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Instructions for use
2025-12-01

CuroCell® iA Automatic and CuroCell® iA Manual
Air mattress system

Instructions for use item number: 95-001456-EN0000

7331345180380

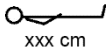
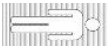
Read the instructions carefully before use.
All user instructions and safety instructions must be followed.

EN

Table of content

1 Symbol key

Symbols to convey medical device information			
CE	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
MD	Medical device		Distributor
UDI	Unique device identifier		Date of manufacture
	Warning		Caution
REF	Catalogue number	LOT	Batch code
SN	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		Drip dry
	Tumble dry		Do not iron
	Wipe clean		Do not dry clean
	Chlorine		Do not dispose of with household waste

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

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.
- Make sure that the patient is lying correctly on the mattress according to the instructions and use a cable holder if possible.
- Regularly check product functionality by performing a hand check.
- To prevent the power supply from being pulled out, exercise caution when there are children and pets in the environment around the equipment.
- 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.

3 Introduction

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

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

CuroCell® iA Automatic and **CuroCell® iA Manual** are compatible with three different mattresses: CuroCell® Ci10 PRO, CuroCell® Ci17 PRO and CuroCell® Ci20 PRO.

This instructions for use contain information about a modular system containing of two control units and three mattresses. 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 systems consists of a control unit and a mattress and are 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 mattress system is intended for use by patients with a recommended minimum length of 120 cm. The specifications for weight are listed in the table below.

Mattress	Recommended patient weight
CuroCell® Ci10 PRO	≤ 180 kg
CuroCell® Ci17 PRO	≤ 210 kg
CuroCell® Ci20 PRO	≤ 240 kg

3.5 Intended user

The mattress system is intended to be used by healthcare professionals. The training of the intended use 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 unhinderedly 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, the patient can also be a lay person.

3.6 User qualification

Training is not mandatory to use the system.

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	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 use manual (IFU)	X	X	X
Inform lay person	X		
Perform CPR on patient in case of emergency	X		
Uninstalling the system	X		
Transport and storage system between patients	X		

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

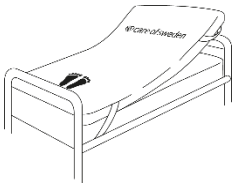
The clinical benefits for CuroCell® iA Automatic and CuroCell® iA Manual together with any of the mattresses included in this instruction for use are:

- As an aid in prevention and treatment of pressure ulcers/pressure injuries 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.

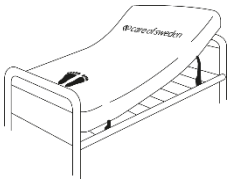
4 Assembly and installation

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. Ensure tubes are not folded and/or compressed during and after installation. The operator should follow and check the below information before use.

When using an overlay mattress (CuroCell® Ci10 PRO):
1a. Place the overlay mattress on the base mattress. Secure the mattress to the base using the 4 straps on the corners of the mattress.



When using a full replacement mattress (CuroCell® Ci17 PRO or CuroCell® Ci20 PRO):
1b. Place the mattress on the bed base. If the mattress has fastening straps, secure the mattress with the straps to the moving parts of the bed.

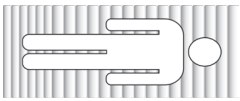


Make sure that the mattress is the correct size for the bed.

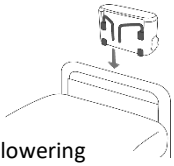
Check the cells and press studs to ensure they are correctly assembled.

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.

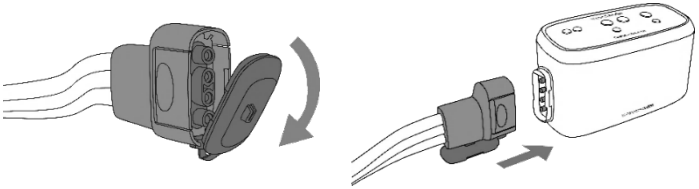


2. Hang the control unit on the foot end of the bed or place it on a level, steady surface. Check that the switch on the side of the control unit it set to '0' (off).

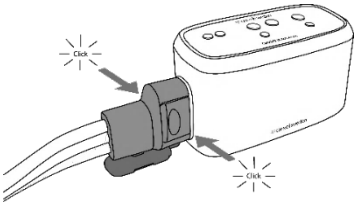


3. If the mattress is equipped with a cable holder, place the power cable in the cable holder. Otherwise, place the power cable so there is no risk of stumbling over it, running over it with the bed wheels, or getting it jammed when raising or lowering the bed. Put the power cable into the control unit.

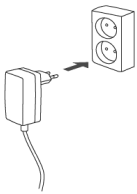
4. Open the lid on the air tube connector (marked CPR) and connect it to the side of the control unit.



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.

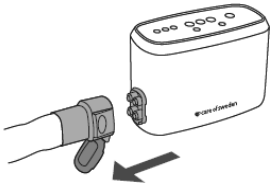
Route the power cable to the control unit carefully to avoid tripping and strangulation.

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

When shutting down the system, follow the steps below:

1. Turn off the main power switch.
2. Disconnect the power cord from the control unit.
3. Disconnect the CPR from the control unit.
4. Roll/fold the mattress until the mattress is empty.
5. Untie and roll up the power cord/power supply.

If the system was delivered in a bag, the control unit shall be placed inside of the rolled/folded mattress.

5.3 Restart

If a restart is required, set the On/Off switch on the side of the control unit to 0 (Off). Wait for approx. 10 seconds and restart the control unit.

5.4 Power failure

In the event of a power failure, the valves will open automatically and even out the air pressure in the mattress. The mattress will retain air for at least 12 hours. Perform a hand check to make sure the pressure of the mattress is not too hard or too soft. See 7.6 for instructions on how to perform a hand check. During a power failure, the information in 7.6 applies regardless of which control unit that is used.

In the event of a power failure, the product has no therapeutic function. The patient should be observed and positioning changes made as necessary. The mattress does not alternate during a power failure.

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.

6 Operation CuroCell® iA Automatic

The following instructions are only applicable to CuroCell® iA Automatic, 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® Ci17 PRO or CuroCell® Ci20 PRO), the safety cells will be inflated first. Then, the remaining cells will be inflated.

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

4. Once the diode 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. 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.

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

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

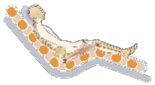
Button	Function
	Mute the information signal
	Panel lock
	Gentle Alternating Low Pressure (GALP)
	Constant Low Pressure (CLP)
	Maximum pressure (caring mode)
	Information signal
	Incorrect connection of the air connector (CPR)
	Cycle time settings (10, 15, 20, 25 minutes). The diodes are also used for error notifications.
	Comfort settings

6.1 Function (Automatic)

The mattress system independently and without manual adjustment controls the inner pressure of the mattress according to the weight, height, 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 height 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 of the mattress inner pressure, the system returns to the previously selected program. Gentle Alternating Low Pressure is pre-set from factory, if the program is changed, the control unit will start up on the latest chosen program after it has been shut off.

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.

6.2 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.

6.3 Program

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

Program	Symbol	Explanation
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		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. This program is recommended, it is also the pre set mode from factory. If the program is changed, the control unit will start up on the latest chosen program after it has been shut off.

6.4 Cardiopulmonary resuscitation - CPR

See section 5.1.

6.5 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 6.13.

6.6 Shut down (Pack&Go)

See section 5.2.

6.7 Restart

See section 5.3.

6.8 Power failure

See section 5.4.

6.9 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 bed entry/exit and during patient care.

6.10 Maximum pressure notification

See section 5.5.

6.11 Comfort settings

The pressure can be increased in two steps depending on the patient's comfort requirements. This increase is made based on the function described in 6.1. 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 may be necessary to raise the setting using the comfort settings.

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 a flashing warning triangle. To mute the warning signal, press the mute button.

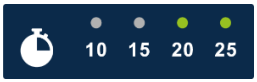
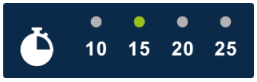
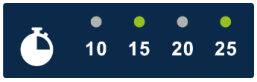
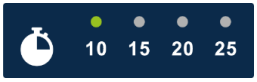
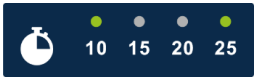
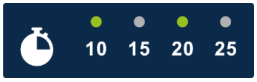
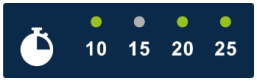
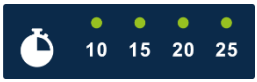
When a notification occurs, the current cycle time diode will turn off and a notification code is shown on the four different cycle time diodes (10, 15, 20, 25). To read the cycle time during the error notification, unlock the control panel.

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. If problem persists, contact an authorized service technician.
	Default settings are not completed. Contact an authorized service technician.
	Incorrect input voltage. Make sure the correct power supply is used, otherwise contact an authorized service technician.
	The display is the probable cause. Contact an authorized service technician.
	Low pressure. Check the CPR, mattress, air tubes and air filter. Restart the control unit. If problem persists, contact an authorized service technician.
	High pressure. The pressure cannot be reduced to the desired value within the time limit. If problem persists, contact an authorized service technician.
	The automatic setting has been restarted too many times during the automatic setting period. Alarm can be caused by too much movement. Restart the control unit, have the user lay still during start-up. If problem persists, contact an authorized service technician.
	Mattress error read. The system cannot detect a mattress connected to the control unit. Check the CPR. If problem persists, contact an authorized service technician.
	The pressure is not increasing fast enough during operation. Check the CPR, air tubes and air filter. If problem persists, contact an authorized service technician.
Notification (light)	Description and troubleshooting
	Leakage in an air cell in a cell section. Check the CPR, mattress and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in green or red cell section.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in the blue section.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in the green section.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in the red section.

7 Operation CuroCell® iA Manual

The following instructions are only applicable to CuroCell® iA Manual, 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. Use the Patient weight settings button to set which weight the patient has.

3. When using a replacement mattress with a safety mattress (CuroCell® Ci17 PRO or CuroCell® Ci20 PRO), the safety cells will be inflated first. Then, the remaining cells will be inflated.

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

5. Once the diode 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.

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
	Gentle Alternating Low Pressure (GALP)
	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.

7.1 Function

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.

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 Programs

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

Program	Symbol	Explanation
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		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. This program is recommended, it is also the pre set mode from factory. If the program is changed, the control unit will start up on the latest chosen program after it has been shut off.

7.4 Seating function

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.

When raising the head end of the bed into a sitting position, always secure the patient´s position. This function is recommended to use for short periods only. For additional support, positioning pillows can be used. To ensure the product functionality, we always recommend performing a function control (hand check), see 7.6.

7.5 Cardiopulmonary resuscitation - CPR

See section 5.1.

7.6 Function control – Hand check

Perform a hand check to ensure that the mattress system works properly. Hand check should be performed regularly; for CuroCell® iA Manual we recommend once every eight hours as well as after installation of the system.

Ensure that the air mattress is filled with air before performing a hand check. This is indicated by a green light.

How to perform a hand check depends on which mattress is used - read the label of the mattress carefully to know which mattress you have.

When using an overlay mattress system (CuroCell® Ci10 PRO):
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® Ci17 PRO or CuroCell® Ci20 PRO):
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 11 'Troubleshooting'.

7.7 Shut down

See section 5.2.

7.8 Restart

See section 5.3.

7.9 Power failure

See section 5.4.

7.10 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. The function should be used during bed entry/exit and during patient care.

7.11 Maximum pressure notification

See section 5.5.

7.12 Notifications

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

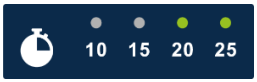
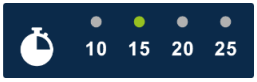
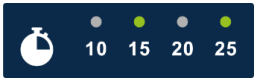
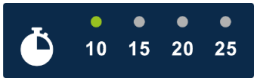
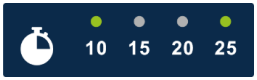
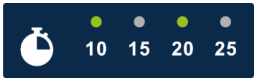
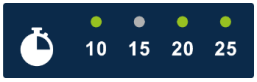
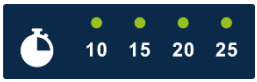
When a notification occurs, the current cycle time diode will turn off and a notification code is shown on the four different cycle time diodes (10, 15, 20, 25). To read the cycle time during the error notification, unlock the control panel.

7.13 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 crease 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. If problem persists, contact an authorized service technician.
	Default settings are not completed. Contact an authorized service technician.
	Incorrect input voltage. Make sure the correct power supply is used, otherwise contact an authorized service technician.
	The display is the probable cause. Contact an authorized service technician.
	Low pressure. Check the CPR, mattress, air tubes and air filter. Restart the control unit. If problem persists, contact an authorized service technician.
	High pressure. The pressure cannot be reduced to the desired value within the time limit. If problem persists, contact an authorized service technician.
	The automatic setting has been restarted too many times during the automatic setting period. Alarm can be caused by too much movement. Restart the control unit, have the user lay still during start-up. If problem persists, contact an authorized service technician.
	Mattress error read. The system cannot detect a mattress connected to the control unit. Check the CPR. If problem persists, contact an authorized service technician.
	The pressure is not increasing fast enough during operation. Check the CPR, air tubes and air filter. If problem persists, contact an authorized service technician.
Notification (light)	Description and troubleshooting
	Leakage in an air cell in a cell section. Check the CPR, mattress and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in green or red cell section.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in the blue section.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in the green section.
	Leakage in one of the sections. Secure the CPR, mattress, and connection tubes. Contact an authorized service technician. Information to service technicians: this notification shows a leakage in the red section.

8 Product description

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

8.1 Product combinations

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

Product configuration – Individualised airflow configuration (PCON002)	
Product group, Individualised airflow-controlled control unit (CE030)	Product group, CuroCell individualized air mattresses (CE040)
CuroCell® iA Automatic CuroCell® iA Manual	CuroCell® Ci10 PRO CuroCell® Ci17 PRO CuroCell® Ci20 PRO

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

Control unit	**Mattress**	**Mattress cover**
CuroCell® iA Automatic CuroCell® iA Manual	CuroCell® Ci10 PRO	Cover Olivia Cover Stone
	CuroCell® Ci17 PRO CuroCell® Ci20 PRO	Top part Olivia Top part Stone Bottom part CuroCell Bottom part Evac Cover Olivia Grip-lock Cover Stone Grip-lock

Mattress specification		
Product	**Size**	**Mattress weight**
CuroCell® Ci10 PRO	80/85/90/100/105/120 x 200/210 x 10 cm	5,2 kg (80x200 cm)
CuroCell® Ci17 PRO	80/85/90/100/105/120 x 200/210 x 17 cm	11,5 kg (80x200 cm)
CuroCell® Ci20 PRO	80/85/90/100/105/120 x 200/210 x 20 cm	12,5 kg (80x200 cm)

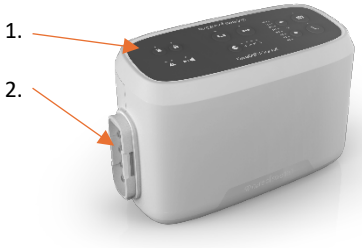
8.2 Control unit

Materials the user comes in contact with:

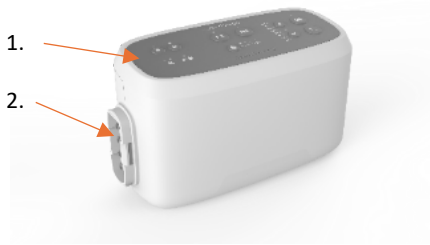
- Polycarbonate/acrylonitrile-butadiene-styrene
- Silicone
- High impact plastic, 94V0 polycarbonate

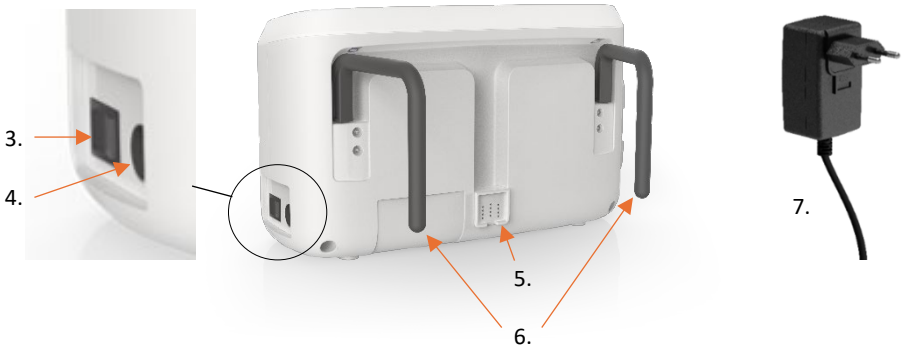
1. Control panel
2. Tube/CPR connection
3. Power switch On/Off
4. Connection power cable
5. Air filter
6. Hangers
7. Power supply

CuroCell® iA Automatic



CuroCell® iA Manual





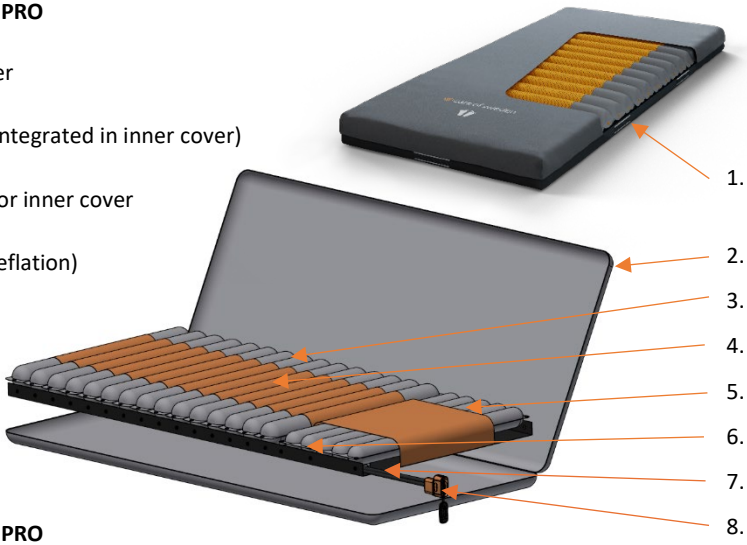
8.3 Mattresses

Materials the user comes in contact with:

- Polycarbonate/acrylonitrile-butadiene-styrene
- Polyester with polyurethane coating (Cover Olivia, Cover Olivia Grip-lock, Cover Top part Olivia,
- Cover bottom part CuroCell)
- Polyamide with polyurethane coating (Cover Stone, Cover Stone Grip-lock, Cover Top part Stone)

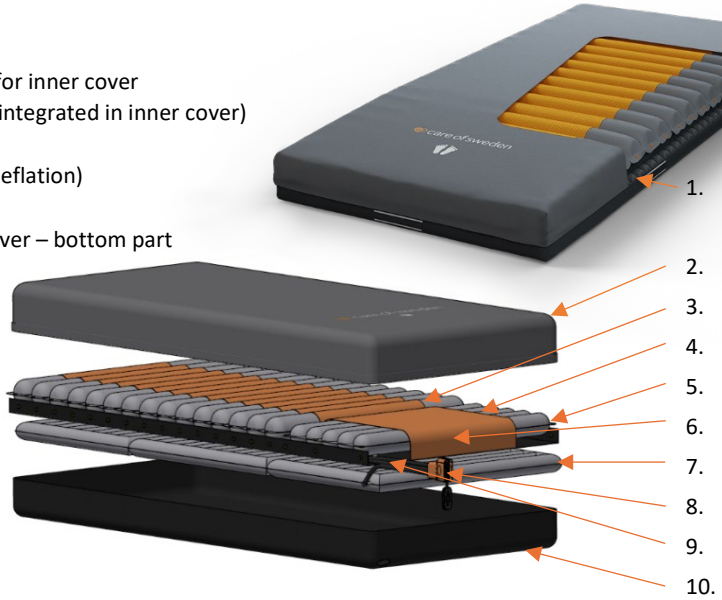
CuroCell® Ci10 PRO

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)



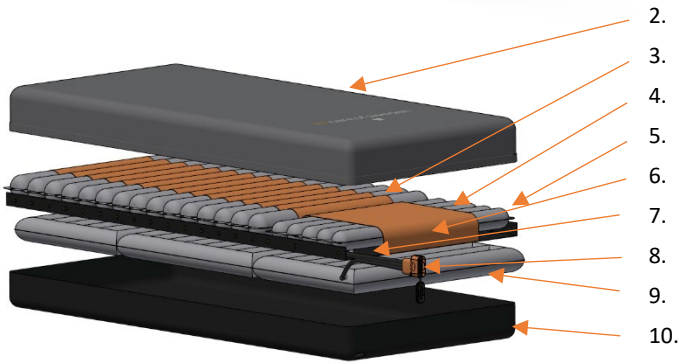
CuroCell® Ci17 PRO

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



CuroCell® Ci20 PRO

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



9 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.

9.1 Cleaning and disinfection

CONTROL UNIT

Wipe off using a damp cloth.

Information on detergent If other agents are used, choose one that does not harm the exterior of the control unit.	
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.

9.2 Reconditioning

CONTROL UNIT

Clean the control unit according to section 9.1 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 9.1 Cleaning and disinfection - Inner cover and Mattress 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 and disinfecting 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 8.3.

Disinfection of mattress

Primarily	1. Disinfect all external surfaces of the mattress with disinfectant according to section 9.1 Cleaning and disinfection - Inner cover and Mattress cover - Wipe off. 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 8.3.

10 Maintenance

10.1 General

We recommend that the service and maintenance schedule in clause 10.2 is 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® iA Automatic and CuroCell® iA Manual.

10.2 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.

10.3 Replacing air filter

Replacing the air filter can be done by a lay person. This shall only be done when the control unit is not in use.

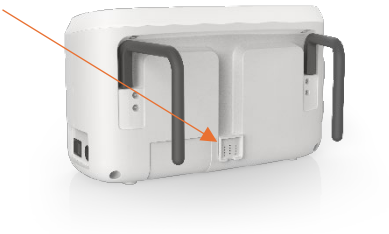
Before any maintenance is done, make sure that the control unit is turned off. Services shall not be done while using the product.

To replace the air filter:
1. Open the protective plate on the back of the control unit.

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.

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



11 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	Ensure that the mattress is secured to the underlying base mattress (applies for overlay mattress) or to the moving parts of the bed (applies for replacement mattress with fastening straps).
Some cells have less air	This is normal for Gentle Alternating Low Pressure (GALP), 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.

12 Technical specification

CONTROL UNIT SPECIFICATION		
Model		CuroCell® iA Automatic, CuroCell® iA Manual
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 classification		Class II, Type BF
Fuse		No Fuse
Mode of operation	CuroCell® iA Automatic CuroCell® iA Manual	Gentle Alternating Low Pressure, and Constant Low Pressure (CLP)
Cycle time	Gentle Alternating Low Pressure	10 min, 15 min, 20 min, 25 min
Patient pressure settings	CuroCell® iA Automatic	Automatic adjustment of patient pressure (internal air pressure) in the mattress
	CuroCell® iA Manual	Operator sets the patient pressure (internal air pressure) in the mattress according to patients' weight. Correct settings to be controlled by hand check
Dimensions (L x W x H)		11 cm x 27 cm x 15,5 cm
Weight		1,7 kg
Sound pressure level according EN ISO 11201	A-weighted emission sound pressure level LpA,eq (dB)	28 dBA (at operator position) 25 dBA (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)	<40 dBA
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

Note: Care of Sweden reserves the right to modify the product specification at any time.

12.1 Standards

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
IEC 60601-1-2	EN-597-1	ISO 11201
IEC 60601-1-11	EN 597–2	IEC 62304
IEC 60601-1-6		EN ISO 14971

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 12.

14 Other information

14.1 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 10.2, the product has an expected lifespan of at least 7 years.

14.2 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.

14.3 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.

14.4 Return

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

14.5 Technical assistance requests

If technical assistance is required, contact the 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.

14.6 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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