Direct Healthcare Group

Advancing Movement & Health®

Dyna-Form® Air Pro-Plus

User Manual

DIRECTHEALTHCAREGROUP.COM

Direct Healthcare Services

The **Dyna-Form® Air Pro-Plus** is a pressure relieving mattress suitable for use with patients at **VERY HIGH RISK** of pressure ulcer damage.

Offering high levels of patient comfort, this mattress is particularly beneficial for use within the patient's home or acute care environment. A higher maximum weight capacity, up to 28 stone / 180kg, 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.

Dyna-Form®
Air Pro-Plus

Important Notice

Before operating this medical equipment, it is important to read this manual and understand the operating instructions and safety precautions. Failure to do so could result in patient injury and/or damage to the product.

If you have any questions, please see contact information on the back cover.

CE

Dyna-Form® Air Pro-Plus

This box contains an assembled mattress system containing a:

A. Dyna-Form® Air Pro-Plus Alternating Mattress

B. Digital Control Unit

C. Power Cord

D. Carry Bag

E. Instructions for Use

Contents

1. Safety Precautions

In General

⚠ Do not use this equipment in the presence of flammable anaesthetics. Explosions could result. In line with MDA/2013/073 the manufacturer warns against the dangers of smoking in bed.

⚠ Bed frames used with the systems can vary greatly depending on the specific health care setting (i.e. hospitals, nursing homes, home care, etc). It is the responsibility of the caregiver to take the necessary precautions to ensure the safety of the patient. This includes, but is not limited to, the appropriate use of side rails to prevent falls and/or patient entrapment.

⚠ Minimise articles between the system surface and patient, and secure bed sheets loosely so as not to affect the alternating cell movement.

⚠ The manufacturer does not require such preventive inspections by other persons.

⚠ The user must check that the equipment functions safely and see that it is in proper working condition before being used.

⚠ No special skills or training of the operator is required, there is no restriction on location or environment.

⚠ Significant risks of reciprocal interference may be posed by the presence of the system during specific investigations or treatments. Potential electromagnetic or other interference between the system and other device may occur. If interference is suspected, move equipment from sensitive devices or contact the manufacturer.

⚠ Preventive inspection and calibration is not required.

⚠ Do not modify this equipment without authorization of the manufacturer.

⚠ Manufacturer will provide circuit diagrams, component part lists, descriptions to assist to service personnel in parts repair.

⚠ The mattress is treated as the applied part.

⚠ Unplug the control unit from the mains power supply to disconnect the power.

Control Unit

⚠ The control unit is tested and approved according to IEC 60601-1-2

⚠ Only plug into a grounded power receptacle and use the power cord supplied with the system.

⚠ Exposure of the electronic Control Unit to any liquid while it is plugged in could result in a severe electrical hazard.

⚠ Only use fuses that have the same specified rating. Using fuses with higher ratings could result in damage and/or injury. (See Technical Specifications on cover).

⚠ The electronic Control Unit is a precision electronic product. Use care when handling or transporting. Dropping or other sudden impacts may result in damage to the unit.

⚠ Do not open the Control Unit – risk of electrical shock. Do not attempt to repair or service the Control Unit. Repairs and service should be conducted by an authorised local distributor (see contact information on cover). If the Control Unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately (see contact information on the back cover for repair and service information).

⚠ Do not place any objects or items, such as blankets, on or over the Control Unit.

⚠ The power cord to the Control Unit should be positioned to avoid a tripping hazard and/or damage to the cord. It is recommended to place the cord under the bed frame and attach it to an electrical outlet by the head of the bed.

⚠ Do not position the system so that it is difficult to operate the disconnection device.

2. Product Overview

Alternating Mattress system (see cover)

Dyna-Form® Air Pro-Plus is an Alternating Mattress Replacement System providing pressure application and release to patients with, or vulnerable to, pressure ulcers. It is designed to replace an existing mattress and can be used on both standard and profiling bed frames.

Mattress

This system includes a static head cell(s) to provide static “pillow” support for optimum user comfort, while air pressure in the other cells is alternated over a 10 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.

Control unit

The Control unit provides the air supply to the Mattress.

- It is controlled via a touch panel with integrated digital display. The Audible Warning sounds when pressure fails or power is interrupted. Audible Warning Mute silences the Audible Warning for maximum of 20 minutes – the Audible Warning resumes if cause of failure is not resolved. The Audible Warning will sound for up to 40 minutes following an interruption to power.
- The Control Unit includes a back up power battery for the Audible Warning. This battery is continuously re-charged and will last the lifetime of the product.
- Buttons on the control panel adjust the three comfort level settings.
- The Warning LED indicator and Audible Warning Mute completes the profile.

The visible and audible warning functions have a number of indicators depending on the cause of the failure.

The mains supply to the Control Unit can be easily disconnected and is designed to detach if tugged too firmly - protecting the internal wiring of the unit. Should this occur, the alternation sequence is suspended and the Mattress cells remain inflated and/or deflated based on the current cycle. The Power Down Audible Warning will sound.

3. Installation

Unpacking & Inspection

⚠ It is recommended that all packing materials and instructions be kept in the carry bag provided in the event the product has to be shipped to DHG or an authorised local DHG distributor. Please see contact information on back cover.

Carefully remove the Control Unit, Mattress Replacement and accessories from the boxes. Inspect all items for any damage that may have occurred during shipping. Any damage or missing components should be reported to DHG or an authorised local DHG distributor as soon as possible. Please see contact information on back cover.

3.1 Mattress (This is the applied part type BF)

Place the **Dyna-Form® Air Pro-Plus** 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.

Ensure that the CPR Connector is firmly secured and that the securing straps located underneath the mattress are fastened to the bed frame.

Wipe the mattress down before covering the mattress with a loose-fitting sheet.

Alternating Mattress Use

The **Dyna-Form® Air Pro-Plus** Mattress can be used as an alternating mattress system by attaching the **Dyna-Form® Air Pro-Plus** Control Unit.

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

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

3.2 Control Unit

Hang the Control Unit onto the footboard. The mounting hooks swivel to suit the thickness of the footboard or rail. Connect the umbilical hose to the Control Unit, place the supplied 3-pin electrical plug into the wall outlet and switch on:

(a) Attach the umbilical hose to the Control Unit by connecting the Air Connector at the end of the umbilical hose to the air inlet connector located 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.

(b) Shut down is the reverse of item (a) above.

3.3 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.

After the Control Unit has been turned on the “Soft”, “Medium” and “Firm” lights will flash together intermittently until the Control Unit has attained its initial operating pressure. Once the Control Unit has attained its initial operating pressure the “Medium” light will stay on constantly and the mattress is ready for use.

4. Operation

Control Unit Panel

A Power Button

Turns system power on and off by pressing the Power button for at least 3 seconds.

B Warning LED *A,B & C

One of *these red light flashes, and an audible warning sounds, to alert when Control Unit or Mattress Replacement pressure fails, or if there is a kink in the air pipe. The warning has four different signals to indicate the cause of the failure (see over).

The Audible Warning also sounds when power is switched off – press Audible Warning Mute to silence.

C Audible Warning Mute Button

Silences the audible warning (on / off). Audible warning will resume after 20 minutes if cause of failure not resolved.

D Pressure Buttons (Soft, Medium & Firm)

Press buttons to increase or decrease pressure setting. The Soft, Medium & Firm settings allow comfort to the user, without clinical compromise. The green LEDs illuminate to indicate which of the three settings is operational.

E Dynamic Function Button

Press Dynamic Mode for alternative cells cyclically inflating and deflating.

Upon power up, the system automatically reverts back to the dynamic mode operating at the previous pressure setting for patient safety.

F Static Function Button

Press to facilitate static mode for clinical procedure / patient transfer purposes.

Press Static Mode for all cells to be fully inflated with no dynamic alternation.

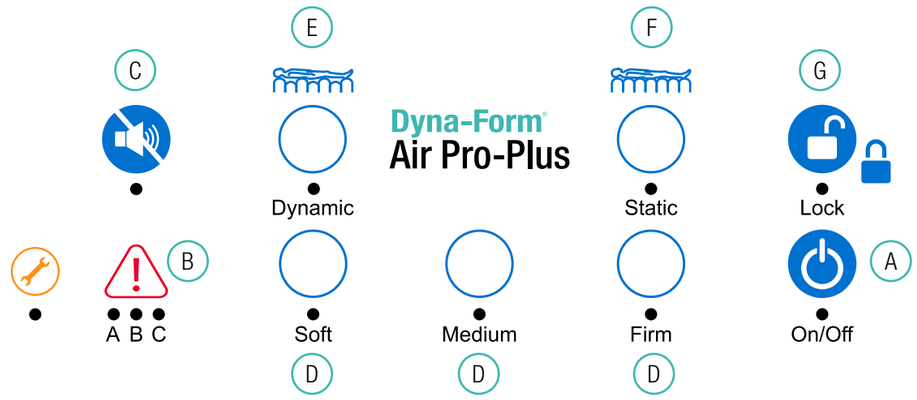
Static Mode will automatically revert to Alternation Mode after one hour for patient safety.

G Control Unit Lock / Unlock Button

Press for at least 3 seconds to lock the Control Unit settings – a beep sounds and the Red LED illuminates to indicate system is locked. When locked, only the Audible Warning Mute and Lock / Unlock buttons remain operational.

Press again for at least 3 seconds to unlock (beep sounds and Red LED turns off).

⚠ The Control Unit will automatically unlock in the event of a power failure.



Operation

Audible Warning Functions

The Red Warning LED (A,B or C) flashes, and an audible alert sounds, to indicate the control unit or mattress pressure has failed. The LED will remain illuminated until appropriate pressure is restored. The audible warning can be silenced by pressing the Audible Warning Mute button.

The system has four different warning signals, identified by illumination sequences.

The signals and corresponding Pressure Setting LED displays are illustrated below.

Display	Warning Signal	
	High pressure	The system cannot reach the set pressure within 10±1 minutes. The system pressure is too high.
	Low pressure	The system cannot reach the set pressure within 8 minutes. The system pressure is too low.
	Mains Failure	Power unit has no power feed.
	Pressure too low	Air pipe kinked.

Operation

Mattress Function

Establishing Pressure (supine patient)

With the patient lying supine (on their back, face upwards), select the soft, medium or firm setting based on patient weight and comfort requirements. You may also select the ‘Dynamic’ or ‘Static’ setting using the relevant buttons.

Before changing or lowering the pressure, ensure the system is working effectively by performing a ‘bottoming out’ test:

Bottoming Out Test

When altering the pressure setting, ensure the patient is not ‘bottoming out’ (insufficiently supported by the air cells and therefore coming in contact with bed base).

1. Ensure system is in alternation mode but is not undergoing an alternation.
2. With the patient lying in a supine position, unzip top cover just past sacral (bottom) region.
3. Slide your hand along a deflated cell under the patients sacral area (bottom). The inner static cell will remain inflated but your hand should slide easily between patient and base.
4. If a hand can pass under patient then the patient is adequately suspended and pressure can be lowered.
5. Repeat Bottoming Out test after pressure has been lowered.

In the event of a system malfunction, the Audible Warning will activate and pressure LEDs will flash.

Establishing Pressure (inclined patient)

When moving the patient to a sitting or more upright position, pressure may need to be increased to a medium or firm setting in order to provide added support and to avoid ‘bottoming out’.

⚠ It is important to return to the original pressure setting when the patient returns to the supine position.

⚠ Wait a minimum of 12 minutes between pressure adjustment and patient assessment, as it may take a cycle for the system to adjust.

CPR Function

The CPR system consists of a manually operated button located on the Air Inlet connector attached to the control unit. By pressing the Red Button, which will release the connector locking system, the user can remove the connector unit which will deflate the mattress.

To re-inflate the system after the connector unit has been removed replace as such, ensuring all sealing connectors are firmly attached and restart the Control Unit. Wait for the Mattress system to gain optimal pressure.

Perform a Bottoming Out test after inflating the mattress following rapid deflation.

Mattress replacement system

The Air Pro-Plus is a replacement mattress system. Remove the standard / foam hospital mattress before patient use.

Operation

Removal & Transport Function

1. Before patient transport, switch modes from alternating to static and wait for 10 -15 minutes for cells to inflate to maximum pressure.
2. Turn off the Control Unit.
3. Remove the mattress connection from the Control Unit. Allow air to escape for a few seconds before sealing with the attached transport cap, see picture on cover. This will soften the Mattress surface for pressure relief and comfort.

   If the patient is responsive, check comfort level based on current pressure and adjust accordingly.

⚠ Always perform a 'bottoming out' test (see page 9) to ensure the patient is adequately supported and not touching bed base.

System Removal

1. Turn off the Control Unit by pressing the Power button for at least 3 seconds and unplug the power cable.
2. Remove the Rapid Release Connector from the Control Unit.
3. Place Control Unit and power cable on top of the Mattress and detach Mattress from the bed frame.
4. Once air has been released from all cells, roll up the Mattress and return all items to Carry Bag for safe keeping.

⚠ Prior to re-starting the system, ensure the Rapid Release Connector is firmly connected to the Control Unit.

5. Troubleshooting

Warning/Fault	Cause	Solution
Control Unit does not operate; no display lights illuminate	The Control Unit may not be attached to a power source or a fuse may need replacing	1. Check the Control Unit is connected to mains power outlet with the correct voltage. 2. Check the Control Unit is switched on. Switch off and unplug the unit before restarting. 3. Check the mains plug fuse (3 AMP) then check both Control Unit fuses (1 AMP) – fuses can be released using a screwdriver to push and turn. ⚠ Do not try to open the Control Unit. Opening the unit could cause personal injury or equipment damage. ⚠ Ensure the replacement of fuses is carried out accordance with local legislation.
Warning LED C + audible warning 	Mains failure / Other	1. Reset the warning -turn off power and press the audible warning mute button. 2. Check the connector is intact, ensuring it is firmly fitted to the control unit and umbilical hose. Check the connector is intact, ensuring it is firmly fitted to the control unit and umbilical hose. 3. 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. 4. Check all cells, pipes and hoses for any air leakage. 5. Switch on power.
Warning LED B + audible warning 	Pressure too low	1. Reset the warning -turn off power and press the audible warning mute button. 2. Check the connector is intact, ensuring it is firmly fitted to the control unit and umbilical hose. Check the connector is intact, ensuring it is firmly fitted to the control unit and umbilical hose. 3. 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. 4. Check all cells, pipes and hoses for any air leakage. 5. Check that the air filter cover is correctly secured and the air filter is clean. 6. Switch on power.

Troubleshooting

Warning/Fault	Cause	Solution
Warning LED A + audible warning 	Pressure too high	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. 3. Check for twists in the air hoses between Mattress and Control Unit. 4. Switch on power.
Warning LED A,B+C + Audible Warning 	Initialising Failure	1. Press the Audible Warning mute button to silence the Audible Warning. 2. 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. 3. Check that the CPR connector is firmly attached to the Control Unit (located on left of control unit casing).
If the aforementioned solutions cannot successfully resolve the problem, please check as below:		
Warning LED Any + audible warning	Alternating Mode Failure (no alternation)	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.
Warning LED Any + audible warning	Power down	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.
Patient is sinking or “bottoming out” whilst lying flat on the Mattress Replacement	The pressure may be set too low for the patient’s weight	1. Increase the pressure setting by pressing up the Pressure button. 2. To check effective system performance, conduct a “bottoming out” test as described on page 9. ⚠ If the problem is not resolved, please contact Direct Healthcare or an authorised local distributor. See contact information on the back cover.

6. Cleaning

Before the cleaning and disinfection procedure, please use hygienic hand disinfection with an alcoholic skin disinfectant.

To protect clothing, use plastic apron, face mask and gloves.

Infection Control and routine cleaning must be carried out in accordance with your local Infection Control Policy. It is suggested that all disinfection be done with a high grade disinfectant in accordance with manufacturer’s instructions.

⚠ Use authorised cleaning and disinfection solutions only.

⚠ The working table and the system must be cleaned and disinfected.

⚠ Concentration and exposure time of the solutions must be noted.

⚠ The top cover seams are sealed to prevent moisture ingress and bacterial growth in the seam stitching.

⚠ Do not use high temperature autoclave, or use Phenolic based products for cleaning.

⚠ It is recommended the system is cleaned between patients and approximately every two weeks if in constant use.

⚠ Refer to the cleaning and disinfection information for the Air Pro-Plus system for additional guidance.

⚠ In case of questions in hygiene please contact an authorised local Direct Healthcare Group distributor.

Mattress Base

Wipe down the outside shell with authorised cleaning and disinfection solutions, ensuring that all surfaces come in contact with the disinfectant. Rinse off well with a clean damp cloth and air dry. Should Air Cells require disinfecting, disconnect Air Cells from the base by unfastening the press studs at each end and disconnecting air pipes from main air hoses before sliding each cell out from the cell straps. Swab with authorised cleaning and disinfection solutions. Dry thoroughly with a soft cloth before refastening.

⚠ Do not machine wash or dry the Air Cells or Mattress base.

⚠ Do not disassemble the Mattress unless cleaning is required. If cleaning or disinfecting is required, do not disconnect the pipes from individual Air Cells.

Cleaning

Top Cover

⚠ Refer to the top cover wash tag for cleaning instructions.

If there are visible signs of body fluids and or substances present, the top cover should be washed. Top covers can be machine washed (up to 95°C) using authorised cleaning and disinfection solutions.

To establish the amount of disinfectant to use, determine the amount of water in the washer and then follow the manufacturers' instructions for dilution.

Soak the top cover in the disinfectant during the wash cycle. Rinse well in clean water and dry thoroughly before use.

⚠ Do not dry the top cover using too high a heat cycle (see Dartex technical recommendations - up to 80°C). Air dry if possible or select an appropriate heat dry cycle within limits as above. If there are no visible signs of body fluids and or substances on the top cover, the top cover should be sanitized and rinsed with fresh water accordingly.

1. Apply an intermediate level authorised cleaning and disinfection solution to the top cover upper surface either by spraying or by hand application.
2. Ensure the surface is completely covered with the disinfectant and remains in contact with the surface according to manufacturer's instructions.
3. Remove disinfectant and rinse thoroughly.
4. Allow to air dry before use.

Connector

The exterior of the Connector can be periodically wiped using a cloth and dampened with authorised cleaning and disinfection solutions.

Control Unit

⚠ Ensure the Control Unit is disconnected from the mains electricity supply before cleaning.

⚠ Do not spray disinfectant directly on to the Control Unit, or immerse the Control Unit in any type of liquid. This could result in a severe electrical hazard as this equipment has no protection against ingress of water.

⚠ This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Wipe down Control Unit with warm water containing detergent (or authorised cleaning and disinfection solution) and dry thoroughly before use.

⚠ In case of notifiable diseases clean and disinfect systems following eventually special procedures revised and published by the local health care authorities. The transport should take place in special plastic bags only.

7. Maintenance

Air Filter Replacement

1. Switch off the power supply to the Control Unit.
2. Disconnect the power lead and air hoses.
3. Place the Control unit on a flat surface with back panel uppermost (place soft cloth under unit to prevent scratches).
4. Carefully remove air filter cover, remove and discard the filter material and fit new filter (there may be a small locking screw – use a small Phillips head screwdriver to remove).
5. Refit the air filter cover to the Control unit. The Control unit is now ready for re-connection.

⚠ Good filter maintenance is critical to maintain your system in optimal operating condition. Failure to keep the filters clean will result in system downtime and increase repair costs. It is recommended that the air filter be replaced annually. Replacement air filters are available from an authorised local Direct Healthcare distributor. Please see contact information on cover.

Fuse Replacement

1. Switch off the power supply to the Control Unit.
2. Remove the power cord from the electrical socket on the side of the base of the Control Unit.
3. Insert a small Flat head screwdriver into the groove and turn anti-clockwise (quarter turn).
4. Remove the "blown" fuse from the fuse holder clip and discard.
5. Insert a new fuse into the plug. Push against the force of the spring and turn clockwise with the screwdriver (quarter turn).

⚠ Ensure the replacement of fuses is carried out accordance with local legislation.

8. Warranty Information

This product is produced to perform in accordance with established specifications, starting from the date the product is shipped.

The warranty period is two years.

During the warranty period repairs and replacement will be made on products that are not performing in accordance with established specifications, unless the problem/failure is due to:

- customer damage, negligence and/or misuse.
- unauthorised repairs.

Items not covered under warranty include, but are not limited to, stains, punctures, cuts, damages to electrical cords, rips or tears, dents and/or lost/missing parts.

Neither the company (see contact information on back cover), its distributors, officers, directors, employees or agents shall be liable for consequential or other damages, including but not limited to personal injury, loss, or any other expense, directly or indirectly arising from the use of its products. The sole remedy for breach of the limited warranty granted herein shall be repair or replacement of the products.

If you have any questions see contact information on back cover.

9. Technical Specification

Definition of Symbols Used

The following symbols may appear in this manual, on the Control Unit, or on its accessories. Some of the symbols represent standards and compliances associated with the Control Unit and its use.

Caution: Consult accompanying documents

Class II equipment

Manufacturer

Serial number

Type BF applied part

DISPOSAL: Do not dispose of this product as unsorted municipal waste.
Collection of such waste separately for special treatment is necessary.

Opertating Instruction: ISO 7010-M002 Refer to instructions manual/booklet

Keep Dry

IP21

IP: INGRESS PROTECTION
2: PROTECTION AGAINST FINGERS OR OTHER OBJECT NOT GREATER THAN 12.5MM IN DIAMETER
1: PROTECTION FROM VERTICALLY DRIPPING WATER

CE
0843

Technical Specification

Declaration – electromagnetic emissions - for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission

The MAT1310001 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	

Technical Specification

Declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The MAT1310001 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	±8 kV contact ±15 kV air		±8 kV contact ±15 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 $\%U_T$	Cycles	Voltage Dips $\%U_T$	Cycles	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.
	>95	0.5	>95	0.5	
	>95	1	>95	1	
	30	25 (50Hz) 30 (60Hz)	30	25 (50Hz) 30 (60Hz)	
	Voltage Interruption $\%\ U_T$	Cycles	Voltage Interruption $\%\ U_T$	Cycles	
	>95	250 (50Hz), 300 (60Hz)	>95	250 (50Hz), 300 (60Hz)	
Power frequency (50Hz) 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.

Technical Specification

Declaration – electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The MAT1310001 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 Vr_{ms} 150 kHz to 80 MHz	3 Vr_{ms}	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 $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.7 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, [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	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.

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 MAT1310001 Alternating Control Unit

The MAT1310001 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 2.7 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.

10. Technical Data

Power Unit (Pump)

Serial Number	As per label on rear of pump
Electrical Supply.	220-240VAC
Power Consumption	Max 20 watts
Fuses	T1AH 250V
Protection against shock	Class 2
Noise Level	At running: 40.8dB
	At warning: 56.6dB
Dimensions	245 x 160 x 95 mm
Weight	2.05 kg
Service Interval	12 months
Expected life	5 years
Shelf life of parts	5 years

Mattress

Serial Number	Label on inside of mattress cover
Number of Air Cells	17 cells & 2 lateral cells
Dimensions	2000 x 880 x 135mm (Nominal)
Weight	7.5-7.6 kg
Expected life of Mattress	5 years
Shelf life of Mattress parts	5 years

11. Optimum Conditions

(Applies to Mattress and Pump)

Environment Conditions for Use

Transport	-25°C – +70°C
Storage	-25°C – +70°C
Usage	+5°C – +40°C
Humidity	10% – 93%
Atmospheric Pressure	700hPa – 1060hPa
Operational Altitude	≤ 2000m

Contraindications For Use (Warning)

The Air Pro-Plus mattress should not be used for patients with unstable fractures, gross oedema, burns, or intolerance to motion.

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 Power Unit (pump).
- 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 (pump) 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.
- 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 System on or close to a source of heat.
- Do not use with hot water bottles or electric blankets.
- DHG strongly advise against smoking whilst the Control Unit (pump) 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 Air Pro-Plus mattress 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.
- 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 or phenols. Chlorine based products which exceed 10,000ppm available chlorine. 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 pressure 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.

12. Detachable/Removable Parts

1. Mattress (Detached from the pump by removing the CPR connector). Part No. MAT1310001 (or variants of the size)
2. Electric power cable. (Removed from the pump by pulling the cable away from the mains inlet on the side of the pump).

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

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

13. Disposal

Please refer to DHG website for recommendations and responsibilities for disposal within the UK WEEE guidelines.

Direct Healthcare Group

Advancing Movement & Health®

Intelligent Pressure Care
Specialist Seating
Rental & Service Solutions

Direct Healthcare Group
Withey Court, Western Industrial Estate
Caerphilly, United Kingdom
CF83 1BF

T: +44 (0) 845 459 9831
F: +44 (0) 845 459 9832
E: info@directhealthcaregroup.com

LIT-00006 Issue 6
Date: December 2018

DIRECTHEALTHCAREGROUP.COM

C22572