Select Medical
purely pressure care

Dynamic Pressure Redistribution Mattress & Mattress Overlay

User Manual

USER MANUAL - OLA 8 & 4

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STATEMENTS AND SYMBOLS


Refer to manual


Warning to highlight potential hazards that, if disregarded, could lead to injury or death.


Caution to highlight potential hazards that if disregarded could lead to equipment damage or failure.

NB: Tips or information users should be aware of

IMPORTANT NOTICE


Before operating this medical equipment, it is important to read this manual and understand the operating instructions and safety precautions. If you have any questions regarding the use of this equipment please contact your supplier.

INTRODUCTION


Thank you for choosing the OLA 8 or OLA 4 pressure redistribution system. This manual should be read carefully before using the mattress as it contains important safety and maintenance information to ensure long lasting and reliable service.

CONTACT INFORMATION

For any service, warranty, sales or customer service information on this product please contact your supplier or if in doubt contact Select Medical Ltd. at the following address:

Select Medical Ltd, Unit 10 Philips Rd, Whitebirk Ind Estate, Blackburn, BB1 5NA.

Customer Service: +44 (0)1254 685538 **Sales:** +44 (0)1254 668899
Email: info@selectmedical.co.uk
www.selectmedical.co.uk

PRODUCT OVERVIEW

Environment

Your dynamic mattress system is intended for use in the following environments:

- A care environment where medical supervision and monitoring are provided (e.g. nursing homes, care home, rehabilitation facilities etc).
- A domestic environment where the mattress is used to alleviate or compensate for an injury or disability.

Intended Use

OLA 8 is an 8" replacement, dynamic pressure redistribution system suitable for individuals up to **very high risk** of developing a pressure ulcer or for those with existing tissue damage.

OLA 4 is a 4" pressure relieving overlay suitable for individuals up to **high risk** of developing a pressure ulcer or for those with existing tissue damage.

OLA 8 & 4 provide regular periods of pressure reduction to vulnerable tissue areas, aiding blood and lymphatic flow which is vital to maintaining healthy tissue. The mattress system is designed to be used on standard or profiling beds.

For assistance in setting up, using or maintaining your dynamic mattress system, or to report unexpected operation refer to the contact details found on page 2.

Features

OLA 8 & 4 Mattress:

- One in two cell-cycle design giving optimum therapy
- Multi-stretch, waterproof and vapour permeable cover
- CPR pull cord for rapid deflation
- Machine washable up to 95°C
- 1 year warranty

OLA 8 Control Unit (Q2-02):

- Audible low pressure alert
- Pressure adjustment for optimum therapy
- External, easy replacement pump filters

OLA 4 Control Unit (D30):

- Low pressure alert
- Pressure adjustment for optimum therapy
- External, easy replacement pump filters

SAFETY

General Safety

- The mattress system & control unit must be installed and used in accordance with the information provided in this manual.
- The mattress system is typically not suitable for children. If it is to be used by a child ensure a risk assessment has been undertaken.
- Before using the system ensure that the mains lead is free from damage and is positioned so as not to cause an obstruction or trip hazard.
- Exposure of the control unit to any liquid while it is plugged in could cause a severe electrical hazard.
- Use care when handling or transporting the control unit. Dropping or other sudden impacts may result in damage to the unit.
- Do not open the control unit or attempt to repair or service the unit. Repairs and servicing should always be undertaken by suitably trained personnel.
- If the control unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately.
- Do not use the system near a heat source or naked flame.
- Do not use with hot water bottles or electric blankets.
- Do not use liquids near the control unit if plugged in.
- Do not place any objects, such as blankets, on or over the control unit.

- Do not use the control unit near flammable gas or in oxygen rich environments as this poses a fire risk or risk of explosion.
- Always assess the risk of intentional or unintentional tampering of the control unit.

Risk Assessment

It is the responsibility of the carer/care provider to carry out the necessary risk assessment to ensure the safety of the patient. This should be carried out before using the mattress system.

A risk assessment should include, but is not limited to:

- Product combinations (bed frame, mattress, side rails etc.)
- Extent of tissue damage (if any)
- Entrapment
- Patient falls
- Small adults (and children)
- Patients with learning difficulties
- Unauthorised people with access to the controls

Contraindicators

Patient conditions for which the application of pressure relief on an alternating mattress system is a contraindication are as follows:

- Cervical or skeletal traction
- Unstable spinal fractures

Other contraindications may be relevant which are specific to the patient or care environment.

Mattress Load

	OLA 8	OLA 4
Minimum Weight Limit	32kg (5 stone)	32kg (5 stone)
Maximum Weight Limit	190kg (30 stone)	114kg (18 stone)

SYMBOL DEFINITIONS: CONTROL UNIT & MATTRESS

Control Unit

The following symbols are found on the control unit:

Warning: beware of potential hazard

Refer to manual: failure to do so could introduce a hazard

Type BF Applied Part
Applied Part: The parts of the device that come into physical contact with the user/occupant in order for it to carry out its intended function.
Type BF: Applied parts which are electrically isolated from earth and other parts of the medical equipment - Complying with specific requirements for protection against electric shock to IEC 60601-1

W.E.E.E Label
(Waste Electrical and Electronic Equipment)

Class II electrical device
The user/occupant is protected by at least two layers of insulation between the current carrying parts (e.g. mains cable) – If damage is noticed to the control unit or mains cable assembly turn off at the mains supply and contact your provider or Select Medical Ltd. immediately.

IP21 Protected from touch by fingers and objects greater than 12 millimetres. Protected from condensation.

Mattress

The following symbols are found on the mattress:

Disinfect by wiping the surface using a hypochlorite solution diluted 1000ppm

Machine wash up to 95°C

Tumble dry on a low setting

Do not use harsh abrasives or Phenol cleaners

Do not iron

Ensure system is dry before storing

Do not place heavy objects on surface of cover other than the patient

Do not use when damp, ensure surface is dry before use

Do not fold. Roll pack the system

Do not use sharp objects

Only use in conjunction with appropriate medical advice

CONTROL UNIT/MATTRESS PARTS

Control Unit

OLA 8 - Q2-02 Control Unit	**OLA 4** - D30 Control Unit
1. Control Panel 2. On/Off switch 3. Mains Power Cable 4. Female Air Connector Port 5. Air Filter 6. Fuse Holders 7. Cushion Bar 8. Hooks	1. Control Panel 2. On/Off switch 3. Mains Power Cable 4. Female Air Connector Port 5. Air Filter 6. Cushion Bar 7. Hooks
	
	

Mattress

1. Top Cover
2. Air Cells
3. Male Air Connector
4. Base Cover
5. Securing Straps (elasticated corner straps only on OLA 4)
6. CPR Pull Cord

INSTALLATION

Before installing the mattress system please read the warning and caution notes carefully. These highlight risk areas to ensure patient safety.

- Ensure the mattress is only used with compatible equipment/ accessories.
- Ensure the mattress is of the correct type for the patient.
- Ensure the CPR pull-cord is easily accessible at all times.
- Ensure the plug is accessible at all times so the mattress can be disconnected from the mains supply quickly, if required.
- Ensure the mains cable is plugged into an appropriate power source at all times.
- Ensure the mains cable is not taut, particularly if being used on a profiling bed that moves up and down (check all positions).
- Ensure that the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.
- Replace any damaged cable immediately as these cables can create a risk of electrocution and/or fire.
- A CE marked extension cable must only be used when it is not possible to reach a wall socket with the equipment mains cable.
- If an extension cable is used never overload it by plugging in appliances that together will exceed the maximum current rating stated for the extension cable.
- Do not use block adaptors.
- Ensure extension cables or sockets are not placed under the bed frame as liquids could leak onto them posing an electrical/ fire risk.

- Ensure the mains supply is compatible with the control unit (see page 23 for electrical specification)
- Avoid placing the mattress system in direct sunlight as this could damage the mattress cover.

1. Carefully open the packaging.
2. Although unlikely, please check the product for any signs of damage. Do not use if damaged and contact your provider or Select Medical Ltd (see page 2).
3. Place the mattress on top of the bed frame (OLA 8), or on top of the existing mattress (OLA 4), with the top cover facing upwards and the air hose at the foot end of the bed.
4. Attach the mattress to the bed frame by securing with the adjustable straps. Additionally, OLA 4 has elasticated corner straps to tuck under the existing mattress.

- On profiling beds it is essential that adjustable straps are secured around the movable sections of the bed frame, otherwise the mattress may be damaged.

5. Check the CPR pull-cord is securely in position.
6. Using the hooks on the back of the control unit, hang the unit over the frame/board at the foot end of the bed. If there is no foot frame/board lay the unit on the floor, under the bed with the front control panel facing upwards.

- If you are placing the control unit on the floor it is advisable to place the unit on a firm surface.

7. Attach the male air connector on the mattress to the female air connector port on the control unit/pump, ensuring the air hose is not kinked or trapped between parts of the bed frame/other equipment.
8. Plug the mains cable into a suitable mains supply and switch on the control unit. At this stage both the mains power and low pressure indicators will illuminate.

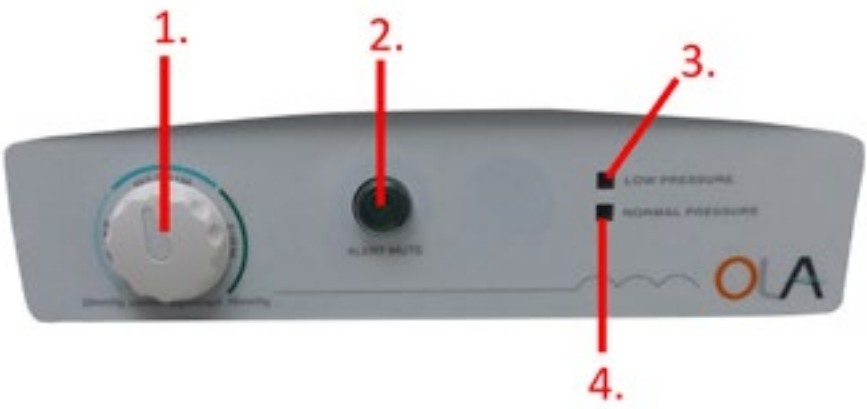
- Ensure the mains cable is positioned so as not to cause a trip hazard.

9. The mattress will start to inflate and will be completely inflated within 30 - 40 minutes.
10. Once fully inflated, adjust the straps that attach the mattress to the bed frame, ensuring the mattress is held in place securely.
11. Cover the mattress loosely with a sheet, ensuring it does not interfere with cell alternation.

OPERATION

Control Panel

OLA 8 - Q2-02 Control Unit	
1. Pressure Adjustment Dial 2. Alert Mute/Reset	3. Low Pressure Indicator 4. Normal Pressure Indicator



1. **Pressure Adjustment Dial**
Turn the dial to set the system for optimum performance.

2. **Alert Mute/Reset**
The audible/visual alert identifies when the pressure is low. To mute the audible alert press the button. The visible alert indicator will now flash. Once the fault has been rectified, re-press the button to reset the alert.

3. **Low Pressure Indicator**
A visible indicator (orange) warns that the pressure is below an acceptable level.

4. **Normal Pressure Indicator**
A visible indicator (green) identifies that the pressure has reached the preset level.

OLA 4 - D30 Control Unit	
1. Pressure Adjustment Dial 2. Low Pressure Indicator	3.Normal Pressure Indicator

1. **Pressure Adjustment Dial**
Turn the dial to set the system for optimum performance.

2. **Low Pressure Indicator**
A visible indicator (orange) warns that the pressure is below an acceptable level.

3. **Normal Pressure Indicator**
A visible indicator (green) identifies that the pressure has reached the preset level.

Mattress Operation

1. Turn on the power on the control unit. The pump starts to inflate the mattress to the pressure selected on the dial.

2. The low pressure indicator (orange) will illuminate as inflation commences.

3. OLA 8 /Q2-02 only - the audible alert is activated, press the ‘alert mute’ button to mute the alarm and its indicator will flash.

4. Once optimum pressure is reached (about 30-40 minutes) the 'normal pressure' indicator will come on and the 'low pressure' indicator (and audible alarm on the OLA 8/Q2-02) will turn off.

NB: If the 'low pressure' indicator (audible alarm) will not go off, refer to troubleshooting on page 20.

5. Adjust the 'pressure/comfort control' dial to provide a comfortable pressure level for the patient. Pressure range:

- OLA 4 / D30: 30-80mmHg
- OLA 8 / Q2-02: 20-60mmHg

6. Using clinical judgement and with continuous monitoring of the patient for up to 72 hours, increase or decrease the pressure levels using the dial to suit the patients comfort levels. If possible, having regular dialogue with the patient is key.

NB: The mattress can be used in an upright position, however the pressure setting may need to be increased. Use clinical judgement to ensure patient comfort and effective pressure relief is maintained.

CPR Function

In an emergency rapid deflation of the mattress may be required. The CPR pull cord is located at the head end of the mattress.

- Carers/care providers should always familiarise themselves with the position of the CPR valve.

To re-inflate push the CPR cord back into the closed position. The mattress will start to inflate. Wait for optimal pressure to be reached before using the mattress.

Using Incontinence Products with the Mattress

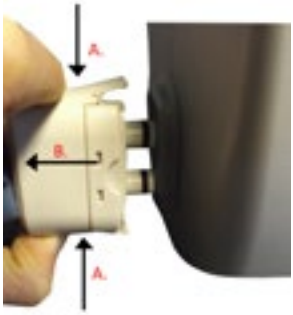
Incontinence products, such as sheets or pads, can be used with the system, however this may compromise the effectiveness of the alternating pressure distribution.

- If incontinence products are being used it is important to carry out a risk assessment and regular patient skin checks.

Transporting the Mattress & Power Cuts

If the mattress is disconnected from the power supply so it can be moved, or in the event of a mains power failure, carry out the following procedure to maintain mattress inflation:

1. Disconnect the male connector from the power unit by squeezing the two tabs (A) and pulling away from the control unit (B).



2. Seal using the cap marked “Transport” which for safety is attached to the male connector.

NB: Complete the action quickly to limit air loss.

3. Switch off the control unit.
4. Disconnect from the power supply.
5. The mattress can now be moved.

- The mattress will remain inflated for up to 24 hours - return the system to the mains supply as soon as possible.
- Whilst unplugged alternating mode will not be operational and pressure relief will not be provided.
- Do not remove the mattress from the bed frame if the occupant is still on the mattress.
- If it is essential that the patient is moved whilst remaining on the mattress, the mattress must be re-plugged in immediately once the desired location has been reached to reduce the risk of tissue damage.

- Never drag the mattress, always carry it.

CLEANING & DECONTAMINATION

Cleaning

Cleaning is required regularly between patients to prevent cross infection. It is therefore important to clean and decontaminate the control unit and mattress following these procedures.

Control Unit

- Disconnect the mains cable from the power socket before attempting to clean the control unit.
- Do not immerse or soak the pump.
- Do not spray any cleaning solution directly on the surface of the control unit.

- If any of the cleaning/washing instructions are not followed the product warranty will be invalidated.
- Do not use phenol based cleaning solutions, solvents, neat bleach or abrasive products to clean the casing as this may cause damage.

1. Check for external damage – do not use if damage is found.

2. Place the pump on a work surface and using a clean cloth wipe the outside of the case with a prepared sodium hypochlorite solution (1000ppm).

3. The control unit should be cleaned by starting with the cleanest parts and systematically moving to the dirtiest parts. Extra care should be taken around areas where excess dirt or dust may gather.

4. Change the cloth if it becomes dirty.

5. Once clean, wipe down with a new clean cloth moistened with clean water to remove detergent residue.

6. Dry off with a paper towel. Always allow the surfaces to dry thoroughly before putting back into use.

Mattress

N.B: Before attempting to clean the mattress the top cover should be checked for physical signs of damage that may lead to strike-through (ingress of fluid through cover). Staining to the underside of the top cover is a sign of strike-through.

- Do not use the cover if strike-through or damage is found – risk of cross infection. Replace with a new top cover.
- Do not use solvents or alcohol-based cleansers e.g. Phenicol, Hibiscrub, Clearsol, Stericol or Hycoline as these will destroy the mattress materials.
- Do not autoclave.

- Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the mattress.

General Cleaning:
1. Wipe down with a clean cloth moistened with a mild detergent and diluted in warm water (40˚C).

2. Rinse with cold clean water and a clean cloth and allow to fully dry before use.

Decontamination
1. Unzip the top cover from the mattress.

2. The top cover can be machine washed up to 95°C and tumble dried on a cool setting.

3. Unsnap the air cells from the mattress base on both sides.

4. Carefully clean with (1000ppm) prepared solution of sodium hypochlorite and allow to dry completely.

5. Make sure to disconnect all the air cells and spray the cleaning solution on all sides, including the connecting tubes and hoses.

6. Re-assemble the mattress and lay it out flat.

7. Ensure the mattress is completely dry before either storing or using for another patient.

STORAGE

Storage
1. Detach the control unit from the mattress.

2. Pull the CPR cord until it is open.

3. Ensure there is no air trapped in the cells.

4. Lay the mattress out flat and roll the mattress from the foot end towards the head end.

5. Store in a sealed polythene bag to protect from dirt, debris, fluids etc. with a suitable identification tag.

6. Store the control unit in a separate, sealed polythene bag to protect from dirt, debris, fluids etc. with a suitable identification tag.

- The mattress system must be decontaminated prior to any storage to avoid risk of cross contamination.

- Do not fold, crease or stack mattresses.
- Do not stack control units.
- Do not store whilst inflated.

Environmental Conditions

The following conditions should be followed when storing the mattress system:

- Ambient temperature: -25°C to +70°C
- Humidity: < 93% max, non-condensing

TROUBLESHOOTING

- DO NOT open the control unit - risk of electrocution
- If mains plug, cable or outer casing is visibly damaged turn off at the mains and contact your approved service engineer.

Problem	Actions
Power Failure	1. Turn off the control unit to silence the alarm and unplug from the mains supply. 2. Check the mains socket is working - plug in a device that is known to work. 3. Plug the control unit back into the wall socket. 4. Turn on the control unit. If control unit still fails to operate: 5. Turn off the control unit at the wall & replace plug fuse. 6. Turn on the control unit. If control unit still fails to operate: 7. Replace control unit fuses – See page 23 for fuse types. 8. Turn on the control unit. If control unit still fails to operate, turn off at the mains and contact your approved service provider.
Incomplete inflation/low pressure	1. Ensure the mattress air connector is properly connected to the control unit, is not constricted in any way and has no kinks. 2. Ensure the CPR pull-cord is firmly in place and no air is leaking. 3. Turn the unit off and then on again to clear the indicator. If the 'low pressure' indicator continues to illuminate: 4. Remove the top cover and ensure there is no air leakage within the mattress – cells, tubing and connectors. 5. Turn the unit off and then on again to clear the indicator. If a low pressure indicator is still evident turn off at the mains and contact your approved service provider
Alternating mode failure	1. Turn off the control unit. 2. Disconnect the male air connector to reduce cell pressure. 3. Reconnect air connector. 4. Turn on the control unit. 5. If alternating mode is still inoperable turn off at the mains and contact your approved service provider.
Patient is bottoming out.	1. Ensure the patient is suited to the rating of the mattress. 2. Ensure the patient is centrally positioned on the mattress. 3. Increase the pressure setting – Refer to 'Mattress Operation' pg 13-14 4. If the patient is still bottoming out refer to 'incomplete inflation' above.

MAINTENANCE

- Always disconnect the control unit from the mains power supply prior to performing any maintenance procedures (when viable).
- No modification of this equipment is allowed.
- The mattress system should be vacated by the patient before any maintenance or inspection takes place. If this is not possible due to the patient's mobility, care should be taken for the service engineer not to make contact with the patient when working on electrical items.
- Only Select Medical approved components specified for OLA 8 & 4 are to be used - if in doubt contact Select Medical Ltd or your local distributor.

- Only authorised service personnel or Select Medical service engineers should carry out repairs or service activities. Failure to do so may result in the product warranty becoming void.
- The mattress system should be serviced once a year, as a minimum.

General Maintenance

Select Medical recommend that frequent visual and operational inspections are undertaken. Clean the air filter, found at the back of the control unit, once a month with mild detegent. If there are any signs of damage, or the system is not performing as it should, withdraw it from service until the system has been repaired and is fit for use again.

Yearly Maintenance

- Check the air filter is in good condition and replace or clean as required.
- Check that all electrical functions operate correctly on the control unit.
- Check that all audible and visual indicators work appropriately (when plugged in and unplugged from mains supply).
- Check that the mattress reaches the required pressures.
- Check the CPR connection on the mattress.
- Check the cover for tears, punctures, abrasion marks and split seams.
- Check for signs of strike-through (fluid ingress) to the underside of the cover.

- Check that all piping and cells within the mattress are in good condition and that there is no kinking evident.
- Check the control unit housing is not cracked or damaged, if damaged the control unit must be removed from operation immediately.
- Check that the mains cable and plug are in good condition, if either is damaged it must be replaced with a complete assembly, the plug must never be re-wired.

Disposing of Parts

When the electrical system has come to the end of its useful life, contact your provider or Select Medical Ltd. (see pg 2) to arrange for collection, alternatively follow local recycling and W.E.E.E. (Waste Electrical and Electronic Equipment) policies.

- The control unit should not be disposed of in general municipal waste. Some of the electrical components could be harmful to the environment and where viable the components can be recovered and reused/recycled.

The metal and plastic components used in both the mattress and control unit are also to be separated and disposed of following local recycling policy as these can also be recovered and reused/recycled.

- The mattress system is to be decontaminated before disposal to avoid risk of cross contamination.

SPECIFICATION

Classification:	Electrical shock protection: Class II, Type BF Applied Part: Mattress Liquid ingress protection: IP21 Not AP or APG equipment*
Supply Rating: Fuse Rating: Mains Plug:	230V, 50Hz, 12W Mains Plug – 5A Q2-02 Control Unit - T1A, 250VAC D30 Control Unit - T1A, 250VAC (internal) Type G/BS1363
Mattress Dimensions (inflated): Maximum Patient Weight: No. of cells: Alternating Therapy: Cycle Time: Pressure Range:	OLA 8: 2000mm x 900mm x 200mm OLA 4: 1850mm x 900mm x 102mm OLA 8: 190kg (30 stone) OLA 4: 114kg (18 stone) OLA 8: 20 OLA 4: 17 AB pattern 12 minutes OLA 8 / Q2-02: 20-60mmHg, ±2mmHg OLA 4 / D30: 30-80mmHg, ±2mmHg
Control Unit Dimensions: Control Unit Weight:	OLA 8: (H) 206mm x (W) 280mm x (D) 104mm OLA 4: (H) 260mm x (W) 140mm x (D) 100mm OLA 8: 2.6kg OLA 4: 2.4kg
Cover Material: Cell Material: Base Material:	Polyurethane coated multi-stretch nylon Nylon/PVC OLA 8: Polyester fabric with PVC coating OLA 4: Polyester fabric with PVC coating
Transport and Storage Conditions: Operational Conditions: Atmospheric Pressure: Operating Altitude: Pollution: UV: Noise level:	Ambient Temp: -25°C to +70°C Humidity: < 93%, non-condensing Ambient Temp: +5°C to +40°C Humidity 15% - 93%, non-condensing 700hPa to 1060hPa ≤ 2000m Degree 2 Intended for indoor use only <40dB(A)
Warranty:	1 year
Safety Standards:	IEC 60601-1: 2005 IEC 60601-1-2:2007 IEC 60601-1-11:2010 CE The control unit is tested and CE marked in line with Medical Device Directive 93/42/EEC
* Not suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.	

ELECTROMAGNETIC COMPATIBILITY

The control unit has been designed to meet the EMC requirements of IEC 60601-1-2:2007. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices. They are in place to provide reasonable protection against dangerous interference in a medical or residential environment.

Immunity to electromagnetic interference - this refers to the levels of electromagnetic interference that the control unit can withstand from nearby sources radiating radio frequency (RF) energy (e.g. from mobile phones, network devices etc).

Electromagnetic emissions - this refers to the levels of RF energy the control unit emits.

The immunity levels are set out in the following manufacturers guidance. If these levels are exceeded then the system may not operate correctly or stop operating. It is important therefore to try to ascertain the source of the interference by turning nearby equipment off. There are simple measures that can be taken to correct the problem:

- Remove or relocate the interfering equipment
- Increase the separation distance between the control unit and the interfering equipment

The RF emissions are set out in the following manufacturers guidance. The control unit generates very low RF energy, however interference to sensitive equipment is still possible. If interference to radio/tv reception and/or other equipment is suspected, turning the control unit off and on can determine if this is the case. There are simple measures that can be taken to correct the problem:

- Relocate the receiving antenna
- Increase the separation distance between the control unit and affected equipment

Due to the increasing number of wireless devices, such as laptops and mobile phones, it is important that the system is installed following the manufacturer's guidance to ensure continued and reliable operation.

Requirements according to IEC 60601-1-2:2007

OLA 8 & 4 are intended for use in the electromagnetic environment specified below.

- The control unit should not be used next to or stacked with other equipment where possible. If this is unavoidable the control unit should be observed to verify normal operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
Emission test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	The control unit 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 emission CISPR 11	Class B	OLA 8 & 4 are suitable for use in all establishments, including domestic establishments and those directly connected to the public, low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV differential mode	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 IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 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.
PPower frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
N.B: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000- 4-6 Radiated RF IEC 61000- 4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the control unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**. Interference may occur in the vicinity of equipment marked with the following symbol: 

N.B: At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Field strengths from fixed transmitters 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 OLA 8 or 4 is used exceeds the applicable RF compliance level above, OLA 8 or 4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienteering or relocating the system.
** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

OLA 8 & 4 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user of OLA 8 or 4 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OLA 8 & 4 system as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the control unit

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m) Electromagnetic environment – guidance		
	150 KHZ TO 80 MHZ $D = 1.2\sqrt{P}$	80 MHZ TO 800 MHZ $D = 1.2\sqrt{P}$	800 MHZ TO 2.5 GHZ $D = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

N.B: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARRANTY & SERVICE

- Select Medical Ltd guarantees this equipment under normal use for a period of 1 year after delivery to the original purchaser, proof of purchase must be presented with any claim.
- For any equipment returned within the warranty period and proven to be defective we agree to either:
  a) correct the defect by product repair
  b) replace the product with one of the same or similar design or
  c) refund the purchase price, without charge.
  Repaired or replaced parts and products are warranted for the remainder of the original warranty period. You will be charged for repair or replacement of the product made after the expiration of the warranty period.
- This warranty excludes equipment damage or failure through acts of god, an incidence of excess voltage or current, shipping, tampering, improper maintenance, carelessness, accidental damage, negligence or misuse, or products which have been altered, repaired or dismantled other than with the manufacturer's written authorisation and by its approved procedures and by properly qualified technicians.
- In no event shall Select Medical be liable for any direct or indirect damages or losses resulting from the use of the equipment.

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