Medical standard certified products

For most medical equipments, customized power supplies are adopted or isolated transformers are used before switching power supply to invite extremely higher cost leading to medical equipments with high cost in total. This time, we would like to introduce our products featuring medical standard-acquired power supplies for UL, CSA, and IEC60601.

What is Medical Standards Management Board?

●**Standard which intend to medical electrical system**
Requirements about electric systems used in clinical practice are contained. Also contained is technical requirement which exceed general information processing system about basic requirement of safety such as electrification, insulation.

●**International Standard**
Based on IEC60601-1, there are various specifications.

Classification		IEC specification NO.(Establishment date)	IEC specification NO.(Establishment date)
Safety	Basic Standard	IEC 60601-1(1988)	-Medical electrical equipment: general requirement of safety ⇔JIS T 0601-1(1999)
		IEC 60601-1(1993)	
		IEC 60601-1(1995)	
		IEC 60601-1-1(1992)	- Safety requirement of medical electrical system ⇔JIS T 0601-1-1(1999)
		IEC 60601-1-1(1995)	
		IEC 60601-1-2(1993)	- Electromagnetic compatibility (EMC) - requirement and test
		IEC 60601-1-3(1994)	- General requirement about radiation protection
		IEC 60601-1-4(1996)	- Medical electrical system for programming - safety
		IEC 60601-1-5(200X)	- Image quality and dose of Diagnostic X-ray apparatus
	Particular Standard	IEC 60601-2-28(1993)	- X-ray source assembly - safety
		IEC 60601-2-32(1994)	- Related equipment(devices) - safety
		IEC 60601-2-45/Ed.1(1998) →IEC60601-2-45/Ed.2(2001) →IEC60601-2-45/Ed.3(200X)	- Breast X-ray apparatus and breast filming stereotactic equipment ⇔JIS Z 4751-2-45(2001)
Quality Management	Basic Standard	IEC 61223-1(1993)	- Evaluation and routine determination of quality maintenance for Medical picture category: general rule ⇔JIS Z 4752-1(2001)
	Particular Standard	IEC 61223-2-10(1999)	- Invariance test for breast X-ray apparatus
		IEC 61223-3-2(1996) →IEC61223-3-2/Ed.2(200X)	- Acceptance for breast X-ray apparatus

What's different from present power supply specification?

Medical Standards (IEC60601-1) will be hard to comply than Information equipment Standards (IEC60950-1). Designing requirements are shown below.

- Fuse is without a tip
- Leakage current: 0.3mA or less necessary at AC264V, 60Hz (patient-care system - class I)
- Dielectric strength: 4kV (between primary and secondary)
- Insulating distance (approx. 1.5 times of IEC60950-1 standard)

Four fields of the standard

●**Medical system are one of the international fields, and are classified into 4 different fields considering the effects on human body.**

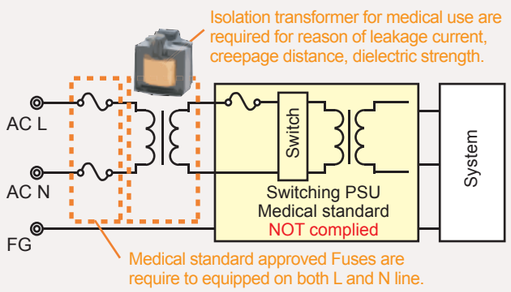
For production and distribution of relatively low risk (class II) system and external diagnostic medicines, private third party certification authority began to certify on behalf of the country. Below is the comparison of classification on acceptance & necessity by the country and certification division of revised law.

mNSP/mPCSA series and mGPSA series matches class I, II.
Please consult about matching systems for class III, IV.

International division	Medical equipment division based on risk	Past	After constriction 2005
Class I	Effects on human body in case of failure is considered very low. (Ex. extrasomatic diagnostic instrument, X-ray film)	Need no certification	Self-certification
Class II	Effects on human body in case of failure is considered lower. (Ex. MRI, electronic blood pressure, digestive catheter, ultrasonograph)	Government certification	Certificarion by third party
Class III	Effects on human body in case of failure is considered higher. (Ex. dialyzer, artificial ventilator)	Government certification	Government certification
Class IV	Effects on human body in case of failure is considered loss of life. (Ex. pace maker, artificial heart valve)		

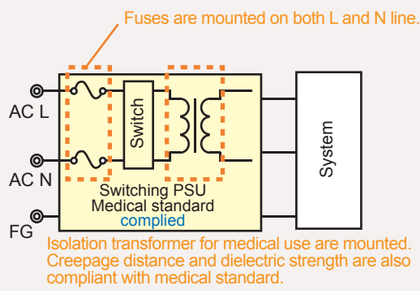
Applying standards for power supply installed system

Power supply not complied



When power supply does not comply with the standards, customers are required to prepare for input fuses and insulating transformer etc. Because fuses and transformer will be installed separately, system will be large and expensive.

Power supply complied



These series are all done to be double and reinforced insulation. That is why we are able to satisfy this requirement.
You will not need to prepare for extra fuses or transformer. Also, it is compact and inexpensive rather than using power supplies those are not complying with the standards.

ATTN:
Please be careful with specifications/cautions for competitors' medical power supply as shown below.

- Certified as basic insulation, extra insulation circuit is required outside the power supply.
- Insulating material must be used in system chassis when it is used near the patient or other than that.
- When applying for medical systems standards, safety standards certified fuses or breaker needs to be connected to input terminal.
- Conducted emissions are FCC-A, VCC-A, ripple will be 1.5 times of standard.

mNSP3-450P-S20 series

Continuous: 301W
Peak: 450.5W

-H7V	With RS232C signal unit
-H6V	With USB signal unit

Medical standard IEC60601-1 certified, nonstop ATX power supply

- Battery back up function at blackout (with dedicated battery pack)
- Double and reinforced insulation type, so that Medical standard approved commercial insulating transformer is unnecessary.
- Fuses are mounted on both L/N line
- Leakage current: 0.1mA typ (At AC 100V input)
- Equipped with thermal-sensing speed control fan, Silent.

Output connectors (Optional): Main (20Pin) | Main (24Pin) | AT | 12V (4Pin) | 12V (8Pin) | PCI-E (6Pin) | AUX | ×5 | S-ATA ×4 | ×1

Safety standard	UL	CSA	EN	CE	CCC
Dimensions	W × H × D (mm) = 150 × 86 × 140 PS/2 size				

Output voltage	+3.3V	+5V	+12V	-12V	+5VSB
Max current/ Max power (Continuous)	20A	22A	22A	0.5A	2A
	Total 160W				
	Total 285W				
	Total 301W				
Peak current/ Peak power (Within 5s)	30A	33A	30A	0.5A	2.5A
	Total 200W				
	Total 432W				
	Total 450.5W				
Min current	0A	0A	0A	0A	0A

mPCSA-500P-X2S

Continuous: 301W
Peak: 500.5W

Medical standard IEC60601-1 certified, ATX power supply

- Double and reinforced insulation type, so that Medical standard approved commercial insulating transformer is unnecessary.
- Fuses are mounted on both L/N line
- Leakage current: 0.1mA typ (At AC 100V input)
- Equipped with thermal-sensing speed control fan, Silent.

Output connectors (Optional): Main (20Pin) | Main (24Pin) | AT | 12V (4Pin) | 12V (8Pin) | PCI-E (6Pin) | AUX | ×5 | S-ATA ×4 | ×1

Safety standard	UL	CSA	EN	CE	CCC
Dimensions	W × H × D (mm) = 150 × 86 × 140 PS/2 size				

Output voltage	+3.3V	+5V	+12V	-12V	+5VSB
Max current/ Max power (Continuous)	20A	22A	22A	0.5A	2A
	Total 160W				
	Total 285W				
	Total 301W				
Peak current/ Peak power (Within 5s)	30A	33A	30A	0.5A	2.5A
	Total 200W				
	Total 482W				
	Total 500.5W				
Min current	0A	0A	0A	0A	0A

mPCSL-210-X2S

Continuous: 210.8W

Medical standard IEC60601-1 certified, slim body ATX power supply

- Slim body with 48mm thick and 90mm width
- Leakage current: 0.17mA typ (At AC 100V input)
- Equipped with thermal-sensing speed control fan, Silent.
- Life expectancy 7 years at ambient temperature 40 deg C and max output (electrolytic capacitor: about 13 years, FAN: about 7 years)
- Conducted emission class B

Output connectors: Main (20Pin) | Main (24Pin) | AT | 12V (4Pin) | 12V (8Pin) | PCI-E (6Pin) | AUX | ×2 | S-ATA ×2 | ×1

Safety standard	UL	CSA	EN	CE	CCC
Dimensions	W × H × D (mm) = 90 × 48 × 273				

Output voltage	+3.3V	+5V	+12V	-12V	+5VSB
Max current/ Max power (Continuous)	10A	10A	12A	0.3A	1.5A
	Total 83W				
	Total 199.7W				
	Total 210.8W				
Min current	0A	0A	0.8A	0A	0A

mGPSA-360/750 series

mGPSA-360 series: Continuous: 360W, Peak: 600W
mGPSA-750 series: Continuous: 720W, Peak: 1920W

Medical standard IEC60601-1 certified, single output power supply with high capacity and high peak power

- Mountable for system rack, convenient size 1U/2U/3U
- +12VSB output equipped
- Blackout detection signal equipped. For 24V output type, battery backup operation during blackout is possible with the battery pack connected.
- Conducted emission class B
- Equipped with thermal-sensing speed control fan, Silent.

*mGPSA-750series: during preparation

Safety standard	UL	CSA	EN	CE	CCC

Dimensions		
	mGPSA-360	W × H × D (mm) = 41 × 128 × 230
	mGPSA-750	W × H × D (mm) = 82 × 128 × 235

	Output voltage		+12V	+24V	+12VSB
Model	mGPSA-360-		12-TP	24-TP	Common
mGPSA-360	Max current/power(Continuous)		30A 360W	15A 360W	0.3A 3.6W
	Peak current/power (Within 5s)	AC100V	40A 480W	20.8A 499.2W	---
		AC200V	40A 480W	25A 600W	---
Model	mGPSA-750-		12-TP	24P-TP	Common
mGPSA-750	Max current/power(Continuous)		56A 672W	30A 720W	0.3A 3.6W
	Peak current/power (Within 5s)	AC100V	70A 840W	40A 960W	---
		AC200V	80A 960W	53.3A 1920W	---