

Technical Article

Understanding Medical EMC 4th Edition (IEC 60601-1-2:2014)

By Delta Product Corporation



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The International Electrotechnical Commission (IEC) in 2014 published the updated revision of the electromagnetic compatibility (EMC) requirements for medical devices, the IEC 60601-1-2:2014, so called 4th edition, with an effective date of April 1, 2017. This revision makes changes to immunity requirements and the analysis of risk management for electromagnetic disturbances of medical devices, in order to make them safer for use in three specifically intended environmental categories: 1) Professional healthcare, 2) Home healthcare, and 3) Special environments.



Figure 1. Delta's MDS ATX series of medical power supplies is suitable for use in medical devices with Type BF classification.

With the roles that power supplies play in medical devices, it is important for Delta to help Design Engineers achieve the most efficient and expeditious way for their designs to meet the 4th edition standard for medical systems and devices. The 3rd edition standard requirements are based on the purpose of the equipment, rather than the environment that it was intended to be used in. The 4th edition standard requirements are broken down into three intended use environmental categories:

- **Professional Healthcare** – Hospitals, clinics, other medical facilities
- **Home Healthcare** – Homes, public spaces
- **Special Environments** – Military installations, industrial zones

These categories more accurately define the operation of medical devices and systems in everyday life, where devices, such as mobile devices or other equipment, may be operating concurrently. Alongside intended use environmental categories, comes new “Intended Use” and “Normal Use” definitions, where:

- Intended use is for the intended medical purpose
- Normal use is for purposes such as transportation, maintenance, standby



Figure 2. Delta's MDS Open Frame and MDS Enclosed series of medical power supplies can be used in a wide variety of equipment for medical and ITE applications.

Beyond use within environmental categories, technical changes within 4th Edition include:

A) Immunity test level increases:

- The range of testing for radiated immunity harmonized up to 2.7GHz (up from 2.5GHz in the 3rd edition)
- Magnetic immunity at 30A/m
- Conducted immunity at 6V in ISM bands
- ESD at 8kV contact and 15kV air (up from 6kV and 8kV respectively in the 3rd edition)
- Voltage dips and interruptions at additional phase angles

B) Changes to Immunity testing:

- Immunity test levels are harmonized with IEC 60601-1-11
- Immunity testing follows same port-by-port convention of the IEC 61000-6 series of Generic EMC standards
- Immunity to proximity fields from RF wireless communications equipment is now included, and is based on a minimum separation distance of 30cm
- There is a procedure for continuing to test a product that is damaged by an immunity test signal

C) Expansion of Risk Management:

- Product manufacturers will be required to submit a test plan and the risk analysis document before testing
- Operating modes are based on risk analysis
- Reasonably foreseeable electromagnetic disturbances shall be taken into risk management process
- The risk management process is used to determine whether subsystem testing is allowed



Figure 3. Delta's MDS Adapter series rides on Delta's market leading adapter technology to provide the same high quality external power supplies for medical systems and equipments.

Table of Immunity Changes:

Port	Basic Standard for Test Method	EN 60601-1-2:2007	IEC 60601-1-2: 2014	
			Professional Healthcare Facility Environment	Home Healthcare Environment
Enclosure Port	IEC 61000-4-2	6 kV (Contact discharge) 8 kV (Air discharge)	8 kV (Contact discharge) 15 kV (Air discharge)	8 kV (Contact discharge) 15 kV (Air discharge)
	IEC 61000-4-3	80 to 2500 MHz / 10 V/m for LIFE-SUPPORTING	80 to 2700 MHz / 3 V/m	80 to 2700 MHz / 10 V/m
		80 to 2500 MHz / 3 V/m for not LIFE-SUPPORTING	Frequency: up to 5785MHz Level: up to 28V/m	Frequency: up to 5785MHz Level: up to 28V/m
IEC 61000-4-8	50,60 Hz 3 A/m	50 or 60 Hz 30 A/m	50 or 60 Hz 30 A/m	
AC input power port	IEC 61000-4-4	2 kV	2 kV / 100kHz	2 kV / 100kHz
	IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth
	IEC 61000-4-6	0.15 to 80 MHz / 10 V for LIFE-SUPPORTING	0.15 to 80 MHz / 3 V	0.15 to 80 MHz / 3 V
		0.15 to 80 MHz / 3 V for not LIFE-SUPPORTING	6 V in ISM bands	6V in ISM bands & amateur radio bands
	IEC 61000-4-11	<5 % UT for 0.5 cycle	<5 % UT for 0.5 cycle at step: 45°	<0 % UT for 0.5 cycle at step: 45°
		40 % UT for 5 cycles 70 % UT for 25 cycles <5 % UT for 5 s	0 % UT for 1 cycle 70 % UT for 25/30 cycles <5 % UT for 250/300 cycles	0 % UT for 1 cycle 70 % UT for 25/30 cycles <5 % UT for 250/300 cycles
DC input power port	IEC 61000-4-4	2 kV	2 kV / 100kHz	2 kV / 100kHz
	IEC 61000-4-5	N/A	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth
	IEC 61000-4-6	0.15 to 80 MHz / 10 V for LIFE-SUPPORTING	0.15 80 MHz / 3 V	0.15 to 80 MHz / 3 V
		0.15 to 80 MHz / 3 V for not LIFE-SUPPORTING	6V in ISM bands	6V in ISM bands & amateur radio bands
	ISO 7637-2	N/A	N/A	ISO 7637-2:2011
Signal input/output parts port	IEC 61000-4-4	1 kV / 5KHz	1 kV / 100kHz	1 kV / 100 kHz
	IEC 61000-4-5	N/A	2kV line to earth for outdoor	2kV line to earth for outdoor
	IEC 61000-4-6	0.15 to 80 MHz / 10 V for LIFE-SUPPORTING	0.15 to 80 MHz / 3 V	0.15 to 80 MHz / 3 V
		0.15 to 80 MHz / 3 V for not LIFE-SUPPORTING	6V in ISM bands	6V in ISM bands & amateur
Patient coupling port	IEC 61000-4-2	N/A	8 kV (Contact discharge) 15 kV (Air discharge)	8 kV (Contact discharge) 15 kV (Air discharge)
	IEC 61000-4-6	N/A	0.15 to 80 MHz / 3 V	0.15 to 80 MHz / 3 V
		N/A	6V in ISM bands	6V in ISM bands & amateur radio bands

Delta Medical Power Supply products compliant with EMC 4th Edition (IEC 60601-1-2:2014):

Model Name	Type	Output Voltage	Output Current	Output Power	Input Voltage	Ingress Protection	Dimension (L x W x D)
MDS-005AAS05 B	Adapter	5V	1A	5W	90-264Vac	IP22	56.5 x 39.5 x 28 mm
MDS-030AAC05	Adapter	5V	3A	15W	85-264Vac	IP22	88.0 x 53.5 x 27.5 mm
MDS-030AAC07	Adapter	7V	3A	21W	85-264Vac	IP22	88.0 x 53.5 x 27.5 mm
MDS-030AAC12	Adapter	12V	2A	24W	85-264Vac	IP22	88.0 x 53.5 x 27.5 mm
MDS-030AAC15	Adapter	15V	2A	30W	85-264Vac	IP22	88.0 x 53.5 x 27.5 mm
MDS-030AAC24	Adapter	24V	1.25A	30W	85-264Vac	IP22	88.0 x 53.5 x 27.5 mm
MDS-040APS12 B	Open Frame	12V	3.33A	40W	90-264Vac		76.2 x 50.8 x 23.0 mm
MDS-040APS15 B	Open Frame	15V	2.67A	40W	90-264Vac		76.2 x 50.8 x 23.0 mm
MDS-040APS18 B	Open Frame	18V	2.22A	40W	90-264Vac		76.2 x 50.8 x 23.0 mm
MDS-040APS24 B	Open Frame	24V	1.67A	40W	90-264Vac		76.2 x 50.8 x 23.0 mm
MDS-060AAS12 B	Adapter	12V	5A	60W	90-275Vac		135.0 x 62.0 x 34.1 mm
MDS-060AAS15 B	Adapter	15V	4A	60W	90-275Vac		135.0 x 62.0 x 34.1 mm
MDS-060AAS19 B	Adapter	19V	3.15A	60W	90-275Vac		135.0 x 62.0 x 34.1 mm
MDS-060AAS24 B	Adapter	24V	2.5A	60W	90-275Vac		135.0 x 62.0 x 34.1 mm
MDS-060BAS12 A	Adapter	12V	5A	60W	90-264Vac	IP22	135.0 x 62.0 x 34.1 mm
MDS-060BAS19 A	Adapter	19V	3.15A	60W	90-264Vac	IP22	135.0 x 62.0 x 34.1 mm
MDS-060BAS24 A	Adapter	24V	2.5A	60W	90-264Vac	IP22	135.0 x 62.0 x 34.1 mm
MDS-065APS12 B	Open Frame	12V	5.42A	65W	90-264Vac		101.6 x 50.8 x 30.0 mm
MDS-065APS15 B	Open Frame	15V	4.2A	63W	90-264Vac		101.6 x 50.8 x 30.0 mm
MDS-065APS18 B	Open Frame	18V	3.61A	65W	90-264Vac		101.6 x 50.8 x 30.0 mm
MDS-065APS24 B	Open Frame	24V	2.71A	65W	90-264Vac		101.6 x 50.8 x 30.0 mm
MDS-080AAS12 A	Adapter	12V	6.7A	80W	90-264Vac	IP22	150.0 x 75.0 x 40.0 mm
MDS-090AAS15 B	Adapter	15V	6A	90W	90-264Vac		150.0 x 60.0 x 35.0 mm
MDS-090AAS19 B	Adapter	19V	4.73A	90W	90-264Vac		150.0 x 60.0 x 35.0 mm
MDS-090AAS24 B	Adapter	24V	3.75A	90W	90-264Vac		150.0 x 60.0 x 35.0 mm
MDS-090BAS24 A	Adapter	24V	3.75A	90W	90-264Vac		150.0 x 75.0 x 40.0 mm
MDS-100AP401 B	Open Frame	5.1V, 12V, +15V, -15V	8A, 3A, 0.8A, 0.8A	100W	90-264Vac		127.0 x 76.2 x 30.5 mm
MDS-100APS12 B	Open Frame	12V	8.33A	100W	90-264Vac		127.0 x 76.2 x 31.0 mm
MDS-100APS15 B	Open Frame	15V	6.7A	100W	90-264Vac		127.0 x 76.2 x 31.0 mm
MDS-100APS18 B	Open Frame	18V	5.55A	100W	90-264Vac		127.0 x 76.2 x 31.0 mm
MDS-100APS24 B	Open Frame	24V	4.17A	100W	90-264Vac		127.0 x 76.2 x 31.0 mm
MDS-100BPS12 B	Open Frame	12V	8.33A	100W	90-264Vac		101.6 x 50.8 x 31.8 mm
MDS-100BPS15 B	Open Frame	15V	6.7A	100W	90-264Vac		101.6 x 50.8 x 31.8 mm
MDS-100BPS18 B	Open Frame	18V	5.55A	100W	90-264Vac		101.6 x 50.8 x 31.8 mm
MDS-100BPS24 B	Open Frame	24V	4.17A	100W	90-264Vac		101.6 x 50.8 x 31.8 mm
MDS-150AAS12 B	Adapter	12V	10A	120W	90-264Vac		170.0 x 85.0 x 40.0 mm
MDS-150AAS19 B	Adapter	19V	7.9A	150W	90-264Vac		170.0 x 85.0 x 40.0 mm
MDS-150AAS24 B	Adapter	24V	6.25A	150W	90-264Vac		170.0 x 85.0 x 40.0 mm
MDS-200APB12 AA	Open Frame	12V	16.67A	200W	90-264Vac		101.6 x 50.8 x 35.6 mm
MDS-200APB24 AA	Open Frame	24V	8.33A	200W	90-264Vac		101.6 x 50.8 x 35.6 mm
MDS-200ADB12 AA	Open Frame with metal enclosure	12V	16.67A	200W	90-264Vac		113.9 x 64.7 x 44.7 mm
MDS-200ADB24 AA	Open Frame with metal enclosure	24V	8.33A	200W	90-264Vac		113.9 x 64.7 x 44.7 mm
MDS-250ADB12 AA	Open Frame with metal enclosure	12V	20.84A	250W	90-264Vac		140.0 x 88.9 x 45.0 mm
MDS-250ADB24 AA	Open Frame with metal enclosure	24V	10.41A	250W	90-264Vac		140.0 x 88.9 x 45.0 mm
MDS-250APB12 AA	Open Frame	12V	20.84A	250W	90-264Vac		127.3 x 76.5 x 36.1 mm
MDS-250APB24 AA	Open Frame	24V	10.41A	250W	90-264Vac		127.3 x 76.5 x 36.1 mm

Model Name	Type	Output Voltage	Output Current	Output Power	Input Voltage	Ingress Protection	Dimension (L x W x D)
MDS-300ADB12 AA	Open Frame with metal enclosure	12V	25A	300W	90-264Vac		140.0 x 88.9 x 45.0 mm
MDS-300ADB18 AA	Open Frame with metal enclosure	18V	16.66A	300W	90-264Vac		140.0 x 88.9 x 45.0 mm
MDS-300ADB24 AA	Open Frame with metal enclosure	24V	12.5A	300W	90-264Vac		140.0 x 88.9 x 45.0 mm
MDS-300ADB48 AA	Open Frame with metal enclosure	48V	6.25A	300W	90-264Vac		140.0 x 88.9 x 45.0 mm
MDS-300APB12 AA	Open Frame	12V	25A	300W	90-264Vac		127.0 x 76.2 x 35.6 mm
MDS-300APB18 AA	Open Frame	18V	16.66A	300W	90-264Vac		127.0 x 76.2 x 35.6 mm
MDS-300APB24 AA	Open Frame	24V	12.5A	300W	90-264Vac		127.0 x 76.2 x 35.6 mm
MDS-300APB48 AA	Open Frame	48V	6.25A	300W	90-264Vac		127.0 x 76.2 x 35.6 mm
MDS-350AD701	Open Frame with metal enclosure	3.3V, 5V, 5Vsb, +12V1, +12V2, -12V, -5V	8A, 9A, 1.25A, 8A, 8A, 0.25A, 0.1A	350W	90-264Vac		194.0 x 100.0 x 40.5 mm
MDS-400ADB12 AA	Open Frame with metal enclosure	12V	33.33A	400W	90-264Vac		140.0 x 88.9 x 44.4 mm
MDS-400ADB24 AA	Open Frame with metal enclosure	24V	16.67A	400W	90-264Vac		140.0 x 88.9 x 44.4 mm
MDS-400APB12 AA	Open Frame	12V	33.33A	400W	90-264Vac		127.0 x 76.2 x 35.6 mm
MDS-400APB24 AA	Open Frame	24V	16.67A	400W	90-264Vac		127.0 x 76.2 x 35.6 mm
MDS-400AUS19 B	Open Frame with U Frame	19V	21.1A	400W	90-264Vac		198.0 x 97.0 x 41.5 mm
MDS-400AUS24 B	Open Frame with U Frame	24V	16.67A	400W	90-264Vac		198.0 x 97.0 x 41.5 mm

Learn More

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