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Instructions for use

2023-03-17

CuroCell S.A.M.® PRO

Constant low pressure reactive air mattress system

Instructions for use item number: 95-001410-EN0000

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CE

EN

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WARNINGS- AND SAFETY PRECAUTIONS

Read all instructions before use or repair

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

1. The product must only be 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.
2. Do not use the pump in wet rooms 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. Be particularly aware of trapping damage the risk of crush injuries when using bed rails.
5. Never use the product if the pump power cable, plug of the pump or power supply housing is defective, the pump casing is damaged or it is not functioning properly. Contact an authorised 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 (vapour is wicked away). 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 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.
12. The pump’s power cable should be positioned to minimise the risk of tripping or other injuries; use a cable holder if possible.
13. 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
14. The mattress is unsuitable for X-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic error.

1 Introduction

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

1.4 Intended user environment

The mattresses are intended to be used in all kinds of healthcare 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 and included category 3 (in association with an individualised plan of care). The mattress system is available in three versions. CuroCell S.A.M.® PRO and CuroCell S.A.M.® PRO CF10 are top mattresses and are placed on an underlying mattress. CuroCell S.A.M.® PRO CF16 is a replacement mattress placed directly on the bed base. The recommended patient weight is up to 250 kg

1.6 Contraindication

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.

1.7 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

Note!

• 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.

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

• Do not store or use the product in direct sunlight. The product may be damaged by the elevated temperature and UV light.

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.

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.® PRO 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 air tubes coming from the mattress to the side of the pump. 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 the power cable into an approved outlet (110 or 220 V depending on the country and the voltage level) that is easily accessible.

Note!

- Check that the CPR valve is closed.
- Make sure that the mattress is the correct size for the bed.
- Make sure the feet are not in direct contact with the brackets of the pump as this may cause damage to the skin.

3 Operation

3.1 Operation (how to get started)

1. Start the pump by pressing “1” (on), on the side of the pump.

2. The pump starts filling the mattress with air. The green light with the symbol ✓ will flash during the inflation phase; it takes about 15 minutes for the mattress to fill with air.

3. When the ✓ symbol shows a steady green light, the mattress is ready to be used.

Note!

- Make the bed with bedsheets.
- It is recommended to not use the product during x-ray.
- If the product has been stored in a cold space, wait some time using it.

3.2 Comfort settings

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

Appropriate air pressure is selected using the knob (0–250 kg). The numbered scale guides your selection. For sitting positions, we recommend that the pressure be raised by +25 kg. Check using the hand check (see section 3.3).

Note!

- When the head end of the bed is raised, the pressure should be increased by 25 kg.
- When only part of the mattress is under load, e.g. for amputees, the pressure should be increased (by 1–2 steps). Then perform a hand check (see section 3.3).

3.3 Hand check (function control)

Hand check is performed to ensure that the mattress system works properly and to ensure that the weight setting is correct. Hand check should be performed regularly; for S.A.M Pro, we recommend once per work shift or every 8 hours, as well as after installation of the system.

For manual systems hand check should also be performed when moving from lying to seating position in bed, in case of positioning changes and when changing the comfort setting (and/or the weight setting).

Note!

- Make sure that the mattress is filled, and that the system has adapted to the patient before performing a hand check.
- How to perform a hand check depends on which mattress is used.
- If the air pressure remains low, search for damage on the mattress and the tubes. Repair when needed or contact the supplier.

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

1a. Open the cover and 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 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).

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.

3.4 Cardiopulmonary rescitation (CPR)

In case of an emergency where CPR (cardiopulmonary resuscitation) is necessary:
Quickly pull the CPR strap on the air tubes between the pump and the mattress. Detach the quick connectors on the side of the pump, for even faster deflation.

Notera!
• After use, make sure that the CPR-conntection is properly attached.

3.5 Low pressure

If there is abnormally low air pressure, see section 8 for Troubleshooting.

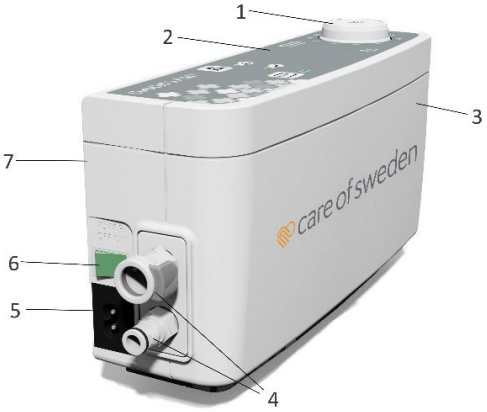
3.6 Transport function

Detach both the tubes from the pump and connect these together; this will put the mattress in "Transport mode". We recommend for this function only be used for a short period of time.

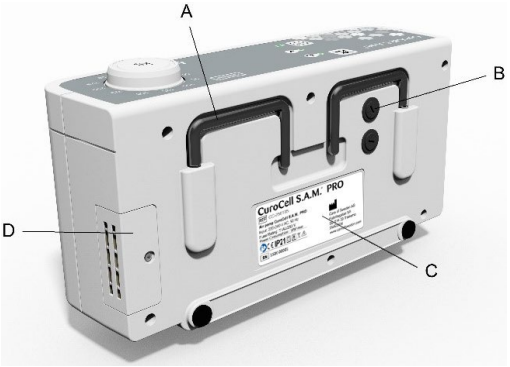
4 Product description

4.1 Pump

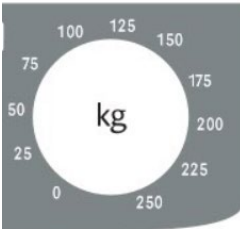
1. Comfort setting knob.
2. Control panel.
3. Casing, front.
4. Tube connector.
5. Power cable connector.
6. Power switch - Used to turn the pump on or off. A green light indicates when the pump is on.
7. Casing, back.



A. Hangers
B. Fuses (2 x T1A/250 V).
C. Label.
D. Air filter.



4.2 Control panel



Comfort setting knob – Comfort settings
The comfort setting knob 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.

Sitting positions
When the patient is sitting in the bed, we recommend that the pressure be raised by +25 kg. Check using a hand check (see section 3.3).

Maximum pressure (Nursing mode)
With this function, the entire mattress is inflated and provides fixed support. This function should be used when nursing the patient, shifting the patient's position or moving the patient in or out of bed. This function automatically reverts to the previous setting after about 30 minutes.

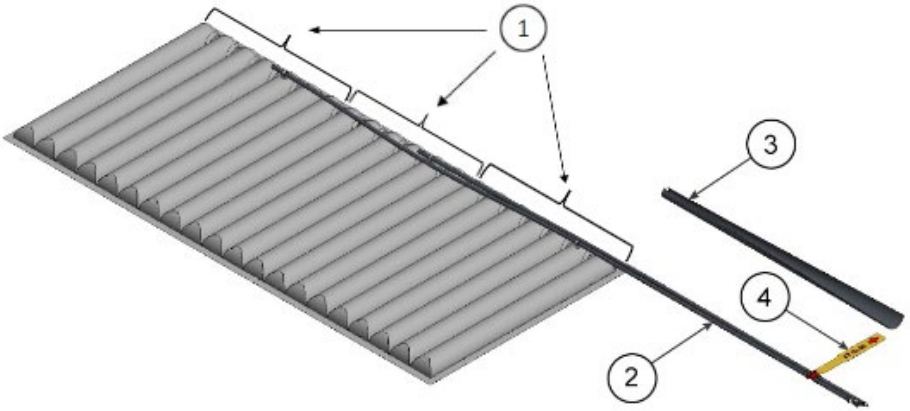
Information signal
If the mattress pressure is too low an audio-visual alarm is triggered. Turning off the information signal

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 8 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.

4.3 Mattress

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



The updated version consists of three separate cell packages that are connected by press studs. Previous version consists of one cell package.

5 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.

5.1 Cleaning and disinfection

CONTROL UNIT

Wipe the control unit with a damp cloth and mild detergent. Primarily use solvent-free soap with a neutral pH value. If necessary, a disinfectant and/or cleaning agent can be used such as: alcohol with or without surfactants or oxidizing solutions such as: chlorine and/or hydrogen peroxide, concentration 1000 ppm/0,1%. In exceptional cases, a maximum concentration of 10,000 ppm/1% can be used.

If another agent is used, choose one that does not harm the exterior of the control unit.

INNER COVER AND MATTRESS COVER

Wipe off

Primarily use solvent-free soap with a neutral pH value. For a daily basis cleaning, a disinfectant and/or cleaning agent can be used such as: alcohol with/without surfactants or oxidizing solutions such as: chlorine and/or hydrogen peroxide, concentration 1000ppm/0,1%. In exceptional cases, a concentration of a maximum of 10,000ppm/1% can be used, then consider that high concentrations can shorten the life of the coating.

Mechanical cleaning

Covers consisting of several parts must be separated before washing.

5.2 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

1. Clean all external surfaces of the mattress according to section 7.1 Cleaning and disinfection - Inner cover and Mattress cover - Wipe off. Ensure that all areas are free of dirt residues.
2. If the mattress is heavily soiled, it is recommended that the mattress is taken apart and cleaned, follow the instructions below according to points 3-5.
3. Remove the covers.
4. 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 and disinfecting agent.
5. 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

1. Disinfect all external surfaces of the mattress with disinfectant according to section 7.1 Cleaning and disinfection - Inner cover and Mattress cover - Wipe off. 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.
4. If the mattress is heavily soiled, it is recommended that the mattress is taken apart and disinfected, follow the instructions below according to points 5-8.
5. Remove the covers.
6. Wipe the cells, tubes and the CPR module with a disinfectant.
7. Allow the disinfectant to work according to the instructions from the agent's manufacturer.
8. 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.

Foam Core (S.A.M Pro CF16) 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 whole product for damage each time it is cleaned. If damaged, it must be replaced or repaired.
- Do not wring or roll the foam core to extract the water. Let it dry in a warm, ventilated area (not in direct sunlight). The foam core must be completely dry before it is used again.

6 Storage

It is advisable to store the mattress and pump in the product bag (accessory). Place the pump 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 pump 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 approves by Care of Sweden. For more information, see Service manual for CuroCell S.A.M PRO.

Following maintenance may be performed by patient:
1. Check the power cable and power supply for damage and scratches.
2. Check the mattress cover to make sure it is undamaged and that covers and cells are correctly assembled.
3. Check that air is coming from the outlets on the side of the pump.
4. Check that no tubes or connectors are damaged or pinched.
Contact the manufacturer or your local distributor for spare parts.

7.1 Air filter and fuse replacement

Air filter (A):
1. Loosen the small protective plate on the rear of the pump 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.

Fuses (B):
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.

8 Troubleshooting

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

Problem	Solution
The pump does not start	Check that the power cable is connected to a socket. Check that all fuses are ok.
Pump is operating but the mattress is not inflating normally	Check that air is coming from the pump and that the power cable is connected correctly. If the pump is working but no air is coming out, the pump 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 3.3). Check that the CPR valve is closed.
Mattress not stationary	Check that the mattress is secured to the underlying mattress with the elastic straps or, if the mattress has an integrated foam core (CuroCell S.A.M.® PRO CF16), secured with the straps to the moving parts of the bed base.
Noisy pump, or vibrations can be felt	Check that the pump is correctly attached to the bed. Resonance may occur in parts of the bed. Remove the pump and listen to see whether there’s any difference. This can be fixed by placing the pump on a level, sturdy surface. Or by putting, for instance, a towel between the pump and the bed.

9 Technical specification

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

PUMP		SPECIFICATION
Model		CuroCell S.A.M.® PRO
Voltage		110-120 V, 60 Hz, 220-240 V, 50Hz
Current		Max 10 W
Fuse type		T1A/250V
Dimensions (LxWxH)		26 x 8 x 13 cm
Weight		1.5 kg
Sound level, max		ISO 3746:2010 - 39 dBA EN ISO 11201:2010 - 22 dBA
Ambient environment	Temperature	Operation: 5 °C ˜ 40 °C
		Storage: -25 °C ˜ 70 °C
		Shipping: -25 °C ˜ 70 °C
	Humidity	Operation & Transport: 5 % ˜ 95 % non-condensing
		Storage: 10 % ˜ 80 % non-condensing
	Atmospheric pressure	Operation: 700 hPa to 1060 hPa
		Storage & Transport 500 hPa to 1060 hPa
Classification		Class II, Type BF, IP21

9.1 Standards

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

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	

9.2 Marking

The mattress is 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.

9.3 Symbol Key

Symbols to convey medical device information			
CE	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
UDI	UDI	MD	Medical Device
	Distributor		
Symbols for traceability and product information			
REF	Item number		Type BF
IP__	IP class (Enclosure class)		Class II Equipment (double insulated). Indicated on the power supply.
Symbols for user information			
X-XXX Kg	Recommended patient weight	XXXX-XX-XX	Year-month-day
Anti shear	Counteracts shear force	Category 1 2 3 4	User information - category
	Placed directly on the bed base	CATEGORY 1 2 3 4	User information - category
	Foot placement		Can be rotated
	Heel function		Can be turned
	The mattress should be used with the patient lying lengthways		Place on top of existing mattress
	Warning of electrical voltage		Read the instructions for use
	Read the instructions for use		

Symbols for cleaning and recycling			
	Machine wash at 95 °C		Do not iron
	Do not machine wash		Chlorine
	Wipe clean		Tumble dry
	Do not dry clean		Do not tumble dry
	Drip dry		Do not dispose of with household waste
	Recycling		Machine wash at 70°C

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 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. Instead, it should be taken to a recycling centre. The product is sorted as “electronic waste”.

Mattress: A used CuroCell® mattress should be taken to a recycling centre. The product is sorted as “combustible waste”.
For more information, please contact Care of Sweden or your local distributor.

10.3 Returns

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

Your own notes

Manufactured by

care of sweden

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