DynaFlow

Alternating and Low Air Loss Pressure Relief System



User Manual

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Please finish reading this manual before using this equipment and keep this instruction handy.

Safety Precautions

When using electrical products, basic safety precautions should always be followed, including the following:

- This device can be used in professional healthcare environment.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State.

⚠ **CAUTION - READ ALL INSTRUCTIONS BEFORE USING THE APPLIANCE**

⚠ **DANGER** – To reduce the risk of electrocution:

1. Always unplug this device immediately after using.
2. Do not use while bathing.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for the device that has fallen into water. Unplug immediately.
6. Do not use when the device is under repair or maintenance.

⚠ **WARNING** – To reduce the risk of burns, electrocution, fire or injury to persons:

1. Connect the Master Control unit to a proper power source. The device should never be left unattended when plugged in.
2. Close supervision is necessary when the device is used by, on, near children or physically challenged individuals.
3. Use the device only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
4. Never operate this device if it has a damaged cord or plug, not working properly, having been dropped or damaged, or dropped into water. Return the device to a service center for examination and repair.
5. Keep the cord away from heated surfaces and anywhere hard to unplug with the device like on the shelves, in a wardrobe or the socket on the ceiling.
6. Never block the air opening of this device or place it on a soft surface such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and other similar debris.
7. Never drop or insert objects into any openings.
8. Do not use this device outdoors.
9. Do not operate this device where aerosol (spray) products are being used or where oxygen / any flammable gases (such as Anesthetic Agents) are being administered.
10. DISCONNECT POWER SUPPLY BEFORE OPENING.
11. The device should only be repaired by authorized and qualified professional.

12. The product has no user/operator serviceable parts.
13. Do not modify the device without the authorization of the manufacturer. Failure to do so may exposure to hazards.
14. Maintain the device regularly. When the device needs repair or maintenance, please turn off the power first and unplug it from the mains, keep empty mattress, and do not use the device.
15. Keep the control unit and mattress away from sources of liquid and open flames.
16. Keep the control unit and mattress away from sharp objects.
17. If pain, irritation, numbness, swelling, or redness occurs discontinue use and contact a healthcare professional.
18. During DIP or power interruption the device would stop functioning and fail the intended use. Please ensure the device is used with a stable power /Uninterruptible Power Supply to prevent this scenario. Do not obstruct the mains plug or position the equipment where the connection to the mains line can be accidentally disconnected.
19. Power cable & control unit shall be placed at the foot-side of the patient to prevent any risk of strangulation due to cable.
20. Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided.
21. Careful consideration of the EMC information is essential when stacking or collocating equipment and when routing cables and accessories.
22. To avoid the risk of cross-contamination, use liner or bed sheet on the mattress.
23. To avoid the risk of death or injury from falling, **side rails need to be in the raised** or guard position when a patient is on the bed.

⚠ **CAUTION** – When choosing a mattress, make sure the distance between top of the mattress (without compression) and top of the side rails and/or restraints is at least **8.66 in (220mm)** to help prevent inadvertent bed exit or falls.

Other Safety Information

Patient Entrance / Exit – It is essential for caregivers to assist patients in exiting the bed.

Brakes – Ensure that caster brakes are locked once the bed is positioned. Always check if the wheels are securely locked before the patient transfers to or from the bed.

Bed Height – To reduce the risk of falls or injury, maintain the bed at the lowest position when the patient is unattended.

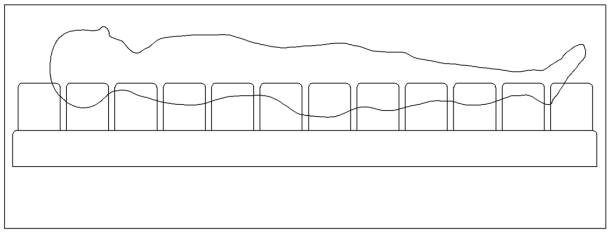
Bed Elevation – To prevent patient migration, keep the head of the bed as low as possible.

The Purpose of this Manual

This operation manual is mainly focused on the set up, cleaning and routine maintenance of the DynaFlow System. We recommend you keeping this manual handy to answer most of the question related to the system.

Intended Use

The DynaFlow System is an innovative specialty mattress replacement unit that employs low air loss technology with a high flow rate to manage pressure and prevent pressure ulcers. Its advanced 3:1 alternating function actively promotes pressure relief, ensuring that two-thirds of the body is always supported at any given time, making it especially beneficial in acute and long-term care settings. Additionally, the DynaFlow System features “pulsation” and “immersion” modes, providing patients with more options beyond the standard alternation and static settings. The soft-firm adjustment allows the patient to adjust the firmness or softness of the surface for optimal comfort through 10 digital scales.



Contraindications for use

Alternating pressure therapy should not be used for patients with unstable fractures/spinal cord injuries, cervical or skeletal traction, gross oedema, burns or an intolerance to motion.

Intended Users

Hospitalized patient, elderly individuals and patients recovering from surgery with age at least fifteen. Operator of this device must be healthcare professionals and have the ability to read and understand English and Westernized Arabic numerals. No patient should be the operator of this device.

Weight Capacity Guidelines

Mattress (applied part)			
Item No.	FM-PHR0008	FM-PHR0047	FM-PHR0048
Maximum weight	350 lbs (36”)	500 lbs (42”)	700 lbs (48”)

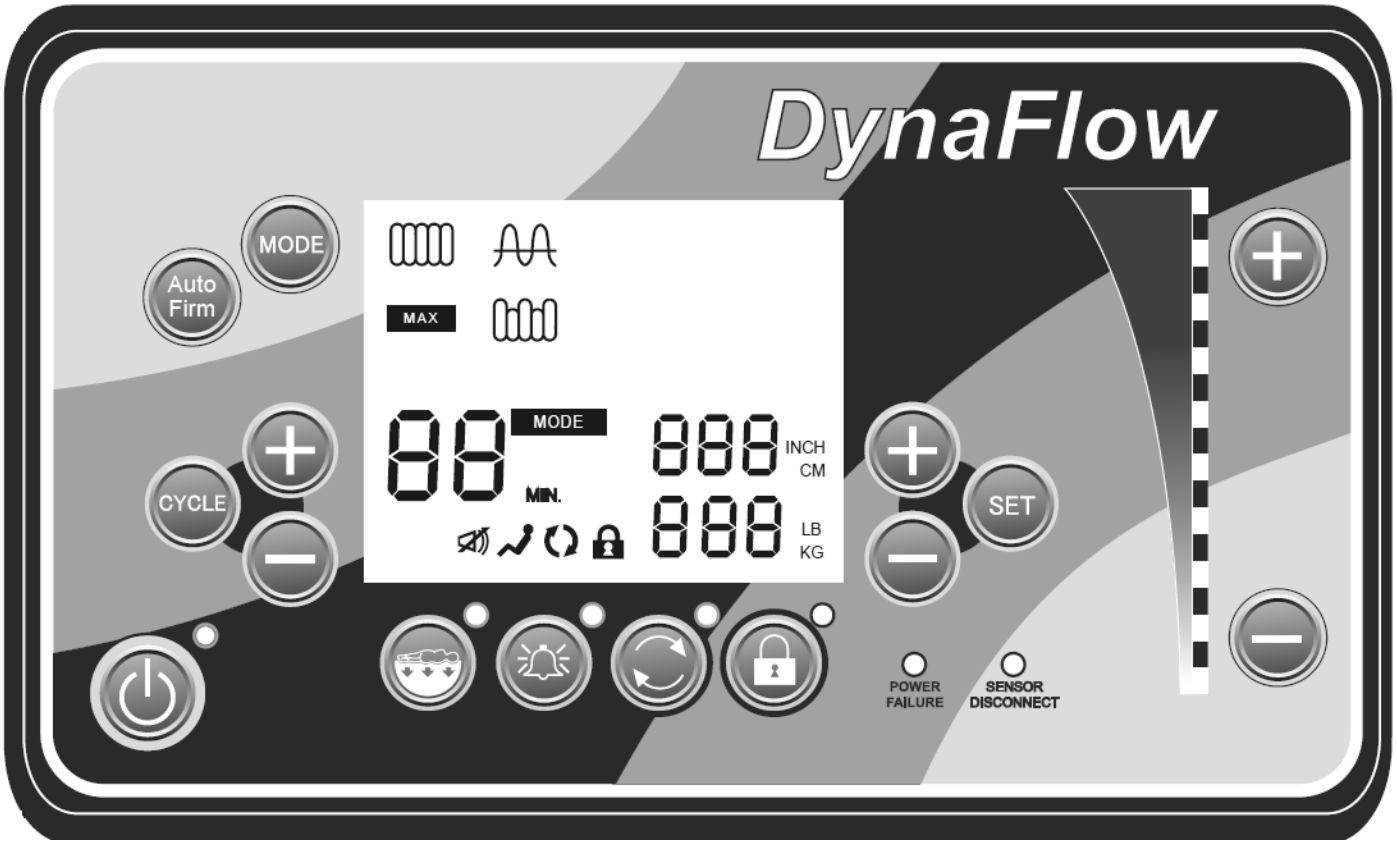
⚠ **CAUTION** – Do not exceed these weight limits at any time to ensure safety of the patient.

Key Features

- **Cycle Time** - alternating time can be adjusted in increments of 3-95 minutes.
- **Static Function** – during alternating function, the caregiver can select the "Static Function" to stop the alternation at any given time.
- **Auto Firm** - the "Auto Firm" function provides uniform firmness for nursing procedures.
- **Audio & Visual Indicators** – adds protection to patient safety during power failures, sensor disconnect and bottom out conditions. The audio indicator can be temporary turned off by pressing the "MUTE" button on the control panel.
- **Low Air Loss (LAL)** – to increase patient comfort by providing air circulation within the mattress, removing patient bodily moisture and lowering patient environment temperature.
- **Auto-Lock** – the control panel automatically locks if left untouched for 2 minutes to prevent accidental changes to modes and settings.
- **Immersion** – to deflate first to relieve pressure and then inflates back to its original setting, creating a zero-pressure experience that feels like floating for the patient.
- **Pulsation** – a dynamic feature of the mattress system that creates rhythmic changes in pressure. This mode provides a soothing experience for patients, making it beneficial for both comfort and therapeutic purposes.
- **Vapor Permeable Cover** – easy to clean, breathable cover, reducing friction and shear whilst optimizing skin microclimate.
- **Cable Management** – cords are retained within the replacement mattress so the risk of tripping and cord pinching is eliminated.
- Enhanced memory retention for user settings (Weight, Height, Mode, and Time) even after power loss.

Control Panel and Function

Control Panel



Functions:

	**Power On/off**: Press the “POWER” button to turn on or off the control unit. After the device is plugged into a power source, the LED indicator will illuminate in amber to indicate it's in standby mode. Press and hold the “POWER” button for 2 seconds to activate the control unit; meanwhile, the LED indicator will light up green.
	**Auto Firm**: Once activated, it switches to static mode and max-inflates all air cells that allows easy repositioning, transfers, and nursing procedures. This function can be initiated any time to fast inflate the mattress. Press the “AUTO FIRM” button to activate the function, and the screen will show MAX icon MAX. Press the “AUTO FIRM” button again to exit Auto Firm mode. For safety purpose, the device will also automatically return to previous setting after 30 minutes.



Mode: Press the “Mode“ button to choose between one of the three therapy settings, and the corresponding icon will display on the screen when the therapy mode is selected. Below are the icons of the three therapy modes:



Static: inflates all the air cells to the selected comfort level for ease of patient transfer or reposition. Under this mode, the system will only provide low air loss therapy.

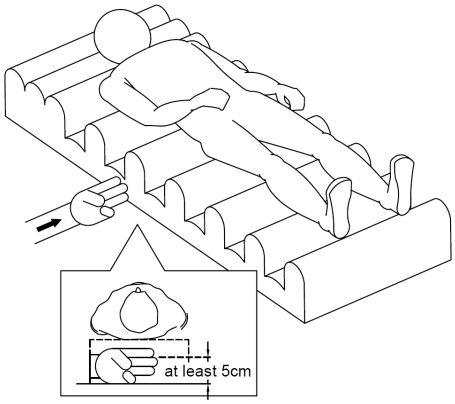


Alternate: enables 3-1 alternating mode, where at least 2/3 of the cells will support patient weight at any time. Alternating time cycle can be adjusted, refer to “Cycle Time” section (p. 8) for more details.



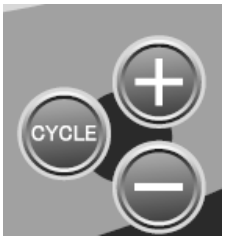
Pulsation: inflates and deflates all air cells simultaneously for pressure-relieve therapy.

NOTE: It is important to perform a hand check during alternating mode to prevent bottoming out. Place a hand under the patient’s buttocks at the deflated cell section -- there should be at least 5 cm (approximately 3 fingers) of clearance between the buttocks and the bottom of the mattress. Caregivers must check the controller settings and the patient's condition every two hours to minimize the risk of bottoming out. The bed frame side rails should be kept in the upright position while the patient is on the mattress.



CAUTION:

Alternating pressure therapy is not recommended to patient who has serious pain or pain-sensitive symptom. In this case, we recommend the application of foam mattress which can be found in ***Caremed Supply, Inc.*** *product range.*

	**Cycle time:** Cycle time can be used under alternation and immersion modes. Under alternation mode, the default setting is 3 minutes cycle. Press the (+) and (-) button to select the desired time (between 3 to 95 minutes) that is suitable for patient, and the selected time will display on the screen. The suggested cycle time is no more than 15 minutes.
	**Immersion:** An advanced alternative to traditional air-fluidized beds. The default cycle consists of a 1-minute deflation followed by a 1-minute inflation. The deflation duration is configurable, allowing for adjustments between 1 to 5 minutes to accommodate individual needs. To activate Immersion mode, press the button on the control panel and the LED will be illuminated in green. Then the deflation time can be modified by pressing "Cycle." Use the (+) and (-) buttons next to "Cycle" to increase or decrease the duration as desired.
	**Function Lockout:** Automatically locks out all functionality 2 minutes after a function change to ensure buttons cannot be inadvertently pressed. When lockout feature is activated, the lock LED indicator illuminate in green, and the lock icon will be displayed on the screen. Caregiver can unlock (or manually lock the device functions) by press and hold “LOCK” button for 3 seconds.
	**Mute:** The control unit is equipped with both a visual and audio alert. When a failure is detected, the audio alert will go off. Press the “MUTE” button to temporary silent the alert (the screen will display a mute icon ; meanwhile, the visual LED indicator will remain illuminated in amber. Two types of failures can be muted: power failure and sensor disconnect. The audio alert will go off again if the problem persists in 20 minutes.
	**Failure Modes:** There are two types of failures that can be detected by the control unit, which will trigger both visual (an amber LED will illuminate) and audio alerts: - Power failure: no power input. Check if the power plug is securely plugged into a mains outlet. - Sensor disconnect: sensor cable is not connected properly. Check the if the sensor cord from the mattress is connected firmly to the control unit. **Note:** The audio indicator and be temporary muted when needed. Please refer to function Mute (p. 8) for more details. If you encounter any other issues while using the device, refer to the Troubleshooting page (p.18) for further guidance.



Auto Set: To streamline patient care, the control unit can automatically adjust to the recommended pressure level based on the patient's height and weight.

Upon startup, the Auto Set will be turned on, and the LED indicator will illuminate in amber. The default values are set to 67 inches (170 cm) in height and 143 lbs (65 kg) in weight, corresponding to a pressure level of 3. To input the correct patient information, follow the steps below:

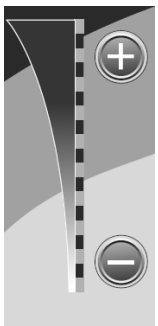


1. Press the SET  button.
2. Use the (+) and (–) buttons to select the preferred units (cm/kg or inch/lb).
3. Press SET again to adjust the patient’s height using the (+) and (–) buttons.
4. Press SET a third time to set the patient’s weight.
5. After entering the correct values, press SET once more to confirm.

The control unit will automatically calibrate to the appropriate pressure level based on the input.

If necessary, caregivers can manually adjust the Comfort Level according to the patient’s preference (see Comfort Level, p. 9).

Note: once the Comfort Level is changed manually, the Auto Set function will be deactivated. To reactivate it, simply press the Auto Set button again. The previously entered height and weight values will remain saved, and do not need to be re-entered.



Comfort Level: 10 comfort levels are available for a variety of patient weights. Use the (+) and (-) buttons to adjust pressure accordingly. After activation, the system will automatically go to the default comfort level setting of level 3, with the green indicator remaining illuminated.

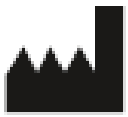


Auto Fowler: The system automatically detects if the patient (mattress support surface) is in upright position. When upright position is detected, it will activate “fowler” mode, where it increases the mattress pressure to avoid patient from bottoming out. When activated, the screen will display the auto fowler icon as shown. When the mattress support surface is no longer in upright position, the fowler mode will automatically be deactivated.

Specification

Control Unit			
Model No:	DynaFlow Control Unit		
Item No.	FC-PHR1057		
Size in Inch (L x W x H):	12.2" x 6.7" x 13.2"		
Weight:	6.5 (kgs)		
Cycle Time:	3-95 Minutes		
Max Operating Pressure	33±5mmHg		
Rated Voltage and Frequency	AC 110-120V, 60Hz		
Max Current	3A		
Fuse Rating and Size	T5AH 250V, Size: ø5x20 mm		
Classification:	Class II (w/ functional earth) Type BF Not AP or APG type 		
Mode of Operation:	Continuous		
Power Cable	15ft, non-shielding, AC powered. The third pin (conductor) in the power cable plug is only a functional earth.		
Environment (Temperature)	Operation: 15° C to 35° C (59° F to 95° F)		
	Storage and transportation: 5 ° C to 60 ° C (41° F to 140° F)		
Environment (Humidity)	Operation: 30% ~ 75% non-condensing		
	Storage and transportation: 30% ~ 90% non-condensing		
Operation Atmospheric Pressure Range	700 hPa to 1060 hPa		
Test Standard:	IEC60601-1, IEC60601-1-2		
Mattress (applied part)			
Item No.	FM-PHR0008	FM-PHR0047	FM-PHR0048
Size in Inch (L x W x H)	80x36x10	80x42x10	80x48x10
Maximum weight	350 lbs (36”)	500 lbs (42”)	700 lbs (48”)
Cells Material	Nylon w/ PU		
Base Material	Woven Polyester fabric w/ PVC backing		
Cover Material	Nylon woven fabric w/ PU coating finish		
Base Material	Woven Polyester fabric w/ PVC backing		

Symbols Used

	Type BF Protection Against Electronic Shock		Class II Equipment
	Refer to Instruction Manual / Booklet *NOTE: Background color: blue / Symbol: white*		Waste Disposal
	Caution, Consult accompanying documents		SGS product certification mark
	Date of manufacture		Manufacturer
	Batch code		Tumble Dry, Normal Low Heat
	Machine Wash. Water temperature should not exceed 40 ° C (104° F)		Do Not Bleach
	No Phenols		Do not dry clean
	Do Not Iron		Keep Dry

Instructions for Use

WARNING – For important precautions, see p. 2~3.

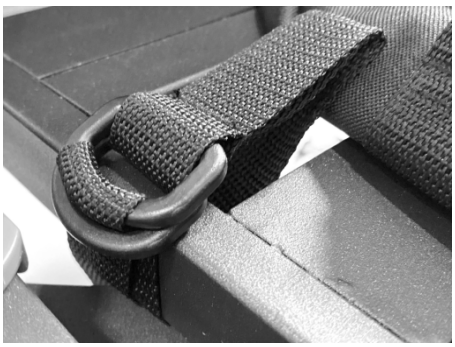
WARNING – Check the power cord and plug for abrasions and excessive wear. Replace if necessary. Do NOT use the device if the power cord is not in a good condition.

CAUTION – Power on the device and activate ‘AUTO FIRM’. Check if the air hose and air cells have air leakage, or if air manifold is kinked or broken. Replace the parts if necessary.

CAUTION – Prior to usage, please allow the product to acclimate to ambient conditions for at least 30 minutes if the ambient temperature is 20°C. This helps ensure optimal performance and prevents potential damage caused by sudden temperature changes from the storage temperature range of 5°C to 60°C.

SETUP:

1. Replace the existing mattress with the DynaFlow System. Orient the mattress so that the air hose is at the foot end of the bed.
2. Secure the straps beneath the mattress to the bed frame back board. Do NOT strap it to the side rail.

3. Connect the power cord to the bottom left side of the control unit.



4. Hang the control unit on the foot board of the bed frame, or place on the floor if there is no foot board attached to bed frame.

5. Attach the air hose and fowler sensor cable to the sockets on the left side of the control unit. Ensure the yellow arrow mark on the hose aligns with the yellow ‘INSERT’ pointer at the connection inlet, as illustrated in the picture below. Once connected, the components will be automatically secured to prevent air leakage.



Air hose inlet



Fowler sensor inlet

6. Check all air hoses to ensure no air hose is kinked.
7. Plug the power cable into the mains outlet, and the power LED will illuminate amber.
8. Press and hold the 'POWER' button for 2 seconds on the control panel to inflate the mattress. While the mattress is being inflated, the mute button and auto set button LED indicators will illuminate in green, and the auto set icon will display on the screen.
9. It takes about 30 minutes for the mattress to be fully inflation. After the mattress is inflated, the system will enter into Static mode , where default comfort setting is set to level 3.
10. Caregivers now can transfer the patient onto the mattress.
11. Please press and hold ‘LOCK’ button for 3 seconds to unlock the control functions.
12. Press the 'SET' button, then use (+) and (–) buttons to select the preferred unit of measure (cm/kg or inch/lb) for patient’s height and weight. Press the 'SET' button again to set patient’s height using the (+) and (–) buttons. Press the 'SET' button the third time to set patient’s weight using the (+) and (–) buttons. After entering the correct information, press 'SET' once more to confirm. The control unit will then automatically calibrate to the appropriate pressure level.

13. Press ‘Mode’ 

to switch to pulsate  or alternate  function (p.7).
14. If alternation mode is selected, it activates the 3-1 alternating therapy. Press the 'CYCLE' button 

and use the (+) and (-) buttons to select your preferred time settings (ranging from 3 to 95 minutes). After selecting the desired time, press the 'CYCLE' button 

again to confirm. The default setting is set to 3 minutes.
15. Or, press the ‘Immersion’ button  to activate the immersion function (p.8). The default cycle consists of a 1-minute deflation followed by a 1-minute inflation. The deflation duration is configurable, allowing for adjustments between 1 to 5 minutes to accommodate individual needs. Press the 'CYCLE' button 

, and then use the (+) and (-) buttons next to "Cycle" to increase or decrease the duration as desired. Press 'CYCLE' button 

again to confirm selection.
16. Perform finger check to ensure the distance between the patient’s buttock area and the bottom of the mattress is at least 5cm (about 3 fingers) – adjust the comfort level as needed.



CAUTION – Caregivers must check the controller settings and the patient's condition every two hours to minimize the risk of bottoming out. The bed frame side rails should be kept in the upright position while the patient is on the mattress.

17. To stop the operation, press and hold the ‘Power’ button  for 2 seconds to turn off the control unit, the LED will illuminate in amber.
18. To pack the DynaFlow System, follow the instruction guidelines as shown in Storage and Care section (p. 17).

Care and Cleaning

WARNING – Turn off the control unit and disconnect the power plug from the mains outlet before cleaning. Failure to do so could result in personal injury or equipment damage.

WARNING – Do not expose the mattress or control unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

WARNING – Do not use harsh cleansers/detergents, such as sourcing pads and heavy-duty grease removers, or solvents, such as acetone. Equipment damage could occur.

WARNING – Do not use high temperature autoclave steam cleaning devices or phenolic based products for cleaning. Equipment damage could occur.

Cleaning and Infection Control

- To prevent from cross contamination, the mattress should be examined and disinfected between patient use.
- If the system is in constant use, it is recommended that the system is cleaned on a weekly basis.

Mattress

For basic care and cleaning, wipe down with damp soft cloth and mild detergent. The mattress top/bottom cover and mattress air cells can be wiped over with a solution of sodium hypochlorite 1000 ppm or any other non-phenolic germicidal solution. Dry thoroughly before reassembly.

If the top cover becomes severely soiled, remove the top cover from the bottom cover before washing. It can also be washed and thermally disinfected in a washing machine at a maximum of 104°F (40°C). Please refer to the top cover washing label for detailed cleaning instructions. Do NOT use the system without top cover.

Do NOT machine wash or tumble dry the air cells or bottom cover.

Control Unit

Disconnect control unit from mains power before cleaning.

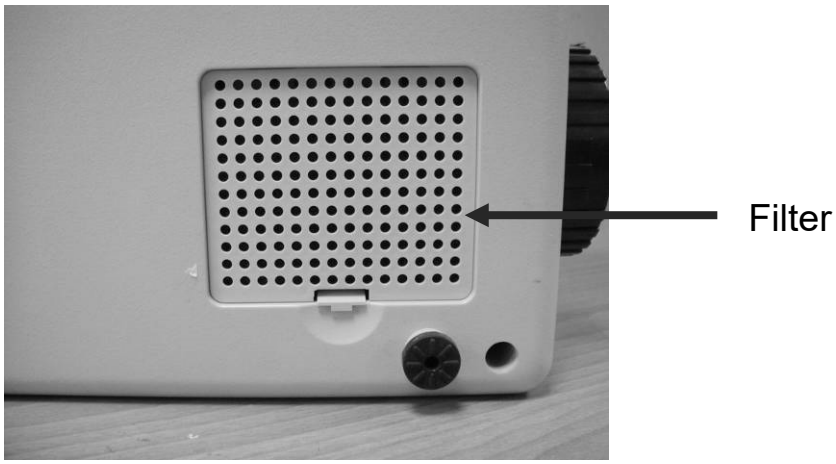
Do not spray disinfectant directly onto the control unit, or immerse the unit in water or other fluid.

Gently wipe down the external case with a soft cloth using a solution of sodium hypochlorite 1000 ppm or any EPA-approved hospital-grade disinfectant. **Do NOT use phenol-based cleaning solutions for cleaning.**

Air Filter

The air filter should be checked and changed regularly, at a minimum of every six months.

To replace the filter, please contact your distributor for further instructions.



Waste Disposal

This device has been supplied from an environmentally aware manufacturer that complies with the WEEE.

This device may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according the legislation. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.

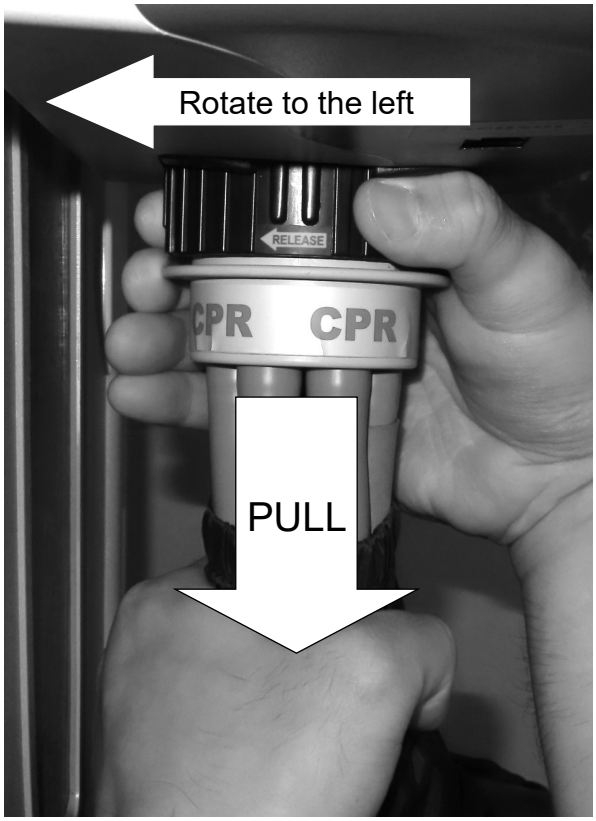


Storage and Care

- Clean the DynaFlow System prior to storage and prior to re-use.

To pack the DynaFlow System, follow the instructions below:

1. Press the ‘Power’ button for 2 seconds to turn off the control unit.
2. Disconnect the sensor cable of the mattress from the control unit.
3. To deflate the mattress, disconnect the hose connector from the control unit. Rotate the black round socket in the same direction as the red RELEASE arrow with one hand, and pull the hose connector away from the control unit with the other hand.
4. Unplug the power cord from the mains outlet, and then tighten it up with a cable strap.
5. Place the control unit inside a plastic bag, then back to the original carton.
6. Roll the mattress starting from the head towards the foot end, pause to squeeze out any trapped air with each roll until it’s fully deflated.
7. Use the base mount straps to secure the rolled mattress. It can now be placed inside a plastic bag and back to the original carton.



It is recommended that the following guidelines are used whenever the system is being stored or transported to another location:

Temperature limitations	5°C to 60°C (41°F to 140°F)
Relative humidity	30% ~ 90% non-condensing

Maintenance & Troubleshooting

Daily maintenance is not required. Preventive maintenance is recommended to be carried out every 12 months. This equipment should only be serviced by authorized qualified technician. Parts and/or accessories supplied are specifically designed for use with this control unit. Use other products/parts in conjunction with the system is prohibited.

Troubleshooting:

Symptom	Inspection Procedure	Possible Solution
Air is pumping out from the control unit, but mattress is not inflating	Check if the connector of the air hose is connected properly	Re-connect the air hose
	Check if there is air leakage from the air hose	Replace with new hose.
	Check if there's any damage or air leakage on the air cells	Replace with new air cell(s)
	Check for kinks in air cell, air manifold, and air hose	Adjust the kinked part to enable smooth air flow
The control unit is not functioning.	Check if the power cord is properly connected	Insert power plug to the mains outlet
	Check if the device is in standby mode	Turn the unit on by pressing POWER button
	Check the power cord for abrasions and excessive wear	Replace a new power cord.
Some of the air cells are not properly inflated.	Check for kinks in air cells and/or air manifold	Adjust the kinked part to enable smooth air flow
	Check if there's any damage or air leakage on the air cells	Replace with new air cell(s)
No power failure visual and audio alert during power outage	When power resumes, check if the control unit is returned to normal operation. If so, leave the control unit plugged to a power source for 8 hours or more for battery charging. Then, unplug the control unit from the power source, and check if the 'POWER FAILURE' LED will illuminate in amber, accompanied by audio power failure alert.	If neither the visual nor audio alert activates, please contact your distributor for further instructions.

If the above measures are unsuccessful, contact your distributor for further instructions.

Warning: Do not attempt to repair the system yourself.

Warning: In case of damage, disconnect the plug from mains outlet. Do NOT use a damaged product.

Electromagnetic Compatibility

WARNING: Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories.

WARNING: That portable RF communications equipment can affect medical electrical equipment. We recommend a safety distance no closer than 30 cm (12 inches) to any part of the DynaFlow Control Unit and at least 1 metre for sensitive equipment.

WARNING: Household electronic devices such as humidifiers, heaters or microwaves may cause interference with the device.

WARNING: X-rays, electric cauterizers, high-frequency, or high-energy devices may cause interference with the device.

CAUTION: If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.

CAUTION: Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.

CAUTION: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Manufacturer's declaration-electromagnetic emissions

The DynaFlow Control Unit is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DynaFlow Control Unit should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for professional healthcare environment)
RF emissions CISPR 11	Group 1	The DynaFlow Control Unit 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 A	The DynaFlow Control Unit is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distance between portable and mobile RF communications equipment and the DynaFlow Control Unit

The DynaFlow Control Unit is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the DynaFlow Control Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DynaFlow Control Unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

The DynaFlow Control Unit is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DynaFlow Control Unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for professional healthcare environment)
Electrostatic discharge(ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV,±4 kV,±8 kV,±15 kV	Contact: ±8 kV Air: ±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1kV line(s) to line(s) ± 0.5kV, ± 1kV, ± 2kV line(s) to earth	± 0.5kV, ± 1kV line(s) to line(s) ± 0.5kV, ± 1kV, ± 2kV line(s) to earth	Mains power quality should be that of a typical professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 30 cycles Voltage interruptions: 0 % *U*T; 300 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the DynaFlow Control Unit requires continued operation during power mains interruptions, it is recommended that the DynaFlow Control Unit be powered from an uninterruptible power supply.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	The DynaFlow Control Unit power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The DynaFlow Control Unit is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DynaFlow Control Unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** DynaFlow Control Unit including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 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 metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The DynaFlow Control Unit is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DynaFlow Control Unit should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for professional healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1845							
1970							
2450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5500							
5785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The DynaFlow Control Unit is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the DynaFlow Control Unit should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for professional healthcare)
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:

(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the PROFESSIONAL HEALTHCARE ENVIRONMENT.

(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

(c) r.m.s., before modulation is applied.

Expected Service Life

- For maintaining basic safety and essential performance in regards to EMC, the DynaFlow Control Unit has an expected service life of five years. To maintain the condition of the device, service the system regularly according to the schedule recommended by Caremed Supply, Inc.
- Medical electrical equipment needs special precautions regarding EMC. Shall the device be used within one-mile distance from AM, FM, or TV broadcast antennas, it needs to be installed according to the EMC information provided.
- Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the device or any of its components.

Warranty

- Prius Healthcare USA guarantees that this equipment is free from defects in materials and workmanship. Our obligation under this warranty is limited to the repair of equipment returned to the place of purchase within 12 months of delivery date.
- We agree to service / adjust any equipment returned, and to replace or repair any part that is proven to be a warranty defect, at no charge.
- This warranty excludes equipment damage through shipping, tampering, improper maintenance, carelessness, accident, negligence or misuse, or products that have been altered, repaired or dismantled other than with the manufacture’s written authorization and by its approved procedures and by properly qualified technicians.
- In no event shall Prius Healthcare USA be liable for any direct, indirect or consequential damages or losses resulting from the use of equipment.

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