BALANCE SYSTEM™ SD

CONFORMANCE TO STANDARDS

950-440	System, Balance SD, 115 VAC 15.6” display
950-441	System, Balance SD, 230 VAC 15.6” display
950-444	System, Balance SD, 100 VAC 15.6” display
950-450	Optional FreeSway Handles

BIODEX
Biodex Medical Systems, Inc.
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FN: 20-139-CLR

BALANCE SYSTEM™ SD (version 4.x)

This document contains the conformance to standards for the Balance System SD.

Additional information and resources are available upon request or directly from the Biodex website: www.biodex.com/balance.

Here, the user can find information from compliance to clinical support, and if the desired information is not found, Biodex can be contacted directly at supportservices@biodex.com.

Thank you,
Biodex Medical Systems, Inc.

Contact information

Manufactured by:

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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, Class 1 Measuring
- FDA Class I Equipment
- EC Certificate: EC #41312068-01

- Type B Applied Part 

Mi-Wi Communication Software - Copyright JD Birck, LLC

United States:

Contains FCC ID: OA3MRF24J40MA

Canada:

Contains IC: 7693A-24J40MA

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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 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 Balance System SD should not be used adjacent to or stacked with other equipment. If the Balance System SD 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 list in Table includes all accessory cables supplied with the Balance System SD for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the Balance System SD.

Table 2. Balance System SD Cables

Cable Description	*Biodex Part No.*	*Cable Length*
USB Printer Cable	C12086	>3m
USB (Belt)	C14099	>3m
AC Mains Balance	950-300-E709/E712	>3m
AC Out to Printer	C12039	<3m
USB (Tran to Balance Sys)	C14098	<3m
Ethernet (Rec to Belt)	950-430-E701	<3m

Declaration of Conformity

Manufacturer's Declaration of Electromagnetic Emissions

The Balance System SD is intended for use in the electromagnetic environment specified below. The customer or the user of the Balance System SD must ensure that it is used in such an environment.

Table 3. Emission Test Table.

Manufacturer's declaration electromagnetic emissions		
The Balance System SD is intended for use in professional healthcare facility electromagnetic environment with the compliance levels specified below. The customer or the user of the Balance System SD should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	The Balance System SD 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 Balance System SD 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.*		

Immunity Test Tables

Table 4. Immunity Test Table

Manufacturer's declaration electromagnetic immunity			
The Balance System SD 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 Balance System SD 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 Balance System SD 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 Balance System SD 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 Balance System SD 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 Balance System SD 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 Balance System SD, 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 Balance System SD is used exceeds the applicable RF compliance levels above, the Balance System SD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Balance System SD.
[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 Balance System SD are detailed in the following table.

The Balance System SD is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Balance System SD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Balance System SD 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 15˚ C to 30˚ C (60˚ to 86˚ F).