

ATOMLAB 500™ DOSE CALIBRATOR

CONFORMANCE TO STANDARDS

086-330



BIODEX

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Conformance to Standards

This equipment conforms to the following safety standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
- ANSI/AAMI ES60601-1:2005 + A1:2012, C1:2009 and A2:2010
- CAN/CSA-C22.2 No. 60601-1:2014
- EN60601-1:2006 + AC:2010 and A1:2013
- IEC 60601-1-2:2014
- CE Marked
- FDA Class II Equipment



Electromagnetic Compatibility

Conformance to Standards

This equipment conforms to the following safety standards:

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 needs 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 500 should not be used adjacent to or stacked with other equipment. If the Atomlab 500 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 500 for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the Atomlab 500.

Table 2. AL 500 Cables Table

Cable Description	Part Number	Cable Length
Power Input Wall Pack	Biodex # C13116	6ft
NEMA Cord Set	Biodex # C11789	10ft
Tablet to Interface Module Cable	Biodex #C14319	1.64ft
Interface Module to Wipe	Biodex # 086-330-E718	3ft
Wipe to Dose Chamber	Biodex # 086-330-E718	3ft
Report Printer USB Cable	Biodex #C12086	15ft
Label Printer USB Cable	Dymo	3ft

Declaration of Conformity

Manufacturer's Declaration Electromagnetic Emissions

The Atomlab 500 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Atomlab 500 must ensure that it is used in such an environment.

Table 3. Emission Test Table.

<i>Manufacturer's declaration electromagnetic immunity</i>		
The Atomlab 500 System is intended for use in the electromagnetic environment specified below. The customer or the user of the Atomlab 500 must ensure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The Atomlab 500 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 500 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: <i>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.</i>		


Manufacturer's Declaration Electromagnetic Immunity

Table 4. Immunity Test Table

<i>Manufacturer's declaration electromagnetic immunity</i>			
The Atomlab 500 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 Atomlab 500 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 Atomlab 500 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 Atomlab 500 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 Atomlab 500 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 Atomlab 500 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 Atomlab 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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	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: 

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 Atomlab 500 is used exceeds the applicable RF compliance levels above, the Atomlab 500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Atomlab 500.

^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 Atomlab 500 are detailed in the following table.

The Atomlab 500 is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Atomlab 500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Atomlab 500 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 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).

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