Series3 Advance

User Manual

OSKA
Pressure Care Experts

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Model No.: 9P-087410

Please read the manual before use.

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USING

DANGER- To reduce the risk of electrocution:

(1). Always unplug this product immediately after using.

(2). Do not use while bathing.

(3). Do not place in or drop into water or other liquid.

(4). Do not place or store this product where it can fall or be pulled into a tub or sink.

(5). Do not reach for a product that has fallen into water. Unplug immediately.

WARNING- To reduce the risk of burns, electrocution, fire, or injury to persons:

(1). Any serious incident that has occurred to a user or patient in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

(2). Never perform servicing or maintenance to the device while it is in use.

(3). Never disassemble this device on your own. Repairs and internal servicing should only be performed by an authorized technician.

(4). Evaluate patients for entrapment risk according to protocol and monitor patients appropriately.

(5). The product may be used with caution for patients with spinal injury, but it is recommended that you consult with a physician before use. However, it should not be used for patients with unstable spinal fractures.

(6). Close supervision is necessary when this product is used on or near children. Electrical burns or choking accidents may result from a child swallowing small parts if they are detached from the device.

(7). Use this product only for its intended use as described in this manual. Do not use another mattress not recommended by the manufacturer.

(8). Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or if it has been dropped into water. Return the product to your supplier or Wellell Inc. for examination and repair.

(9). Keep the cord away from heated surfaces.

(10). Never block any air openings of this product or place it on soft surfaces, such as a bed or couch, where openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.

(11). Never drop or insert any object into any opening or hose.

(12). No modification of this equipment is allowed unless it is conducted by the authorized technician.

(13). Mattress covers have passed skin sensitization and skin irritation tests. If you suspect that you may have had or are having an allergic reaction, please consult a physician immediately.

(14). Do not leave long lengths of tubing around the top of your bed. It could lead to strangulation.

(15). Keep the pump away from flammable liquids or gases.

(16). Do not use the extension cord for an extended period of time.

(17). If there is a possibility of electromagnetic interference with mobile phones, please increase the distance (3.3m) between devices or turn off the mobile phone.

(18). The device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

(19). Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information. Contact the home care provider regarding EMC installation information.

(20). Always comply with the local regulations for disposing of such equipment.

(21). Store the product in a dry place. Keep out of direct sunlight. Use or store the product only in the following conditions:

- Operation: 10°C to 40°C (50°F to 104°F); 10% to 90% RH, non-condensing
- Storage: -15°C to 50°C (5°F to 122°F); 10% to 90% RH, non-condensing

CAUTION – Reducing the risk of damage to the device.

(1). Mobile RF communications equipment can affect medical electrical equipment.

(2). Do not place the device directly onto flammable materials.

(3). The equipment must not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected.

(4). Be careful not to place the device where it can be taken or touched by children and pets.

NOTE, CAUTION AND WARNING STATEMENTS:

NOTE: Indicates some tips.

⚠ **CAUTION: Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property**

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

SYMBOLS

	Manufacturer		Date of manufacture
	Importer		Authorized representative in the European Community
	Type BF applied part		Refer to instruction manual or booklet
	Identifies a product as a medical device		Serial number
	Unique device identifier		Consult instructions for use
	Catalogue number		POWER/STANDBY
	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.		Temperature limit
	Power “ON”		Power “OFF”
	CE marking	IP21	Protected against solid objects greater than 12.5 mm; Protected against vertically falling drops of water
	Class II equipment		Caution
	Wipe down		Maximum/minimum user weight

	This way up		Do not use cutter
	Keep dry		Use no hooks
	Fragile, handle with care		Recycling
	No bleaching		Do Not Iron
	No dry cleaning		Tumble dry possible at low temperature; exhaust temperature max. 60°C (140°F)
	Maximum washing temperature 95°C, normal process		Do not use phenol or phenolic-based cleaning solutions
	Attention – Observe proper Disposal of Electrical & Electronic Equipment (WEEE): This product should be handed over to an appropriate collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.		

1. Introduction

This manual should be used for the initial setup of the system and for reference purposes.

1.1 General Information

The system is a high-quality mattress system suitable for the prevention of pressure injury. The system has been tested and successfully approved to the following standards:

CE

IEC/EN 60601-1
IEC/EN 60601-1-2
IEC/EN 61000-3-2, Class A
IEC/EN 61000-3-3
CISPR 11 Group 1, Class B

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

1.2 Intended Use

The system is intended to prevent the development of pressure injuries in patients at risk. It can only be operated by personnel with adequate pressure injury prevention training in acute care settings, long-term care facilities, and home environments.

1.3 Indications for Use

The system is indicated for patients whose weights are within the system's specified minimum and maximum support weight limits.

1.4 Contraindications

Do not use on patients with unstable fractures, including unstable spinal fractures, or those undergoing cervical traction or skeletal traction.

2. Product Description

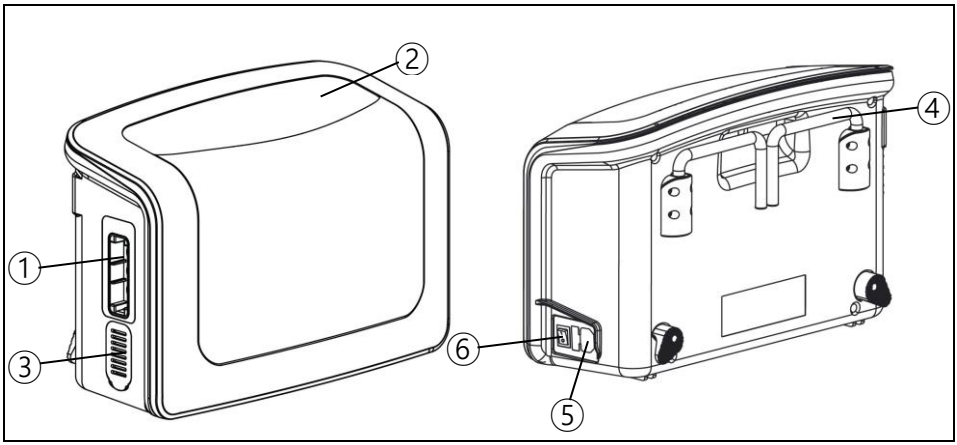
2.1 Content of Package

Unpack to check for any damage that may have occurred during shipment. If there is damage, please contact your service provider immediately.

This system comes with the following items.

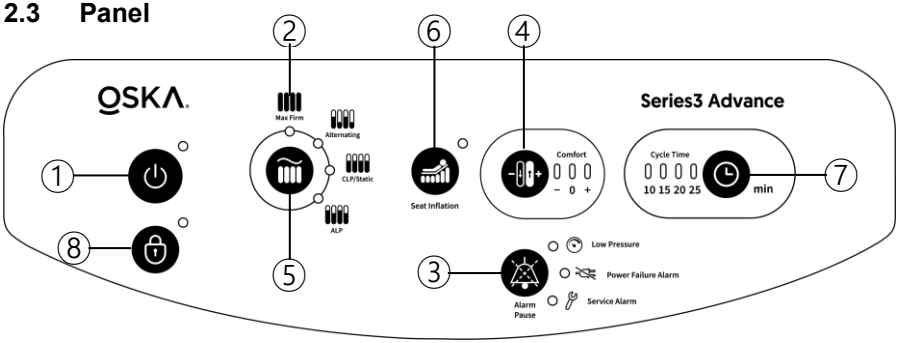
(1). Pump Unit x1
(2). Mattress x1
(3). Power cord x1 (16 ft)
(4). User Manual x1

2.2 Pump Unit



(1). Quick Connector Port
(2). Front Panel
(3). Filter Cover
(4). Mounting Brackets
(5). Power Cord Port
(6). Power Switch

2.3 Panel



(1). STAND-BY

To start/stop the treatment. The pump automatically detects the mattress and lights solid green.

NOTE: Always press the STAND-BY button to turn off the pump.

(2). Max Firm

To inflate the mattress to ensure that the maximal operating pressure is available. This mode lasts for 20 minutes and then automatically returns to the previous mode. This mode provides solid and firm support for the patient and is optimal for patient transfers or care practices.

- Press the Mode Button to select the Max Firm function.
- Press again to stop inflation. The system will then return to the next or selected mode.

(3). Alarm Pause Button

Audible and visual alarms (solid orange indicator) are provided to alert users. Press here to silence the audible alarm, and the alarm will resume after 3 minutes if the problem persists.

	Power Failure Alarm (PFA) Power source not detected. **NOTE: The pump seals the air inside the mattress, which temporarily keeps the patient from bottoming out during a power failure. Move the patient elsewhere if the situation cannot be resolved quickly.**
	Service Alarm Possible system failure. Contact service provider for assistance.
	Low Pressure Alarm The pressure inside the mattress is lower than normal. Refer to troubleshooting for details.

(4). Comfort Level Button

Press to adjust the given air pressure. Always perform a hand-check after pressure re-setting to prevent the patient from bottoming out.

−	Make the mattress softer.
0	Preset mattress firmness.
+	Make the mattress firmer.

(5). Mode Button

Press to select the preferred treatment mode. The default is alternating mode.

	**Alternating** The odd and even rows of air cells take turns to inflate and deflate, creating a wave-shaped surface that aims to relieve surface pressure periodically.
	**Continuous Low Pressure (CLP, Static)** Air cells don't alternate and are equally inflated at a lower air pressure, creating a flat surface that aims to distribute the patient's weight by maximizing contact area.
	**Alternating Low Pressure (ALP)** Air cells alternate but more mildly than in alternating mode, creating a flatter wave-shaped surface. This mode is recommended for patients who cannot tolerate the wave-shaped surface of the alternating mode and prefer minimal disturbance while resting.

(6). Seat Inflate Button

Increase the pressure for every cell to support the patient during an upright position without bottoming out.

(7). Cycle Time Button

There are four selectable cycle times that can be found on the control panel. By pressing the button, the user can select one of four cycle times based on patient comfort and desired outcome.

(8). Panel Lock Button

Press to lock/unlock the control panel.

The panel locks automatically 5 minutes after the last operation. This prevents the settings from being accidentally changed.

NOTE: Always unlock the panel before any operation.

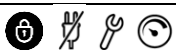
Auto Adjustment (AA)
This feature automatically optimizes the mattress' pressure-relieving performance in accordance with the patient's weight distribution.

To stop, press and hold the **Comfort Level button (4)** for 3 seconds.

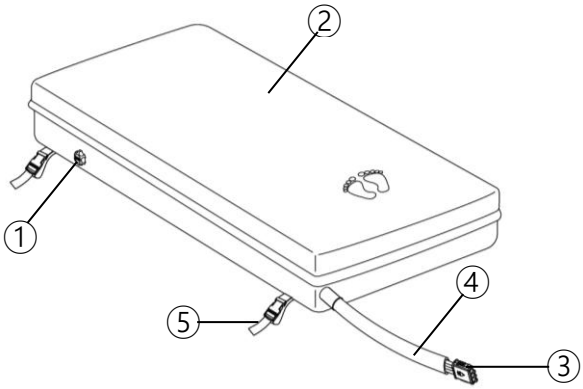
NOTE: During the auto-adjustment operation, it is normal that the system goes through a series of inflation and deflation.

- **Indicator Status**

Indicators are shown in two colors: green and orange. See below for meanings.

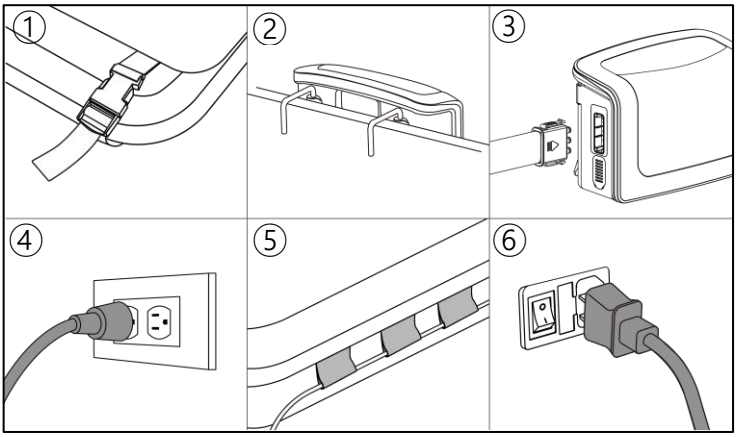
ICON		
COLOR / STATUS	green	orange
solid	Features enabled	• Features enabled • Errors. See section 9.1 for details.
flash	Inflation in progress	Errors persist
dim	Disabled	Disabled Normal operation

2.4 Mattress



(1). CPR unit
(2). Top cover
(3). Quick connector
(4). Air hose
(5). Straps

3. Installation



3.1 Mattress

(1). Place the mattress on the bed frame with the footprint towards the foot end. There are fastening straps at the base of the mattress. Fasten the straps at each corner to secure the mattress.

NOTE: Make sure that all the connectors/CPR units are closed and locked in position.

NOTE: It is best to place the patient directly onto the mattress without another sheet or bed linen in between. The extra layer of fabric might reduce the benefit of the mattress and should always be avoided.

(2). Hang the pump from the bed panel at the foot end.

(3). Remove the cover of the quick connector. Connect the mattress' air hose to the pump. To ensure the connection is made, you should hear/feel a "click".

WARNING: To prevent tripping, place the air hose away from walking areas.

NOTE: Make sure that the air hose is not kinked or tucked under the mattress.

(4). Plug the power cord into the mains power.

NOTE: Make sure the pump unit is suitable for the local power voltage.

NOTE: The plug can also be used to disconnect the device.

(5). The cable management tape is provided along the side of the mattress to manage the power cord. After installation, any extra length of the power cord should be neatly tucked away to prevent tripping and away from moving bed mechanisms or other potential entrapment points.

NOTE: Do not position the device so that it is difficult to disconnect the plug.

WARNING: Please make sure that the power cord does not show any signs of damage.

(6). Turn on the power switch on the side of the pump and press the STAND-BY on the panel to activate the system.

⚠ **CAUTION: Use the pump unit only with the mattress authorized by the manufacturer. Do not use the pump for any purpose other than that specified in this manual.**

⚠ **CAUTION: Place the patient on the mattress ONLY when it is fully inflated.**

WARNING: Do not cover the CPR unit with a bed sheet. Covering the CPR unit could prevent cardiac arrest team members from noticing the CPR unit.

4. Operation

NOTE: Always read the instructions before use.

NOTE: The patient is NOT supposed to lie on the mattress before it is fully inflated. Place the patient onto the mattress only when the auto-adjustment process is about to start.

NOTE: Once the patient is on the mattress, the pump automatically senses and adjusts the pressure in the cells to support the patient.

4.1 General Operation

(1). Switch on the power switch.

(2). Press the STAND-BY to activate the system. The system will be fully inflated.

NOTE: Place the patient on the mattress ONLY when it is fully inflated.

(3). Once the inflation is complete, the system enters Auto Adjustment mode. The feature decides an appropriate pressure based on the detected weight to enhance the patient's comfort.

4.2 Mode Operation

The Mode button switches among the Max Firm, Alternating, Continuous Low Pressure, and Alternating Low Pressure modes. Press the Mode button to toggle selections in a cycle; the indicator will illuminate on the operating mode.

4.3 Seat Inflation

Press the Seat inflation button to activate additional support for the patient during the upright position. The indicator light will illuminate when the feature is active. To disable this function, press the Seat Inflation button again.

4.4 Adjusting alternating cycle time

Press the Cycle time button to toggle through the selections in a cycle; the indicator will illuminate on the selected cycle time.

4.5 Pressure FINE-TUNE

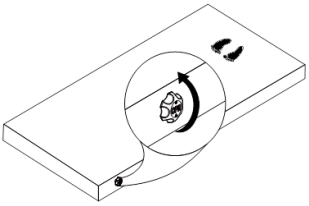
Press the Comfort Level button to adjust the mattress pressure to meet the patient's needs.

NOTE: Manually check whether the pressure is adequate or not by sliding one hand between the deflated air cells and the patient to feel the patient's bottom. Users may feel minimal contact. Always leave at least 2.54 cm (1 inch) space between

the patient and the air cell to prevent bottoming-out.

4.6 Emergency CPR Operation

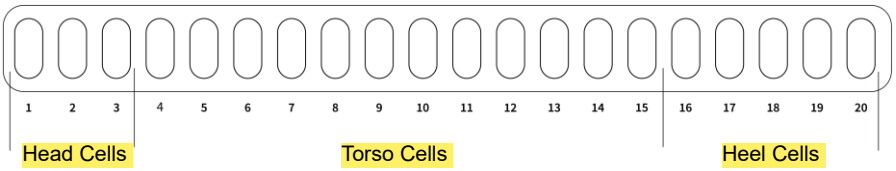
The CPR unit is located at the HEAD END of the mattress. When there is an emergency to perform CPR on the patient, quickly turn the CPR knob to release air from the mattress. The CPR knob is located at the head-end, right-hand side of the mattress. The quick connector on the pump unit can be disconnected for even faster deflation.



4.7 Relief Function

All air cells feature orange relief connectors, allowing caregivers to easily deflate them to relieve pressure. You may offload more than one area on the patient for extended periods, but with the following restriction:

Only one cell may be deflated within each of the head (1-3 cells), torso (4-15 cells), and heel sections (16-20 cells) at a time.

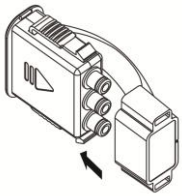


NOTE: Except for special cases—such as temporary clinical procedures—only one cell per section may be deflated at any given time. Deflating more than one cell per section may affect the auto adjustment setting.

NOTE: Deflating more than two adjacent cells may affect the support to the patient during the normal alternating cycle.

NOTE: After deflating the cells and positioning the patient, perform a hand check to ensure proper support.

4.8 Transportation



Always activate CLP/Static when you need to move the patient elsewhere to prevent bottoming out.

The quick connector lid is designed to seal the air inside. Always attach the lid to the air hose to keep the mattress inflated for at least 24 hours. Duration may vary depending on your settings.

4.9 Evacuation

In the event of an emergency, always follow the instructions of caregivers to evacuate patients from the facility quickly and safely.

4.10 Filter Replacement

The filter is disposable. It should be replaced after 6 months of use, or sooner if it appears dirty.

Replace the air filter inside the filter cover. The filter is reusable and can be washed gently with a mild detergent and water. Air-dry the filter before use. Check and replace the air filter regularly.

5. Cleaning and Disinfection

It is important to follow the cleaning procedures to avoid cross-infection. Ensure to clean in a dry and dust-free environment.

WARNING: To prevent cross-infection, always clean and disinfect the system after each patient.

5.1 Before cleaning

(1). Turn off the system.

(2). Un-plug the device.

(3). Pull off the air hose from the pump unit.

(4). Dilute the detergent according to its manufacturer's instructions to prepare the cleaning solution. The use of a mild detergent with a pH between 6 and 8 is recommended.

⚠ **CAUTION: Never apply detergents directly to the pump or mattress, as this might affect performance.**

WARNING: Do not use detergents that may deposit calcium carbonate.

WARNING: Do not use detergents or disinfectants that may damage the plastic casting, such as benzene, toluene, phenol, acetone, 70% isopropyl alcohol (IPA), or others.

⚠ **CAUTION: Do not use phenolic-based products for cleaning.**

5.2 General Cleaning

General cleaning should be carried out at least once a week to maintain hygiene.

- **Pump Unit**
  (1). Dampen a clean cloth with the cleaning solution. Wipe clean the pump unit, particularly its panel, label, or hanger, to remove any visible dirt.
  (2). Wipe again with water about 18 to 40°C (64.4 to 104°F) to remove any remaining detergent. Repeat this step if necessary to ensure a detergent-free finish.
  (3). Dry with a dry cloth.
  (4). Allow to air dry. Keep out of direct sunlight.

⚠ **CAUTION: Do not immerse or soak the pump unit.**

⚠ **CAUTION: Make sure that no liquid gets inside the pump.**

⚠ **CAUTION: The pump does not need oil lubrication.**

WARNING: Do not remove the housing of the pump to avoid electrical shock.

WARNING: Never disassemble the system by yourself. All disassembly or repair should be done by professional technicians.

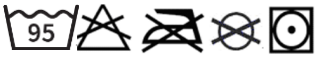
- **Mattress**
  (1). Unzip to separate the top cover, cell parts, and bottom cover.
  (2). Check for visible damage or possible leaks. Replace if found leaking or damaged.
  (3). Dampen a clean cloth with the cleaning solution and wipe the surface clean.
    - Particularly, the top cover, the bottom cover, or the straps, to remove any visible dirt.
    - Unzip the top cover and bottom cover to wipe clean every cell inside.
  (4). Wipe again with fresh water about 18 to 40°C (64.4 to 104°F) to remove any remaining detergent. Repeat this step if necessary to ensure a detergent-free finish.
  (5). Dry with a dry cloth.
  (6). Allow to air dry. Keep out of direct sunlight.

⚠ **CAUTION: Keep out of direct sunlight. Dry before use.**

WARNING: Wipe gently! Do not scrub.

5.3 Advanced Cleaning

Advance cleaning should be carried out between patients to avoid cross-infection as the product is in direct contact with the patient.

Top Cover: Stretch	

- **Top Cover/bottom cover**
  (1) Put to machine laundry. Do not exceed the limit specified below.
    - ✓ With detergent:
      At temperatures below 60°C (140°F) for 10 to 15 minutes.
    - ✓ Without detergent:
      - ■ Top Cover: At temperatures below 95°C (203°F) for 10 to 15 minutes.
      - ■ Bottom Cover: At temperatures below 60°C (140°F) for 10 to 15 minutes.

  (2) Tumble dry at a medium-low temperature of 40°C/104°F for 50 minutes.

WARNING: Please follow the cleaning instructions. Do not exceed the limit.

- **Cell parts**
  Cell parts include the air cell and the air cell base.

  (1) Dampen a clean cloth with the cleaning solution and wipe the cell to remove any visible dirt.

  (2) Wipe again with fresh water between 18 to 40°C (64.4 to 104°F) to remove any remaining detergent. Repeat this step if necessary to ensure a detergent-free finish.

  (3) Dry with a dry cloth.

  (4) Allow to air dry. Keep out of direct sunlight.

WARNING: Never machine wash the cell parts.

5.4 Disinfection in Healthcare Settings

Disinfection should be carried out after each patient to avoid cross-infection. Disinfect only after thorough cleaning.

WARNING: Do not disinfect in the presence of patients to avoid eye or skin irritations.

⚠ **CAUTION: Do not autoclave or boil any part of the product.**

⚠ **CAUTION: Always wipe clean again with fresh water. This ensures that no residue remains.**

WARNING: Dry before use.

- **Before disinfection**

(1). Conduct advance cleaning. Please refer to section 5.3 for more information.

(2). Prepare a damp cloth pre-soaked with disinfectants. Recommended disinfectants are listed below.

- 75% alcohol solution
- Sodium hypochlorite solution with 1,000 to 10,000 ppm

⚠ **CAUTION: Never apply disinfectant directly to the pump or mattress.**

⚠ **CAUTION: Do not use sodium hypochlorite solution with a concentration higher than 10,000ppm as prolonged use may reduce the performance of the coating and shorten the life of the product.**

⚠ **CAUTION: Do not use 70% Isopropyl alcohol (IPA) for disinfection.**

⚠ **CAUTION: Do not use ozone or UV for disinfection.**

- **Pump unit**

(1). Wipe clean the pump unit, particularly the casting, panel, label, and hanger.
(2). Wait for the disinfectant to take effect according to the instructions.
(3). Wipe again with water about 18 to 40°C (64.4 to 104°F) to remove the remaining disinfectants. Repeat this step if necessary to ensure a disinfectant-free finish.
(4). Dry with a dry cloth.
(5). Allow to air dry. Keep out of direct sunlight.

WARNING: To avoid electrical shock, always unplug the power cord from the mains power before disinfecting.

⚠ **CAUTION: Make sure that no liquid gets inside the pump.**

- **Mattress**

(1). Wipe clean, particularly the straps.

(2). Unzip the top cover and bottom sheet to wipe the cell parts inside for thorough disinfection.

(3). Wait for the disinfectant to take effect according to the instructions.

(4). Wipe again with water about 18 to 40°C (64.4 to 104°F) to remove the remaining disinfectants. Repeat this step if necessary to ensure a disinfectant-free finish.

(5). Dry with a dry cloth.

(6). Allow to air dry. Keep out of direct sunlight. Dry before use.

WARNING: Wipe gently! Do not scrub.

6. Storage

(1). Lay the mattress out flat.
(2). Roll from the foot end towards the head end with the CPR unit open.
(3). The head-end strap can then be stretched around the rolled mattress to prevent unrolling.

⚠ **CAUTION: Do not kink, crease, or stack the mattresses and do not store the system in direct sunlight, high temperature or moist areas.**

7. Maintenance

(1). Check the mains power cord and plug for abrasions or excessive wear.

(2). Check the cover for signs of wear or damage. Ensure the mattress cover and tubes are stubbed together correctly.

(3). Make sure all the connectors for the air cell are connected.

(4). Check the air hose for a kink or break. For replacement, please contact the service provider or place of purchase.

8. Disposal

Always comply with the local regulations for disposing of such equipment.

9. Troubleshooting

Listed below are the problems/alarms that users might have when using the device. Act accordingly based on the solutions provided. Contact the service provider if the problem persists. Never disassemble this device on your own.

Q 1 Patient is bottoming out.
Check all the joint parts to see if they are well-connected, or if there is leakage, along with kinked or broken parts that need to be addressed.

Q 2 The mattress is dislodged.
- Check if all the snap buttons or straps of the mattress are fastened properly.
- Check that the mattress is secured to the bed frame with straps.

Q 3 No air is produced from some of the air outlets.
This is normal for the ALTERNATING mode. The air outlets alternate to deliver air with the selected cycle time.

9.1 Alarms

The alarms come with audible and visual reminders to alert users when the system detects abnormal operation. Alarms are explained below. Call for service if the problems persist.

ICON	MEANING	WHAT TO DO
	Possible power failures	● Check if the plug is connected to the mains power. ● Check the switch on/off position. ● Check if there is a power outage. ● Check if the power cord is connected to the pump properly.
	Possible system failure.	● Stop using the system and move the patient onto another support surface. ● Call customer service for further assistance.
	The pressure does not reach the desired values for a certain time.	Check all the joint parts to see if they are well-connected or if there is leakage, along with broken parts that need to be addressed.

10. Technical Specifications

Item		Specification
Power Supply		AC 220V–240V, 50Hz, 0.15A
Fuse Rating		T1.6AL, 250V
Cycle Time		Four selectable (10, 15, 20, 25 minutes)
Dimensions (L x W x H)		34.0 x 15.0 x 23.4 cm / 13.4” x 5.9” x 9.2”
Weight		3.3 kg / 7.28 lb
Environment	**Atmospheric Pressure**	700 hPa to 1060 hPa
	Operating	10°C to 40°C (50°F to 104°F) 10% to 90% RH, non-condensing
	Storage	-15°C to 50°C (5°F to 122°F) 10% to 90% RH, non-condensing
	Transport	-15°C to 70°C (5°F to 158°F) 10% to 90% RH, non-condensing
Applied Part		Mattress
Classification		Class II, Type BF, IP21 **NOTE: Not suitable for use in the presence of a flammable anesthetic mixture (No AP or APG protection).**
Service Life (Design Life)		System: 7 years

Mattress	**Model**	8” Air cell mattress
	Dimensions (L x W x H)	200 x 87 x 20 cm 78.7” x 34.3” x 8” or 200 x 89 x 20 cm 78.7” x 35” x 8” (with CPR)
	Recommend Frame Size	
	Max. Support Weight	250 kg / 550 lb
	Min. Support Weight	40 kg / 88 lb
	Weight	9 kg / 20 lb
Operating Noise	< 30 dBA	

NOTE: The specifications are also suitable for areas with the same power supply.

NOTE: Consult the distributor or EU representative for further technical documents.

NOTE: Dimension and weight of the mattress are measured without the foam base.

NOTE: Check the size of the mattress with the CPR included. Make sure the system fits the intended bed frame.

11. Servicing

The products are intended to offer safe and reliable operation when used or installed according to the instructions provided by OSKA. OSKA recommends that the system be inspected and serviced by authorized technicians if there are any signs of wear or concerns with device function and indication on products. Otherwise, service and inspection of the devices generally should not be required.

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Warning:

1. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
2. Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Basic EMC standard	Immunity Test Levels: Professional healthcare facility environment	Immunity Test Levels: HOME HEALTHCARE ENVIRONMENT	Compliance Levels	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±8 kV contact ± 2, 4, 8, 15 kV air		±8 kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC61000-4-4	±2 kV, 100 kHz for power supply line ±1 kV, 100 kHz for input/output line		±2 kV, 100 kHz for power supply line	Mains power quality should be that of a typical commercial or hospital environment

Surge IEC61000-4-5	± 0.5, 1 kV (line to line) ± 0.5, 1, 2 kV (line to earth)		± 0.5, 1 kV (line to line)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Voltage Dips: i) 100% reduction for 0.5 period, ii) 100% reduction for 1 period, iii) 30% reduction for 25/30 period, Voltage Interruptions: 100% reduction for 250/300 period		230 Vac	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \sqrt{P}$ 150 kHz to 80 MHz $d = 0.6\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz 380 - 5800 MHz, 9-28 V/m, Pulse modulation or FM ±5 kHz deviation , (1kHz sine)	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz 380 - 5800 MHz, 9-28 V/m, Pulse modulation or FM ±5 kHz deviation, (1kHz sine)	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz 380 - 5800 MHz, 9-28 V/m, Pulse modulation or FM ±5 kHz deviation, (1kHz sine)	

NOTE 1: U_T is the a.c. mains voltage prior to the application of the test level NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device:

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \sqrt{P}$	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.7 GHz $d = 1.2\sqrt{P}$
0.01	0.1	0.06	0.12
0.1	0.31	0.19	0.38
1	1	0.6	1.2
10	3.1	1.9	3.8
100	10	6	12
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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876001-6970 V1.0_Print_2025-12-24