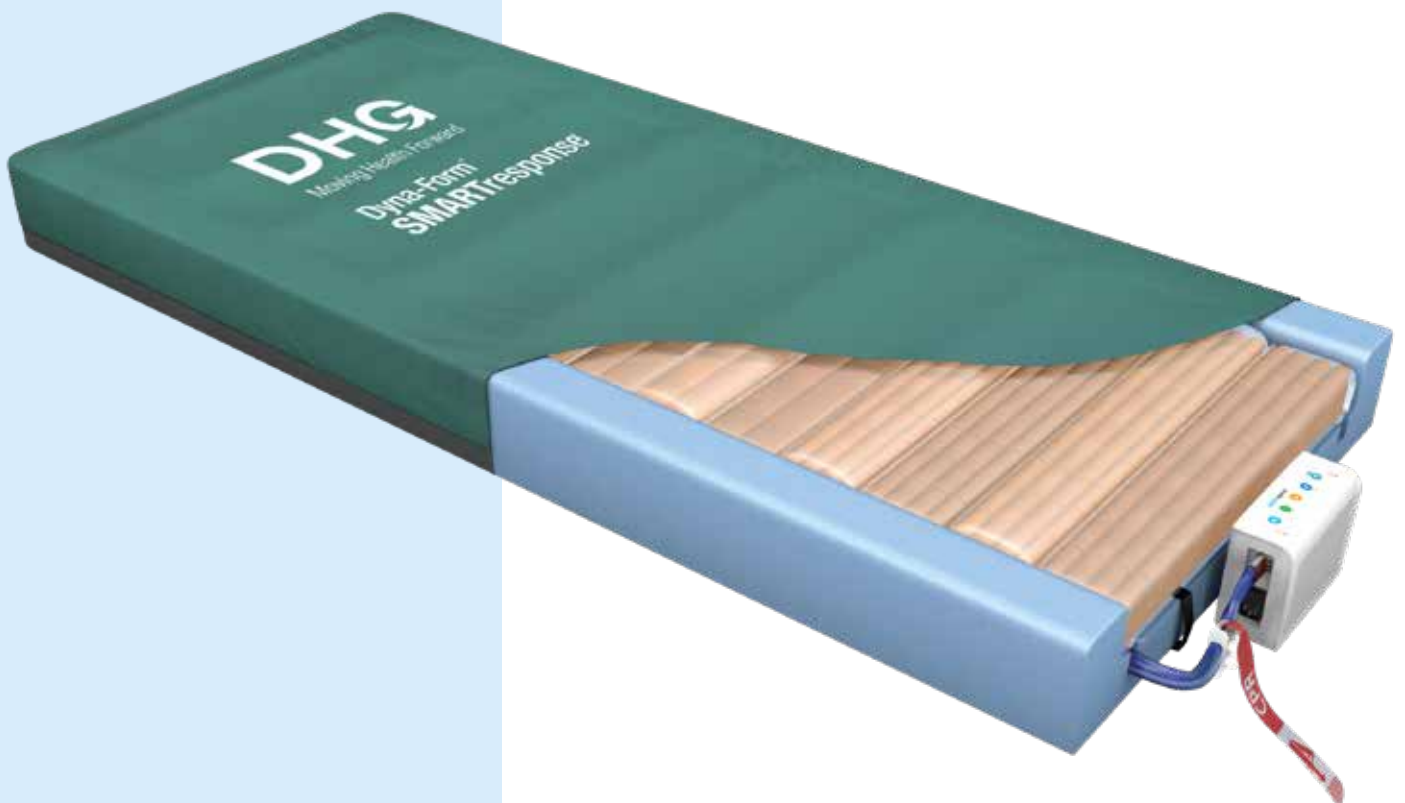




Moving Health Forward

# Dyna-Form<sup>®</sup> **SMART**response<sup>®</sup> System

## User Manual



# Dyna-Form® SMARTresponse®

The **Dyna-Form SMARTresponse** is a pressure relieving mattress and pump system suitable for use with patients at **VERY HIGH RISK** of pressure ulcer damage.

Offering high levels of patient comfort, this unique system has the facility to “step up” to that of a dynamic mattress when clinically required. Similarly, the mattress’s function can be downgraded as the patient’s condition improves.

These features make it particularly beneficial for use within the patient’s home or palliative care environment and help reduce logistic and decontamination costs. The clinical benefits of a single system are equally applicable to those of a modern hospital setting. A higher maximum weight capacity, up to 40 stone / 254kg, allows the product to meet the modern challenges of those heavier clients. All component parts are interchangeable and replaceable, maximising product life and reducing environmental impact.

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## 1. Introduction

**Dyna-Form SMARTresponse** is an innovative solution in the prevention and treatment of pressure ulcers. It offers effective dual therapy in a single surface by combining advanced, clinically proven technologies previously only available in separate hybrid surfaces. Advanced air displacement technology incorporated into a unique 4 zone configuration now provides more effective pressure redistribution.



When used in non-powered mode, clinically proven advanced air displacement technology continually optimises and improves pressure redistribution in response to patient body weight and movement. The unique 'air only' heel zone effectively offloads pressure on the vulnerable heel area.

When used in powered/dynamic mode **Dyna-Form SMARTresponse** delivers pressure relief via a series of connected alternating foam and air cells. Unencumbered by a top layer of foam on the mattress, the unique 'foam in air cell' construction ensures the delivery of effective pressure relieving therapy. Dependant on clinical judgement, the alternating function can be operated on either a Low or High Pressure.

The digital Control Unit controls air flow into, or out of the air cells as required according to the selected operating mode. It also maintains the air pressure within the mattress at the required level and controls the action of the Audible/Visual Warning System in the event of mains supply failure or over or under inflation pressure.

## 2. Indications/Contraindications for Use

### 2.1 Intended Use

**Dyna-Form SMARTresponse** is a mattress replacement system designed to offer pressure relief and prevention of pressure sores to patients spending the majority of their time in bed.

The intended patient population is for individuals aged between Paediatric – Geriatric with a body weight >10kg.

### 2.2 Contraindications

The **Dyna-Form SMARTresponse Mattress System** should not be used for patients with unstable fractures, gross oedema, burns or intolerance to motion.

## 3. Quick Reference Guide (Frequently used functions)

This is a quick reference guide for the **SMARTresponse System**

Product Code PUM1610001

**SMARTresponse Control Unit (Pump)**



A red indicator light signals a warning, notifying that an immediate response is required.

An orange indicator light signals that a particular mode has been selected or to notify of a necessary service that does not require immediate or prompt action.

### Power Switch/Audible Warning Reset

The power switch simply switches the mains power to the Control Unit on and off.

When the Control Unit detects an Audible Warning condition, this can be silenced (see below) and re-set by switching the Control Unit off and then back on again.



### CPR Valve

Please ensure that the CPR connector is always placed fully home, prior to inflating the mattress. NB: The mattress will NOT inflate properly should this not be the case.

The CPR connector is only to be used in the event of a clinical emergency for priority use. However, disconnecting this function will cleverly deflate air rapidly from the mattress in readiness for transport / static mode.



### LED Mode Settings

This symbol is used to represent Manual mode. When illuminated (the orange indicator light) is used to indicate that the equipment is on or ready for use and also to identify which of the functions of the pump is operation.

When a patient requires a true dynamic function or indeed more pressure in the cells, as they may be uncomfortable or feel as though the support surface is too soft or unstable, then please select a "H" setting (pressure 26mmHg). This must only be used by a trained clinician as too high pressures can further agitate certain patient conditions.

When a patient requires less pressure in the cells, as they may be uncomfortable or indeed hyper sensitive to cell movement or indeed if the patient is still reddening further, then please select a "L" setting (pressure 18mmHg). This must only be used by a trained clinician.

When a patient requires a static constant low pressure (6mmHg), select "S".



This function is used to silence the Audible Visual Indicator. Once muted, the Audible Visual Indicator will re-sound after thirty (30) minutes if the fault has not been resolved. Refer to the power switch in order to reset fully. If the Audible Indicator continues to sound repeatedly, along with an illuminated light, then an engineer must be called.

The red LED below the warning symbol will remain lit if the Audible Warning has been silenced previously, however a fault is still detected. Refer to the power switch in order to re-set fully. If the Audible Warning continues to sound repeatedly, along with an illuminated light, then an engineer must be called.



This symbol when illuminated indicates a Service is required.

DHG recommends an annual service. The service light will illuminate every 8760 hours of operation (one continuous year running).

To unlock the **SMARTresponse** features of the Pump (three buttons located on the central left hand side of the panel), press and hold the Alert Me and Bed Exit button together until the unlocked message is displayed on the front face panel of the pump.

After 20 seconds of not pressing/using the buttons on the top pump panel, the pump will automatically revert back to being locked. Again a locked message will briefly be displayed on the screen letting the user know the **SMARTresponse** features are locked.

The control unit must be paired with the mattress before the system is used. To pair the control unit with the mattress, ensure that the control unit is connected, via the tubeset, to the mattress and switched on. Press and hold the Bed Exit button for 7 seconds to enable the pairing to start.

Alert Me symbol when selected will alert the carer via the app if no patient movement is detected. Upon selection of Alert Me, the pump user must input an estimated weight classification. If the weight of the individual lying on the mattress is not known, then an auto calibration can be selected that will determine the user's weight. Calibration can take approximately 12 minutes.

To toggle user weight selection on the weight selection screen, simply continue to press the Alert Me button until the appropriate option is displayed on the screen: 0-45kg, 45-65kg, 65-85kg, Above 85kg and Auto Calibrate.

To confirm selection, hold down the Alert Me button for 3 seconds. If less than 3 full body movements (torso turns) detected in an hour, the carer will be sent a notification with the option of turning on the pump.

If the carer does not respond to the alert in 15 minutes another notification will be sent to them via the app.

Again if the customer does not respond to the second message alert. The pump will automatically turn on.

Auto Start symbol, when selected, automatically turns on the mattress alternation system when no patient movement is detected.

Upon selection of Auto Start, the pump user must input an estimated weight classification. If the weight of the individual lying on the mattress is not known, then an auto calibration can be selected that will determine the user's weight. Calibration can take approximately 12 minutes.

To toggle user weight selection on the weight selection screen, simply continue to press the Auto Start button until the appropriate option is displayed on the screen: 0-45kg, 45-65kg, 65-85kg, Above 85kg and Auto Calibrate.

To confirm selection, hold down the Auto Start button for 3 seconds.



Bed Exit symbol when activated can detect if a patient is in the bed. If a Bed Exit is detected, the pump will send a notification to the the carer via the app. In scenarios where a Bed Exit is detected, the pump will sound with an audible warning and display on the front pump Bed Exit Detected. Press this button once to activate Bed Exit indication and press again to deactivate it. No calibration occurs when Bed Exit is selected.



### SMARTresponse App

The features of the **SMARTresponse** Control Unit can be monitored by the clinician via the **SMARTresponse** app. This is a secondary monitoring feature whilst the pump remains the primary monitoring device.

The only feature that allows clinician remote access interaction with the pump control unit is the "Alert Me" function. This function allows the clinician to "Step Up" care by turning on the alternation system when requested to do so by the pump control unit.

All functions are for monitoring purposes only and should not replace regular assessment and turning by a trained clinician.

For detailed instructions in the use of the **SMARTresponse** app, please refer to separate app user manual.

This can be located on the Direct Healthcare Group website: [www.directhealthcaregroup.com](http://www.directhealthcaregroup.com).

Note: Please ensure (when available) that all securing straps on the base of the mattress are secured onto the moving parts of the bed frame.

For shut down procedure, see 6.2 Control Unit section.



## 4. Warnings and Cautions

### General Information (Caution) (Warning)

- There are no special skills required to operate the system.
- The Medical Professional is responsible for applying his/her best medical judgment when using the system.
- The electricity supply is of the type indicated on the Control Unit.
- Check the mains lead is free from damage and is positioned so as not to cause an obstruction, or injury. E.g. Strangulation of a child or trip hazard.
- Ensure the mains lead cannot become trapped or crushed, e.g. by raising or lowering of the bed or bed rails or any other moving object.
- The Control Unit must only be used with a suitably approved power cord and plug set as supplied by DHG.
- The system is not to be used in the presence of flammable anaesthetics.
- Ensure the Control Unit is not exposed to:
  1. Excessive heat sources e.g. fires, radiators etc.
  2. Water, particularly immersion.
- Suitable for continuous use.
- Not suitable for sterilisation.
- Do not position the Control Unit to make it difficult to disconnect the power supply or plug.
- Do not place the Mattress on or close to a source of heat (i.e. a radiator) as this excessive exposure to heat may weaken the cell material.
- Do not use with hot water bottles or electric blankets.
- DHG strongly advise against smoking whilst the Control Unit is in use. This is to prevent accidental secondary ignition of items which may be flammable e.g. bed linen. The materials used in the manufacture of the **Dyna-Form SMARTresponse** System comply with the required fire safety regulations.
- Do not use sharp objects on or near the mattress system as this will cause damage.
- Do not store in damp conditions.
- Do not use in an oxygen enriched environment.
- Not suitable for use in an Outdoor Environment.
- Intended for both Home Healthcare and Professional Healthcare environments.
- Do not connect to any other medical device or equipment.
- Correct fuse rating **MUST** be used. Failure to do so could result in the risk of a fire.

- The System should be cleaned after use or between patients. Refer to Cleaning section.
- There is a risk that the user or operator may be exposed to bodily fluids.
- All internal and external hoses must be free of twists, kinks. The external hose should also be properly connected and positioned so that the risk of obstruction or injury is eliminated.
- Do not use bleach, phenols. Chlorine based products which exceed 1000ppm. Solvents or alcohol based cleaners.
- All the above warnings and cautions together with safety considerations should be observed at ALL times during its use.
- Select correct setting 'High' or 'Low' as required. Care should be taken not to accidentally change settings once set. This may affect the desired requirement of the therapy. This could also be caused by pets, pests or children.
- This device does not emit radiation.

## 5. Installation

### 5.1 Mattress (This is the applied part type BF)

The device should only be installed and used by a clinician or a trained lay operator. A lay operator shall be considered trained once they have fully read this user manual.

The temperature of the Control Unit may have decreased or increased, whilst in storage or during transportation, beyond the limits of the allowable operating temperatures. Do not use the Control Unit until it has been at room temperature (c.20°C) for at least two (2) hours. This time is required for all components of the Control Unit to reach the normal, recommended operating temperature.

Place the **Dyna-Form SMARTresponse** Mattress directly on to the bed platform ensuring that the Blue multi-stretch waterproof cover is on top and that the umbilical hose is located at the left-hand corner at the foot end of the bed. Note: The umbilical hose can be located inside the cover under the "Open Here for Air Inlet" printed in the bottom left hand corner of the mattress. Typically the mattress user will be placed in a supine position on the mattress. Wipe the mattress down before covering the mattress with a loose-fitting sheet.

#### Static Mattress Use

The **Dyna-Form SMARTresponse** Mattress can be used as a pressure reducing mattress for patients at High Risk of pressure ulcer damage without the need to attach the Control Unit.

#### Alternating Mattress Use

If / When required, the **Dyna-Form SMARTresponse** Mattress can be used as an alternating mattress system by attaching the **Dyna-Form SMARTresponse** Control Unit system.

**No other system should be attached to the mattress as the design settings and internal air pressure properties of the Dyna-Form SMARTresponse Control Unit) are specific to this mattress only.**

The **Dyna-Form SMARTresponse** is a replacement mattress system and should NOT be placed on top of any existing mattress.

### 5.2 Control Unit

Hang the Control Unit onto the footboard, ensuring that the position of the Control Unit does not make it difficult to disconnect the device if required. The mounting hooks swivel to suit the thickness of the footboard or rail. Connecting the Umbilical Hose to the Control Unit, place the supplied 3-pin electrical plug into the wall outlet and switch on:

- Open the zip located at the bottom left hand side of the mattress and pull out the Blue Umbilical hose.
- Attach the Blue Umbilical Hose to the Control Unit by connecting the air connector at the end of the Umbilical Hose to the air inlet connector at the bottom left hand side of the Control Unit. Ensure that the Red CPR Release button is located on top of the Air Inlet connector after connection is complete.
- Re-close the zip as far as possible without clamping the Blue Umbilical Hose to ensure the mattress and air cells are sealed within the cover.



The expected operator position of the control unit is from the foot end of the bed. The expected position of the mattress user under normal use is centrally placed on the mattress in the supine, side lying or prone position.

## 6. Operation

Attach the supplied mains cable to the Control Unit by inserting the "kettle" type connector into the recess located on the left-hand side of the Control Unit. The mains cable has been designed specifically as a removable part to aid in easy replacement should it become damaged in use.

Power cables not supplied by Direct Healthcare Group are not recommended for use with this Control Unit. The mains plug should be turned off and removed from wall socket as a means of isolation. Plug the mains cable into a suitable 230v mains socket and switch on the Control Unit using the on/off switch.

Once the Control Unit has been turned on, the word "Hello" is displayed on the front screen panel symbolising its initialisation.

After this the pump would revert to the Manual mode "High" (26mmHg) and attain that operating pressure.

To cease operation of the device, simply turn the switch located at the side of the pump to the off position.

Upon first use of the mattress and control unit together they must be paired. To pair the mattress and control unit, ensure that the control unit is connected to the mattress via the tubeset and the control unit is powered on. Keep the Bed Exit button pressed for 7 seconds to start pairing. This must be performed on first operation prior to a patient laying down on the mattress.

### 6.1 Static (S) / Low (L) / High (H) Settings

The **SMARTresponse** pump, in Alternating Mode, has two pressure settings "High" (H) and "Low" (L) (18mmHg & 26mmHg) and also has a Continuous Low Pressure mode (6mmHg) referred to as Static (S).

The initial setting that the control unit will revert to upon set up is "High" (26mmHg).

The "Low" comfort setting is ideal for the lighter patient or those who feel discomfort when on a normal alternating air type mattresses system. However, for patients with existing pressure damage or those at Very High Risk, it is recommended that, dependant on the clinical judgement of the clinician, the "High" setting is selected by pressing the "M" button, which is located on top of the Control Unit, until the LED light under "H" is illuminated.

In "High" Mode the Control Unit attains more of the characteristics of an alternating air mattress system whilst still utilising the advantages of the static foam inserts. Repeatedly pressing the 'mode' button enables the Static, Low or High modes to be selected in turn.

**WARNING: High and Low modes should only be used by a trained clinician.**

### 6.2 CPR Deflation

The CPR system consists of a manually operated tag located on the blue umbilical attached to the Control Unit.

Pulling the red CPR Tag will deflate the mattress air system back to that of a static foam mattress.

Warning: Removal of the Dual Function Connector alone will not expel air as quickly as the CPR Tag.

Do not rely on the Dual Function Connector for CPR, always use the CPR Tag to expel air from the mattress quickly.



Note: After a short period as the Mattress deflates the 'Low Pressure' Audible Warning is activated and can be cancelled by switching the Control Unit off.

### 6.3 Troubleshooting

For assistance (if needed) in setting up, using or maintaining the **Dyna-Form SMARTresponse** System, or to report unexpected operation or events, please contact Direct Healthcare Group on the contact details on the reverse of this manual.

## 7. Audible/Visual Indicators

Warning conditions are indicated by a flashing red display accompanied by an Audible/Visual Indicator and a message on the pump interface.

In each case the user should respond by turning the Control Unit's switch off and investigating the cause. Full details of the warnings can be found in Troubleshooting (pg 12).



### 7.1 High Pressure Indicator

This condition could be caused, for example by a kinked Umbilical Hose or visitors, and others, sitting suddenly on the Mattress.

### 7.2 Low Pressure Indicator

This condition could be caused, for example by incorrect fitting of the air inlet connector, opening of the CPR Valve or a leak in the Mattress due to a cut or puncture.

### 7.3 Mains Failure Indicator

This condition may be caused, for example if Mains power is lost.

### 7.4 Alternating Mode Failure (no alternation)

This will be indicated by a warning LED and an Audible Warning.

1. Reset the warning – turn off Power and press the Audible Warning mute button.
2. Disconnect the air hoses to reduce pressure – reconnect when pressure has decreased.

### 7.5 Initialising Failure

This will be indicated by a warning LED and an Audible Warning Indication will sound.

1. Press the Audible Warning mute button to silence the Audible Warning.
2. Check the power cable is firmly plugged into the mains outlet and the Control Unit; and check the mains power is switched on.
3. Check the Control Unit fuse (1 AMP) – fuses can be released using a screwdriver to push and turn.

## 8. Transportation

To change the location of the mattress, remove the Umbilical Cord and allow the mattress to return to its Static Mattress form.

Switch off the Control Unit using the on/off switch and disconnect the electrical supply cable from the mains socket.

The mattress can now be moved to a new location where it must immediately be reconnected to the mains electrical supply and the Control Unit switched back on. Once the Mattress has been refilled, the 'Alternating' mode will automatically revert back to the Low setting and should be reselected to High should this be desired by the clinician.

Warning: The Mattress will not 'alternate' when disconnected from Control Unit and /or the mains electrical. Also, refer to environmental conditions section at rear of this manual.

## 9. Cleaning & Maintenance Procedures

### 9.1 Cleaning Procedures

**Warning: Before cleaning the System make sure that the Control Unit is disconnected from the mains electricity supply.**

Do not immerse the Control Unit in water or other fluids.

Do not autoclave, nor use phenol for cleaning.

Do wash hands before commencing the cleaning process.

Wear appropriate protective clothing such as gloves, apron and a mask.

Ensure all work surfaces are cleaned before and after contact with the Mattress.

#### 9.1.1 Cleaning the Mattress

1. Cleaning should take place before and after use, and between patients.
2. With cover left on the Mattress disconnect the Mattress from the Control Unit.
3. Clean the surface of the wash down table with Hypochlorite solution or equivalent disinfectant.
4. Wash Mattress top using hot water (60 degrees C) containing detergent – dry with a paper towel.
5. Use a Hypochlorite solution 1,000 parts per million available chlorine. For heavy contamination use a Hypochlorite solutions 10,000 parts per million available chlorine. Please ensure thorough rinsing after cleaning.
6. Using suitable brush, hot water, detergent or Hypochlorite solution, clean Umbilical Hose and CPR Valve. Dry with paper towel.
7. If required, the Mattress Cover may be removed and machine-washed at a temperature of 80 degrees C, for not less than 10 minutes. The individual Air Cells can be wiped down with established disinfectants.
8. To avoid shrinkage of the coverline dry in an indoor clean environment or tumble dry on a low heat setting not exceeding 40 degrees C and not for longer than 10 minutes. Covers must be thoroughly dried before re-fitting to the mattress.

#### 9.1.2 Cleaning the Control Unit

The Control Unit can be cleaned by wiping with a cloth dampened with a detergent solution with the above recommended DiffX dissolved within a spray bottle filled with 500ml of warm water. Also, refer to symbol chart.

#### 9.2 Maintenance

The Control Unit has a light that when illuminated indicates a Service is required.

**Change the air filter:** Remove air filter holder by pressing the plastic catch downwards and lifting the air filter holder up. Take out the filter and put in a new one and put the filter holder back.



#### 9.3 Servicing

Direct Healthcare Group recommend that the control unit be serviced annually from installation. The service light will illuminate after 8760 hours of operation (one year of continuous operation). The unit contains no user serviceable parts. For service, maintenance and any questions regarding this please contact DHG.

## 10. Troubleshooting

Warning / Fault	Cause	Solution
<b>Control Unit Does Not Operate; No Display Lights Illuminate</b>	The Control Unit may not be attached to a power source or a fuse may need replacing.	<ol style="list-style-type: none"> <li>1. Check the Control Unit is connected to mains power outlet with the correct voltage.</li> <li>2. Check the Control Unit is switched on. Switch off and unplug the unit before restarting.</li> <li>3. Check the mains plug fuse (5 AMP) then check both Control Unit fuses (1 AMP) – fuses can be released using a screwdriver to push and turn.                             <ul style="list-style-type: none"> <li>⚠ Do not try to open the Control Unit. Opening the unit could cause personal injury or equipment damage.</li> <li>⚠ Ensure the replacement of fuses is carried out accordance with local legislation.</li> </ul> </li> </ol>
<b>Audible Warning Indicator Light + Continuous Beep Audible Warning Indicator + No Message On Pump</b>	Mains failure / Other See above, plus:	<ol style="list-style-type: none"> <li>1. Check the Control Unit is connected to mains power outlet with the correct voltage.</li> <li>2. Check the Control Unit is switched on. Switch off and unplug the unit before restarting.</li> <li>3. Check the mains plug fuse (5 AMP) then check both Control Unit fuses (1 AMP) – fuses can be released using a screwdriver to push and turn.                             <ul style="list-style-type: none"> <li>⚠ Do not try to open the Control Unit. Opening the unit could cause personal injury or equipment damage.</li> <li>⚠ Ensure the replacement of fuses is carried out accordance with local legislation.</li> </ul> </li> </ol>
<b>Audible Warning Indicator Light + Continuous Beep Audible Warning Indicator + “Pressure Too Low” Message On Pump</b>	Pressure too low	<ol style="list-style-type: none"> <li>1. Reset the warning – turn off power and press the Audible Warning mute button.</li> <li>2. Check that the CPR connector is firmly attached to the Control Unit (located on the left of the Control Unit case). Check all air hoses along the inside of the mattress – each should be firmly connected. Check each air cell is securely attached to its connecting air pipe.</li> <li>3. Check all cells, pipes and hoses for any air leakage.</li> <li>4. Check that the air filter cover is correctly secured and the air filter is clean.</li> <li>5. Switch on power.</li> </ol>
<b>Audible Warning Indicator Light + Continuous Beep Audible Warning Indicator + “Air Pipe Kinked” Message On Pump</b>	Pressure too low / Air pipe kinked	<ol style="list-style-type: none"> <li>1. Check blue external umbilical air pipe that is between mattress and CPR connector is not kinked, twisted or damaged.</li> <li>2. Check all air hoses along the inside of the mattress – each should be firmly connected.</li> <li>3. Check each air cell is securely attached to its connecting air pipe.</li> </ol>
<b>Audible Warning Indicator Light + Continuous Beep Audible Warning Indicator + “Pressure Too High” Message On Pump</b>	Pressure too high	<ol style="list-style-type: none"> <li>1. Reset the warning – turn off power and press the Audible Warning button.</li> <li>2. Disconnect the air hoses to reduce pressure, reconnect when pressure has decreased.</li> <li>3. Check for twists in the air hoses between Mattress and Control Unit.</li> </ol>
<b>Audible Warning Indicator Light + Continuous Beep Audible Warning Indicator + “Alternating Mode Failure” Message On Pump</b>	Mattress fails to alternate	<ol style="list-style-type: none"> <li>1. Contact an engineer</li> </ol>
<b>Audible Warning Indicator Light + Continuous Beep Audible Warning Indicator + “Initialising Failure” Message On Pump</b>	Control unit fails to initialise	<ol style="list-style-type: none"> <li>1. Contact an engineer</li> </ol>

## 11. Technical Specification

### Declaration – Electromagnetic Emissions – for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The PUM1610001 is intended for use in the electromagnetic environment specified below.		
The customer or the user of the system should ensure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The system 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	The system 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	

### 11. Technical Specification

#### Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Emission				
The PUM1610001 is intended for use in the electromagnetic environment specified below.				
The customer or the user of the system should ensure 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 floor 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 line(s)		±2 kV for power supply lines ±1 kV for input/output line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Surge Immunity Test 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	Voltage Dips %U <sub>T</sub>	Period (Cycles)	Voltage Dips %U <sub>T</sub>	Period (Cycles)
	30	25	30	25
	60	5	60	5
	>95	0.5	>95	0.5
	Voltage Interruption % U <sub>T</sub>	Seconds	Voltage Interruption % U <sub>T</sub>	Seconds
>95	5	>95	5	
Power frequency (50Hz) 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.
NOTE U <sub>T</sub> is the a.c. mains voltage prior to application of the test level.				

### 11. Technical Specification

#### Declaration – Electromagnetic Immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PUM1610001 is intended for use in the electromagnetic environment specified below.			
The customer or the user of the system should ensure 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 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	Portable and mobile RF communications equipment should be used no closer to any part of the CT515, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance d = 1.167√P d = 1.167√P      80 MHz to 800 MHz d = 2.333√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 meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol: (⚡)
Radiated RF IEC 61000-4-3	3 V/m (Professional Healthcare Environment) 10 V/m (Home Healthcare Environment) 80 MHz at 2.7 GHz	10 V/m	
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 Span system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.			
b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			



### 11. Technical Specification

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for ME EQUIPMENT or ME SYSTEM that are not LIFE – SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the PUM1610001 Alternating Control Unit.

The PUM1610001 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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 $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

### 12. Technical Data

#### 12.1 Control Unit

Serial Number ..... As per label on rear of Control Unit  
 Electrical Supply ..... 220 – 240 volts, 50 Hz  
 Power Consumption ..... 50VA  
 Fuses ..... TA1H 250V  
 Protection against shock ..... Class 2  
 Noise Level ..... Approx. 35 dB (A)  
 Dimensions ..... 245 x 160 x 95 mm  
 Weight ..... 2.5 kg  
 Service Interval ..... 12 months / 8760 hours  
 Expected life ..... 5 years  
 Shelf life of parts ..... 5 years

#### 12.2 Mattress

Serial Number ..... Label on inside of mattress cover  
 Number of Air Cells ..... 14 Air Cells / 1 Static Foam Cell  
 Dimensions ..... 1980 x 880 x 150mm (Nominal)  
 Weight ..... 13.3kg  
 Expected life of Mattress ..... 5 years  
 Shelf life of Mattress parts ..... 5 years  
 Biocompatibility .... No exposure to harmful materials as tested to ISO10993

### 13. Optimum Conditions

(Applies to Mattress and Control Unit)

#### 13.1 Environment Conditions for Use













Transport ..... -25°C - +70°  
 Storage ..... -25°C - +70°  
 Usage ..... +5°C - +40°C  
 Humidity ..... 15% - 90%  
 Atmospheric Pressure ..... 700hPa - 1060hPa  
 Altitude ..... ≤ 3000m

#### 13.2 Exposure

Exposure to direct sunlight, dust, lint and general debris is not considered to be an issue with this System.

### 14. Symbols Guide

#### Mattress Symbols

 WASH AT 80°	 TUMBLE DRY ON LOW	 DO NOT DRY CLEAN
 REFER TO USER MANUAL	 UK CA	 TYPE BF APPLIED PART
 DO NOT BLEACH	 DO NOT IRON	 NO SMOKING
 MAXIMUM USER WEIGHT LIMIT 254 KG / 40 STONES	 DO NOT USE SHARP INSTRUMENTS	 DO NOT USE PHENOL







**WARNING**  
 THIS IS A STATEMENT THAT ALERTS THE USER TO THE POSSIBILITY OF SERIOUS INJURY OR OTHERWISE ADVERSE REACTIONS WITH THE USE OR MISUSE OF THE DEVICE

**CAUTION**  
 THIS IS A STATEMENT THAT ALERTS THE USER TO THE POSSIBILITY OF A PROBLEM WITH THE SYSTEM ASSOCIATED WITH ITS USE OR MISUSE

#### General Symbols

 CAUTION	 PROTECT FROM HEAT AND RADIOACTIVE SOURCES
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#### Control Unit Symbols

 SERVICE REQUIRED	 REFER TO USER MANUAL	 DO NOT DISPOSE OF WITH HOUSEHOLD WASTE. PLEASE REFER TO DHS WEBSITE
 "ON" POWER	 "OFF" POWER	 DOUBLE INSULATED CLASS II

**MD**  
 MEDICAL DEVICE

**IP22**  
 IP: INGRESS PROTECTION  
 2: PROTECTION AGAINST FINGERS OR OTHER OBJECTS GREATER THAN 12MM  
 2: PROTECTION FROM VERTICALLY DRIPPING WATER WHEN TILTED UP TO 15°

## 15. Detachable/Removable Parts

1. Mattress (Detached from the Control Unit by removing the CPR connector). Part No. MAT1620002 (or variants of for the size)  
Electric power cable. (Removed from the Control Unit by pulling the cable away from the mains inlet on the side of the Control Unit).  
Part No. SP021016

N.B. The battery is an integral part of the PCB and is not removable or changeable.

### Caution

**Use of detachable parts not listed is not recommended by Direct Healthcare Group.**

## 16. Disposal

All contaminated mattresses must be disposed of as clinical waste in accordance with regional and local regulation and guidelines.

Control Units are electrical/electronic medical devices and must be disposed of in line with the Waste Electrical and Electronic Equipment Directive (WEEE).

Please refer to [www.directhealthcaregroup.com](http://www.directhealthcaregroup.com) for recommendations and responsibilities for disposal within the UK WEEE guidelines.



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