care of sweden
SUPPORTING LIFE

Instructions for use

2022-12-07

CuroCell UNO®

Air mattress system

Instructions for use item number: 95-001401-EN0000

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Table of contents

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. 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 3.7).

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 patient 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 to pull out the power cable by accident. Also make sure that the patient 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.

11. Do not use the product in bathrooms or other areas 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. 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 a patient lying on it. All other use takes place under your own liability and is not covered by the product warranty.

18. To prevent the Power supply from being pulled out, exercise caution when there are children and pets in the environment around the equipment.

19. 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.

20. In order to minimize the risk of wounds occurring on the feet, make sure that the patient doesn't come into contact with the hangers of the control unit.

1 Introduction

CuroCell® UNO is an automatic air mattress system used as an aid to prevent and treat pressure ulcers/pressure injuries. The automation means that the control unit's built-in sensors use software to adjust the inner pressure of the mattress according to the patient's weight, height, position, and change in position. This means that no manual action needs to be performed to adjust the inner pressure of the mattress to conform to the patient.

Always read the instructions for use prior to use.

1.1 General information

The product 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.

1.2 Intended purpose

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

1.3 Intended user

The mattress systems are intended to be used by all kind of patients, including lay persons. Prescription shall be made by persons authorized for prescriptions and with clinical education. Note that the patient also may be the operator.

1.4 Intended use environment

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

1.5 Indications

Suitable for a wide range of patients with increased risk for pressure ulcers/injuries, including those with superficial ulcers, up to category IV and unclassified PU/PI (unstageable and suspected deep tissue injury) (in association with an individualised plan of care). The mattresses are intended for use by patients of a recommended minimum length of 120 cm.

1.6 Contraindications

There are no known contraindications.

1.7 Clinical benefit

The clinical benefits for the mattresses included in this instruction for use are:

- Prevention and treatment of pressure ulcers/pressure injuries up to and including category IV and unclassified PU/PI.
- Reduction of shear forces.
- Safety, comfort, pressure redistribution and easy to handle.
- Silent running control unit.

Note!

- For certain patients, e.g. amputees, the recommended length measurement may not be reached. Patients in these groups may, however, require other settings, as the entire surface is not under load. For function controls, refer to section 3.7.
- When used together with positioning pillows, read the pillow instructions for use carefully for correct positioning of the patient.
- Whenever this product is used with evacuation equipment, it is the responsibility of the authorised personnel to ensure that evacuation can be performed safely.
- Be careful when using bed rails or other protection on the bed so that the mattress does not become crushed or damaged.
- The mattress must not be lifted with a patient lying on it, or used for any other type of transport other than as recommended in these instructions.
- This mattress is unsuitable for use during x-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic errors.
- If the system is used with an unreliable mains power supply, the variant with a backup battery is recommended. In the event of a power cut or similar, the mattress will retain air for at least eight hours.
- We recommend a change in position regularly. The interval must be assessed by responsible personnel, depending on the status, diagnosis, and general condition of the patient.

2 Assembly and 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.

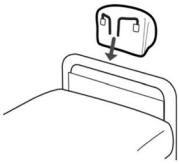
1. Place the mattress on the bed base. Secure the mattress to the bed using the straps on the underside of the mattress.

If the mattress is used on an adjustable bed, the straps shall be fastened to the non-movable parts of the bed. The straps at the head end of the bed shall be fastened at the moving part of the head end. The straps at the foot end of the bed shall be fastened at the moving part of the foot end.

Note!

- Make sure that the mattress is the correct size for the bed.
- Check the air cells and press studs to ensure they are correctly assembled.
- Make the bed with sheets for added comfort.

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

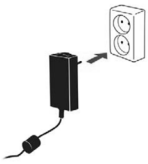


With a cable holder: Place the power cable in the cable holder of the mattress by opening the press studs, placing the cable in the gap and closing the press studs again.

Without a cable holder: 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.

3. Connect the air tubes (marked 'CPR') coming from the mattress on the control unit side. A click is heard and felt when correctly connected. Always check that it has been correctly connected.

4. Check that the switch on the side is set to '0' (off). Plug the power adaptor into an easily accessible approved electrical socket (100-240 V).



Check that the power cable has been correctly connected to the control unit and that the correct power adaptor has been used, see section 9 for technical specification.

The power adaptor 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 or 70°C), wait at least 1 hour before starting it. This time is based on an ambient temperature of 20°C.

Note!

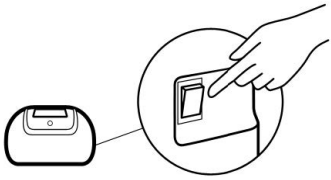
- Equipment with an electrical safety class of II must always be used for home care and in nursing homes.
- In hospitals and equivalent sites, equipment with an electrical safety class of I or II may be used, depending on whether or not the socket is earthed.
- Do not hold the 12 V plug while touching the patient.
- Check that cables and tubes are laid such that the patient or children cannot become caught up in them, due to risk of strangulation.
- Always use the power cable when starting the control unit. This also applies if the control unit has a back-up battery. The control unit shall not be started on the backup battery.

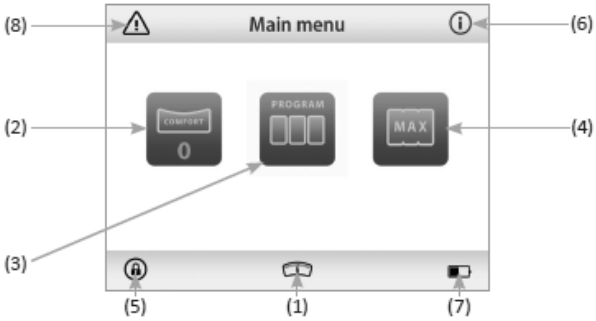
3 Operation

OPERATION CuroCell UNO®
1. Set the on/off switch on the side of the control unit to 1 (on).
2. Air will start to be pumped into the mattress. Depending on the size of the mattress it takes 20-40 minutes for the mattress to fully inflate.
3. The mattress can be used once the function button on the front of the control unit light up in green.

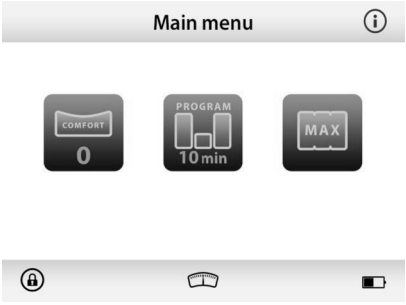
Note!

- Each time the system starts up, the control unit will always begin by completely inflate the safety mattress, followed by the other air cells and then perform an automatic setting.
- Once an automatic setting is complete, it switches to the basic setting of Alternating mode when used for the first time, or to the previous setting when it has been used before.
- If necessary, the patient can lie on the mattress even when not inflated. In this case the safety mattress will carry the load. When using a mattress with an air safety mattress, this must be inflated.

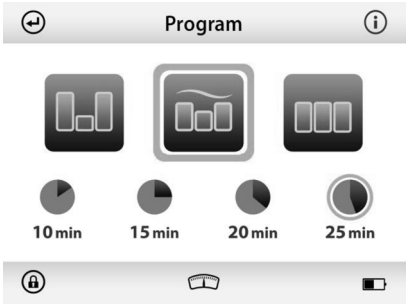




1. Automatic setting
2. Comfort settings
3. Programs
4. Maximum pressure
5. Screen lock
6. Information
7. Battery indicator
8. Notification



The current selected settings are always shown in the program symbols on the main menu. In the example above, the settings are 'Alternating – 10 minutes'.



On the program menu, the settings are displayed with an orange frame around the selected setting. In the example above, the settings are 'Pulsating – 25 minutes'.

3.1 Function

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:

1. 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.
2. If the patient moves noticeably or changes their position, the system will independently control the inner pressure of the mattress.
3. 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. At start-up, Pulsating Mode is always pre-set.

3.2 Program

There are three programs to choose from:

Alternating mode means that the air pressure in the air cells are different and alternates regularly after chosen cycle periods.

Pulsating mode combinates CLP with the alternating function.

Constant low pressure (CLP) means that the air pressure in all of the air cells is the same in the whole mattress.

Choose program by pushing the button for the program.

1. Alternating mode: The cycle period can be changed according to the patient 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. The cycle period can be changed according to the patient 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.

3. Constant low pressure. No cycle period is needed.

Note!

- During battery operation, it is possible to select Constant low pressure and Pulsating mode, but it is not possible to choose the cycle period. The cycle period will be 20 minutes (or longer if this was set before the transition to battery operation).

3.3 Maximum pressure (caring mode)

With this function, the entire mattress is inflated and provides fixed support. This function automatically switches to the preceding setting after approx. 20 minutes. This function should be used when nursing the patient, shifting the patient's position, or moving the patient in or out of bed.

Note!
The automatic settings are disengaged when using this program.

3.4 Screen lock

Press the Screen Lock button to lock or unlock the screen. The display indicates when the screen 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 padlock  and confirm using  again

3.5 Comfort setting

The air pressure in the mattress can be adjusted in three stages: a basic setting set by the control unit (0) according to the patient's weight, which can be increased in two stages (+1 or +2) according to the patient's wishes.

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.

3.6 Automatic setting

The mattress system regulates the mattress's internal pressure independently and without manual adjustment to different values based on the patient'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 system performs an automatic setting when the system has been started.
2. The system itself will start this function if any significant changes occur during use.
3. The system performs an automatic setting at fixed intervals even if no significant changes have occurred.

Once automatic setting is complete, the system will revert to the previously used program. At first start-up, the setting is the basic setting of Pulsating mode, 10 minutes.

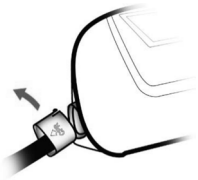
3.7 Hand check (function control)

Hand check is performed to ensure that the mattress system works properly. Hand check should be performed regularly, we recommend once per work shift or every 8th hour.

Open the cover and insert a hand between the upper air cells beneath the patient's pelvic region (centre of the mattress). Check to ensure that there is a gap to the underlying mattress so that the patient does not 'bottom out'. We recommend a gap of one or two finger widths. If the gap is too small, try a restart.

3.8 CPR (cardiopulmonary resuscitation)

In case of an emergency where CPR (cardiopulmonary resuscitation) is necessary, remove the connection (marked 'CPR') from the control unit in order to empty the mattress of air quickly.



3.9 Transport function

With a control unit without a backup battery:
If the patient needs to be moved in bed, the power adaptor can be removed from the wall socket and the control unit left over the end of the bed during transport. For optimum comfort, Care of Sweden recommends first placing the control unit in Constant low pressure mode and waiting for 5 minutes before disconnecting. The mattress will retain air for at least eight hours.

With a control unit with a backup battery:
The control unit will automatically switch to this function when the mains cable is removed. The control unit will automatically switch to Constant low pressure mode and warn in good time before the battery is completely exhausted. The battery lasts for at least five hours.

We recommend using this function for short periods only.

3.10 Pack&Go

After use, the product can be packed as follows:
1. Ensure that no-one is lying on the mattress.
2. On the main menu, press (i) in the top right hand corner. This takes you to the Information menu from which the Deflation function can be activated  .
3. Confirm by pressing 
4. The function button will flash orange 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.
5. Carefully fold the mattress together, place the control unit between the folds of the mattress and place in a transportation bag (accessory) or equivalent for protective storage. Ensure that the power adaptor is packed away. After Pack&Go has been completed, the system returns to factory settings.

3.11 Restart

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

3.12 Battery indicator

If the control unit has been fitted with a backup battery (variant), the condition of the battery is shown as follows:

	Battery 100%
	Battery 75%
	Battery 50%
	Battery <25% Charge immediately (control unit prepares constant low pressure therapeutic mode)
	Battery charging

Note:
To ensure optimum function and condition, the backup battery should never be discharged completely. The battery charges up when the control unit is operating. A fully charged battery lasts for at least five hours.
If the control unit is left without operating for a long period, the backup battery should be charged every six months for maintenance purposes.

3.13 Information (i)

Button that takes you to the information menu. In the information menu you will find:

- Information about the product
- Contact information for Care of Sweden
- Shortcut to quick tour
- Deflation function

3.14 Notifications

Notifications are shown with a warning triangle on the main menu, with a dedicated display image, or with a sound and flashing orange light in the function button on the front.

Notifications are silenced and acknowledged (disabled) using the function button on the front. If problems occur with Notifications, see section 8 for Troubleshooting.

Different notifications exist based on how serious the warning is (Major or Silent notification)

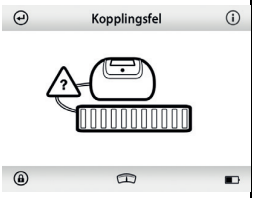
Major notification:
The error is of great significance for operation or function and the control unit will indicate an error by notifying with information on the display, light and sound. After 10 min, the frequency of how often the notification sound is reduced if it is not acknowledged. Information on the type of error is shown in the display, see noitification types below

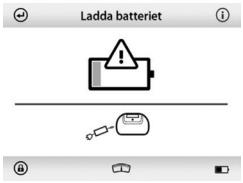
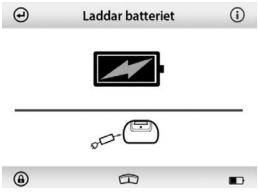
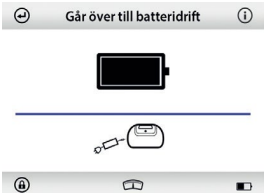
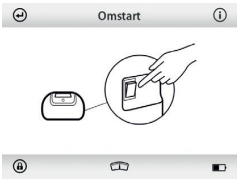
Major notifications cannot be acknowledged (disabled) without rectifying the error. The sound can be silenced temporarily via the function button but will return after approx. 5 min unless the error is rectified. In the event of a power failure and high system temperatures, information is not shown in the display, instead sound and light notify using the function button until the power is used up.

Silent notifications
The error has minor or no significance for operation or function and should not disturb the patient unnecessary. Silent notification also contains information.

Information on the type of error is shown in the display, see notification types below, and when acknowledging, the system continues to work with the triangle lit up in the left hand corner of the main menu.

3.15 Table of notifications

Maj	
Power failure (the control unit is receiving insufficient power)	When the control unit is no longer receiving power, it activates an audible warning and orange light in the function button. The control unit will turn itself off when the power in the control unit has been used up completely. Make sure that the power adaptor is connected to the wall and the control unit. Also check that the On/Off switch on the side of the control unit is set to position 1 (On).
High system temperature	The control unit will turn itself off for cooling. The control unit will restart after cooling. Make sure that the control unit's filter is not clogged and that the control unit is not positioned in direct sunlight.
Low/high pressure	Sound and light warnings that are activated in the event of high/low pressure in the mattress. Turn off the sound notification by pressing the function button on the front. It will be activated again after approx. five minutes if the pressure has not returned to normal. Check all connections in the mattress and that the CPR connection is connected correctly. 
Connection error	If the correct air pressure is not achieved in the mattress within 20–40 min (depending on the size of the mattress) from start-up and when filling, the control unit will notify of a connection error. Make sure that the tube connection is correctly fitted to the control unit. Make sure that the mattress is the correct size for the control unit (read from article number, i.e 080200 is 80x200 cm both on mattress and control unit). 

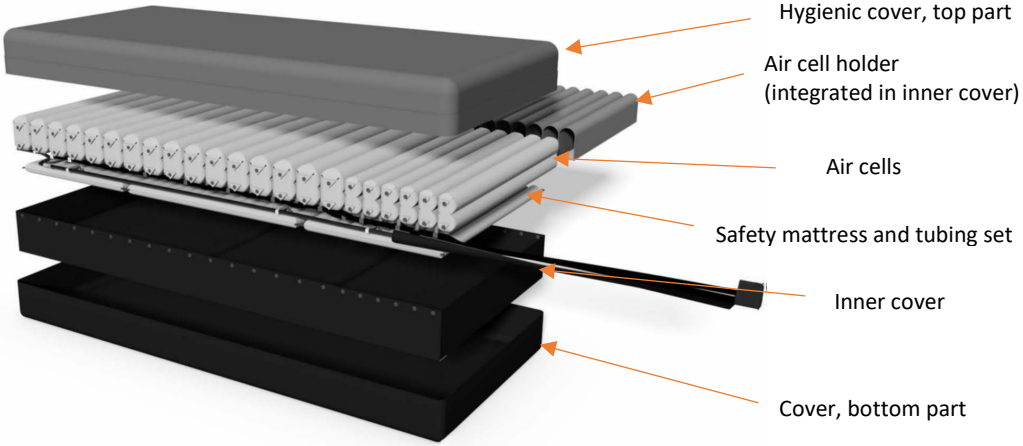
Silent notifications	
Service If the control unit is in need of service, this is shown with an image. The service codes refer to different service actions, depending on which firmware version the control unit has installed. To find out which firmware version is installed, press the information button on the display. Always try to restart the device before contacting service.	
Low power (during battery operation wit battery backup)	In the event of low power during battery operation, press the Function button and the software will return to the main menu but with the 'low battery' symbol in the lower right-hand corner lit (7). See section 2.3. The program switches to Constant low pressure mode and no changes can be made before the control unit is connected to the mains power. Connect the power adaptor to a power outlet. 
Switching to battery operation start-up	When starting up the system on the backup battery, a confirmation is required by acknowledging that the system should start, and the images disappear. Audio notification is also given in this case. Connect the power adaptor to the power outlet for normal operation or acknowledge using the function button to operate the control unit by battery. 
Charging battery	Shows that the mains power is connected, and that the battery is charging. Goes off automatically after 5 sec. 
Battery operation	Shows that the control unit has switched over to battery operation. Goes off automatically after 5 sec. Connect the power adaptor to the power outlet for normal operation or let the control unit operate by battery. 
Restart	When a restart is required, the control unit signals using a sound and the orange function button. Acknowledge using the function button and turn off the power by turning the On/Off switch at the side of the control unit to 0 (Off). Wait for approx. 10 seconds, then turn the control unit on again immediately and turn the On/Off switch to 1 (On). 

4 Product description

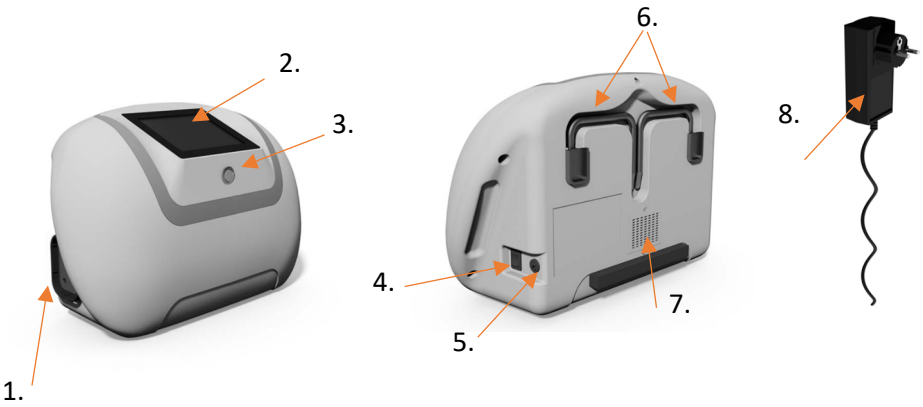
4.1 Mattress and Control unit

1. Mattress
2. CPR (Quick deflation)
3. Tube connection control unit
4. Control unit

4.2 Mattress

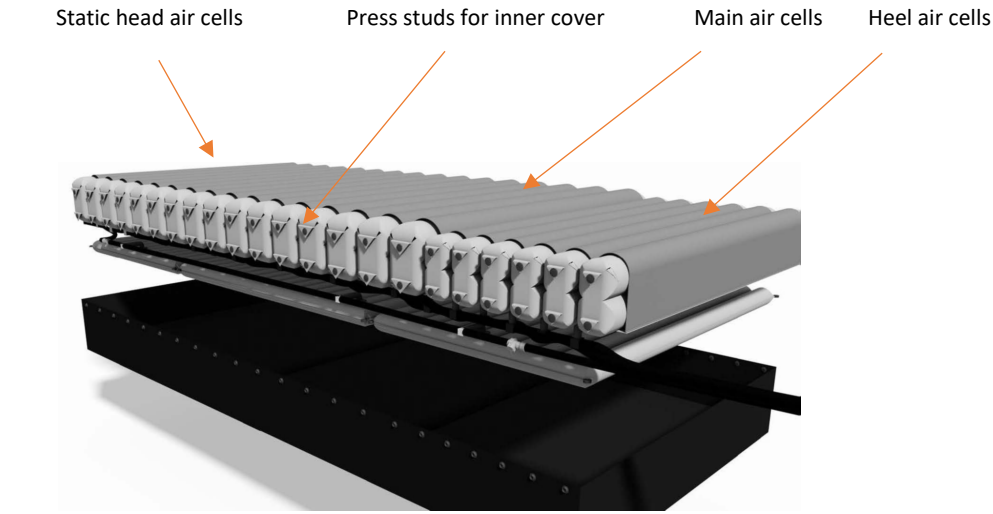


4.3 Control unit



1. Tube/CPR connection
2. Touch display
3. Function button
4. Power switch, On/Off (1/0)
5. Connection power cable
6. Hangers
7. Air filter
8. Power adaptor

4.4 Air Cells and tubing set



5 Reuse and cleaning

The product is reusable. Before using the product again for a new patient, it is recommended to clean the product. Follow the instructions below for cleaning and reconditioning. Consult your hygiene manager or Care of Sweden for help and instructions if you are unsure.

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 %.

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 %.

MATTRESS

1. Disconnect the tube connector from the control unit and remove the air from the mattress.
2. Remove the covers.
3. Move the mattress to a clean area that is suitable for cleaning.
4. Wipe off the air cells, 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.
5. Wipe off the work surfaces using a suitable detergent and/ or disinfectant.
6. Put the mattress together. If air cells for any reason have become loose from the tubes, these must be replaced according to the drawing in section 4.2.

Note!

- Check the hygiene cover, air 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.
- The air cells can be divided using a quick-release connector, making it easier to clean the air cells.

6 Storage

It is advisable to store the mattress and control unit in the product bag (accessory). Handle the packaged product with care. Do not place any heavy objects on top of it. For additional information about storage temperature, see section 9.If the control unit has a backup battery (variant) this must be charged up every six months if the control unit is not in use.
The control unit should be stored in a dry environment indoors and out of direct sunlight.

7 Maintenance

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. For more information, see Service manual for CuroCell UNO.

7.1 General

Each time the product is used, check that:
1. The power cable and power adaptor 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 air 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.

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

7.2 Replacing the air filter

Replace the air filter once a year:
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 twice a year or more.

7.3 Backup battery

To ensure optimum function and condition, the backup battery should never be discharged completely. The battery charges up when the control unit is operating. If the control unit is left without operating for a long period, the backup battery should be charged every six months for maintenance purposes by connecting the power adaptor to the wall socket and the control unit.

8 Troubleshooting

If the problems keep occurring, please contact
Care of Sweden or your local distributor.

Problem	Solution
The control unit does not start	Check that the power adaptor has been connected to the mains supply. Check that the LED on the power adaptor is showing green.
The control unit is making a noise and flashing but the display is off	Check that the power adaptor has not become loose (both the main supply and the control unit). Check that the switch is set to ’1’ (On). If the control unit is warm, the overheating protection may have triggered. If so, wait a while and try again.
The patient is ‘bottoming out’	Restart the control unit. See section 3.11. The control unit will initiate a weighing. Wait for the weighing symbol to go out and the control unit to go quiet. Perform a further hand check (see section 3.7). If the gap is still too small, raise the comfort setting in stages.
The mattress moves around	Check that the air 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 air cells have less air	This is normal if the Alternating program has been selected, as the air supply switches between alternating air 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.

9 Technical specification

CuroCell UNO®		
Model		CuroCell UNO®
Input voltage		100-240 V / 50-60 Hz
Power consumption		15A
Fuse		No Fuse
Mode of operation		Constant low pressure, Pulsating and Alternating
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 RR9KE5000LRPYIMG2806
Dimensions (L x W x H)		15,6 cm x 38,7 cm x 25,1 cm
Weight		5.2 kg (fully equipped)
Sound level, control unit, max		EN ISO 11201:2010 -20 dBA (at operator position), 18 dBA (at head end). ISO 3746:2010 -40 dBA.
Environmental	Temperature	Operation: +5 °C – 40 °C Storage: - 25 °C – 70 °C
	Version with backup battery	Storage: - 20 °C – 45 °C Transport: - 25 °C – 70 °C
	Humidity	Operation: 15 % – 93 % non-condensing Storage: < 93 % non-condensing
	Atmospheric	700 hPa – 1060 hPa
Backup battery (option)		10 x Ni-MH, 1.2 V, 3500 mAh
Electrical classification		Class I, Class II, Type BF
IP classification		IP42
Degree of safety in presence of inflammable anastethics		The device is not intended for use with flammable anaesthetic gases
Applied part		Mattress

9.1 Standards

The system has been tested and approved according to following standards where applicable demands are fulfilled:

IEC 600601-1 EN 597-1 EN ISO 10993
IEC 60601-1-2 EN 597-2 EN ISO 14971
IEC 60601-1-11 EN 12182

9.2 Symbol key

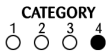
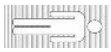
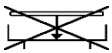
Symbols to convey medical device information

CE	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
MD	Medical Device		Distributor
UDI	UDI		

Symbols for traceability and product information

REF	Item number		Typ BF
SN	SN-number	IP__	IP class (enclosure class)
	Temperature range		

Symbols for user information

	Place directly on the bed base		Foot placement
	Minimum length		Recommended patient weight
	Counteracts shear		Do not rotate
	Heel function		Do not turn around
	User info - category		Place directly on the bed base
	The mattress should be used with the patient lying lengthways		Do not place on existing mattress
XXXX-XX-XX	Year-Month-Day		Read the instructions for use
	Read the instructions for use		

Symbols for cleaning and recycling

	Machine wash 95°C		Wipe clean
	Drip dry		Chlorine
	Do not dry clean		Do not iron
	Tumble dry		Recycling
	Do not disope of with household waste		

10 Other information

10.1 Recommended lifetime of the product

The estimated lifetime of this product is 5 years.

10.2 Disassembly and recycling

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

Control unit

A control unit without a backup battery must not be disassembled. It should be recycled as electronic waste.

A control unit with a battery backup must be disassembled and the battery removed for special battery recycling in accordance with local regulations. It is recommended that this is performed by authorised service technicians or that the control unit is returned to Care of Sweden for scrapping.

Mattress

A mattress should be sorted as combustible waste.

Note!

- If it is assessed that the product is or could be contaminated (e.g. used by patients 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.
- Handle batteries carefully, do not subject to mechanical pressure. Do not disassemble battery packs and be careful in the event of leakage. In the event of contact with battery fluid, always rinse with water and seek medical attention.

10.3 Returns

Contact Care of Sweden or your local distributor before returning the product.

11 Your own notes

Manufactured by

care of sweden

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SWEDEN

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