

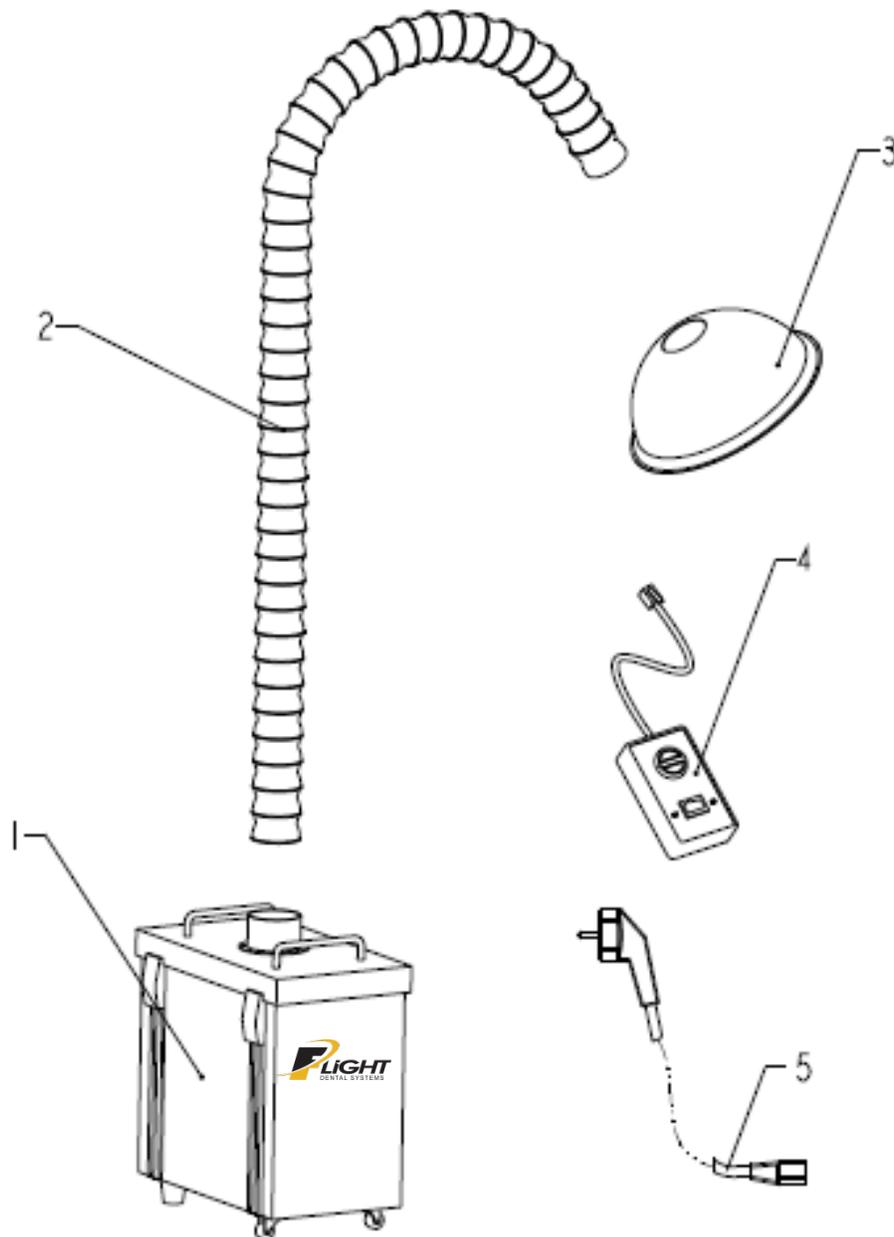
# DEFENDME AEROSOL EVAUCATOR USER MANUAL

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## 1.0 Scope of DefendMe Aerosol Evacuator

1. Main Enclosure
2. Directional Duct
3. Suction Nozzle
4. Speed Controller
5. Power Cord



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## 2.0 Symbols

 <b>WARNING</b>	If the instructions are not followed properly, operation of this device may lead to hazards for the user/patient and failure of the equipment
 <b>NOTE</b>	Additional information: Explanation of operation and performance.
	Serial number
	Catalogue number
	Date of Manufacturing
<b>LOT</b>	Lot Number
	Protective earth (ground)
	Type B applied part
	Fuse
	WEEE directive marking
	Keep dry
	Temperature Range
	Humidity Range
	Atmospheric pressure Range
	Manufacturer's LOGO
	CE Marking
<b>E C REP</b>	Authorized Representative in the European Community
	Consult instructions for use

## 3.0 Introduction

### 3.1 Device Description

The Flight DefendMe Aerosol Evacuator is used to reduce aerosols created by the use of handpieces, scalers, prophy abrasion, abrasion powder, mercury vapour and any other device that creates aerosols during a dental procedure. The device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

### 3.2 Safety Instructions

1. Please read the manual before use.
2. The DEFENDME system must be placed upright while being used. Laying the unit on its side or upside down is prohibited, doing so will cause damage to the machine and shorten its service life.
3. After replacing the filter or after opening the main enclosure, please ensure that the rubber gasket/seal is flat or the device will leak and the suction power will be reduced.
4. When closing the lid of the main enclosure make sure to press the top cover down firmly and then fix the latch or the latch may become damaged.
5. The main filter is heavy, be careful when replacing it. The DEFENDME Aerosol Evacuator is heavy, so be careful when moving it.
6. When replacing the primary filter, it should be noted that the dense side faces the filter and the sparse side faces the air inlet.



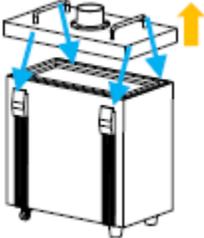
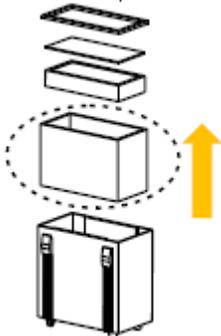
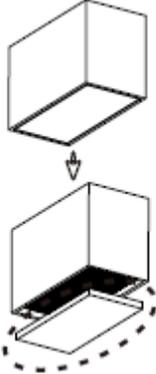
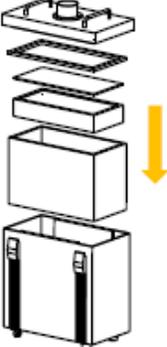
#### **WARNING**

1. The device can capture airborne bacteria and viruses in aerosols created during dental procedures. The device will vacuum aerosols into the system and filter and disinfect any viruses or bacteria. Please note that the device cannot be used to prevent the spread of viruses and bacteria in the air that is not filtered through the device.
2. The device must not be placed in a humid environment or anywhere where it can come into contact with any type of liquids.
3. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in safe environment.
4. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls and do not use this system near active HF Surgical Equipment in the hospital. Portable RF communications equipment (Including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 Inches) to any part of the DEFENDME Aerosol Evacuator or the performance of the device will be affected.
5. Do not operate or store in high temperatures. Please comply with the specified operating and storage conditions.
6. If irregularities occur in the device during treatment, switch it off, contact an authorized representative/distributor.
7. Device should only be serviced by an authorized representative or the warranty will be void.

## 4.0 Installation

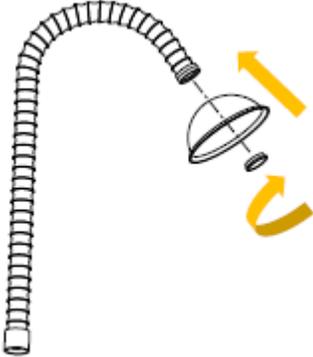
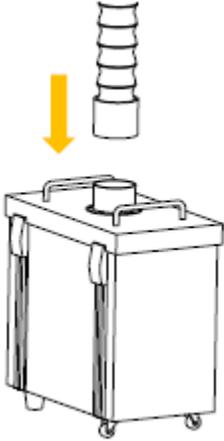
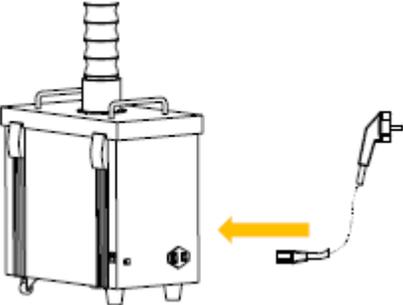
### 4.1 Removing the Protective Foam

Before using the machine for the first time, please remove the foam at the bottom of the main filter assembly otherwise the machine will not work properly. Please refer to the following steps to remove the foam.

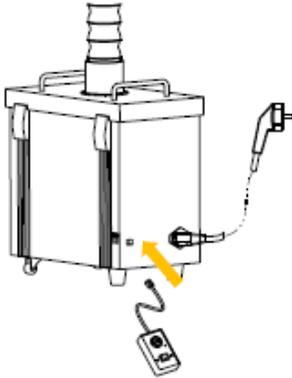
Step	Diagram	Description
1		<p><i>Removing Top Cover:</i> Remove the top cover by undoing the 4 latches marked by the blue arrows and remove the top cover.</p>
2		<p><i>Remove the main filter assembly:</i> Remove the rubber gasket/seal and filter elements in sequence. Then take out the main filter assembly circled in the diagram.</p>
3		<p><i>Remove the foam:</i> Remove the foam installed at the bottom of the main filter element. The foam can be discarded accordingly.</p>
4		<p><i>Reassembling the Unit:</i> Reinstall all the filters in the same order that they were removed and secure the four latches to the top cover. Ensure that the gasket is flat and that the top cover is secured before using.</p>

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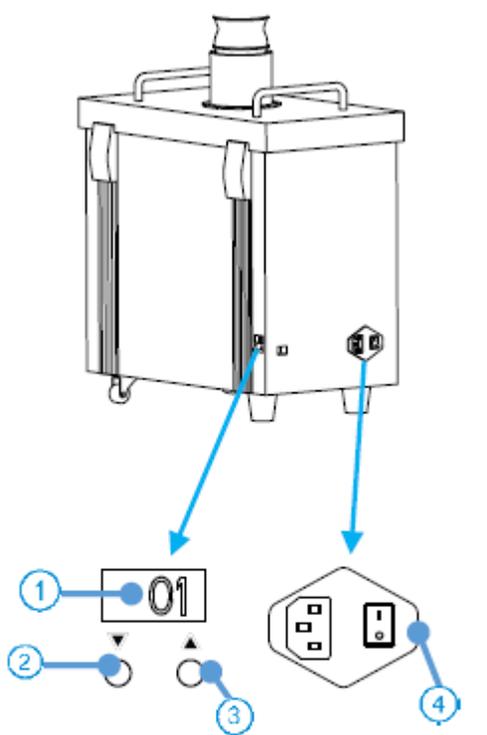
## 4.2 Installing DefendMe Aerosol Evacuator

Step	Diagram	Description
1		<p><i>Installation of the Suction Nozzle:</i> Fasten the suction nozzle to the directional duct by screwing the nut onto the duct</p>
2		<p><i>Installation of the Directional Duct:</i> Plug the direction duct to the top of the cover.</p> <p> <b>NOTE</b> Directional duct should be installed vertically and perfectly secured or the suction power will be reduced.</p>
3		<p><i>Connecting power cord:</i> Connect the power cord to the main enclosure and plug into a 110/220V outlet.</p> <p> <b>NOTE</b> Only the original power cord should be Used.</p>

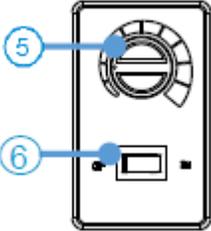
# Flight DEFENDME Aerosol Evacuator R.1.2

4		<p><b>Connect the Speed Controller:</b> Plug the connector of the speed controller into the main housing as shown in the picture.</p>
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## 5.0 User Interface

 <ol style="list-style-type: none"><li>1. Screen Display</li><li>2. Speed Increase</li><li>3. Speed Decrease</li><li>4. Power Switch</li></ol>	<p><b>Turn power On</b> Press Power Switch to “” to turn on.</p> <p><b>Speed Increase</b> Press speed up key to change air volume from 1 to 10.</p> <p><b>Speed Decrease</b> Press the Speed Down key to change air volume from 10 to 1.</p> <p><b>Turn Power Off</b> Press Power switch to “” to turn off.</p>
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 <p>5. Speed Setting Knob 6. Speed Controller Power Switch</p>	<p><b>Turn on the Controller:</b> Press speed Controller power switch to “ON”</p> <p><b>Speed Setting:</b> Rotate Speed Setting knob clockwise to increase air volume from 1 to 10 and counter clockwise to reduce the speed.</p> <p><b>Turn of the Controller:</b> Press the Speed Controller power switch to “OFF”</p>
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### 6.0 Operating Instructions



#### **WARNING**

Do not block the air inlet to avoid damage to the motor. After the filter is blocked please replace the filter immediately to avoid damage to the motor.



#### **NOTE**

- Before using the device for the first time, be sure to remove the foam placed under the main filter.
- When using the latch, be sure to press the top cover down firmly to avoid damaging the latch.
- Fix the Directional air duct by adjusting the direction of the air duct according to the individuals needs.
- Make sure that the power supply is connected and the power switch is turned on. When the controller is not plugged in the value displayed on the screen is the previous setting prior to being turned off.
- When the unit turns on, the display will show a number between 1 to 10. If the device does not turn on within 3 minutes, the total flow value will be displayed. The flow value is a three-digit value, the cumulative value is 001 when the fan rotates 5.76 million revolutions.

#### **6.1 Air Volume Setting**

A speed of 1-10 can be set for the air volume. Click the up button or down button to set the air volume accordingly. 1 is the lowest air speed and 10 is the highest air speed.

#### **6.2 Connect the Speed Controller for Air Volume Adjustment**

When the air volume controller is connected, the up arrow or the down arrow on the machine fails, and the air volume can only be adjusted by the knob on the controller. When the air volume is large, the suction capacity of the machines is strong. It is recommended to work under the condition of larger air volume.

#### **6.3 Power Off**

Turn off the device by pressing the volume controller power switch to “OFF” and the window will

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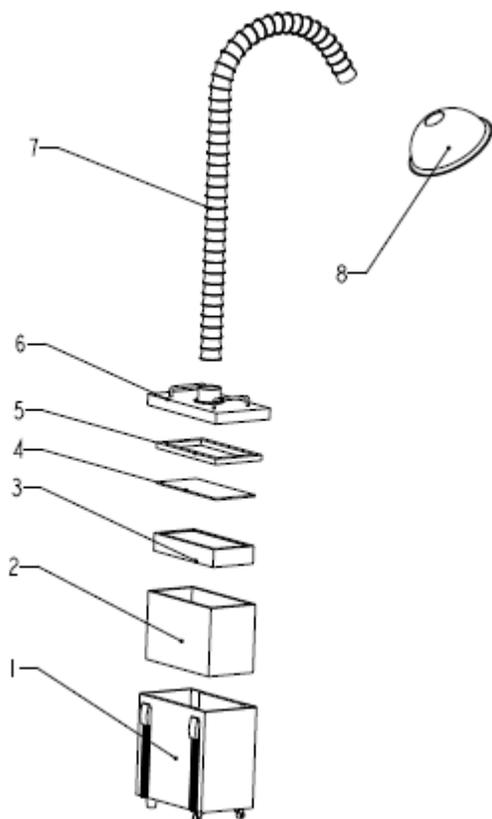
display “OFF”. To disconnect the power supply please press the power switch on the main enclosure box.



### **WARNING**

Condensation may appear on the suction nozzle if the temperature of the suction nozzle is much lower than the atmospheric temperature. If this occurs, run the device for 15-30 minutes continuously without suctioning any aerosols to make sure there is no water vapour in the directional duct and suction nozzle before continuing to use.

## 7.0 Maintenance



### **Components:**

1. Main Enclosure
2. Main Filter Assembly
3. Secondary Filter Assembly
4. Primary Microfiber Filter
5. Rubber Gasket/Seal
6. Top Cover
7. Directional Duct
8. Suction Nozzle

## 7.1 Cleaning and Disinfection

### *7.1.1 Cleaning*

For hygiene and safety purposes, the suction nozzle must be cleaned and disinfected before each use to prevent any cross-contamination. The components directional duct, main enclosure, power cord and speed controller should be cleaned and disinfected regularly according to the frequency of use. Comply with your local regulations for cleaning and disinfection.

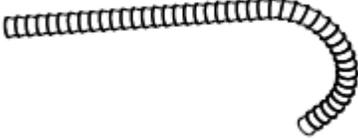
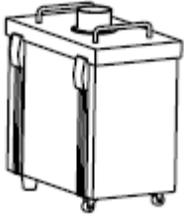
The device should no longer be used if there are signs of damage to the device or any its

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components. Please contact your authorized dealer for repair or replacement of any components.

### 7.1.2 General Recommendations

- The user is responsible for disinfecting the product before use.
- For your own safety, please wear the appropriate personal protective equipment (PPE) (gloves, safety glasses, gowns etc) when using and cleaning this device.
- Use only the correct disinfection solutions or wipes as approved by your local regulators (FDA, Health Canada) and in accordance with the IFU of the manufacturer
- For cleaning of the components please use distilled water only.
- Do not use bleach or chloride disinfectant materials.

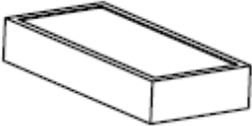
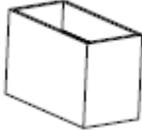
<b>Components to Disinfect</b>		
<p>Suction Nozzle</p> 	<p>Directional Duct</p> 	<p>Main Enclosure</p> 
<p>Power Cord</p> 	<p>Speed Controller</p> 	
<p>Wipe all the surfaces with a cloth or wipe with at least 70-80% ethanol or an approved disinfectant. Wait at least 2 minutes and repeat 5 times. Or follow the recommendations of the disinfectant manufacturer.</p>		
<p> <b>NOTE</b></p> <p>Do not spray excessive ethanol or disinfection solution as it may go into the system and damage the components inside.</p>		

## 7.2 Filter Replacement

### 7.2.1 Frequency of Filter Replacement

<b>Components</b>	<b>Frequency</b>	
	<b>Durability</b>	<b>Flow Value (Usage)</b>
<p>Primary Microfiber Filter</p> 	<p>1-3 months</p>	<p>Display 010 or a multiple of it Eg. 010/020/030.</p>

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Secondary Filter Assembly 	3-6 months	Displays 050 or a multiple of it. Eg.050/100/150
Main Filter Assembly 	12 Months	Display 100 or a multiple of it Eg. 100/200/300
 <b>NOTE</b> Replace relevant filter according to the duration (months) or if the flow value has been reached. Or when the LED display shows a circle than the filter must be replaced. The flow value is a three-digit value; the cumulative value is 001 when the fan rotates 5.76 million revolutions.		

### 7.2.2 How to Replace Filters

Release the four latches on the upper cover of the machine and remove the top cover. Inside you will see the primary microfiber filter, secondary filter assembly and main filter in that order. Replace each filter accordingly. When replacing the main filter ensure that the filter is placed correctly and that the plug for the fan is connected to the bottom of the filter.

 **NOTE**  
 When replacing the filter ensure that the power is turned off and the unit is unplugged.

## 8.0 Troubleshooting

If the device malfunctions please follow the table below before contacting your dealer to resolve the issue. If the problem persists please contact your local authorized distributor or dealer.

Problem	Reason	Solution
The display flashes "OFF" and a circle rotates clockwise on the display or the alarm goes off and the fan stops working	The air inlet is completely blocked.	Turn off the power and check the directional air duct and suction nozzle to see if there is a blockage. Remove any blockages. If the problem persists, open up the upper cover and check

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		if there is a blockage between the directional duct and the top cover preventing air from going into the main enclosure. After these steps, restart the machine and observe for one minute if the alarm still comes on. If it does than replace the filters.
LED Display has “ERR” alarm, and the fan and motor has stopped working	The fan has malfunctioned or the connection to the fan has a problem.	Turn off the power and restart the machine to check whether the fan is working properly, if not check the fan and the connections to the fan to ensure they are all secure.

### 9.0 Technical Data

<b>Manufacturer</b>	HR Dental Products Inc. o/a Flight Dental Systems
<b>Model</b>	DefendMe Aerosol Evacuator
<b>Model #</b>	AE-1000
<b>Dimensions</b>	16 x 9 x 18” (L x W x H)
<b>Duct</b>	Diameter 3 inch x 59 inch Length (D75 x 1500L)
<b>Weight</b>	46 lbs (21kg)
<b>Input</b>	100-120V/60hz
<b>Power</b>	250W Max
<b>Filter Efficiency (0.3um)</b>	99.97%
<b>Static Pressure</b>	3000pa
<b>Air Rate</b>	14 m/s
<b>Volume (Filter Included)</b>	3.7m <sup>3</sup> / min
<b>Ultraviolet</b>	Ultraviolet lamp intensity: 2260uW/cm <sup>3</sup> , Wavelength: 265-285nm
<b>Electrical Safety Class</b>	Class I
<b>Applied Part</b>	B
<b>Operating Conditions</b>	Use: In Enclosed Spaces Ambient Temperature: 5C to 40C Relative Humidity: <80% Operating Altitude <3000m above sea level
<b>Transport and Storage Conditions</b>	Ambient Temperature: -20C to +55C Relative Humidity: 20% to 80% Atmospheric Pressure: 70kPa to 106kPa

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## 10.0 EMC Tables

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
The <b>DEFENDME</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>DEFENDME</b> should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The <b>DEFENDME</b> 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 <b>DEFENDME</b> 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 IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
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Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact  +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact  +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 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 transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.

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Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV  Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV  Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°  0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°  0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	

Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact  +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact  +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 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 transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV  Line to earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV  Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°  0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°  0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery

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Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
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Rated Power frequency magnetic field IEC 61000- 4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz

### Guidance and manufacturer's declaration – electromagnetic immunity

The **DEFENDME** is intended for use in the electromagnetic environment specified below. The customer or the user of the **DEFENDME** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted dis-turbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands be- tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the <b>DEFENDME</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3V/m	<b>Recommended minimum separation distances</b> See the RF wireless communication equipment

Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	table in "Recommended minimum separation distances"
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### Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **DEFENDME** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications

equipment and the **DEFENDME** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810						
870	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
930						