Viola II

Dynamic Cushion Replacement System

UPRA1717-2 and UPRA2020-2

User Manual

Issue 9 – 17/12/2020
UPRA1717-2+UPRA2020-2.UM-9

Contents

1. Introduction

This User Manual contains instructions for the installation, use and maintenance of the Ultimate Healthcare Viola II dynamic cushion replacement system. You must read and fully understand this manual before using the system.

- *Caution: Ultimate Healthcare shall not be liable for any damage or injury caused by failure to follow the proper instructions as described in this User Manual.*

- *Caution: Before using the dynamic cushion replacement system all staff must familiarise themselves thoroughly with the various parts and controls as detailed in this User Manual.*

Note: Ultimate Healthcare reserves the right to modify the information in this User Manual at any time. The information in this User Manual may vary slightly with respect to the basic design of the product.

2. Intended Use

The intended use of this product is to prevent and/or manage pressure ulcers while optimising patient comfort for patients up to 160kg / 25 stone on UPRA1717-2 and 220kg / 34 stone on UPRA2020-2.

2.1 Contraindications

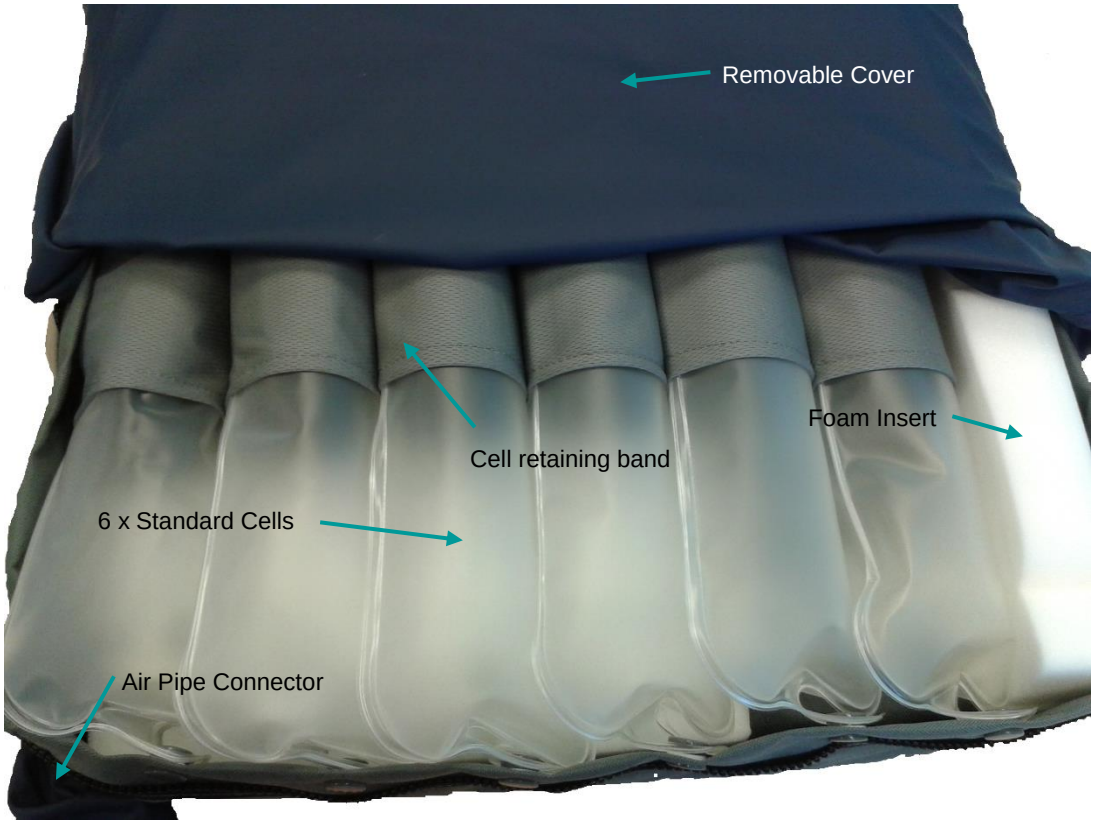
- The cushion is not suitable for use on patients with unstable fractures.

3. About the Product

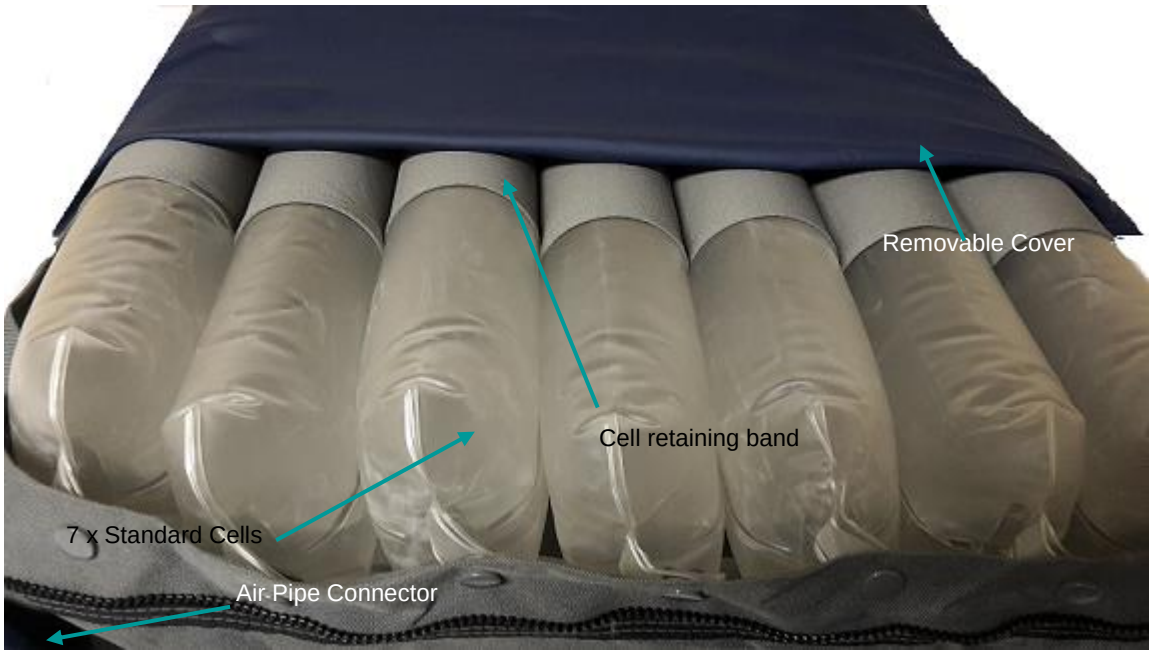
The Viola II dynamic cushion replacement is a compact, lightweight and easy to operate system which provides optimum pressure relief and comfort in a multitude of care environments.

Patient comfort requirements are enhanced by a waterproof and vapour permeable ***PU cover*** and a user friendly ***comfort control dial***.

Cushion
UPRA1717-2



UPRA2020-2



Power Unit

4. Symbols and Statements

	Note: Indicates tips and advice for the correct use of this product.
	Caution: Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the product or other property.
	Warning: Indicates potential danger that requires correct procedures or practises in order to prevent personal injury.
	BF symbol, indicates this product is according to degree of protection against electric shock for type BF equipment
	The operator must read this document (User Manual) before use.
IP21	Water and dust protection classification.
	Disposal of electrical and electronic equipment (WEEE): This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment.
CE 0197	CE certified.

5. Important Safety Information

Please read all instructions prior to using any Ultimate Healthcare supplied product. The Viola II dynamic cushion replacement system must be used in accordance with this User Manual.

The cushion must only be operated by personnel who have been properly trained or have suitable experience with products of this nature.

Ensure a clinical Risk Assessment is conducted, which should take account of the suitability of use of this product, patient's condition, any ancillary equipment in use and the surrounding environment. Pressure settings should be advised or prescribed by a medical practitioner.

Only personnel trained or formally approved by Ultimate Healthcare in operation and maintenance of Ultimate Healthcare products may perform maintenance; modification or repair work on any Ultimate Healthcare supplied product.

Ensure the power cable is not trapped or twisted and is routed suitably to avoid crushing or entrapment when connected to the product.

Do not use your cushion system power unit in the presence of flammable gases. This excludes oxygen cylinders.

Avoid hazards caused by inappropriate handling of the power cable e.g. by kinking, shearing or other mechanical damages.

The power cable for this product must be unplugged from the mains power outlet socket and suitably stowed before moving, cleaning or maintenance activities.

Disconnect from mains (power supply) before cleaning the power unit.

When cleaning do not immerse the power unit in water.

Use only the cleaning and disinfectant agents recommended in this User Manual.

When connecting product after transportation or storage, inspect the power cable visually for any signs of damage. If evident, do not use product and contact Ultimate Healthcare or your local distributor for repair.

When storing, ensure the product is stored away from direct sunlight and extreme cold conditions.

Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where their openings may be blocked. Keep the air opening free of lint, hair, and other similar particles. Air ventilation through the power unit is vital for correct and safe operation.

If this product is used for any activity other than detailed within this User Manual then personal risk to the end user or patient may occur. Ultimate Healthcare shall not be held liable/responsible for such an event.

Do not smoke, or allow the patient to smoke when using this product. Keep all possible ignition sources clear of this product.

6. Technical Specification

6.1 Power unit

Dimensions:	280mm x 145mm x 130mm (D x W X H)
Weight:	2.4 kg
Alternating cycle time:	10 mins
Output pressure range:	30 to 70mmHg (+/-5)
Power supply:	AC 230V 50 Hz
Current:	0.12 A
Classification:	Class I, Type BF
Warranty:	2 years
Operation environment:	5^0C to 40^0C 15%RH ~ 93%RH (no condensation)
Storage environment:	-25℃~70℃ ≦93%RH (no condensation)
Environment pressure:	70 kPa-101.3 kPa
Water & dust protection classification:	IP21

6.2 Cushion

Dimensions:	430mm x 430mm x 100mm (L x W X H) 510mm x 510mm x 100mm (L x W x H)
Weight:	1.7 kg
No of cells:	17 x 17 = 6 cells and foam base / 20 x 20 = 7 cells
Cover material:	2 way stretch polyester with PU Coated
Bottom material:	PU coated polyester
Max user weight:	440mm x 440mm = 160 kg 25 stone / 510mm x 510mm = 220 kg / 34 stone

7. Installation and Set-Up

7.1 Setting up Cushion

For the comfort and safety of the patient do not put them onto the cushion until system indicates that it is fully inflated. The cushion is designed to completely replace any existing cushion which may be in use on a bed.

Remove any existing cushion and ensure that there are no protruding parts or sharp objects on the seat which could cause damage to the cushion. Lay the cushion on the seats surface ensuring that it is located as per the label.

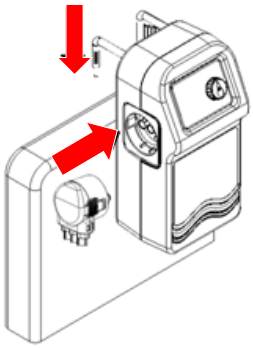
To check if the pressure is adequately supporting the patient, slide 2 fingers between the air cushion and the patient's bottom. You should be able to slide in-between confirming the inflated cells are supporting the patient.

7.2 Setting up power unit

The power unit can be placed on the floor underneath the chair.

- *Caution: Ensure that the power cable is routed in such a manner so that it cannot be twisted, trapped, crushed or stressed.*

7.3 Connecting cushion to the power unit



Remove the cover of the air pipe connector and connect the air pipe connector to the power unit and then ensure that the air tubes are free from any kind of obstruction, and are not kinked.

Plug the power cable into a suitable electrical socket and switch 'ON' using mains power switch found at the side of the power unit. All indicators on control panel will light up.

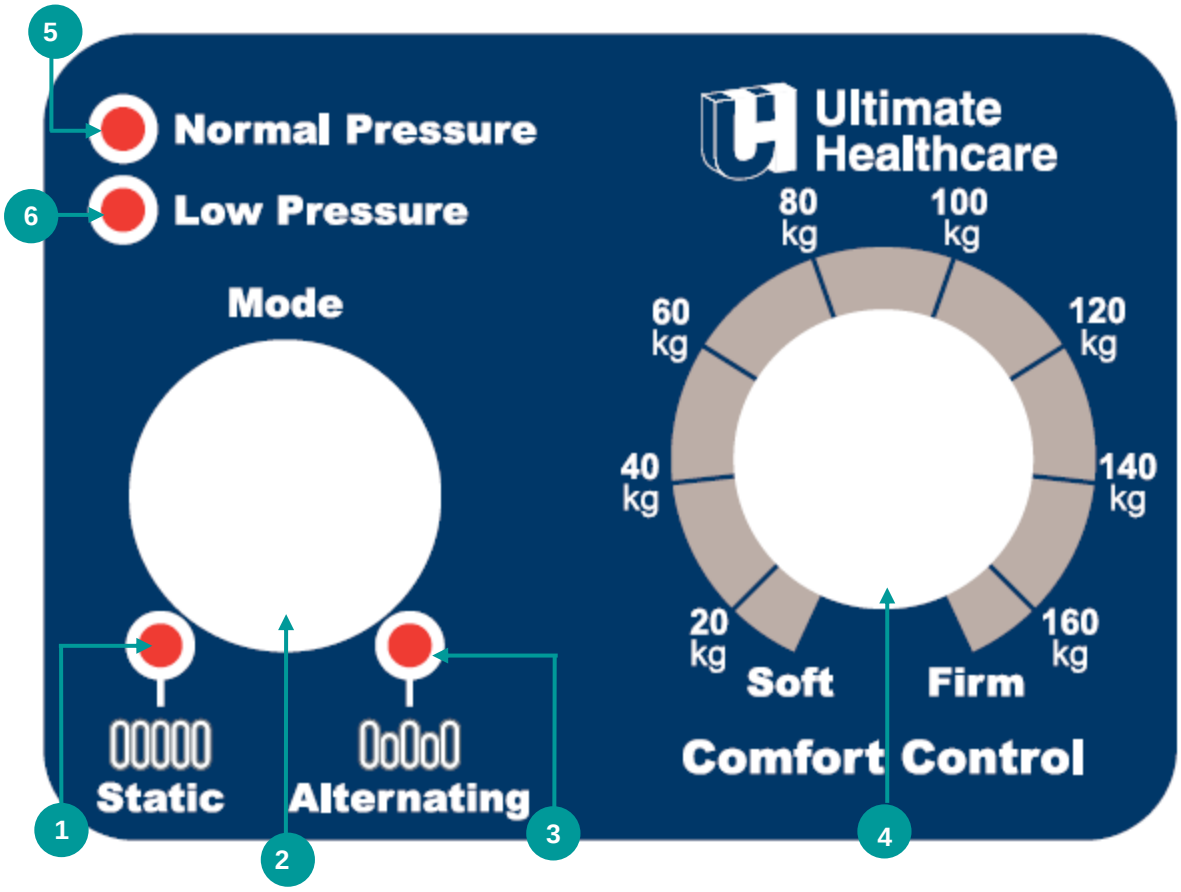
The power unit will start Inflation (inflation mode) and the ***Normal Pressure*** indicator will flash. Turn the comfort control to the maximum.

Once the cushion replacement is fully inflated, you can then set to the appropriate setting suitable for the patient.

- *Caution: The power unit must only be connected to the cushion replacement recommended by the manufacturer. Do not use it for any other purpose.*

8. Control Panel Operation Guide

The Control Panel of the power unit is used to make adjustments to the cushion replacement and also indicates fault conditions. These are either visual (indicator lights) or audible.



1	Static Mode Indicator	4	Comfort Control Dial
2	Function Mode Selection Button	5	Normal Pressure Indicator
3	Alternating Mode Indicator	6	Low Pressure Indicator

8.1 Comfort level

The comfort level adjustment dial allows carers to adjust pressures within a safe pre-set range to provide patients with enhanced comfort or support whilst maintaining a very good level of protection and therapy. Qualified clinical advice must always be taken before adjusting cushion replacement pressures.

When the dial is turned towards ***Firm***, the output pressure will increase to provide a higher pressure output and thus increased support.

When the dial is turned towards ***Soft***, the output pressure will be decreased to provide a lower pressure output and thus increased comfort.

To check if the pressure is adequately supporting the patient, slide one hand between the cushion replacement and chair cushion to feel under the patient's bottom. You should be able to slide the hand in-between and an acceptable range is approximately 25 to 40 mm (1" to 1-1/2") to ensure the patient is not bottoming out.

8.2 Function mode switch

8.2.1 Alternating

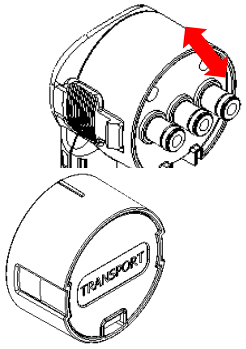
Alternating mode is the default mode for the system. Within this mode the cushion replacement will operate in an alternating 1-in-2 cell cycle. The alternating cycle will continue until another mode is selected.

8.2.2 Static

Pressing the ***Mode*** button until the ***Static*** indicator illuminates puts the system into ***Static*** mode.

Within this mode the cushion replacement will maintain a selected constant pressure. The power unit **MUST** be manually switched back to alternating mode.

9. Transport Mode



If the patient is being moved on the cushion replacement, or there is a power cut, general pressure can be maintained in the system for an adequate period of time whilst disconnected from the mains.

Simply disconnect air pipe connector and place the connector cover over it. The air pressures in the cushion replacement will now equalise, but maintain a degree of comfort. This will maintain the cells in their present state for approximately 48 hours.

It is important to restore the Viola II dynamic cushion replacement as quickly as possible by reconnecting the supply tubes to the power unit.

10. Alarm Indicator

The Viola II is equipped with a visual alarm indicator.

10.1 Low pressure alarm

Upon detection of low pressure, the ***Low Pressure*** indicator will illuminate. The ***Low Pressure*** indicator will continuously illuminate until the low pressure fault condition is resolved.

This condition could be caused, for example, by incorrect fitting of the air pipe connector or a leak in the cushion replacement due to a cut or puncture.

11 Troubleshooting

PROBLEM	SOLUTION
No lights on power unit	• Check the power unit is connected to the mains power supply and that the mains switch is turned ON. • Check power unit for any blown fuses.
Low Pressure indicator is flashing	• Check whether power was suddenly shut down. • Check that the connection between air tube and power unit is tightly secured. • Check that all tubing connections along the cushion are secured.
Patient is bottoming out (without alarm being triggered)	• Pressure setting might be inadequate for the patient, adjust comfort level to Firm and wait for a few minutes for a better comfort.
The power unit is operating but the cushion is not alternating	• Ensure that the cushion inflation process is complete. • Check that the 'Alternate' indicator on the control panel is illuminated. If not, turn the Mode dial to switch to alternating mode.
Power unit is noisy	• Ensure that the power unit is resting against a solid surface.

If the problem persists, contact Ultimate Healthcare or your local service provider.

12 Cleaning and Decontamination

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility of use.

The Viola II system should be routinely decontaminated between patients and at regular intervals while in use; as is good practice for all reusable medical devices.

- *Warning: Disconnect the power unit from the electricity supply before carrying out cleaning/decontamination procedures.*
- *Do not immerse or soak power unit.*

12.1 Basic cleaning information

- *Caution: Only use disinfectants designed for cleaning healthcare equipment i.e. Sodium Hypochlorite or similar (up to 10,000 ppm available chlorine).*

- *Caution: Do not use abrasives (scouring powder), scourers or other materials/agents which could damage the cushion system.*
- *Caution: Do not use sodium carbonate or phenol based solutions.*
- *Caution: Do not use fabric softener or biological washing detergents.*
- *Caution: Do not immerse the power unit in water.*

- *Caution: When cleaning/disinfecting, ensure that only a damp cloth is used.*
- *Caution: After cleaning, dry the cushion out of direct exposure to sunlight.*

- *Caution: Using inappropriate detergents or disinfectants and not observing the manufacturer's guidelines may result in damage to the cushion which Ultimate Healthcare cannot be held liable for.*

- *Caution: The appropriate qualified staff must be consulted when specifying a suitable cleaning fluid. Ultimate Healthcare shall not be liable for any damages caused by the use of inappropriate detergents or disinfectants.*

12.2 Cushion and cover disinfection

The Viola II cushion replacement, cushion cover and air pipe cover can be cleaned using the following simple procedures in accordance with your Local Infection Control Policy:

- Liberally swabbing with a damp cloth pre-soaked with hot water at 84°C containing detergent, and then drying.
- Swabbing with a solution of sodium hypochlorite (up to 10,000 parts per million available chlorine) and then drying.

- Caution: Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of cushion. Surfaces must be protected during use and rinsed and thoroughly dried after application of a disinfectant.

12.3 Power unit disinfection

The power unit can be cleaned by wiping down with a cloth dampened with hot water at 60^0C containing detergent or with sodium hypochlorite (up to 10,000 parts per million available chlorine).

12.4 Cover laundering

The cushion cover and air pipe cover can also be machine washed. Cushion covers and air pipe cover should be completely removed prior to laundering.

Where required cushion covers can be laundered in a pre-wash at 60^0C for up to 15 minutes and in a main wash at 84^0C for up to 15 minutes. This should be followed by a cold rinse and extraction.

However it is recommended that you check your local policy to determine the time/temperature ratio required to achieve thermal disinfection.

Cushion covers may be tumble dried or air dried. They may be tumble dried on a low heat for up to 90 minutes. Drying temperature must not exceed 40^0C.

The cushion cover and cushion must be dry prior to refitting.

- Caution: Exceeding the temperature can cause significant damage to the cushion cover.

13 Storage

The cushion replacement should be loosely rolled lengthwise with the cover innermost, taking care not to strain the air pipe. It should then be placed in in a suitable protective cover with the power unit and stored in an area appropriate for electronic medical devices.

- Disconnect the air hose connector to release the air.
- The power cord could be wrapped around the power unit bumper or disconnected for storage.

- *Caution: Do not fold or crease cushions*

14 Service and Maintenance

It is recommended that this product be part of a routine preventative maintenance schedule with a planned service every 12 months regardless of product usage.

14.1 General

(1) Check power cable and plug if there are abrasions or excessive wears.
(2) Check cushion cover for signs of wear or damage. Ensure cushion cover and tubes are stubbed together correctly.
(3) Check the air hoses for any kink or break. For replacement, please contact Ultimate Healthcare or your local distributor.

14.2 Fuse replacement

(1) Disconnect the plug from mains power when a blown fuse is suspected.
(2) Remove the cover of the fuse holder by means of a small screwdriver.
(3) Insert a new fuse of the correct rating in, and replace the cover of the fuse holder back. The fuse should be rated as T1A.

14.3 Air filter replacement

(1) Replace the air filter located at the handle on the back of the power unit.
(2) The filter is reusable and can be washed gently with a mild detergent and water. Dry the filter before use.
(3) Check and replace air filter regularly if environment is dirty.

15 EMC Information

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment			
TheAlternating Pressure Air Flotation Mattress is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of theAlternating Pressure Air Flotation Mattress can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Alternating Pressure Air Flotation Mattress as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=\left[\frac{3,5}{1}\right]P$	**80 MHz to 800 MHz** $d=\left[\frac{3,5}{1}\right]P$	**800 MHz to 2.5 GHz** $d=\left[\frac{7}{1}\right]P$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.33**
10	**3.7**	**3.7**	**7.37**
100	**11.67**	**11.67**	**23.33**

TheAlternating Pressure Air Flotation Mattress declaration – electromagnetic immunity

TheAlternating Pressure Air Flotation Mattress system is intended for use in the electromagnetic environment specified below. The customer or the user of theAlternating Pressure Air Flotation Mattress system 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 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	

Declaration – electromagnetic immunity

TheAlternating Pressure Air Flotation Mattress system is intended for use in the electromagnetic environment specified below. The customer or the user of theAlternating Pressure Air Flotation Mattress system should assure that it is used in such an environment.

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 for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common 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. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic emissions

TheAlternating Pressure Air Flotation Mattress is intended for use in the electromagnetic environment specified below. The customer or the user of theAlternating Pressure Air Flotation Mattress should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
CE emissions CISPR11	Group 1	TheAlternating Pressure Air Flotation Mattress 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.
RE emissions CISPR11	Class B	TheAlternating Pressure Air Flotation Mattress is 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	

Notes:

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