Enhance RDX

Mattress Replacement System

User Manual

Control Unit: FC-PHR0046
Mattress: FM-PHR0046

Prius Healthcare USA

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Content

IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

CAUTION - READ ALL INSTRUCTIONS BEFORE USING THE APPLIANCE

WARNING – To reduce the risk of electrocution:

1. Always unplug product immediately after use.
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 liquids.
5. Do not reach for product that has fallen into water. *Unplug immediately*.

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

1. The product should never be left unattended when plugged in.
2. Close supervision is necessary when the product is used by, on, near children or physically challenged individuals.
3. Use the product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
4. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it is has been dropped or damaged, or dropped into water. Return the product to a service center for examination and repair.
5. Keep the cord away from heated surfaces.
6. 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.
7. Never drop or insert objects into any openings.
8. Do not use outdoors, operate where aerosol (spray) products are being used or where oxygen is being administered.
9. DISCONNECT POWER SUPPLY BEFORE OPENING.
10. The product has no user serviceable parts except for fuse replacement.
11. Keep the pump and tubing (including protective sleeves) away from sources of liquid and open flames.
12. Keep the pump and tubing away from sharp objects.
13. If pain, irritation, numbness, swelling, or redness occurs discontinue use and contact a healthcare professional.
14. Power cable & pump shall be placed at the foot-side of the patient to prevent any risk of strangulation due to cable.
15. Please ensure the Enhance RDX Alternating Pressure System is used with stable power or in connection with UPS.
16. This device can be used in home healthcare and professional healthcare environment.
17. This device should not be used adjacent to or stacked with other equipment.
18. Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided.
19. Do not obstruct the mains plug or position the equipment where the connection to the mains line can be accidentally disconnected.

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.

Contraindications for use

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

1. The Purpose of this Manual

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

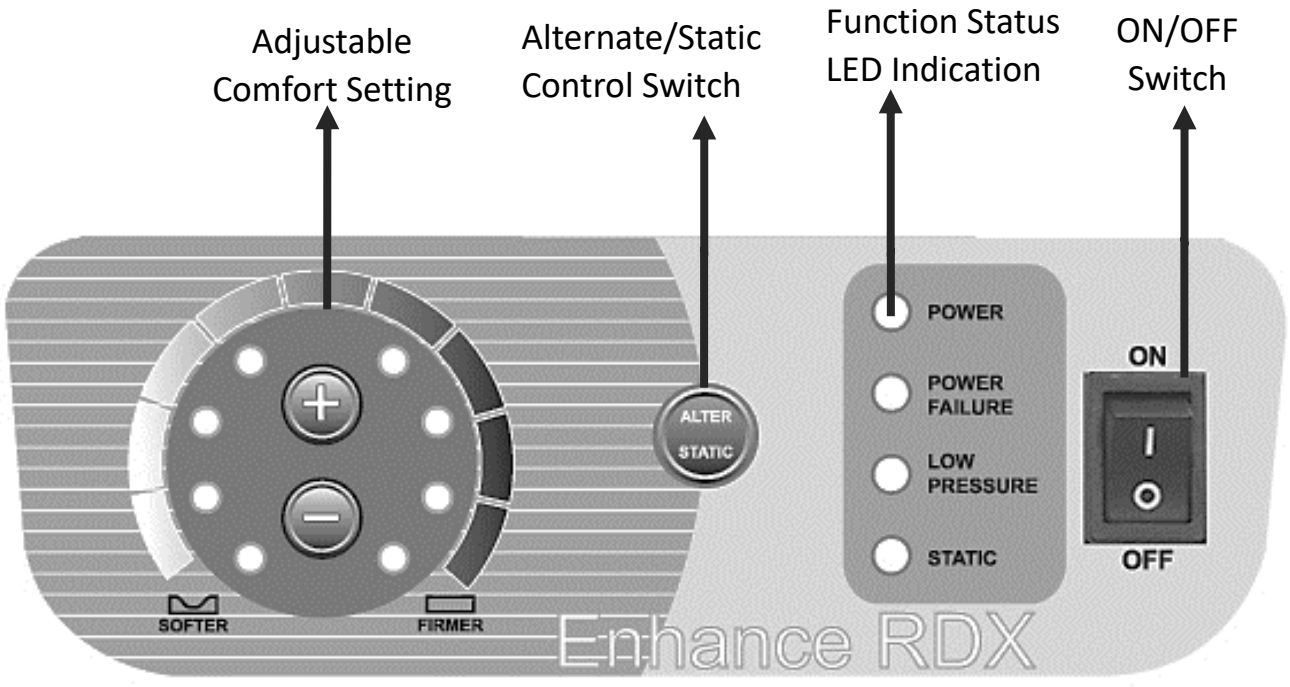
2. Product Description

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.

<u>Master Control Unit Features</u>

- 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.
- Integrated power cable management for organization and safety.

3. Technical Data

Master Control Unit

Model Name	Enhance RDX Control Unit
Ref No.	FC-PHR0046
Size (inch)	10.1” (L) x 4.5” (W) x 8.3” (H)
Weight (lbs)	4.85
Cycle Time	10 min
Min Operating Pressure	20 +/- 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
Operation Altitude	0 meters to 2000 meters
Standard	IEC 60601-1, CAN/CSA C22.2 No. 60601-1, IEC 60601-1-2, IEC 60601-1-11

Mattress Replacement (applied part)

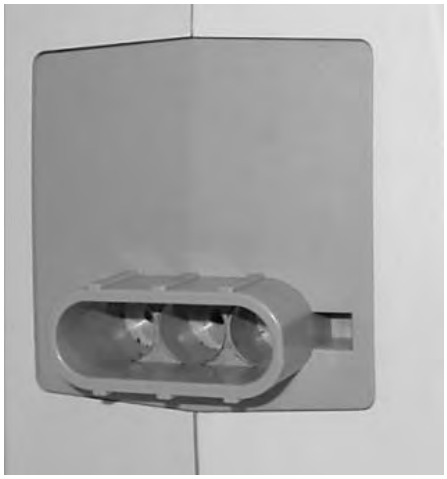
Model Name	Enhance RDX mattress
Model No	FM-PHR0046
Size (inch)	80” x 36” x 8”
Weight (lbs.)	37
Cell Number	18cells
Cells Material	Blue Nylon with PU coating
Cover Material	Blue Nylon w/ PU coating finish
Base Material	Blue Polyester w/ PVC coating
Weight Capacity	350lbs

Symbol Definition

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

4. Instruction for Proper Use

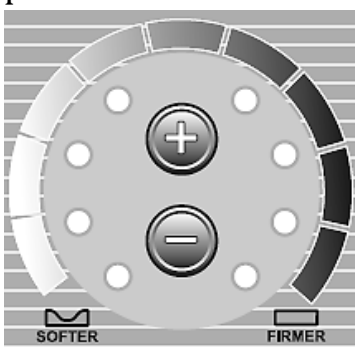
1. Unpack the system and place the pump at the foot end of the bed.
2. Remove the existing mattress from the bed frame.
3. Place the **Enhance RDX** mattress on the frame and position mattress so the air tube is at the foot of the bed.
4. Secure the **Enhance RDX** mattress straps to the bed frame.
5. Hang the control unit on the foot board of the bed frame.
6. Connect the mattress air hose to pump.



7. Check air hoses under the mattress to make sure they are not kinked.
8. Plug in the control unit and turn it on.

9. The pump will now inflate the mattress.
10. Press the control button on pump to select alternation or static therapy.

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



12. 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.

13. For emergency mattress deflation open the CPR valve located at the head.

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

<u>Alarm Function</u>

The **Enhance RDX** Alternating Anti-Decubitus 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 illuminated. 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.

5. Cleaning

DO NOT MACHINE WASH OR MACHINE DRY

Cleaning DO's

- DO clean all stains promptly
- DO use only fabric-safe cleaning agents or disinfectants
- DO use appropriate quaternary or phenolic type disinfectants if nylon fabric needs to be sanitized
- DO dilute all disinfectants and germicides in accordance with manufacturer's instructions
- DO wipe fabric clean with neutral soap suds and lukewarm water
- DO rinse thoroughly
- DO allow adequate drying time before returning to service
- DO use a soft sponge with liquid cleaner as specified on the manufacturer's product label for hard-to-clean areas
- DO clean daily to control or prevent odors on long term incontinent applications
- DO use a scented cleaner or disinfectant that is designed for use on fabrics if needed to control odors on long term incontinent applications
- DO disinfect blood contamination with a 1:10 dilution of household bleach (5.25% sodium hypochlorite) as recommended by the CDC (Center for Disease Control, US Department of Health and Human Service, February 1989); a weaker dilution, e.g. 1:100 may be used, but may not be in accordance with CDC recommendations
- DO be aware that staining chemicals and cleaning agents can affect fabric strength, finish and color
- DO inspect mattresses frequently to ensure that new stains can be treated promptly
- DO ask your support surface manufacturer for additional information related to the care and cleaning of the support surface

Cleaning DON'Ts

- DO NOT machine wash or machine dry
- DO NOT use harsh cleaners or solvents
- DO NOT use cleaning agents designed for use on hard, non-porous or metal surfaces
- DO NOT use iodophor type disinfectants, such as Betadine, because they will stain the fabric
- DO NOT use household bleach or concentrated cleaning agents, disinfectants or germicides without diluting the product according to the manufacturer's instructions
- DO NOT allow any cleaning agent to remain in contact with the fabric or "dwell" on the fabric for a prolonged time
- DO NOT fail to adequately rinse the cleaning agent or disinfectant from the fabric

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. If the case is soiled the pump can be wiped down with a solution of sodium hypochlorite dilution, 1000ppm, or any EPA approved hospital grade disinfectant. **(Do not use a phenol based cleaning solution.)**

The air filter should also be cleaned and checked at a minimum of every six months. The air filter can be removed by removing filter cover and pinching center of the filter and pulling outward from the back of the cover.

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.

Waste Disposal

This Product has been supplied by an environmentally conscious manufacturer and complies with the WEEE.
This product may contain substances that can be harmful to the environment if disposed of in places that are not approved by your state, local or federal laws. 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.

6. Storage and Care

Master Control Unit:

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

Mattress:

- Check the air manifold for kinks or breaks and replace if necessary.
- Pull out CPR plug and disconnect the air hose to the pump. The mattress will now deflate and can be packed for storage.

It is recommended that the following proceedings are used whenever the system is being stored or transported to another location:
Temperature limitations: 5°C (41°F) ~ 60°C (140°F)
Relative humidity: 15% ~ 90%

7. Maintenance & Troubleshooting

No daily maintenance is required. This equipment should only be serviced by a qualified and authorized technician. For common trouble shooting tips please refer to the chart below. Caregivers should check the patient and control unit setting every two hours.

Symptom	Inspection Procedures	Possible Solution
The pump is not functioning or power failure.	1. Check power source connection. 2. Check fuse.	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.	1. Check hoses and hose connections. 2. Check CPR plug. 3. Check air cells for holes or tears other than where designed.	1. Make sure all connections are secure. 2. Make sure CPR plug is pulling out from tubes. 3. Replace damaged air cell if necessary. 4. Refer to qualified service technician if problem persist.
Pump is noisy.	1. Make sure pump is resting against a solid surface.	1. Reposition the pump. 2. Refer to qualified service technician if problem persist.
Power failure LED or alarm sound in abnormal when power off	1. Turn off the power in the standard process then restart the control unit to check if alarm still existing. 2. Check PCB function	1. Refer to qualified service technician.

8. EMC Related Notifications

Manufacturer's declaration-electromagnetic emissions		
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.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
RF emissions CISPR 11	Group 1	The **Enhance RDX** 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 **Enhance RDX** 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 Enhance RDX

The **Enhance RDX** 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 **Enhance RDX** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Enhance RDX** 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 **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 **Enhance RDX.** requires continued operation during power mains interruptions, it is recommended that the **Enhance RDX** 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 **Enhance RDX** power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT 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 80 % AM at 1 kHz	3 Vrms: 0.15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio 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 Enhance RDX** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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	**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.

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							
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.

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.

9. Expected Service Life

- For maintain basic safety and essential performance in regards to EMC, the **Enhance RDX** has an expected service life of five years. To maintain the condition of the alternating mattress system, service the system regularly according to the schedule recommended by Prius Healthcare USA
- 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 **Enhance RDX** system or any of its components.

10. Warranty

- Prius Healthcare USA guarantees this equipment to be free from defects in material and workmanship for up to 12 months from the date of delivery.
- All warranty work will be performed at the service address below, shipping charges prepaid.
- At Manufacturers descreton we agree to service, repair or replace any equipment or part found to be defective at no charge.
- 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 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 damage or loss resulting from the use of equipment.
- Warranty is non-transferrable.

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