USER GUIDE

OptiCell 3 PRO® V2

Alternating pressure air mattress

Järven Health Care

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Thank you for choosing the OptiCell 3 PRO V2 alternating pressure air mattress from Järven Health Care.

Our goal is for you to be satisfied with the mattress in terms of both function and service life. Therefore, please take a few minutes to read through this guide to understand the best way to manage and care for your mattress.

If you have any questions that are not answered here, please contact us at Järven Health Care. You can find our contact information at the back of this guide.

SYMBOLS USED THROUGHOUT THIS GUIDE

Important note:
All instructions denoted by this symbol must be observed. It highlights information and guidelines that are important to the user.

Risk of damage to mattress:
Important information denoted by this symbol must be observed in order not to damage the mattress or other material.

CE MARKING

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

CE

QUALITY

Our quality standards 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 and trust.

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 INSTRUCTIONS

Read the following information before using your OptiCell mattress!

- **The product should only be used in accordance with this user guide.**
- The product should not be assembled, combined or repaired with any parts or accessories other than those described in this guide or in other documentation from Järven Health Care.
- Ensure that the mattress does not become misshapen or damaged during storage.
- Avoid sharp objects near the mattress so that the surface does not get damaged.
- Avoid severe physical impact from other objects.
- The mattress is fire safety tested according to standard **SS 8760001**, **EN 597-1** and **EN 597-2**. It is the customer's responsibility to make a fire risk assessment of the intended usage environment and then use the right product. Please contact us if you have any questions.
- In order to avoid damage, the mattress should not come into contact with heat sources or fire, such as burning cigarettes, heat lamps or the like.
- Make sure that you use the correct mattress size for the bed and the appropriate model for the patient.
- Connect the product to the nearest situated power outlet in order to reduce the amount of power cable lying across the floor.
- Follow appropriate electrical safety standards.
- Always check electric cable before use
- Damaged or broken power cable must not be used.

THE PRODUCT MUST NOT BE USED FOR:

- 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.

PRODUCT INFORMATION

OPTICELL 3 PRO V2 AIR MATTRESS SYSTEM

The product is designed to help prevent and treat pressure ulcers from Categories 1-4 (low risk to very high risk) for patients within the weight range 20-230 kg.

The product is intended for use with a sheet between the patient's skin and the mattress surface.

The mattress can be used within the following environments, defined by IEC 60601-2-52:

- Operating environment 1 *(emergency care)*.
- Operating environment 2 *(short-term care in hospitals or other healthcare facilities)*.
- Operating environment 3 *(long-term care in healthcare facilities)*.
- Operating environment 4 *(care in the home environment)*.
- Operating environment 5 *(outpatient care)*.

In accordance with directives from the European and the US National Pressure Ulcer Advisory Panels (EPUAP and NPUAP), it is recommended that each patient's condition be checked regularly.

PREPARATION

This user guide contains information for general use, maintenance and improved safety.
It is very important to read this guide carefully before using the product. Care personnel must be given access to this user guide and also be informed of the risks that may arise when using electrical equipment. Training on the product can be provided on request.

Before using the product for the first time, or when it is retrieved from a storage location:

- Check the condition of the electrical system and its compliance with applicable safety standards.
- Connect the product to the mains power supply.
- The power outlet used should be easily accessible so that the product can be disconnected if necessary.
- Ensure that all of the product's functions are in good working order.
- Ensure that the product and the care environment are in good hygienic condition.
- Check that the product is positioned in a safe manner in the care environment.
- Carry out a Hand Check test (see page 11).

If the mattress is used with other medical devices, it is the user's responsibility to meet all relevant safety and compliance requirements.

Järven Health Care recommend that the product is disinfected before the first use.

THE OPTITEX™ COVER

OptiTex is a durable hygiene cover with unique features contributing to the mattress's pressure relieving properties.

The multi-stretch, breathable cover is made of a polyurethane (PU) material. The entire cover (both upper and lower parts) can be cleaned with disinfectants or machine washed at maximum 95° C and tumble dried.
The OptiTex cover has an integrated waterproof cable holder that reduces the risk of bacteria spreading, keeps the electrical cord out of the way and protects the air hoses.
Cells and hoses can easily be removed from the cover and rinsed clean with disinfectants or with warm water at maximum 70° C.

The Low Air Loss function allows air to escape from the cells whilst at the same time remaining waterproof. This microclimate management together with the bi-elastic surface layer reduces the risk of shear and other complications for the patient.

Fluid protection flap and waterproof zip on four sides, with welded seams.

Anti-slip underside which grips to bed base, in addition to four fastening straps.

Four transportation handles to enable easy moving.

APPLICATIONS

The OptiCell 3 PRO V2 is an alternating pressure air mattress, with an integrated foam core, which is placed directly onto a bed base. It aids the prevention and treatment of pressure ulcers up to and including Category 4.
OptiCell 3 PRO V2 has a height of 18cm and comes with a durable OptiTex cover and a CPR valve for emergency situations.
The supplied pump can provide both static and alternating pressure. It is easy to use and automatically adjusts to the patient's weight, length, location, movements and position in the bed. The pump has four pre-programmed cycle times of 10, 15, 20 and 30 minutes.

EXPECTED SERVICE LIFE

Under normal conditions and maintenance, the expected service life of our OptiCell systems is 5 years.

FIRE PROTECTION

The OptiCell 3 PRO V2 mattress is tested and approved according to **SS 8760001**, **EN 597-1** and **EN 597-2**.

SYSTEM FEATURES

The OptiCell 3 PRO V2 air mattress is constructed so that individual cells can be disconnected, even while a patient is lying on the mattress. The mattress has three different types of cells:

- **Head cells** – 13 cm high continuously inflated air cells that are positioned under the patient's head.
- **Standard cells** – 13 cm high alternating air pressure section.
- **Ventilation cells** – function as standard cells, but with ventilation holes releasing small amounts of air up into the cover. This creates air circulation that helps keep the top of the cover dry.

Individual cells can easily be disconnected:

- Release the air hose from the chosen cell (press the black button on the air hose coupling).
- Press the two buttons on the short sides of the cell.

AIR HOSE PUMP CONNECTION

The OptiCell 3 PRO V2 air mattress is connected to the pump by three air hoses.

The red air hose, positioned in the middle, is used to fill the head cells situated under the patient's head. It also fills the lower chambers of the standard cells and the ventilation cells. This ensures that there is always air in the mattress no matter how the pump is set, or if the pump should stop working (for example, due to power failure).

The outer two air hoses provide either alternating or static pressure to the standard cells and ventilation cells. See the section "Air hose connection" (page 10) for more information.

THE PUMP'S DIFFERENT WORKING METHODS

By changing the pump settings, you can choose to have either a static mattress or an alternating air pressure mattress with different degrees of air pressure. Examples of different working methods include:

- By removing individual cells, relief can be given to specific body parts (for example the heels).
- By inserting a ventilation cell, a fresher feeling can be created when the patient senses that the cover feels warm in a specific area.

USE OF PRODUCT

RECEIVING AND UNPACKING

The OptiCell 3 PRO V2 air mattress is delivered rolled up in cardboard. Use of knives should be avoided when unpacking and handling due to risk of damage.

An OptiCell air mattress system contains:

- 1 pump
- 1 power cable (6 meters)
- 1 mattress, with air hose cable, CPR valve and OptiTex cover

Check that the product is not damaged. In the event of transport damage, see page 17.

The mattress can be set in place and made ready for use immediately.

PLEASE NOTE:

- The air pump should not be used in humid areas nor should it be left outdoors in damp weather conditions. If the pump is exposed to water, avoid handling it until it has dried.
- Take care when handling the pump, power cable and air hoses. Air hoses can be pinched and damaged by bed rails etc.
- The mattress's comfort and function change depending on its air pressure in relation to the patient's weight. Keep in mind that a tall patient can weigh the same as a short patient, but may need a different pressure. This must always be carefully observed for each patient.
- The biggest risk for the patient is to "bottom out" on the mattress. The basic rule is that the part of the body to be unburdened must not be subject to pressure. If the patient "bottoms out", the objective of the mattress is lost. See page 11 for information on the Hand Check test.
- The patient should not be positioned with their respiratory system turned towards the mattress.

It is important that no sharp objects come in contact with the mattress.
To prevent damage to the mattress avoid knives, keys and other objects with a cutting or puncturing ability from coming into contact with the mattress.

STORAGE

The OptiCell 3 PRO V2 air mattress system should be stored in the dry and at room temperature.
We recommend that the mattress be kept rolled up in one of our optional transport bags. The mattress should not be treated carelessly when stored, as it risks being damaged.
Avoid exposing the mattress to direct sunlight for prolonged periods.

The mattress can be used immediately after delivery and unpacking. Inflating the mattress takes about 15 minutes and should be done before the patient is placed on the mattress.

AUTOMATIC ADJUSTMENT AND ALTERNATING PRESSURE

The pump will automatically adjust the air pressure based on the patient's weight, length, location, movements and position on the mattress. This feature makes it easy to start using the mattress.

The comfort level can be adjusted by raising or lowering the general air pressure. This is done by pressing the **"Comfort"** button *(position B on page 14)*. Ensure that the patient does not "bottom out". See Hand Check test on page 11.

The time interval for alternating pressure is selected by pressing the **"Cycle Time"** button *(position D on page 14)*. The patient's experience of the mattress and their pressure ulcer needs are the basis for choosing the time interval.

STATIC MODE

In some cases, it is necessary to switch the mattress's air pressure from alternating to static. It can be for instance, during nursing care procedures or when the patient does not want to be disturbed by an alternating pressure. Press the **"Care/Static"** button *(position E on page 14)* to select either **"Care"** mode or **"Static"** mode:

- **"Care"** (also called Auto-firm mode) provides maximum pressure to facilitate nursing care.
- **"Static"** adjusts the air pressure after setting the comfort mode.

The correct therapeutic effect is achieved with alternating air pressure in Dynamic mode. Static air pressure (constant low pressure) should only be used when necessary.

LOW PRESSURE ALARM

If the mattress air pressure falls too low, the **"Leaking"** lamp lights up and an audio alarm starts.

To respond, start by pressing the **"Alarm"** button *(position C on page 14)* to silence the alarm and then check the following points to find the cause.

- Check that the air hose is connected correctly to the pump.
- Check that no air is leaking from the valves connecting the air cells and air hose.
- Check that the CPR valve is properly attached.
- Check all air cells for leakage. This is easiest to do when the pump is set to **"Care"** (Auto-firm mode) and all cells are properly connected.

If the alarm still persists and the **"Leaking"** lamp does not switch off, the mattress should be replaced. Contact Järven Health Care for consultation and advice – information can be found on the back cover of this manual.

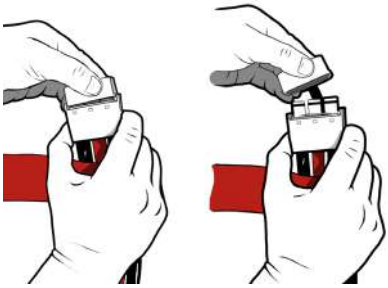
AIR HOSE CONNECTION

Connecting the air hoses to the pump:

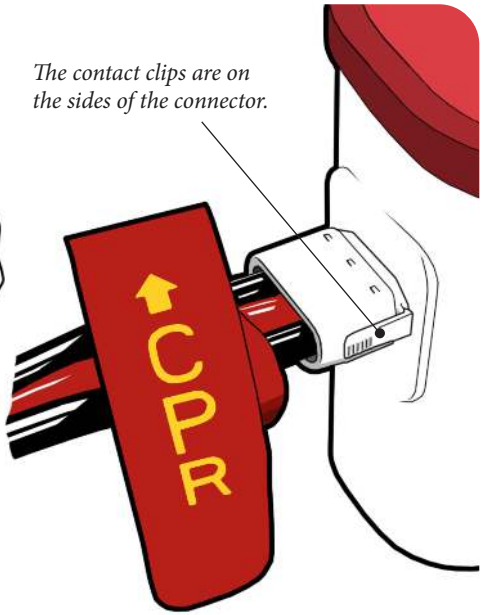
To remove the protective caps and to connect or disconnect the air hose, push in the two contact clips on the side of the connector. This action releases the hooks that hold the connector in place. The protective caps should be put back on the connector if the air hose is disconnected from the pump.

To minimise the risk of air leakage during hose connection, check:

- That the two hooks are not damaged and their clips are intact.
- That the black o-rings on the connector's three air hoses are not cracked or missing.
- That no debris has entered the connector causing a bad connection or blocking the air hoses.



The air hose connector is fitted by a simple hand motion. No special tools are required.



HAND CHECK TEST

Test the mattress's function with a simple hand check.

To ensure that the mattress is providing the right therapeutic function, a simple hand check is performed. The test should be performed each time a mattress is taken into operation in order to detect any problems with the mattress's air pressure. The test ensures that the patient does not "bottom out".

How the hand check is performed.

The hand check should always be performed when the patient is positioned on the mattress. It is important to ask the patient not to try and lift their body during the test and to stay lying as usual. It is not uncommon for patients to lift their body in the belief that it is easier for the staff, but it may give an incorrect test result.

- Fold away the sheets and unzip the mattress cover to access the cells.
- Put one hand between two cells with the patient lying on the mattress. *(See illustration)*. Depending on the size of the hand, it may sometimes be sufficient to use 2-3 finger height.
- Ensure that when the hand is in position, it fits between the bed base and the patient.

The important conclusion of the check is that there is space between the patient and the bed base.

If the hand check shows that the patient is "bottoming out".

If the patient is "bottoming out" and no alarm has triggered on the pump, the comfort level should be raised *(position B on page 14)*. If it is already set to maximum and the patient does not weigh more than the recommended maximum weight, then the mattress and pump need troubleshooting by authorised personnel (see page 12).

INSPECTION AND TROUBLESHOOTING

INSPECTION OF YOUR OPTICELL AIR MATTRESS SYSTEM

An inspection plan should be established in order for your air mattress to function and last for as long as possible. Please contact us if you would like assistance with this. Järven Health Care's contact details can be found on the back cover of this guide.

INSPECTION OF THE MATTRESS AND PUMP

- Check the electrical cord and plug for signs of damage or abnormal wear.
- Check the mattress surface for signs of damage or abnormal wear.
- Check that the cells of the mattress are correctly connected to the air hoses.
- Start the pump and examine the air flow from the pump (with the air hoses disconnected). The air flow should alternate between the two outer holes each cycle time. The middle hole should release no air.
- Check the air hoses for signs of damage or abnormal wear.
- Check the air hose connector (see page 10).

INSPECTION OF THE OPTITEX COVER

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

TROUBLESHOOTING

The pump does not work or does not start:

- Make sure the electrical plug is properly inserted, then turn on the pump's power switch.
- If the power indicator is off, there may be a problem with the electrical socket. Test another power outlet.
- If the power indicator is on but the pump does not work, contact Järven Healthcare.

The mattress does not inflate properly (pressure too low):

- Set the pressure to maximum, check if the air hoses are pinched anywhere or if there is air leakage from any cell. Check that the CPR valve is closed.

Poor air flow:

- A dirty air filter can reduce air flow. Wash the air filter with mild detergent. The air filter is easily accessible on the back of the pump and can be released with a simple motion.

CLEANING

CLEANING THE PUMP

To clean the pump, use a damp cloth and mild detergent on the pump housing and the power cable.

CLEANING THE OPTITEX COVER

The cover is made of a polyurethane (PU) material on both top and bottom. The entire cover (both upper and lower parts) can be cleaned with disinfectants. Use alcohol-based disinfectants.

Healthcare textiles (mattress coverings, bedding, etc.) can be contaminated by pathogenic microorganisms. These should be washed at a minimum of 70° C for at least 10 minutes with unscented detergent, according to standard ***"BS-EN 14065: 2016 Textiles – Laundry Processed Textiles - Biocontamination Control System"***.

The OptiTex cover can be machine washed at a maximum of 95° C.

CLEANING THE CELLS AND AIR HOSES

The cells can be washed separately or in groups using a damp cloth and mild detergent. The air hoses can also be wiped with a wet cloth and mild detergent.

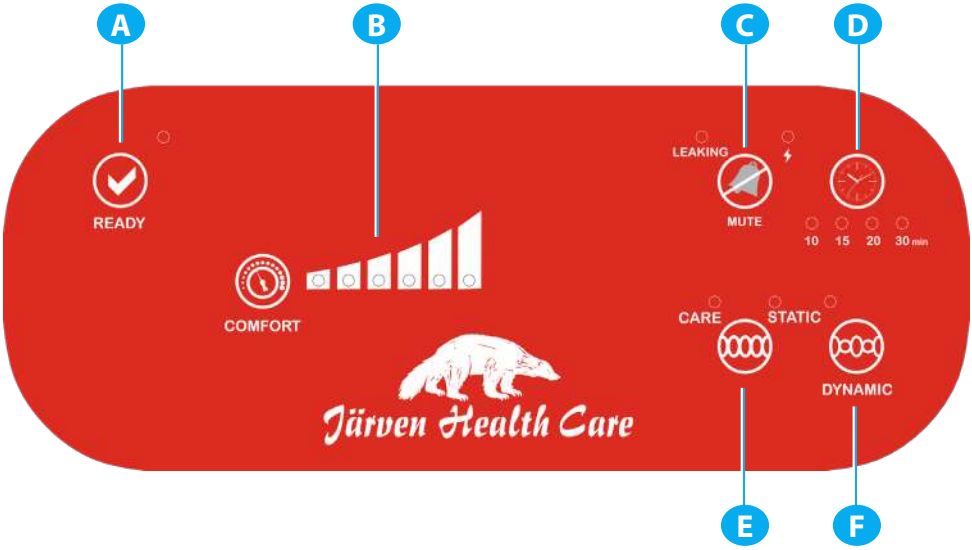
CLEANING THE AIR FILTER

The pump has an air filter located on the back. The filter can be easily accessed through a protective cover. See picture below.

The filter can be washed with mild detergent.

Protective cover for air filter

PUMP OVERVIEW – OC30 V2



The power switch is located on the right side of the pump. Press **"On/Off"** to start or stop the pump.

A **READY**
Inflating the mattress takes approximately 15 minutes. When the **"Ready"** lamp is lit, the mattress is ready to use.

B **COMFORT**
There are six comfort modes to choose from. The patient's experience of lying on the mattress is affected by the comfort mode chosen. Press this button to cycle through modes.

C **ALARM**
If the alarm sounds, press this button to mute and reset. The adjacent **"Leaking"** lamp will light up if the air pressure in the mattress is too low. Check if necessary for any air leakage (see page 12). The adjacent lamp marked "ϟ" will light up in the event of a power failure.

D **CYCLE TIME**
Use this button for setting the preferred cycle time for alternating pressure.

E **CARE/STATIC**

Press this button to select **"Care"** (auto-firm) mode or **"Static"** mode.

When the adjacent **"Care"** lamp is lit, the pump provides maximum static pressure to facilitate nursing care procedures. After 30 minutes the mattress will automatically return to the previous setting in use before the auto-firm mode was selected.

When the adjacent **"Static"** lamp is lit, the desired comfort level is then selected using the **"Comfort"** button *(position B)*.

F **DYNAMIC**

Press this button to switch mattress to dynamic alternating air pressure mode.

SPECIFICATIONS

Pump OC30 V2	Specifications
Size	28.0 x 11.0 x 20.5 cm
Weight	2.6 kg
Pressure range	20 ~ 70mm Hg
Cycle time	10, 15, 20 or 30 minutes

System	Specifications
Classification	Class II; IPXO, No AP/APG; Type BF
Applied part	Mattress
Power rating	~230V AC/50 Hz 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

RECYCLING

All materials in your OptiCell air mattress system, with the exception of certain parts of the pump, are energy-recoverable by incineration at designated combustion plants.

PUMP

An OptiCell pump must not be disassembled, but should be disposed at a recycling station and sorted as "Electronic waste".

MATTRESS

The OptiCell air mattress can be disposed of at a recycling station and sorted as "Combustible waste". For more information contact Järven HealthCare.

Järven Health Care takes environmental responsibility seriously.
We strive to always use materials and products with the least possible impact on the environment. We are constantly working to develop and improve production techniques. Järven Health Care is affiliated with the Swedish FTI and El-Kretsen recycling agencies to maintain its responsibilities as a producer.
For more information on our environmental work contact Järven Health Care.

OTHER INFORMATION

PRODUCT LIABILITY

Product liability legislation (EU Directive 85/374/EEC, Swedish Law SFS 1992: 18) establishes the manufacturer's, importer's or seller's statutory liability for any damage caused by the product. The regulations apply to physical products in the form of movables, even if incorporated into another movable or into an immovable. If there is no product which has been the cause of some form of property or personal injury, then product liability legislation is not relevant.

RETURNS AND COMPLAINTS

Any complaints regarding the product must be notified in writing to Järven Health Care. The return of products must be done in accordance with our instructions.

Returning a product before a complaint case is processed will result in the case being considered closed and customer compensation will not be paid.

DAMAGE UPON DELIVERY

Any damage of the product must be noted on the accompanying delivery document before accepting possession. Then contact Customer Service at Järven Health Care (+46 660-22 28 50, healthcare@jarven.se) 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 Järven Health Care's 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 classification of the pressure relief properties of the mattresses.

YOUR NOTES

If you require any further information or assistance, please get in touch with us. We will be happy to help you!

OPTICELL 3 PRO V2 user guide.

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