Enhance DX

Mattress Replacement System

User Manual

Prius Healthcare USA

580 Corporate Center
4025 Tampa Road, #1117
Oldsmar, FL 34677, USA

TEL: (813)854-5464
FAX: (813)854-5442

Content

Warning

- Connect the Master Control unit to a proper power source.
- Keep the pump and mattress away from open flame.
- Keep sharp objects away from mattress.
- Do not place heating device on or near the mattress system.
- Do not use the system in the presence of any flammable gases. (Such as anesthetic agents)

⚠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 should 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: 15-40°C (59-104°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 ***Enhance DX*** Alternating Anti-Decubitus System. We recommend keeping this manual available to answer questions related to the system.

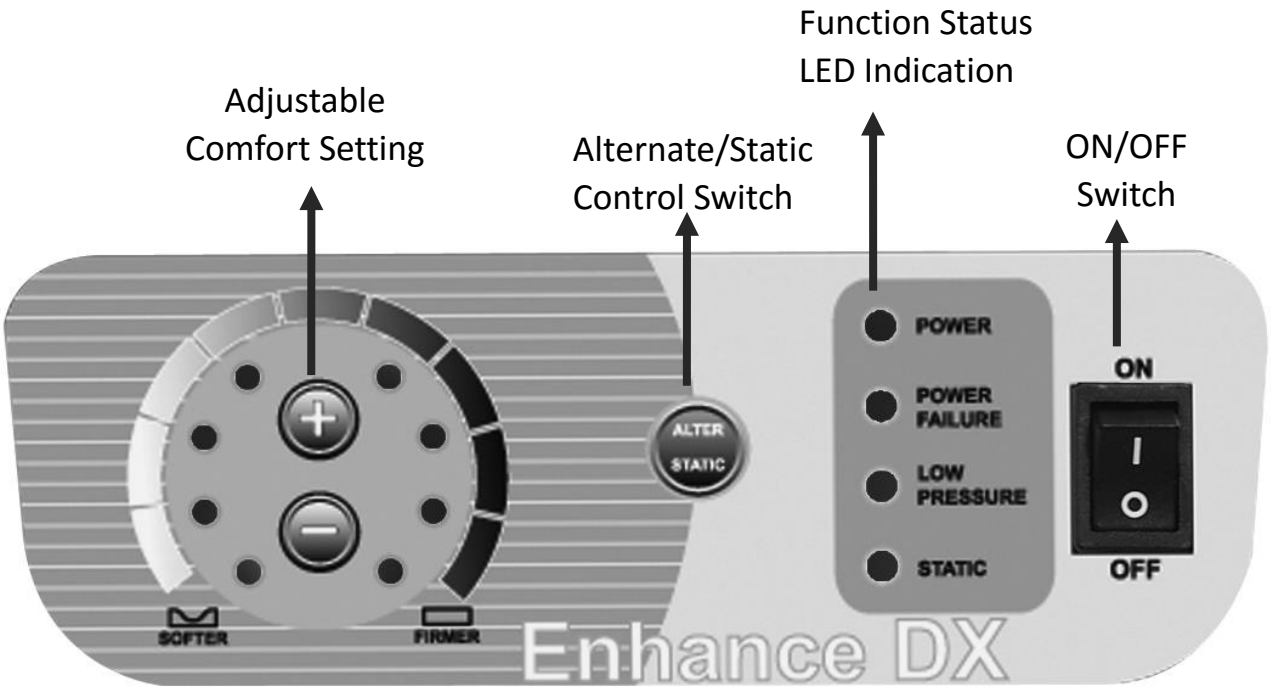
2. Product Description

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

The ***Enhance DX*** 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 DX*** offers patients a comfortable and relaxing support surface which can prevent skin breakdown and enhance wound healing.

The *Enhance DX* Control Unit Features

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



Mattress Features

- Therapeutic micro low air loss helps manage moisture and provides alternating therapy to prevent and treat pressure ulcers.
- 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 DX***
Model No.	FC-PHR0004
Size (inch)	10.1” (L) x 4.5” (W) x 8.3” (H)
Weight (lbs)	5.1
Cycle Time	10 min
Min Operating Pressure	12 +/- 5mmHg
Max Operating Pressure	47 +/- 5mmHg
Rated Voltage	AC 110-120V
Rated Frequency	60 Hz
Fuse Rating	1A 250V
Max Current	0.1A
Classification	Class I, Type BF Not AP or AGP type 
Operation Temperature	15°C (59°F)~ 35°C(95°F)
Operation Humidity	30% ~ 75%
Mode of Operation	Continuous
Standard	IEC 60601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-1-2

Enhance DX Mattress Replacement

Model No	FM-PHR0004
Size (inch)	36” (W) x 80” (L) x 8” (H)
Weight (lbs.)	21
Cell Number	18cells
Cells Material	Black Nylon with PU coating
Cover Material	Blue Nylon w/ PU coating finish
Base Material	Black Polyester w/ PVC coating
Weight Capacity	500lbs

Symbol Definition

	Refer to Accompanying Documents
	Waste Disposal
	Type BF Applied Part
	Alternating Current
	Caution

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 DX mattress on the frame and position mattress so the air tube is at the foot of the bed.
4. Secure the Enhance DX 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 selected pressure the "Low Pressure" LED will illuminate and an alarm will sound.
13. For emergency mattress deflation turn the CPR valve to the ''OPEN'' position. The mattress should deflate within 20 seconds. To close the CPR simply turn the valve to the ''CLOSE'' position.

Open

Close

5. Cleaning

<u>The Mattress</u>

The mattress should be cleaned weekly using a damp soft cloth and mild detergent.
The mattress cover can be washed and thermally disinfected in a washing machine by following the procedure below. **(Do not use a phenol based cleaning solution)**

Industrial	Pre-Wash	Cold	10 minutes
	Main Wash	60°C(140°F)	6 minutes
	Main Wash	70°C(158°F)	10 minutes
	Spin Cycle		2 minutes
	3 Cold Rinses		
	Spin Cycle		5 minutes
Domestic	Pre-Wash	Cold	
	Main Wash	70°C(158°F)	10 minutes
	Spin Cycle		2 minutes
	Cold Rinses		
	Spin Cycle		5 minutes

Tumble Drying or Tunnel Drying is not recommended.

Mattress cells can be wiped down 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. 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.

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.
- Set CPR valve to "OPEN" 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: 30% ~ 75%

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.

Symptom	Inspection Procedures	Possible Solution
The pump is not functioning.	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 valve. 3. Check air cells for holes or tears other than where designed.	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.	1. Make sure pump is resting against a solid surface.	1. Reposition the pump. 2. Refer to qualified service technician if problem persist.

8. EMC Related Notifications

Guidance and manufacturer's declaration – electromagnetic emissions		
The air pump is intended for use in the electromagnetic environment specified below. The customer or the user of the air pump is responsible for making sure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The air pump 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 air pump is suitable for use in all establishments including 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended distances between portable and mobile RF communications equipment and the air pump			
The air pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the air pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the air pump 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 2,5 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The air pump is intended for use in the electromagnetic environment specified below. The customer or user of the air pump is responsible for making sure it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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	±2 kV for power supply lines ±1 kV for input/output Lines	±2 kV for power supply lines ±1 kV for input/output lines	The Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	The Main power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	The Main power quality should be that of a typical commercial or hospital environment. If the user of the air pump requires continued operation during power interruptions it is recommended that the air pump is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The air pump is intended for use in the electromagnetic environment specified below. The customer or the user of the air pump is responsible for making sure it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the air pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\ \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\ \sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\ \sqrt{P}$ 800 MHz to 2,5 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the air pump is used exceeds the applicable RF compliance level above the air pump should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary such as reorienting or relocating the air pump.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9. Warranty

- Prius Healthcare 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 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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