

Instructions for use

2025-11-06

CuroCell® S.A.M. PRO

Constant low pressure reactive air mattress system

Instructions for use item number: 95-001410-EN0000



























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










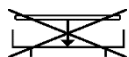

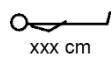




Table of content	
1	Symbol key 3
2	Warnings- and safety precautions 5
3	Introduction 6
3.1	General information 6
3.2	Intended purpose 6
3.3	Indications 6
3.4	Intended patient population 6
3.5	Intended user 6
3.6	User qualification 7
3.7	Intended use environment 7
3.7.1	Optimum environmental conditions 7
3.8	Contraindications 7
3.9	Clinical benefit 7
4	Assembly and installation 8
5	Operation CuroCell® S.A.M. PRO 9
5.1	Function 11
5.2	Cardiopulmonary resuscitation - CPR 11
5.3	Function control (hand check) 11
5.4	Maximum pressure (caring mode) 11
5.5	Comfort settings 12
5.6	Transport function 12
5.7	Power failure 12
5.8	Sitting positioning 12
6	Product description 13
6.1	Product combinations 13
6.2	Control unit 14
6.3	Mattresses 15
7	Reuse and cleaning 17
7.1	Cleaning and disinfection 17

7.2	<i>Reconditioning</i>	18
8	Maintenance	19
8.1	<i>General</i>	19
8.2	<i>Replacing air filter</i>	19
8.3	<i>Replacing fuses</i>	20
9	Troubleshooting	20
10	Storage	21
11	Technical specification	21
11.1	<i>Standards</i>	21
12	Other information	22
12.1	<i>Technical lifetime</i>	22
12.2	<i>Warranty</i>	22
12.3	<i>Disassembly and recycling</i>	22
12.4	<i>Return</i>	22
12.5	<i>Technical assistance requests</i>	22
12.6	<i>Customer responsibilities</i>	22


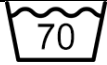










1 Symbol key

Symbols to convey medical device information			
	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	Medical device		Distributor
	Unique device identifier		Date of manufacture
	Warning		Caution
	Catalogue number		Batch code
	Serial number		Read the instructions for use
	Consult instructions for use		
Symbols for product information – Control unit			
	Temperature limit (room temperature)		Type BF
	Ingress protection class		Class II equipment (double isolated)
	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		Can be rotated
	Can be turned		

Symbols for cleaning, reconditioning and recycling

	Machine wash at 95 °C		Machine wash at 70 °C
	Tumble dry		Do not iron
	Wipe clean		Do not dry clean
	Chlorine		Drip dry
	Do not machine wash		Do not tumble dry
	Recycling		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.
- Regularly check product functionality through a “hand check” (see section 5.3). Also check that the comfort setting is correct as indicated in the table on the control unit.
- The mattress is protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
- The hygiene cover does not allow liquid or air to penetrate but is vapour permeable (vapour is wicked away). Make sure that the patient is positioned correctly to avoid the risk of suffocation.



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

- The product must only be used for its intended purpose as described in this manual. The product may not be combined, assembled or repaired with other parts, accessories or spare parts other than those described in this manual or other documentation from Care of Sweden.
- Do not use in the vicinity of or in contact with fire sources/hot surfaces, such as fire, burning cigarettes or hot lamps. Although the product has undergone fire testing, it could become damaged if it comes into contact with fire sources.
- Continual monitoring is required when the product is used for individuals needing special supervision, such as children.
- Prevent damage to the hygiene cover from sharp objects.
- If the cover is equipped with handles on the long sides, these handles are only to be used for lifting and moving the mattress itself. All other use is not covered by the product warranty.
- There is a risk of strangulation if the power cable accidentally ends up around the patient's neck; if possible, use a cable holder and make sure that the patient is lying correctly on the bed according to the instructions



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

- Do not use the control unit in wet rooms where there is a risk of the control unit coming into contact with water or another liquid. Never handle a control unit 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.
- Never use the product if the control unit power cable, plug of the control unit or power supply housing is defective, the control unit casing is damaged or it is not functioning properly. Contact an authorized service technician for examination and repair.

3 Introduction

This instructions for use contain information about one control unit that can be configured with three different 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 is intended to be used for prevention and as an aid in the treatment of pressure ulcers/pressure injuries (PU/PI).

3.3 Indications

Suitable for a wide range of persons with increased risk for pressure ulcers/injuries, including those with superficial ulcers, category 2-3 (in association with an individualized plan of care).

3.4 Intended patient population

Regardless of which mattress that is used, the recommended patient weight is up to 250 kg.

3.5 Intended user

The mattresses are intended to be used by all kind of patients, including lay persons.



The mattress is unsuitable for X-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic error.

3.6 User qualification

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

3.7 Intended use environment

The mattresses are intended to be used in all kinds of healthcare environments, including home care.

3.7.1 Optimum environmental conditions

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

3.8 Contraindications

It is necessary for the prescriber of the mattress to make an individual assessment of the patient and decide whether the characteristics of the mattress is beneficial for the patient based on diagnosis.

3.9 Clinical benefit

Care of Sweden's clinical benefits and claims for CuroCell® CLP reactive air mattresses systems consist of:

- Safety
- Comfort
- Pressure redistribution
- Easy to handle

4 Assembly and installation

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

When using an overlay mattress (CuroCell® S.A.M. PRO or CuroCell® S.A.M. PRO CF10):

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.



Remember that the underlying mattress is important for the product's functionality.

When using a full replacement mattress (CuroCell® S.A.M. CF16):

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 that the CPR valve is closed.

2. Hang the control unit by the foot end of the bed or place it on a flat, sturdy surface. Place the power cable so there is no risk of stumbling over it, run it over with the bed wheels or getting it jammed when raising or lowering the bed.

3. Connect the air tubes coming from the mattress to the side of the control unit. The control unit and hoses are equipped with quick connectors; an audible “click” will be heard when these have been connected correctly.

4. Check to make sure that the power is set to “0” (off). Plug the power cable into an approved outlet (110 or 220 V depending on the country and the voltage level) that is easily accessible. Ensure that the power supply always can be reached when the system is used.

5 Operation CuroCell® S.A.M. PRO



If the control unit has been stored in its minimum or maximum storage temperature (-25° C or 70° C, wait at least one hour before starting the control unit. This time 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 Comfort settings to set a suitable weight for the patient.
3. The mattress starts to inflate. This takes about 15 minutes. When the mattress is inflating, the symbol below flashes.



4. When the symbol shows a steady green light, the patient can be placed on the mattress.



Make sure that the feet are not in direct contact with the brackets of the control unit as this may cause damage to the skin.



When used together with positioning pillows, read the pillow instructions for use carefully for correct positioning of the patient.

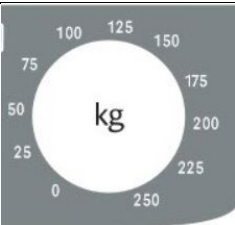






If you are using this product with an evacuation sheet, it is the user's responsibility to ensure that it is safe to use for evacuation.



Do not use the product in direct sunlight.



Button	Function
	Comfort settings
	Maximum pressure (Nursing mode)
	Information signal If the mattress pressure is too low an audio-visual alarm is triggered. Turning off the information signal
	Turning off the information signal Turn off the audio alarm by pressing the Audio off button. The audio alarm is re-activated after seven minutes if the pressure has not returned to normal. In the event of problems with notifications, see section 9 for troubleshooting.
	Normal pressure The light shows steady when the mattress is ready to be used. It flashes when air is being pumped into the mattress.

5.1 Function

The control unit CuroCell® S.A.M. PRO is configurable with three different mattresses. The control unit allows the user to choose the individual comfort level which allows the product to be used for a long time and in different care environments.

5.2 Cardiopulmonary resuscitation - CPR

In case of an emergency where CPR (cardiopulmonary resuscitation) is necessary, pull the CPR strap on the air tubes between the control unit and the mattress. For even faster deflation, detach the quick connectors on the side of the control unit.

5.3 Function control (hand check)

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

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



Make sure the mattress is filled and that the system has adapted to the patient before performing a hand check.

When using an overlay mattress (CuroCell® S.A.M. PRO or CuroCell® S.A.M. PRO CF10):

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® S.A.M. PRO CF16):

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 9.

5.4 Maximum pressure (caring mode)

With this function, the entire mattress is inflated and provides fixed support. This function should be used during bed entry/exit and during patient care. This function automatically reverts to the previous setting after about 30 minutes.

5.5 Comfort settings

The air pressure in the mattress can be adjusted according to the patient's comfort preference. Always consult the prescriber or other authorized personnel for the appropriate setting.

Appropriate air pressure is selected using the Comfort setting knob. The numbered scale guides your selection. When the knob is turned clockwise, the air supply and pressure in the mattress increase. When the knob is turned counterclockwise, the air supply and pressure in the mattress decrease.



When the head end of the bed is raised, it is recommended to increase the pressure with at least 25 kg.



When only parts of the mattress are under load, e.g. for amputees, the pressure should be increased by 1-2 steps.

After changing the comfort setting, always perform a function control (hand check) to ensure the setting is correct.

5.6 Transport function

If the patient needs to be moved in bed it is important to do the following preparation. Detach the tubes from the control unit and connect these together. This will put the mattress in Transport mode. We recommend using this function for short periods only.

5.7 Power failure

In the event of a power failure, disconnect the tubes from the control unit and connect the tubes together. The mattress will retain air for at least 10 hours. Perform a hand check to ensure that the pressure in the mattress is not too hard or too soft.

5.8 Sitting positioning



When the patient is sitting in the bed, it is recommended to increase the pressure with at least 25 kg by using the Comfort setting knob. Always perform a function control (hand check) to ensure the setting is correct.



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.



6 Product description

6.1 Product combinations

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

Product configuration – CuroCell® CLP reactive configuration (PCON004)	
Product group, CuroCell reactive control unit (CE090)	Product group, CuroCell reactive air mattresses (CE100)
CuroCell® S.A.M. PRO	CuroCell® S.A.M.
	CuroCell® S.A.M. PRO CF10
	CuroCell® S.A.M. PRO CF16

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

Control unit	Mattress	Mattress cover
CuroCell® S.A.M. PRO	CuroCell® S.A.M. PRO CuroCell® S.A.M. PRO CF10	Cover Steel
	CuroCell® S.A.M. PRO CF16	Top part Stone Top part Olivia Top part Steel Bottom part CuroCell

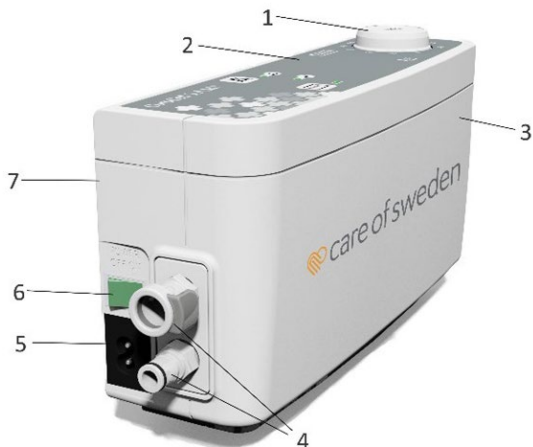
Mattress specification		
Product	Size	Mattress weight
CuroCell® S.A.M. PRO	80/85/90/105/120 x 200/210 x 10 cm	3,5 kg (80x200 cm)
CuroCell® S.A.M. PRO CF10	80/85/90/105/120 x 200/210 x 10 cm	4 kg (80x200 cm)
CuroCell® S.A.M. PRO CF16	80/85/90/105/120 x 200/210 x 16 cm	8,5 kg (80x200 cm)

6.2 Control unit

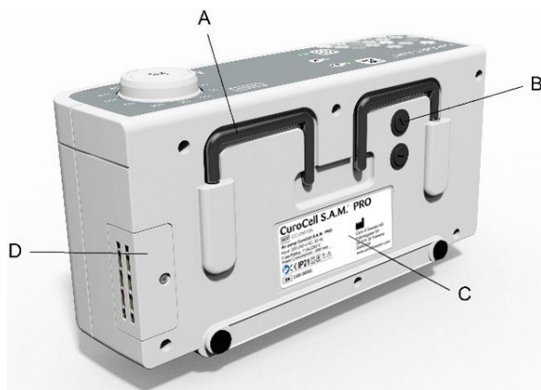
Materials the user comes in contact with:

- Acrylonitrile-butadiene-styrene

1. Comfort setting knob
2. Control panel
3. Front casing
4. Tube connector
5. Power cable connector
6. Power switch
7. Back casing



- A. Hangers
- B. Fuses (2xT1A/250V)
- C. Label
- D. Air filter

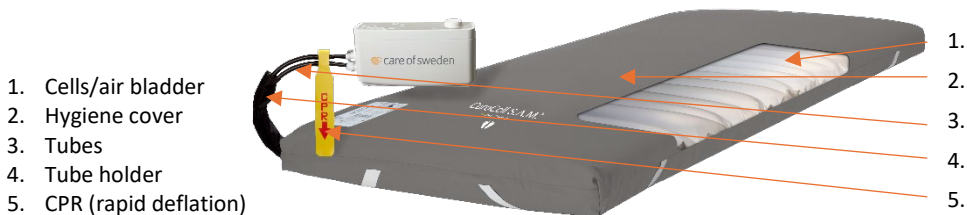


6.3 Mattresses

CuroCell® S.A.M. PRO

Materials the user comes in contact with:

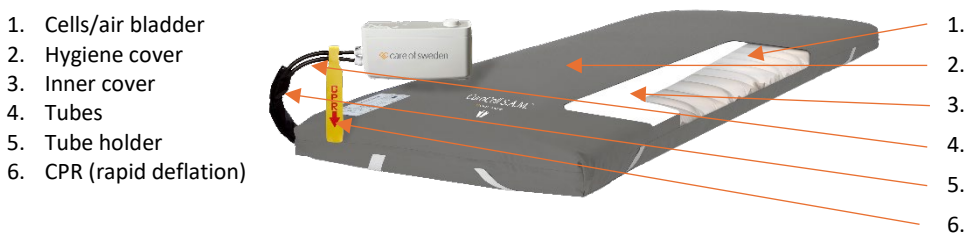
- Thermoplastic polyurethane
- Polyester
- Polyethylene



CuroCell® S.A.M. PRO CF10

Materials the user comes in contact with:

- Thermoplastic polyurethane
- Polyester
- Polyethylene



CuroCell® S.A.M. PRO CF16

Materials the user comes in contact with:

- Thermoplastic polyurethane
- Polyester
- Polyethylene



7 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.



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.



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. Failure to follow hygiene routines may result in persistent odor.

7.1 Cleaning and disinfection

CONTROL UNIT

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

INNER COVER AND MATTRESS COVER

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.

7.2 Reconditioning

CONTROL UNIT

Clean the control unit according to section 7.1 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 7.1 Cleaning and disinfection - Inner cover, hygiene cover and comfort cover. Ensure that all areas are free of dirt residues.
If necessary	<ol style="list-style-type: none">1. Remove the covers.2. Wipe off the cells, tubing and the CPR module with a cleaning agent according to local instructions and the instructions for use of the cleaning agent.3. When all parts are dry, assemble the mattress. If cells have become detached from the tubes, these must be put back according to drawing in section 6.3.

Disinfection of mattress

Primarily	<ol style="list-style-type: none">1. Disinfect all external surfaces of the mattress with disinfectant according to section 7.1 Cleaning and disinfection - Inner cover, hygiene cover and comfort cover. Ensure that all areas are free of dirt residue.2. Allow the disinfectant to work according to the instructions from the manufacturer of the agent.3. Let the cover dry.
If necessary	<ol style="list-style-type: none">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 6.3.

8 Maintenance

8.1 General

We recommend that the control unit is regularly serviced and inspected to maintain functionality and performance.



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® S.A.M. PRO.



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.

The following maintenance may be performed by the user:

- Check the power cable and power supply for damages and scratches.
- Check the mattress cover to make sure it is undamaged and that covers and cells are correctly assembled.
- Check that air is coming from the outlets on the side of the control unit.
- Check that no tubes or connectors are damaged or pinched.

Contact the manufacturer or your local distributor for spare parts.

8.2 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.

To replace the air filter:

1. Loosen the small protective plate on the rear of the control unit using a screwdriver.
2. Remove the filter from the holder.
3. Insert the new filter in the holder, put the protective plate back in place and secure using the screws.



8.3 Replacing fuses

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

1. Use a screwdriver to remove the fuse holder.
2. Replace the old fuse with a new one marked T1A/250 V; note that there are two fuses.
3. Use a screwdriver to put the fuse holder back in place.



9 Troubleshooting

Problem	Solution
The control unit does not start.	<ul style="list-style-type: none">• Check that the power cable is connected to a socket.• Check that all fuses are ok.
Control unit is operating but the mattress is not inflating normally.	<ul style="list-style-type: none">• Check that air is coming from the control unit and that the power cable is connected correctly. If the control unit is working but no air is coming out, the control unit should be serviced.• Check that the CPR valve is closed.• Check that the mattress and the mattress connector are not damaged.• Check that the tubes are intact.• Check that the air filter is not blocked.
The patient is “bottoming out”	The comfort settings might be incorrectly set. Adjust the pressure and wait a few minutes. Check again using the “hand check” (see section 5.3). Check that the CPR valve is closed.
Mattress not stationary	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).
Noisy control unit, or vibrations can be felt	Check that the control unit is correctly attached to the bed. Resonance may occur in parts of the bed. Remove the control unit and listen to see whether there’s any difference. This can be fixed by placing the control unit on a level, sturdy surface. Or by putting, for instance, a towel between the control unit and the bed.

10 Storage

It is advisable to store the mattress and control unit in the product bag (accessory). Place the control unit so that it is protected by the mattress. Handle the stored product with care. Do not place any heavy objects on top of it. The control unit should be stored in a dry environment indoors and out of direct sunlight.

11 Technical specification

CONTROL UNIT SPECIFICATION		
Model		CuroCell® S.A.M. PRO
Voltage		110-120 V, 60 Hz, 220-240 V, 50 Hz
Current		Max 10 W
Fuse type		T1A/250V
Dimensions (L x W x H)		26 cm x 8 cm x 13 cm
Weight		1,5 kg
Sound level, max		ISO 3746:2010 – 39 dBA EN ISO 112010:2010 – 22 dBA
Environmental	Temperature	Operation: +5 – +40 °C Storage: -25 – +70 °C Transport: -25 – +70 °C
	Humidity	Operation: 15% – 95% non-condensing Storage: 10% - 80% non-condensing
	Atmospheric	700 hPa – 1060 hPa
Classification		Class II, Type BF, IP21

11.1 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 60601-1-1-2	EN 597-1	ISO 11201
IEC 60601-1-1-11	EN 597-2	
IEC 60601-1-6	EN ISO 14971	
IEC 62304		

12 Other information

12.1 Technical lifetime

The technical lifetime of the product is 5 years when used under normal conditions.

12.2 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.

12.3 Disassembly and recycling



The products shall not be disposed of with household waste.

Control unit: Sort the control unit as electronic waste.

Mattress: Sort the mattress 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.

12.4 Return

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

12.5 Technical assistance requests



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

12.6 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 (control unit) 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



Contact:

Phone: + 46 771 106 600 Fax: + 46 325 12840

Email: export@careofsweden.se

Internet: www.careofsweden.com

Address:

Care of Sweden AB

P.O. Box 146

SE-514 23 Tranemo

SWEDEN

Visit address:

Fabriksgatan 5A

SE-514 33 Tranemo

SWEDEN

Cargo address:

Byns väg 4A

SE-514 33 Tranemo

SWEDEN

Distributed by:

Care of Sweden and CuroCell are trademarks of Care of Sweden AB

© Care of Sweden AB, 2025