packaging to store and transport the product.
- The product must be placed and used so that it does not become trapped or damaged. Be particularly aware of trapping damage when using side rails.
- The mattress has a hygiene cover, avoid using multiple hygiene covers as this can affect the vapor permeability of the cover.
- The mattress has a hygiene cover, make sure that the patient is positioned correctly to avoid the risk of suffocation. The hygiene cover does not allow liquid to penetrate, but is vapor permeable.
- Use of this product adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this product and the other equipment should be observed to verify that they are operating normally.



Adhere to the following points to minimize risk for fire, personal injury, equipment- or property damage.

- When the product is used for individuals needing special supervision, such as children, continuous monitoring is required.
- Do not use close to or in contact with fire sources/hot surfaces, such as fire, burning cigarettes, hot lamps, heating fans or heating stoves/open fires as this could damage the product.
- Do not store or use the product in direct sunlight. The product may be damaged by the elevated temperature and UV light.
- The product must not be combined, assembled or repaired with parts (e.g. control unit and mattress), accessories or spare parts other than those described in this manual or other documentation from Care of Sweden. The product must not be modified in any way as this might result in hazards.
- The handles on the mattress are only intended for lifting the mattress without a patient on.



Adhere to the following points to minimize risk for damage caused by electronic components.

- Do not open the control unit housing – risk for electric shock. Servicing and maintenance must be performed by Care of Sweden or one of its authorized service technicians.
- Do not use the product in bathrooms or other area where there is a risk of the control unit coming into contact with water or other liquids. Except for specified cleaning, never handle a product that has come into contact with water/liquid. Pull the plug out of the electrical socket immediately and send the product to an authorized service technician for servicing.
- Strong magnetic fields or wireless communication equipment (e.g., wireless home network products, mobile phones, walkie-talkies, cordless phones and their base stations, radio transmitters, etc.) may affect the product's functionality and should be kept at a distance of at least 1 meter from the control unit.
- Never use the product if the power cable, plug of the control unit or power supply housing is defective, if the control unit housing is damaged, or if it is not functioning properly. Contact an authorized service technician for examination and repair.
- Never connect anything other than the Care of Sweden supplied power supply to the control unit power cable connector.
- Never use the external communication input (3,5mm connector), this input should only be used by the manufacturer.
- Pull out the power supply from the electrical socket before the product is cleaned/reconditioned.
- The mains adapter's connector is not insulated against liquid, do not let the mains adapter come into contact with liquid.
- Check that the mains voltage and frequency printed on the plug of the mains adapter are correct according to your electrical outlet. Also, ensure that the shape and configuration of the contact connector is compatible with the connection.
- Never connect any other mains adapter to the control unit besides the one from Care of Sweden.

3 Introduction

These air mattress systems may be used as an aid to prevent and treat pressure ulcers/pressure injuries.

CuroCell® IQ is a control unit that weighs the patient and adjusts the pressure without an option for the operator to choose program.

CuroCell® A4 is a control unit that sets the air pressure in the mattress based on the patient's length, weight and position without need for manual settings. It offers the operator the option to adjust program and comfort.

CuroCell® M4 is a control unit where the operator must manually adjust the pressure in the mattress based on the weight of the patient.

CuroCell® IQ, CuroCell® A4 and CuroCell® M4 are compatible with four different mattresses: CuroCell® CX10, CuroCell® CX15, CuroCell® CX16 and CuroCell® CX20. See more information about the mattresses in section 9.3.

These instructions for use contain information about three different systems. Read the label of your products carefully to understand which products you are using.



For safety reasons you shall carefully read the recommendations and instructions in these instructions for use before installing and using the product.

3.1 General information

The system is a medical device with CE marking in accordance with MDR (EU) 2017/745. According to this regulation the manufacturer is required to report all accidents or incidents involving the products. All information involving accidents or incidents relating to our products, shall be reported immediately to Care of Sweden.

3.2 Intended purpose

The mattress system consists of a control unit and a mattress and is intended to be used as an aid in the prevention and treatment of pressure ulcers/pressure injuries (PU/PI).

3.3 Indications

Suitable for a wide range of patients with increased risk for pressure ulcers/injuries, including those with superficial ulcers, up to category IV in association with an individualized plan of care.

3.4 Intended patient population

The mattresses are intended for use by patients with a recommended minimum length of 120 cm. Patients who, due to amputated legs, do not reach 120 cm can use the air mattress system. The specifications for weight are listed in the table below.

Mattress	Recommended patient weight
CuroCell® CX10	≤ 200 kg
CuroCell® CX15	≤ 220 kg
CuroCell® CX16	≤ 200 kg
CuroCell® CX20	≤ 250 kg



For certain patients, e.g. amputees, the recommended length measurement may not be reached. Patients in these groups may require other settings as the entire surface is not under load. For these patients, an air mattress system that allows for adjustment of settings may be suitable, eg. CuroCell A4.

3.5 Intended user

The mattress system is intended to be used by healthcare professionals. The training of the intended user shall be in compliance with local regulations. In a home care environment, the intended user can also be a lay person.

A lay person is defined as any person who is over 16 years old and has a minimum of 8 years of elementary school education. The lay person must be able to read unhindered and must not have any cognitive impairments. The lay person must also not have impaired vision or hearing as light and sound signals must be able to be interpreted. If the patient fulfils these criteria's the patient can also be a lay person.



The mattress may be inappropriate for use during x-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic errors.

3.6 User qualification

Training is not mandatory to use the system. Lay persons are qualified to operate the air mattress systems.

The table below describes common user scenarios and what type of user that shall perform each activity. **Healthcare professionals shall inform lay persons on which activities the lay person is allowed to perform according to the table below.**

User scenario	Healthcare prof.	Lay person*	Patient
Prescribe mattress system	X		
Transportation of system to patient	X		
Unpacking and installing the system	X		
Patient entry/exit mattress	X	X	X**
Connect mattress to control unit	X		
Use of mattress	X	X	
Use of control unit	X	X	X**
Cleaning the system	X		
Reading and understanding the user manual (IFU)	X	X	X
Inform lay person	X		
Perform CPR on patient in case of emergency	X	X	
Uninstalling the system	X		
Transport and storage system between patients	X		
Reconditioning and disposal of the system	N/A	N/A	N/A
Placing the control unit when 3-meter tube is connected	X	X	
Open and clean comfort cover	X	X	

* Definition of 'Lay person' according to MDR 2017/745: 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline.

** Maxfirm can be activated by patient when a long hose is used.

3.7 Intended use environment

The mattress system is intended to be used during hospital care, long term care and home care. Avoid direct sunshine and extensive noise in the room.

3.7.1 Optimum environmental conditions

The product is intended to be used indoors in room temperature.

3.8 Contraindications

There are no known contraindications. It is necessary for the prescriber of the mattress to make an individual assessment of the patient and decide whether the characteristic of the mattress is beneficial for the patient based on diagnosis.

3.9 Clinical benefit

The clinical benefits for CuroCell® IQ, CuroCell® A4 and CuroCell® M4 together with any of the mattresses included in this instruction for use are:

- As an aid in prevention and treatment of pressure ulcers/pressure injuries (PU/PI) up to and including category IV.
- Reduction of shear forces.
- A safe, comfortable pressure redistribution mattress system which is easy to handle.
- Silent running control units.

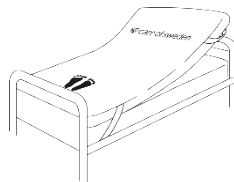
4 Assembly and installation

When the product is unpacked, check that no parts are damaged. If damage is found, contact Care of Sweden or your local distributor before using the product. Do not use sharp objects when unpacking as it might damage the product. The operator should follow and check the below information before use.

4.1 Install the mattress with a 1 meter tubing set

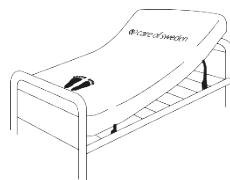
When using an overlay mattress (CuroCell® CX10):

1a. Place the overlay mattress on the base mattress. Secure the mattress to the base using the fastening straps under the mattress.



When using a full replacement mattress (CuroCell® CX15, CuroCell® CX16, CuroCell® CX20):

1b. Place the mattress on the bed base. Secure the mattress to the bed using the fastening straps on the under the mattress. If the mattress has fastening straps, these can be used to fasten the mattress to the moving parts of the bed



Make sure that the mattress is the correct size for the bed.



Check the cells and press studs to ensure they are correctly assembled.



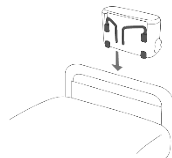
Make the bed with sheets.



The mattress should be used lying in lengthwise direction on the mattress, with feet at the foot end of the bed, marked with the foot symbol.



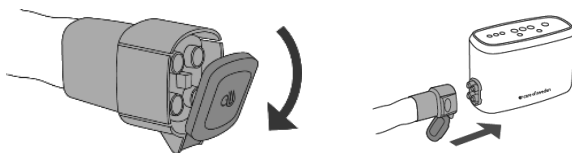
2. Hang the control unit on the foot end of the bed or place it on a level, steady surface.



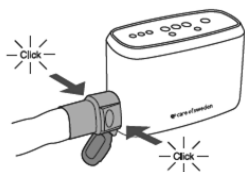
3. If the mattress is equipped with a cable holder, place the power cable in the cable holder. Otherwise, place the power cable so there is no risk of stumbling over it, running over it with the bed wheels, or getting it jammed when raising or lowering the bed. Put the power cable into the control

unit.

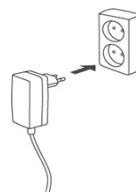
4. Open the lid on the air tube connector (marked CPR) and connect it to the side of the control unit. Ensure that the CPR connector always can be reached when the system is used.



5. A click is heard and felt when correctly connected. Ensure that both sides of the connection are closed.



6. Plug the external power supply that comes with the product into an approved and easily accessible electrical socket (100– 240 V). Check that the switch on the side of the control unit is set to '0' (off). Ensure that the power supply always can be reached when the system is used.



Do not hold the 12V plug on the power supply while touching the patient.



Never use a power supply that is not provided by Care of Sweden.



The power supply is a potential risk. Never use the 3,5 mm outlet, this shall only be used by authorized technicians or Care of Sweden.



Route the power cable to the control unit carefully to avoid tripping and strangulation.

4.2 Install the mattress with a 3 meter tubing set



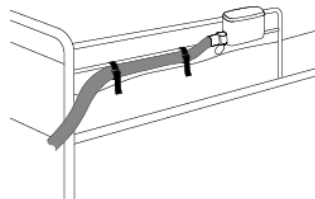
Read the entire instruction before installation is executed.

1. Ensure that the power cable is not plugged into the control unit. This is to avoid the power cable getting caught and causing potential damage.
2. Place the control unit by either hanging it on the bed rail or placing it on a flat, stable surface beside the bed. The control unit can be placed on either the right or left side of the bed. To avoid the risk of tripping over the hose, it is preferable to place the control unit on the side of the bed that is not used for entering or exiting.

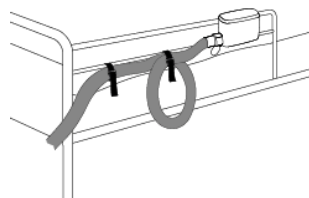


When using a 3 meter tubing set, the control unit should not be placed on the foot end of the bed.

3. Place the control unit so that the patient can safely see and reach the control panel while sitting.
4. To prevent the risk of tripping over the hose, secure the hose with the two fastening straps as shown in the figure to the right.



5. If the tubing needs to be shortened, a “loop” can be made and attached to the bed using the fastening straps as shown in the figure to the right.



If the control unit must be placed on the same side as entering or exiting due to a wall or similar, it is advisable to make the “loop” at the foot end of the bed.



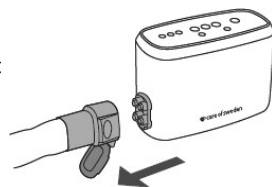
Ensure that the tubing is positioned in a way to eliminate the risk of tripping over it or causing it to be caught when the bed is raised or lowered. Be particularly careful if the tubing has been placed on the same side as bed entry/exit. Also, ensure that there is no risk of running over the tubing with the bed.

5 Common operations

The following operations apply to all products included in this instruction for use.

5.1 Cardiopulmonary resuscitation – CPR

In case of an emergency where CPR (Cardiopulmonary resuscitation) is necessary, remove the connection (marked 'CPR') from the control unit and leave the lid open to empty the mattress of air quickly.



5.2 Shut down (Pack&Go)

The product may be packed as follows:

1. Ensure that no-one is lying on the mattress.

2.  Unlock the panel by pressing the Panel lock button for 2 seconds.

3.  Press the Pack&Go® button and hold it down for 2 seconds.

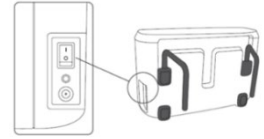
4. The Pack&Go® diode will flash during deflation. The mattress will empty of air and be ready to be folded together within 20 minutes. The control unit gives an audible signal once deflation is complete.

5. Carefully fold the mattress together, place the control unit between the folds of the mattress and place the system in a transportation bag (accessory) or equivalent for protective storage. Ensure that the whole power supply is packed.

5.3 Restart

If a restart is required:

1. Set the On/Off switch on the side of the control unit to '0' (off).
2. Wait for approximately ten (10) seconds.
3. Set the On/Off switch on the side of the control unit to '1' (on).



5.4 Power failure

In the event of a power failure, unplug the CPR connection, close the lid, and place the CPR connection at the end of the bed. The mattress will retain air for at least 12 hours. Check that the pressure in the mattress is not too hard or too soft.

5.5 Maximum pressure notification



When the function Maximum pressure has been used for a long time, the Maximum pressure diode will blink. If the use is intentional, ignore the notification.

5.6 Transport function

If the patient needs to be moved in bed it is important to do the following preparations.

1. Unplug the CPR connection.
2. Close the lid on the CPR.
3. Place the CPR connection at the end of the bed.
4. Remove the power supply from the electrical socket.

The mattress will retain air for at least 12 hours. We recommend using this function for short periods only.

5.7 Sitting positioning



If the head of the bed needs to be elevated, elevate the knees before or along with the head to create a counterforce, ensuring support and preventing sliding or shearing.



When the Gentle Alternating Low Pressure Mode or the Pulsating Mode is used and the head end of the bed is raised, make sure that the patient and/or the mattress does not move downwards due to the movement in the mattress.

6 Operation CuroCell® IQ

The following instructions are only applicable to CuroCell® IQ, regardless of which mattress that is used. Read the label of the control unit carefully to know which product you have.



If the control unit has been stored in its minimum or maximum storage temperature (- 25°C or 70°C), wait at least one (1) hour before starting the control unit. This time is based on an ambient temperature of 20°C.

How to start the system:

1. Set the on/off switch on the side of the control unit to 1 (On).
2. When using a mattress with a safety mattress (CuroCell® CX15, CuroCell® CX16 or CuroCell® CX20), the safety cells will be inflated first. Then, the remaining cells will be inflated.

The inflation of the cells takes about 20-40 minutes, depending on the size of the mattress. When the mattress is inflating, the diodes below light up in orange.



3. Once the diodes goes out, the patient can be placed on the mattress.



When using a lift to place the patient on the mattress while the head end of the bed is raised, make sure that the patient is not placed too high on the mattress. Otherwise, there is a risk of shear.



To minimize the risk of wounds occurring on the feet, make sure that the patient does not come in contact with the hangers of the control unit.

4. The control unit adapts the inner pressure of the mattress to the patient. During this time, the diode above the selected program flashes. While the LED is flashing, the system is working to set the correct pressure. When the LED stops flashing, the mattress has adapted the internal pressure to the patient.

5. Perform a function control to ensure that the settings are correct.



During use, the control panel might reach a temperature of 56°C.



Button	Function
	Mute the information signal
	Pack & Go®. Function for deflating the system
	Maximum pressure (caring mode)
	Information signal
	Incorrect connection of the air connector (CPR)
	Check-symbol. System is ready to use
	Notification diodes

6.1 Function (Automatic)

The mattress system independently and without manual adjustment controls the inner pressure of the mattress according to the weight, length, and position of the patient. No manual action needs to be performed to adjust the inner pressure of the mattress. This function works as follows:
At start-up, automatic setting of the inner pressure of the mattress is always carried out according to the weight and length of the patient. If the patient moves noticeably or changes their position, the system will independently control the inner pressure of the mattress. The system performs an automatic setting at fixed intervals even if no significant changes have occurred.
After automatic setting, the system returns to Pulsating Mode.

6.2 Program

Program	Symbol	Explanation
Pulsating mode		A dynamic program that combines alternating movements with a constant low pressure. This gives a large contact area and reduces high peak pressures. When the Check symbol is green, the Pulsating mode is activated.

6.3 Cardiopulmonary resuscitation - CPR

See section 5.1.

6.4 Function control

A function control shall be performed regularly to ensure that the product is working correctly.



Ensure that the air mattress is filled with air before performing function control. This is indicated by a green light above the chosen program.

The function control is performed by verifying that a green light is illuminated on the control panel for the selected program. Additionally, check for any notifications on the control panel that may indicate a malfunction. If any notifications are visible, follow the steps in section 6.13.

6.5 Shut down (Pack&Go)

See section 5.3.

6.6 Restart

See section 5.4.

6.7 Power failure

See section 5.4.

6.8 Maximum pressure (caring mode)



With this function, the entire mattress is inflated and provides firmed support. This function reverts to the previous setting after 20 minutes. Use this function during caring, shifting the patient’s position, or during bed entry and bed exit.

6.9 Maximum pressure notification

See section 5.5.

6.10 Transport function

See section 5.6.

6.11 Sitting positioning

See section 5.7.

6.12 Notifications



Different notifications exist based on how serious the warning is. With a malfunction or an error, a notification will be given by way of a flashing warning triangle. To mute the warning signal, press the mute button.



When a notification occurs, the current cycle time diode will turn off and a notification code is shown on the four different cycle time diodes (10, 15, 20, 25). To read the cycle time during the error notification, unlock the control panel.

6.13 Table of notifications

Information about each notification is shown in the notification table on the next page.

Notifications that are described under ‘Notification (sound)’ are shown by both light and sound. The error code will be displayed until the error has been rectified. If the mute button is pressed the audible warning will cease for a period of 5 minutes and will return until the error has been rectified.

Notifications that are described under ‘Notification – (light)’ are shown only by light. The error code is shown until the system is restarted.

Notification (sound)	Description and troubleshooting
	High temperature. Valves and compressors are turned off. If the control unit is in direct sunlight, relocate it. Otherwise, contact the technical support.
	Default settings are not completed. Contact the technical support.
	Incorrect input voltage. Make sure that the correct power supply is used, otherwise contact the technical support.
	Low pressure. Secure the CPR, mattress, air tubes and air filter. If the problem remains, contact the technical support.
	Automatic setting failure. The correct pressure has not been reached within the time limit. If the problem remains, contact the technical support.
	Leakage under the automatic setting period. The mattress is leaking too much for the weighing to be accomplished. Control the mattress and the air connections. If the problem remains, contact the technical support.
	High pressure. The pressure cannot be reduced to the desired value within the time limit. Contact the technical support.
	The automatic setting has been restarted too many times during the automatic setting period. Contact the technical support.
	The mattress control parameters have not been read. Connect the CPR or contact the technical support.
	The mattress control parameters have been changed during the use. Restart the system. If the problem remains, contact the technical support.

Notification (light)	Description and troubleshooting
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Information to service technicians: this notification shows a leakage in the blue cell section. More information in the service manual for CuroCell® IQ.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Information to service technicians: this notification shows a leakage in the green cell section. More information in the Service manual for CuroCell® IQ
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Information to service technicians: this notification shows a leakage in the red cell section. More information in the Service manual for CuroCell® IQ

7 Operation CuroCell® A4

The following instructions are only applicable to CuroCell® A4, regardless of which mattress is used. Read the label of the control unit carefully to know which product you have.



If the control unit has been stored in its minimum or maximum storage temperature (- 25°C or 70°C), wait at least one (1) hour before starting the control unit. This time is based on an ambient temperature of 20°C.

How to start the system:

1. Set the on/off switch on the side of the control unit to 1 (On).
2. When using a mattress with a safety mattress (CuroCell® CX15, CuroCell® CX16 or CuroCell® CX20), the safety cells will be inflated first. Then, the remaining cells will be inflated.

The inflation of the cells takes about 20-40 minutes, depending on the size of the mattress. When the mattress is inflating, the diodes below light up in orange.



3. Once the diodes goes out, the patient can be placed on the mattress.



When using a lift to place the patient on the mattress while the head end of the bed is raised, make sure that the patient is not placed too high on the mattress. Otherwise, there is a risk of shear.



To minimize the risk of wounds occurring on the feet, make sure that the patient does not come in contact with the hangers of the control unit.

4. The control unit adapts the inner pressure of the mattress to the patient. During this time, the diode above the selected program flashes. While the LED is flashing, the system is working to set the correct pressure. When the LED stops flashing, the mattress has adapted the internal pressure to the patient.

5. Perform a function control to ensure that the settings are correct.



During use, the control panel might reach a temperature of 56°C.



Button	Function
	Mute the information signal
	Panel lock
	Pack & Go®. Function for deflating the system
	Maximum pressure (caring mode)
	Information signal
	Incorrect connection of the air connector (CPR)
	Comfort settings
	Cycle time settings (10, 15, 20, 25 minutes). The diodes are also used for error notifications.
The old version of display has the following buttons for program modes	
	Gentle Alternating Low Pressure (GALP)
	Pulsating mode
	Constant Low Pressure (CLP)

The new version of display has the following buttons for program modes <i>Manufactured from 2025-03-27</i>	
	Gentle Alternating Low Pressure Mode (GALP)
	Pulsating mode
	Constant low pressure (CLP)

7.1 Function (Automatic)

The mattress system adjusts the inner pressure of the mattress according to the weight, height, and position of the patient. No manual action is needed to adjust the inner pressure of the mattress. This works as follows:

At start-up, an automatic setting of the inner pressure of the mattress is carried out according to weight and height of the patient. If the patient moves noticeably or changes their position, the system will adjust the inner pressure of the mattress. The system also performs an automatic setting at fixed intervals even if no significant changes have occurred.

7.2 Panel lock



Press the Panel Lock button to lock or unlock the control panel. The button indicates when the panel has been locked. The screen locks automatically if left untouched for five minutes. This is to prevent the settings being changed accidentally. To unlock, press the button for 2 seconds.

7.3 Program

Choose program by pressing the button on the control unit. Choose between three programs:

Program	Symbol	Explanation
Old version of display for program modes		
Constant Low Pressure (CLP)		Air pressure is distributed evenly in all air cells. The control unit adapts the pressure according to the patient's weight and length. No cycle time settings are needed.
Gentle Alternating Low Pressure (GALP)		A dynamic program that regularly alternates the air pressure to relieve pressure on the body. The cycle period can be changed according to patient needs and requirements. Choose between 10, 15, 20 or 25 minutes. The longer the cycle period, the slower the alternations. Ten (10) minute cycles are recommended.
Pulsating mode		A dynamic program that combines alternating movements with a constant low pressure. This gives a large contact area and reduces high peak pressures. The cycle period can be changed according to the patient needs and requirements. The longer the cycle period, the slower the alternations. Ten (10) minute cycles are recommended. This program is recommended due to its documented clinical effect.
New version of display for program modes		
Constant low pressure mode (CLP)		Air pressure is distributed evenly in all air cells. The control unit adapts the pressure according to the patient's weight. No cycle time settings are needed.
Gentle Alternating Low Pressure Mode (GALP)		A dynamic program that regularly alternates the air pressure to relieve pressure on the body. The cycle period can be changed according to patient needs and requirements. Choose between 10, 15, 20 or 25 minutes. The longer the cycle period, the slower the alternations. Ten (10) minute cycles are recommended.
Pulsating mode		A dynamic program that combines alternating movements with a constant low pressure. This gives a large contact area and reduces high peak pressures. The cycle period can be changed according to the patient needs and requirements. The longer the cycle period, the slower the alternations. Ten (10) minute cycles are recommended. Pulsating mode is recommended due to its documented clinical effect.

7.4 Cardiopulmonary resuscitation - CPR

See section 5.1.

7.5 Function control

A function control shall be performed regularly to ensure that the product is working correctly.



Ensure that the air mattress is filled with air before performing function control. This is indicated by a green light above the chosen program.

The function control is performed by verifying that a green light is illuminated on the control panel for the selected program. Additionally, check for any notifications on the control panel that may indicate a malfunction. If any notifications are visible, follow the steps in section 7.15.

7.6 Shut down (Pack&Go)

See section 5.2

7.7 Restart

See section 5.3

7.8 Power failure

See section 5.4

7.9 Maximum pressure (caring mode)



With this function, the entire mattress is inflated and provides firmed support. This function reverts to the previous setting after 20 minutes. Use this function during caring, shifting the patient's position, or during bed entry and bed exit.

7.10 Maximum pressure notification

See section 5.5

7.11 Transport function

See section 5.6

7.12 Sitting positioning

See section 5.7

7.13 Comfort settings



The pressure can be increased in two steps depending on the patient's comfort requirements. This increase is made based on the automatic setting in 7.1. The selected setting is shown by a green light.



When only parts of the mattress are under load, for example in the case of amputees, it might be necessary to raise the comfort setting.

7.14 Notifications



Different notifications exist based on how serious the warning is. With a malfunction or an error, a notification will be given by way of a flashing warning triangle. To mute the warning signal, press the mute button.



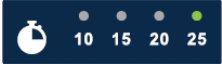
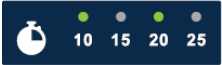
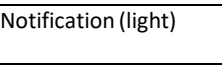
When a notification occurs, the current cycle time diode will turn off and a notification code is shown on the four different cycle time diodes (10, 15, 20, 25). To read the cycle time during the error notification, unlock the control panel.

7.15 Table of notifications

Information about each notification is shown in the notification table on the next page.

Notifications that are described under ‘Notification (sound)’ are shown by both light and sound. The error code will be displayed until the error has been rectified. If the mute button is pressed the audible warning will cease for a period of 5 minutes and will return until the error has been rectified.

Notifications that are described under ‘Notification – (light)’ are shown only by light. The error code is shown until the system is restarted.

Notification (sound)	Description and troubleshooting
	High temperature. Valves and compressors are turned off. If the control unit is in direct sunlight, relocate it.
	Default settings are not completed.
	Incorrect input voltage. Make sure that the correct power supply is used, otherwise contact the technical support.
	Low pressure. Secure the CPR, mattress, air tubes and air filter.
	Automatic setting failure. The correct pressure has not been reached within the time limit.
	Leakage under the automatic setting period. The mattress is leaking too much for the weighing to be accomplished. Control the mattress and the air connections.
	High pressure. The pressure cannot be reduced to the desired value within the time limit.
	The automatic setting has been restarted too many times during the automatic setting period.
	The mattress control parameters have not been read. Connect the CPR.
	The mattress control parameters have been changed during the use. Restart the system.
Notification (light)	Description and troubleshooting
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Information to service technicians: this notification shows a leakage in the blue cell section. More information in the Service manual for CuroCell® A4.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Information to service technicians: this notification shows a leakage in the green cell section. More information in the Service manual for CuroCell® A4.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Information to service technicians: this notification shows a leakage in the red cell section. More information in the Service manual for CuroCell® A4.

8 Operation CuroCell® M4

The following instructions are only applicable to CuroCell® M4, regardless of which mattress is used. Read the label of the control unit carefully to know which product you have.



If the control unit has been stored in its minimum or maximum storage temperature (- 25°C or 70°C), wait at least one (1) hour before starting the control unit. This time is based on an ambient temperature of 20°C.

How to start the system:

1. Set the on/off switch on the side of the control unit to 1 (On).
2. Use the patient weight settings to set a suitable weight for the patient.
3. When using a mattress with a safety mattress (CuroCell® CX15, CuroCell® CX16 or CuroCell® CX20), the safety cells will be inflated first. Then, the remaining cells will be inflated.

The inflation of the cells takes about 20-40 minutes, depending on the size of the mattress. When the mattress is inflating, the diodes below light up in orange.



4. Once the diodes goes out, the patient can be placed on the mattress.



When using a lift to place the patient on the mattress while the head end of the bed is raised, make sure that the patient is not placed too high on the mattress. Otherwise, there is a risk of shear.



To minimize the risk of wounds occurring on the feet, make sure that the patient does not come in contact with the hangers of the control unit.

5. Select program by pressing the corresponding button on the control panel. Pulsating mode is pre-set.

6. The mattress is filled according to the selected weight setting. During this time, the diode above the selected program flashes. When the LED stops flashing, the mattress has adapted the internal pressure to the patient.

7. Perform a function control (hand check) to ensure that the settings are correct.



During use, the control panel might reach a temperature of 56°C.



Button	Function
	Mute the information signal
	Panel lock
	Pack & Go®. Function for deflating the system
	Gentle Alternating Low Pressure (GALP)
	Pulsating mode
	Constant low pressure (CLP)
	Maximum pressure (caring mode)
	Patient weight settings
	Information signal
	Incorrect connection of the air connector (CPR)
	Seating function
	Cycle time settings (10, 15, 20, 25 minutes). The diodes are also used for error notifications.

8.1 Function (Manual)

At start-up, the inner pressure of the mattress must be set manually based on the weight and height of the patient. The mattress system maintains the pre-set inner pressure regardless of movement and position changes. This means that when the patient changes position, for example, the mattress's inner pressure must be adjusted manually. The weight settings on the control unit are used to change the inner pressure.

8.2 Panel lock



Press the Panel lock button to lock or unlock the control panel. The button indicates when the panel has been locked. The screen locks automatically if left untouched for five minutes. This is to prevent the settings being changed accidentally.
To unlock, press the button for 2 seconds.

8.3 Program

Choose program by pressing the button on the control unit. Choose between three programs:

Program	Symbol	Explanation
Constant Low Pressure (CLP)		Air pressure is distributed evenly in all air cells. The control unit adapts the pressure according to the patient's weight. No cycle time settings are needed.
Gentle Alternating Low Pressure (GALP)		A dynamic program that regularly alternates the air pressure to relieve pressure on the body. The cycle period can be changed according to patient needs and requirements. Choose between 10, 15, 20 or 25 minutes. The longer the cycle period, the slower the alternations. Ten (10) minute cycles are recommended.
Pulsating mode		A dynamic program that combines alternating movements with a constant low pressure. This gives a large contact area and reduces high peak pressures. The cycle period can be changed according to the patient needs and requirements. The longer the cycle period, the slower the alternations. Ten (10) minute cycles are recommended. This program is recommended due to its documented clinical effect.

8.4 Cardiopulmonary resuscitation - CPR

See section 5.1.

8.5 Function control (hand check)

Hand check is performed to ensure that the mattress system works properly and to ensure that the weight setting is correct. Recommendation on when to perform a hand check:

- Once per work shift
- After installation of the product
- After positioning changes
- After changes in comfort setting
- After changes in weight settings

When using an overlay mattress (CuroCell® CX10):

1a. Open the cover and identify a cell with less air at the patient's sacrum. Insert a hand with the palm facing up between the overlay mattress and the underlying mattress. The hand is inserted beneath the patient's sacrum (center of mattress).

When using a full replacement mattress (CuroCell® CX15, CuroCell® CX16 or CuroCell® CX20):

1b. Open the cover and identify a cell with less air at the patient's sacrum. Insert a hand with the palm facing up between the top cells and the underlying safety mattress. The hand is inserted beneath the patient's sacrum (center of mattress).

2. Ensure there is a gap between the patient and the underlying mattress so that the patient does not bottom out.

3. If you can feel the patient's sacrum resting in the palm of your hand, the gap is too small. See section 12.

8.6 Shut down (Pack&Go)

See section 5.2

8.7 Restart

See section 5.3

8.8 Power failure

See section 5.4

8.9 Maximum pressure (caring mode)



With this function, the entire mattress is inflated and provides firmed support. This function reverts to the previous setting after 20 minutes. Use this function during caring, shifting the patient's position, or during bed entry and bed exit.

8.10 Maximum pressure notification

See section 5.5

8.11 Transport function

See section 5.6

8.12 Sitting positioning

Press the button for “Seating function” if the patient is sitting in bed. A visible and audible notification is generated when the seating function has been active for two consecutive hours, notifying that repositioning of the individual may be necessary. The control unit will also notify if an attempt is made to switch on the system while seating function is active. Also, see section 5.7.

8.13 Notifications



Different notifications exist based on how serious the warning is. With a malfunction or an error, a notification will be given by way of a flashing warning triangle. To mute the warning signal, press the mute button.

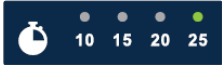
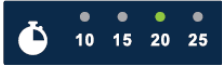
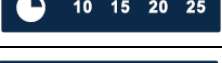
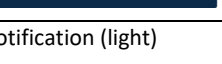


When a notification occurs, the current cycle time diode will turn off and a notification code is shown on the four different cycle time diodes (10, 15, 20, 25). To read the cycle time during the error notification, unlock the control panel.

8.14 Table of notifications

Information about each notification is shown in the notification table on the next page. Notifications that are described under ‘Notification (sound)’ are shown by both light and sound. The error code will be displayed until the error has been rectified. If the mute button is pressed the audible warning will cease for a period of 5 minutes and will return until the error has been rectified.

Notifications that are described under ‘Notification – (light)’ are shown only by light. The error code is shown until the system is restarted.

Notification (sound)	Description and troubleshooting
	High temperature. Valves and compressors are turned off. If the control unit is in direct sunlight, relocate it.
	Default settings are not completed.
	Incorrect input voltage. Make sure that the correct power supply is used.
	Low pressure. Secure the CPR, mattress, air tubes and air filter.
	High pressure. The pressure cannot be reduced to the desired value within the time limit.
	The mattress control parameters have not been read. Connect the CPR.
	The mattress control parameters have been changed during the use. Restart the system.
Notification (light)	Description and troubleshooting
	Leakage in one of the sections. Secure the CPR, mattress and connection tubes. Information to service technicians: this notification shows a leakage in the blue cell section. More information in the Service and repair manual for CuroCell® M4.
	Leakage in one of the sections. Secure the CPR, mattress and connection tubes. Information to service technicians: this notification shows a leakage in the green cell section. More information in the Service and repair manual for CuroCell® M4.
	Leakage in one of the sections. Secure the CPR, mattress and connection tubes. Information to service technicians: this notification shows a leakage in the red cell section. More information in the Service and repair manual for CuroCell® M4.

9 Product description

Read the label of your products carefully to identify which products you are using.

9.1 Product combinations

The products in this instruction for use are combinations of the product groups below.

Product configuration – Active airflow configuration (PCON001)	
Product group, Active airflow-controlled control unit (CE010)	Product group, CuroCell active air mattresses (CE020)
CuroCell® IQ CuroCell® A4 CuroCell® M4	CuroCell® CX10 CuroCell® CX15 CuroCell® CX16 CuroCell® CX20

The table below shows which products that are possible to combine.

Control unit	Mattress	Mattress cover
CuroCell® IQ CuroCell® A4 CuroCell® M4	CuroCell® CX10	Cover Olivia Cover Stone
	CuroCell® CX15 CuroCell® CX16 CuroCell® CX20	Top part Olivia Top part Stone Bottom part CuroCell Bottom part Evac

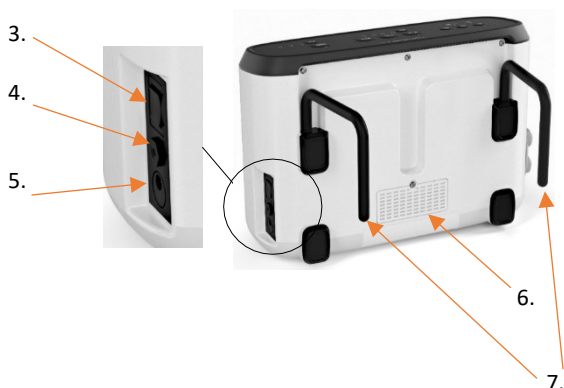
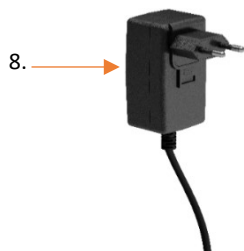
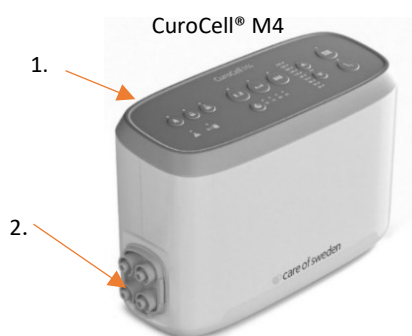
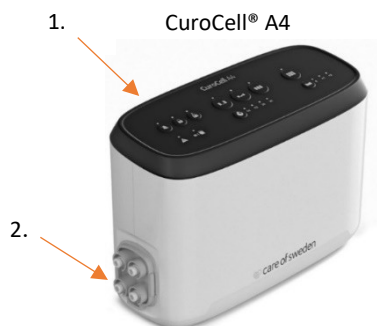
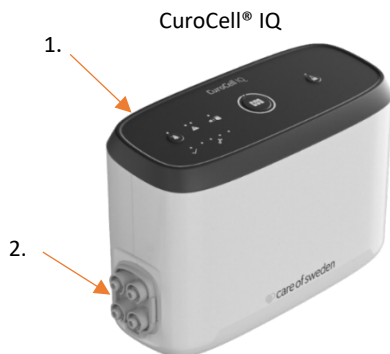
Mattress specification		
Product	Size	Mattress weight
CuroCell® CX10	80/85/90/100/105/120 x 200/210 x 10 cm	5,2 kg (80x200 cm)
CuroCell® CX15	80/85/90/100/105/120 x 200/210 x 15 cm	10 kg (80x200 cm)
CuroCell® CX16	80/85/90/100/105/120 x 200/210 x 16 cm	11,5 kg (80x200 cm)
CuroCell® CX20	80/85/90/100/105/120 x 200/210 x 20 cm	11 kg (80x200 cm)

9.2 Control unit

Materials the user comes in contact with:

- Polycarbonate/acrylonitrile-butadiene-styrene
- Silicone
- High impact plastic, 94V0 polycarbonate

1. Control panel
2. Tube/CPR connection
3. Power switch, On/Off
4. 3,5 mm plug input
5. Connection power cable
6. Air filter
7. Hangers
8. Power supply



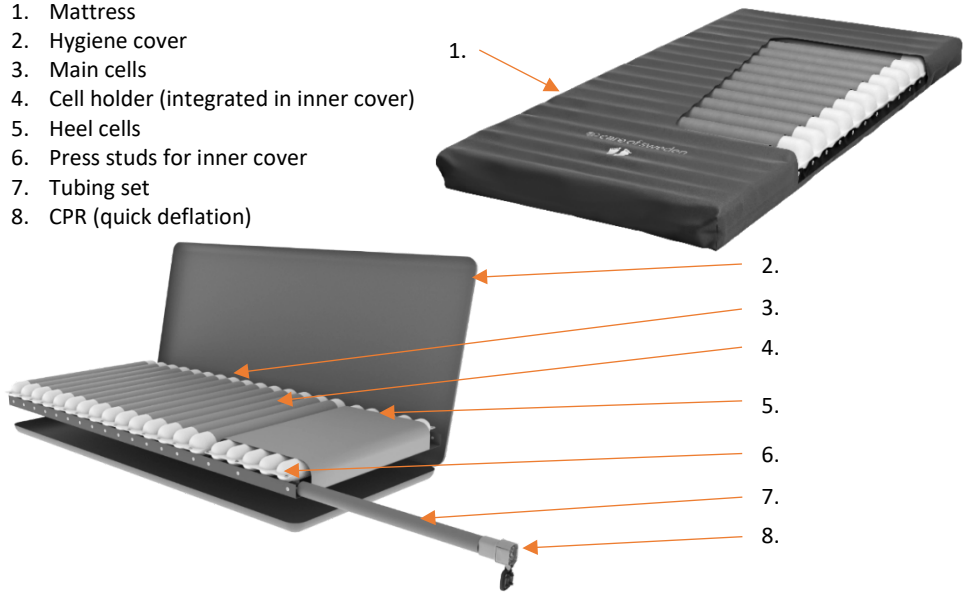
9.3 Mattresses

Materials the user comes in contact with:

- Polycarbonate/acrylonitrile-butadiene-styrene
- Polyester with polyurethane coating
- Polyamide with polyurethane coating

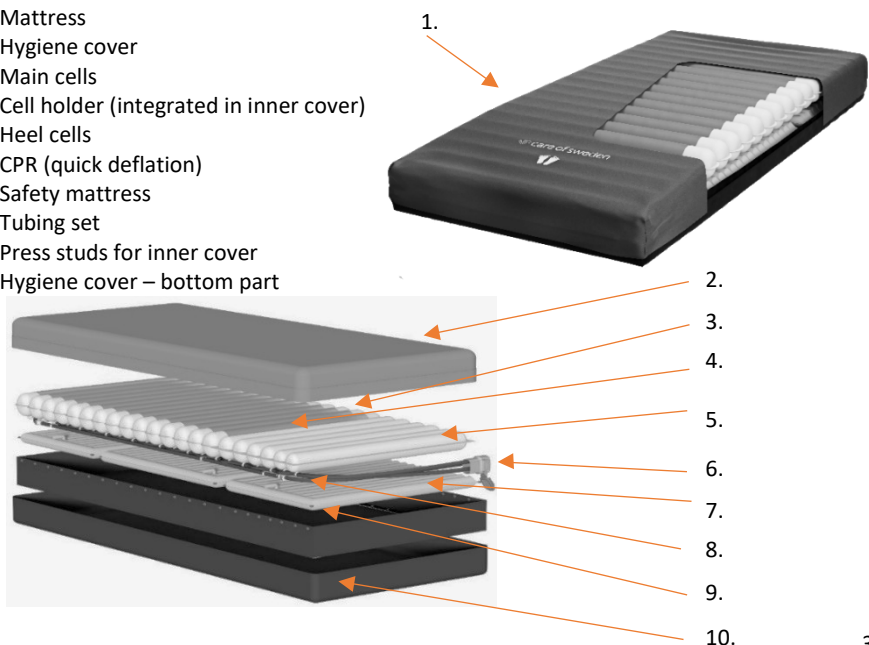
CuroCell® CX10

1. Mattress
2. Hygiene cover
3. Main cells
4. Cell holder (integrated in inner cover)
5. Heel cells
6. Press studs for inner cover
7. Tubing set
8. CPR (quick deflation)



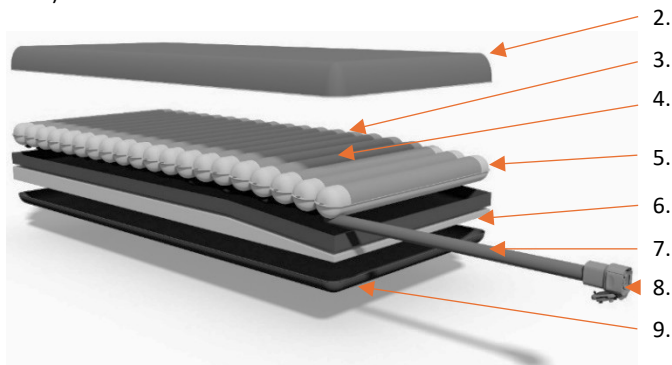
CuroCell® CX15

1. Mattress
2. Hygiene cover
3. Main cells
4. Cell holder (integrated in inner cover)
5. Heel cells
6. CPR (quick deflation)
7. Safety mattress
8. Tubing set
9. Press studs for inner cover
10. Hygiene cover – bottom part



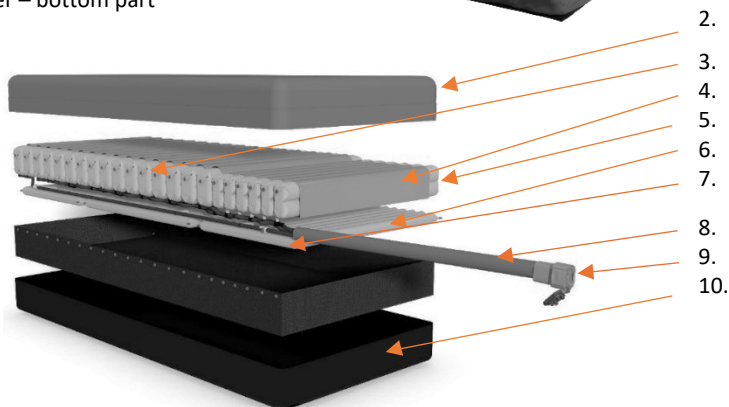
CuroCell® CX16

1. Mattress
2. Hygiene cover
3. Main cells
4. Cell holder (integrated in inner cover)
5. Press studs for inner cover
6. Safety mattress
7. Tubing set
8. CPR (quick deflation)
9. Bottom part



CuroCell® CX20

1. Mattress
2. Hygiene cover
3. Main cells
4. Cell holder (integrated in inner cover)
5. Heel cells
6. Safety mattress
7. Press studs for inner cover
8. Tubing set
9. CPR (quick deflation)
10. Hygiene cover – bottom part



10 Reuse and cleaning

The product is reusable. Before reusing, it is important to follow the instructions below for cleaning, disinfection, and reconditioning. Disinfection is recommended between patients according to the instructions below.

To ensure maintained hygiene, the mattress should not be exposed to urine or other body fluids for an extended period of time. If such an incident occurs, the mattress must be cleaned in accordance with the applicable cleaning and disinfection procedures below. Failure to follow hygiene routines may result in persistent odor.



Always follow local instructions and the instructions for use of the cleaning and disinfecting agent. Consult your hygiene manager or Care of Sweden for help and instructions in case of uncertainty.



Check the hygiene cover, air cells and hoses each time the product is cleaned. Also, check the control unit, tube connectors and power cable during cleaning. Damaged parts must be repaired or replaced.

10.1 Cleaning and disinfection

CONTROL UNIT

Wipe off using a damp cloth.

Information on detergent <i>If other agents are used, choose one that does not harm the exterior of the control unit.</i>	
Primarily	Solvent-free soap with a neutral pH-value.
If necessary	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 1000 ppm (0,1%).
Exceptional cases	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 10 000 ppm (1%).

INNER COVER AND MATTRESS COVER

Wipe off.

Information on detergent	
Primarily	Solvent-free soap with a neutral pH-value.
If necessary	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 1000 ppm (0,1%).
Exceptional cases	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 10 000 ppm (1%). Note: Using 1% solution regularly may damage and fade the surface of the cover.

Mechanical cleaning



Covers consisting of several parts must be separated before washing.

10.2 Reconditioning

CONTROL UNIT

Clean the control unit according to section 10.1 Cleaning and disinfection – CONTROL UNIT.

MATTRESS

Disconnect the tube connector from the control unit and remove the air from the mattress.

Cleaning of mattress

Primarily	Clean all external surfaces of the mattress according to section 10.1 Cleaning and disinfection - Inner cover, hygiene cover and comfort cover. Ensure that all areas are free of dirt residues.
If necessary	1. Remove the covers. 2. Wipe off the cells, tubing and the CPR module with a cleaning agent according to local instructions and the instructions for use of the cleaning agent. 3. When all parts are dry, assemble the mattress. If cells have become detached from the tubes, these must be put back according to drawing in section 9.3.

Disinfection of mattress

Primarily	1. Disinfect all external surfaces of the mattress with disinfectant according to section 10.1 Cleaning and disinfection - Inner cover and mattress cover. Ensure that all areas are free of dirt residue. 2. Allow the disinfectant to work according to the instructions from the manufacturer of the agent. 3. Let the cover dry.
If necessary	1. Remove the covers. 2. Wipe the cells, tubes and the CPR module with a disinfectant. 3. Allow the disinfectant to work according to the instructions from the agent's manufacturer. 4. When all parts are dry, assemble the mattress. If cells have become detached from the tubes, they need to be put back according to the drawing in 9.3.

11 Maintenance

11.1 General

We recommend that the service and maintenance schedule in section 11.3 be followed to maintain the function and performance of the product.



Service and maintenance must always be performed by Care of Sweden or one of its authorized technicians. Only use spare parts approved by Care of Sweden. Only perform service and maintenance when the system is not in use. For more information, see the service manual for CuroCell® A4 and IQ.



11.2 Between patients

Between patients, the Pack&Go® function should be used to reset the system. When starting up the product again it will be set on the Pulsating Mode.

Between patients, also check that:

- The power cable and power supply are undamaged.
- The connecting tubes (marked CPR) on the side of the control unit are positioned correctly and not leaking.
- The hygiene cover is intact, and the cover and cells are correctly assembled.
- No tubes or connectors are damaged or jammed.

Contact Care of Sweden or your local distributor if any spare parts are required.

11.3 Service- and maintenance schedule



Service in the right column shall always be performed by an authorized service technician.



Always ensure that the control unit is shut off before any maintenance or service is performed. Maintenance and/or service shall never be performed while the product is in use.

	Maintenance		Service
	Before every use (or every 2 weeks if used continuously)	After each use (between users)	Every 5 years
Control unit			
Visual inspection of exterior	X	X	
Cleaning of exterior		X	
Visual inspection of power cable/supply	X		
Test function on control panel		X	
Visual inspection of the connecting tubes (marked CPR), they shall be positioned correctly and not leaking		X	
Replace air filter*			X*
Change valve module			X
Mattress and cover			
Visual inspection of cover, no damages		X	
Test function of zipper		X	
Visual inspection of connecting tubes	X		
Other			
Function control		X	

*If the control unit is used in dusty environments the air filter should be checked regularly and replaced if needed.

11.4 Replacing air filter

Replacing the air filter can be done by a lay person.



Always ensure that the control unit is shut off before any maintenance or service is performed. Maintenance and/or service shall never be performed while the product is in use.

To replace the air filter:

1. Loosen the protective plate on the rear of the control unit using a size T10 Torx screwdriver.
2. Remove the filter from the holder.
3. Place the new filter in the holder with the pink side facing outwards.

Put the protective plate back in place and secure using the screws.

If the control unit is used in a dirty environment, the filter should be checked regularly.



12 Troubleshooting

Problem	Solution
The control unit does not start	Check that the power supply has been connected to the mains supply. Check that the LED on the power supply is showing green.
The patient is bottoming out	If the patient is bottoming out on several air cells, we recommend to re-start the control unit (see section 5.3). Wait until the diodes stop flashing. If the issue remains, contact Care of Sweden or your distributor.
The mattress moves around	Check that the mattress is fastened to the bed frame with the fastening straps.
Some cells have less air	This is normal for the Pulsating Mode or Gentle Alternating Low Pressure Mode, as the air supply switches between alternating cells for a predetermined cycle period (one cycle = 10–25 minutes).
The control unit makes a noise; vibrations can be felt	Check how the control unit is hanging on the bed. Resonance can occur, in parts of the bed. Remove the control unit and listen to find out if this vibrations makes a difference. The problem may be resolved by putting the control unit on a flat, steady surface or by placing a towel between the control unit and bed.

13 Storage

It is advisable to store the mattress and control unit in the product bag (accessory), original package or equivalent for protective storage. Handle the packaged product with caution. Do not place any heavy objects on top of it. For additional information about storage temperature, see section 14.

14 Technical specification

CONTROL UNIT SPECIFICATION		
Model		CuroCell® IQ, CuroCell® A4, CuroCell® M4
Input voltage		100-240 V / 50-60 Hz / 0,6 A
Output voltage		12 V DC
Power supply	Ungrounded AC outlet, electrical safety class II	Use only power supply with P/N WR9QE1500LRPCIMG3138
Power consumption		Max 18 W
Electrical class.		Class II, Type BF
Fuse		No Fuse
Mode of operation	CuroCell® IQ	Pulsating mode
	CuroCell® A4 CuroCell® M4	Pulsating mode, Gentle Alternating Low Pressure (GALP), Constant Low Pressure (CLP)
Cycle time	Pulsating mode & GALP	10 min, 15 min, 20 min, 25 min
Patient pressure settings	CuroCell® OQ CuroCell® A4	Automatic adjustment of patient pressure (internal air pressure) in the mattress
	CuroCell® M4	The operator sets the pressure based on the patient's weight
Dimensions (LxWxH)		11 cm x 30 cm x 20 cm
Weight		2,9 kg
Sound pressure level according EN ISO 11201	A-weighted emission sound pressure level $L_{pA,eq}$ (dB)	Normal use: <17 dB (at bystander position) <16,5 dB (at head end) Pump phase: 23 dB (at bystander position) <19,5 dB (at head end) When placing the control unit on the foot end.
Sound power levels according to EN ISO 3746	A-weighted sound power level L_{WA} (dB)	Normal use: < 25 (dB) Pump phase: 35,5 (dB)
Environmental	Temperature	Operation: +5 – +40 °C, Storage: -25 – +70 °C, Transport: -25 – +70 °C
	Humidity	Operation: 15 % – 93 % non-condensing Storage: < 93 % non-condensing
	Atmospheric	700 hPa – 1060 hPa
IP classification		IP42
Degree of safety in presence of inflammable anesthetics		The device is not intended for use with flammable anaesthetic gases
Applied part		Mattress, control unit

14.1 Standards

The system is tested and approved according to the following European standards, where applicable requirements are met.

The system is tested and approved according to the following European standards, where applicable requirements are met.

IEC 60601-1	EN ISO 10993	ISO 3746
IEC60601-1-2	EN 597-1	ISO 11201
IEC 60601-1-11	EN 597-2	
IEC60601-1-6	EN ISO 14971	
IEC 62304		

15 Other information

15.1 Technical lifetime

The product is service-free for the first 5 years. With normal use and proper maintenance in accordance with the service and maintenance table 11.3, the product has an expected lifespan of at least 7 years.

15.2 Warranty

The product warranty covers manufacturing defects and is valid from the date the product is shipped with intent of usage, either directly from Care of Sweden or through one of Care of Sweden’s designated distributors. The product warranty does not cover normal wear and tear, issues resulting from improper use, or damage caused by non-compliance with usage instructions. Any intentional damage, such as modifications, disassembly, or unauthorized repairs, voids the warranty. Contact Care of Sweden or your distributor for more information.

15.3 Disassembly and recycling



The products shall not be disposed of with household waste.

Control unit: The control unit shall be sorted as electronic waste.

Mattress: The air tube connector (marked ‘CPR’) shall be disassembled and sorted as plastic waste. The remaining mattress shall be sorted as combustible waste.



If the product is, or could be, contaminated the product must be handled according to the healthcare provider’s or local authority’s procedures for contaminated waste.

15.4 Return

Contact Care of Sweden or your distributor before the product is returned.

15.5 Technical assistance requests



If technical assistance is required, contact the name supplier at the address indicated on the invoice at the time of delivery of the unit; otherwise contact the local Engineer or Technician suggested by the Supplier. If required Circuit diagram, components parts and instruction of parts will be made available to the technical person to perform technical assistance.

15.6 Customer responsibilities

The safety of the unit and of the operator cannot be guaranteed if the following conditions are not satisfied:

- The mains should be compatible with the voltage and current specifications indicated on the nameplate placed on the rear of the unit. It is also advisable to periodically check the efficiency of the electric system.
- It is recommended that the control unit to be plugged into a power surge protector for additional protection from power surges and fluctuations.
- Before connecting or disconnecting the control unit (pump) should be switched off.
- Always use mattress cover, never keep sharp objects nearby mattress.
- Operators should be familiar with the procedures, prohibitions and warning described in this manual, in addition with safety regulations applicable.

Manufactured by



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