

Enhance RDX

Alternating Pressure Mattress System

User Manual



This manual **MUST** be given to the user of the product.
BEFORE using this product, this manual **MUST** be read and saved for future
reference.

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1. Safety

The safety section contains important information for the safe operation and use of this product. Read this information and any other safety information included with the product.

⚠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.
- ❖ Use the product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
- ❖ If pain, irritation, numbness, swelling, or redness occurs discontinue use and contact a healthcare professional.
- ❖ This device can be used in home healthcare and professional healthcare environment.
- ❖ This device should not be used adjacent to or stacked with other equipment.
- ❖ Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided.
- ❖ The product should never be left unattended when plugged in.
- ❖ Close supervision is necessary when the product is used by, on, near children or physically challenged individuals.
- ❖ Never block the air opening of this product 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.
- ❖ Never drop or insert objects into any openings.
- ❖ DISCONNECT POWER SUPPLY BEFORE OPENING.
- ❖ Power cable & pump shall be placed at the foot-side of the patient to prevent any risk of strangulation due to cable.
- ❖ Please ensure the Enhance RDX Alternating Pressure Mattress System is used with stable power or in connection with UPS.
- ❖ To reduce the risk of electrocution:
 - Always unplug product immediately after use.
 - Do not use while bathing.
 - Do not place or store product where it can fall or be pulled into a tub or sink.
 - Do not place in or drop into water or other liquids.
 - Do not reach for product that has fallen into water. *Unplug immediately.*
- ❖ Do not obstruct the mains plug or position the equipment where the connection to the mains line can be accidentally disconnected.

Caution

- ❖ The mattress system should always be used in accordance with your Institution's 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.

2. The Purpose of this Manual

This operation manual is mainly focused on the set up, cleaning and routine maintenance of the **Enhance RDX** Alternating Pressure Mattress System. We recommend keeping this manual available to answer questions related to the system.

3. Intended Use

The Enhance RDX system is intended for patients who are at risk of developing pressure ulcers according to your sound clinical judgment. The device can also be used for patients who have an existing stage 1, 2, and 3 pressure ulcers, in conjunction with your policy on pressure area management.

4. Indications for Use

Indicated for patients who are at risk of developing pressure ulcers according to your sound clinical judgment.

5. 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 patient.

6. Contraindications for use

Alternating pressure therapy should not be used for patients with unstable fractures, gross edema, burns or an intolerance to motion.

7. Product Description

This product is intended to help reduce the incidence of pressure ulcers while optimizing patient comfort.

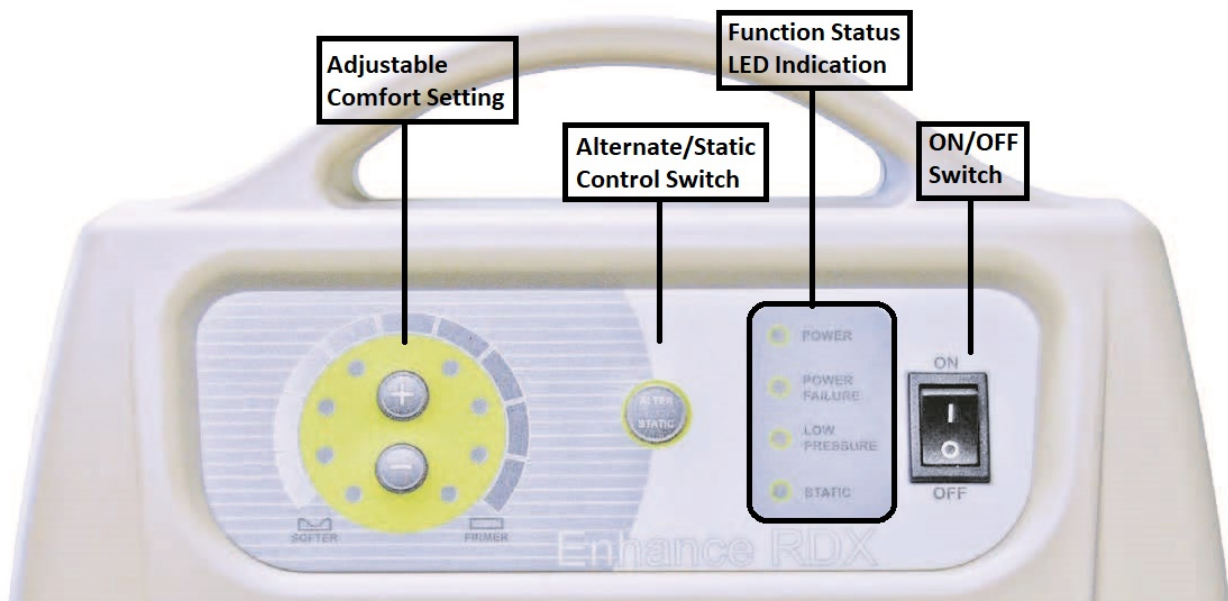
The Enhance RDX is an alternating mattress replacement system used in the prevention and treatment of pressure ulcers. By using the established principles of alternating therapy the Enhance RDX offers patients a comfortable and relaxing support surface which can prevent skin breakdown and enhance wound healing.

Master Control Unit Features

- LED indicator for function status.
- Electronic adjustable comfort setting.
- 2-in-1 alternation with 10 minutes cycle time.


Mattress Features

- Modularized design for easy air cell replacement.
- A vapor permeable, oversized, pliable, quilted nylon top cover provides low shear, friction and moisture protection.
- CPR quick release for rapid deflation.
- Cell in cell design provides additional protection for upper torso and sacrum in the event there is a loss of power
- Integrated power cable management for organization and safety.



8. Technical Data







Master Control Unit

Model Name	Enhance RDX Control Unit
Model No.	FC-PHR0035
Size (inch)	10.1" (L) x 4.5" (W) x 8.3" (H)
Weight (lbs)	4.85 lbs (2 kg)
Max Flow Rate	5 L/min
Cycle Time	10 min
Min Operating Pressure	14 +/- 6mmHg
Max Operating Pressure	60 +/- 6mmHg
Rated Voltage	AC 110-120V
Rated Frequency	60 Hz
Fuse Rating	T1AH 250V
Max Current	0.1A
Classification	Class II, Type BF  Not AP or AGP type
Ingress of Water Protection	IP21
Mode of Operation	Continuous
Power Cable	15ft, non-shielding, AC powered
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)	15% to 90% non-condensing
Operation Atmospheric Pressure Range	800 hPa to 1060 hPa
Standard	IEC 60601-1, CAN/CSA C22.2 No. 60601-1, IEC 60601-1-2 IEC 60601-1-11

Mattress Replacement (applied part)

Model Name	Enhance RT Mattress
Model No	FM-PHR0034
Size (inch)	36" (W) x 80" (L) x 8" (H)
Weight (lbs.)	22 lbs (10 kg)
Cell Number	18 cells
Cells Material	Blue Nylon with PU coating
Cover Material	Blue Nylon w/ PU coating finish
Base Material	Black Polyester w/ PVC coating
Weight Capacity	350 lbs (159 kg)

Symbols information essential for proper use

	Type BF Protection Against Electronic Shock		Class II Equipment
	Consult instructions for use		Waste Disposal
	Caution, Consult accompanying documents		SGS product certification mark

9. Instructions for Proper Use

1. Remove the existing mattress from the bed frame.
2. Replace the standard mattress with mattress system and make sure to orient mattress so that the air tube is placed at the foot of the bed.
3. Secure the straps beneath the mattress to the bed frame.
4. Hang the Master Control Unit on the foot-board of the bed frame.
5. Attach the air tubes connectors to socket on the left panel of the Master Control Unit.



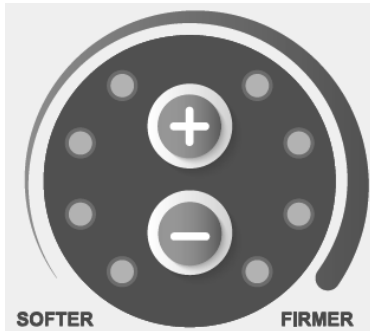
6. Ensure the air hoses are not kinked under the mattress. (Could be verified by simple visual check).
7. Plug in the control unit and turn it on.



8. The pump pressure dial blinks to Max setting and will now inflate the mattress.
9. Do not press the control button on pump to select alternation or static until pump pressure dial defaults to solid light and mattress is fully inflated .



10. Set the required pressure by pressing the “+” to increase pressure or “-“to reduce pressure.



11. Pressure is constantly monitored by the control unit. When pressure is less than the pump set pressure the “Low Pressure” LED will illuminate and an alarm will sound.



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

Alarm Function

The Enhance RDX Alternating Pressure System is equipped with a visual and audible alarm in the event of low pressure. During the initial inflation period the system is in low pressure mode and the low pressure LED will illuminate. The audible alarm is set with a delay function to take into consideration the inflation time. The alarm will activate automatically after 45 minutes if the unit does not inflate properly.

When the mattress pressure drops from the set pressure during patient repositioning the audible alarm will switch to a 5 minute delay to avoid undesired alarm activation.

CPR Deflation

For emergency mattress deflation turn the CPR valve to the “OPEN” position. The mattress should deflate within 30 seconds. To close the CPR simply turn the valve to the “CLOSE” position.



10 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)	16 minutes
	Extraction		2 minutes
	Cold Rinses		
	Extraction		5 minutes
Domestic	Pre-wash	Cold	
	Main Wash	60°C (140°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 hypochlorite 1000ppm 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

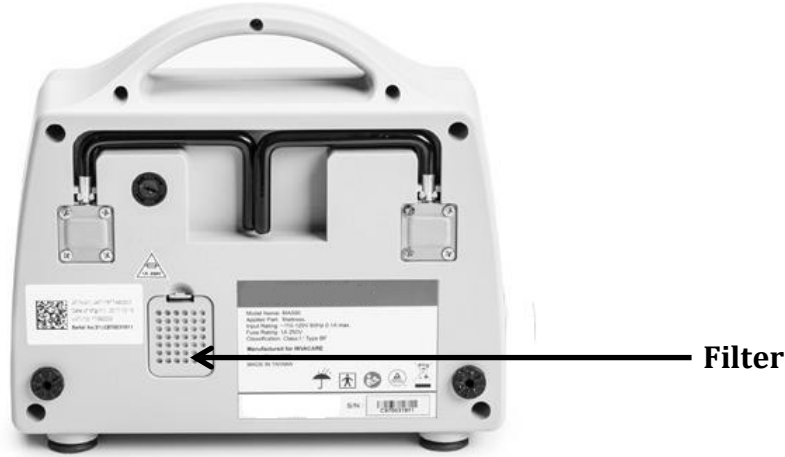
The pump unit should also be cleaned weekly using a damp soft cloth and mild detergent.

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.

IP21

The IP Code (or International Protection Rating, sometimes also interpreted as Ingress Protection Rating*) consists of the letters IP followed by two digits and an optional letter.

● **First Digit: Solids**

The first digit indicates the level of protection that the enclosure provides against access to hazardous parts (e.g., electrical conductors, moving parts) and the ingress of solid foreign objects.

● **Second Digit: Liquids**

Protection of the equipment inside the enclosure against harmful ingress of water.

IP Number	First Digit - SOLIDS	Second Digit - LIQUIDS
IP21	Protected from touched by fingers and objects greater than 12.5mm.	Against water : Vertical water drips.

11. Storage and Handling

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.
- Set CPR valve to “OPEN” and disconnect the air hose to the pump.
The mattress will now deflate and can be packed for storage.
- 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 (41°F) ~ 60°C (140°F)

Relative Humidity: 15% to 90% non-condensing

12. Maintenance & Troubleshooting

No daily maintenance is required. Caregivers should check the patient and control unit setting every two hours. It is intended this equipment should only be serviced by properly qualified, authorized technical personnel. In case of minor trouble please refer to the Troubleshooting table in this section. Contact the provider or Invacare for questions and repair information.

Symptom	Inspection Procedures	Possible Solution
The pump is not functioning or power failure.	<ol style="list-style-type: none"> 1. Check power source connection. 2. Check fuse. 	<ol style="list-style-type: none"> 1. Connect to proper power source. 2. Replace fuse. 3. Refer to qualified service technician if problem persist.
Low pressure LED is constantly illuminated or the mattress is not inflating while pump is in operation.	<ol style="list-style-type: none"> 1. Check hoses and hose connections. 2. Check CPR valve. 3. Check air cells for holes or tears other than where designed. 	<ol style="list-style-type: none"> 1. Make sure all connections are secure. 2. Make sure CPR valve is in the “CLOSE” position. 3. Replace damaged air cell if necessary. 4. Refer to qualified service technician if problem persist.
Pump is noisy.	<ol style="list-style-type: none"> 1. Make sure pump is resting against a solid surface. 	<ol style="list-style-type: none"> 1. Reposition the pump. 2. Refer to qualified service technician if problem persist.
Power failure LED or alarm sound in abnormal when power off.	<ol style="list-style-type: none"> 1. Turn off the power in the standard process then restart the control unit to check if alarm still existing. 2. Check PCB function 	<ol style="list-style-type: none"> 1. Refer to qualified service technician if problem persist.

13. EMC Related Notifications

Manufacturer's declaration-electromagnetic emissions		
<p>The <u>Enhance RDX</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the <u>Enhance RDX</u> should assure that it is used in such an environment.</p>		
Emission test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The <u>Enhance RDX</u> 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 <u>Enhance RDX</u> 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	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distance between portable and mobile RF communications equipment and the <u>Enhance RDX</u>			
<p>The <u>Enhance RDX</u> is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the <u>Enhance RDX</u> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <u>Enhance RDX</u> as <u>recommended below</u>, according to the maximum output power of the communications equipment.</p>			
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
<p>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.</p> <p>NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Manufacturer's declaration-electromagnetic immunity

The Enhance RDX is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the Enhance RDX should assure that it is used in such an environment.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and 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 home 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) Not applicable	Mains power quality should be that of a typical home 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 home healthcare environment. If the user of the <u>Enhance RDX</u> requires continued operation during power mains interruptions, it is recommended that the <u>Enhance RDX</u> 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 <u>Enhance RDX</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

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

- * During DIP interference, the pump will outage these normal. The cells connected with pump still have air inside which won't affect the use and function of the system.
- * During DIP, the LED of front panel board might anomalous blinking with indicating sound. The pump will back to normal function after DIP disturbance.
- * During DIP, pump will show abnormal but won't affect essential performance and no need to worry the basic safety.

Manufacturer's declaration-electromagnetic immunity

The Enhance RDX is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.
 The customer or the user of the Enhance RDX should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>Enhance RDX</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>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</p> <p>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).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

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 Enhance RDX is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.
 The customer or the user of the Enhance RDX 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 home and 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							
1 720	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
1 845							
1 970							
2 450	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
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

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.

⚠ 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.

14. Expected Service Life

The Enhance RDX pump has an expected service life of five years. To maintain the condition of the pump, have the pump serviced regularly according to the schedule recommended by Caremed. Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the Enhance RDX system.

15. Warranty

- a.** Prius Healthcare guarantees this equipment to be free from defects in material and workmanship for up to 12 months from the date of delivery.
- b.** All warranty work will be performed at the service address below, shipping charges prepaid.
- c.** At Manufacturers discretion we agree to service, repair or replace any equipment or part found to be defective at no charge.
- d.** This warranty excludes equipment damaged through shipping, tampering, improper maintenance, carelessness, accident, negligence, misuse, or which has been altered, repaired or dismantled other than with the manufacture's written authorization following approved procedures and performed by certified technicians.
- e.** In no event shall Prius Healthcare be liable for any direct, indirect, consequential damage or loss resulting from the use of equipment.
- f.** Warranty is non-transferrable.