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USER MANUAL AND TECHNICAL DECRRIPTION

Air2Care 4

Seat Cushion System

CE

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1. IMPORTANT SAFEGUARDS AND STATEMENTS

When using electrical products, especially when children are present, basic safety present, basic safety precautions should always be followed, including the following:

Warning

If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Danger

To reduce the risk of electrocution:

- Always unplug this product immediately after use.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquids.
- Do not reach for a product that has fallen into water. Unplug immediately.

Warning

To reduce the risk of bums, electrocution, fire, or injury to persons:

- A product should never be left unattended when plugged in.
- Close supervision is necessary when this product is used by, on, or near children or invalids.
- Use this product only for its intended use as described in this manual.
- Do not use attachments not recommended by the manufacturer.
- ONLY use adaptor and rechargeable battery recommended by the manufacturer.
- Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center for examination and repair.
- Keep the power supply cord away from heated surfaces.
- Never block the air openings of the product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
- Never drop or insert any object into any opening or hose.
- Do not use outdoors or operate where aerosol (spray) products are being used.
- Connect this product to a properly grounded outlet only.
- Do not play with the supply cord and air hose of the product to prevent strangulation.

Note

Indicates some tips or some information users should be aware of.

Caution

Indicate correct operating or maintenance procedure in order to prevent damage to or destruction of the equipment or other property.

2. INTRODUCTION

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

2.1 General

Air2Care 4 is a high quality, affordable pressure relief seat cushion system for wheelchair users. It helps to decrease the concentrated pressure, distribute the pressure over the entire contact interface and stimulate capillary blood flow for the prevention of pressure ulcers.

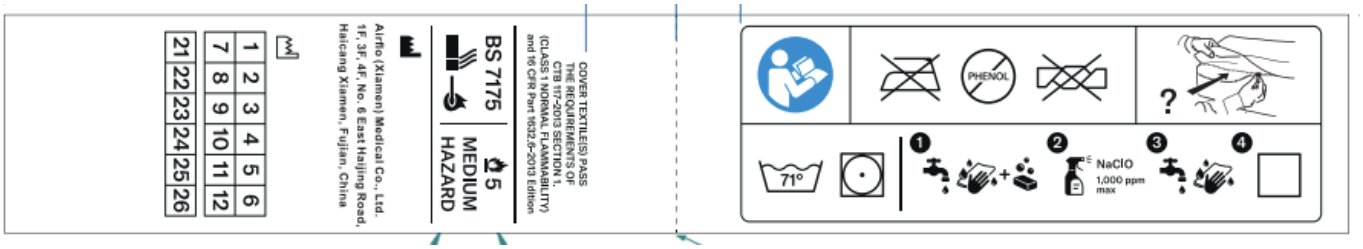
The system has been tested and certified for the following standard:

- EN 60601-1:2006/A1:2013,
- EN 60601-1-2:2015
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013
- BS7175 (non-harmonized)
- BS5852 (non-harmonized)

2.2 Product Label and Technical Label

The legal label and UDI label are located on the back of the pump (system control unit). The serial number, model number, and the input rating can be found on the label. This information is required if any issue occurs.

Figure 1. Wash Label (Air2Care 4 Seat Cushion)



3. INTENDED USE

- To help and reduce the incidence of pressure ulcers while optimizing patient comfort.
- For home care, long-term care, and hospital care patients suffering from pressure ulcer.
- For pain management as prescribed by a physician.
- The PATIENT can be an intended OPERATOR.

Warning:

- No servicing and maintenance can be performed while the product is in use.
- All the functions can be operated by patient.
- No maintenance except for cleaning can be performed by patient.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- The pump has no AP or APG protection.

4. CONTRAINDICATIONS

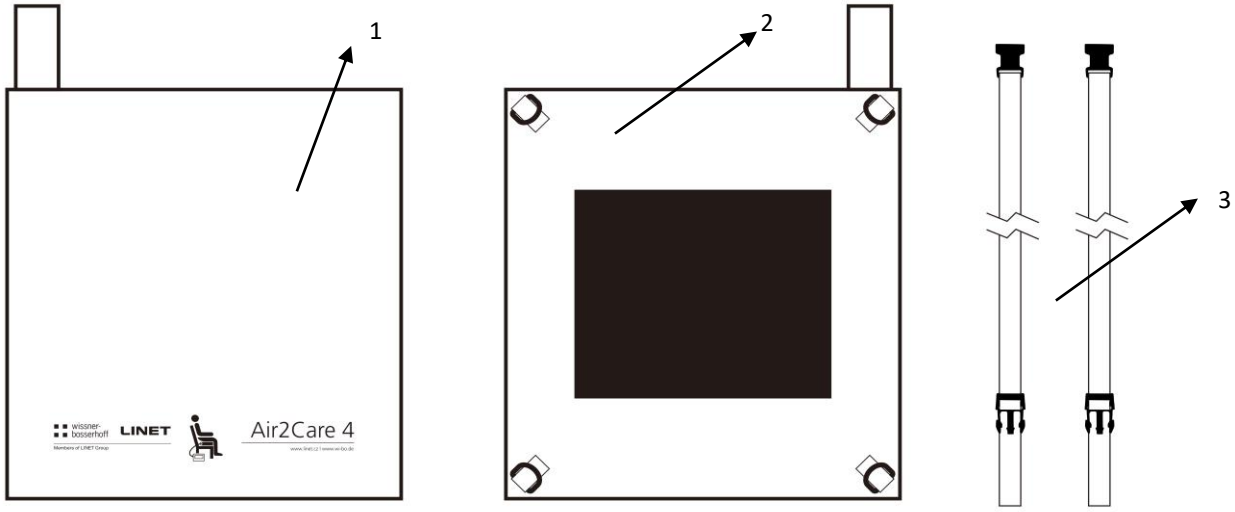
Patient conditions for which the application of pressure relieving therapy on an alternation system is contraindicated are as following:

- The patient's wound cannot be in direct contact with the cushion.

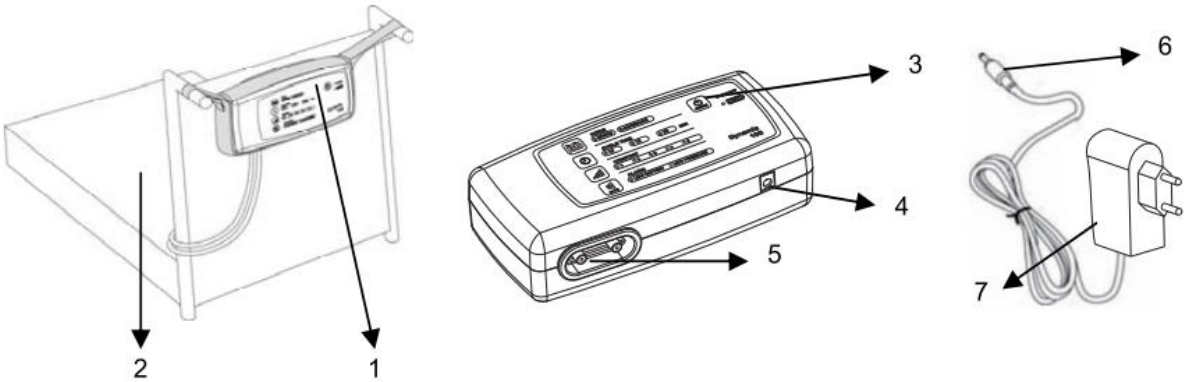
5. PRODUCT DESCRIPTION

The device is an active alternating pressure seat cushion system and consists of a reliable pump and seat cushion providing the best pressure relief. It comes equipped with a fully digitalized pump and each function mode can be adjusted individually, such as cycle time and comfort range. It provides you with total pressure management control and runs on AC power supply or a Lithium rechargeable battery.

5.1 Pump and Seat Cushion System



1. Seat cushion from the upper side
2. Seat cushion from the bottom side
3. 2 fixing straps to xi to chair if required



1. Pump unit
2. Cushion
3. Control Panel
4. DC Power Socket
5. Air outlet
6. DC Plug
7. AC/DC Adaptor

Caution:

- Do not drop water on to the device.
- Do not apply shock to the device.
- Do not disassemble or modify the device.
- Do not block the air outlet.

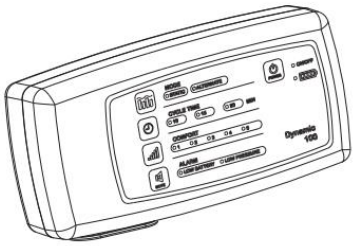
- **Do not use any power adapter and battery pack not provided by the manufacturer.**
- To prevent battery pack damage, please remove the battery pack from the battery compartment when not using the device for a long period.

6. INSTALLATION

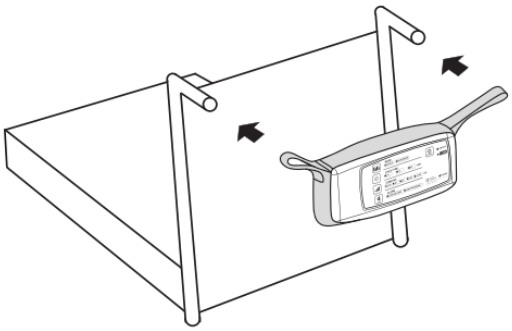
6.1 Unpacking

Unpack the box to remove the pump unit, seat cushion and other accessories and check for any damage, which may have occurred during shipping. If there is any damage, please contact your dealer immediately.

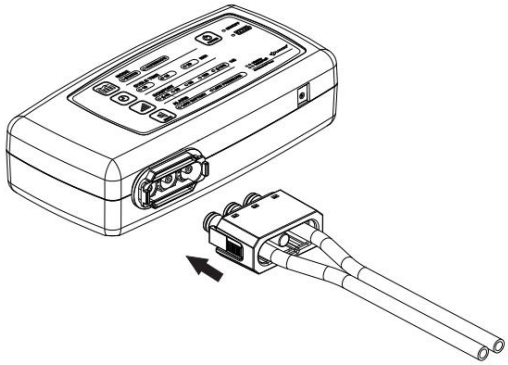
6.2 Setting Up



1. Place the seat cushion on top of the (wheel) chair. The anti-slip mat at the bottom of cushion will prevent slippery. If required the fixing straps can be used to fix to chair.

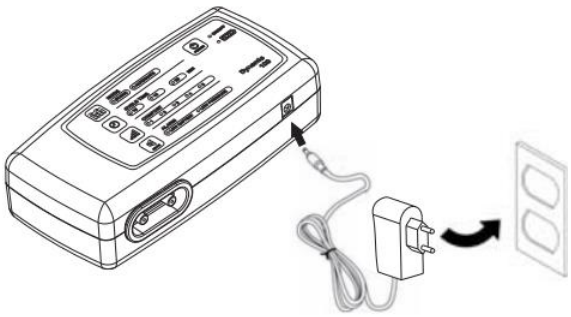


2. Put the pump into the carry bag and hang the pump on the (wheel) chair handle or frame with the straps of the carry bag.



3. Connect air tubes from the seat cushion to the pump unit.

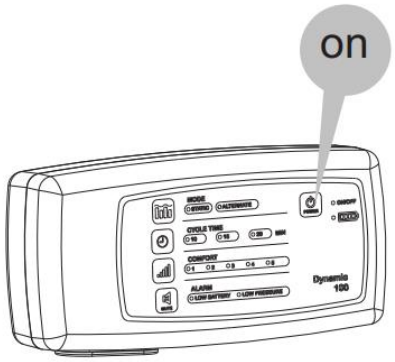
   Note: *Check and ensure the air tubes have no kinks in them and are not tucked under the cushion.*



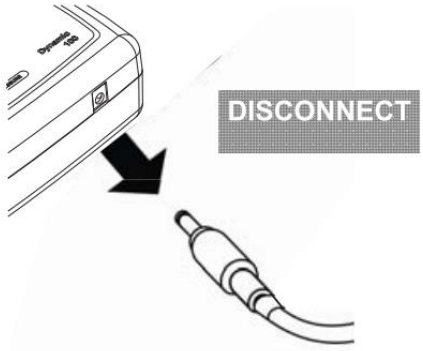
4. Connect the AC/DC adaptor to DC power socket of the pump unit Plug into mains electrical outlet.

   Note: *Use only with original manufacturer's adaptor, improper use of adaptor or charge with adapters other than supplied from the manufacturer will possibly cause damages and will not be covered under the warranty.*

   Note: *The system can operate in battery mode only when the DC Plug is disconnected from the pump unit.*

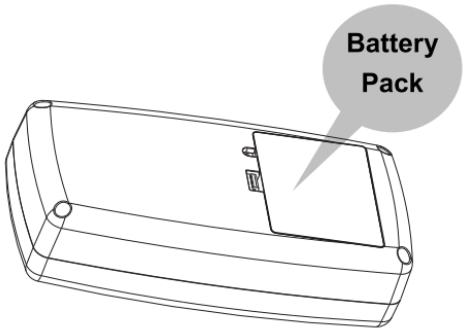


5. Press the power button for 1 second to start the working. When the pump unit is turned on, the ON/OFF indicator will light up.



6. Battery Pack instruction:

- Please make sure the battery is fully charged (the battery charge indicator light turns off). The typical charging period is 4 hours.
- Do not use this product while charging, it may extend the charging time of the battery or the battery may not charge fully.
- After the battery is fully charged, the pump has 24-48 hours of continuous operation time depending on cycle time set by user.
- The lifetime of the rechargeable battery is about 12 months or more.



Note: To operate from the battery, the AC/DC adaptor must be removed from the DC power socket of the pump unit.

7. Replace the battery recommended by the manufacturer, if the performance becomes undesirable.

Caution: If the battery charge indicator continues to illuminate after 24 hours of charging. Please do disconnect the adaptor and do NOT continue to charge.

6.3 Battery Status Indicator

Regularly check the battery indicator on the control panel to determine the status of the rechargeable battery. The following indicators indicate the battery status:

- Low Battery indicator light on: Battery charging is required.
- Battery Charge indicator light on: AC power is charging the battery.

⚠ *Caution:*

1. Please keep the battery pack out of the reach of children.
2. The battery pack is a Lithium rechargeable battery, which can explode if not properly replaced, used, handled or disposed of.
3. Dispose of the battery as required by local ordinance or regulation.

7. CLASSIFICATION

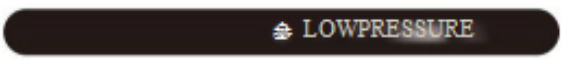
- Electrical safety class - Class II
- Type BF Applied Part (The mattress is applied part).
- IP21.
- Continuous operation.

⚠ ***Caution:*** The plug of supply cord is used as the isolation means from mains, do not to position the product to make it difficult to operate this disconnection device

8. OPERATION

Note: Always read the operating instruction before use.

8.1 Function Description

Control Button & Indicator	Function Description
Power 	Press this button for 1 second, then turn on control unit. Press this button for 1 second again, then turn off control unit.
Alarm Mute 	Press this button to mute the audible alarm.
Therapy 	To switch the mode: alternate or static mode.
Cycle Time 	To adjust the pressure alternating cycle time to 10, 15 or 20 minutes.
Comfort 	To adjust the comfort level according to user's preference or doctor's advice. There are 5 different comfort levels: 1 is the softest & 5 is the firmest.
Low Battery Indicator 	The light indicates the battery power is low. When the power in the battery pack becomes low, the low battery indicator flashes to indicate that only a few minutes of battery power remain. You must recharge the battery pack or use AC power source immediately.
Low Pressure Indicator 	The light indicates that the cushion pressure is under 10 mmHg.
Battery Charge Indicator 	The light indicates that the rechargeable battery pack is charging.

8.2 Operating Instructions

1. Press the POWER button on the display panel to start the system.
2. Before cushion is fully inflated, user can change the comfort setting according to their preference or doctor's recommendations.

8.3 Comfort and operation mode setup

Users can adjust the comfort levels according to their preference or doctor's advice. The unit provides two operation modes for option, alternating and static pressure mode. Please select the correct settings. The

pressure alternating cycle time is also adjustable 10, 15 or 20 minutes.

8.4 Low pressure

When low pressure occurs, the Low Pressure indicator will light on and flash. The alarm will restart in 30 seconds, if the pump still exists low-pressure condition after pressing the alarm mute button. Once the low-pressure condition is not solved in 15 minutes, the pump will turn off automatically.

8.5 Low battery

When low battery occurs, the Low battery indicator will light on and flash. The alarm will restart in 30 seconds, if the pump still exists low-battery condition after pressing the alarm mute button. Once the low-battery condition is not solved in 15 minutes, the pump will turn off automatically.

9. CLEANING

This section describes the procedures to clean the system. It is important to follow these procedures and thoroughly clean a used system. It will greatly help to prevent the possibility of patients getting infection.

⚠ ***Caution:*** Do not use phenol based products for cleaning. Please ask your distributor for suitable and locally available cleaner.

9.1 Pump Unit

Wipe with a damp cloth and a mild detergent and keep dust away from it. If another detergent is used, choose one that will have no chemical effects on the surface of the pump unit. All parts should be air dried thoroughly before use.

⚠ ***Caution:*** Ensure the pump unit is disconnected from the mains before cleaning.

9.2 Seat Cushion

The carrying bag should be turned inside out and completely wiped down using disinfectant solutions. Allow it to air-dry thoroughly. Once the inside is dry, turn it back and wipe down the outside of the bag with disinfectant solutions.

⚠ ***Caution:*** Dry the Seat Cushion in SUNLESS area after cleaning.

10. STORAGE

1. Disconnect the air tube from the cushion to the pump.
2. Protect the air tube by putting it inside of seat cushion.
3. For storage period more than 3 months, disconnect the Lithium battery pack from the pump.

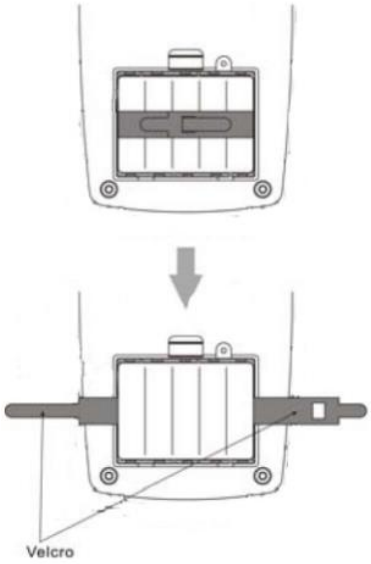
11. MAINTENANCE

11.1 General

1. Check main power cord and plug to see if there is any damage.
2. Check the covers of seat cushion for damage. Ensure tubing is stacked together correctly.
3. Check the air tubes to see if there are kinks. For replacement, please contact local distributors.

12. BATTERY PACK REPLACEMENT

To replace the battery pack, follow the instructions below.



1. Remove the AC power source & disconnect the DC plug.
2. Open the battery cover by removing the screw on the back of the pump unit.
3. Unfasten the Velcro and take out the battery pack.
4. Insert a new battery pack and secure the Velcro again.
5. Put the cover on and screw back.
6. Connect the DC plug to the DC power socket on the pump unit.
7. Plug the AC/DC adaptor into electrical outlet to charge the battery.

⚠ ***Caution:*** It is prohibited to use the battery pack not from the dealerThe charging function of the pump is designed for the battery pack only. The dealer will not warranty any damage from another battery pack not supplied by the dealer.

Note: Higher temperature will shorten life of the battery pack, please keep the battery in a cold place and avoid direct sunlight.

Note: The Velcro serves to secure the battery for the purpose of ensuring the stability of battery pack. It's recommended to check if the Velcro is secured before screw the cover back.

13. TROUBLE SHOOT

Problem	Solution
Power is not ON	• Check if the plug is connected to mains. • Check if the power cord is well connected to the pump • To operate from battery, check if the DC plug is disconnected from the pump unit
Alarm is on (audible & visual)	• Check if the connection between air tube connector to pump unit is tightly secured. • Check if all tubing connections along cushion are secured. • Check if there is any leakage from air cells. • Check if the battery is low
Cushion becomes too firm and pressure can't be lowered	• The pressure is too firm for long time, release some air by disconnecting the air tube connector and change to your preferred setting.
No air is produced from the air outlet of the air tube connector	• This is normal since it is at alternating mode. Air outlets take turns to produce air during their preset cycle time.
Low pressure, fail to resolve.	• Check each air cell. Please select the operation mode as static mode so that all the air cells will be inflated. Then ensure each single cell is not broken. • Examine for air leakage from tubes. Ensure no leakage occurs. • If any leakage occurs, please contact your dealer.. • Plug in the pump unit and check the airflow from the hose connection port.
Battery fail to obtain full charge.	• After the battery is fully charged (about 4 hours), the pump immediately has 36 hours of continuous operation time. If it is unable to operate 30 hours, the battery pack might need to be replaced. • If the low battery indicator still lights up after it has been properly recharged for approximately 4 hours, the battery pack might need to be replaced. Replacement • required after about 12 months.

14. SYMBOLS

Symbol	Meaning
	Power ON.
	Power OFF.
	Alternating current.
	Manufacture.
	Authorized representative in the European Community.
	Date of manufacture.
	Series number.
	Class II Medical electric equipment.
	Type BF applied part.
	Refer to instruction manual/ booklet.
IP21	Degree of protection against harmful ingress of water and particulate matter.
	Caution.
CE 0197	CE certification.
	General warning sign.
	Do Not Bleach
	Do Not Iron
	Tumble Dry, Normal, Low Heat
	Dry clean, Any Solvent Except Trichloroethylene
	Machine wash, regular / normal, 95 degrees C (203 degrees F)
	Disposal of Electrical & Electronic Equipment (WEEE): This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

15. TECHNICAL SPECIFICATIONS

Item		Specification
Power Supply		DC12.6V, 0.95A by adaptor
Power consumption		12V DC, 300mA
Device Dimension (L x W x H)		21x10.5x6 cm/8.3x4.1 x2.4 inch
Device Weight		0.75 kg /1.65 lb (battery and adaptor included)
Environment	Temperature	Operation: 5°C to 40°C (41 °F to 104°F) Storage: -10°C to 50°C (14°F to 122°F) Shipping: -10°C to 70°C (14°F to 158°F)
	Humidity	Operation: 30% to 75% non-condensing Storage: 10% to 75% non-condensing Shipping: 10% to 90% non-condensing
Classification		Type BF, IP21
		Applied part: Air Seat Cushion Not suitable for use in the presence of a flammable anaesthetic mixture (No AP or APG protection)
Pressure Range		Five selectable settings
Cycle Time		10, 15, 20 minutes
Battery Pack		12V Lithium Battery (2200 mAh)
Cushion		**Specification**
Dimension (Lx Wx H)		46 x 48 x 10 cm /18 x19 x 4 inch
Weight		1.8 kg or 3.9 lb

Note:

1. The battery performance may be reduced if the device is used in a cold environment.
2. Consult the distributor for other technical documents.
3. Please follow national requirements to dispose of the unit properly.
4. The manufacture reserves the right to change product specification without prior notice

16. EMC GUIDANCE

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

Caution:

1) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
2) This unit has been thoroughly tested and inspected to assure proper performance and operation.
3) This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in 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	

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d=1.2\times P^{1/2}$	**80 MHz to 800 MHz** $d=1.2\times P^{1/2}$	**800 MHz to 2,5 GHz** $d=2.3\times P^{1/2}$
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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±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.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U T (>95% dip in U T .) for 0.5 cycle 40 % U T (60% dip in U T) for 5 cycles 70% U T (30% dip in U T) for 25 cycles <5% U T (>95 % dip in U T) for 5 sec	<5 % U T (>95% dip in U T .) for 0.5 cycle 40 % U T (60% dip in U T) for 5 cycles 70% U T (30% dip in U T) for 25 cycles <5% U T (>95 % dip in U T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the model Scorpio be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 10 V/m 80 MHz to 2.7 GHz **385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 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)**	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[3,5/V_1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ *80 MHz to 800 MHz* $d=2.3\times P^{1/2}$ *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,[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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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EC REP

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