care of sweden
SUPPORTING LIFE

Instructions for use

2021-06-03

CuroCell® A4 OP10
CuroCell® A4 CX10
CuroCell® A4 CX15
CuroCell® A4 CX16
CuroCell® A4 CX20

Automatic air mattress systems

Instructions for use item number: 95-001430-EN0000

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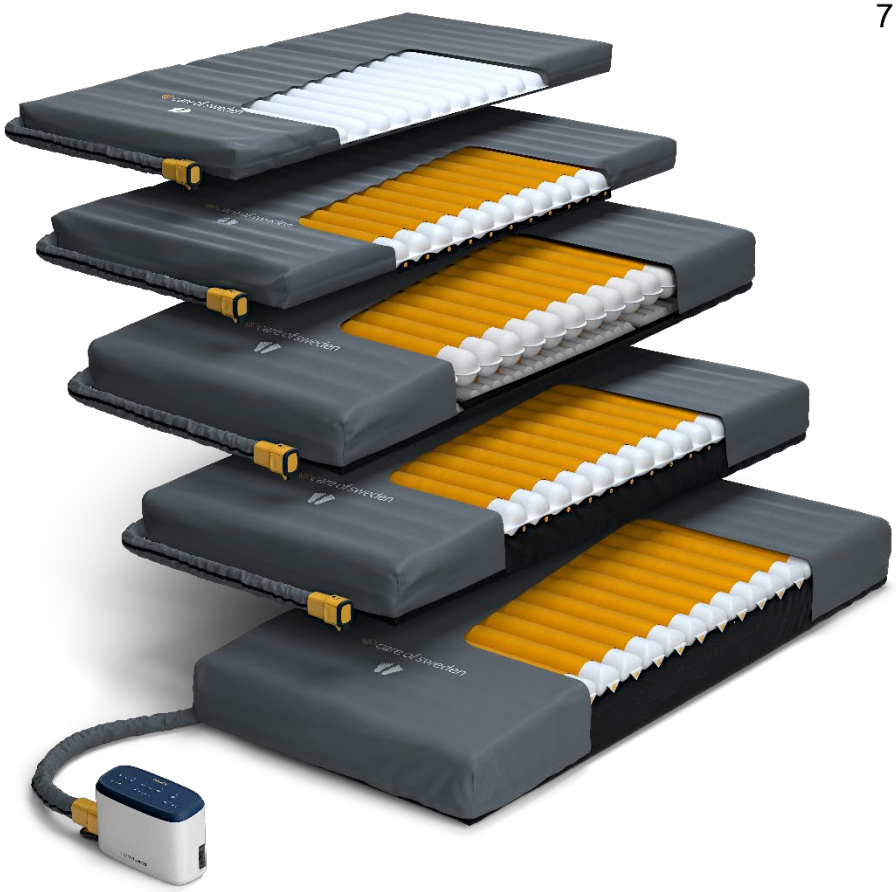

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WARNINGS AND SAFETY PRECAUTIONS

Read all instructions before use or repair

WARNING! To minimize the risk of fire, personal injury and equipment/property damage adhere to the following instructions:

1. The product must only be installed and used for its intended purpose according to the instructions in this manual and/or other documentation from Care of Sweden. 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.
2. The product must be placed and used so that it does not become trapped or damaged. Note: Be particularly aware of trapping damage when using side rails. Always make sure that the mattress is the correct size for the bed.
3. Regularly check product functionality by performing a hand check (see section 3.3).
4. When the product is used for individuals needing special supervision, such as children, continuous monitoring is required.
5. The mattress is protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
6. The hygiene cover does not allow liquid or air to penetrate, but is vapour permeable. Make sure that the user is positioned correctly to avoid the risk of suffocation.
7. Be careful with sharp objects to prevent damage to the hygiene cover.
8. 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.
9. Route the power cable to the control unit carefully to avoid tripping. Also make sure that the user is lying correctly on the mattress according to the instructions and use a cable holder if possible.
10. To avoid the risk of strangulation, make sure that the cable and tubes are routed to prevent someone getting caught up in them.

Note: The responsible healthcare provider must inform the user/operator of the following:

11. 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
12. 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.
13. Do not store or use the product in direct sunlight. The product may be damaged by the elevated temperature and UV light.
14. 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 meters from the control unit.
15. 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.
16. Never connect anything other than the Care of Sweden supplied power supply to the control unit power cable connector.
17. Never use the external communication input (3,5mm connector), this input should only be used by the manufacturer.
18. If the hygiene cover is equipped with side handles, these are intended for managing or relocating the mattress. Do not use the handles to lift the mattress with the user lying on it. All other use takes place under your own liability and is not covered by the product warranty.
19. To prevent the power supply from being pulled out, exercise caution when there are children and pets in the environment around the equipment.
20. 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.
21. In order to minimize the risk of wounds occurring on the feet, make sure that the user doesn't come into contact with the hangers of the control unit.

1. Introduction

CuroCell® A4 is an automated and modern air mattress system designed to provide good comfort while aiding in the prevention and treatment of pressure ulcers/pressure injuries. The system identifies the user and automatically manages all settings to adapt the pressure according to the user's needs.

Unprevented/untreated pressure ulcers/pressure injuries can very quickly deteriorate resulting in higher risk of complications, pain and suffering for the user.

CuroCell® A4 is available in five versions, as a mattress overlay (CuroCell® A4 OP10 and CuroCell® A4 CX10) or as a full replacement mattress (CuroCell® A4 CX15, CuroCell® A4 CX16 and CuroCell® A4 CX20).

Always read the instructions for use prior to use.

For further questions regarding installation, use or maintenance please contact Care of Sweden or your local distributor.

1.1 General information

This system is a medical device with CE marking in accordance with MDR (EU) 2017/745.

The system has been fully or partially designed and verified in accordance with the standards listed in section 9.2. Standards.

According to statutory regulations made by the authorities regarding medical devices, the manufacturer is required to report all accidents or incidents involving the products. We would be very grateful for all information involving accidents or incidents relating to our products, by reporting them immediately to us, at Care of Sweden.

1.2 Intended use

The systems consist of a control unit actively controlling and managing the air flow in the mattress, enabling them to be used for prevention and as an aid in the treatment of pressure ulcers/pressure injuries (PU/PI).

1.3 Indications

Suitable for a wide range of persons with increased risk for pressure ulcers/injuries, including those with superficial ulcers, up to category 4 and unclassified PU/PI (unstageable and suspected deep tissue injury)[1] (in association with an individualised plan of care).

The mattresses are intended for use by persons of a recommended minimum length of 120 cm. The recommended user weight depends on which mattress is being used. The specifications are listed in the table below.

Mattress	Recommended user weight
CuroCell® OP10	0-160 kg
CuroCell® CX10	0-200 kg
CuroCell® CX15	0-220 kg
CuroCell® CX16	0-200 kg
CuroCell® CX20	0-250 kg

1.4 Contraindications

There are no known contraindications.

1.5 Intended user

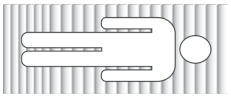
The mattress systems are intended to be used by all kind of users, including lay persons

1.6 Intended use environment

The mattress systems can be used in all kinds of health care environments, including home care.

We recommend that position changes are made regularly. The time interval must be evaluated by the responsible personnel, depending on the user's status, diagnosis and general condition.

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



No training or special skills are required for the use of CuroCell® A4. It is designed to be easy to handle and understand, reading the quick guide and the instructions for use before use is recommended.

Prescription shall be made by persons authorized for prescriptions and with clinical education. Note that the user also may be the operator.

NOTE:

1. For certain users, e.g. amputees, the recommended length measurement may not be reached. Users in these groups may, however, require other settings, as the entire surface is not under load. For function controls, refer to section 3.2.
2. When used together with positioning pillows, read the pillow instructions for use carefully for correct positioning of the user.
3. Whenever this product is used with evacuation equipment (evacuation sheet), it is the responsibility of the authorised personnel to ensure that evacuation can be performed safely.
4. 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.
5. In the event of a power cut or similar, the mattress will retain air for at least 12 hours.

(1) European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline.* Emily Haesler (Ed). EPUAP/NPIAP/PPPIA: 2019

1.7 Other information

Action plan for pressure ulcers/pressure injuries
For the best possible results when using this product, we recommend a structured and planned approach. Examples that can be applied to the use of our products can be found in the 'Action plan for pressure ulcers' guidelines.

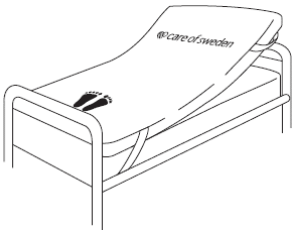
The Mattress Guide
This guide provides guidance to personnel and prescribers when choosing a mattress from Care of Sweden. The CuroCell® A4 OP10, CuroCell® A4 CX10, CuroCell® A4 CX15 CuroCell® A4 CX16 and CuroCell® A4 CX20 are mattresses in function group C.

This information can be obtained from our website, www.careofsweden.com, or ordered from Customer Services (see contact information on the final page).

2. Assembly/installation

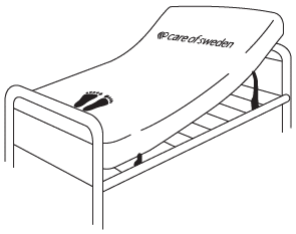
When unpacking, check that no parts are damaged. If any damage is found, contact Care of Sweden or your local distributor before using the product.

When using an overlay mattress (CuroCell® OP10 or CuroCell® CX10):



1a. Place the overlay mattress on the base mattress. Secure the mattress to the base using the straps on the corners of the mattress.

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

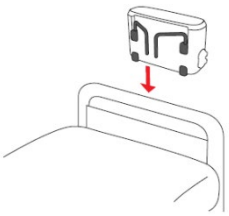


1b. Place the mattress on the bed base. Secure the mattress to the bed using the fastening straps on the underside of the mattress.

Note:

- Make sure that the mattress is the correct size for the bed.
- Make the bed with sheets for added comfort.
- If an adjustable bed is used with a full replacement mattress with fastening straps (CuroCell® CX15, CuroCell® CX16 or CuroCell® CX20), the mattress should be fixed only to the moving parts of the bed.
- Check the cells and press studs to ensure they are correctly assembled.

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



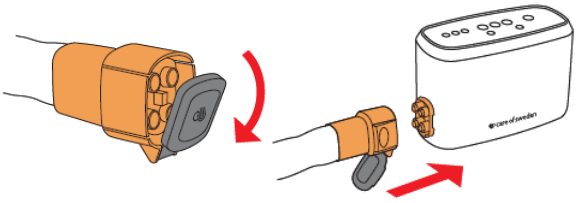
When using an overlay mattress (CuroCell® OP10 or CuroCell® CX10):

3a. If the mattress is equipped with a cable holder, place the power cable in the cable holder by opening the press studs, placing the cable in the gap and closing the press studs again. 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.

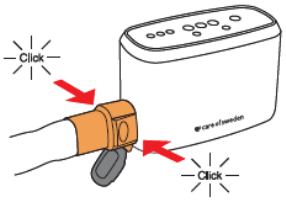
When using a full replacement mattress (CuroCell® CX15, CuroCell® CX16 or CuroCell® CX20):

3b. Place the power cable in the cable holder of the mattress by opening the press studs, placing the cable in the gap and closing the press studs again.

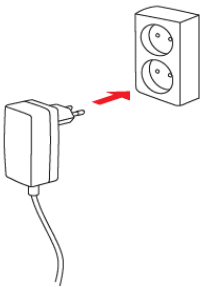
4. Open the lid on the air tube connector (marked 'CPR') and connect it to the side of the control unit.



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



6. Check that the switch on the side of the control unit is set to '0' (off). Plug the power supply into an approved electrical socket (100– 240 V).



7. Check that the power cable has been correctly connected to the control unit and that the correct power supply has been used. (See section 9.1 Technical specification).
The correct P/N must be shown on the label on the power supply. The power supply is part of the equipment and may not be replaced.

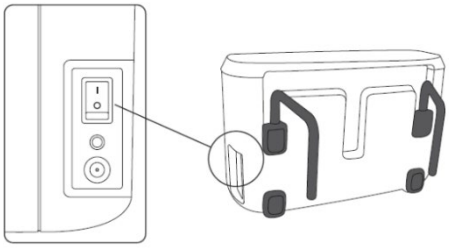
If the control unit has been stored in its minimum or maximum storage temperature (-25°C to 70°C), wait at least 1 hour before starting it. This time is based on an ambient temperature of 20°C.

NOTE:

- Do not hold the 12 V plug on the power supply while touching the user.
- Plug the power supply into an easily accessible socket if there will be a need to unplug the power supply and completely cut the power to the control unit.

3. Operation

3.1 Start



1. Set the On/Off switch on the side of the control unit to position 1 (On).
2. Air will start to be pumped into the mattress and the diode over the chosen program will blink. Upon completion of the inflation process, the program mode diode will remain green constantly. Depending on its size, it takes approximately 20–30 minutes for the mattress to inflate fully.
3. When the green diode for the chosen program mode is constant, the mattress system can be taken into use.
4. It will take approximately 20-30 minutes for the system to adjust to the user.

NOTE:

- Each time the system starts up, it will operate as follows:
  When using a mattress without an air safety mattress (CuroCell® OP10, CuroCell® CX10 and CuroCell® CX16), the control unit will completely inflate the main cells and then perform an automatic setting.
  When using a mattress with an air safety mattress (CuroCell® CX15 or CuroCell® CX20), the control unit always begins by completely inflating the safety mattress, followed by the other cells, and then perform an automatic setting.
- Once automatic setting is complete, the control unit switches to a basic setting of Pulsating mode (when used for the first time) or to the previous setting. For more information see section 3.2.
- During the automatic setting, try to avoid larger movements on the mattress, otherwise, the automatic setting time will be extended.
- When using a mattress with a safety mattress in foam (CuroCell® CX16), the user can lie on the mattress even when not inflated.
  When using a mattress with an air safety mattress (CuroCell® CX15 or CuroCell® CX20), this must be inflated before the user can lie on the mattress.
  In both cases, the safety mattress will carry the load.

3.2 Control unit functions

Button	Function
	Mute the information signal
	Panel lock
	Pack & Go. Automatic deflation of the system
	Alternating mode
	Pulsating mode
	CLP mode (Constant low pressure)
	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

3.2.1 Automatic Setting

The mattress system regulates the mattress's internal pressure independently and without manual adjustment to different values based on the user's weight and position. No manual action is required to affect the internal pressure of the mattress. This function works in the following three ways:

1. The control unit carries out an automatic setting immediately after switching the system on.

2. During usage, if any significant change occurs, the control unit will perform an automatic setting.

3. When in use, the control unit will carry out automatic settings at fixed intervals to ensure correct control of the pressure in the mattress at all times.

Once the automatic setting has completed, the control unit will either start in the default Pulsating mode (with first time use) or in the previously set mode function.

3.2.2 Programs

Three programs are available. Press the button to switch between the programs. We recommend the Pulsating mode as the basic setting and this is also the default setting from start.

1. Alternating mode. The pressure alternates between the cells. The cycle period can be changed according to the user needs and requirements. Choose between 10, 15, 20 or 25 minutes. The longer the cycle period, the slower the alternations. We recommend a basic setting of 10 minutes.

2. Pulsating mode. A comfort mode that combines Constant low pressure (CLP) with Alternating mode. The cycle period can be changed according to the user needs and requirements. The longer the cycle period, the slower the alternations. We recommend a basic setting of 10 minutes.

3. CLP mode. The pressure will be the same in all cells. This is also called 'Constant low pressure'.

3.2.3 Maximum pressure (caring mode)

With this function, the entire mattress is inflated and provides firmed support. This function automatically reverts to the previous setting after approx. 20 minutes. The function should be used when caring the user, shifting the user's position or moving the user in or out of bed.

3.2.4 Panel lock

Press the Key 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.

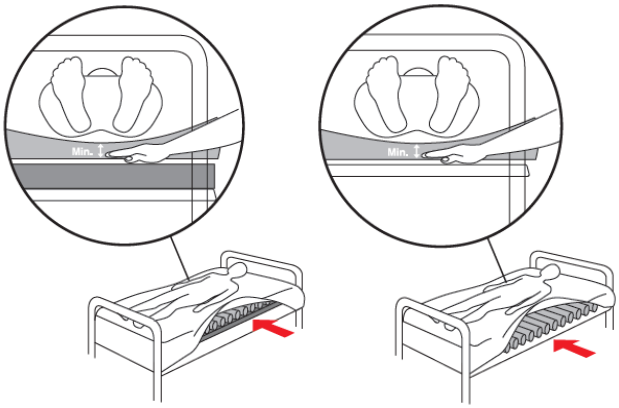
3.2.5 Comfort settings

Depending on the user needs, the air pressure in the mattress can be adjusted. The adjustments are done based on the automatic setting performed by the control unit (0) according to the user weight.

Note: 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.

The selected setting is shown by a green light.

3.3 Hand check (function control)



Hand check when using an overlay mattress system

Hand check when using a full replacement mattress system

The hand check is used to ensure that the mattress is working properly.

This must be performed regularly; we recommend once per shift, or every eight hours.

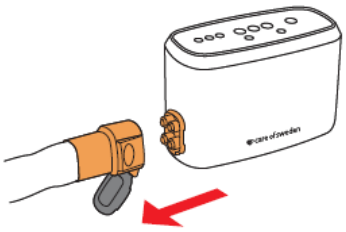
Open the cover and insert a hand between the upper cells beneath the user's sacrum (center of the mattress). Check to ensure that there is a gap to the underlying mattress so that the user does not 'bottom out'. If you can feel the user's sacrum resting in the palm of your hand, the gap is too small. Make a new automatic setting or see section 8 Troubleshooting.

3.4 Sitting positioning in bed

When raising the head end of the bed into a sitting position, always secure the user´s position. To ensure the product functionality, we always recommend to perform a hand-check (see section 3.3). For additional support, positioning pillows can be used. We recommend that a sitting position only shall be used for short periods of time.

3.5 CPR (Cardiopulmonary resuscitation)

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 in order to empty the mattress of air quickly.



3.6 Notifications

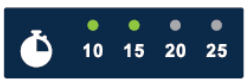
Different notifications exist based on how serious the warning is. With a malfunction or an error, a notification will be given by way of a flashing warning triangle. To mute the warning signal, press the mute button.

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. For more information about the different notification codes, see section 3.6.1.

3.6.1 Table of notifications

Information about each notification is shown in the notification table:

- Notifications from 1-10 are both audible and visual. 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.
- The notifications 11-13 have no audible alarm. The error code is shown until the system is restarted.

Notification		Description and troubleshooting
1		High temperature. Valves and compressors are turned off. If the control unit is in direct sunlight, relocate it. Otherwise, contact the support.
2		Default settings are not completed. Contact the support.
3		Incorrect input voltage. Make sure that the correct power supply is used, otherwise contact the support.
4		Low pressure. Secure the CPR, mattress, air tubes and air filter. If the problem remains, contact the support.
5		Automatic setting failure. The correct pressure has not been reached within the time limit. If the problem remains, contact the support.
6		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 support.
7		High pressure. The pressure cannot be reduced to the desired value within the time limit. Contact the support.
8		The automatic setting has been restarted too many times during the automatic setting period. Contact the support.
9		The mattress control parameters have not been read. Connect the CPR or contact the support.
10		The mattress control parameters have been changed during the use. Restart the system. If the problem remains, contact the support.
11		Leakage in blue cell section. Secure the CPR, mattress and connection tubes. See section 4.2 for more information. If the problem remains, contact the support.
12		Leakage in green cell section. Secure the CPR, mattress and connection tubes. See section 4.2 for more information. If the problem remains, contact the support.
13		Leakage in red cell sections. Secure the CPR, mattress and connection tubes. See section 4.2 for more information. If the problem remains, contact the support.

3.6.2 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.

3.7 Transport function

If the user needs to be moved in bed, there are two ways to perform the transportation:

- Unplug the CPR connection, close the lid, place the CPR connection at the end of the bed and remove the control unit from the bed. The mattress will retain air for at least 12 hours.

or

- Remove the power supply from the wall socket and leave the control unit hanging on the bed during transport. The mattress will retain air for at least 12 hours.

We recommend using this function for short periods only.

3.8 Pack&Go® function (deflation)

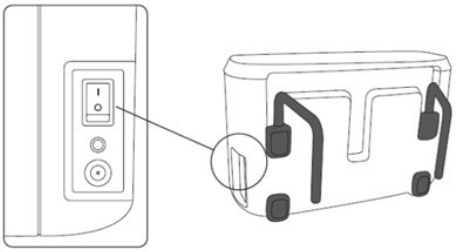
After use, the product can easily be packed as follows:

- Ensure that no-one is lying on the mattress.
- On the control panel, press the lock/unlock button.
- Press the Pack&Go® button and hold it down for 2 seconds.

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

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 power supply is packed complete.

3.9 Restart

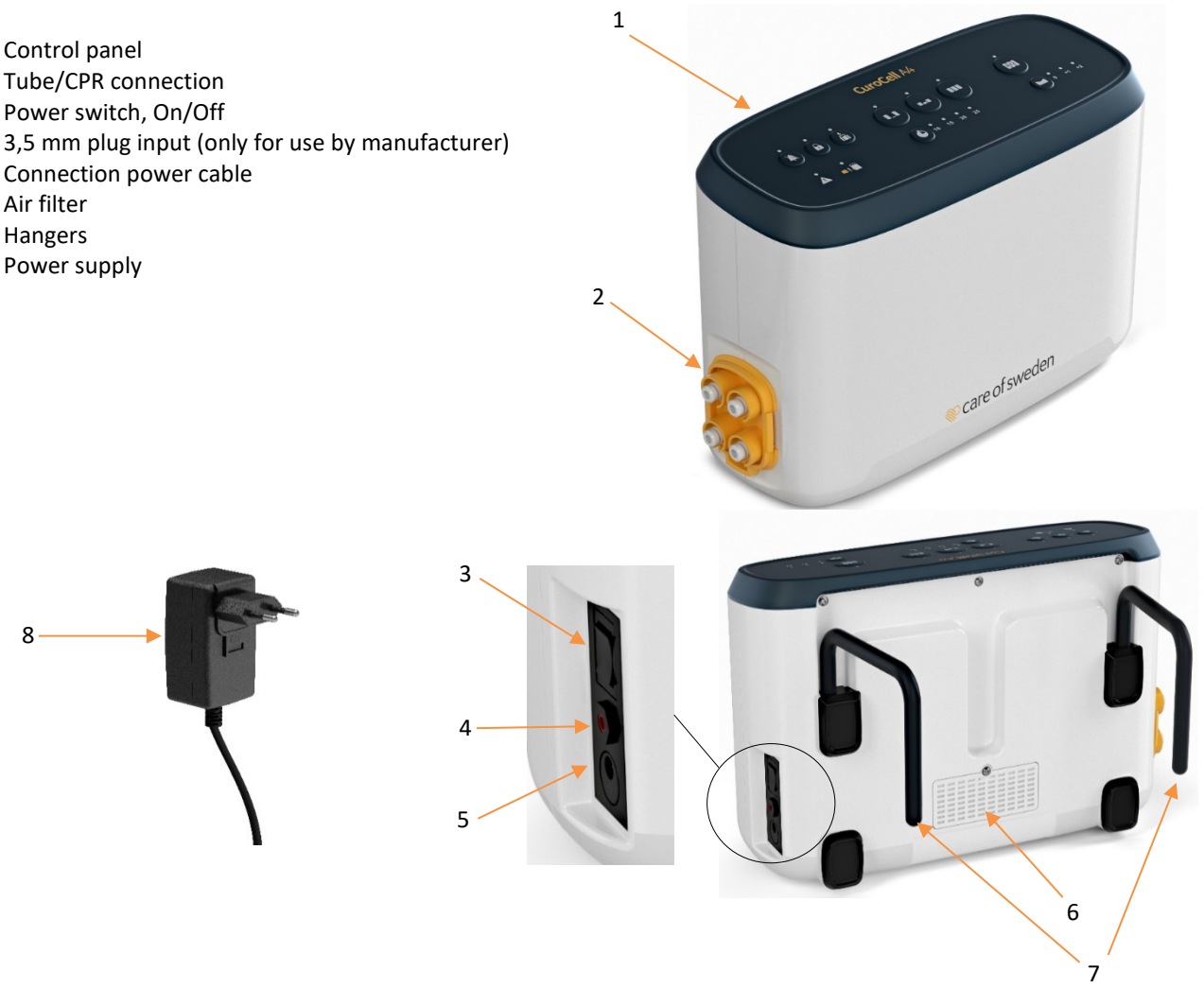


If a restart is required, set the On/Off switch on the side of the control unit to position 0 (Off). Wait for approx. 10 seconds and restart the control unit.
The control unit will now start up. See section 3.1.

4. Product description

4.1 Control unit

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



4.2 Mattresses

Heel function
The CuroCell® A4 mattresses have a built-in heel function, designed to reduce pressure on sensitive heels.

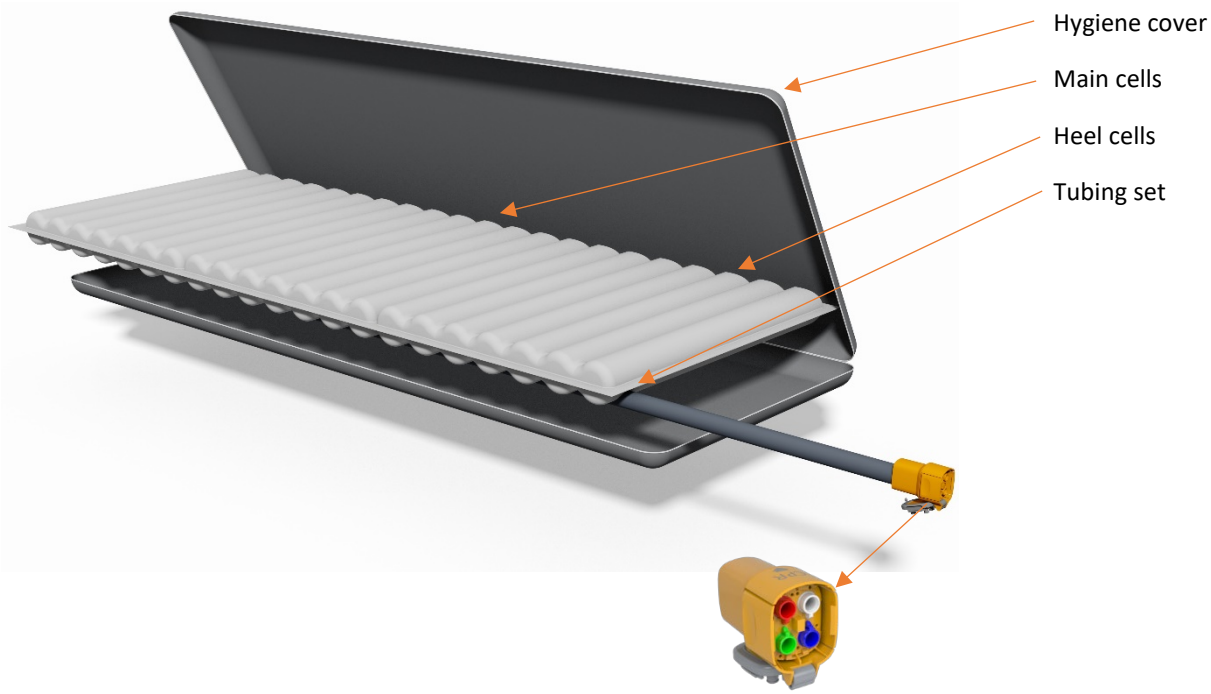
Covers
The CuroCell® A4 mattresses are supplied with a hygiene cover. It is easy to handle and maintain and conforms to the stringent requirements in respect of cleaning and hygiene. The hygiene cover is vapour-permeable, i.e. the vapour is transported away, thus reducing the risk of skin maceration. The following covers are available for the CuroCell® A4 mattresses:

Cover Olivia – A removable cover with a drip-proof zip fastener. Color: light grey. Used for CuroCell® OP10 and CuroCell® CX10.
Cover Stone – A removable cover with a drip-proof zip fastener and welded seams. Color: dark grey. Used for CuroCell® OP10 and CuroCell® CX10.
Cover Olivia/CC – A removable cover with a drip-proof zip fasterner. Divisible (top and bottom part). Functional handles for repositioning the mattress. Color: light grey/black. Used for CuroCell® CX15, CuroCell® CX16 and CuroCell® CX20.
Cover Stone/CC – A removable cover with a drip-proof zip fasterner and welded seams. Divisible (top and bottom part). Functional handles for repositioning the mattress. Color: dark grey/black. Used for CuroCell® CX15, CuroCell® CX16 and CuroCell® CX20.

CuroCell® A4 OP10

1. Mattress
2. Tube connection & CPR (quick deflation)
3. Control unit

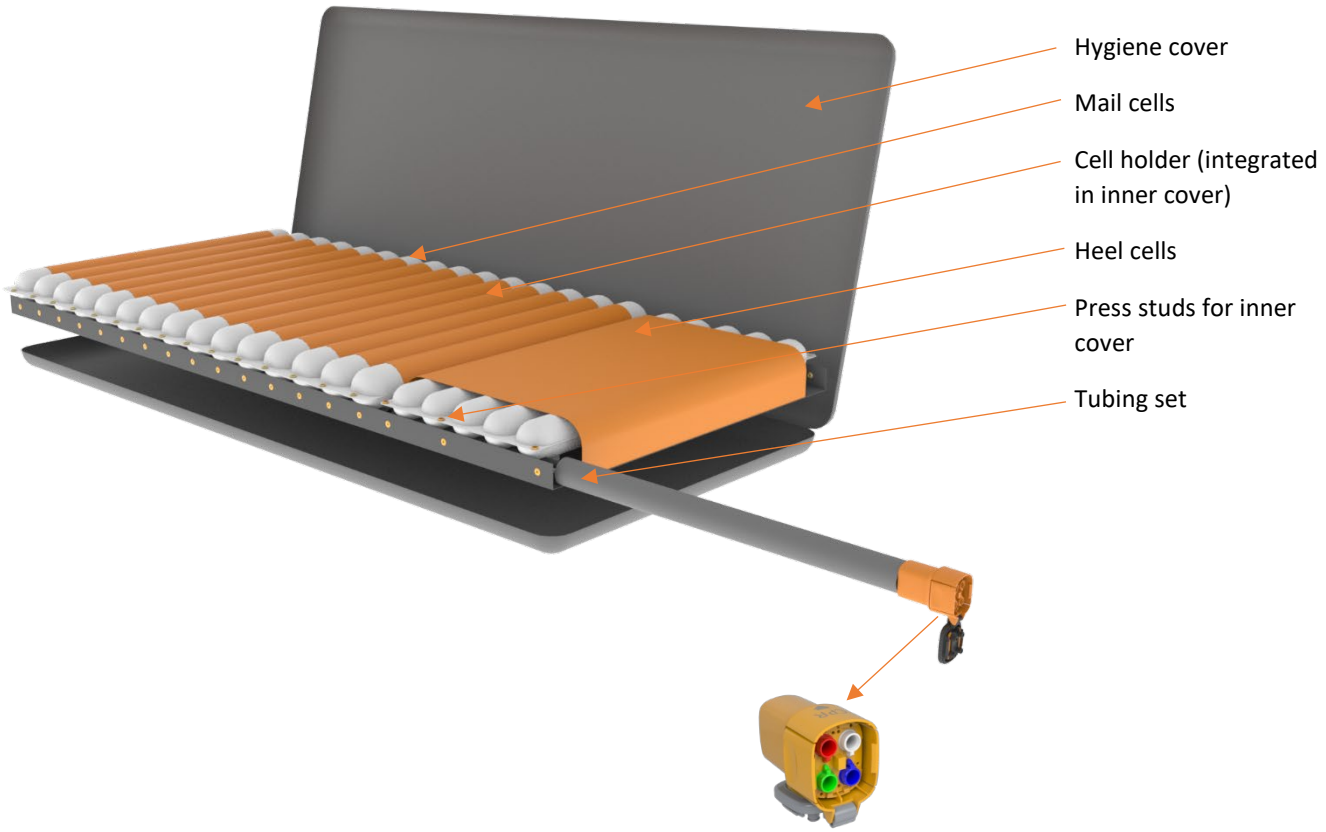
CuroCell® A4 OP10 with cover Stone



CuroCell® A4 CX10

1. Mattress
2. Tube connection & CPR (quick deflation)
3. Control unit

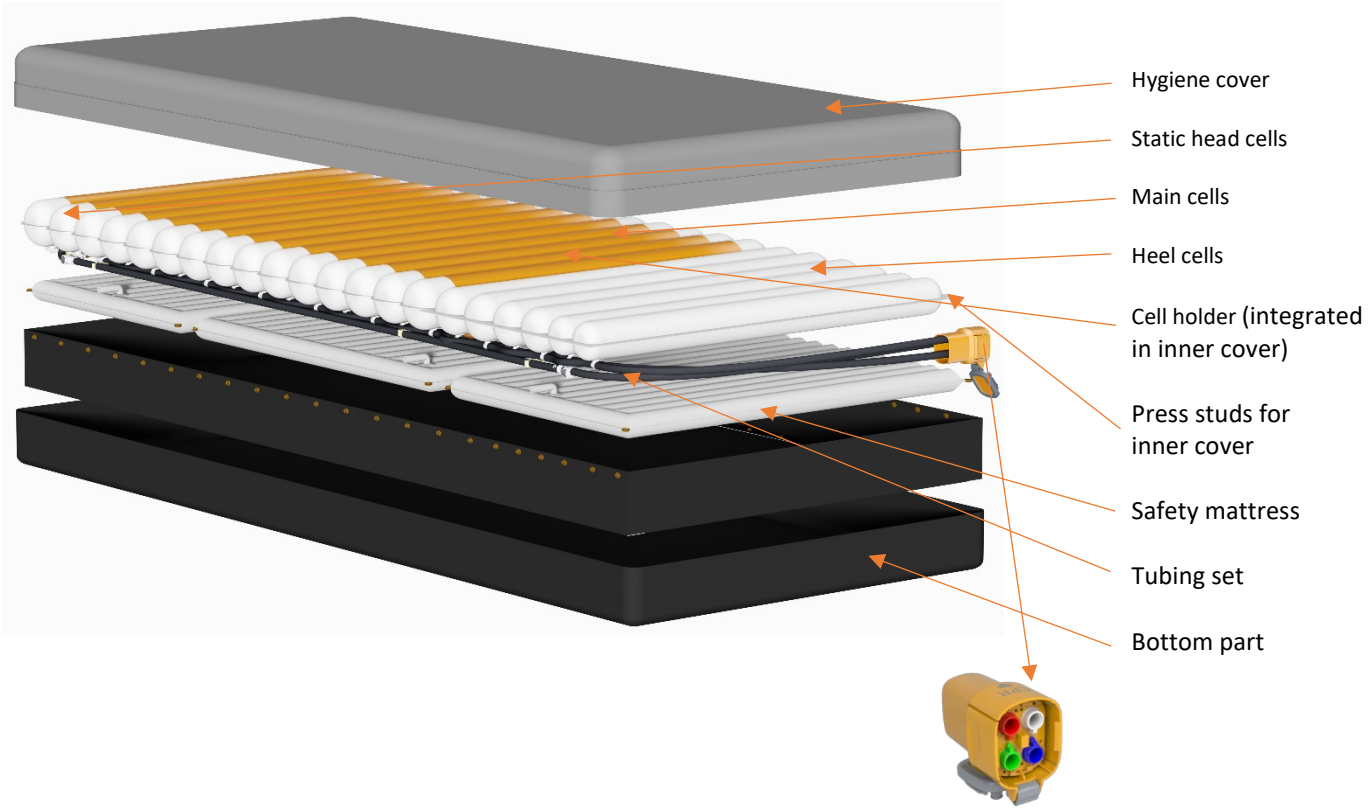
CuroCell® A4 CX10 with cover Stone



CuroCell® A4 CX15

1. Mattress
2. Tube connection & CPR (quick deflation)
3. Control unit

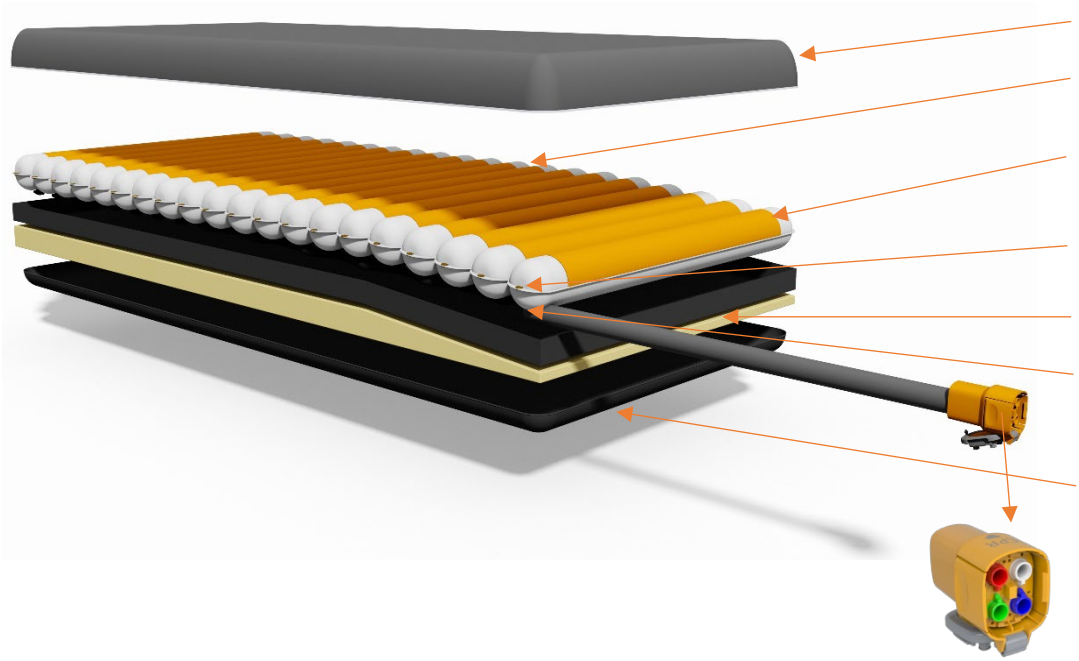
CuroCell® A4 CX15 with cover Stone



CuroCell® A4 CX16

1. Mattress
2. Tube connection & CPR (quick deflation)
3. Control unit

CuroCell® A4 CX16 with cover Stone/CC



Hygiene top part

Cells

Cell holder (integrated in inner cover)

Press studs for inner cover

Safety mattress

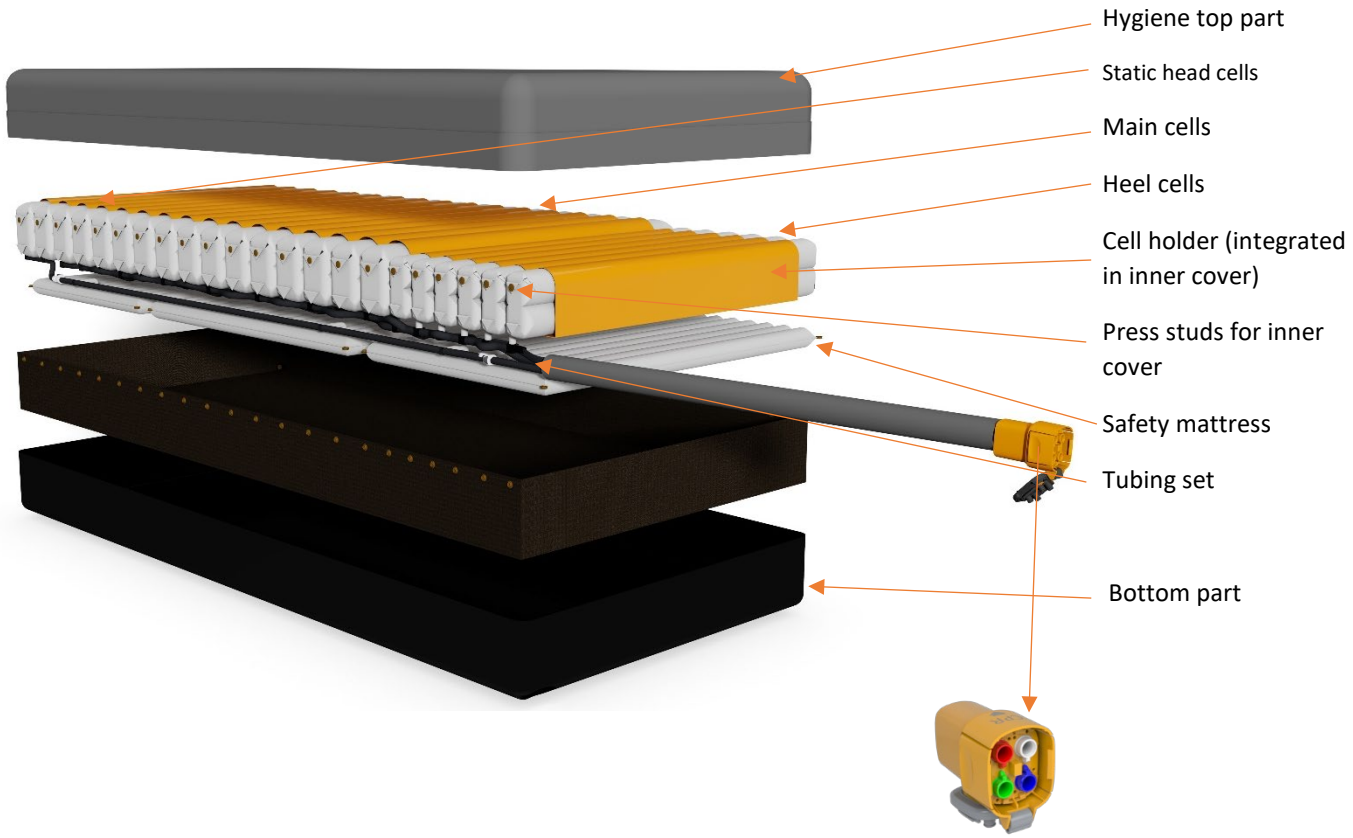
Tubing set

Bottom part

CuroCell® A4 CX20

1. Mattress
2. Tube connection & CPR (quick deflation)
3. Control unit

CuroCell® A4 CX20 with cover Stone/CC



5. Reuse, cleaning and reconditioning

The product is reusable. When reusing, it is important to follow the instructions below for cleaning and reconditioning. Before using the product again for a new user, it is recommended to clean the mattress in accordance with the instructions below. Consult your hygiene manager or Care of Sweden for help and instructions if you are unsure.

Cleaning and reconditioning should otherwise be performed as required.

5.1 Cleaning

CONTROL UNIT

Wipe off the control unit with a damp cloth and mild cleaning solution for this purpose: such as alcohol with or without tenside surfactants, oxidizing solutions, chlorine max 1 % or hydrogen peroxide max 1,5 %.

If using a different agent, choose one that does not affect the control unit.

MATTRESS COVER

Covers can be wiped off with a mild cleaning solution for this purpose such as: alcohol with or without tenside surfactants, Isopropanol 70 %, oxidizing solutions, chlorine max 1 % (max 10% for cover Stone) or hydrogen peroxide max 1,5 %.

Excrement and blood stains must be removed as soon as possible using cold water. Carefully follow local instructions and the instructions for the detergent.

Multi-layer covers should be divided before washing. The parts should be washed with similar colours.

Chlorine and phenol-based cleaners could adversely affect the PU surface and should be avoided. If chlorine is used, we recommend a mixture of max 1 % (max 10% for cover Stone).

INNER COVER

Clean the affected area with a mild cleaning solution for this purpose such as: alcohol with or without tenside surfactants, Isopropanol 70 %, oxidizing solutions, chlorine max 1 % or hydrogen peroxide max 1,5 %.

5.2 Reconditioning

CONTROL UNIT

See section 5.1 for instructions.

MATTRESS

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

2. Remove the covers. For more information of cleaning the covers, see section 5.1.

3. Move the mattress to a clean area that is suitable for cleaning.

4. Wipe off the cells, all tubes and the CPR module with a mild cleaning solution for this purpose such as: alcohol with or without tenside surfactants, Isopropanol 70 %, oxidizing solutions, chlorine max 1 % or hydrogen peroxide max 1,5 %. Let it dry.

Note: When using the CuroCell® CX15 or CuroCell® CX20, the air cells can be divided using a quick-release connector, making it easier to clean the cells.

5. Wipe off the work surfaces using a suitable detergent and/or disinfectant.

6. Put the mattress together. If cells for any reason have become loose from the tubes, these must be replaced according to the drawing in section 4.2.

FOAM CORE

Clean the affected area with a mild detergent (such as washing-up liquid) and water or with an alcohol-based disinfectant (cleaner intended for this purpose. Gently squeeze out any water.

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

Do not wring or roll the foam core to extract the water. Let it dry in a warm, ventilated area (not in direct sunlight). The foam core must be completely dry before it is used again.

6. 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 9.

7. Maintenance

7.1 General

The CuroCell® A4 air mattress is a medical device, in accordance with Medical Device Regulation (EU) 2017/745, that is used as an aid in preventing and treating pressure ulcers/pressure injuries. For this reason, we recommend that the control unit be regularly serviced and inspected to maintain functionality and performance. Like other technical devices, a control unit that is properly cared for works better and lasts longer.

Servicing and maintenance must always be performed by Care of Sweden or one of its authorized technicians. Only use spare parts that have been approved by Care of Sweden. Use of non-approved spare parts invalidates the warranty. For more information, see the CuroCell® A4 service manual.

Faults and defects regarded as warranty faults are fixed free of charge.

A warranty claim must be submitted to Care of Sweden before the product is returned

After the product is used, check that:

1. The power cable and power supply are undamaged.

2. The connecting tubes (marked CPR) on the side of the control unit are positioned correctly and not leaking.

3. The hygiene cover is intact and the cover and cells are correctly assembled.

4. No tubes or connectors are damaged or jammed.
Contact Care of Sweden or your local distributor if any spare parts are required.

7.2 Replacing the air filter

Before any maintenances are 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. Loosen the small 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 very dirty environment the filter should be checked regularly.

8. 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 user is 'bottoming out'	Restart the control unit. See section 3.9. The control unit will initiate an automatic setting. Wait until the automatic setting is complete. Perform a further hand check (see section 3.3). If the gap is still too small, raise the comfort setting in stages. If the problem keeps occurring, contact Care of Sweden or your local distributor.
The mattress moves around	Check that the mattress is fastened to the bed frame with the straps underneath (two at the head end and two on each of the long sides).
Some cells have less air	This is normal with a Pulsating or Alternating 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 hung on the bed. Resonance can occur, vibrations are felt in parts of the bed. Remove the control unit and listen to see whether this makes a difference. Can be resolved by putting the control unit on a flat, steady surface or by placing a towel between the control unit and bed. If the problem keeps occurring, contact Care of Sweden or your local distributor.

If the above information does not answer your questions, please contact Care of Sweden or your local distributor.

9. Technical description

9.1 Technical specification

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

CONTROL UNIT SPECIFICATION		
Model		CuroCell® A4
Input voltage		100-240 V / 50-60 Hz
Power consumption		1.5 A
Mode of operation		Alternating, Pulsating and CLP (Constant low pressure)
Duty cycle	(Pulsating and Alternating)	10 min, 15 min, 20 min, 25 min
Power supply	Ungrounded AC outlet, electrical safety class II	Use only power supply with P/N WR9QE1500LRPCIMG3138
Dimensions (L x W x H)		11 cm x 30 cm x 20 cm
Weight		2.9 kg
Sound level, control unit, max:		EN ISO 11201:2010 -17 dBA (at operator position), 16,5 dBA (at head end). ISO 3746:2010 – 25 dBA.
Environmental	Temperature	Operation: +5 to 40°C Storage: -25 to 70°C Transport: -25 to 70 °C
	Humidity	Operation: 15 % – 93 % non-condensing Storage: < 93 % non-condensing
	Atmospheric	700 hPa – 1060 hPa
Electrical classification		Class II, Type BF
IP classification		IP42
Degree of safety in presence of inflammable anesthetics:		The device is not intended for use with flammable anesthetic gases
Applied part		Mattress

MATTRESS SPECIFICATION		
Model	**Dimensions (WxLxH)**	**Weight**
CuroCell® OP10	80/85/90 x 200/210 x 10 cm	3,7 kg (80x200 cm)
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	10,0 kg (80 x 200 cm)
CuroCell® CX16	80/85/90/100/105/120 x 200/210 x 16 cm	12,0 kg (80x200 cm)
CuroCell® CX20	80/85/90/100/105/120 x 200/210 x 20 cm	11,0 kg (80x200 cm)

9.2 Standards

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

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-11
IEC 60601-1-6
IEC 62304

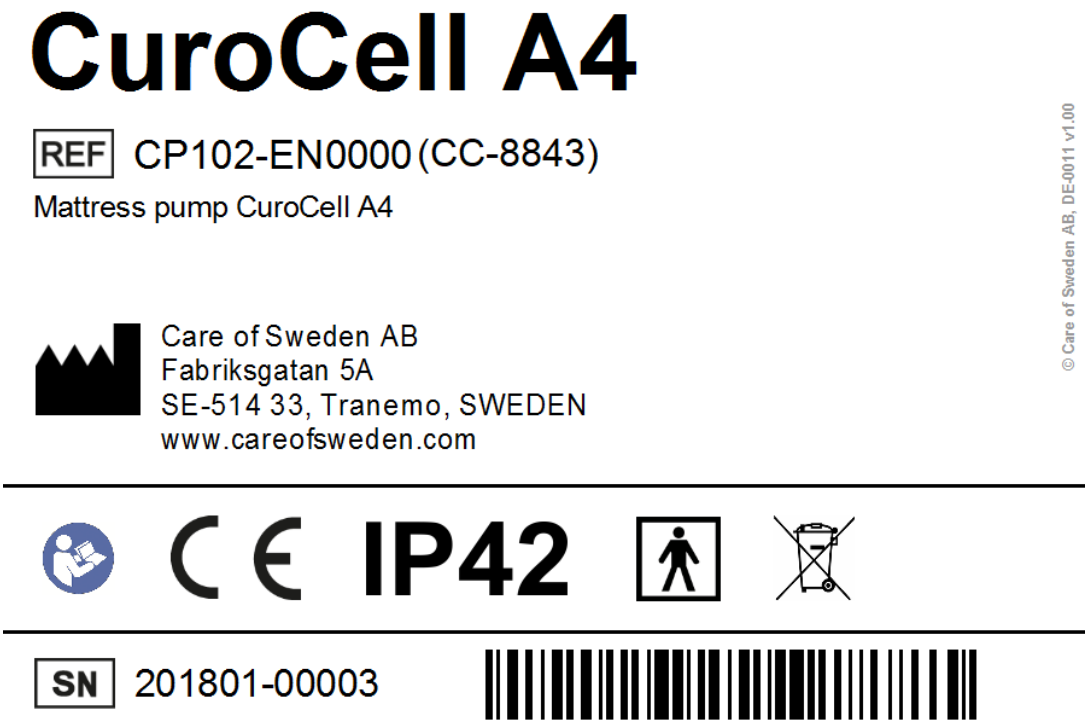
EN ISO 10993
EN 12182
EN 597-1
EN 597-2
EN ISO 14971

ISO 3746
ISO 11201

9.3 Marking

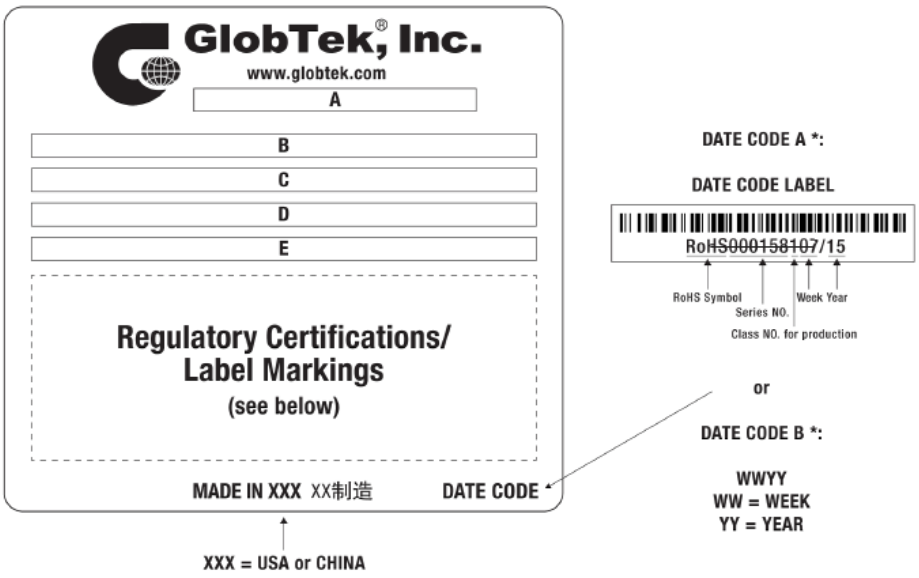
THE CONTROL UNIT

The control unit is marked as shown below (example). For an explanation, see section 9.4 Symbol key.



POWER SUPPLY

The power supply is part of the control unit and is marked as shown below (example).

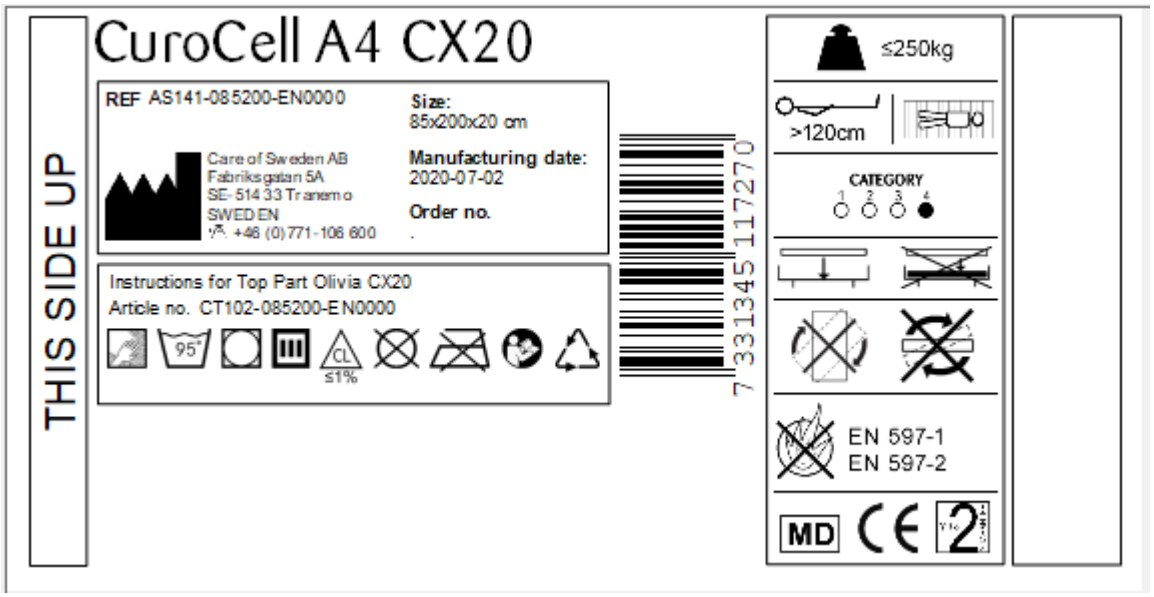


A=ITE / Medical Power Supply/Class 2/Household Power Supply
B=P/N: (料号) WR9QE1500LRPCIMG3138
C=Model (型号) GTM96180-1817.9-5.9
D=Input (输入) 100-240V~, 50-60 Hz, 0.6 A
E=Output (输出)12 V ⎓ 1.5 A, 18.0W

For an explanation, see section 9.4 Symbol key.

THE MATTRESS

The mattress, cover and inner cover are marked as shown below (example).



For an explanation, see section 9.4 Symbol key.

9.4 Symbol key

Item number

Manufacturer

XXXX-XX-XX

Year-Month-Day

Foot placement

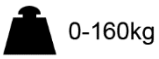
Read the instructions for use

Type BF

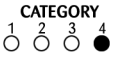
CE-marked in accordance with Medical Device Regulation (EU) 2017/745

Recycling

Do not dispose of with household waste; follow recycling instructions



Recommended user weight



User information – category

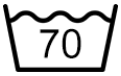
Placed directly on the bed base

Counteracts shear

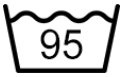
Heel function

Place on top of existing mattress

Do not machine wash

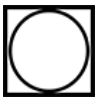


Machine wash at 70 °C



Machine wash at 95 °C

Chlorine



Tumble dry

Do not tumble dry

Drip dry

Do not iron

Do not dry clean

Wipe clean

Do not rotate

Do not turn around

Fire requirements

Minimum length

Serial number

Class II equipment (Double-insulated). Indicated on the power supply.

IP class (Enclosure class)

The mattress should be used with the user lying lenghtways.

Distributed by

Medical Device

UDI

10. Warranty

10.1 Scope

This CuroCell® system is covered by a 2-year warranty for manufacturing defects. The warranty does not apply to normal wear and tear or damage due to negligence or improper handling/care.

10.2 Recommended life time of the product

The estimated life time of this product is 5 years.

11. Other information

11.1 Disassembly and recycling

Except for certain parts of the control unit, energy recovery is possible for almost all material in CuroCell® products through incineration in waste incineration facilities.

NOTE! If it is assessed that the product is or could be contaminated (e.g. used by users with a known bloodborne infection), the product must be handled in accordance with the healthcare provider's or local authority's procedures for contaminated waste.

Control unit:
The air tube connector (marked 'CPR') is easy to disassemble and is sorted as "plastic waste". The other parts of the control unit must not be disassembled and are sorted as "electronic waste".

Mattress:
A used CuroCell® mattress should be taken to a recycling center. The product is sorted as 'combustible waste'.

Care of Sweden complies with its manufacturer responsibility by being affiliated to the Swedish Packaging and Newspaper Collection Service (FTI) and the electrical and electronic product recycling service company, El-Kretsen. For more information contact Care of Sweden or your local distributor.

11.2 Returns and warranty claims

Contact Care of Sweden or your local distributor before returning the product. The return postage will be paid by Care of Sweden where the fault is covered by the product warranty; otherwise, it will be paid by the customer.

Manufactured by:

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Distributed by: