

## Instructions for use

2021-04-20

### CuroCell S.A.M.<sup>®</sup>

Constant low pressure reactive air mattress system

Instructions for use item number: 95-001298



7 33 13 45 04 02 26



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# WARNINGS AND SAFETY PRECAUTIONS

Read all instructions prior to use

**WARNING!** To minimise the risk of fire, electric shocks or physical 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 cable 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 is protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
9. The hygiene cover does not allow liquid or air to penetrate but is vapour permeable. Make sure that the user is positioned correctly to avoid the risk of suffocation.
10. Prevent damage to the hygiene cover from sharp objects.
11. If the cover is supplied with handles on the long sides, these 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.
12. In order to minimize the risk of wounds occurring on the feet, make sure that the user doesn't come into contact with the hangers of the pump.

# 1. Introduction

CuroCell S.A.M.® is a constant low pressure reactive air mattress system that can be used in all kinds of caring environments and it is very functional and cost effective.



Always read the instructions for use prior to use.

## 1.1 General information

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

The system has been fully or partially designed and verified in accordance with the standards listed in section 8.2 Standards.

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

## 1.2 Intended use

The system consists of a pump and a mattress and are used for prevention and as an aid in the treatment of pressure ulcers/pressure injuries (PU/PI).

## 1.3 Indications

For users with pressure ulcers/pressure injuries (PU/PI) up to and including category 2<sup>1</sup>. As well as for users in risk of PU/PI.

## 1.4 Contraindications

There are no known contraindications.

## 1.5 User application

The systems can be used in all kinds of health care environments. It is available in three versions. CuroCell S.A.M.® and CuroCell S.A.M.® CF10 are overlay mattresses and are placed on an underlying mattress. CuroCell S.A.M.® CF16 is a replacement mattress placed directly on the bed base. The recommended user weight is up to 200 kg.

## NOTE!

- When used together with positioning pillows, read the pillow instructions for use carefully for correct positioning of the user.
- 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) European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed). EPUAP/NPIAP/PPPIA: 2019*

## 1.6 Other information

### Action plan pressure ulcers/pressure injuries

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

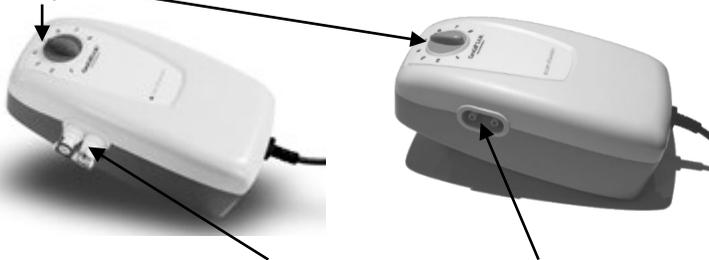
### Mattress guide

This guide provides guidance to personnel and prescribers when choosing a mattress from Care of Sweden. CuroCell S.A.M® is a mattress in function group B. This information can be obtained from our website, [www.careofsweden.com](http://www.careofsweden.com), or ordered from Customer Services (see contact information on the final page).

## 2. Product description

### 2.1 Pump

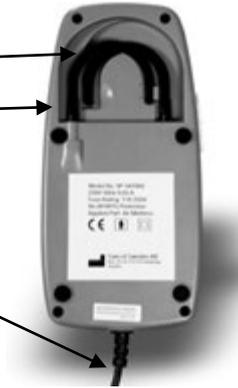
#### 1. Front panel



#### 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 cable



## 2.2 Front panel

### Comfort settings

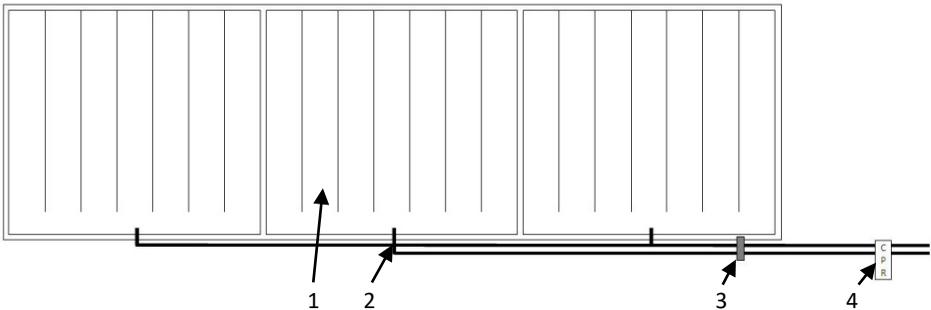
The comfort setting adjusts the air pressure in the mattress. When the knob is turned clockwise, the air supply and pressure in the mattress increase. When the knob is turned counter clockwise, the air supply and pressure in the mattress decrease.

Appropriate air pressure is set between 1 and 8. The table on the pump gives guidance, see 3.3. Comfort settings.



## 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)
- 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 distributor before using the product.

1a. If the mattress is an overlay mattress, 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.

or

1b. If the mattress is a replacement mattress and 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 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 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 cable into an approved outlet (220 V).

#### **NOTE!**

- Make 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 instructions for use 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.

### 3.3 Comfort settings

The air pressure in the mattress can be adjusted according to the user'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 (function control)

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 troubleshooting.

### 3.7 Transport function

If the pump and mattress are equipped with quick connection and the user must be moved in bed, the tubes can be connected together (detached from the pump) and the mattress is 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 Care of Sweden or your local distributor.

## 4. Reuse, cleaning and reconditioning

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

Cleaning and reconditioning should otherwise be performed as required.

### 4.1 Cleaning

#### **PUMP**



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

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

#### **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 %.

## 4.2 Reconditioning

### PUMP

See section 4.1 for instructions.

### MATTRESS

1. Disconnect the tube connector from the pump and remove the air from the mattress.
2. Remove the covers. For more information of cleaning the covers, see section 4.1.
3. Move the mattress to a clean area that is suitable for cleaning.
4. Wipe off the cells, all tubes and the CPR module with a mild cleaning solution for this purpose such as: alcohol with or without tenside surfactants, Isopropanol 70 %, oxidizing solutions, chlorine max 1 % or hydrogen peroxide max 1,5 %. Let it dry.
5. Wipe off the work surfaces using a suitable detergent and/ or disinfectant.
6. Put the mattress together. If cells for any reason have become loose from the tubes, these must be replaced according to the drawing in section 2.3.

### FOAM CORE

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

#### **NOTE!**

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

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

## 5. Storage

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 cable 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 Care of Sweden or your local distributor for spare parts.

## 7. Troubleshooting

Problem	Solution
The pump does not start	Check that the power cable 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 has 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.

If your questions are not answered by the above information, please contact Care of Sweden or your local distributor 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		T1A/250V
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!** Care of Sweden reserves the right to modify the product specification at any time.

#### **WARNING!**

Follow the operation and maintenance instructions carefully in order to prevent physical injury, as well as damage to the product or other equipment.

### 8.2 Standards

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

ICE 60601-1	EN ISO 10993	ISO 3746
IEC 60601-1-1-2	EN 12182	ISO 11201
IEC 60601-1-1-11	EN 597-1	
ICE 60601-1-6	EN 597-2	
ICE 62304	EN ISO 14971	

### 8.3 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.

## 8.4 Symbol key



Item no



Manufacturer

XXXX-XX-XX

Year-Month-Day



Foot placement



Read the instructions for use



Group of function



CE marked acc. to Medical Device Regulation (EU) 2017/745



Recycling



Do not dispose of with household waste; follow recycling instructions



Recommended user weight



User 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)



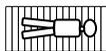
Type BF



IP-class (Ingress Protection Rating)



Temperature range



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



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## 9. Spare parts

### Covers, CuroCell S.A.M® and CuroCell S.A.M® CF10

Size	Cover Steel, blue	Cover Stone, grey
	Art. No	Art. No
80x200 cm	294-080200	290-080200
80x210 cm	294-080210	290-080210
85x200 cm	294-085200	290-085200
85x210 cm	294-085210	290-085210
90x200 cm	294-090200	290-090200
90x210 cm	294-090210	290-090210
105x200 cm	294-105200	290-105200
105x210 cm	294-105210	290-105210
120x200 cm	294-120200	290-120200
120x210 cm	294-120210	290-120210

### CuroCell S.A.M.® CF16

Size	Top part Olivia	Top part Stone	Bottom part CuroCell
	Art. No	Art. No	Art. No
80x200 cm	431-080200	452-080200	CC-905610
80x210 cm	431-080210	452-080210	CC-905611
85x200 cm	431-085200	452-085200	CC-905612
85x210 cm	431-085210	452-085210	CC-905613
90x200 cm	431-090200	452-090200	CC-905614
90x210 cm	431-090210	452-090210	CC-905615
105x200 cm	431-105200	452-105200	CC-905616
105x210 cm	431-105210	452-105210	CC-905617
120x200 cm	431-120200	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-908066	Tubing set incl. quick connection (and CPR)
CC-908067	Tubing set incl. quick connection

If other spare parts are needed, please contact Care of Sweden or your local distributor 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 to CuroCell S.A.M.® 80-90cm
CC-9093	Transportation and Storage Bag to CuroCell S.A.M.® CF10 80-105 cm and CuroCell S.A.M.® 105-120 cm
CC-9094	Transportation and Storage Bag to CuroCell S.A.M.® CF10 120 cm
58-900909	Transportation and Storage Bag to CuroCell S.A.M.® CF16 80-90 cm
58-900905	Transportation and Storage Bag to CuroCell S.A.M.® CF16 105-120 cm

### 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 distributor 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 damage due to negligence or improper handling/care.

## **11.2 Service and repairs**

This CuroCell® mattress is a medical device, in accordance with Medical Device Regulation (EU) 2017/745, that is used as an aid in preventing and treating pressure ulcers/pressure injuries. For this reason, we recommend that the product 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.

During the expected lifespan of the product, some parts of the pump will experience wear and will require servicing by a certified service technician in order to retain good functionality and performance. The scope of the servicing and the servicing intervals will depend on how often and to what degree the product is used.

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 distributor if you have questions regarding warranty and service.

## **11.3 Lifetime**

This product's lifetime is estimated to be 5 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 distributor.

### **12.2 Returns and complaints**

Complaints are to be reported to the distributor. Return of a product shall follow the distributor'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.







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