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1. Explanation of Label Symbols and Statements

	Read the user manual		Example of a UDI label (located on the rear of the power unit and in the seam of the cover/base tray)
	Warning		Foot End
	Medical Devices Directive 93/42/EEC Medical Device Regulation 2017/745		Min. - Max. patient weight
	Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)		Safe Working Load
	Class II Equipment (Double Insulated)		Machine wash 73°C max.
	Do not dispose of with the normal household waste		Tumble dry low heat
	Manufacturer		Do not dry clean
	Date of manufacture		Do not iron
	Suitable for connection to type BF applied parts		Do not bleach
IP21	IP: Ingress Protection 2: Protection against finders or other objects not greater than 80mm in length and 12mm in diameter 1: Protection from vertically dripping water		Do not use Phenol
MD	Medical Device		Do not use sharp instruments
REF	Article Number		No smoking
SN	Serial Number		Fragile, handle with care
0	Power OFF		Keep dry
I	Power On		Protect from heat and radioactive sources
	Operating Instructions		Temperature limitation
WARNING	This is a statement that alerts the user to the possibility of serious injury or other adverse reactions with the use or misuse of the device		Humidity limitation
CAUTION	This is a statement that alerts the user to the possibility of a problem with the system associated with its use or misuse		Atmospheric pressure limitation
EC REP	Authorised Representative in the European Community		

2. Introduction

Thank you for choosing to use a QUATTRO Plus Nexus active support surface, designed to reduce the risk of pressure related tissue injury via an active therapy alternating air pressure cycle.

3. Important Information

3.1 Intended Use

QUATTRO active support surfaces are designed to reduce the risk of pressure related tissue injury in patients who are identified as being at an elevated risk of pressure ulceration and / or to help manage patients with existing pressure related tissue injury.

3.2 Intended Environments

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

- Hospital
- Professional Healthcare facilities
- Home Healthcare

and for the following scenarios:

- Bed Mattress Replacement (replaces an existing mattress)

3.3 Contraindications for Use

Active support surfaces should not be used for patients with unstable fractures, gross oedema, burns or an intolerance to motion.

3.4 General Warnings, Cautions and Information



- There are no special skills required to operate the system.
- The medical professional is responsible for applying his/her best medical judgment when using this system.
- Select correct setting for therapy required. Care should be taken not to accidentally change pressures once set as the efficiency of the therapy may be reduced. This could also be caused by pets, pests or children.
- The electricity supply is of the type indicated on the power unit
- Check the mains power cord is free from damage and is positioned so as not to cause an obstruction, or injury, e.g. strangulation.
- Ensure the mains power cord or power unit cannot become trapped or crushed, e.g. via raising or lowering of bed or bed rails or any other moving object.
- The power unit must only be used with a suitable approved cord and plug set as supplied by Direct Healthcare Group.
- Do not use in the presence of flammable anaesthetics.
- Electric shock hazard; do not remove back of power unit.
- Refer servicing to qualified service personnel.
- When servicing use only identical parts.
- Suitable for continuous use.
- To disconnect the power unit from the mains supply remove the mains power cord from the mains outlet wall socket.
- Do not position the power unit in such a way that makes it difficult to disconnect the mains power cord from the device or the mains outlet.
- Do not position the power unit in such a way that makes it difficult to disconnect the mattress from the power unit.
- Do not place device on or near a heat source.
- Do not use with hot water bottles or electric blankets.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Direct Healthcare Group advise against smoking whilst the system is in use, to prevent the accidental secondary ignition of associated items which may be flammable, such as bed linen.
- Do not allow sharp objects to penetrate the mattress material.
- WARNING: No modification of this equipment is allowed.
- Do not store in damp conditions.
- Do not use in an oxygen enriched environment.
- Do not use in an outdoor environment.
- No part of the medical device should be serviced while it is in use by the patient.
- The medical equipment requires 5 hours to warm from the minimum storage temperature before it is ready for its intended use.
- The medical equipment requires 1 hour to cool from the maximum storage temperature before it is ready for its intended use.
- Intended for use in hospital, professional healthcare facility and home healthcare environments.

- The power unit is intended to be hung over the footboard of a bed.
- Wireless equipment such as mobile phones should be kept at least 1 foot or 0.3 metres away from the equipment.
- Do not connect the power unit or mattress to any other medical device or equipment.
- Risk of fire if incorrect fuse used.
- The mattress and power unit should be cleaned between patient use, please refer to Care and Maintenance section for all warnings and cautions.
- Not suitable for sterilisation.
- The mattress must be properly set up as directed.
- Check periodically to ensure patient support and comfort, adjusting the COMFORT CONTROL setting if desired.
- All hoses must be free of kinks, twists, properly connected and positioned so as not to cause an obstruction or injury.
- In order for the alternating air pressure mattress/cushion to operate effectively, please avoid placing objects on the surface that may obstruct the movement of air between the cells. For the same reason, please discourage people from sitting on the edge or on the end of the mattress whilst it is in use.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline, as these may destroy the cover materials (*see Care and Maintenance).
- The system is used as part of a pressure ulcer prevention and/or management program, not solely relied upon for this purpose.
- It should be noted that the use of a cushion will increase the patient's seated height by approximately 5cm, and care should be taken to ensure the patient's comfort and security regarding height of foot and arm rests.
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

4. Installation Guidelines

4.1 Installing Mattresses

NB. The power unit display default language is English, but can be changed to the language of your choice (please see 'Setting/Changing Power Unit Display Language').

1. Remove any existing mattress from the bed frame (the QUATTRO mattresses are intended to completely replace the bed mattress).
2. Place the mattress on the bed frame. Ensure the mattress hose exits at the foot end on the right hand side and the coloured cover is uppermost (Fig. 1).
3. Secure the mattress to the bed frame using adjustable straps - pass straps around bed frame mattress platform and secure with the buckles (Fig. 2), allowing for moving components on electric bed frames. This is important as it stops the mattress becoming detached from the bed frame and causing possible injury to the patient. A strap extension kit is available for use with divan beds (part number 11062).
4. Suspend the power unit from the foot board of the bed having first adjusted the hanger brackets as follows:
 - a) Rotate each hanging bracket away from the pump.
 - b) Position the brackets to hang the pump on bed.
 - c) Fold the brackets towards the pump when not in use.

Alternatively the power unit may be placed on the floor.

5. Attach the air supply hose to the power unit by aligning the black line on the air supply hose connector with the black line on the power unit connector and pushing together. Rotate the mattress hose connector clockwise until the green indicator fills the indicator hole on the power unit connector (Fig. 3).
6. Plug the smaller end of the power cord into the left hand side of the power unit, and the other end into mains outlet in wall. Ensure that the power cord and tubing cannot become trapped in the bed frame.
7. Switch the power on at the outlet, and at the side of power unit adjacent to the power cord entry.

Fig. 1

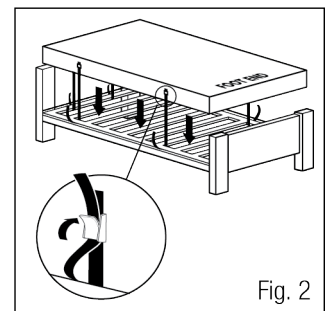
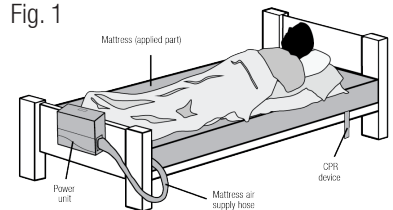


Fig. 2

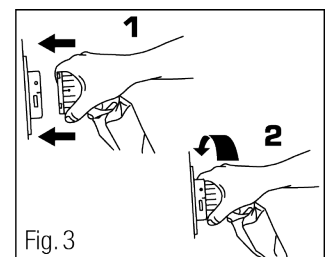


Fig. 3

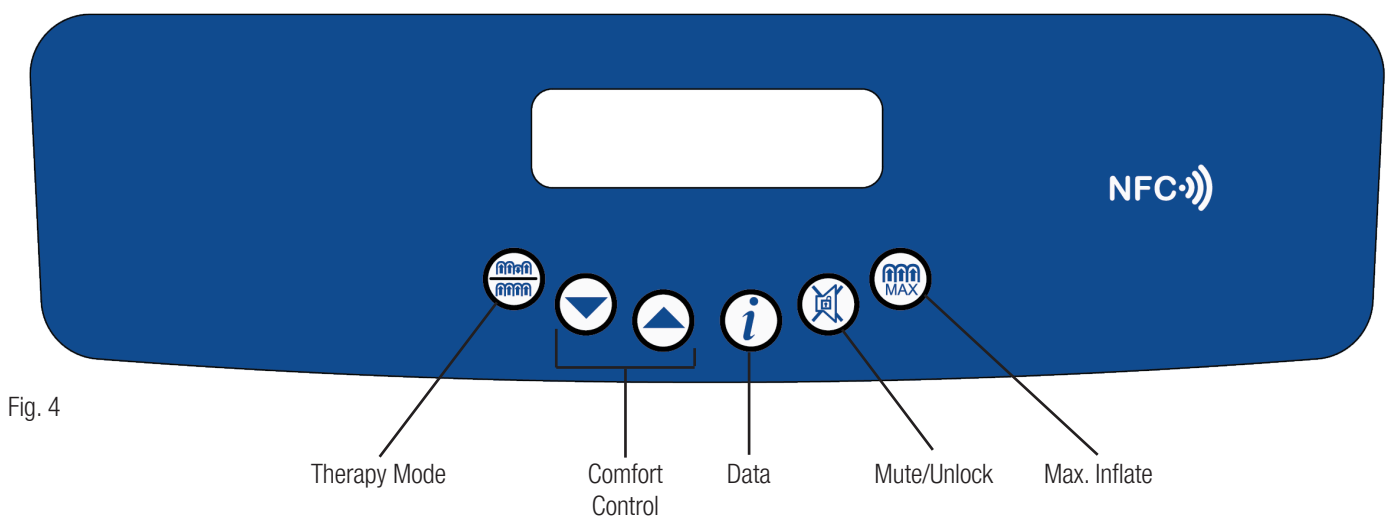
8. The system will display STARTING, then INITIALISING whilst the mattress inflates (this will take between 15 - 20 minutes).
Note: It is important that during the INITIALISING phase the mattress connector is not disconnected from the power unit. If this is done, the power unit must be switched off, MUTE button pressed when the sounder is heard, the mattress connector re-engaged, and the power unit restarted. If UNCALIBRATED is displayed when switched on, the system will continue to operate but should be recalibrated as soon as possible.
9. When a bed sheet is added to the mattress, ensure that it is left loose to allow the mattress surface to conform with the patient's body as much as possible.
10. Allow the mattress to inflate before positioning the patient on the mattress.
11. Once inflated the system will automatically default to ACTIVE mode. CONTINUOUS LOW PRESSURE therapy can be selected via the THERAPY MODE button (please see THERAPY MODE). The comfort setting can be adjusted using the up and down arrow buttons (see COMFORT CONTROL).
NB. The power unit will automatically lock 2 minutes after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by '🔒' on the display screen. Press and hold the MUTE/UNLOCK button until power unit beeps if further button operation is needed (i.e. change of therapy mode or comfort setting).
12. Place the user manual in a safe place for future use.

5. Operation Guidelines

5.1 Operation Controls

N.B. Before any operation buttons will function (except MUTE), the power unit must be unlocked** - press and hold the MUTE/UNLOCK button until the power unit beeps and the lock symbol clears from the display screen.

The operation buttons on the face of the power unit (Fig. 4) provide the following functions.



Therapy Mode

Pressing the THERAPY MODE button will toggle between ACTIVE (1 in 4 alternating air pressure cycle) and CONTINUOUS LOW PRESSURE therapy modes. The selected therapy mode is shown on the display screen. The default mode is ACTIVE therapy. To switch to CONTINUOUS LOW PRESSURE mode (once unlocked**), press THERAPY MODE button for 2 seconds until an audible tone is heard. The system will then display 'PLEASE WAIT' and requires approximately 2 minutes to initialise



Comfort Control

Air pressure is regulated within each of the cells throughout the cycle so that support, posture and therapy are constantly maintained at optimum levels, in response to patient weight, movement and position. Equalisation of cell pressure automatically takes place at each stage of the alternating air pressure cycle, **again to ensure precise pressure and therapy is provided. The automatic default comfort setting is MEDIUM.** However, if the patient requires a firmer or softer mattress, increase or decrease the comfort control setting accordingly (once unlocked**) using the UP and DOWN arrow buttons (SOFT/MEDIUM/FIRM). The comfort setting is shown on the display screen. Check periodically to ensure patient support and comfort, adjusting the COMFORT CONTROL setting if required.



Data (Used for accessing information only, does not affect mode of operation)

Pressing the DATA button at any time switches the display into DATA mode. Use the up and down arrow buttons to scroll through the product data and user information set. Pressing the DATA button again returns the display to the previous mode.



**Mute/Unlock

Press to silence the sounder and to clear the message from the display screen. The power unit will automatically lock 2 minutes after the last button operation when running to prevent the inadvertent operation of button functions (except MUTE), as indicated by '🔒' on the display screen. Press and hold the MUTE/UNLOCK button until the power unit beeps if further button operation is needed (i.e. comfort setting). The power unit will lock again 2 minutes after the last button operation.

NB. After power failure/switching the power off, pressing MUTE cancels the system's previous settings. When power returns the default setting of ACTIVE mode, MEDIUM comfort setting is invoked. (Note that previous settings are automatically cancelled if the duration between switch off and switch on is greater than 12 seconds. If power returns before a period of 12 seconds has passed and the MUTE button has not been pressed, the system will return to the previous mode of operation.)



Max. Inflate

Necessary for some nursing procedures, the MAX INFLATE mode inflates the mattress to maximum static pressure for a period of 15 minutes. After pressing the MAX INFLATE button (once unlocked**) to inflate mattress, the system displays 'PLEASE WAIT' followed by 'READY' and a 5 second audible tone when maximum pressure is achieved and 'MAX INFLATE' is shown on the display screen. After 15 minutes the system automatically returns to the ACTIVE mode of operation.

5.2 Setting/Changing Power Unit Display Language

The power unit display default language is English, but can easily be changed to the language of your choice, as follows:

1. Plug the power cord into the power unit and into the mains outlet. Switch the power unit on with DOWN arrow button pressed at the same time. Once the power unit has started, release the DOWN arrow button. This enables you to enter the test menu. The power unit will display "TEST MODE CAL" (Fig. 5a).
2. Now press UP arrow button once and the power unit will display "TEST MODE Set language" (Fig. 5b).
3. Press and hold the DATA button to scroll through the list of available languages. Release the DATA button when the required language is displayed. The unit will now be in the language you have selected (Fig. 5c). Switch the power unit off to exit the test menu. At next switch on the power unit will display your selected language.

Fig. 5a

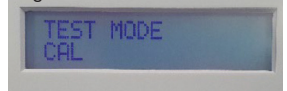


Fig. 5b

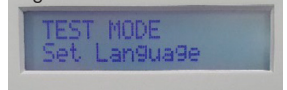


Fig. 5c



The language can be changed as many times as required.

NB. The power unit language cannot be changed whilst the power unit is running.

Languages available include: French; German; Spanish; Italian; Dutch; Finnish; Norwegian; Danish, Swedish (other languages may also feature).

5.3 CPR Facility

The CPR device is situated at the head end on the right hand side of the mattress (viewed from foot end), as indicated by the two tags on the mattress (fig. 6). For rapid deflation pull on both tags simultaneously. If re-inflating the mattress, make sure that the pull tags are secured to re-seal the air within the system.

Fig. 6



5.4 Patient Transport Facility (Fig. 7)

Press MAX. INFLATE button to fully inflate the mattress. When maximum pressure is achieved, detach the mattress air supply hose from the power unit by rotating the mattress hose connector anti-clockwise until the black lines align, and pull the mattress hose connector away.

The mattress will remain inflated, so supporting the patient.

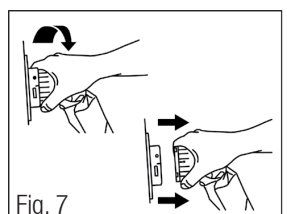


Fig. 7

5.5 NFC (RFID) (Fig. 8)

The power unit contains a passive NFC tag which contains supplementary information and can be viewed at any time by a compatible NFC enabled device (such as a smartphone or tablet). Place the device over the NFC symbol on the top of the product and the following will be displayed on the device:

- Model
- Part number (REF)
- Serial number (SN)
- Manufacturer contact details (TEL)



Please note you may need to download an NFC read app to view information.

5.6 Additional Information

- Allow the mattress to inflate before positioning the patient on the mattress.
- Mattresses can be used on profiling bed frames, slatted frames, in-filled frames and divans.
- Back rests or pillows for support should be placed beneath the mattress to allow uninterrupted body contact with the mattress surface.
- Place the bottom sheet loosely on the mattress to allow the mattress surface greater contact with the patient's body.
- Avoid using fitted sheets. The use of incontinence sheets / excessive bedding beneath the patient may reduce the pressure relieving effect of the mattress.
- To remove air from the mattress when dismantling the system, use the CPR device as described above.
- Care should be taken when raising and lowering bed safety side rails in order to avoid possible interference with the mattress air supply hose, the CPR and cushion connection port where fitted.
- A gap of 2.5cm on either side of the mattress should not be exceeded when side rails are deployed.

5.7 Using the Mattress in the Fowler's (Seated) Position

When the patient is placed in the Fowler's Position (headrest >45° elevation), it is recommended that the mattress is placed into the ACTIVE therapy mode on the FIRM setting.

5.8 Min. - Max. Patient Weight/Max. Load Guidelines



6. Care and Maintenance

6.1 Mattress - Exterior Components

- Always keep the cover as clean as is practicable. The material is waterproof and vapour permeable.
- Inspect top cover for signs of damage or wear which could result in the contamination of the interior, e.g. tears, holes, damage to seams or zips, underside staining, etc. The frequency of these checks should be at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients).
- Care should be taken to avoid puncturing cover with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- The cover may be removed and cleaned in accordance with The Revised Healthcare Cleaning Manual June 2009 subject to the following action: Following the use of a detergent and or disinfectant solution the cover should be rinsed with clean water using a clean cloth and allowed to dry. Frequent or prolonged exposure to high concentrations of aggressive disinfectant solutions will reduce the useful life of the cover.
- Where high concentration disinfectants e.g. > 10,000ppm chlorine releasing agent (e.g. Haztab or bleach) or combined cleaning/chlorine releasing agent (e.g. Chlorclean, Actichlor) and detergent solutions are used to remove blood or other body fluids, covers should be thoroughly rinsed with clean water to remove any residues. This will help prevent any possible long term compatibility issues associated with disinfectant residues (* see Care and Maintenance).
- Alternatively disinfection may be achieved by laundering the top cover at temperatures not exceeding 65°C for 10 minutes or 73°C for 3 minutes which may include a chlorine rinse. The base sheet should not be laundered, and should be wiped down only.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline, as these may destroy the cover materials (*see Care and Maintenance)
- Do not iron.
- Ensure that the cover is thoroughly dried before remaking the bed or placing in storage.

6.2 Mattress - Interior Components

- Check air cells and mattress/cushion interior for signs of damage or contamination, e.g. staining or evidence of fluid ingress. The frequency of these checks should be at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients)
- Care should be taken to avoid puncturing air cells with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- The individual cells can also be wiped clean with a mild disinfectant solution (*see Care and Maintenance).
- All cells are replaceable and can be obtained easily from Direct Healthcare Group.

6.3 Power Unit

Always disconnect the power unit from the electricity supply before carrying out maintenance, repairs, servicing or cleaning. To disconnect the power unit from the mains supply and thereby safely terminate operation of the device, remove the mains power cord from the mains outlet wall socket. Check all electrical connections and power cord for signs of excessive wear. The power unit can be wiped down with detergent or disinfectant solution or wipe*. Do not use solvents. Unsuitable for sterilisation. Disposal of the power unit / mattress / cushion in accordance with the local regulations including WEEE requirements.

* In line with the MHRA Medical Device Alert (MDA/2013/019), Direct Healthcare Group advises customers to use pH neutral, high level disinfectant cleaning products to sanitise reusable medical devices to prevent damage to materials and the degradation of plastic surfaces after prolonged use. The use of inappropriate cleaning and detergent materials on medical equipment could damage surfaces and may compromise the ability to decontaminate medical devices adequately or may interfere with device function.

6.4 Servicing

Direct Healthcare Group recommend that all power units should be serviced annually or as indicated by the 'hours to service' display. The unit contains no user serviceable parts and should only be serviced by either Direct Healthcare Group or an authorised dealer. Direct Healthcare Group or the authorised dealer will make available on request service manuals, component parts lists and other information necessary for a competent electrical engineer to repair or service the system. For service, maintenance and any questions regarding this, please contact Direct Healthcare Group or an authorised dealer.

It is the customer's responsibility to ensure the following prior to collection:

- The system is cleaned of any obvious contaminants.
- Contamination status is documented.
- Assistance is given to Direct Healthcare Group personnel to bag the equipment if the mattress has been in a known or suspected infectious environment.

6.5 Transport and Storage

Handle with care. Please report instances of damage or impact to Direct Healthcare Group Service Department.

–25 °C without relative humidity control; and

+70 °C at a relative humidity up to 93 %, non-condensing.

An atmospheric pressure range of 700 hPa to 1,060 hPa.

Suitable for all standard modes of transport when in the correct packaging.

6.6 Operational Conditions

A temperature range of +5 °C to +40 °C;

A relative humidity range of 15% to 93%, non-condensing; and

Operational Atmospheric Pressure: 700 hPa to 1,060 hPa

Suitable for pollution degree 2

Operational altitude ≤ 2 000 m

IP Rating: IP21 power unit only

6.7 Transportation of Mattress System

Place the mattress hose across the top of the mattress and roll loosely from foot end to head end, with the cover innermost, taking care not to strain the mattress hose. It can then be transported with the power unit, mains cable and this booklet. Do not stack rolled mattresses more than two high to avoid strain on the umbilical.

7. Fault Finding

The power unit can be reset by pressing the MUTE button once. This also silences the sounder and clears the message from the display screen. All systems have a fault log that records the last 5 faults via the DATA display mode. If problems reoccur contact Direct Healthcare Group.

AC FAIL fault – indicates a mains power failure, a sounder will be heard if power is interrupted, e.g. power unit switched off, power cut, disconnection of power cord. Press MUTE or re-connect to power supply.

ROTOR SYSTEM fault – indicates the automatic sequential cycle has stopped or there is a fault in the system. Switch power off, press MUTE button, then switch power on again. If the fault re-occurs, contact Direct Healthcare Group.

LOW PRESSURE fault – indicates pressure has fallen below the minimum allowable levels. Check that the hose is connected to the power unit correctly. Check that the CPR seal is fully closed, i.e. the tubeset is completely sealed off with the pull tab. Check that the internal cells are connected and that no cell is punctured. Press the MUTE button to clear the message and to silence the sounder. If the fault re-occurs, contact Direct Healthcare Group.

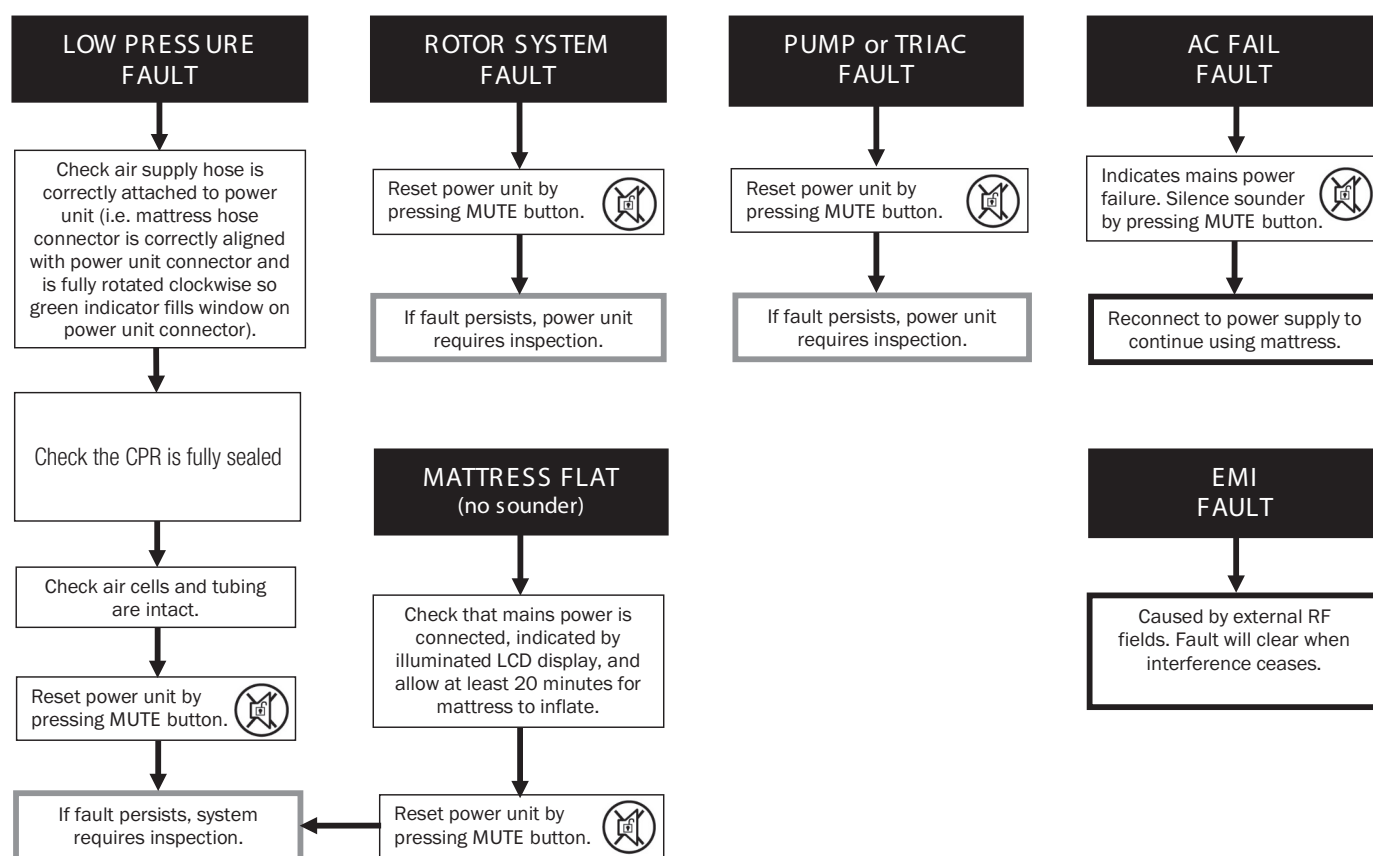
EMI fault – indicates that the unit detects the pressure sensor amplifier is adversely affected by external RF fields. This will clear when interference ceases.

Other Faults

PUMP OR TRIAC fault - indicates a pump control failure or an open pump coil fault. Should this occur, contact Direct Healthcare Group.

UNCALIBRATED - contact Direct Healthcare Group for recalibration.

If you have any queries relating to this system please contact Direct Healthcare Group or your local authorised dealer.



8. Technical Specifications

8.1 Alternating Air Pressure Power Unit

(Medical Device Classification: Class IIa)

Model Ref.: Type 19R
 Construction: ABS plastic
 Dimensions: 346mm (W) x 258mm (H) x 156mm (W)
 Weight: 4.0kg

CE 1639 UK 0120

Mains Cable: 5 metres
Electricity Supply: 230V ~ 50Hz (CE marked)/230V ~ 60Hz
Rated Input: 9.4VA
Fuse Rating: T500mA 250V HRC (cermaic) 5mm x 20mm
IP Rating: IP21
Noise Level: 33.5 dB(A)
Cycle time: 16 minutes (continuous)

8.2 Alternating Air Pressure Mattress (Accessory to Type 19R)

(Medical Device Classification: Class IIa)

Construction: Base: 70D 2378C nylon +0.3mm PVC coated both sides
Cells: TPU film 0.3mm
Cover: PU coated stretch nylon
Sizes: 195/205cm (L) x 80/85/90cm (W) x 18cm (H)
Weight: 10.0kg
Fire Retardancy: BS7177
BS 7175 Crib 5 test method BS 6807



8.3 Additional Technical Specifications

Expected Service Life: The expected service life of the medical device and its accessories is five (5) years.
Specified Shelf Life: The product has no specified shelf life.

Products are free from TSE species-derived materials, medicinal substances, human blood derivatives, and phthalates.

Products are manufactured to comply with National and International safety standard and are certified to ISO 13485, Medical Devices Directive 93/42/EEC and Medical Device Regulation 2017/745.

This medical device is compliant with:

IEC 60601-1 3rd edition medical electrical equipment safety and essential performance
IEC 60601-1-11 home healthcare environment

8.4 Manufacturer's Guarantee/Warranty

All power units and mattresses are covered by a two (2) year manufacturer's guarantee/warranty.

9. EMI/EMC Statement and Manufacturer's Declaration

This equipment has been tested and found to comply with the limits of EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in both a medical and residential environment.

This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with manufacturer's instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception or other equipment, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the receiver or equipment was connected.

The equipment having been tested to operate within the limits of electromagnetic compatibility. (Immunity to interference from nearby sources radiating radio frequency energy). Sources exceeding these limits may give rise to operation faults. Where possible the system will sense the interference and if it is of short duration transparently take countermeasures whilst operating near normally, or failing this will issue a warning and take measures for the continued safety of the user. Further increased levels of energy may cause the system to stop operating, continuously generate random faults or continuous resets. Try to ascertain the source of the interference by turning nearby or suspect equipment off, and see if the interference effects stop. In any such event the user is encouraged to try to correct the interference by one of the following measures:

- Have the interfering equipment repaired or replaced.
- Reorient or relocate the interfering equipment.
- Increase the separation between the equipment and the possible source of the interference.
- Connect the equipment to an outlet on a circuit different from that to which the interfering equipment was connected.

Information regarding Electro Magnetic Compatibility (EMC) according to IEC60601-1-2

With the increased number of electronic devices such as PCs and mobile telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. The EMC (Electro Magnetic Compatibility) standard IEC60601-1-2 defines the levels of immunity to these electromagnetic interferences. On the other hand, medical devices must not interfere with other devices. IEC60601-1-2 also defines the maximum levels of emissions for these medical devices. The QUATTRO conforms to this IEC60601-1-2 standard for immunity and emission. Nevertheless, special precautions need to be observed:

- The QUATTRO needs to be installed and put into service according to the EMC information below.
- The QUATTRO is intended for use in the electromagnetic environment specified in the tables below. The user of the QUATTRO should assure that it is used in such environment.
- In general, although the QUATTRO complies too the EMC standards, it can be affected by portable and mobile RF communications equipment (such as mobile telephones).
- The QUATTRO should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the QUATTRO should be observed to verify normal operation.


Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions (IEC 60601-1-2)		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Class B	The QUATTRO systems 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	

Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100kHz repetition frequency	±2 kV for power supply lines 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge Immunity Test IEC 61000-4-5	± 2 kV line(s) to ground ±1kV line(s) to line	± 2 kV line(s) to ground ±1kV line(s) 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 IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Span system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
	0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
NOTE U _T is the a.c. mains voltage prior to application of the test level.			

Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000- 4-6	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} 150 kHz to 90 MHz in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 V_{rms} 6 V_{rms}	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: 
Radiated RF IEC 61000-4-3	10V/m 80 MHz ~ 2.7 GHz	10 V/m	
Radiated Fields in Close Proximity IEC 61000-4-39	30 kHz 134.2 kHz 13.56 MHz At 50mm for 1 minute	30 kHz 134.2 kHz 13.56 MHz At 50mm for 1 minute	The carrier shall be modulated using a 50% duty cycle square wave signal.
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.			
NOTE 3: Refer to IEC 60601-1-2 annex ZA			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 QUATTRO is used exceeds the applicable RF compliance level above, the QUATTRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the QUATTRO.			
^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

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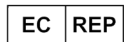
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