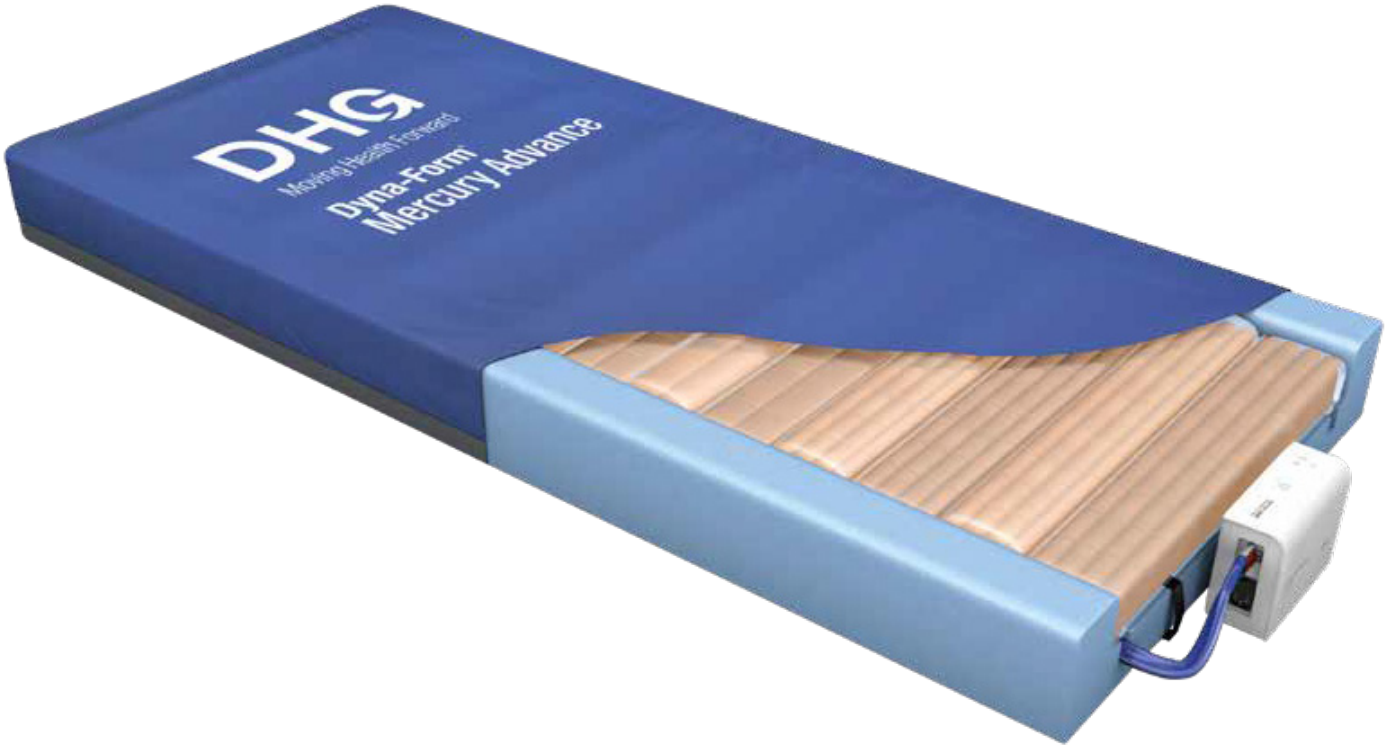
Dyna-Form® Mercury Advance

MD CE 1434

Instructions for Use - English
Bruksanvisning – Svenska
Brugsvejledning – Dansk
Käyttöohje – Suomi
Handleiding – Nederlands
Brukermanual – Norsk
Manuel d'utilisation – Français
Gebrauchsanweisung – Deutsch
Manuale utente – Italiano
Manual de usuario – Español



REF

MAS12
MAT12
PUM12

DHG
Moving Health Forward

LIT-00007 Issue 16 2024-06-26

Table of Contents

1. Intended Use of the Product

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

2. Indications for Use

The Dyna-Form Mercury Advance mattress range is intended to be used by all kinds of users, including lay persons, in all healthcare environments including professional healthcare facilities and home healthcare. The intended patient population is for individuals aged between Paediatric - Geriatric with a body weight of >10kg. The mattresses is suitable for persons who are at very high risk of pressure ulcers, including those with category 1, category 2, category 3, or category 4 pressure ulcers, alongside an individualised care plan.

3. Contraindications for Use

The Dyna-Form Mercury Advance should not be used for patients with unstable fractures, gross oedema, burns or intolerance to motion.

4. Safety Information

Visual inspection

- Inspect the packaging for any damage.
- Check that the correct product has been delivered.
- Check to ensure that the mattress is free from damage.

Always Read the User Manual

- Always read the user manual before use.
- Keep the user manual where it is accessible to users of the product.
- Always ensure that you are referring to the latest version of the user manual.
- The most recent version of the user manual is available to download from the DHG website: www.dhg-healthcare.com
- It is strongly prohibited to modify the original product.

⚠ 5. Warnings and Cautions

Warnings

- The Medical Professional is responsible for applying 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, 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 Direct Healthcare Group (DHG).
- The system is not to be used in the presence of flammable anaesthetics.
- 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 (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.
- Select correct setting 'Hi' or 'Low' as required.
- Care should be taken not to accidentally change settings once set, as this may affect the desired ouput of the therapy.
- To prevent accidental changes to the settings ensure that children, pets and pest are kept away from the Control Unit.
- 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.
- Suitable for continuous use.
- The Mattress will not 'alternate' when disconnected from Control Unit and /or the mains electrical.
- Do not use in an oxygen enriched environment.
- 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 Mercury Advance 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.

- Not suitable for use in an Outdoor Environment.
- Do not connect to any other medical device or equipment.
- The System should be cleaned after use or between patients. Refer to the Cleaning section.
- Do not use bleach, phenols, chlorine based products which exceed 1000ppm available chlorine, solvents or alcohol based cleaners.
- Do not immerse the Control Unit in water or other fluids.
- Do not autoclave any parts of the Mercury Advance Mattress System.
- The system is not suitable for sterilisation.
- Before cleaning make sure that the Control Unit is disconnected from the mains electricity supply.
- Only qualified technicians trained or formally approved by DHG in the operation and maintenance of DHG products may carry out maintenance, modification or repair work on the equipment. Unqualified personnel attempting to work on DHG Control Units risk serious injury to themselves and others and possibly death by electrocution.
- Inlet fuse NOT to be replaced by operator or patient, to be replaced by service personnel only.
- Correct fuse rating MUST be used. Failure to do so could result in the risk of a fire.
- Modification of this product in any way without authorization from DHG is strongly prohibited.

Cautions

- It is recommended that an audit of all mattresses is carried out at least annually.
- Mattresses can become damaged if stored incorrectly. Mattresses should be stored in a clean and dry environment.
- It is not advised that mattresses are stored near heating devices, such as electrical fires or radiators.
- Take care when handling the mattress to prevent damaging the cover or foam.
- Avoid contact with abrasive surfaces, and do not drag the mattress.
- Use of detachable parts not listed is not recommended by DHG.

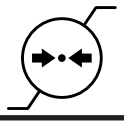
All the above warnings and cautions together with safety considerations should be observed at ALL times during use of the Mercury Advance Mattress System.

6. Serious Incidents

Any serious incident that has occurred in relation to the Dyna-Form Mercury Advance system should be reported to DHG or the Authorised Representative and the Competent Authority of the country in which the user and/or patient is established.

7.Symbols

General Symbols

	Read the user manual		Atmospheric pressure limitation
	Medical device		Protect from heat and radioactive sources
	Class IIa product conforming to the requirements of UK MDR 2002 for Medical Devices, MDD 93/42/EEC		
	General warning symbol		
	Temperature limitation		
	Humidity limitation		

Mattress Symbols

	Refer to the User Manual		No smoking
	Wash at 80°C		Maximum user weight of 254kg
	Tumble dry on low		Do not use phenols
	Do not dry clean		Do not use sharp instruments
	Do not bleach		Type BF applied part
	Do not iron		Class IIa product conforming to the requirements of UK MDR 2002 for Medical Devices, MDD 93/42/EEC

Control Unit Symbols

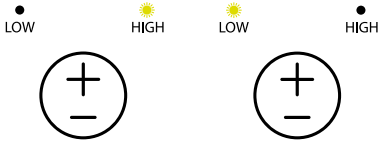
	Refer to the User Manual		Double insulated Class II
	Service indicator		Class IIa product conforming to the requirements of UK MDR 2002 for Medical Devices, MDD 93/42/EEC
	Do not dispose of with household waste		Medical device
IP22	IP: Ingress Protection 2: Protection against fingers or other object(s) not greater than 80mm in length and 12mm in diameter 2: Protection against falling drops of water, if the case is disposed up to 15° from vertical		

8. Quick Reference Guide (Frequently Used Functions)

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 reset by switching the Control Unit off and then back on again.

CPR Valve
Please ensure that the CPR connector is always fully secured 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.
Disconnecting the CPR will rapidly deflate air from the mattress in readiness for CPR, or for use in transport/static mode.



LED Mode Settings
This symbol, when illuminated, is used to indicate that the equipment is on or ready for use.
When clinically required, the “High” setting (pressure 26mmHg) can be selected.

When clinically required, the “Low” setting (18mmHg) can be selected.

This function is used to silence the Audible Warning. The LED 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 reset fully. If the Audible Warning continues to sound repeatedly, along with an illuminated light, then an engineer should be called.

This symbol indicates an “Audible Warning Failure”.
Please see troubleshooting guide below for how to rest.

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).

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 the Control Unit section.

9. Installation

Installing the 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 Mercury Advance 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.

It is permissible to use the mattress with adjustable, profiling beds. Ensure that the bed's knee break is utilised when putting the user into a seated position.

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

If the cover needs to be removed, this is easily done by locating the zip in the bottom left corner and unzipping along the three (3) sides of the mattress. This will allow for the mattress cover to be completely removed.

Static Mattress Use
The Dyna-Form Mercury Advance 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 Mercury Advance Mattress can be used as an alternating mattress system by attaching the Dyna-Form Mercury Advance 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 Mercury Advance Control Unit are specific to this mattress only.

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

The startup time from static to dynamic mode is immediate.

Control Unit
Hang the Control Unit onto the footboard. The mounting hooks swivel to suit the thickness of the footboard or rail. Connecting the Umbilical Hose to the Control Unit , place the supplied power cable electrical plug into the wall outlet and switch on:
(a) Open the zip located at the bottom left hand side of the mattress and pull out the blue Umbilical hose.

(b) 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.

(c) 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.

(d) Shut down is the reverse of items a, b & c above.

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

10. Operation

Attach the supplied mains cable to the Control Unit by inserting the power supply 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 DHG are not recommended for use with this Control Unit.

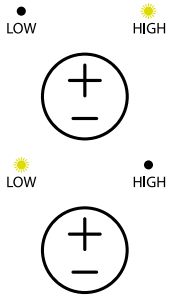
Power cables not supplied by DHG are not recommended for use with this Control Unit.

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 both the “High “and the “Low” 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 “Low” light will stay on constantly and the mattress is ready for use.

Low/High Settings

The Dyna-Form Mercury Advance Mattress, in Alternating Mode, has two pressure settings. The initial setting that the control unit will revert to upon set up is “Low”. 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, dependent on the clinical judgement of the clinician, the “High” setting is activated by pressing the +/- button once, which is located on top of the Control Unit.



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 Low and High modes to be selected in turn.

CPR Deflation

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 air system back to that of a static foam mattress.

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.

Troubleshooting

For assistance (if needed) in setting up, using or maintaining the Mercury Advance System, or to report unexpected operation or events, please contact DHG on the contact details on the reverse of this manual.

Fire Evacuation System (If Applicable)

The Dyna-Form Mercury Advance can be fitted with an optional fire evacuation system. In the event of an evacuation occurring, the following steps should be taken to provide the safest possible transport of the user:

1. The Dyna-Form Mercury Advance Fire Evac system has clearly marked instructions on the foot and head for ease of use.
2. Open the zips at the shortest ends of the mattress (head end and foot end) to gain access to the Fire Evac harness system.
3. Pull out harnesses from the mattress and remove the patient securing straps.
4. Place patient securing straps around both the mattress and the patient, adjust the straps accordingly to ensure the patient is secure.
5. Drag both the mattress and the patient on the floor to an area of safety.

11. 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.

12. Troubleshooting

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 (5 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 in accordance with local legislation.
LED C **+ Audible Warning** 	Mains failure/Other. See above, plus:	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 (5 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 in accordance with local legislation.
LED B **+ Audible Warning** 	Pressure too low	1. Reset the warning – turn off power and press the Audible Warning mute button. 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. 3. Check all cells, pipes and hoses for any air leakage. 4. Check that the air filter cover is correctly secured and the air filter is clean. 5. Switch on power.
LED B+C **+ Audible Warning** 	Pressure too low/ Air pipe kinked	1. Check Blue external umbilical air pipe that is between mattress and CPR connector is not kinked, twisted or damaged. 2. Check all air hoses along the inside of the mattress – each should be firmly connected. 3. Check each air cell is securely attached to its connecting air pipe.
LED A **+ Audible Warning** 	Pressure too high	1. Reset the warning – turn off power and press the Audible Warning 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.
LED A+B **+ 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.
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).

13. Maintenance Procedures

13.1 Control Unit

Safety Warning
Only qualified persons trained and formally approved by DHG in the operation and maintenance of DHG products may carry out maintenance, modification or repair work on the equipment. Any warranty provided with the Dyna-Form Mercury Advance system will be void if servicing and/or repair is performed by a non-qualified person. Unqualified personnel attempting to work on DHG Control Units risk serious injury to themselves and others and possibly death by electrocution. Inlet fuse NOT to be replaced by operator or patient, to be replaced by service personnel only.

Servicing
DHG 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 and should only be carried out by persons as described above.

DHG will make available on request all manuals, component parts lists and other information necessary for any suitably qualified person to carry out repair or service the system. For service, maintenance and any questions regarding this please contact DHG.

13.2 Mattress

Safety Warning
Mattress audits should not be carried out when patients are in situ.

Inspection
Direct Healthcare Group recommends that mattress audits are carried out to inspect both the cover and foam every 6 months to check for ingress, covers and foam damage /wear and any other defects.

DHG will make available on request all manuals, component parts lists and other information necessary for any suitably qualified person to carry out repair or service the system. For service, maintenance and any questions regarding this please contact DHG.

14. Cleaning

14.1 Mattress

- Cleaning should take place before and after use, and between patients.
- With cover left on the Mattress, disconnect the Mattress from the Control Unit.
- Ensure all work surfaces are cleaned with a 1000ppm available chlorine sodium hypochlorite solution or equivalent disinfectant before and after contact with the Mattress.
- Wash Mattress top using hot water (60 degrees C) containing detergent – dry with a paper towel.
- Use a 1000ppm available chlorine sodium hypochlorite solution. For heavy contamination use a 10,000ppm available chlorine sodium hypochlorite solution. Please ensure thorough rinsing after cleaning.
- Using a suitable brush, hot water, detergent or sodium hypochlorite solution, clean the Umbilical Hose and CPR Valve. Dry with a paper towel.
- 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.
- To avoid shrinkage of the cover, line 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.

14.2 Control Unit

Safety 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.

- The Control Unit can be cleaned by wiping with a cloth dampened with a detergent solution or a 1000ppm available chlorine sodium hypochlorite solution

15. Detachable/Removable Parts

1. Mattress (Detached from the Control Unit by removing the CPR connector). Part No. MAT12 (or variants of for the size).
2. 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

Note: The battery is an integral part of the PCB and is not removable or changeable. Use of detachable parts not listed is not recommended by DHG.

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.dhg-healthcare.com for recommendations and responsibilities for disposal with the UK WEEE guidelines.

17. Technical Information

Control Unit

Electrical Supply	220-240VAC, 50/60Hz or 100-120VAC, 50/60Hz
Power Rating	10VA (220-240VAC) or 8VA (100-120VAC)
Fuses	TA1H 250V
Protection Against Shock	Class 2
Noise Level	30dB(A)
Dimensions	245mm (W) x 160mm (H) x 95mm (D)
Weight	1.7kg

Service Interval	12 months / 8760 hours
Expect Life	5 years
Shelf Life of Parts	5 years
Alternating Cycle Type	1-in-2
Alternating Cycle Time	10 minutes
Warranty	2 years

Mattress

Number of Air Cells	14 foam-in-air cells / 1 static foam head cell
Air Cell Size	Variable (W) x 8cm (H) x 10cm (D)
Foam Density (kg/m³)	U-Core: 38-40 Insert: 38-40
Nominal Hardness (N)	U-Core: 200 Insert: 120
Minimum User Weight	10kg
Maximum User Weight	254kg

Weight of Mattress	13.3kg
Expected Life of Mattress	8 years
Fire Testing	BS 7177, Medium hazard
Sizes	Length: 100-220cm Width: 60-180cm Height: 15cm
Warranty	2 years

18. Optimum Conditions (Applies to Mattress and Control Unit)

Environmental 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

Exposure

Exposure to direct sunlight, dust, lint and general debris is not considered to be an issue with the Dyna-Form Mercury Advance System.

19. Electromagnetic Compatibility (EMC)

Declaration - Electromagnetic Emissions - for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturer's Declaration – Electromagnetic Emission The MAS12 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 emissions 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	

Declaration - Electromagnetic Emissions - for all ME EQUIPMENT and ME SYSTEMS

<table>
<tr><td colspan="6">Guidance and Manufacturer's Declaration – Electromagnetic Emission
The MAS12 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.</td></tr>
<tr><th>Immunity Test</th><th colspan="2">IEC 60601
Test Level</th><th colspan="2">Compliance Level</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2</td><td colspan="2">±8 kV contact
±2kV, ±4kV, ±8kV</td><td colspan="2">±8 kV contact
±15 kV air</td><td>Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Electrical fast transient/burst
IEC 61000-4-4</td><td colspan="2">±2 kV for power supply lines
±1 kV for input/output line(s)</td><td colspan="2">±2 kV for power supply lines
±1 kV for input/output line(s)</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge Immunity Test
IEC 61000-4-5</td><td colspan="2">± 1 kV line(s) to line(s)
±0.5kV, ±1kV, ±2kV Line to ground</td><td colspan="2">±1 kV differential mode
±2kV Line to ground</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td rowspan="6">Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>Voltage Dips
%U_T</td><td>Period
(Cycles)</td><td>Voltage Dips
%U_T</td><td>Period
(Cycles)</td><td rowspan="6">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.</td></tr>
<tr><td>30</td><td>25</td><td>30</td><td>25</td></tr>
<tr><td>60</td><td>5</td><td>60</td><td>5</td></tr>
<tr><td>>95</td><td>0.5</td><td>>95</td><td>0.5</td></tr>
<tr><td>Voltage Interruption
% U_T</td><td>Seconds</td><td>Voltage Interruption
% U_T</td><td>Seconds</td></tr>
<tr><td>>95</td><td>5</td><td>>95</td><td>5</td></tr>
<tr><td>Power frequency (50Hz) magnetic field
IEC 61000-4-8</td><td colspan="2">3 A/m</td><td colspan="2">3 A/m</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td></tr>
<tr><td colspan="6">NOTE U_T is the a.c. mains voltage prior to application of the test level.</td></tr>
</table>

Declaration - Electromagnetic Emissions - for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The MAS12 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 Radiated RF IEC 61000-4-3	3 Vr_{ms} 150 kHz to 80 MHz 3 V/m (Professional Healthcare Environment) 10 V/m (Home Healthcare Environment) 80 MHz at 2.7 GHz	3 Vr_{ms} 10 V/m	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:

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.

Recommended separation distances between portable and mobile RD 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 MAS12 Alternating Control Unit.			
The MAS12 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.			

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CE 1434

Class IIa product conforming to the requirements of UK MDR 2002 for Medical Devices, MDD 93/42/EEC