# *Salute RDX*

## 3-1 Alternating
## Anti-Decubitus System


# User Manual

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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:
*HOUSEHOLD USE ONLY*
**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.

# 1. The Purpose of this Manual

This operation manual focuses on the set up, cleaning and routine maintenance of the *Salute RDX 3-1 Alternating Anti-Decubitus System*. We recommend keeping this manual available to answer question related to this system.

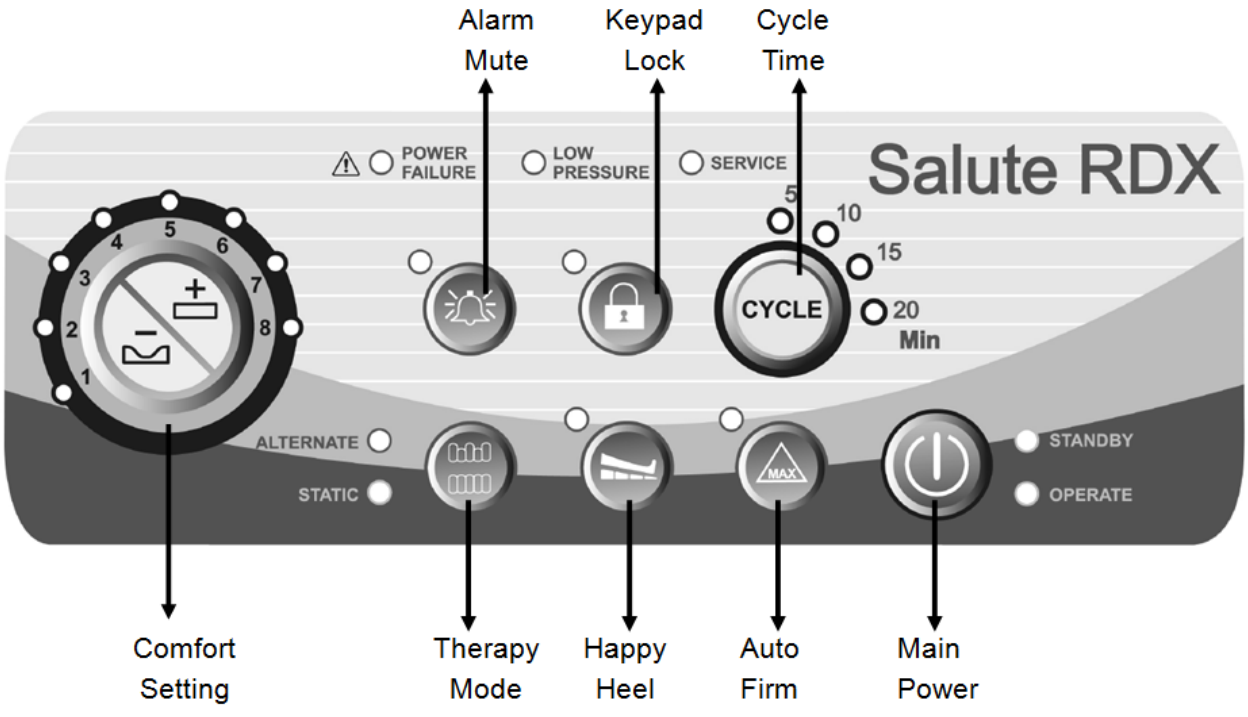
# 2. Product Description

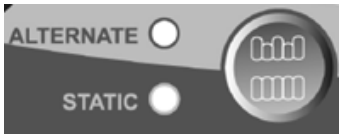
**Salute RDX 3-1 Alternating Anti-Decubitus System** is a pressure ulcer prevention mattress replacement system designed for use in the home, at a nursing facility or in a hospital environment. Use of this system on a standard bed frame is possible; however the use of this system on a bed frame designed for a healthcare environment is preferred.

The system consists of an electronic control unit with a membrane control panel and a replacement mattress containing 18 air cells arranged in a transverse manner. The air cells are designed with Micro Low Air Loss feature to assist in managing the moisture on a patient's skin by allowing additional air to circulate on mattress surface. Another unique feature is the **Happy Heel ™** which provides independent comfort control settings for the heel section allowing improved patient outcomes as well as additional patient comfort.

**<u>Master Control Unit Features</u>**

- 3-1 alternation and static therapy
- Intuitive LED indicator for function status
- 8 adjustable comfort setting
- Visual and audible alarms for low pressure and power failure
- Happy Heel ™ provides extra comfort settings for the heel section
- Keypad lock out function
- Maintenance service LED remainder



| Main Feature | Description |
|---|---|
|  | Therapy Mode allows you to select Alternation or Stactic Therapy. |
|  | Happy Heel is an independent pressure control for the heel section of the mattress to assist in improved patient outcome as well improving patient comfort. |
|  | Auto Firm allows for a quick inflation in stactic mode. |
|  | Alarm Mute allows you to mute the alarm while corrective action is being taken to determine the cause of alarm. |

**Salute RDX Air Mattress Therapy System** is recommended for use in the prevention and treatment of decubitus (pressure) ulcers stage I – III (medium risk). For higher risk patients please contact ***PRIUS Healthcare USA*** for additional product offerings to address higher risk patients. (813) 854-5464

## ⚠ Caution

Alternating pressure therapy is not recommended for patients who have serious pain or pain-sensitive symptom. In such cases please contact ***PRIUS Healthcare USA*** for additional product offerings. (813) 854-5464.

**Mattress Features**

- Therapeutic micro low air loss helps manage moisture and provides alternating therapy to prevent and treat pressure ulcers
- Modularized design allows for easy cleaning and replacement of air cells
- Highly vapor permeable and oversized pliable quilted nylon top cover provides low shear, friction and moisture protection
- CPR quick release for rapid deflation
- Integrated power cable management assists in safety and organization of power cables
- Cell in cell design provides addition protection for upper torso and sacrum in the event there is a loss of power
- 2” convoluted foam base provides additional safety in the event of a loss of power
- Recommended maximum safe working capacity of 500 lbs

# 3. Technical Data

## Master Control Unit

| | |
|---|---|
| Model Name | Salute RDX Control Unit |
| Model No. | FC-PHR0032 |
| Size (inch) LxWxH | 13.5“ x 5.4“ x 8.3“ |
| Weight(lbs) | 7.5 |
| Cycle Time (min) | 5, 10, 15, 20 min |
| Min Operating Pressure | 12 +/- 5mmHg |
| Max Operating Pressure | 47 +/- 5mmHg |
| Max Flow-rate | ≧6 l/min |
| Rated Voltage | AC 110-120V |
| Max Current | 0.2 Amp |
| Fuse Rating | 1A 250V |
| Rated Frequency | 60 Hz |
| Classification | Class II, Type BF<br>Not AP/APG type  |
| Ingress of Water Protection | IP21 |
| 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% to 90% non-condensing |
| Standard | IEC 60601-1,<br>CAN/CSA C22.2 No. 601.1,<br>IEC 60601-1-11<br>IEC 60601-1-2 |

## Mattress Replacement

| | |
|---|---|
| Model Name | Salute RDX Air Mattress |
| Model No. | FM-PHR0033 |
| Size (inch) LxWxH | 80“ x 36“ x 8“ |
| Weight (lbs) | 25.3 |
| 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 |

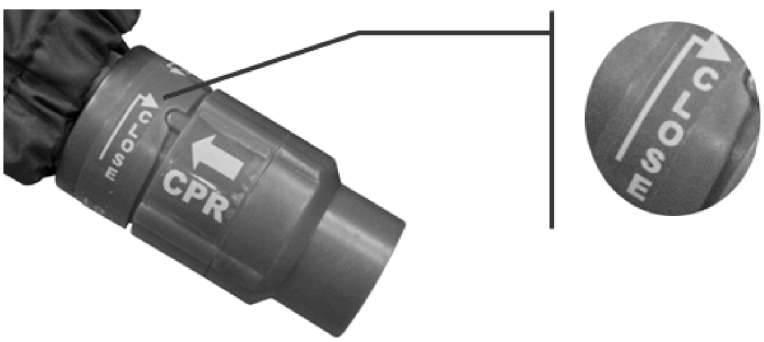
**Symbol Definition**

| | | | |
|---|---|---|---|
| | Type BF<br>Protection Against<br>Electronic Shock | | Class II Equipment |
| | Operating Instructions | | Waste Disposal |
| | Caution, Consult accompanying documents | | Alternating Current |

# 4. Instruction for Proper Use

1. Remove the control unit from the box and hang it at the foot end of the bed using the hooks on the back of the control unit.
2. Plug the power cord into an appropriate outlet.
3. If applicable remove the existing mattress from the bed frame.
4. Remove the Salute RDX replacement mattress from its packaging and place it directly on the bed frame.
5. Make sure that the connecting hose is positioned at the foot of the bed near the control unit.
6. Secure the mattress to the bed frame using the straps on the bottom of the replacement mattress to prevent it from moving.
7. Connect the mattress hose connector to control unit. Make sure the connection is secure.

8. Check the CPR valve to make sure it is set in the “Close” position.



9. Turn on the control unit using the power switch located on the side of the unit. Select the auto firm comfort control dial for quick inflation.






10. During the inflation process, the low pressure LED will be displayed until the mattress is properly inflated, . The inflation time of the mattress can take 30 to 40 minutes. For quicker inflation a portable blower unit is available. Please contact Prius Healthcare USA for additional information, (813) 854-5464.


11. When the mattress is fully inflated , set the dial in accordance with the patient's size and weight.
    - Run the system check.
    - The system is ready for use.
    - Now the patient can be transferred onto the mattress.

## Alarm Function

The ***Salute RDX 3-1 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 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 re-positioning the audible alarm will switch to a 5 minute delay to avoid undesired alarm activation.

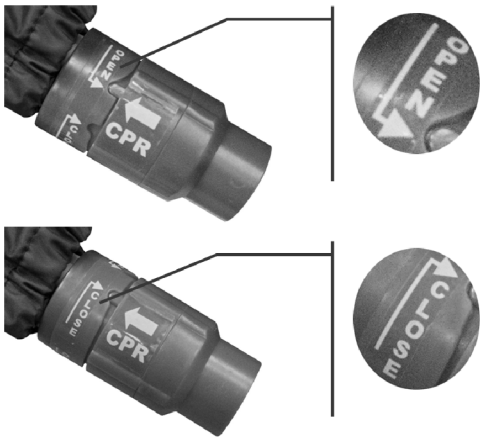
| Alarm Indication | Description |
|---|---|
|  | Indicates a loss of power. |
|  | Indicates low pressure. |
|  | Indicates service is required after 8760 hours of use. |

**Deactivation of audible alarm:**

Switch the pump off then back on, to deactivate the audible alarm.


## CPR Valve

The ***Salute RDX 3-1 Alternating Anti-Decubitus System*** is equipped with a CPR emergency valve which facilitates a rapid deflation by turning the CPR valve to the "OPEN" position.



# 5. Cleaning

## The Mattress

The mattress should be cleaned weekly using a damp soft cloth and mild detergent. If the top cover or base cover becomes excessively soiled, put on clean gloves, plastic gown and eye protection and remove top and base covers from the air cells and tubing. Place soiled covers in an appropriate container in accordance with your facilities standard operating procedures for contaminated waste, replace mattress with clean covers.

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

| | | | |
|---|---|---|---|
| Industrial | Break wash | Cold | 10 minutes |
| | Main wash | 60°C(140°F) | 6 minutes |
| | Main wash | 70°C(158°F) | 10 minutes |
| | Extraction | | 2 minutes |
| | Cold Rinse | | |
| | Extraction | | 5 minutes |
| Domestic | Pre-wash | Cold | |
| | Main Wash | 70°C(158°F) | 10 minutes |
| | Extraction | | 2 minutes |
| | Cold Rinse | | |
| | Extraction | | 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-phenol based germicidal cleaning 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

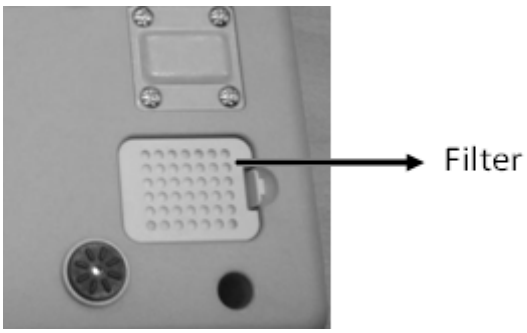
The pump unit should also be cleaned weekly using a damp soft cloth and mild detergent. The pump casing is manufactured using ABS plastic, if the case is soiled the pump can be wiped down with a sodium hypochlorite solution dilution of 1000ppm or any EPA approved hospital grade disinfectant.

**(NOTE: 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. The air filter can be accessed through the air filter cover on the back of the unit. To remove, pinch the center of the filter and pulling outward.

**Replace Air Filter**

1. Remove air filter cover to access air filter. Pinch the center of air filter and pull outward, replace with a new filter.
2. If air filter opening is soiled use a soft bristle brush to remove dust and dried-on soil.




**NOTE:**

1. Do not use any 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 by an environmentally conscious manufacturer that complies with the WEEE.
This product may contain substances that could 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 or excessive wear.
- Plug in the control unit and verify air flows from the units hose connection ports.
- Place in plastic bag for storage.

**Overlay Mattress:**

- Check the air manifold for kinks or breaks and replace if necessary.
- Turn the CPR valve to the open position and disconnect the air tubes from the control unit to allow the mattress to quickly deflate. Starting at the head end of the mattress roll the unit up and use the base mount straps to secure.
- Place mattress in a plastic bag of storage.

Please follow the recommended guidelines below when the system is being stored or transported to another location:

| | |
|---|---|
| Temperature limitations: | 5°C (41°F)~ 60°C (140°F) |
| Relative Humidity: | 30% to 90% |

# 7. Maintenance & Troubleshooting

Daily maintenance is not required. This equipment should only be serviced by a qualified and authorized technician. For common troubleshooting tips please refer to the chart below.

| Symptom | Inspection Procedures | Possible Solution |
|---|---|---|
| The pump is not functioning. | 1. Check power source connection.<br>2. Check for blown fuse. | 1. Connect to proper power source.<br>2. Replace fuse.<br>3. Refer to qualified service technician if problem persist. |
| Low pressure LED is constantly illuminated or mattress is not inflating while pump is in operation. | 1. Check for loose hose connections.<br>2. Check CPR valve.<br>3. Check for air cells for holes or tears other than intended designed. | 1. Make sure connectors are secured.<br>2. Make sure CPR valve is set to “CLOSE” position.<br>3. Replace damaged air cell if necessary.<br>4. Refer to qualified service technician if problem persist. |
| Pump is noisy. | 1. Make sure pump is resting against solid surface. | 1. Reposition the pump.<br>2. Refer to qualified service technician if problem persist. |

# 8. EMC Related Notifications

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Salute RDX is intended for use in the electromagnetic environment specified below. The customer or the user of the Salute RDX is responsible for making sure that it is used in such environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions<br>CISPR 11</td><td>Group 1</td><td>The Salute RDX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.</td></tr>
<tr><td>RF emissions<br>CISPR 11</td><td>Class B</td><td rowspan="3">The Salute 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 power for domestic purposes.</td></tr>
<tr><td>Harmonic emissions<br>IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3</td><td>Complies</td></tr>
</table>

## Recommended separation distances between portable and mobile RF communications equipment and the Salute RDX

The **Salute RDX** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Salute RDX** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Salute RDX** as recommended below, in accordance 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 **Salute RDX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Salute RDX** is responsible for making sure that 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<br>±8 kV air | ±6 kV contact<br>±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<br><br>IEC 61000-4-4 | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | The main power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 kV line(s) to line(s)<br><br>±2 kV line(s) to earth | ±1 kV line(s) to line(s)<br><br>±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<br><br>IEC 61000-4-11 | <5 % *U*T<br>(>95 % dip in *U*T)<br>for 0,5 cycle<br><br>40 % *U*T<br>(60 % dip in *U*T)<br>for 5 cycles<br><br>70 % *U*T<br>(30 % dip in *U*T)<br>for 25 cycles<br><br><5 % *U*T<br>(>95 % dip in *U*T)<br>for 5 sec | <5 % *U*T<br>(>95 % dip in *U*T)<br>for 0,5 cycle<br><br>40 % *U*T<br>(60 % dip in *U*T)<br>for 5 cycles<br><br>70 % *U*T<br>(30 % dip in *U*T)<br>for 25 cycles<br><br><5 % *U*T<br>(>95 % dip in *U*T)<br>for 5 sec | The main power quality should be that of a typical commercial or hospital environment. If the user of the **Salute RDX** requires continued operation during power main interuptions, it is recommended that the **Salute RDX** be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in 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 **Salute RDX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Salute RDX** is responsible for making sure that 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 **Salute RDX**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance**<br><br>$d = 1{,}2\sqrt{P}$<br><br>$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz<br><br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey:<br><br>a. Should be less than the compliance level in each frequency range.<br><br>b. Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m | |

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 and 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 **Salute RDX** is used exceeds the applicable RF compliance level above, the **Salute RDX** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Salute RDX**.

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

# 9. Expected Service Life

The Salute RDX pump has an expected service life of two 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 Salute RDX system.

# 10. 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 discretion 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 following approved procedures and performed by certified technicians.
- In no event shall Prius Healthcare be liable for any direct, indirect, consequential damage or loss resulting from the use of equipment.
- Warranty is non-transferrable.

**Prius Healthcare USA**

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