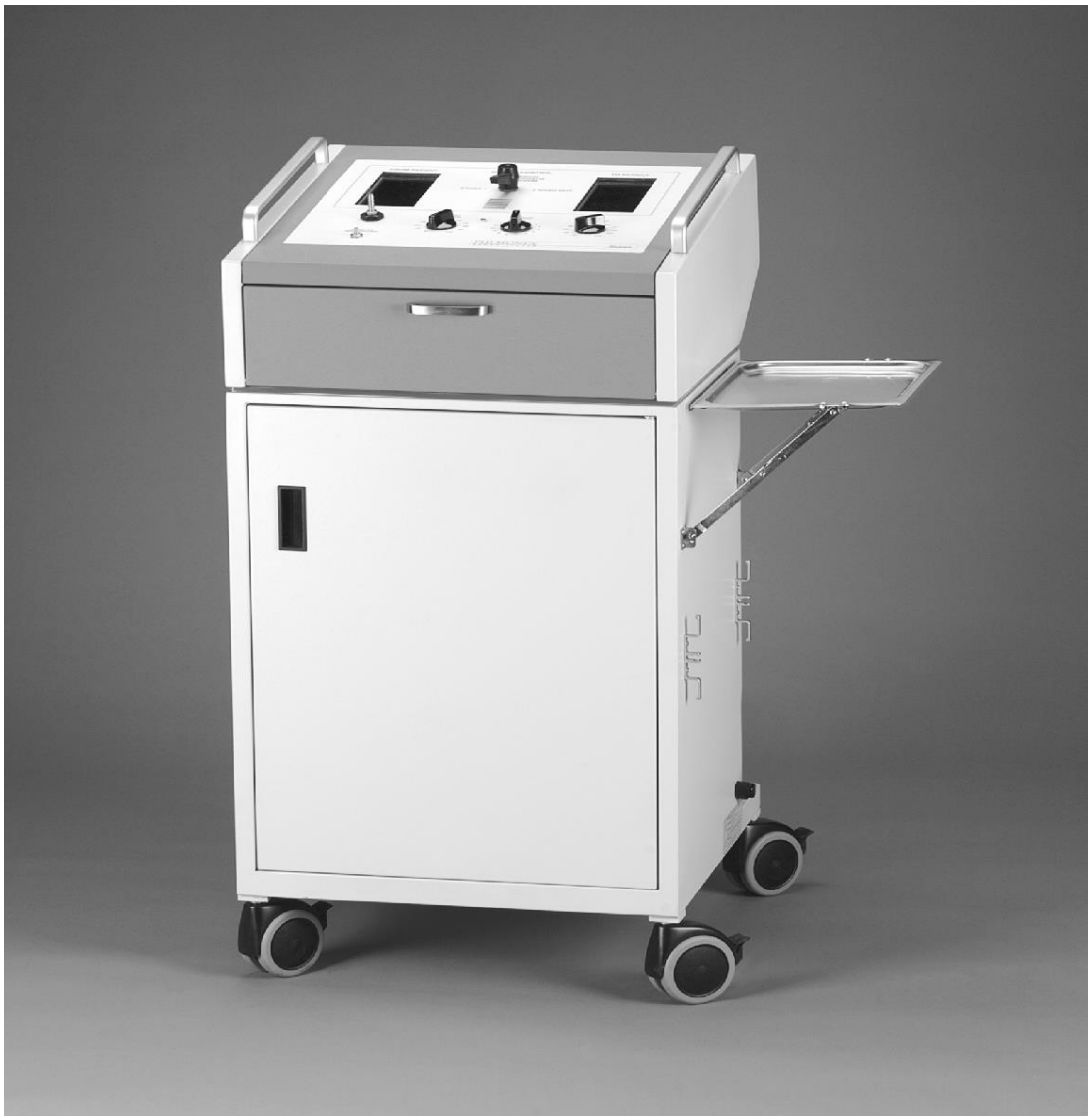
PULMONEX® II DOUBLE-TRAP XENON SYSTEM

CONFORMANCE TO STANDARDS

132-503



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Conformance to Standards

This equipment conforms to the following safety standards:

- AAMI ES60601-1:2005+A1
- CSA C22.2 #60601-1:2014 Ed. 3
- IEC 60601-1-6:2010 Ed. 3+A1
- Class II, ordinary equipment. Continuous operation.

- Type B Applied Part 
  Applied Parts: <To Patient> and <From Patient> breathing hose, Disposable Bacteria Filter, Mouthpiece, Mask, and Face Mask Harness.

Definition of Symbols

The following symbols and their associated definitions are used and implied throughout this manual.

Symbol	Definition
	Carefully read these instructions prior to use
	Operating Instructions
	Caution
	General Warning
	General Mandatory Action
	Dangerous Voltage
	“On” Power
	“Off” Power
	Pinch Point
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Non-Ionizing Electromagnetic Radiation
	Waste in Electrical Equipment
	Disposal Classification and Identification of Equipment
	Date of Manufacture
	Manufactured By
	Type B Applied Part

Electromagnetic Compatibility

Table 1. Safety Standards Conformance Table

Standard	Edition and/or Date
IEC60601-1-2	4th ed / 2014-02

Accompanying EMC Documents

WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as relocating the (ME EQUIPMENT or ME SYSTEM) or shielding the location.

AVERTISSEMENT: Cet équipement/système est destiné à être utilisé uniquement par les professionnels de la santé. Cet équipement/système peut causer des interférences radio ou perturber le fonctionnement de l'équipement voisin. Il peut être nécessaire de prendre des mesures d'atténuation, telles que le déplacement du (ME EQUIPMENT ou le système ME) ou le blindage de l'emplacement.

This medical electrical equipment requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of accessories, transducers, and cables other than those specified, with the exception of accessories, transducers, and cables sold by the manufacturer of this equipment, as replacement parts for internal and external components, may result in increased emissions or decreased immunity of the equipment.
- The Pulmonex should not be used adjacent to or stacked with other equipment. If the Pulmonex is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

List of Cable Accessories

The table below includes all accessory cables supplied with the Pulmonex for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the Pulmonex.

Table 2. Pulmonex Cables Table

Cable Description	Part Number	Cable Length
Power Cable	Biodex # 945-110-E730	10ft

Declaration of Conformity

Manufacturer's Declaration Electromagnetic Emissions

The Pulmonex is intended for use in the electromagnetic environment specified below.

The customer or the user of the Pulmonex must ensure that it is used in such an environment.

Table 3. Emission Test Table

Manufacturer's declaration electromagnetic emissions		
The Pulmonex is intended for use in professional healthcare facility electromagnetic environment with the compliance levels specified below. The customer or the user of the Pulmonex must ensure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	The Pulmonex generates RF energy only for its internal functions. Therefore, its RF emission is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Pulmonex is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network supplying buildings used for domestic purposes.
Harmonic distortion EN 61000-3-2	Class A	
Voltage fluctuations and flicker EN 61000-3-3	Complies	
Note: *The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.*		

Manufacturer's Declaration Electromagnetic Immunity

Table 4. Immunity Test Table

Manufacturer's declaration electromagnetic immunity			
The Pulmonex is intended for use in a professional healthcare facility electromagnetic environment with the immunity compliance levels specified below. The customer or the user of the Pulmonex should assure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test Level**	**EN 60601-1-2 Compliance Level**	**Electromagnetic Environment -Guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 2, 4, 6, 8 kV contact ± 2, 4, 8, 15 kV air	± 2, 4, 6, 8 kV contact ± 2, 4, 8, 15 kV air	Floor should be wood, concrete or ceramic tiles. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/ burst EN 61000-4-4	± 0.5, 1, 2 kV power input ± 0.25, 0.5, 1 kV input/output ports	± 0.5, 1, 2 kV power input ± 0.25, 0.5, 1 kV input/output ports	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, 1 kV differential mode ± 0.5, 1, 2 kV for common mode	± 0.5, 1 kV differential mode ± 0.5, 1, 2 kV for common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0 % UT; for 0.5 cycle[c] At 0,45,90,135,180,225, 270, & 315 degs 0% UT; for 1 cycle 70% UT; 25 cycles[d] And 0% UT: 250 cycles Single phase: at 0 deg	0 % UT; for 0.5 cycle[c] At 0,45,90,135,180,225, 270, & 315 degs 0% UT; for 1 cycle 70% UT; 25 cycles[d] And 0% UT: 250 cycles Single phase: at 0 deg	Mains power quality should be that of a typical commercial or hospital environment. If a better mains power quality is required, it is recommended that the Pulmonex is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the Pulmonex display further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: *UT is the AC. mains voltage prior to application of the test level.*			

Manufacturer's declaration electromagnetic immunity

The Pulmonex is intended for use in a professional healthcare facility electromagnetic environment with the immunity compliance levels specified below. The customer or the user of the Pulmonex should assure that it is used in such an environment.

Immunity Test	**EN 60601-1-2 Test Level**	**EN 60601-1-2 Compliance Level**	**Electromagnetic Environment -Guidance**
Conducted RF EN 61000-4-6	3 Vrms, 150 KHz to 80 MHz 6 Vrms in ISM bands at 6.765, 6.795, 13.553, 13.567, 26.957, 27.283, 40.660, 40.700Mhz 80 % AM @ 1KHz	3 Vrms, 150 KHz to 80 MHz 6 Vrms in ISM bands at 6.765, 6.795, 13.553, 13.567, 26.957, 27.283, 40.660, 40.700Mhz 80 % AM @ 1KHz	Portable and mobile RF communications equipment should be used no closer to any part of the Pulmonex, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 $\sqrt{P}$ 150 KHz to 80 MHz d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer, and is the recommended separation distance in meters (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: 
Radiated RF IEC 61000-4-3 Radiated RF Proximity fields IEC 61000-4-3 (per IEC 60601-1-2 Ed.4)	3 V/m, 80 mHz to 2.7 GHz 80 % AM @ 1Khz 9 V/m – 28V/m per IEC 60601-1-2 Ed.4, Table 9. 0,90,180, 270 Vert @3m 0,90,180, 270 Horiz @3m	3 V/m, 80 mHz to 2.7 GHz 80 % AM @ 1Khz 9 V/m – 28V/m per IEC 60601-1-2 Ed.4, Table 9. 0,90,180, 270 Vert @3m 0,90,180, 270 Horiz @3m	

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 reflections from structures, objects and people.*

[a] Field strength from mixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM or FM 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 Pulmonex is used exceeds the applicable RF compliance levels above, the Pulmonex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulmonex.
[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.
[c] Applicable only to ME equipment and ME systems connected to single phase a.c. mains.
[d] E.g., 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

Recommended Separation Distances

Table 5. Separation Distance Table

Recommended separation distances between portable and mobile RF communications equipment and the Pulmonex are detailed in the following table.

The Pulmonex is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Pulmonex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Pulmonex as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output Power of Transmitter [W]	**Separation Distance According to Frequency of Transmitter [m]**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.7 GHz**
	$\mathbf{d = 1.2\sqrt{P}}$	$\mathbf{d = 1.2\sqrt{P}}$	$\mathbf{d = 2.3\sqrt{P}}$
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.

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.*

Operating Temperatures

Do not expose the equipment to a temperature change of more than 5˚ F (3˚ C) per hour. Limits of low and high operating temperature ranges are 50˚ to 86˚ F (10˚ C to 30˚ C).