

# ATOMLAB 960 (PC) MEDICAL SPECTROMETER

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CONFORMANCE TO STANDARDS

187-600

187-601

187-602



## BIODEX

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## Contact information



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## Conformance to Standards

This equipment conforms to the following safety standards:

- ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010
- CAN/CSA C22.2 No: 60601-1:14
- IEC 60601-1:2012
- CE Marked.
- FDA Class II Equipment

- Type B Applied Part 



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# Electromagnetic Compatibility

**Table 1. Safety Standards Conformance Table**

Standard	Edition and/or Date
IEC60601-1-2	2014

## 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.

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 Atomlab 960 Thyroid Uptake System should not be used adjacent to or stacked with other equipment. If the Atomlab 960 Thyroid Uptake System 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 Atomlab 960 Thyroid Uptake System for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the Atomlab 960 Thyroid Uptake System.

**Table 2. Atomlab 960 Thyroid Uptake System Cables**

Cable Description	Part Number	Cable Length
Power Input Cable 120VAC	Biodex # 945-250-E703	14ft
Power Input Cable 220VAC	Biodex #945-395-E733	14ft

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## Declaration of Conformity

### Manufacturer's Declaration Electromagnetic Emissions

Table 3. Emission Test Table

<i>Manufacturer's declaration electromagnetic immunity</i>		
The Atomlab 960 Thyroid Uptake System is intended for use in the electromagnetic environment specified below. The customer or the user of the Atomlab 960 Thyroid Uptake System must ensure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The Atomlab 960 Thyroid Uptake System 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 Atomlab 960 Thyroid Uptake System 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	
<b>Note:</b> <i>It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to ensure that they meet the minimum specifications.</i>		


# Manufacturer's Declaration Electromagnetic Immunity

Table 4. Immunity Test Table

<i>Manufacturer's declaration electromagnetic immunity</i>			
The Atomlab 960 Thyroid Uptake is intended for use in the electromagnetic environment specified below. The customer or the user must ensure that it is used in such an environment.			
<b>Immunity Test</b>	<b>EN 60601-1-2 Test Level</b>	<b>EN 60601-1-2 Compliance Level</b>	<b>Electromagnetic Environment -Guidance</b>
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 <sup>c</sup> At 0,45,90,135,180,225, 270, & 315 degs 0% UT; for 1 cycle 70% UT; 25 cycles <sup>d</sup> And 0% UT: 250 cycles Single phase: at 0 deg	0 % UT; for 0.5 cycle <sup>c</sup> At 0,45,90,135,180,225, 270, & 315 degs 0% UT; for 1 cycle 70% UT; 25 cycles <sup>d</sup> 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 C-Arm Table is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m RMS	30 A/m RMS	If image distortion occurs, it may be necessary to position the C-Arm Table 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.
<b>NOTE:</b> UT is the AC. mains voltage prior to application of the test level.			

*Manufacturer's declaration electromagnetic immunity*

The Atomlab 960 Thyroid Uptake System is intended for use in the electromagnetic environment specified below. The customer or the user of the Atomlab 960 Thyroid Uptake System must ensure 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 IEC 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 Atomlab 960 Thyroid Uptake System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m, 80 mHz to 2.7 GHz  80 % AM @ 1Khz	3 V/m, 80 mHz to 2.7 GHz  80 % AM @ 1Khz	<p>Recommended separation distance:</p> $d = 1.2 \sqrt{P} \text{ 150 KHz to 80 MHz}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup>, should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

**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.

<sup>a</sup>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 Atomlab 960 Thyroid Uptake System is used exceeds the applicable RF compliance levels above, the Atomlab 960 Thyroid Uptake System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Atomlab 960 Thyroid Uptake System.

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

<sup>c</sup>Applicable only to ME equipment and ME systems connected to single phase a.c. mains.

<sup>d</sup>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 Atomlab 960 Thyroid Uptake System are detailed in the following table.

The Atomlab 960 Thyroid Uptake System is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Atomlab 960 Thyroid Uptake System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Atomlab 960 Thyroid Uptake System 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
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 Temperature

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).

**BIODEX**  
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