Mallinckrodt™ Pharmaceuticals

Technical Bulletin

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Product: INOmax DS$_{IR}$® / INOmax DS$_{IR}$® Plus / INOmax DS$_{IR}$® Plus MRI / INOflo® DS

Priority: Low

Classification: Information for Distribution

Affected parts: INOmax DS$_{IR}$, INOmax DS$_{IR}$ Plus, INOmax DS$_{IR}$ Plus MRI and INOflo DS

Subject: **Volume of Auditory Alarm Signals; Standards and Electromagnetic Immunity Updates**

Volume of Auditory Alarm Signals

During alarm conditions and information signals, the INOmax DS$_{IR}$, INOmax DS$_{IR}$ Plus, INOmax DS$_{IR}$ Plus MRI and INOflo DS create sound pressure levels depending on the alarm condition and the position of the user in relation to the device. Please refer to the table below for the high priority alarm sound pressure level range:

Volume of Auditory Alarm Signals			
Alarm Condition	**Volume Level Setting**	**Measurement position**	**Typical A- Weighted* sound pressure level averaged over measurement surface (dBA)**
High Priority	5	Right side	63
High Priority	5	Rear	60
High Priority	5	Left side	57
High Priority	5	Front	60
*Calculated A-weight Background sound pressure level based on 8.2.2 of ISO3744:2010. Value calculated to be less than 30dB(A). Notes: Measurements made 1 meter from the device. A–weighted alarm sound pressure level is at minimum +6 dB above A-weighted background level.			

Standards Updates

The INOmax DS$_{IR}$, INOmax DS$_{IR}$ Plus, INOmax DS$_{IR}$ Plus MRI and INOflo DS are certified to be compliant with the latest national and international consensus standards. In addition to the latest standards, these devices maintain certification to an older version of the base safety standard for those countries that have not yet acknowledged the latest versions. Below is the current list of certifications these devices meet:

CSA certified to meet the following for medical electrical equipment:
(IEC 60601-1 second edition citations)

- UL 60601-1 (1st edition) Medical Electrical Equipment part 1: General requirements for safety
- IEC 60601-1:1988 (Second Edition) +A1: 1991+A2:1995 General requirements for safety

(IEC 60601-1 third edition citations)

- ANSI/AAMI ES60601-1:2005/(R) 2012, AND C1:2009 AND A2:2010(R)2012 (Consolidated text – edition 3.1) General requirements for basic safety and essential performance
- IEC 60601-1:2005 edition 3.0 + AMENDMENT 1, 2012-07, MOD General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 (Third Edition) + A1:2013, IDT General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1- 8: 2006 (Second Edition) + Am.1: 2012 for use in conjunction with IEC 60601-1: 2005 (Third Edition) + Am.1: 2012 Medical Electrical Equipment – Part 1-8 – General Requirements, Tests and guidance for alarm systems
- CAN/CSA-C22.2 No.60601-1:14 General requirements for basic safety and essential performance
- CAN/CSA-C22.2 No.60601-1-6:11 General requirements for basic safety and essential performance – Collateral standard: Usability
- CAN/CSA-C22.2 No.60601-1-8:08 General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical equipment and medical equipment systems
- IEC 60601-1-2 Ed. Ed. 4 b:2014 Medical electrical equipment — Part 1-2: .General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests

Electromagnetic Immunity Updates

The INOmax DS_{IR}, INOmax DS_{IR} Plus, INOmax DS_{IR} Plus MRI and INOflo DS have been tested to and COMPLIES with all the new compliance levels of the updated standard. Please refer to the table below:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The INOmax DSIR system is intended for use in the electromagnetic environment specified below. The user of the INOmax DSIR system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV Air	± 8 kV Contact ± 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 transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Line(s) to Line(s) ± 2 kV Line(s) to earth	± 1 kV Line(s) to Line(s) ± 2 kV Line(s) to earth	Mains power quality should be that of a typical commercial and/ or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0,5 cycle occurring at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 0 % UT (100 % dip in UT) for 1 cycle occurring at 0º 70 % UT (30 % dip in UT) for 25/30 cycles	0 % UT (100 % dip in UT) for 0,5 cycle occurring at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 0 % UT (100 % dip in UT) for 1 cycle occurring at 0º 70 % UT (30 % dip in UT) for 25/30 cycles	Mains power quality should be that of a typical commercial and/ or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.

	Voltage interruption at test Voltage level: 0 % UT 100 % dip in UT for 250/300 cycles	Voltage interruption at test Voltage level: 0 % UT 100 % dip in UT for 250/300 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m Home Healthcare	30 A/m	Home Healthcare Levels
NOTE UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The INOmax DSIR system is intended for use in the electromagnetic environment specified below. The user of the INOmax DSIR system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 6 Vrms 150 kHz to 80 MHz in ISM bands[a]	3 Vrms (V1) 6 Vrms (V2)	Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the INOmax DSIR system than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=3.5*\sqrt{P}/V1$ $d=12*\sqrt{P}/V2$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 26 MHz to 2.7 GHz (E1)	$d=12*\sqrt{P}/E1$ 80 MHz to 800 MHz $d=23*\sqrt{P}/E1$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Proximity fields from RF wireless communications equipment	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHZ 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHZ 9 V/m; PM 50%; 217 Hz 800 - 960 MHZ 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHZ 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHZ 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHZ 9 V/m; PM 50%; 217 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHZ 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHZ 9 V/m; PM 50%; 217 Hz 800 - 960 MHZ 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHZ 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHZ 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHZ 9 V/m; PM 50%; 217 Hz	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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that a portable communications device could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio 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 INOmax DS_{IR} system is used exceeds the applicable RF compliance level above, the INOmax DS_{IR} system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the INOmax DS_{IR} system.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the INOmax DS_{IR} Plus system				
The INOmax DS_{IR} Plus system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the INOmax DS_{IR} Plus system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the INOmax DS_{IR} Plus system as recommended below, according to the maximum output power of the communications equipment.				
Rated Maximum Output Power of Transmitter (W)	**Separation distance according to frequency of transmitter** (meters)			
	150 kHz to 80 MHz Outside ISM bands $d=1.2*\sqrt{P}$	**150 kHz to 80 MHz In ISM bands** $d=2*\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2*\sqrt{P}$	**800 MHz to 2.7 GHz** $d=2.3*\sqrt{P}$
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.63	0.38	0.73
1	1.2	2.0	1.2	2.3
10	3.8	6.3	3.8	7.3
100	12	20	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.				

For technical assistance regarding the INOmax DS_{IR}, please contact Technical Support at 1-877-566-9466 (North America) or your specific country manager.

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