DynaFlow

Alternating Low Air Loss Pressure Relief System

User Manual

Prius Healthcare USA

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Content

Warning

- Connect the Master Control unit to a proper power source.
- Don't use the system in the presence of any flammable gases. (such as Anesthetic Agents)
- Keep the pump and mattress away from open flame.
- Keep sharp objects away from the mattress.
- The device is not AP/APG protected.
- Do not place a heating device on or close to the mattress system.

⚠Caution

- The Alternating System should always be used in accordance with your Institutions pressure care guidelines.
- Re-positioning of the patient is always recommended when using an alternating pressure air mattress (APAM).
- The Control unit can only be repaired by an authorized technician.
- Do not drop the control unit.
- Do not store the system in direct sunlight or extreme cold conditions
- Operation Temp: 15-35°C (59-95°F) R.H. : 30-75 %

1. The Purpose of this Manual

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

2. Product Description

The ***DynaFlow*** system is a unique and innovative specialized mattress replacement unit. The system utilizes true low air loss technology with a high flow rate that provides pressure management for the treatment of pressure ulcers. The advanced 3 in 1 alternating function also provides active prevention for pressure relief, especially for those in acute care and long-term care settings (the cells inflate and deflate in a 3:1 cycle, meaning 2/3 of the body is always supported at any one time). The system is also come with pulsation which simulates a massage to assist in maximizing a patient's comfort. This DynaFlow system is intended for use by those who are at least fifteen years in age.

The DynaFlow Control Unit Features

- User-friendly controls
- Large LCD display on each function status.
- CPR quick release
- Patient Care mode provides quick maximum inflation within seconds to help transfers and nursing procedures.
- Auto Set mode sets mattress pressure based on patient's height and weight.
- Lock out function avoids tampering with settings.

Mattress Features

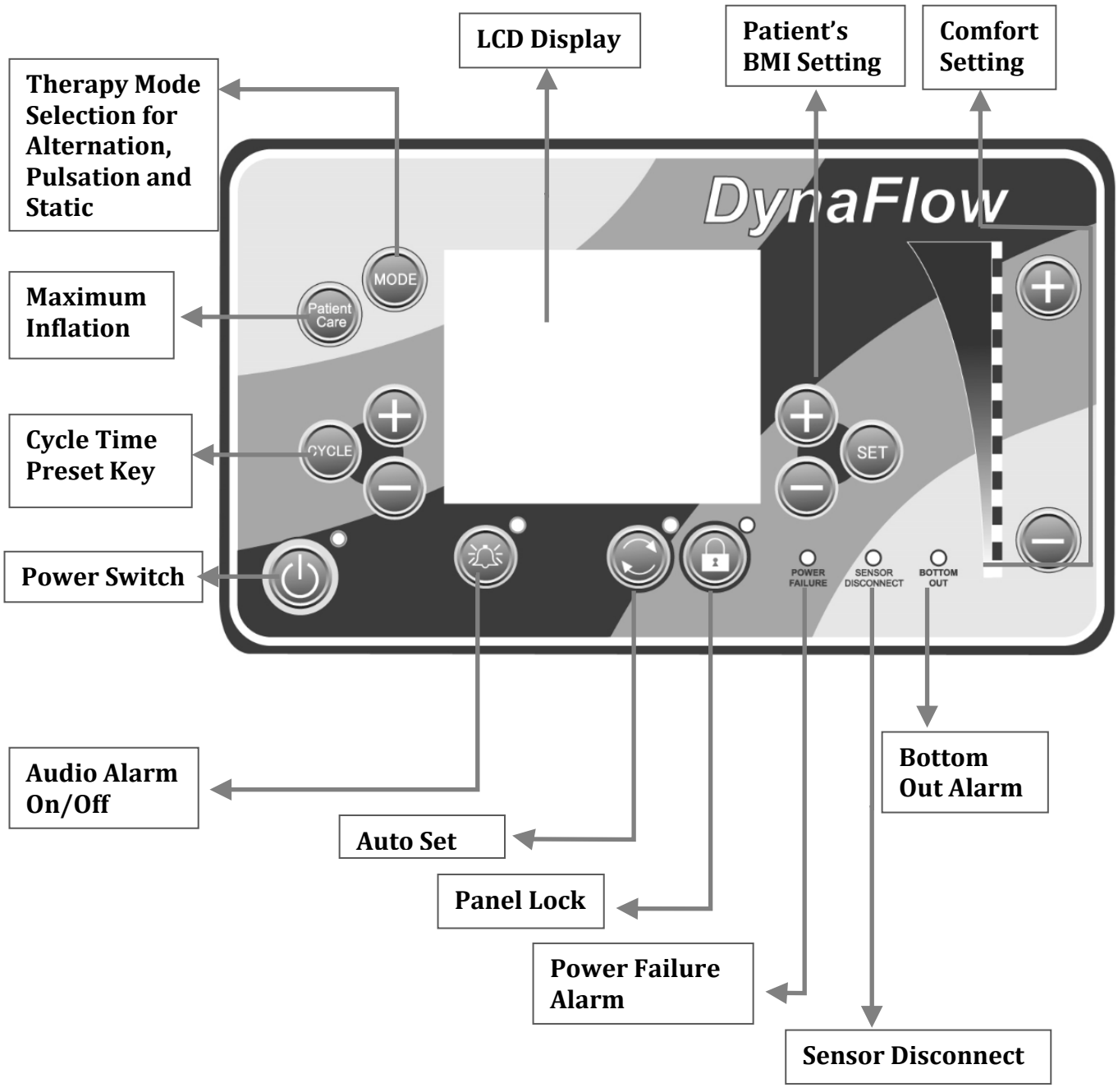
- Therapeutic micro low air loss helps manage moisture and provides alternating therapy to prevent and pressure ulcers treatment
- Modularized design on each air cell for easy replacement
- Highly vapor permeable and oversized pliable quilted nylon top cover providing low shear, friction and moisture protection
- CPR quick release for rapid deflation
- Integrated power cable management for tidiness
- 2" convoluted foam base provides additional safety
- Incorporate sensor technology with Auto mode to constantly monitoring the mattress pressure based on inputting patient's height and weight
  - ■36": 350lbs
  - ■42": 500lbs
  - ■48": 700lbs

Intended Users

- Healthcare professionals or caregivers who are at least fifteen years in age, with the ability to read and understand English and Westernized Arabic Numerals.
- This device should not be operated by patients.

⚠Caution

Alternating pressure should not be applied to pain or pain-sensitive patients. In these cases, we recommend the application of static mode or other suitable foam overlays or other materials which can be found in sample supply in the ***PRIUS Healthcare USA*** product range.



3. Technical Data

Master Control Unit

Model No.	FC-PHR0028
Model Name	DynaFlow
Size (inch) LxWxH	12.2“ x 13.2“ x 6.7“
Weight	15.5 Lbs
Cycle Time (min)	3 - 95
Min Operating Pressure	8 +/- 5mmHg
Max Operating Pressure	33 +/- 5mmHg
Max Flow-rate	≧700 l/min
Rated Voltage	AC 110-120V
Max Current	3 Amp
Fuse Rating	T5AH 250V
Rated Frequency	60 Hz
Classification	Class II(W/functional earth), Type BF Not AP/APG type
Mode of Operation	Continuous
Environment (Temperature)	Operation: 15°C to 35°C (59°F to 95°F)
	Storage:5°C to 60°C (41°F to 140°F)
Environment (Humidity)	Operation: 30% to 75% non-condensing
	Storage: 30% to75% non-condensing
Operation Atmospheric Pressure Range:	700 hPa to 1060 hPa
Operation altitude:	-1017 feet to 9,843 feet (-310 meters to 3000 meters)
Standard	IEC 60601-1, CAN/CSA C22.2 No. 60601-1, IEC 60601-1-2

Mattress Replacement

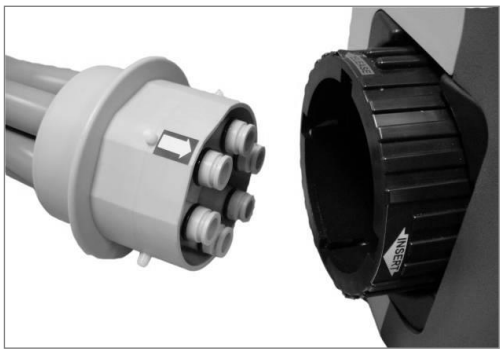
Model No	FM-PHR0008(36“) FM-PHR0047(42“) FM-HR0048(48“)
Size (inch) LxWxH	80“ x 36“ x 10“ 80“ x 42“ x 10“ 80“ x 48“ x 10“
Weight (lbs)	35.5 Lbs
Cells Number	18 cells
Cells Material	Nylon coated with PU
Cover Material	Nylon woven fabric w/ PU coating finish
Base Material	Woven Polyester fabric w/ PVC backing

Symbol Definition

	Type BF Protection Against Electronic Shock		Class II Equipment
	Caution, Consult accompanying documents		Refer To Instruction Manual / Booklet NOTE : Background color: blue Symbol : white
	Keep dry		Waste Disposal
	SGS product certification mark		Alternating Current

4.Instruction for Proper Use

1. Remove the existing mattress from the bed frame.
2. Replace the standard mattress with mattress replacement system (orient mattress so that the air tube is at the foot of the bed). Remove the mattress replacement from the box and place it directly on the bed.
3. Secure straps beneath the mattress to the bed frame.
4. Position the control unit on the foot board of the bed frame.
5. Attach the air tube connector and auto sensor connector to control unit's socket.



6. Verify that air hoses are not kinked under the mattress.
7. Attach cover to mattress.

8. Plug in the control unit and turn on the power which is located on the left side corner on control panel (the STANDBY LED will illuminate).

9. Press the STANDBY/OPERATE switch button on the control panel (OPERATE LED will now be illuminated and the control unit will be in operation)

10 Make sure to turn the power off when the system not in use.

Auto Set Mode

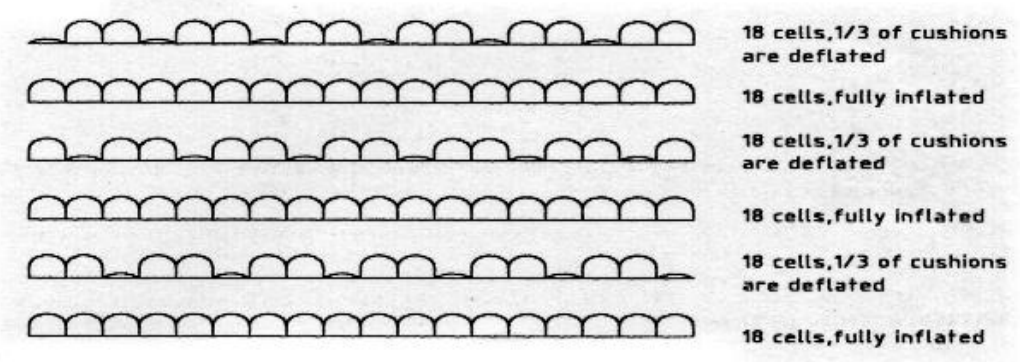
Ensure the auto sensor connector is connected properly before pressing Auto SET button. When Auto SET function is activated, control unit is automatically optimizing patient's comfort setting base on patient's BMI input. Press the PATIENT CARE button for fast inflation. Allow 4-7 min for full inflation.

1. Press the SET button to enter into settings mode to input patient's BMI. Settings is divided into three portions. The first settings mode will allow for selection between Inch/Lbs & Cm/Kgs (Height and Weight will flash on LCD screen during this mode). Press the SET button a second time to enter into the next settings mode that allows for selection of height (Height will flash on the LCD screen during this mode). Press the SET button again to enter into the last settings mode that allows for selection of weight (Weight will flash on the LCD screen during this mode). Finally press the SET button to exit settings mode completely with your selected settings for height & weight.
2. When the mattress is fully inflated, the caregiver can transfer the patient onto the mattress. (Note: the mattress can be inflated while a patient is laying on it)
3. Press PATIENT CARE again to return previous setting.
4. By activating the PATIENT CARE function, all chambers of the mattress system are inflated with maximum system pressure for 30 minutes. After 30 minutes, the system defaults back to previous setting.

Alternate Mode

1. Press the "MODE" button to select the Alternate and Static Function to enable the 3-1 alternating functions.

Alternation Cycle Illustration



2. Press "CYCLE" button for alternating time setting. Alternating time can be adjusted from 3 min to 20 min by increments of 1 min and 20 min to 95 minutes by increments of 5 min. The Alternating time will be displayed on the Time display window on the control panel.

Static Mode

1. Press the "MODE" button to select the Static Mode and adjust the comfort control by pressing the SOFT/FIRM button to achieve maximum patient comfort.

2. On this mode the system provides low air loss therapy. Perform a hand heck by placing a hand under the patient's buttocks between the cells and foam. The patient should have at least 4cm of clearance between the buttocks and the bottom of the mattress. If the STATIC function is selected the time display will remain blank.

Note: The caregiver can select the "Static Mode" to provide the patient with only low air loss therapy.

Fowler

When Fowler function is activated (Auto-Set), the mattress will increase the comfort level setting by 3 levels and provided additional support to the patient (it is not reccomended for the patient to **NOT** be placed on Fowler setting for more than 60 minutes to prevent being on a higher pressure setting than what is necessary). The Fowler function will engage when patient head angle is larger than 30 degrees.

Alarm On/Off

The Alarm will be triggered when a Sensor Disconnect & Bottoming Out is detected. Disable the alarm by pressing the button.

Lock Button

1. The Prius DynaFlow is equipped with auto-locking intelligence. All function keys will be automatically disabled if the control panel is not in operation for 2 minutes and when this function is engaged an green LED will illuminate.
2. To unlock the control panel, simply press and hold the “LOCK” button for 5 seconds.

Note: The pressure level settings on the weight chart are only a guideline. The proper adjustment of the pressure level must be applied according to individual patient.

CPR Deflation

The air hose connectors can be disconnected from the controller to quick release the air when in an emergency situation where CPR is to be performed.

5. Cleaning

The Mattress

The mattress should be cleaned on the bed weekly using a damp soft cloth and mild detergent. If top cover or base cover becomes grossly soiled, put on clean gloves, plastic gown and eye protection before removing top and base covers and disposing according to standard hospital procedures for contaminated waste and replace with clean covers.

Covers can be washed and thermally disinfected in a washing machine by following below procedure: **(Never use phenol based cleaning solutions)**.

Industrial	Break washes	Cold	10 minutes
	Main washes	60°C (140°F)	6 minutes
	Main washes	70°C (158°F)	10 minutes
	Extraction		2 minutes
	Cold Rinses		
	Extraction		5 minutes
Domestic	Pre-wash	Cold	
	Main Wash	70°C (158°F)	10 minutes
	Extraction		2 minutes
	Cold Rinses		
	Extraction		5 minutes

Tumble Drying or Tunnel Drying is not recommended.

Mattress Cells can be wiped over with a solution of sodium hypochlorite1000ppm or any other non-phenolic germicidal solution.

The Master Control Unit

⚠Caution

SWITCH OFF THE ELECTRICAL SUPPLY TO THE PUMP AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION

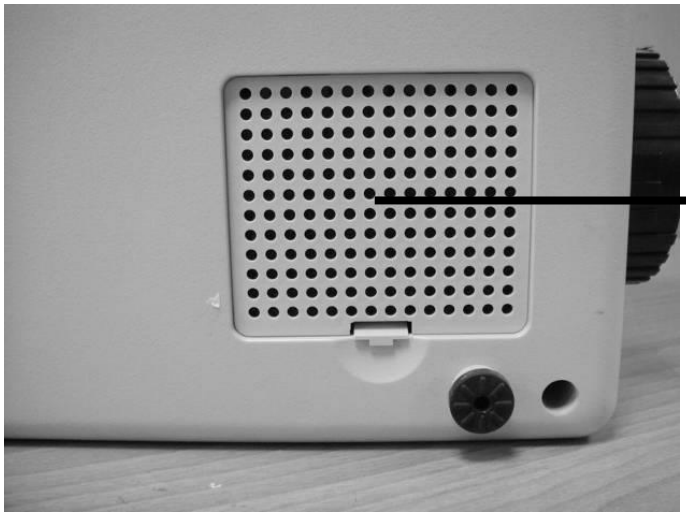
The pump unit should also be cleaned weekly using a damp soft cloth and mild detergent.

The pump casing is manufactured from ABS plastic and if the case is soiled the pump can be wiped down with a sodium hypochlorite solution to dilution of 1000ppm or any EPA- approved hospital grade disinfectant. **(Do not use phenol based cleaning solution)**.

The air filter should also be cleaned and checked as often as possible at a minimum of every six months. Air Filter can be removed by pinching center of the filter and pulling outward from the back of the control unit.

Replace Air Filter

1.Remove air filter and replace with a new one.
2.Use a soft bristle to remove dust and difficult dried-on soil.



NOTE:

1. Do not use phenol based cleaning solutions.
2. Switch off the electrical supply to the pump and disconnect the power cord from the main supply before cleaning and inspection)

Waste Disposal

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

6. Storage and Care

Master Control Unit:

- Check the power cord and plug for abrasions or excessive wear.
- Plug in the unit and verify air flows from the units hose connection ports.
- Place in plastic bag for storage.

Mattress:

- Check the air manifold for kinks or breaks. Replace if necessary.
- Twist the CPR plug at the head of the mattress and disconnect the air feed tubes. All the air will now be expelled. Starting at the head end, the mattress can now be rolled. Use the base mounted straps for containment.
- Place in plastic bag of storage.

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

Temperature limitations:	5°C ~ 60°C
Relative Humidity:	30% to 75%

7. Maintenance & Troubleshooting

No daily maintenance is required. It is intended this equipment should only be serviced by properly qualified, authorized technical personnel. Caregivers should check the patient and control unit setting every two hours. In case of minor trouble please refer as following Troubleshooting.

Symptom	Inspection Procedures	Possible Solution
The pump is not functioning.	1. Check for correct power voltage connected. 2. Check for blown fuse.	1. Connect to correct main power source. 2. Replace new fuse. 3. Refer to service if problem persist.
Bottom out LED is constantly illuminated or The mattress is not inflating while pump is in operation.	1. Check for any loose connections. 2. Check for CPR valve. 3. Check for air leakage on air cells.	1. Ensure all connectors are properly attached. 2. Ensure CPR valve is set to “CLOSE” position. 3. Replace faulty air cell if necessary. 4. Refer to service if problem persist.
Pump is noisy.	1. Ensure pump is resting against solid surface.	1. Repositioning the pump. 2. Refer to service if problem persist.

8. EMC Related Notifications

<table>
<tr><th colspan="3">Manufacturer's declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The DYNAFLOW is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DYNAFLOW should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance (for professional healthcare)</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The DYNAFLOW 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The DYNAFLOW 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations /flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

Manufacturer's declaration-electromagnetic immunity			
The DYNAFLOW is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the DYNAFLOW 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 Not applicable	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 a typical professional healthcare environment. If the user of the DYNAFLOW requires continued operation during power mains interruptions, it is recommended that the DYNAFLOW be powered from an uninterruptible power supply or a battery.
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 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 is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DYNAFLOW should assure that is used in such and 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 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800MHz 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.

Recommended separation distance between portable and mobile RF communications equipment and the DYNAFLOW

The DYNAFLOW 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 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DYNAFLOW 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
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The DYNAFLOW is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DYNAFLOW 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	1700 – 1990	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	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28	28
5240	5100 – 5800	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.

9. Warranty

- Prius Healthcare Products guarantees that this equipment is free from defects in material and workmanship. Our obligation under this warranty is limited to the repair of equipment returned to the service address given below, transportation charges prepaid, within 12 months after delivery to the original purchaser for all equipment.
- We agree to service and/or adjust any equipment returned for that purpose and to replace or repair any part, which is proven to be defective at no charge.
- This warranty excludes equipment damage through shipping, tampering, improper maintenance, careless, accident, negligence or misuse, or products which 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 Products be liable for any direct, indirect of consequential damages or losses resulting from the use of equipment.

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