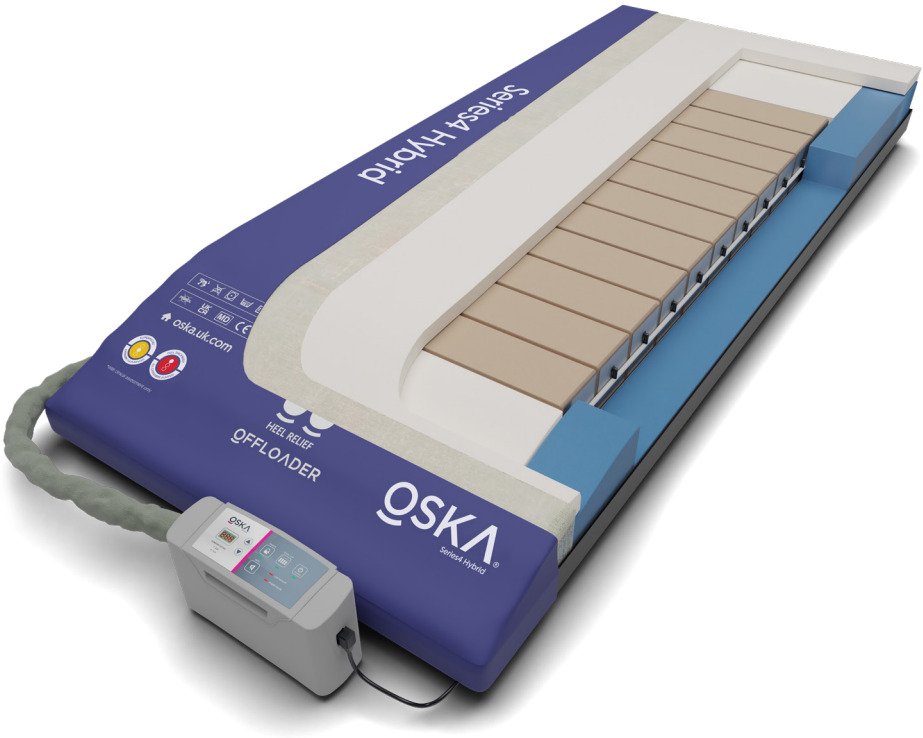
OSKA®

User Guide

Series4H



Version 3: 02.10.2025

Contents

Please read the following instructions carefully and
observe the warning instructions before using the system.

CE 0197

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01 Explanation of Symbols & Statements

WARNING / CAUTION

WARNING: A statement that alerts the user to the possibility of serious injury or other adverse reaction with the use or misuse of the device.

CAUTION: A statement that alerts the user to the possibility of a problem arising from the use or misuse of the device.

WARNING

To avoid injury, before using the device always read this Instructions For Use and any associated documentation.

Mandatory to read the Instructions For Use

	Manufacturer		Wipe down in line with cleaning and disinfection instructions
	Foot end		Recycling
	Refer to User Manual / Instructions for Use		Batch code
	Catalogue number		Does not contain natural rubber latex
	Do not use phenol or phenolic-based cleaning solutions.		Importer
	Machine wash at 95°C		Serial Number
	Drip dry		Authorised representative in the European Community
	Routine disinfection at 1,000ppm available Cl		Conforms to the Medical Device Regulation 2017/745
	Medical Device according to European and UK Medical Device Regulations		Class II Electrical Device The user is protected by at least two layers of insulation between the current carrying parts and the metal accessible parts
	Date of manufacture		Caution / Warning
	Non sterile		Suitable for connection to type BF applied parts
	Do not iron		Maximum patient weight
	Tumble dry – Low Heat		No smoking
	High / very high risk Management: Superficial / full thickness pressure ulcers.		Disposal of Electrical & Electronic Equipment (WEEE). See section 16.
	Keep dry	IP21	IP: Ingress Protection 2: Protection against fingers or other object not greater than 80mm in length and 12mm in diameter 1: Protection from vertically dripping water
	Refer to Instructions for Use		Resistant to ignition
V-GUARD TECHNOLOGY	V-Guard Technology	UK CA	UKCA marked

02 Product Description

The OSKA Series4 Hybrid full mattress replacement system (also referred to as the Series4H) is designed to be placed directly on the bedframe or bed base. It consists of a high specification foam mattress with 11 integral, foam filled air cells located under a layer of specialist pressure redistributing Aerolite foam.

In its non-powered state, it operates as a reactive support surface.

Connecting the umbilical air hose to the electrically powered Series4H pump, the system offers a degree of active (alternating) therapy to patients / users.

The Series4H mattress has a dedicated heel relief slope, and the top layer of Aerolite foam can be folded under itself to create the heel Offloader feature.

The 11 air cells are arranged transversely (side to side) across the patient support surface. When the Series4H mattress is attached to the pump, these air cells inflate and deflate in an alternating pattern (referred to as a 1-in-2 cell cycle) every ten minutes.

The mattress cover is waterproof, breathable, and multi-stretch to help it conform to patients.

03 Indications for Use

Intended use

The OSKA Series4H mattress is intended for the prevention and management of pressure related tissue injury in patients at an elevated risk of pressure ulceration.

In its non-powered (reactive) state, the Series4H is intended to reduce the risk of pressure related tissue injury in patients at an elevated risk of pressure ulceration up to and including those at 'high-risk' of pressure ulcers. In addition, it is intended to support the management of patients with existing partial thickness (Category 1 and 2) pressure ulcers*.

NOTE

*With the heel Offloader feature set up correctly to float the heels (see Section 10.1) it may be used to support the management of any category of heel pressure ulcer.

As a powered (active) support surface, the Series4H is intended to reduce the risk of pressure related tissue injury in patients up to and including those at 'high to very-high risk' of pressure ulcers. In addition, it is intended to support the management of patients with existing pressure ulcers, including both partial-thickness and full-thickness pressure ulcers.

See 'Indications' for further information on use of the Series4H system.

Intended Environment

The OSKA Series4H system is intended to be used in the following environments:

- Hospital
- Professional Healthcare facilities, including care homes, nursing homes and hospices
- Home Healthcare / Community Healthcare settings

Intended user group

The Series4H mattress system is intended to support a single patient up to 250Kg (39.4 Stone) in weight. For patients of very low weight, typically less than 40Kg and / or small stature, OSKA recommends the healthcare provider uses clinical judgement to determine suitability.

It is intended that the system is set up and adjusted by a professional user who has received product training / instruction on correct set up and use of the product.

Indications

The OSKA Series4H System is indicated for use as follows:

- Non-powered Hybrid: Patients at an elevated risk of pressure ulcers, up to and including those at 'high-risk', with or without existing Category 1 or 2 pressure ulcers. See 'NOTE' below.
- Powered Hybrid: Patients at an elevated risk of pressure ulcers, up to and including those at 'very-high risk', with or without existing pressure ulcers. See 'NOTE' below.

NOTE

Support surfaces represent only one element of a patient's pressure ulcer prevention and management care bundle. Other elements of an effective pressure ulcer care bundle include pressure ulcer risk assessment, regular patient repositioning, nutritional support, skin care etc. The OSKA Series4H should only be used once a holistic assessment of the patient's individual care needs has been completed by the prescribing clinician / care provider.

04 Safety & Contraindications

Risk Assessment

Before using the OSKA Series4H, a patient-specific risk assessment should be performed at a local level by the care provider / the clinician in charge of the patient. As a minimum, this should include the following:

- Product combination (i.e. bed frame + mattress + side rails etc.) to ensure compatibility of products being used for patient care. Specific consideration should be given to any risk of entrapment and falls. For further information refer to:
    - IEC 60601-2-52:2009 (Medical electrical equipment. Part 2-52: Particular requirements for the basic safety and essential performance of medical beds)
    - MHRA Guidance Bed rails: management and safe use. Guidance on managing and using bed rails safely. Published 30 August 2023.
- Pressure ulcer risk assessment to determine the patient's risk level for pressure related tissue injury.
- Full body skin check to determine anatomical location and severity of any existing pressure ulceration.

Contraindications

- Do not use the OSKA Series4H system as a powered (active therapy) support surface for patients:
    - with unstable spinal fractures.
    - where use of an active therapy support surface could result in any harm or exacerbate their medical condition.
    - with an intolerance to motion.

05 General Warnings, Cautions and Information

The following general warnings, cautions and information should be observed regularly during use of the product and not just upon mattress installation.

GENERAL WARNINGS

- It is the responsibility of the clinician in charge of the patient / care provider to ensure the user can use this product safely. NOTE: The Series4H is not typically intended for children. When children are the intended recipients, ensure a full risk assessment is performed which considers the child's size in relation to the product and equipment in use.
- The device is to be installed and put into service in accordance with the instructions provided.
- Do not use the mattress without a cover.
- Due to the range of available bed frames, mattresses and bed rails, the customer / care provider is responsible for performing a risk assessment to ensure the bed frame, mattress, bed rails etc are compatible, and that the proposed combination does not impact on patient safety in any way. The combination of bed frame + mattress + side rails should not result in any gap large enough to entrap a patient's head, body or limb. Care should be taken to prevent gaps arising as a result of compression or movement of the mattress. Death or serious injury may occur.
- The combination of products should not permit hazardous ingress or egress where entanglement with the mains power cord or air hoses may result. Death or serious injury may occur.
- If the patient is to be left unattended, the decision to use bed side rails should be based on clinical assessment and in line with local policy. Key considerations for safe use of side rails are risk of entrapment and risk of falls. Refer to MHRA guidance and local policy on the safe use of side rails.
- Electrical equipment may be hazardous if misused. No modification of this equipment is allowed, and only accessories designed and approved for use with this system are permitted.
- There are no user serviceable parts inside the pump unit. The pump unit case must only be removed / opened by OSKA engineers or OSKA authorised technical personnel.
- The mains plug is the disconnect device for the means of isolating the control unit from the mains supply. The mains power socket / plug must be accessible at all times.
- Ensure the mains power cord and air hoses are:
    - Intact and free from damage. Damaged electrical cables can create a risk of electrocution and / or fire.
    - Positioned to avoid causing an obstruction or injury. Loose or hanging cables / air hoses can cause a trip hazard or risk of strangulation arising from baby, child, or patient entanglement.
    - Clear of moving bed mechanisms such as bed rails or bedframe mattress

platform (or other entrapment areas or crush points) which may result in damage.

NOTE: Use the Hybrid's cable management feature to minimise potential mains cable issues.

- DO NOT smoke whilst on or near the device – Risk of fire. Cigarettes, lighters, matches and naked flames are all sources of ignition and could ignite clothing, bed linen, blankets, duvets etc. In the event of a fire, a breach in the mattress could result in air loss from the product which may act as a fan effect to assist the flames. It is advised that a full fire risk assessment is carried out prior to using this equipment, and for patients at risk, consider using alternative pressure area care equipment and fire-retardant bedding.

  NB. Other external sources of ignition such as exposed heating elements in electric fires, open fires, lamps/light bulbs, candles, and electrical appliances should also be kept away from the mattress.

- The system is not intended for use in the oxygen rich environment and presence of flammable anaesthetic mixtures with air, oxygen, or nitrous oxide – Risk of fire.

- Do not place blankets, bedding or other items over the pump unit – Risk of fire.

- No servicing or maintenance activities should take place with the patient in-situ.

- The mattress cover is not freely air permeable and may present a suffocation risk if used incorrectly. The healthcare professional responsible for the patient must ensure this product is suitable for the user and that they can safely use this product.

- Polythene bags used as part of the product packaging may present a risk of suffocation. To avoid the risk of suffocation, keep bags away from small children and babies.

⚠ CAUTIONS

- When the OSKA Series4H has been kept in conditions close to the minimum / maximum storage temperatures, a minimum of three hours is required for the system to adjust to room temperature prior to it being plugged into a mains electrical supply.

- For optimal pressure area care performance keep layers of bedding / pads between the mattress cover and the patient to a minimum. Similarly, secure bed sheets loosely to prevent areas of 'hammocking' / high pressure.

- Do not allow sharp objects to penetrate the mattress cover.

- Do not use abrasive cleaners, biological or phenolic based cleaners.

- Do not store or use the system in direct sunlight or use in an outdoor environment.

- Do not store in damp conditions or a moisture rich environment.

- The mattress should be cleaned regularly and always between patients.

- Do not use hot water bottles or electric blankets when using the mattress system.

Information

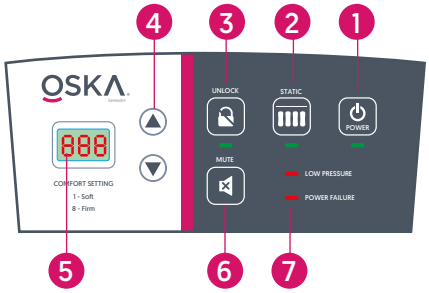
- Set up the mattress as directed. Once set up, the mattress does NOT need to be turned or rotated on the bed frame.
- Always supervise children and pets closely when in the vicinity of the mattress system.
- The mattress is for single person use. Additional weight could damage the system or affect performance.
- Note to the user and/or patient: any serious incident that has occurred specifically in relation to this device should be reported to the manufacturer (or where appropriate, the importer or distributor) and the UK MHRA or the relevant competent authority of the EU member state in which the user and/or the patient is established.

06 Parts Identification

6.1 Hybrid Pump Unit

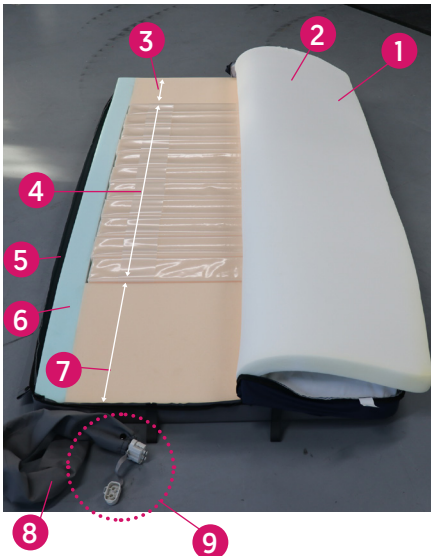
Number	Series4H Pump Unit Feature / Part
1	Control panel (see 6.2 below)
2	Mains power cable
3	Umbilical attachment point / CPR
4	Bed hooks
5	Fuse (x2)

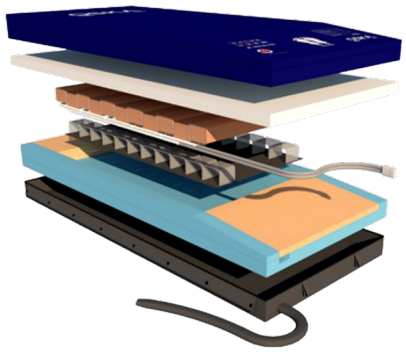
6.2 Pump Control Panel



Number	Pump Control Panel Feature / Part
1	ON / OFF power button
2	Static mode button
3	Lock / Unlock button
4	Comfort control
5	Comfort setting display
6	Mute button
7	Indicator lights for low pressure and power failure alarms

6.3 Hybrid Mattress





Number	Mattress Feature / Part
1	Removable top cover
2	Aerolite foam layer
3	Foam head section
4	Foam filled air cells (x11)
5	Base cover
6	Foam side former
7	Heel relief slope
8	Umbilical / Air hose
9	Transport cap
10	Cable management flap (located on the patient's left as they are lying on the mattress)

07 Installation

The OSKA Series4H is easy to install, set up and use. It can be used with or without the pump.

Without the pump, it operates as a reactive (non-powered) support surface.

With the pump attached and working, it can deliver a degree of active pressure redistribution to the patient.

To install the system correctly, follow the steps below.

7.1 System preparation

Remove the OSKA Series4H system from its packaging. The system consists of the following items:

- Hybrid mattress with integral umbilical (air hose).
- Mattress Pump
- Mains power cord

7.2 Mattress installation

> **NOTE**
>
> The OSKA Series4H is designed to be placed directly onto the bedframe / bed base. DO NOT place the OSKA hybrid mattress on top of any other mattress.

1. Check the bed frame for sharp objects or edges that could damage the mattress.

2. Place the mattress directly onto the bed frame.
3. Ensure the white 'feet' symbol on the blue mattress cover is facing upwards and located at the foot end of the bed.
4. To optimise the pressure area care offered by the mattress, ensure the cover is loose, and any sheets are loose fitting.
5. In this configuration, the OSKA Series 4H can be used as a reactive support surface. To deliver active therapy to the patient, you will need to install the pump as described in Sections 7.3, 7.4 and operate the pump as described in Section 8.

7.3 Pump installation

> **NOTE**
>
> Where patients require a degree of active (alternating) therapy to support their pressure area care needs, the Series 4 H pump will need to be attached to the mattress. Follow the steps below to ensure the correct pump placement and effective cable management and refer to section 7.4 to attach the mattress to the pump.

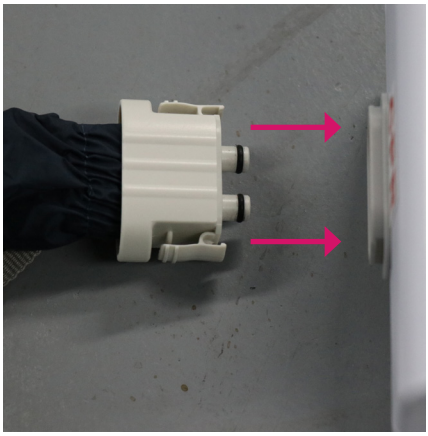
1. Position the OSKA Series4H pump either by using the two brackets on the back of the pump to hang it from the foot board of the bed, or place it upright on the floor at the foot end of the bed.

2. Insert the mains power cable into the Series 4H pump and insert the plug into a suitable mains power outlet. Switch the mains socket on.
3. Run the mains power cable along the left-hand side of the mattress (from the patient's perspective).
4. Locate the cable management flap which runs the length of the mattress.
5. Open the cable management flap, lay the cable in to the flap and secure the cable management flap back together, enclosing the mains cable within the material flap. This will secure the cable and raise it off the floor to reduce the risk of trips.

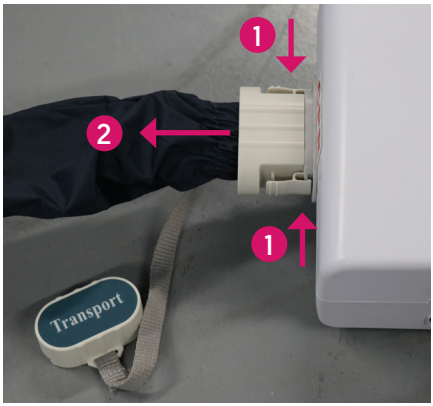
6. DO NOT route the mains cable through or round any mechanical bed assemblies where the cable could be crushed, trapped, or snagged.
7. The mains cable should not be in tension when the bedframe / platform is operated throughout its full range of potential movement.

7.4 Connecting / Disconnecting the Pump and Mattress

1. To connect the pump and mattress, remove the 'transport cap' from the air hose (umbilical) coming from the foot end of the mattress.

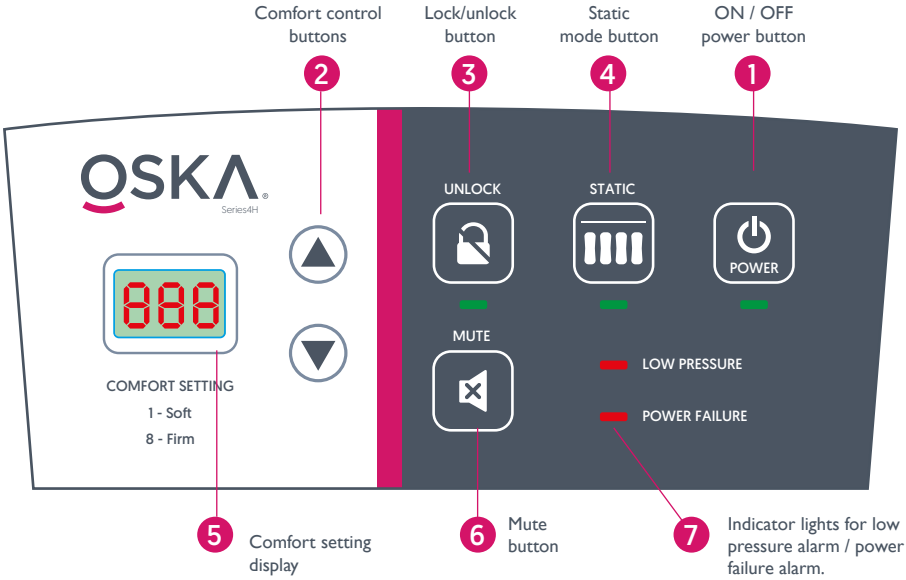


2. Align the plastic connector on the end of the umbilical with the 'CPR' connector on the pump.
3. Push the two fittings together until you hear a 'CLICK'.
4. Once the mattress and pump have been installed correctly and connected, the system is ready for use.



5. To disconnect the air hose (umbilical) from the pump unit, use your finger and thumb to squeeze the tabs on the top and bottom of the umbilical fitting together (1).
6. Keeping the two tabs squeezed together, pull the umbilical away from the mattress pump (2) until it fully detaches from the pump

08 Pump Functions (Controls, Alarms and Indicators)



With the OSKA Series 4 H mattress attached to the pump the Series4H delivers a degree of active (alternating) pressure area care therapy to the patient. It does this using an alternating 1-in-2 cell cycle over a 10-minute cycle time.

8.1 Power On/Off

The On/Off power button is located on the right-hand side of the pump control panel – see above.

To power-up the pump, push the On/Off POWER button. You will feel the button click and hear a beep as the unit starts up. The green indicator light immediately below the POWER button will flash while the system reaches the correct pressure. Once it is at the required pressure, the green light will cease to flash and remain constantly illuminated.

To power down the pump (firstly unlock the pump – see below), push the POWER button once until you feel a click and hear a beep. All lights will turn off and the system is now OFF.

8.2 Comfort Control buttons

The comfort control buttons on the left of the control panel allow air pressure within the mattress to be adjusted between 1 (Soft) and 8 (Firm), to optimise patient comfort.

NOTE

A firmer comfort setting may offer enhanced support for a heavier patient; however the clinician in charge of the patient is responsible for selecting the most appropriate comfort setting to meet the patient's needs when using the mattress.

To adjust the OSKA Series4H in response to a change in patient weight, position, or to meet a patient's individual comfort needs, use the up / down arrows as required to select the appropriate comfort level for the patient (this can be done whilst the patient remains on the mattress).

8.3 Unlock (Lock) button

The UNLOCK button allows the user to 'unlock' the control panel to adjust the settings on the pump during use.

When the pump is locked, the green light under the UNLOCK button will be permanently illuminated. To unlock the control panel, push and hold the UNLOCK button for 3 seconds. The system will beep, and the light will go out to indicate the pump is now unlocked. After adjusting the settings, the pump can be locked again by pushing and holding the UNLOCK button (the system will beep, and the light will illuminate again). Alternatively, the system will lock automatically after five minutes of inactivity.

8.4 Static Mode button

The STATIC mode button can be used to create a static support surface without alternating pressure therapy.

With the pump unlocked (see 8.3 above), push the STATIC button once to select static mode. The button will click, and you will hear a beep. The green indicator light immediately below the STATIC button will illuminate to indicate that STATIC mode has been selected.

Twenty (20) minutes after STATIC mode has been selected, the system will automatically return to an active therapy (alternating) support surface and the green light below the STATIC button will go out.

To return to an alternating support surface before the default twenty minutes, unlock the control panel and push the STATIC mode button again. The green light will turn off, and the system will return to its active therapy cycle.

8.5 Comfort Setting display

The comfort setting display will show the comfort level selected for the patient. This will range from 1 (soft) to 8 (firm). See Section 8.2 above for more information.

8.6 Mute button

The MUTE button will mute the audible element of the pump's LOW PRESSURE alarm and it will cancel the POWER FAILURE alarm. To mute the LOW PRESSURE alarm, push the MUTE button once. Pushing the button again will unmute the alarm.

8.7 Low Pressure & Power Failure Indicators (Alarms)

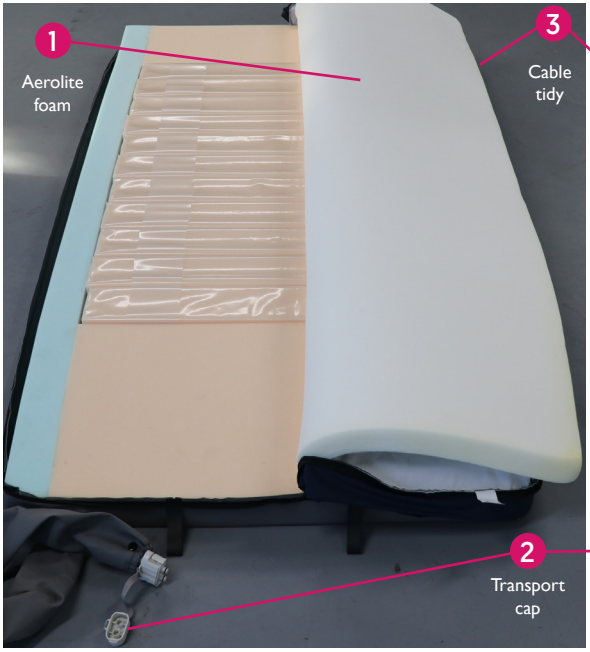
The flashing red LOW PRESSURE indicator light will display as a result of the system operating at a consistently low pressure for approximately fifteen (15) minutes. See Section 10.6 (Alarms / Fault Conditions) for more information.

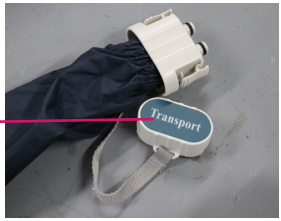
The flashing red POWER FAILURE indicator light will illuminate as a result of the mains power turning off, or the mains power lead being disconnected from the pump unit.

NOTE

The power failure alarm will NOT activate as a result of turning the pump unit off via the POWER (On/Off) button on the control panel.

09 Mattress Functions





9.1 Aerolite Foam

The low density, highly conformable, Aerolite foam enhances immersion and envelopment into the mattress to support pressure ulcer prevention and management. The Aerolite foam can be reconfigured to float the heels or to support a lateral tilt position for the patient (see Section 10.1).

9.2 Transport Cap (transport mode)

The Transport Cap is attached to the end of the umbilical with a length of webbing to ensure it is available when required. The transport cap is placed over the end of the umbilical to seal air within the mattress for an extended period.

9.3 Cable Tidy

The Cable Tidy feature runs down the left side of the mattress (from the patient's perspective when lying on the mattress) and allows the mains cable to be neatly positioned off the floor and away from any mechanical / moving parts of the bed frame.

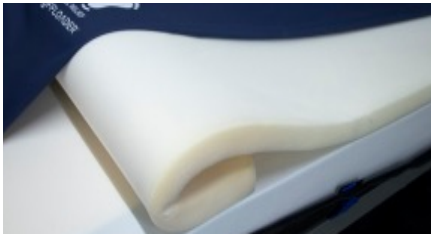
10 System Operation

The following instructions explain the basic day-to-day operation of the OSKA Series4H mattress system. General maintenance, repair and servicing should be carried out by suitably qualified personnel.

Refer to Sections 7, 8 and 9 of this User Manual for further information on installation, set up, controls and functions of the OSKA Series4H mattress system.

10.1 Mattress Use – Reactive Therapy (non powered)

On its own, without the pump attached, the OSKA Series4H functions as a reactive (static, non-powered) mattress. Refer to Section 7.2 for details of how to set the mattress up for non-powered use.



To reconfigure the Aerolite foam to float the heels or to support the patient in a lateral tilt position, unzip the cover, fold the foam back under itself at the foot end to create a 'zero-pressure' heel zone, or along the length of the mattress to support lateral tilt. Once the Aerolite foam is positioned correctly, zip the cover back up.

To return the mattress to its original flat format, unzip the cover, unfold the Aerolite foam and zip the cover back up.

10.2 Mattress Inflation – Active Therapy (powered)

1. Set the system up as described in Section 7 and turn the pump on as described in Section
2. Select the appropriate COMFORT SETTING for the patient.
3. As the system is inflating, the green 'POWER' indicator light will flash.
4. Once the system reaches the correct pressure, the flashing green 'POWER' indicator light will automatically be replaced by a constant green indicator light.
5. The system is now ready for use as a powered hybrid

NOTE

It will take approximately 5 minutes or less for the system to inflate.

10.3 Mattress Deflation

1. To deflate the mattress after use, turn off the pump and disconnect the umbilical from the pump unit as detailed in Section 7.4.

10.4 Static Mode

To create a static (non-alternating) mattress using the 'static mode' button, follow steps 1-3 below. To deselect static mode and return to an alternating support surface, follow steps 4-5 below.

1. With the system set up and operating normally, push and hold the UNLOCK button for three seconds until the power unit is 'unlocked'.
2. Press the 'STATIC' button on the front of the control panel once. The button will click, and you will hear a beep. The green indicator light immediately below the STATIC button will illuminate to indicate that STATIC mode has been selected and the pump will now inflate all 11 air cells in the mattress to the same pressure.
3. The system will remain in static mode for a period of twenty (20) minutes, after which time it will automatically revert to an active (alternating) support surface and the green light below the STATIC button will go out.

NOTE

When static mode is selected, the patient is NOT receiving any alternating therapy and is exposed to constant unrelieved pressure.

4. To return the mattress to an alternating pressure support surface before the twenty-minute default period is complete, unlock the To return the mattress to an alternating pressure support surface before the twenty-minute default period is complete, unlock the pump and push the static button to deselect the STATIC mode.
5. Once deselected, the green light below the STATIC button will turn off and the mattress will return to its alternating mode.

10.5 Transport Mode

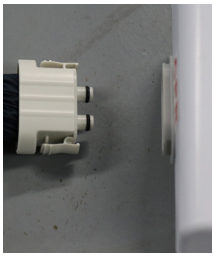
'Transport mode' effectively seals the air within the mattress for an extended period. This can be useful when disconnecting the pump from the power supply to move patients a short distance, during a power cut, or when there is a planned power supply interruption.

To put the mattress system into 'Transport mode':

1. Remove the umbilical air hose from the pump unit (see Section 7.4)
2. Seal the air within the mattress by placing the Transport Cap (attached to the end of the umbilical) over the exposed end of the umbilical air hose. This needs to be done quickly to minimise air loss from the mattress.
3. Push the Transport Cap onto the exposed end of the umbilical until it 'CLICKS' into place.
4. Turn the pump off via the On/Off switch.

To return the mattress system to normal operation:

1. Remove the transport cap from the end of the umbilical.
2. Re-attach the mattress to the pump by pushing the connector at the end of the umbilical onto the pump until it CLICKS into place.
3. Switch the pump on and wait for it to reach its normal operating pressure.



NOTE

When the mattress is in transport mode the patient is NOT receiving any alternating therapy and is exposed to constant unrelieved pressure (similar to using the Series4H as a non-powered system).

Over time (hours), air will gradually leak from the mattress and the patient will ultimately revert to using the system as a non-powered hybrid.

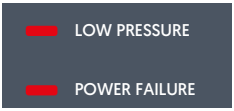
Patient weight along with the amount of air in the mattress at the point the Transport Cap was used will both affect how long the mattress remains inflated.

10.6 CPR

During a cardiac arrest or other medical emergency, the mattress can be rapidly deflated by disconnecting the mattress umbilical from the pump. Refer to Section 7.4.

10.7 Alarm Indicators / Fault Conditions

LOW PRESSURE ALARM



A 'low pressure' fault condition will result in the pump simultaneously displaying a flashing red 'LOW PRESSURE' indicator light on the control panel and generating a persistent, beeping audible alarm which continues until it is muted, or the fault condition is rectified.

See below for a list of possible causes and solutions for a LOW PRESSURE alarm.

Possible Cause	Solution
Damaged, kinked, or disconnected air cells or piping within the mattress.	Unzip the mattress cover and check for damaged, kinked, or disconnected air cells and piping.
Damaged or disconnected air pipe / umbilical between the mattress and pump.	Check to ensure the umbilical is intact and the connector is correctly plugged into the pump.

Successfully resolving a low-pressure fault will result in the pump unit returning to normal and the LOW PRESSURE fault will be automatically ended.

Muting the Audible LOW PRESSURE Alarm

To mute the audible LOW PRESSURE alarm, press the 'MUTE' button on the front of the control panel once.

> **NOTE**
>
> This will not resolve the fault and the red indicator light will continue to flash until the fault is resolved.

To unmute the audible alarm, simply push the MUTE button again and the low-pressure alarm will continue to sound.

If the alarm cannot be resolved, contact OSKA for further advice / support.

POWER FAILURE ALARM

In the event of a power failure (e.g. interruption to mains power or unplugging the power lead), the mattress pump will simultaneously display a flashing red 'POWER FAILURE' indicator light on the control panel and generate a persistent, beeping audible alarm which continues until it is muted (cancelled), or the fault condition is rectified (i.e. power is returned to the pump unit).

See below for a list of possible causes and solutions for a POWER FAILURE alarm.

Possible Cause	Solution
Power cut / power outage	Wait for power to be restored.
Mains power socket switched off or plug removed	Check switch is on, and lead plugged into socket.
Mains lead unplugged from pump	Check mains lead is securely in place at the pump

> **NOTE**
>
> Pushing the MUTE button once will CANCEL the POWER FAILURE alarm. Muting (cancelling) the power failure alarm DOES NOT rectify the fault. Refer to the above table for possible causes and solutions to a POWER FAILURE alarm.

11 Care, Maintenance, & Servicing

⚠ WARNING

Always turn the Series4H pump off and disconnect it from the mains power supply prior to any product maintenance or servicing.

Wear appropriate Personal Protective Equipment (PPE) and clothing when performing all maintenance and servicing. Refer to local policies and guidelines.

Only OSKA engineers or an OSKA approved engineer is to perform system servicing / repairs.

11.1 Pump care and maintenance

OSKA recommends the following actions:

- Keep pump clean.
- Regular inspection of pump case for signs of damage (cracks, chips, dents etc.)*.
- Regular inspection of power cord and plug for signs of damage / excessive wear*.
- Check the front panel display is intact, legible and in good working order*.
- Check air connectors are intact and not damaged*.
- Check air filter and replace annually as part of routine annual servicing.

* If damaged, remove from use and repair / replace damaged item before re-use.

11.2 Mattress Care and Maintenance

Check the mattress regularly for signs of wear / damage which could impact on device performance or compromise the integrity of the cover and pose a potential risk of infection or cross contamination for the patient or carer.

OSKA recommends the following actions are performed weekly wherever possible:

- Keep the mattress clean.
- Regular visual inspection of the mattress cover for cuts, needle sticks, tears, scuffing, abrasions, delamination, seams splitting, zip damage etc.
- Regular checks inside the top cover for signs of staining / strike-through (this will indicate a breach in the cover integrity and will require a replacement top cover). If strikethrough is apparent, check air cells / tubing inside mattress for fluid ingress. If present send system for cleaning / decontamination in line with local guidelines.
- Regular inspection of the umbilical air-line tubing and connector.

NOTE

Between patients, the system should be cleaned / decontaminated, and a full visual inspection performed to ensure the system is intact prior to re-use.

11.3 Servicing

OSKA recommends an annual service of the Series4H system from an OSKA engineer or an OSKA approved service provider.

Only OSKA components or OSKA approved component parts can be used for servicing / repair of the Series4H system.

12 Decontamination: Cleaning, Disinfection and Washing

The following processes are recommended by OSKA as appropriate infection prevention procedures to reduce the risk of infection / cross infection from the Series4H system during use and re-use of the device.

The following recommendations may need to be adapted to comply with national or local medical device decontamination guidelines. Seek advice from your local Infection Prevention & Control specialist where appropriate.

OSKA recommends the Series4H system is cleaned and decontaminated at regular intervals when in use and always before it is used for a new patient.

⚠ WARNING

Always turn the Series4H pump off and disconnect it from the mains power supply prior to any product cleaning, disinfection or maintenance.

DO NOT immerse or soak the pump unit during cleaning / disinfection – risk of electric shock.

DO NOT spray the pump unit directly with any cleaning or disinfection solutions or chemicals.

Wear appropriate Personal Protective Equipment (PPE) and clothing when performing all cleaning and disinfection processes. Refer to local policies and guidelines.

Failure to adhere to these instructions could adversely affect the performance, safety, efficacy, and durability of the Series4H system.

After cleaning or disinfection, always check the top cover for signs of potential damage that may permit the ingress of fluid (strikethrough) into the internal mattress components. Damage includes pin-prick holes (needle sticks), scuffing, abrasion, tears, delamination, damaged seams etc. To check for damage not visible to the naked eye, unzip the cover and examine the white underside of the cover for staining / discolouration. This is an indication of fluid strikethrough.

⚠ WARNING

Damaged covers present a risk of infection / cross-infection and must be replaced prior to the product being re-used.

⚠ CAUTION

DO NOT use abrasive cleaners, biological or Phenol or phenolic-based cleaning solutions.

DO NOT sterilise, autoclave, boil, mangle or wring the mattress cover or components.

12.1 General Cleaning

For general cleaning, OSKA recommends the following four-step process:

1. Using a clean damp cloth or disposable wipe, moistened with neutral detergent and clean water, wipe down all external surfaces of the mattress and pump unit.
2. Ensure all organic matter has been removed and the pump unit and mattress cover are visibly clean.
3. Wipe thoroughly with a clean, damp cloth, or disposable wipe moistened with clean water.
4. Air dry or use paper towels to dry thoroughly prior to re-use or storage.

12.2 Disinfection / Decontamination

Where the mattress is heavily soiled and/or it has been exposed to body fluids, or a patient with a known infection, seek advice from your local Infection Prevention Specialist or alternatively refer to the guidelines below.

- OSKA recommends using a concentration of 1,000 parts per million (ppm) available chlorine solution such as sodium hypochlorite (NaOCl) when disinfecting the Series4H system.

NOTE

Concentration of cleaning solution may vary depending on the level of mattress contamination and local policy / guidelines.

For disinfection / decontamination, OSKA recommends following the following process:

1. After completing steps 1-3 in the 'General Cleaning' procedure above, use a clean, damp cloth, or disposable wipe, moistened with the disinfectant solution and wipe down all external surfaces of the mattress and pump unit.
2. Do not allow water, cleaning, or disinfectant solutions to collect on the pump surface, or pool on the mattress.
3. Wipe thoroughly with a clean damp cloth or wipe moistened with clean water.
4. Air dry or use paper towels to dry thoroughly prior to re-use or storage.

NOTE

For customers wishing to use alternative cleaning and disinfecting formulations / solutions to those detailed above, OSKA recommends contacting the chemical supplier to confirm suitability.

12.3 Washing

Refer to Section 14 Technical data for information on the mattress cover laundry guidelines.

13 Warranty

Your OSKA product comes with a two-year parts and labour warranty.

All product sales are covered by OSKA's standard terms and conditions, a copy of which is available from the website (www.oska.uk.com) or on request.

The warranty is based on statutory regulations and does not apply if the goods supplied by OSKA are processed, handled, or modified in any way by other parties without prior consent from OSKA, or if these Instructions for Use are not followed.

If during inspection it is found that damages are due to wear and tear, or are not subject to warranty, then OSKA is empowered to claim the expenses (inspection, transport costs etc) from the client.

14 Technical data (specification)

Pump	
Model	OSKA Series4 Hybrid
Power supply	220-240V 50Hz, 1A
Fuse rating	T1AL 250V
Size	27.6cm (L) x 16cm (W) x 10cm (H)
Weight	2.0 Kg
Case material	ABS plastic
Air output	8 litres per minute
Cycle time	10 minutes
Pressure range	10mmHg – 24mmHg
Noise level	<30dB (within 1.9m)
Modes	Alternating mode (1-in-2 cell cycle) Static mode
Electrical protection	Class II
Applied parts	Type BF Hybrid Mattress
Ingress protection	IP21
Usage	Continuous operation
Operating environment	Ambient Temp range: 5°C – 40°C Ambient humidity range: 15% - 90%, non-condensing
Transport / Storage environment	Ambient Temp range: -25°C – 70°C Ambient humidity range: 10% - 90%, non-condensing

Mattress	
Maximum user weight	250 Kg / 39.4 Stone
Size	200cm (L) x 87cm (W) x 18.5cm (H) 200cm (L) x 105cm (W) x 18.5cm (H)
Weight	9 Kg
Orange foam	Combustion Modified PU Foam (Hardness 100-140N; Density 37-41Kg/m^3)
White foam	Combustion Modified PU Foam (Hardness 55-75N; Density 47.5-52.5K/m^3)
Blue foam	Combustion Modified PU Foam (Hardness 170-230N; Density 37-41Kg/m^3)
Air cell configuration	11 individual air cells
Alternation Cycle	1-in-2
Cover material	PU coated nylon
Top cover properties	Moisture-vapour permeable; two-way stretch
Flammability / Fire retardancy	Cover complies with BS 7175
Machine washing temperatures	Recommended Temp: 40°C Maximum Temp: 95°C NOTE: Use neutral detergent only, no fabric conditioners / softeners
Tumble drying temperatures	Tumble dry on low heat Maximum Temp: 60°C

15 Troubleshooting

Issue	Possible Cause	Solution
Pump not 'On' / running.	No mains power to the pump.	Connect mattress pump to mains power supply and turn on.
	POWER button not pushed.	Push the 'POWER' button once to turn the pump on. Green light beneath the POWER button will flash during start up until system reaches pressure, after which it will show a constant green light.
	Fuse in plug is blown.	Unplug pump from mains supply, replace fuse. Plug pump back into mains and switch pump on.
Pump 'On' and running but mattress not inflating, or running at low pressure.	Umbilical not connected to pump.	Ensure umbilical connector is 'clicked' into place on the side of the pump.
	Umbilical tubing kinked.	Check tubing for kinks. If kinked, unplug from pump, unkink the tubing and re-attach to pump.
	Damaged air cell.	Unzip cover and check air cells for leaking. Replace any damaged air cells.
System does not appear to be alternating.	Umbilical tubing kinked.	Check tubing for kinks. If kinked, unplug from pump, unkink the tubing and re-attach to pump.
	Static mode is selected.	Deselect STATIC mode by 'UNLOCKING' the pump and pushing the STATIC mode button. The green STATIC mode indicator light will go out when deselected.
Pump is noisy	Pump placement.	Re-position the pump to ensure it is resting against a solid surface.
Low pressure alarm	Damaged, kinked, or disconnected air cells or piping within the mattress.	Unzip mattress cover, check for damaged, kinked, or disconnected air cells and piping. Repair / replace as required. Replace cover.
	Damaged or disconnected umbilical between pump and mattress.	Check umbilical is intact, and the connector is correctly plugged into the pump.

If the issue cannot be resolved, contact OSKA for additional support.

16. Disposal of parts / End of life disposal

Decontaminate the OSKA Series4H prior to disposal to reduce any risk of cross infection / contamination during the disposal process.

Once clean, the mattress can be disposed of as general waste in line with local waste management policies / guidelines which may be landfill or combustion.

The OSKA Series4H pump contains electrical components and equipment and should therefore not be disposed of as general waste. Instead, the pump should be treated as Waste Electrical and Electronic Equipment (WEEE) and disposed of in line with local or national policy for WEEE equipment using approved WEEE recycling facilities.

17. Mattress Compatibility

Due to the range of available bed frames and bed rails, the customer / care provider is responsible for performing a risk assessment to ensure the proposed combination of bed frame + bed rails + OSKA Series4H are compatible with one another, and the combination of products does not impact on patient safety in any way.

⚠ WARNING

The combination of bed frame + mattress + side rails should not result in any gap large enough to entrap a patient's head, body or limb. Care should be taken to prevent gaps arising as a result of compression or movement of the mattress.

Death or serious injury may occur.

⚠ WARNING

When using side rails, a patient risk assessment must be undertaken to ensure (1) the distance between the top of the side rail and the top of the mattress meet the minimum requirements / specifications*; (2) the proposed product combination is acceptable from a risk-management perspective, and (3) this does not introduce an additional or increased falls hazard to the patient.

Death or serious injury may occur.

* Refer to the following documents for additional information.

- IEC 60601-2-52:2009 Medical electrical equipment. Part 2-52: Particular requirements for the basic safety and essential performance of medical beds.
- National Patient Safety Alert: Medical beds, trolleys, bed rails, bed grab handles and lateral turning devices: risk of death from entrapment or falls (NatPSA/2023/010/MHRA)
- MHRA Guidance. Bed rails: management and safe use. Guidance on managing and using bed rails safely.

18. Electromagnetic Compatibility [EMC]

With regard to the OSKA Series4H system's capacity to generate / radiate or be affected by radio frequency (RF) energy, the system has been tested for compliance with IEC 60601-1-2 and EN 60601-1-2. The OSKA Series4H system complies with the above standards and whilst this device is unlikely to cause any interference with nearby electronic equipment, it is still a possibility that interference with sensitive nearby electronic equipment could occur in some circumstances.

To minimise any potential impact from or to this device, OSKA advises the following precautions are taken wherever possible:

- The OSKA Series4H is used in accordance with the following Warnings and Declarations.
- Only use the device in the electromagnetic environment specified below and in line with the Intended Use of the device.

⚠ WARNING

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.

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.

Portable RF communications equipment such as mobile phones, cordless telephones, and base stations etc. (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

18.1 Declaration – Electromagnetic Emissions

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

The OSKA Series4H is intended for use in the electromagnetic environment specified below. The customer or the user of the OSKA Series4H should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	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 domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

18.2 Declaration – Electromagnetic Immunity

Guidance & Declaration: electromagnetic immunity

The OSKA Series4H is intended for use in the electromagnetic environment specified below. The customer, or the user of the OSKA Series4H, should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV 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	±2kV for power supply lines ±1kV for Input/out lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line to line ±2 kV line to earth	±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	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30 % dip in U_T) for 25/30 cycles <5 % U_T (>95 % dip in U_T) for 5/6 sec	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	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.

⚠ NOTE

U_T is the a.c. mains voltage prior to application of the test level.

Guidance & Declaration: Electromagnetic Immunity

The OSKA Series4H is intended for use in the electromagnetic environment specified below. The customer, or the user of the OSKA Series4H, should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vms 150 kHz to 80 MHz 6 Vms in an amateur radio bands	3 Vms 150 kHz to 80 MHz 6 Vms in an amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the OSKA Mattress, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	**Recommended separation distance** $d=[3,5/V_1]_x P^{1/2}$ $d=1.2xP^{1/2}$ 80 MHz to 800MHz $d=2.3xP^{1/2}$ 800 MHz to 2.7GHz 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). 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.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz 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.

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 OSKA Mattress pump is used exceeds the applicable RF compliance level above, the OSKA Mattress pump should be observed to verify normal operation. If abnormal performance is observed, additional measured may be necessary, such as reorienting or relocating the device.

b) Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.

Notes

Notes

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