

User manual

2015-11-17

CuroCell S.A.M.[®] Static Antidecubitus Mattress

User manual item number: 95-001298



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Contents

Important safety instructions	3
Introduction	4
Product description	5
Installation and start-up	6
Cleaning and reconditioning	9
Storage	10
Maintenance	11
Troubleshooting	11
Technical description	12
Spare parts	14
Options and accessories	15
Warranty	16
Other information	16
Own notes	17

IMPORTANT SAFETY INSTRUCTIONS

Read all instructions prior to use

WARNING! To minimise the risk of fire, electric shocks or bodily injury:

1. 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 (e.g. pump and mattress), accessories or spare parts other than those described in this manual or other documentation from Care of Sweden.
2. Do not use the pump in wet rooms or where there is a risk of the pump coming into contact with water or another liquid. Never handle a pump that has come into contact with water/liquid. Pull the plug out of the electrical socket immediately and send the product to an authorised service technician for servicing.
3. **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.
4. Position and use the product in a manner that prevents it from becoming trapped or damaged. **NOTE:** Be particularly aware of trapping damage when using bed rails.
5. Never use the product if the pump power cord or plug is defective, the pump casing is damaged or it is not functioning properly. Contact a service technician for examination and repair.
6. Regularly check product functionality through a hand check (see section 3.4). Also check that the comfort setting is correct as indicated in the table on the pump.
7. Continual monitoring is required when the product is used for individuals needing special supervision, such as children.
8. The mattress are protected with a hygiene cover; Please try to avoid the simultaneous use of multiple hygiene cover with this mattress. Because of the risk of vapour permeability can be destroyed.
9. 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.
10. Prevent damage to the hygiene cover from sharp objects.
11. If the cover are supplied with handles on the long sides, theses handles are only to be used for lifting and moving the mattress itself. All other use will be at your own responsibility and is not covered by the product warranty.

1. Introduction

CuroCell S.A.M.[®] is a static air mattress that can be used in all kinds of caring environments and it is very functional and cost effective.



Always read the user manual prior to use.

1.1 General information

This CuroCell[®] mattress is a medical device in accordance to MDD 93/42/EEC. According to statutory regulations made by the authorities regarding medical devices, the manufacturer is required to report all accidents or incidents involving these products. We would be very grateful for all information involving accidents or incidents relating to our products, by reporting them immediately to us, here at Care of Sweden. This system has been tested and approved according to the following standards: EN 60601-1, SS 876 00 04, SS-EN ISO 12182, SS-EN ISO 14971, SS-EN ISO 10993, EN 597-1, EN 597-2, EN 14126.

1.2 Intended use

CuroCell S.A.M.[®] can be used in all types of medical environments and is intended to assist in the prevention and treatment of pressure ulcers, up to and including category 2⁽¹⁾. The recommended user's weight is up to 200 kg.

It is available in two models. As an overlay mattress (CuroCell S.A.M.[®] or CuroCell S.A.M.[®] CF10) to be placed on top of an existing mattress or as a mattress replacement (CuroCell S.A.M.[®] CF16)

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

The mattress must always be cleaned between patients.

NOTE!

- When used together with positioning pillows, read the pillow user manual 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.
- 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 person lying on it or used for any other type of transport other than a possible evacuation using an evacuation sheet.
- This mattress is unsuitable for x-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostics errors.

(1) National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.

1.3 Other information

Action plan Pressure ulcers

To achieve the best possible result for this product it is recommended that a well-planned and well-structured working environment be used. In our guideline "Action plan" you will find examples which can be applied and put into practice when using our products.

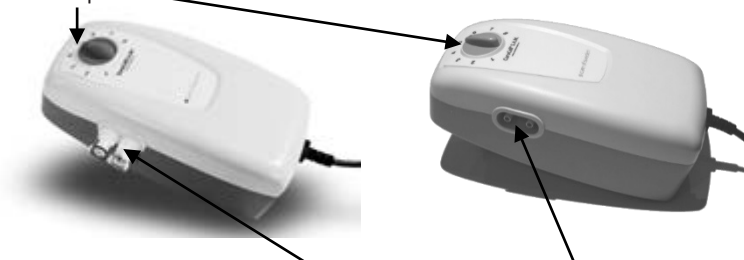
Mattress guide

This practical guide gives you as a care giver, help in choosing the correct mattress from the Care of Swedens range. CuroCell S.A.M® is a mattress in function group B. This information can be found on our website www.careofsweden.com or you can order a copy from our Customer services by sending your details to info@careofsweden.se.

2. Product description

2.1 Pump

1. Front panel



2 Tube connections, with quick connection and without quick connection

Back side

1. Bed hooks

2. Main power switch (side)

For switching on/off the pump.
Green lamp indicates when the pump is running.

3. Power cord



2.2 Front panel

Comfort settings

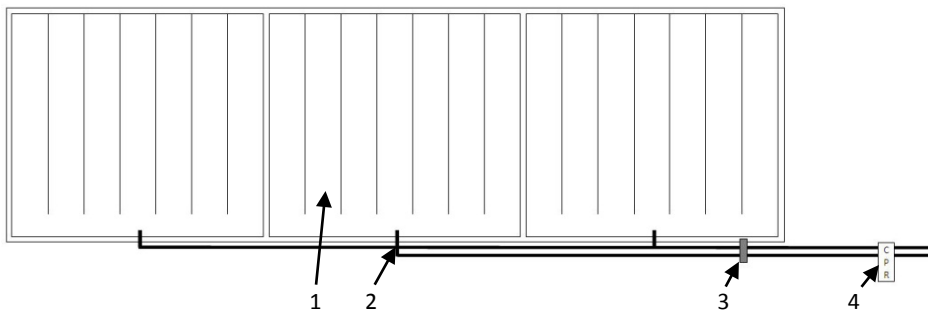
The comfort setting adjusts the air pressure in the mattress. When the knob is turned clockwise, the air supply and pressure in the mattress increase. When the knob is turned counter clockwise, the air supply and pressure in the mattress decrease.

Appropriate air pressure is set between 1 and 8. The table on the pump gives guidance.



2.3 Mattress

1. Cells/air bladder 2. Tubes 3. Tube holder 4. CPR (Rapid deflation)



2.4 Other parts

Hygiene cover

Inner cover Soft (accessory)

Transport and Storage Bag (accessory)

Pump bag (accessory)

Integrated foam core (only CuroCell S.A.M.® CF16)

3. Installation and Start-up

3.1 Installation

When unpacking the mattress, check that none of the parts are damaged. In the event of damage, contact Care of Sweden or your local dealer before using the product.

1. Place the mattress on top of an existing mattress. If possible, secure it by pulling the elastic bands on the bottom over the corners of the underlying mattress.

Note! If the mattress have an integrated foam core (CuroCell S.A.M.® CF16), place the mattress directly on to the bed base. Use the straps on the cover to fasten the mattress to the bed base.

2. Hang the pump by the foot end of the bed, or place it on a flat sturdy surface. Place the power cord 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.



NOTE! A pump bag is available as an option.

3. Connect the mattress' air hoses to the side of the pump. If the pump 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 in the power cord into an approved outlet (220 V).

NOTE!

- Make up the bed with sheets to increase user comfort.
- Check that the CPR-valve is closed.

3.2 Start-up and settings





NOTE! Always read the user manual prior to use.

1. Start the pump by pressing '1' (on), on the side of the pump. The green light is lit.
2. The pump starts filling the mattress with air. It takes approximately 15-20 minutes.
3. If necessary the patient can lie on the mattress even when not inflated, in this case, the underlay will carry the load. When using a mattress with an air underlay, this must be inflated.

3.3 Comfort settings

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

Adjust the pressure with the comfort setting knob according to the table on the pump.

kg		
0-20	1	2
30-50	2	3
60-70	3	4
80-90	4	5
100-120	5	6
130-150	6	7
160-180	7	8
190-200	8	8

NOTE!

- When the head end of the bed is raised, the pressure should be increased at least one (1) step.
- For amputated users, when only part of the mattress is under load, the pressure should be increased by 1-2 steps.
- Recommended users weight is up to 200 kg.

3.4 Hand check

Hand check is used to ensure that the mattress is properly inflated. This should be done regularly, once per shift, after changing the position in the bed or changing the comfort settings.

Open the cover. Place a flat hand under the air cells directly underneath the user's pelvic region and make sure that the user does not lay directly on the underlying mattress. There should be about 1-2 fingers margin.



If you can feel the user's body resting on your hand you need to increase the comfort settings to next highest step. Wait 10 minutes and perform a new hand check.

3.5 CPR

In case of an emergency where CPR (cardiopulmonary resuscitation) is necessary: Rapidly pull the CPR band on the tubes between the pump and the mattress. Remove the tube connections on the side of the pump, for even faster deflation.

Note! Make sure that the CPR connector is properly connected after use.



3.6 Low pressure

By an abnormally low air pressure, see chapter 7 for trouble shooting.

3.7 Transport function

If quick connection and the patient must be moved in bed, the tubes can be connected together (detached from the pump) and the mattress put in "transport mode". We recommend using this mode only for short periods of time.

WARNING!

If the air pressure remains low, search for damages on the mattress and the tubes. Repair when needed or contact the supplier.

4. Cleaning and reconditioning

It is important to follow the instructions below before using the product for another user. Consult the hygiene responsible or the supplier for help and instructions when unsure.

4.1 Cleaning

PUMP

WARNING!

Do not open the pump housing – risk of electric shock. Service and maintenance must be performed by authorised technicians. Do not get the pump wet or submerge it in any liquid.



Wipe off the pump with a damp cloth and a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %. If using a different agent, choose one that does not affect the plastic of the pump housing.

MATTRESS COVER



Covers can be wiped off with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %. Excrements and blood spots must be removed immediately with cold water. Carefully follow local instructions and usage instructions for the cleaner.



Multi-layer covers should be divided before washing. Wash with like colours.



Chlorine and phenol-based cleaners could have a negative impact on the PU surface and should be avoided. If chlorine is used, we recommend a mixture of max. 1%.

INNER COVER SOFT (accessories)



Clean the affected area with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %.

4.2 Reconditioning

PUMP

See section 4.1 for instructions.

MATTRESS

1. Disconnect the tubes and let the air out, also open the CPR valve.
2. Remove the cover. See instructions in chapter 4.1 for cleaning covers. If the product is equipped with a foam core this should be removed and cleaned separately.
3. Move the mattress to a clean area, which is suitable for cleaning.
4. Wipe off the cells, all tubes and the CPR valve with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %.
5. Wipe off and disinfect all the work surfaces with an alcohol-based cleaning agent intended for this purpose.
6. Put the mattress together. If cells for any reason have loosened from the tubes, these must be replaced according to drawing in chapter 2.3.

FOAM CORE (CuroCell S.A.M.® CF16)



Clean the affected area with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70%, oxidating solutions or chlorine max 1 %.

Press out the water carefully. Let the foam core dry in a warm, ventilated area, without direct exposure of sunlight. The foam core needs to be completely dry before it is used again.

NOTE!

Check the hygiene cover each time the product is cleaned. If damaged, it must be replaced or repaired. Also check the pump, tube connectors and power cord during cleaning. Damaged parts must be replaced or repaired.

5. Storage and packing

It is advisable to store the mattress and pump in the product bag (accessory). Handle the packed product very carefully. Do not place any heavy objects on top of it.

6. Maintenance

1. Check the power cord and plug for damages and scratches.
2. Check the mattress cover to make sure it is undamaged and that cover and cells are correctly assembled.
3. Check that air is coming from the outlets on the side of the pump.
4. Check for damaged or pinched tubes and connectors.

Contact the manufacturer or your local dealer for spare parts.

7. Trouble shooting

Problem	Solution
The pump does not start	Check that the power cord is connected to an electrical outlet. Check that all fuses are OK.
The user lies directly on the bed	Pressure might be incorrectly set. Adjust it according to the weight table, and wait a few minutes. Check again using the 'hand check', see chapter 3.4. Check that the CPR-valve is closed.
The mattress moves around	Check that the mattress is secured with the elastic bands to the underlying mattress. Or, if the mattress have an integrated foam core (CuroCell S.A.M.® CF16), secured by using the straps on the cover to fasten the mattress to the bed base.
The pump makes a noise, or vibrates	Check how the pump is hung on the bed. Remove the pump and listen whether this makes a difference. Can be resolved by putting the pump on a flat, steady surface or by placing a towel between the pump and bed. Pump bag (accessory) can also be used.

If your questions are not answered by the above information, please contact Care of Sweden or your local dealer for further assistance.

8. Technical description

8.1 Technical specification

PUMP		SPECIFICATION
Model		CuroCell S.A.M.®
Voltage		220 V-240 V, 50 Hz
Current consumption		0.05 A
Fuse type		T1AL, 250 V
Dimensions (LxWxH)		25 x 12.5 x 8.5 cm
Weight		1.4 kg
Surroundings	Temperature	Operations: 10°C - 40°C
		Storage: -15°C - 50°C
		Shipping: -15°C - 70°C
	Humidity	Operations: 10% - 90% non-condensing
		Storage: 10% - 90% non-condensing
	Athmospheric pressure	700hPa-1013,25hPa
Classification		Class II, Type BF, IP21
MATTRESS		SPECIFICATION
Model		CuroCell S.A.M.®,/ CuroCell S.A.M.® CF10 /CuroCell S.A.M.® CF16
Dimensions (WxLxH)		80/85/90/105/120x200/210x10/16 cm
Weight		2.7 kg

NOTE! The manufacturer can at any time change the specifications for the product.

WARNING!

Follow the operations and maintenance instructions carefully in order to prevent bodily injuries, as well as damages to the product or other equipment.

8.2 Labelling

The mattress are labelled with product name production date, article number, size, care and wash instructions, EAN-bar code, as well as space for own labelling. The product also displays which side is up/down and head/foot.

8.3 Symbol Definitions



Article No



Manufacturer

XXXX-XX-XX

Year-Month-Day



Foot placement



Read the user manual



Group of function



CE marked acc. to
MDD 93/42/EEC



Recycling



Not in domestic refuse,
follow recycling instructions



Recommended user weight



Patient information
– category



Directly on bed base



Place on top of
existing mattress



Counteract shear force



Heel function



Do not wash



Machine wash at 70 °C



Machine wash at 95 °C



<1%
Chlorine



Tumble dry



Do not tumble dry



Drip dry



Do not iron



Do not dry clean



Wipe off



Class II equipment
(Double Insulated)



Type BF



IP-class
(Ingress Protection Rating)



Temperature range



The mattress should only be
used lying in the lengthwise
direction on the mattress

9. Spare parts

Cover, Curocell S.A.M® and CuroCell S.A.M® CF10

Cover Steel, blue

Art. No	Size
294-080200	80x200 cm
294-080210	80x210 cm
294-085200	85x200 cm
294-085210	85x210 cm
294-090200	90x200 cm
294-090210	90x210 cm
294-105200	105x200 cm
294-105210	105x210 cm
294-120200	120x200 cm
294-120210	120x210 cm

CuroCell S.A.M.® CF16

Size	Top part Olivia	Top part Steel	Top part Stone	Bottom part CuroCell
80x200 cm	431-080200	451-080200	452-080200	CC-905610
80x210 cm	431-080210	451-080210	452-080210	CC-905611
85x200 cm	431-085200	451-085200	452-085200	CC-905612
85x210 cm	431-085210	451-085210	452-085210	CC-905613
90x200 cm	431-090200	451-090200	452-090200	CC-905614
90x210 cm	431-090210	451-090210	452-090210	CC-905615
105x200 cm	431-105200	451-105200	452-105200	CC-905616
105x210 cm	431-105210	-	452-105210	CC-905617
120x200 cm	431-120200	451-120200	452-120200	CC-905618
120x210 cm	431-120210	-	452-120210	CC-905620

Air cells incl. tubes with CPR

Art.No	Size
CC-250570	80x200x10 cm
CC-250571	80x210x10 cm
CC-250573	85x200x10 cm
CC-250574	85x210x10 cm
CC-250576	90x200x10 cm
CC-250577	90x210x10 cm
CC-250578	105x200x10 cm
CC-250580	105x210x10 cm
CC-250579	120x200x10 cm
CC-250581	120x210x10 cm

Air cells incl. tubes with CPR and quick connection

Art.No	Size
CC-250630	80x200x10 cm
CC-250631	80x210x10 cm
CC-250633	85x200x10 cm
CC-250634	85x210x10 cm
CC-250636	90x200x10 cm
CC-250637	90x210x10 cm
CC-250638	105x200x10 cm
CC-250639	105x210x10 cm
CC-250640	120x200x10 cm
CC-250641	120x210x10 cm

Art.No	Description
CC-250101-E3	CuroCell S.A.M.®, pump without quick connection
CC-250102	CuroCell S.A.M.®, pump incl. quick connection
CC-908032	Tubing set incl, CPR

If other spare parts are needed, please contact Care of Sweden or your local dealer for further assistance.

10. Options and accessories

10.1 Options

Inner cover Soft

Enhances the comfort further, can also be used for very sensitive users. This is included for CuroCell S.A.M.® CF10 and CuroCell S.A.M.® CF16. Place the air cells inside the cover with the soft foam side up.

Sturdy transportation bag

Transportation and storage bag.

Cover

With welded seams.

10.2 Accessories

Cover, Curocell S.A.M® and CuroCell S.A.M® CF10

Inner cover Soft

Art. No	Size
CC-928040	80x200 cm
CC-928041	80x210 cm
CC-928043	85x200 cm
CC-928044	85x210 cm
CC-928046	90x200 cm
CC-928047	90x210 cm
CC-928048	105x200 cm
CC-928050	105x210 cm
CC-928049	120x200 cm
CC-928051	120x210 cm

CuroCell S.A.M.® CF16

Inner cover Soft with foam pocket

Art. No	Size
CC-928060	80x200 cm
CC-928061	80x210 cm
CC-928063	85x200 cm
CC-928064	85x210 cm
CC-928066	90x200 cm
CC-928067	90x210 cm
CC-928068	105x200 cm
CC-928070	105x210 cm
CC-928069	120x200 cm
CC-928071	120x210 cm

Art.No

Description

CC-9091	Transportation and Storage Bag
CC-9093	Transportation and Storage Bag to CuroCell S.A.M.® with Inner cover Soft
58-900909	Transportation and Storage Bag to CuroCell S.A.M.® CF16
CC-9098	Pump bag, black

10.3 Other accessories

To ensure the best level of comfort, we recommend use of accessories from Care of Sweden since our products are designed to work well together. Please contact Care of Sweden or your local dealer for accessories or more information on our products.

11. Warranty

11.1 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 product impairment or damage stemming from negligence or improper handling/care.

11.2 Service and repairs

This CuroCell® mattress is a medical device, in accordance with MDD 93/42/EEC, that is used as an aid in preventing and treating pressure ulcers. For this reason, we recommend that the pump be regularly serviced and inspected to maintain functionality and performance. Like other technical devices, a pump that is properly cared for works better and lasts longer.

Service and maintenance must always be performed by Care of Sweden or one of its authorised technicians. Only use spare parts that have been approved by Care of Sweden. Use of non-approved spare parts invalidates the warranty.

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

Please contact Care of Sweden or your local dealer if you have questions regarding warranty and service.

11.3 Life expectancy

This product's expected life is estimated to be 3 years.

12. Other information

12.1 Disassembly and recycling

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

Pump:

A used CuroCell® pump must not be disassembled. It must instead be taken to a recycling centre and sorted as electronic waste.


Mattress:

A used CuroCell® mattress must be taken to a recycling centre and sorted as combustible waste.

For more information contact Care of Sweden or your local dealer.

12.2 Returns and complaints

Complaints are to be reported to the supplier. Return of a product shall follow the supplier's instructions and can only be done after the complaint has been reported. Damages due to the transportation should be reported to the transportation agent.

 Manufactured by

 **care of sweden**
Supporting Life

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Supplied by