

Staebel OptiCell Air1 **User Manual**





Thank you for choosing OptiCell.

We aim to ensure you are satisfied with your mattress in terms of both performance and durability. We therefore kindly ask you to spend a few minutes reading through these user instructions to ensure you can take the best possible care of your mattress.

If you have any questions that are not answered in these user instructions, please contact us at Staebel. You will find our contact details on the back page of these user instructions.

CE MARKING

The OptiCell Air Mattress system CE marked according to Medical Device Regulation MDR (EU) 2017/745 class 1. The CE marking means that OptiCell has the manufacturer's responsibility to ensure that this product meets the essential requirements of relevant European legislation. This includes the provision oftechnical documentation and assurance which is maintained for at least ten years after the product is placed on the market.

QUALITY ASSURANCE

Our quality assurance and customer focus goals are realised by responding to the needs and expectations of our customers. We believe in building long-term relationships through collaboration

Continuous improvement in our products and services is the basis of our ability to satisfy both current and future customers. Our approach includes the development of evaluation methods and standards that offer the customer a guaranteed quality in terms of comfort, function, durability and price.

Through our team of skilled and dedicated employees, we are focused on supporting education, development and innovation within the healthcare profession. Our goals are to facilitate high quality care aimed at preventing pressure ulcers, to reduce healthcare related infections and to improve fire safety within healthcare environments.

SAFETY INFORMATION

Please read the following information before using your OptiCell air mattress!

- The product must only be used in accordance with these instructions for use.
- The product must not be combined, assembled or repaired using parts, accessories or spareparts other than those described in these instructions or other documentation from Staebel
- Ensure that the mattress does not get pinched or damaged during storage.
- Avoid sharp objects near the mattress.
- Avoid mechanical impact.
- The OptiCell mattress system is fire tested to standard SS 876 00 01, EN 597-1 & 2. The customeris responsible for a fire risk assessment and then choosing the right product. Please contact us if you have any questions.
- To avoid risk of damage, our products must not come into contact with hot sources or fire, e.g. lighted cigarettes and hot light bulbs.
- Ensure that you use the correct size of mattress for the bed and the correct model for thepatient concerned.
- If the mattress is used with other medical devices, it is the care provider's responsibility to ensure safety and compliance requirements are met.

THE PRODUCT MUST NOT BE USED BY

- Patients with unstable spinal fractures. For other unstable fractures, a medical examination is required to determine if it is appropriate to use the product.
- Patients with abnormal anatomies.
- Patients undergoing cervical traction or leg traction





INTENDED USE

The mattress systems covered by these instructions are intended for use in emergency medical treatment and after-care environments, including long-term care, care in the home & private homes.

The OptiCell Air1 has been developed to prevent and treat pressure ulcers up to and including category 4 when combined with an individualised and comprehensive pressure ulcer treatment programme (e.g. repositioning, nutritional supplements and skin care).

The mattress systems are intended to be used with a sheet between the patient and mattress. The OptiCell Air1 is part of procedures for the management of pressure sores (pressure ulcers). Other care aspects should be taken into account by the prescribing physician. If existing pressure ulcers do not improve or if new sores arise, the entire treatment programme should be reviewe by the prescribing physician. In all pressure ulcer care, a clinical assessment and experience should form the basis for whether an air pressure system should be used, and which one.

An OptiCell air mattress system can be used as a mattress in the following environments, as defined in standard IEC 60601-2-52

- Application area 1 (emergency medical treatment).
- Application area 2 (short-term care in a hospital or other healthcare clinics).
- Application area 3 (long-term care in a hospital or clinic).
- Application area 4 (care in the home).
- Application area 5 (outpatient or day patient care).

Contra Indications

The systems covered by these instructions must not be used by patients with unstable cervical, thoracic and/or lumbar fractures, cervical traction or skeletal traction.

Precautionary Measures

If the patient has other unstable fractures or conditions that may be complicated by a softor moving surface, the appropriate physician should be consulted before use.

Expected Useful Life

Under normal conditions and correct care, our OptiCell air mattress systems have an expected useful life of 5-10 years.

BEFORE USE

Receiving & Unpacking

The OptiCell Air1 is delivered packaged in cardboard. Avoid using a knife when unpacking and handling the product to prevent risk of damage. First check the product for any damage. In the event of transport damage, see page 30.

OptiCell Air1 comes with:

- Mattress with integrated cells
- Cable for air system
- Cover OptiTex™

Also delivered, depending on the model:

- Air1 Hand pump
- Air1 S 1 pump OC20 with power cabel (6 meter)
- Air1 SX 1 pump OC55 with power cabel (6 meter)





The OptiCell Air1 can be installed and used immediately.

- The air pump must not be used in damp areas, nor left outdoors during inclement weather. Avoid handling a pump that has been exposed to damp until it is dry again.
- The comfort and function of the mattress changes depending on the user weight. Also remember that a tall user may have a similar weight to a smaller user but need a different pressure. This must always be checked carefully for each user.
- The user must not be positioned so that their respiratory tract faces the mattress. Please sort and recycle the packaging to reduce environmental impact.

TO THINK ABOUT

- Handle the air hoses, pump and electrical wiring (Air1 S and Air1 SX) with care. Air hoses and electrical wiring (Air1 S and Air 1 SX) can be squashed and damaged by bed rails etc.
- The comfort and function of the mattress changes depending on the air pressure of the mattress in relation to user weight. Keep in mind that a tall user may have a similar weight to a smaller user but prefer a different pressure. This must always be checked carefully for each user.
- The user must not be positioned so that their respiratory tract faces the mattress



It is important that no sharp objects come in contact with the mattress.

Avoid knives, keyrings or other objects that could cut or puncture the mattress if they come in contact with it.

CARE IN THE HOME

Before using the OptiCell mattress system in a home environment, the personnel or family members who will manage the system should read and understood these user instructions and be given training from experienced personnel or Järven Health Care.

Pets must be kept way from the mattress to reduce the risk of damage to the cover, air hoses and cells. Other safety aspects that these user instructions cover also apply to home care.

Beds in private homes often have spring mattresses. These must not be used as there is a risk that the Air1 and user could slide off the bed.

WHAT TO THINK ABOUT WHEN INSTALLING A MATTRESS IN A HOME ENVIRONMENT

When installing the mattress system in a home environment, special consideration should be given to ensuring:

- Pets do not come into contact with the mattress.
- That the user instructions are available.

For Air1 S and Air1 SX the following also applies:

- That air hoses and electrical wiring are intact and fully protected against damage.
- That the hose and electric cable do not pose a suffocation risk for children.
- That the pump is not placed such that it risks falling onto the floor.
- That the pump is visible and not covered.
- That no unauthorised person can access the pump





GENERAL INFORMATION ABOUT THE AIR1 AIR MATTRESS SYSTEM

The OptiCell air mattress system is supplied with an OptiTex® PU hygiene cover. A stretch cover with a structure that enhances the pressure-relieving properties of the mattress.

The OptiTex™ cover has an integrated, waterproof cable channel that reduces the risk of bacterial spread, keeps the power cable out of the way and protects the air hoses. The top and underside are made of PU and the cover has a drip-proof waterproof zip on all four sides.

The underside of the cover has an anti-slip function and four straps to attach the mattress to the bed frame. There are also 4 handles on the length of the cover for ease of transport and moving the mattress. The seams of the cover are welded (not the bottom part).

The entire cover (both top and bottom) can be cleaned with disinfectant agents or machinewashed at 70° C (maximum 95° C) and tumble dried.

The cells can be easily deflated and then removed from the foam core and washed in hot water (max 70° C) or a disinfectant agent. The hose set can also be washed in this way. The mattresses are designed to be used with a sheet between the patient and the cover.

OptiCell air pressure mattresses are tested and comply with SS 876 00 01, EN 597-1 and EN 597-2.

Restore Factory Settings

Factory reset of the pump (Air1 S and Air1 SX) is done by holding down the "Silence alarm" button while the pump starts. If this is done correctly, three beeps will be heard at start-up indicating that the pump has been restored to its factory settings.

If the pump does not emit any beeps, restart the pump and hold down the "SILENCE ALARM" button. If it still does not beep, contact Staebel.

OptiCell Air1 - Three Models

Air1 is the OptiCell series of pressure-relieving hybrid mattresses with a foam core and integrated air cells. The air cells form a closed air system, which distributes air in the mattress to produce uniquely low test values in pressure tests. The OptiCell Air1 has been designed as an aid in preventive and therapeutic pressure ulcer care.

- OptiCell Air1 up to and including category 3.
- OptiCell Air1 S och OptiCell Air1 SX up to and including category 4.
- The mattresses are available in two different depths; 18 cm (R7) och 20 cm (R8)

Opticell Air1 R7 (all models) 230 kg Opticell Air1 R8 (all models) 250 kg

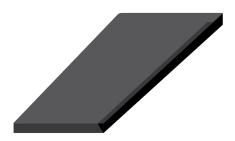




THE MATTRESS STRUCTURE

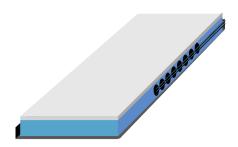
OptiCell air pressure mattresses are structured as below.

Underside of the Cover (PU)



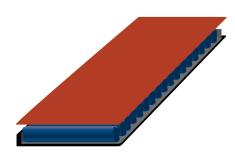
The underside of the mattress is made of hardwearing PU with four sturdy handles (not the bed mattress) for moving the mattress without the patient. The color of the underside is black. The underside also features an integrated cable channel with waterproof zipper and drip edge (applies to Air1 S and Air1 SX).

Foam Core with Cells



The OptiCell Air1 has a foam core with drilled channels for the air cells. The air cells have non-return valves and are interconnected by two air hoses.

Top of the Cover (PU)



The mattress top is made of a soft, silent, elastic polyurethane fabric.





The four handles at the bottom are designed to move the mattress without a patient. These must not be used when a patient is on the mattress.



AIR1 - HAND PUMP

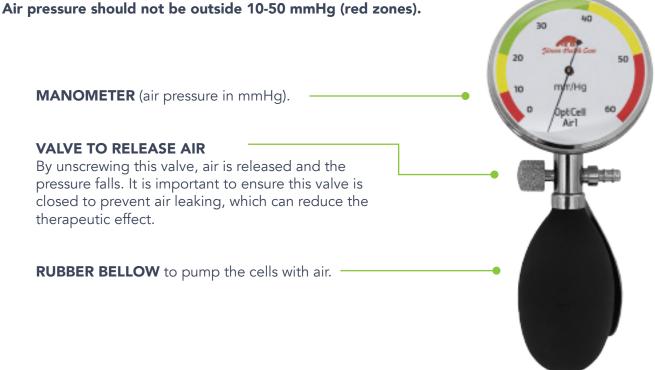
Air1 is supplied with the hand pump below.

Please note that the hand pump is available in different models and may differ from the image below. The hand pump is used to check the air pressure in the cells and, if necessary, add or release air to adjust the air pressure in the cells.

Recommended air pressure is 30 mmHg for a good therapeutic effect with a tolerance of +/- 10 mmHg (green zone). If there are special needs or the patient wishes to adjust the comfort level, the

air pressure can be adjusted by +/- 20 mmHg (yellow zones) in consultation with

an approved medical practitioner.





The hand pump is sensitive to physical impact and must be handled with care. Ensure that it is not subjected to shocks or dropped on the floor.



AIR1 S - OC20 AIR PUMP

The Air1 S is supplied with an OC20 air pump.





AIR1 SX - O550 AIR PUMP

The Air1 SX is supplied with an OC55 air pump.





INSTALLATION

Before installation, check that the bed frame is compatible with the size of the mattress in question. Using the wrong size mattress for the bed frame can lead to undesirable effects.

Inspection of the System

Before installation, make a visual inspection of the hose set, covers and cells. If any damage or contamination is suspected, a more thorough check must be carried out before using the system. If the air pressure system is damaged, the product must not be used and must be replaced. In the event of contamination, the system should be cleaned if possible. (See Care - Cleaning p.21)

Positioning of the Mattress

(Models Air1, Air S and Air1 SX)

The mattress is placed directly on the bed frame. Then use the fastening straps on the underside of the mattress to fasten the mattress to the bed frame. This is to secure the mattress in the bed frame. The care provider is responsible for ensuring the mattress is secured to the bed frame.

Positioning of the Pump

(Models Air1 S and Air1 SX)

We recommend hanging the pump on the foot end of the bed frame via the pump suspension hooks. (See image.) If it is placed otherwise, ensure the pump is not at risk of damage due to falling, or being struck. The care provider is responsible for ensuring the pump is in a safe position.



CONNECTING AND STARTING PUMP AIR1 S AND AIR1 SX

Check the mattress is placed according to the instructions on the previous page.

As the Air1 S and Air1 SX are supplied with a pump and power cable, now follow the steps below.

- Place the pump power cable in the mattress cable channel together with the hose set air hoses to avoid the risk of anyone tripping over a loose cable. For the same reason try to run the power cable to the power socket as discreetly as possible.
- Power cable and hose set are connected to air pump.
- With the pump switch in the off position, connect the power cable to a socket. The power socket must be within easy reach to enable the mattress to be disconnected if necessary.

On New Installation

Perform factory reset as below. Confirm that the comfort mode is set to '0'. If you are using Air1 SX, ensure that the cycle time is set to 10 minutes. (See Overview p. 24 or 26)

When Reintsalling at the same user

Start the pump. Previous settings are retained. Check that the pump comfort mode and cycle time settings are as expected. (See Overview p. 24 or 26)

Bed and combination mattresses can be started with the patient on the mattress as these have a foam mattress core underneath. A totally empty replacement mattress takes about 15 minutes to inflate. When the "READY" light comes on, the system is ready for use. When the pump "READY" light is on, place the patient on the mattress and perform a hand test.

This is to ensure that the patient does not lie through (bottom out).



Factory Setting

Factory reset of the air system pumps is done by holding down the "Silence alarm" button when the pump starts. If this is done correctly, three beeps will be heard at start-up indicating that the pump has been restored to its factory settings.

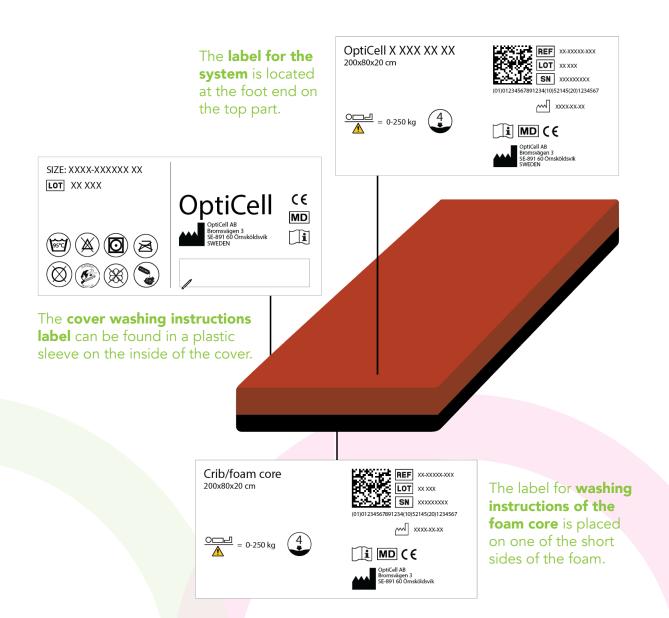
If the pump does not emit any beeps, restart the pump and hold down the "SILENCE ALARM" button. If it still does not beep, contact Järven Health Care.

Restoring the pump factory settings is a good habit to get into when installing a mattress. This will ensure that any stored patient settings in the pump built-in memory will be deleted.

MARKING

Mattress Labels

Your OptiCell mattress system has several labels. Below is a schematic of where to find them. Please note that individual designs may vary.





CARE - INSPECTION

Inspection of your Air1 Mattress

An inspection plan for the mattress system should be produced to ensure function and durability. Contact Staebel if you need any help with this. Please see contact details on the back page of this user manual.

Inspection of Optitex[™] Hygiene Cover

Regularly check the cover for visible signs of damage or wear and tear, such as tears, cracks, holes, stains or discolouring. Check all sides (including the underside of the cover).

Inspection of your Air1 Mattress

- Check the air hoses for damage or abnormal wear.
- Check the connection of the air hoses.
- Check that the air hoses are correctly connected to the cell valves.
- Check the cover for damage or abnormal wear.

Inspection of Pump (Air1 S and Air1 SX)

Check that the pump has no visible signs of damage or wear and tear, such as cracks, holes, stains or dirt. Check all sides (including the underside of the pump).

Also check the power cable and plug for damage and abnormal wear.

CARE - CLEANING

Cleaning of Cover

The top and bottom of the cover are made of PU and can simply be wiped clean with an alcohol-based disinfectant. For more thorough cleaning wash the entire cover (top and bottom) at min 700 C for at least 10 minutes with unscented detergent (according to standard "SS-EN 14065:2016 Textiles - Laundry processed textiles - Biocontamination control system (Swedish Standard). Maximum temperature for washing cover is 950 C.

The cover can be cleaned with a chlorine-based cleaner if the chlorine content is below 1 000 ppm (0,1%.)

Cleaning of Cells & Air Hose

The cells can be washed individually or together. Use a damp cloth and alcohol-based cleaning agent or a mild cleaning agent.

The air hose can be wiped clean with a damp cloth and mild detergent.

Cleaning the Pump (AIR1 S and AIR1 SX)

Always disconnect the power cable before cleaning the pump. The pump can then be cleaned with a damp cloth and mild detergent (both pump housing and power cable).

Cleaning the Air Filter (AIR1 S and AIR1 SX)

The pump has an air filter that is accessed by opening the inspection cover on the back of the pump. (See below). Wash the filter with water and a mild detergent.





WHAT TO DO IF THE ALARM SOUNDS (AIR1 S AND AIR1 SX)



The alarm indicates there is a fault with the system.

START TROUBLESHOOTING TO FIND THE CAUSE IMMEDIATELY.

Checking the Air Pressure in the Mattress

The mattress can lose air pressure for various reasons. It is therefore important to check that the patient does not lie through which would entail a risk of complications. An assessment must be made on if the patient should be moved to another mattress or that the fault can be rectified within a reasonable time. Most faults can usually be quickly corrected, and moving the patient will not be necessary.

IF THE ALARM INDICATES AN ELECTRICAL FAILURE 1

- Check that the power cable is fully connected to both the pump and wall socket.
- Check the wall socket. Test other equipment (e.g. a bedside lamp) to check the wall socket is working.
- Check the pump fuse. (See image below)

If after performing all the above checks, the fault cannot be found, the pump should be replaced.

IF THE ALARM INDICATES A FAULT WITH THE AIR PRESSURE

- Check the connection of the air hoses at the pump. Make sure the connector is in place correctly. Check the black rubber rings (O-rings) on the connector.
- Check the hose set. Check that the hoses are connected to each cell in the correct way. Open the cable channel in the cover and check that the two quick connectors on each hose are correctly in place.
- Check the cells. Inspect the cells for any damage causing air leakage.

If after performing all the above checks, the fault cannot be found, the pump should be replaced. Air pressure fault alarm has a delay of 30 minutes at start-up and 20 minutes thereafter. This is to prevent the alarm from going off when the bed and mattress are moved.



Image 1

The pump fuse is inside a cover, located under the power connector. The cover can be twisted open with a small screwdriver or similar.

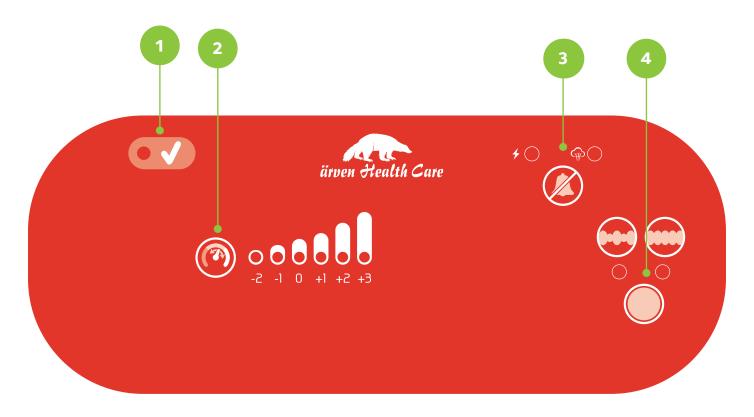
ALARM RESET

Once the cause of the alarm has been identified and addressed, reset the alarm by holding down the "Silence Alarm" button while turning the pump off and then on again. This action restores the pump to its factory settings, and the alarm is reset. If done correctly, three beeps will sound during start-up. All lights will flash initially; press any button to turn them off. If the patient had specific pump settings, readjust the pump accordingly.

If the alarm is triggered again, it suggests either the issue hasn't been correctly resolved or there's an additional fault. In such cases, repeat the troubleshooting checklist provided on the previous page.



OVERVIEW - PUMP OC20 (AIR1 S)



The power switch is on the right side of the pump. Press ON/OFF to start/stop the pump.

1. Green light indicates that the mattress is ready to use. Inflating an empty mattress normally takes approx. 15 minutes. When the light comes on, the mattress is ready to use.

2. Comfort mode setting

The air pressure of the mattress can be fine-tuned by pressing this button. The comfort mode selected is to improve the user experience and comfort. The factory setting of the pump is position '0'.

3. Silence alarm

In the event of an air pressure or electrical fault, the pump sounds an alarm. Press this button to silence this beep and begin troubleshooting. See page 22 – What to do if the alarm sounds. In the event of an electrical fault, the " " light comes on. In the event of an air pressure fault, the "4" light comes on.

4. Dynamic or Static mode

Press this button to toggle the pump operating mode between dynamic (alternating) and static mode. Dynamic mode is the pump factory setting and is recommended under normal conditions. When the right indicator is on, the mattress is set to static mode.

When the left indicator is on, the mattress is set to dynamic mode (alternating pressure). The alternating pressure cycle time is 10 minutes.

1800 772 287



SPECIFICATIONS

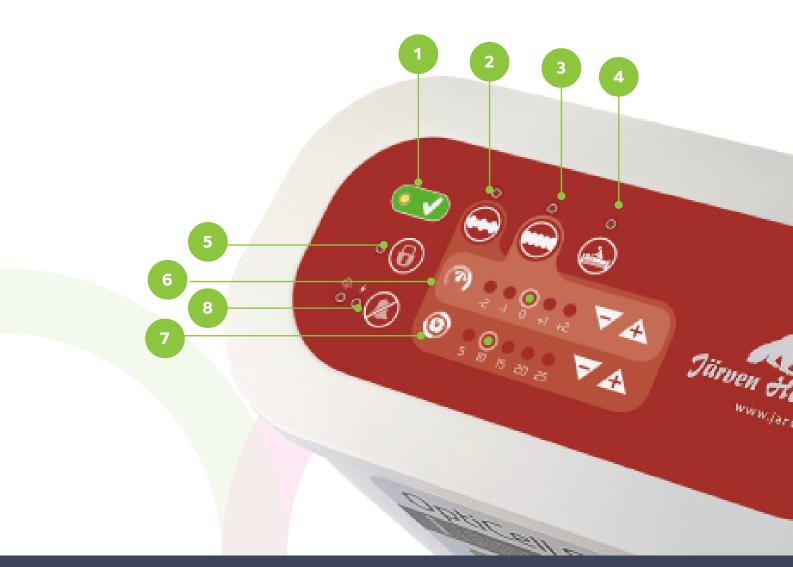
Pump OC20 V2	Specifications
Size	280 x 110 x 205 mm
Weight	2.6 kg
Pressure Range	20 ~ 70 mm Hg
Cycle Time	10 mins
System	Specifications
Classification	Electrical Classification: Class II; IP Rating 21 (IP21); No AP/ APG; Type BF**
Applied Part	Mattress
Power Rating	~230 V AC/50 Hz, alt. 110-240 universal power supply 1A , 12W
Fuse Rating	250V, T 1 A
Operating Environment	Temperature Use: 10° ~ 35° C Storage: -15° ~ 50° C Transport: -15° ~ 70° C Humidity Use: 20% ~ 80% without condensation Storage: 10% ~ 90% without condensation
Safety Standard	CE-Marked

For spare parts and accessories please contact your distributor or Staebel. See back page for contact details.



OVERVIEW - PUMP OC55 (AIR1 SX)

- 1. Inflating the mattress normally takes approx. 15 minutes. When the light comes on, the mattress is ready to use.
- 2. Dynamic mode, select to set the pump to dynamic (alternating) mode.
- 3. Static mode, select to set the pump to static mode.
- 4. Nursing mode, provides maximum static pressure to facilitate nursing care times. The mattress automatically returns to the previous settings after 30 minutes.
- 5. The buttons on the panel are locked to prevent unauthorised adjustment of pump operation. To unlock the panel, hold this button in for 5 seconds.
- 6. Adjust comfort mode, there are five comfort modes to choose from. The patient experience of the mattress is affected by the comfort mode chosen.
- 7. Select the cycle time for switching in minutes.
- 8. Silence alarm, press to silence possible alarm signals. The " " light comes on when the air pressure in the mattress is low. Check for leaks. The " $\frac{1}{2}$ " light comes on in the event of a power failure. See page 22 - What to do if the alarm sounds.





SPECIFICATIONS

Pump OC20 V2	Specifications
Size	280 x 110 x 205 mm
Weight	3.4 kg
Pressure Range	20 ~ 70 mm Hg
Cycle Time	10, 15, 20 or 30 minutes
System	Specifications
Classification	Electrical Classification: Class II; IP Rating 21 (IP21); No AP/ APG; Type BF**
Applied Part	Mattress
Power Rating	AC 220-240 alt. 110-240 universal power supply - 50 Hz 1A, 17W
Fuse Rating	250V, T 1 A
Operating Environment	Temperature Use: 10° ~ 35° C Storage: -15° ~ 50° C Transport: -15° ~ 70° C Humidity Use: 20% ~ 80% without condensation Storage: 10% ~ 90% without condensation
Safety Standard	CE, IP21

For spare parts and accessories please contact your distributor or Staebel. See back page for contact details.



KEY TO SYMBOLS











of manufacture



Please read the user instructions before use



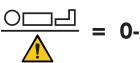
The product is a medical device



This product is CE marked to MDR 2017/745



Manufacturer





Maximum user weight.

Wound category the mattress is designed for.



Hand wash



Disinfect with alcohol-based agents or detergents with surfactants



Do not spin



Do not dry clean



MAc temperature when washing



Do not use detergents containing chlorine



Tumble dry low



Do not iron



not be used



Fabric softener must Fire rated to SS 876 00 01 EN 597 1+2

CE MARKING

OptiCell air mattress systems are CE marked to MDR 2017/745.

This includes manufacturer liability and assurance that the product meets essential requirements and that technical documentation and assurance are stored for at least ten years.



OTHER INFORMATION

PRODUCT LIABILITY

Product liability refers to manufacturer, importer or seller statutory damage claim liability for any damage caused by the product.

The Product Liability Act (EU Directive 85/374/EEC, Swedish Act SFS 1992:18) establishes manufacturer, importer or seller statutory liability for damage caused by a defect in their products. The rules apply to physical products in the form of movables, and products that are connected to other movables or fixtures. If no product has caused any kind of property or personal injury, product liability legislation is not relevant.

JÄRVEN HEALTH CARE QUALITY ASSURANCE

Our quality assurance work and customer focus are posited on responding to customer needs and expectations and by doing our utmost to cooperate based on trust and adopting a long-term approach. Current and future customer satisfaction is based on improving our products and services. Our basic quality assurance also includes finding evaluation methods and standards that guarantee customer quality in terms of comfort, function, useful life and price. In particular, Järven Health Care focuses on developing professional and committed em-ployees via regular training and skills development of healthcare personnel. Our hope is that this will lead to highquality care with a focus on preventing pressure ulcers and care-related infections, as well as reducing incidences of fire in healthcare.

HEALTH CARE AND THE ENVIRONMENT

Järven Health Care works continuously to improve our environment performance. We aim to always use materials and products with the smallest possible environmental footprint. Järven Health Care is listed with the REPA register and El-kretsen AB and thereby meets its producer liability. For more information about our environmental work, please contact Järven Health Care.

TRANSPORT DAMAGE

Any damage of the product must be noted on the accompanying delivery document before accepting possession. Please then contact your local distributor and provide relevant information.

NOTE! For faster processing of your case, we ask you to photograph the transport damage as thoroughly as possible before contacting Customer Service.

PRESSURE ULCER PREVENTION WORK

A clinical assessment of the patient's risk of developing pressure ulcers should be carried out. Aids to the assessment include the Norton scale, Braden scale and Risk Assessment Pressure Sore (RAPS) scale. The assessment must be done on arrival or at the beginning of a care period, regardless of whether the patient is in a care facility or cared for in his or her own home. According to the European Pressure Ulcer Advisory Panel's (EPUAP) international guidelines, the recommendation is within 8 hours. The assessment is made to identify the specific needs of the patient regarding pressure relief and must be conducted by staff with adequate knowledge and education.

Based on the patient's assessed status, the appropriate mattress is chosen for the correct purpose and pressure relief needs. Routinely change the patient's location and position on the mattress throughout the care period. In addition, regularly examine the patient and check their skin condition and nutritional status.

All of the OptiCell mattresses have undergone pressure measurement testing according to SS 8760013 at Swerea IVF. The results of the pressure measurement test form the basis for the