

## User manual

2021-03-04

### CuroCell® Nova CX13 CuroCell® Nova CX19 Alternating pressure system

Item number user manual: 95-001062



## **Contents**

Important safety precautions	3
Introduction	4
Product description	5
Assembly/Installation	7
Operation	8
Cleaning and reconditioning	19
Storage	12
Maintenance	12
Troubleshooting	13
Technical description	14
Spare parts	16
Options and accessories	17
Warranty	18
Other information	19

# IMPORTANT SAFETY PRECAUTIONS

## Read all instructions prior to use

**Warning!** To minimize 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 product 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 authorized 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. Pay extra attention when using bed rails that no wires become trapped between the bed and the rail. Contact a service technician for examination and repair.
6. Regularly check product functionality through a hand check (see section 4.4). 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 are 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.

# 1. Introduction

CuroCell® air mattresses operate according to the alternating pressure principle, a technique that is well proven and been used for a long time. Alternating pressure is when the pressure regularly alternates between the mattress cells to replicate body movement. Variable pressure cycles are set up where there is little or no pressure. This is optimal for skin improvement or to prevent skin damage.



Always read the user manual prior to use.

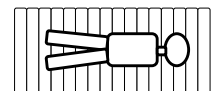
## 1.1 General information

This CuroCell® mattress is a medical device in accordance to Medical Device Regulation MDR (2017/745). According to statutory regulations made by the authorities regarding medical devices, the manufacturer is required to report all accidents or incidents involving there 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. The system has been tested and approved according to the following standards: IEC 600601-1, IEC 60601-1-2, SS-EN ISO 12182, SS-EN ISO 14971, SS-EN ISO 10993, EN 597-1, EN 597-2.

## 1.2 Intended use

CuroCell® Nova CX is an alternating pressure mattress system that can be used in all kinds of caring environments to prevent pressure ulcers, as well as treatment up to category 2<sup>(1)</sup> pressure ulcers. It is available in two versions, as an overlay (CuroCell® Nova CX13) or as a replacement mattress (CuroCell® Nova CX19). We recommend that position changes are made regularly. The time interval must be evaluated by the responsible personnel, depending on the user's status diagnosis and general condition. The mattress is meant for use for persons of a recommended minimum length of 120 cm. The recommended user weight is up to 150 kg.

The mattress should only be used lying in the lengthwise direction on the mattress with the feet at the end marked with the feet symbol.



The mattress must always be cleaned between users.



## NOTE!

- For certain users, such as amputees, are the recommended minimum weight not valid. These users may however have other requirements as the entire mattress is not being loaded. Please refer to sections 4.2 and 4.3 for operating control.
- When used together with positioning pillows, read the user's manual carefully to ensure 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 trapped 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 use during x-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic 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

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

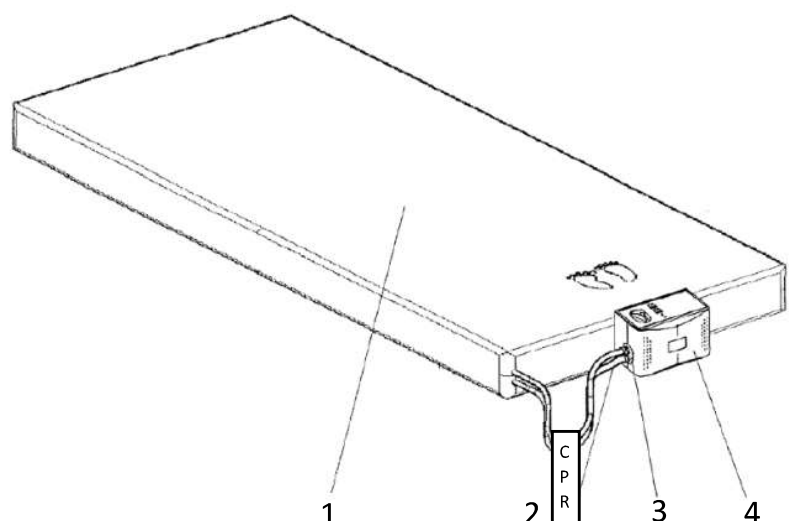
This guide provides guidance to personnel and prescribers when choosing a mattress from Care of Sweden. CuroCell Nova CX13 and CuroCell Nova CX19 are mattresses in function group C.

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 and mattress

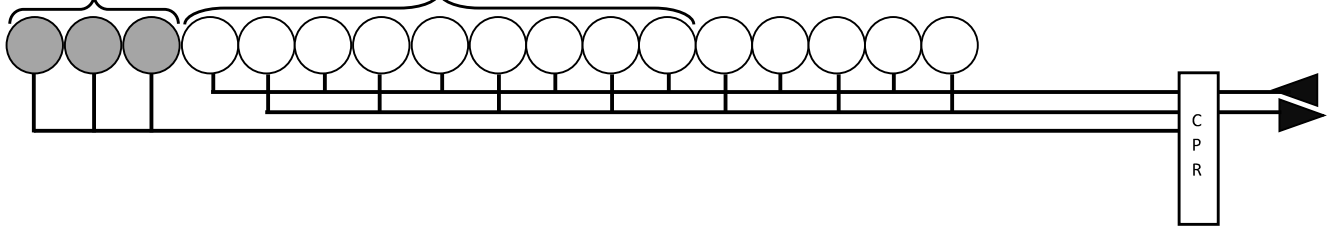
1. Mattress
2. CPR (rapid deflation)
3. Pump connector
4. Pump



## Tubing system

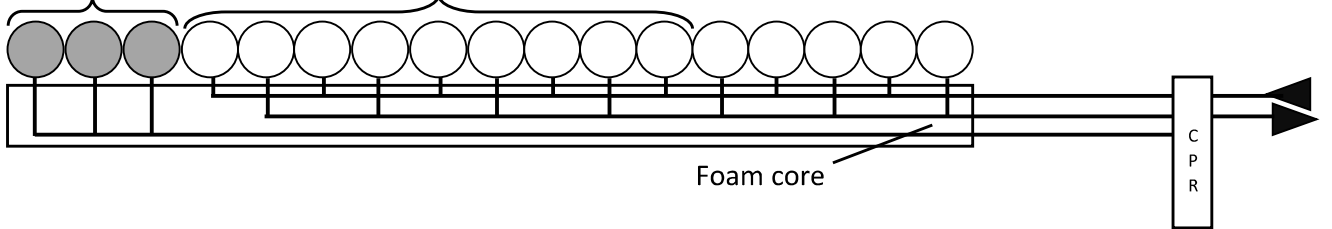
### CuroCell Nova CX13

3 static head cells. If the product is fitted with ventilated cells, they are located here (9 cells).

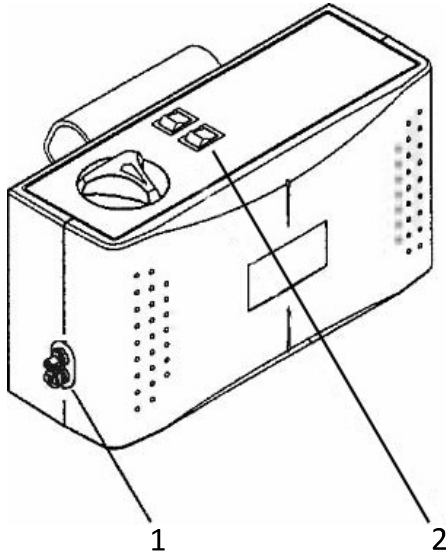


### CuroCell Nova CX19 with integrated foam core and tubing system

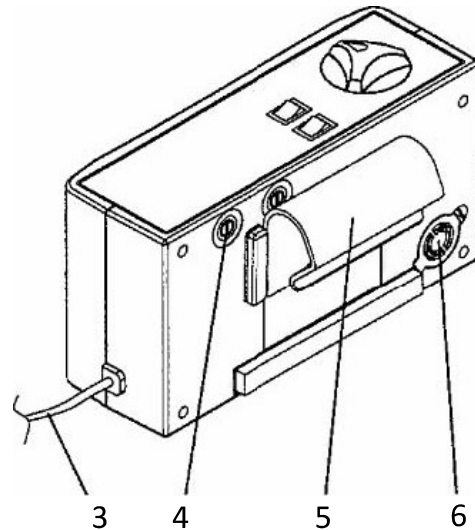
3 static head cells. If the product is fitted with ventilated cells, they are located here (9 cells).



## 2.2 Pump

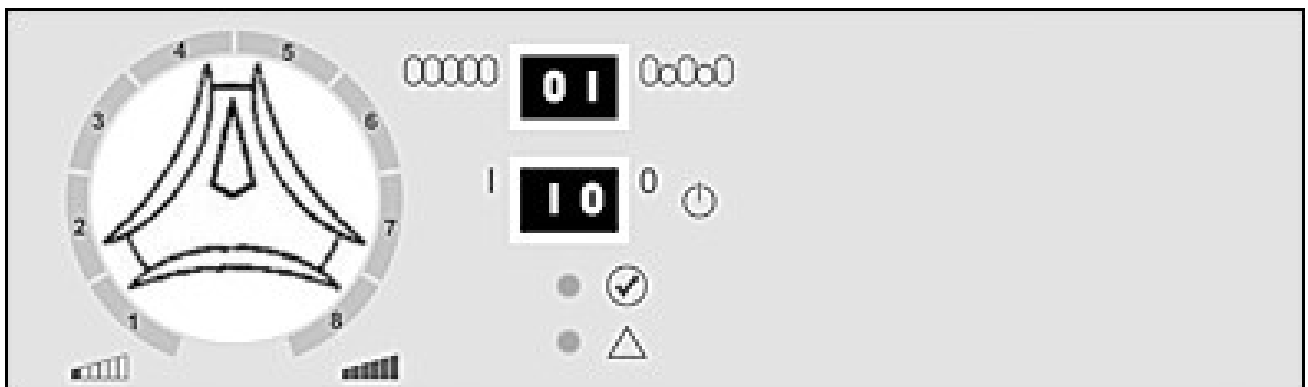



1 Connection tubes  
2 On/Off



3 Power cord  
4 Fuses (2)  
5 Bed hook  
6 Filter

## 2.3 Pump functions – control panel



 Button for switching between static/alternating (0/1) function.



= Mode 1 = Alternating mode, every other cell is inflated (not the three static head cells). The pressure change between cells, a cycle is ten minutes. We recommend that this mode is used by default.



= Mode 0 = Static mode, the same pressure in all cells. When the Static button is pressed, the alternating process is terminated and the pressure between the cells evens out. The function can be used in association with user care, repositioning/transferring in and out of bed, or as a treatment mode.



Power off/on (1/0).



Suitable air pressure is set with the comfort dial (1-8). Guidelines based on user weight is given in the table on the pump. **NOTE!** In all uses where the head end of the bed is raised, the pressure must be increased at least one (1) step.



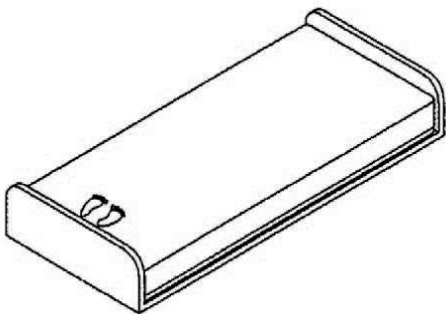
Lights when the mattress is ready for use.



Alarms for low pressure. In order to solve it see chapter 8, troubleshooting.

### 3. Assembly/Installation

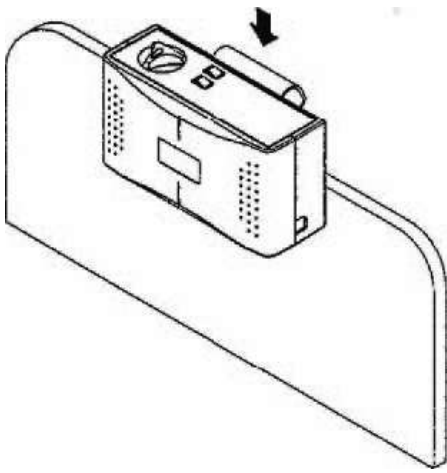
When unpacking the mattress, check that none of the parts are damaged. In the event of damage, contact the manufacturer or your local dealer before using the product.



1. Place the mattress on the existing mattress and fasten it with the elastic bands around the underlying mattress. If the mattress has a built-in foam pad (CuroCell® Nova CX19), it can be placed directly on the bed frame. Secure the mattress to the bed base with straps on the cover.

#### **Note!**

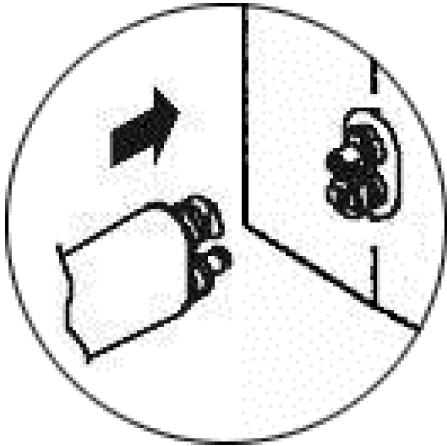
- Make the bed with sheets for added comfort.
- Check that the CPR valve is closed.
- The mattress must be attached to the bed's moving parts, if it is height adjustable (CuroCell® Nova CX19).
- Check that all the press studs in each cell and cover are fastened correctly.



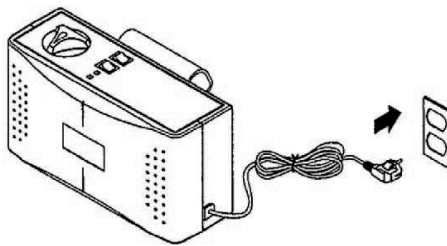
2. Hang the pump at the foot end of the bed or place it on a flat, sturdy surface.

Route the power cord so that there is no risk of it causing someone to trip, being run over by the bed wheels or getting crushed when the bed is raised or lowered.

If a cable holder is used (optional): open the press studs, position the power cord in the pocket and close the press studs.



3. Connect the air tubes from the mattress to the side of the pump. There is an audible "click" sound when the connectors are properly attached.



4. Check that the switch on the pump is in the "0" position (Off). Connect the plug to an approved electrical socket. (220 V).

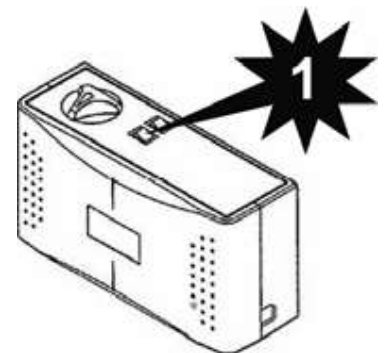
## 4. Operation



**Note!** Always read the user manual prior to use.

### 4.1 Start-up

1. Start the pump by pressing "1" (On).
2. Air starts to fill up the mattress. It takes about 20 minutes to inflate the mattress.
3. If necessary the user 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.




**Note!** We recommend that the comfort dial be set to max when inflating a deflated mattress.



## 4.2 Choice of programs

There are two different programs, see section 2.3 for details. We recommend alternating mode by default.

## 4.3 Comfort setting

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.

1. Use the comfort dial to set a suitable air pressure based on the table on the pump.
2. When the lamp , -symbol is lit, the mattress is ready for use.

kg		
0-40	1	2
50-60	2	3
70-80	3	4
90-100	4	5
110-120	5	6
130-140	6	7
150	7	8

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### NOTE!

- If the head of the bed is being raised, pressure must be increased at least one (1) level.
- When only parts of the mattress are under load, e.g. if the user is an amputee, the pressure should be increased 1 or 2 levels.
- Hand check the pressure at all times. Please refer to section 4.4.
- Recommended user weight: up to 150 kg.

## 4.4 Hand check (function control)

The hand check is used to ensure that the mattress is working properly. This must be performed regularly; we recommend once per shift, or every eight hours.

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.




## 4.5 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.



## 4.6 Low pressure

At an abnormally low air pressure in the mattress, the symbol the symbol for "Low pressure" lights up . The lamp goes out when the pressure returns to normal.

Please refer to chapter 8 for troubleshooting.

### **WARNING!**

If the air pressure remains low, check the mattress and tubes for damage. Repair as necessary or contact Care of Sweden or one of its authorised repair technicians.

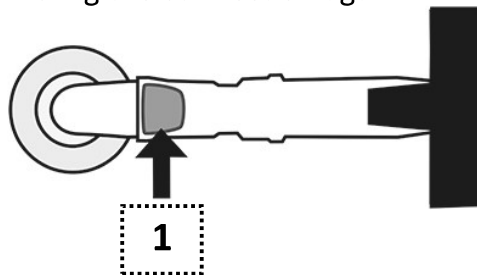
## 4.7 Transport function

If 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". This mode should only be used for short periods of time.



## 4.8 Heel function (with check valves, option)

This feature allows pressure relief of the heels. Disconnect the air cell which is directly under the heel. This air cell will then be emptied for air. Press the bottom (1) and disconnect the plug. Let the cell remain in its place in the mattress. The air cell is activated by assembling the connection again.



# 5 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.

## 5.1 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 of 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 colors.



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 AND DISTANCE FABRIC (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 %.

## 5.2 Reconditioning

### PUMP

See section 5.1 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 5.1 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 2.1.

### FOAM CORE



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.

## 6. Storage

The mattress and pump are best stored in the product bag (optional extra). Handle the packed product with care. Do not put anything heavy on top of it.

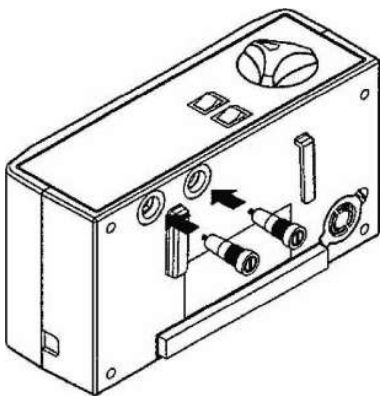
## 7. Maintenance

### 7.1 General

1. Check the power cord and plug for damage and scratches.
2. Check that the mattress cover is intact and that the cover and air cells are correctly assembled.
3. Check that the air flow alternates between each outlet on the side of the pump.
4. Check for damaged or pinched tubes and connectors.

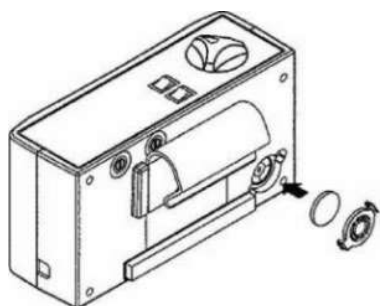
Contact the manufacturer or your local dealer for spare parts.

### 7.2 Changing fuses



1. Pull the plug out of the electrical socket before replacing fuses.
2. Remove the cover for the fuses with a screwdriver. Pull out the fuse holder.
3. Fit a new fuse of the same type (T1A/250 V) and screw the protective cover back in place. There are two fuses.

### 7.3 Changing the air filter



1. Loosen the small round cover plate at the back of the pump.
2. Lean the pump back and the filter slides out of its holder.
3. Place the new filter in the holder and put back the cover plate.

The filter should be cleaned regularly if the pump is used in a very dirty environment.



## 8. Troubleshooting

Problem	Solution
Pump does not start	<p>Check that the power cord is connected to the power socket.</p> <p>Check the fuses.</p>
No air in head cells	<p>When the mattress is inflated, the 3 static head cells are filled last.</p>
Alarms for low pressure (light) = mattress loses air	<p>Check that the air tubes are connected to the pump.</p> <p>Check that the CPR valves are closed.</p> <p>Open the mattress and look for any leakage.</p>
User is bottoming ("falls through")	<p>Comfort knob may be set up. Adjust the pressure slightly and wait a few minutes.</p> <p>Check that the CPR valve is closed.</p> <p>Check for leaks from air cells or tubes.</p> <p>Check again with the "hand check", see section 4.4.</p>
Mattress moves around	<p>Check that the air mattress is secured to the underlying mattress with the elastic straps. If the mattress has a built-in foam pad, fasten it to the bed frame with the straps.</p>
Some cells have less air	<p>This is normal since the air flow alternates between every other cell for a set cycle time (one cycle = 10 minutes).</p>
Pump is noisy, vibrations are felt	<p>Check how the pump is hung on the bed. Resonance can occur in parts of the bed. Remove the pump and listen to see whether this makes a difference. Can be remedied by putting the pump on a flat, steady surface or by placing a towel between the pump and bed.</p>

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

## 9. Technical description

### 9.1 Technical specification

PUMP		SPECIFICATIONS
Model		CuroCell® Nova
Voltage		220 V-240 V, 50-60 Hz
Power consumption		0.05 A
Type of fuse		T1A/250 V
Cycle periods		10 min
Dimension (LxWxH)		25 x 13.5 x 9.5 cm
Weight		1.8 kg
Surroundings	Temperature	Operation: 10°C - 40°C
		Storage: -15°C - 50°C
		Shipping: -15°C - 70°C
	Humidity	Operation: 10% - 90% non-condensing
		Storage: 10% - 90% non-condensing
	Atmospheric pressure	700hPa-1013, 25hPa
Classification		Class II, Type BF, IP2X
MATTRESS		SPECIFICATION
Model		CuroCell® Nova CX13/ Nova CX19
Dimension (LxWxH)		80/85/90/105/120x200/210x13/19 cm
Weight		5.2 kg (80x200 cm, 8.5 kg with built-in foam pad)

NOTE: Care of Sweden retains the right to modify the product specification at any time.

#### **WARNING!**

Follow operating and maintenance instructions carefully to prevent injury, as well as damage to the product or other equipment.

### 9.2 Labelling

The mattresses are labelled with 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 Definitions



Article No



Manufacturer

XXXX-XX-XX

Year-Month-Day



Foot placement



Read the user manual



Group of function



CE marked acc. to Medical Device Regulation MDR (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



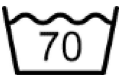
Counteract shear force



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)



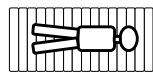
Type BF



IP-class (Ingress Protection Rating)



Temperature range



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



Distributed by



Medical Device



UDI

## 10. Spare parts

For CuroCell® Nova CX13

<b>Art. no.</b>	<b>Description</b>	<b>Size</b>
295-080200	Cover Olivia, grey, zip on three sides	80x200 cm
295-080210	Cover Olivia, grey, zip on three sides	80x210 cm
295-085200	Cover Olivia, grey, zip on three sides	85x200 cm
295-085210	Cover Olivia, grey, zip on three sides	85x210 cm
295-090200	Cover Olivia, grey, zip on three sides	90x200 cm
295-090210	Cover Olivia, grey, zip on three sides	90x210 cm
295-105200	Cover Olivia, grey, zip on three sides	105x200 cm
295-120200	Cover Olivia, grey, zip on three sides	120x200 cm

For CuroCell® Nova CX19 (mattress with built-in foam pad)

<b>Art. no.</b>	<b>Description</b>	<b>Size</b>
CC-906010	Top part Olivia, grey	80x200 cm
CC-906011	Top part Olivia, grey	80x210 cm
CC-906012	Top part Olivia, grey	85x200 cm
CC-906013	Top part Olivia, grey	85x210 cm
CC-906014	Top part Olivia, grey	90x200 cm
CC-906015	Top part Olivia, grey	90x210 cm
CC-906016	Top part Olivia, grey	105x200 cm
CC-906018	Top part Olivia, grey	120x200 cm
CC-905610	Bottom part CuroCell	80x200 cm
CC-905611	Bottom part CuroCell	80x210 cm
CC-905612	Bottom part CuroCell	85x200 cm
CC-905613	Bottom part CuroCell	85x210 cm
CC-905614	Bottom part CuroCell	90x200 cm
CC-905615	Bottom part CuroCell	90x210 cm
CC-905616	Bottom part CuroCell	105x200 cm
CC-905618	Bottom part CuroCell	120x200 cm

<b>Art. no.</b>	<b>Description</b>	<b>Size</b>
CC-901001-K	Air cell, PU	80x13 cm
CC-901002-K	Air cell, PU	85x13 cm
CC-901003-K	Air cell, PU	90x13 cm
CC-901004-K	Air cell, PU	105x13 cm
CC-901005-K	Air cell, PU	120x13 cm

Please make a note on your order when ordering ventilating cells.

CC-8217	Fuse (set of 2)
CC-8202	Filter

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

# 11. Options and accessories

## 11.1 Options

### Comfort fabric (only CuroCell® Nova CX19)

For users who are sensitive for the fluctuations in the mattress a padded inner cover can be placed over the air cells to increase comfort.

### Heel section

Options available to relieve sensitive heels. Emptying the air cell with release valve.

**NOTE!** These options are only available with new orders.

### Cable holder (only CuroCell® Nova CX19)

A pocket along one long side of the mattress that holds the power cord in place to minimise the risk of tripping over the cord or the cord becoming trapped under the wheels of the bed.

**NOTE!** This option is only available with new orders.

### Sturdy transport bag

Transport and storage bag.

### Sheet holder (only CuroCell® Nova CX19)

Specialised clips to which the sheet can be attached. Six required per mattress.

### Ventilated cells (Low-Air-Loss)

Micro-ventilation in 9 of the cells.

## 11.2 Accessories

For CuroCell® Nova CX13

Art. no.	Description	Size
CC-9093	Sturdy transport bag	80/85/90 cm
CC-9094	Sturdy transport bag	105/120 cm

For CuroCell® Nova CX19 (mattress with built-in foam pad)

Art. no.	Description	Size
CC-907210	CuroCell Comfort fabric	80x200 cm
CC-907211	CuroCell Comfort fabric	80x210 cm
CC-907212	CuroCell Comfort fabric	85x200 cm
CC-907213	CuroCell Comfort fabric	85x210 cm
CC-907214	CuroCell Comfort fabric	90x200 cm
CC-907215	CuroCell Comfort fabric	90x210 cm
CC-907216	CuroCell Comfort fabric	105x200 cm
CC-907218	CuroCell Comfort fabric	120x200 cm
58-900909	Sturdy transport bag	80/85/90 cm
58-900905	Sturdy transport bag	105/120 cm

Top part CuroCell LF (low friction) (only CuroCell® Nova CX19) - Top part with increased sliding function, can be used for heavy, immobile users.

Art. no.	Description
CC-9075	Sheet holder (one of)
CC-900220	Heel function with release valve (4 cells)
CC-900222	Heel function with release valve (3 cells)

### **11.3 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.

## **12. Warranty**

### **12.1 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.

### **12.2 Service and repairs**

This CuroCell® mattress is a medical device, in accordance with Medical Device Regulation MDR (2017/745), 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.

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 dealer if you have questions regarding warranty and service.

### **12.3 Life expectancy**

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

## 13. Other information

### 13.1 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, please contact Care of Sweden or your local dealer.

### 13.2 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

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**Contact:**

Phone: + 46 771 106600

Fax: + 46 325 12840

Email: [export@careofsweden.se](mailto:export@careofsweden.se)

Internet: [www.careofsweden.com](http://www.careofsweden.com)

**Address:**

Care of Sweden AB  
P.O. Box 146  
SE-514 23 Tranemo  
SWEDEN

**Visit address:**

Fabrikgatan 5A  
SE-514 33 Tranemo  
SWEDEN

**Cargo address:**

Byns väg 4A  
SE-514 33 Tranemo  
SWEDEN

**Supplied by**