OSKA®

User Guide

Air Overlay

Version 5: 24.02.2026

Contents

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

CE 0197
Airflo (Xiamen) Medical Co., Ltd.
1F, 3F, 4F No.6, East Haicang Road, Haijing, Xiamen, Fujian, China

EC REP
Share Info GmbH
Am Schulzentrum 12, 41564 Kaarst, Germany

OSKA Care Ltd.
Edward House, 5 Penner Road, Havant, Hampshire, PO9 1QZ, UK

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.

	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
	Prevention: Category 1-2		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		

02 Product Description

The OSKA Air Overlay is an alternating pressure air overlay system, designed to be used on top of a base mattress or underlay. It consists of a single layer of air cells attached via an umbilical air hose to an electrically powered pump

The overlay consists of a series of seventeen air cells. The three 'head cells' at the top of the overlay are static and do not alternate; the remaining fourteen air cells are active, alternating air cells. The cells are arranged transversely (side to side) across the patient support surface.

When 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 overlay cover is waterproof, breathable and multi-stretch to help it conform to patients.

⚠ WARNING

It is NOT designed to be placed directly on the bed base and using it without a suitable mattress or underlay underneath it may expose the patient to additional risks.

03 Indications for Use

Intended use

The intended use of the OSKA Air Overlay system is to reduce the risk of pressure related tissue injury in patients at an elevated risk of pressure ulceration, up to and including those patients 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.

See 'Indications' for further information on use of the Air Overlay.

Intended Environment

The OSKA Air Overlay 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

This alternating pressure air overlay is intended to support a single patient between 40Kg and 160Kg in weight. For patients of very low weight, typically less than 40Kg and / or small stature, OSKA recommends that 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 Air Overlay System is indicated for use as follows:

- 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.
- The overlay is to be placed on top of the existing foam bed mattress or a dedicated foam underlay with a minimum depth of 50mm.

⚠ WARNING

Failure to use a suitable mattress or underlay product beneath the OSKA Air Overlay could increase the risk of pressure related tissue injury for the patient.

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 Air Overlay system 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 Air Overlay, a patient-specific risk assessment should be performed. As a minimum, this should include the following:

- Product combination (i.e. bed frame + mattress + overlay + 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 Air Overlay system for patients with unstable spinal fractures.
- Do not use the OSKA Air Overlay system for patients where use of an active therapy support surface could result in any harm or exacerbate their medical condition.
- Do not use the OSKA Air Overlay system for patients 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 overlay installation.

⚠ GENERAL WARNINGS

- It is the responsibility of the clinician in charge of the patient / care provider to ensure that the user can use this product safely. NOTE: the Air Overlay 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 overlay is to be installed and put into service in accordance with the instructions provided.
- Do not use the overlay 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 and OSKA Air Overlay are compatible, and that the proposed combination does not impact on patient safety in any way. The combination of bed frame + mattress + overlay + 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 / mattress overlay. 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 overlays cable management feature to minimise potential mains cable issues.

- DO NOT smoke whilst on or near the Air Overlay – 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 overlay could result in air loss from the product which may act as a fan effect to assist the flames. It is advised 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 overlay.

- 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 Air Overlay 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.
- Ensure the CPR tag on the overlay is always visible and easily accessible when

the system is in use.

- 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 Air Overlay 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 overlay 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 overlay cover.
- Do not use abrasive cleaners, biological or phenolic based cleaners.
- Attach the overlay to the moveable parts of the bed frame only.
- 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 overlay should be cleaned regularly and always between patients.
- Do not use hot water bottles or electric blankets when using the overlay system.

Information

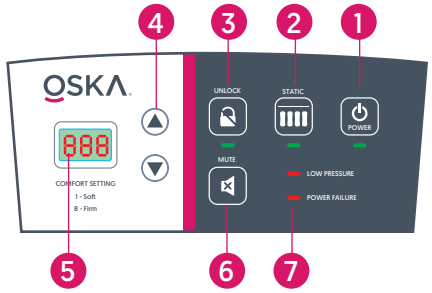
- Set up the Air Overlay as directed. Once set up, the Air Overlay does NOT need to be turned or rotated on the bed frame.
- Always supervise children and pets closely when in the vicinity of the overlay system.
- The overlay is for single person use. Additional weight could damage the system or affect 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 Overlay pump unit

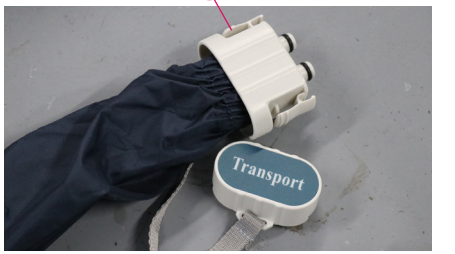
Number	Overlay Pump Unit Feature / Part
1	Control panel (see 6.2 below)
2	Mains power cable
3	Umbilical attachment point / CPR
4	Bed hooks
5	Fuse (x2)

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 Overlay



Number	Overlay Feature / Part
1	Removable top cover
2	Static head cells (x3)
3	CPR
4	Alternating air cells (x14)
5	Base cover
6	Fixing straps (x4; 2 each side)
7	Umbilical / Air hose
8	Transport cap
9	Cable management flap (x2; one each side of the overlay)

07 Installation

The OSKA Air Overlay system is easy to install, set up and use. To install the system correctly, follow the steps below.

7.1 System preparation

Remove the OSKA Air Overlay system from its packaging. The unboxed system consists of the following items:

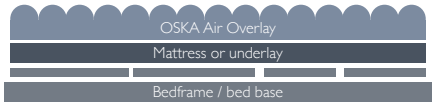
- Air Overlay with integral umbilical (air hose).
- Air Overlay Pump
- Mains power cord

7.2 OSKA Air Overlay installation

NOTE

The OSKA Air Overlay is designed to be placed on top of the current mattress or underlay. DO NOT place the OSKA Air Overlay directly onto the bed base, always use a mattress or underlay.

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



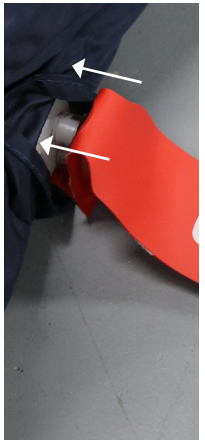
2. Unroll the overlay and place it directly onto the mattress, or underlay.
3. Ensure that the white 'feet' symbol on the blue overlay cover is facing upwards and located at the foot end of the bed.

4. Using the four fixing straps (two on each side of the overlay), attach the overlay to the bed frame.

NOTE

If the bed frame is a multi-section profiling bed then attach the overlay to the movable parts of the bedframe only.

5. To prevent air leaking from the overlay, ensure that the CPR cap, attached to the red CPR tag at the head end of the device, is fully pushed onto the two air tubes protruding from the white connector.



NOTE

If the CPR cap is not fully in place the overlay may fail to inflate, resulting in a low-pressure alarm fault.

6. Ensure the red CPR tag at the head of the overlay is visible, not covered by bedding and the 'pull' arrow on the tag is pointing towards the floor.
7. To optimise the pressure area care offered by the overlay, ensure the overlay cover is loose, and any sheets are loose fitting

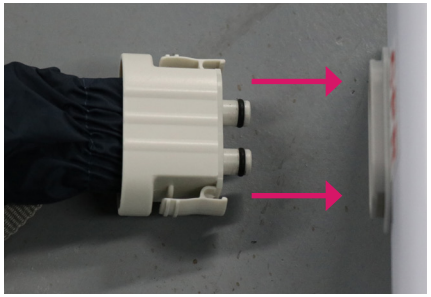
7.3 Pump installation

1. Position the air overlay 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 overlay pump and insert the plug into a suitable mains power outlet. Switch the mains socket on.
3. Choose which side of the overlay you wish to run the mains power cable along.
4. Locate the cable management flap which runs the length of the overlay on each side.
5. Open the Velcro fastenings, lay the cable into the flap and secure the Velcro 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.

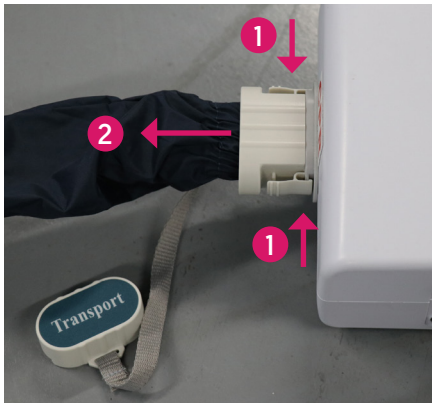
7.4 Connecting / disconnecting the Pump and Overlay

1. To connect the pump and overlay, remove the 'transport cap' from the air hose (umbilical) coming from the foot end of the air overlay
2. Align the plastic connector on the end of the umbilical with the connector on the pump.
3. Push the two fittings together until you hear a 'CLICK'.

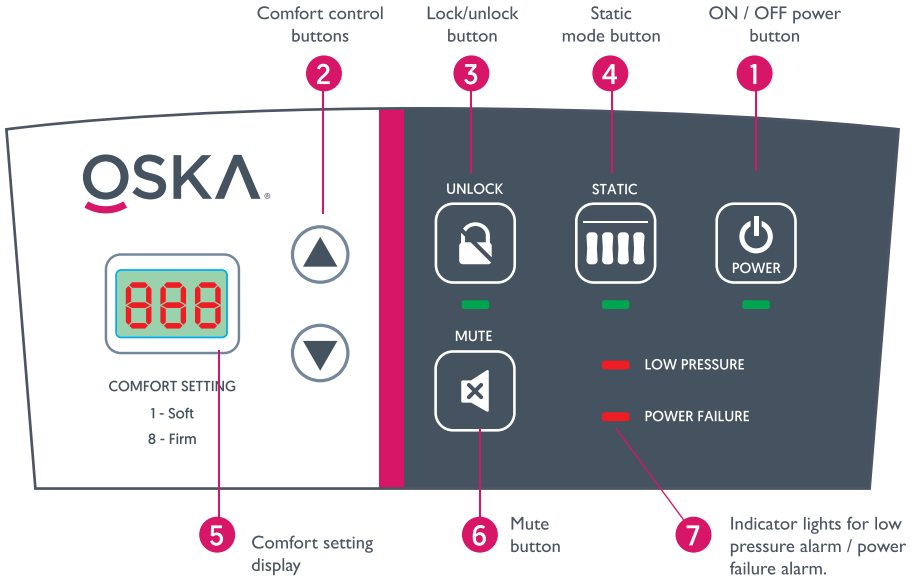


4. Once the overlay and pump have been installed correctly and connected, the system is ready for use.

5. To disconnect the 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 overlay pump (2) until it fully detaches from the pump.



08 Pump Functions (Controls, Alarms and Indicators)



Under normal operation the OSKA Air Overlay System delivers alternating pressure area care therapy. 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) press 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 overlay 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 overlay.

To adjust the OSKA Air Overlay in response to a change in patient weight, position, or to meet patients' 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 overlay system).

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. If the fault persists, the audible alarm will automatically be reactivated in 10 minutes.

8.7 Low Pressure & Power Failure Indicators (Alarms)

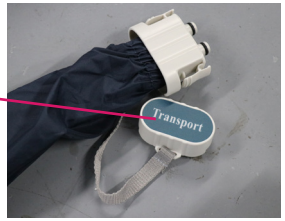
The flashing red LOW PRESSURE indicator light will display as a result of the system operating at a consistently low pressure for approximately fifteen minutes. See Section 10.6 (Alarms / Fault Conditions) for more information.

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.

⚠ CAUTION

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 Air Overlay Functions



9.1 CPR

To rapidly deflate the OSKA Air Overlay System, for example during a cardiac arrest, use the CPR tag at the head of the overlay. Optimise the rate of deflation by unplugging the umbilical hose from the pump (see Section 7.4).

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 overlay for an extended period of time.

9.3 Cable Tidy

The Cable Tidy feature runs down each side of the Air Overlay and allows the mains cable to be neatly positioned off the floor and away from any mechanical / moving parts of the bed frame.

9.4 Fixing Straps

There are four overlay fixing straps, two on each side of the overlay. These allow the overlay to be secured to the moving parts of the bedframe to help provide a stable support surface during patient ingress/egress from the bed.

10 System Operation

The following instructions explain the basic day-to-day operation of the OSKA Air Overlay 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 Air Overlay System.

10.1 Overlay inflation

⚠ WARNING

Wait until the green 'POWER' indicator light is constantly illuminated before placing a patient onto the Air Overlay System.

1. Set the system up as described in Section 7 and turn the pump on as described in Section 8.
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.

NOTE

It will take approximately 10 minutes for the system to inflate from flat.

10.2 Overlay deflation

1. To deflate the overlay after use, turn off the pump and disconnect the umbilical from the pump unit.
2. Pull the CPR tag down towards the floor to remove the bung from the tubes at the head of the overlay. If the CPR is not disconnected, the 3 static head cells will remain inflated.

10.3 Static mode

To create a static (non-alternating) support surface, 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 17 air cells in the overlay 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 back to an active (alternating) support surface and the green light below the STATIC button will go out.

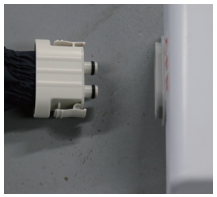
NOTE

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

4. To return the Air Overlay 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 overlay will return to an alternating support surface.

10.4 Transport mode

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



To put the overlay system into 'Transport mode':

1. Remove the umbilical air hose from the pump unit (see Section 7.4)
2. Seal the air within the overlay 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 overlay.
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 overlay system to normal operation:

1. Remove the transport cap from the end of the umbilical.
2. Re-attach the overlay 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.

⚠ WARNING

Patients should be routinely nursed with the system in its normal (alternating) mode. TRANSPORT mode should only be used when necessary for the shortest time possible as part of patient transfer, clinical procedures, or during a power cut. Failure to return the Air Overlay System to active therapy at the earliest opportunity could increase the risk of pressure related tissue injury to the patient.

⚠ CAUTION

When the overlay is in transport mode, the patient is NOT receiving any alternating therapy and is exposed to constant unrelieved pressure.

Over time (hours), air will gradually leak from the overlay and the patient will ultimately end up resting on the mattress / underlay. Patient weight, along with the amount of air in the overlay at the point the Transport Cap was used, will both affect how long the overlay remains inflated.

Transport mode should be used as a temporary measure and the system returned to alternating (active) therapy as soon as possible.

10.5 CPR

During a cardiac arrest or other medical emergency, the overlay can be rapidly deflated by locating the red CPR tag at the head end of the overlay and pulling it down towards the floor until the bung is detached from the air hoses. The system will deflate rapidly.

To increase the rate of deflation, disconnect the overlay umbilical from the pump (see Section 7.4)

10.6 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 overlay.	Unzip the cover and check for damaged, kinked or disconnected overlay air cells and piping.
Damaged or disconnected air pipe / umbilical between the overlay and pump.	Check to ensure the umbilical is intact and the connector is correctly plugged into the pump.
CPR plug not correctly pushed onto the air pipes.	Ensure CPR plug is correctly located and in place.

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.

If the fault persists, the audible alarm will automatically be reactivated in 10 minutes.

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 overlay 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

⚠ CAUTION

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

11 Care, maintenance, & servicing

⚠ WARNING

Always turn the Air Overlay System 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 Overlay care and maintenance

Check the overlay regularly for signs of wear / damage that 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 overlay clean.
- Regular visual inspection of the overlay 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 overlay 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.
- Check CPR plug is firmly in place.

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 Air Overlay 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 Air Overlay 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 Air Overlay 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 Air Overlay 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 Air Overlay System 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 Air Overlay 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 overlay 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 sterilize, autoclave, boil, mangle or wring the overlay 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 overlay and pump unit.
2. Ensure all organic matter has been removed and the pump unit and overlay 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 overlay 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 Air Overlay system.

> **NOTE**
>
> Concentration of cleaning solution may vary depending on the level of overlay 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 overlay and pump unit.
2. Do not allow water, cleaning or disinfectant solutions to collect on the pump surface or pool on the overlay.
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**
>
> Between patients the system should be cleaned / decontaminated, and a full visual inspection performed to ensure the system is intact prior to re-use.

12.3 Washing

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

13 Warranty

Your OSKA product comes with a one-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 Air Overlay
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	20mmHg – 55mmHg
Noise level	<30dB (within 1.9m)
Modes	Alternating mode Static mode
Electrical protection	Class II
Applied parts	Type BF Mattress Overlay
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

Air Overlay	
Size	203cm (L) x 90cm (W) x 12.5cm (H)
Weight	3.8 Kg
Air cell configuration	17 individual air cells (3 static head cells; 14 alternating cells)
Air cell material	Nylon / PVC
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 overlay 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 overlay 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.
	CPR bung unplugged from overlay.	Check CPR plug at head end of overlay is firmly pushed into place and no air is leaking from the connection.
	Damaged air cell.	Unzip cover and check air cells for leaking. Replace any damaged air cells.
	Pressure setting incorrect for patient weight.	Adjust the pressure setting accordingly.
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 overlay.	Unzip cover, check for damaged, kinked or disconnected overlay air cells and piping. Repair / replace as required. Replace cover.
	Damaged or disconnected umbilical between pump and overlay.	Check umbilical is intact, and the connector is correctly plugged into the pump.
	CPR plug not correctly pushed onto the air pipes.	Check CPR plug is correctly located and pushed firmly into place.

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

16. Disposal of parts / End of life disposal

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

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

The OSKA Air Overlay 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. Air Overlay Compatibility

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 proposed combination of bed frame, mattress, bed rails and OSKA Air Overlay are compatible, and the combination of products does not impact on patient safety in any way.

⚠ WARNING

The combination of bed frame + mattress + overlay + 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 / mattress overlay.

Death or serious injury may occur.

⚠ WARNING

When placing the OSKA Air Overlay on top of a mattress, this will increase the height of the top surface. 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 surface of the overlay meets the minimum requirements / specifications*; (2) the addition of the overlay to the mattress 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 Air Overlay 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 Air Overlay 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 Air Overlay 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 30 cm (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 Air Overlay is intended for use in the electromagnetic environment specified below. The customer or the user of the OSKA Air Overlay should assure 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 Air Overlay is intended for use in the electromagnetic environment specified below. The customer or the user of the OSKA Air Overlay should assure 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 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30 % dip in UT.) for 25/30 cycles <5 % UT (>95 % dip in UT.) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30 % dip in UT.) for 25 cycles <5 % UT (>95 % dip in UT.) 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

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

Guidance & Declaration: electromagnetic immunity

The OSKA Air Overlay is intended for use in the electromagnetic environment specified below. The customer or the user of the OSKA Air Overlay should assure 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 Air Overlay, 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** $d=[3,5/V1]xP^{1/2}$ $d=1.2xP^{1/2}$ 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 Air Overlay is used exceeds the applicable RF compliance level above, the OSKA Air Overlay 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.

Pressure Care Experts

Edward House, 5 Penner Road, Havant, PO9 1QZ

02394 318 318 | ask@oska.uk.com

oska.uk.com