Revolution changing the medical world

Special topics about medical power supply

For PC system of colorful diagnostic imaging, speedy dynamic picture image, and ATX power supply which provides DC power to speedy& high capacity video card using more and more evolving GPU, 800W-1000W class products are required. Also, other medical equipment has DC power source.

This time, Nipron has developed various kinds of medical standards complied power supply, and we feature requirements and specifications that are specially needed as medical electric systems.

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	IEC60601-1 (1988) IEC60601-1 IEC60601-1	・Medical electrical equipment: general requirement of safety ⇔JIS T 0601-1(1999)
		IEC60601-1-1 (1992)	・Safety requirement of medical electrical system ⇔JIS T 0601-1-1(1999)
		IEC60601-1-1	
		IEC60601-1-2 (1993)	・Electromagnetic compatibility (EMC) ― requirement and test
		IEC60601-1-3 (1994)	・General requirement about radiation protection
		IEC60601-1-4 (1996)	・Medical electrical system for programming ― safety
		IEC60601-1-5 (200X)	・Image quality and dose of Diagnostic X-ray apparatus
	Particular Standard	IEC60601-2-28 (1993)	・X-ray source assembly ― safety
		IEC60601-2-32 (1994)	・Related equipment(devices) safety
		IEC60601-2-45/ 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	IEC61223-1 (1993)	・Evaluation and routine determination of quality maintenance for Medical picture category: general rule ⇔JIS Z 4751-2-1(2001)
	Particular Standard	IEC61223-2-10 (1999)	・Invariance test for breast X-ray apparatus
		IEC61223-3-2 (1996) →IEC61223-3-2/Ed. 2(200X)	・Acceptance for breast X-ray apparatus

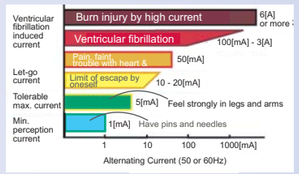
What's different from present power supply specification?

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)

Macro shock

Graph is the reaction of human body when alternating current (50 or 60[Hz]) flow in through surface of skin.
These show the current value when the current flowed 1 sec. in adult male's body.
2/3 of its value is said for female, and 1/2 for children.
It starts feeling pins-and-needles sensations at approx.1 [mA]=(1/1000[A]) and it is called minimum perception current. When the current is large, it flows not only through the surface but also inner part of the body, which causes various symptoms.
If a certain level of the current flowed through the heart, muscle of the heart starts excitation contraction and stops pumping out the blood. This kind of heart condition is called "ventricular fibrillation".
It is also said that ventricular fibrillation will happen when the amount of the current flowed through the surface of the skin goes up to 100[mA] or more.



Micro shock

It is said that human body can cause "ventricular fibrillation" with aprox.100[uA](=0.1[mA]) when the current directly flowed into the body especially near heart.
This current value is called "micro shock ventricular fibrillation induced current".
Therefore, medical system that its electrode is used near heart is regulated to reduce especially "the leakage current" by JIS standards.

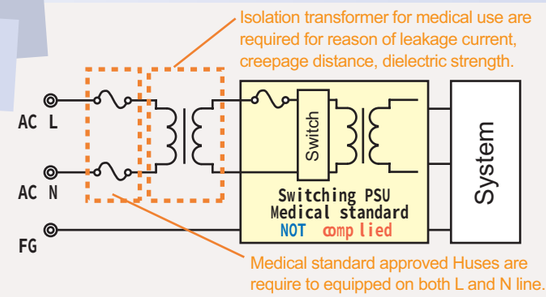
Reference website: "Toranomon-byouin"

Advantages of medical standards complied power supply

● Applying standards for power supply installed system

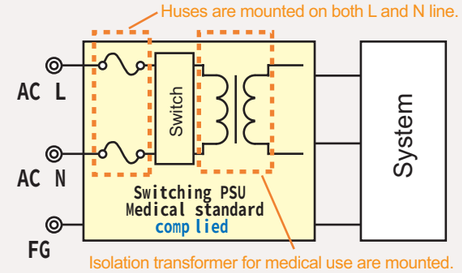
・Power supply NOT complied

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.



・mNSP3/mPCSA, mGPSA series (complied)

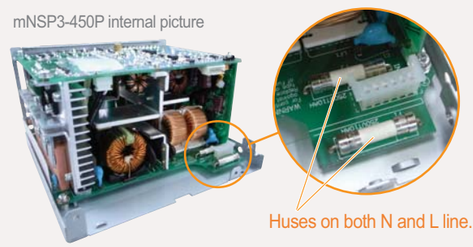
These series are all done to be double and reinforced insulation. That is why we are able to satisfy this requirement.
You will not need to prepare for extra fuses or transformer. Also, it is compact and inexpensive rather than using power supplies those are not complying whith the standards.



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 internal picture



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.

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	Certification 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)		

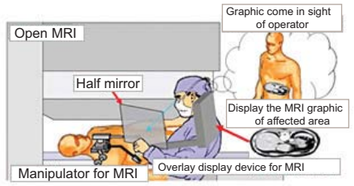
mNSP/mPCSA series and mGPSA series matches class I, II.
Please consult about matching systems for class III, IV.

Transition of Medical Standards

- At present, IEC60601-1 3rd is issued.
  From this standard, risk management is required.
  Because it was not enough to manage the quality of medical systems only by ISO9001,
  ISO14971 is issued and we will have to satisfy the requirements based on it.
  (Certification authority such as UL etc. are not ready to deal with it. It will be applied some time later.)
- Medical Standards are hard to complied, contains various kinds, and is keep changing many times. It is risky for us NIPRON, but we will investigate and handle it with full efforts.

Realizing minimally invasive surgery by image information

Precision surgery
by image-guidance



Reference website: Graduate school of information science and technology, the University of Tokyo

(image)

Highly-reliable/highly-functional medical computers Had been waited eagerly for

Medical Standard "UL, CSA, IEC60601-1" Complied PSU

mNSP3/mPCSA Series

Backup operation available

Nonstop power supply
mNSP3-450P-S20-H1V

Intelligence battery pack "Mi-Pack II" connectable. Dectects battery life span. Schedule function.

Continuous max. 300W | Peak 450W

Without Backup operation

mPCSA-500P-X2S

Continuous max. 300W | Peak 500W

Input/output specification

[ ]:mPCSA-500P-X2S

Output voltage	+3.3V	+5V	+12V	-12V	+5VSB
Max. current/ power (continuous)	20A	22A	22A	0.5.A	2A
	Total 285 W				
	Total 301 W				
Peak current/ power (within 5s)	30A	33A	30A	0.5A	2.5A
	Total 432 W [482 W]				
	Total 450.5 W [500.5 W]				
Min. current	0A	0A	0A	0A	0A
Input voltage	AC85~264V				

▪ Low leakage current specification

Satisfy 0.3mA or less leakage current (AC264V input) to comply Medical standard IEC60601-1 and class I (3P input plug with earthing).

Load condition: Rated

Leakage current measured value (example)

Rated input V	mNSP3-450P-S20-H1V	mPCSA-500P-X2S
AC100V	0.09 mA	0.09 mA
AC264V	0.25 mA	0.25 mA

▪ Conducted emission class B compliant

Generally, conducted emission is tend to be sacrificed to specify low leakage current (generate more noise), but we satisfy conducted emission class B for low leakage current spec.
(installed in computer chassis, measured at load factor 70%)

Because it is double and reinforced insulation type,
Medical standards matched commercial insulating transformer is unnecessary (low cost, downsizing)

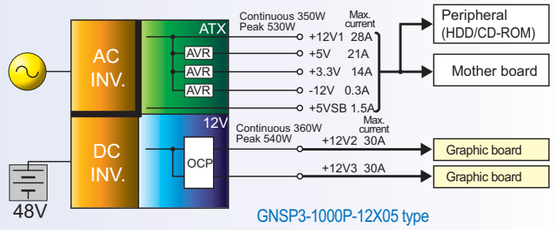
New Product Development News

We are under development for 1000W class nonstop type ATX power supply towards release in April 2010.
Design to comply with medical standard IEC 60601-1, energy saving 80 Plus compliant.

<ATTN> For customers who needs
1000W output ATX PSU (Medical Standard incompliant)

As great capacity ATX power supply

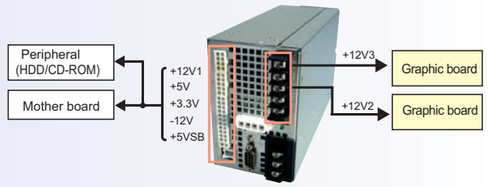
There is a growing need for 1000W output class ATX power supply for the graphic board (VGA) which capacity is becoming greater and greater.
As a power supply to satisfy these needs, GNSP2-1000P-12X05 perfectly suits the field that handles with image processing apparatus including systems for medical purpose.



GNSP3-1000P-12X05 type

Output specification

	+3.3V	+5V	+12V1	-12V	+5VSB	+12V2	+12V3
Max. output current	14A	21A	28A	0.3A	1.5A	30A	30A
Max. output capacity	348.1W					360W	
	708.1W						
Peak output current	20A	30A	40A	0.3A	1.5A	45A	45A
Peak output capacity	527.5W					540W	
	1067.5W						



Front PC power supply for medical system

High cost, heavy weight commercial insulating transformer will be UNNECESSARY.

mGPSA-360/750 Series

Battery pack

mGPSA-360 Series mGPSA-750 Series

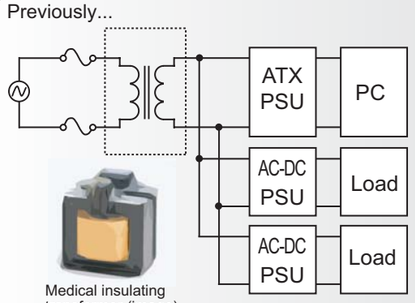
Medical Standard (UL,CSA,IEC60601-1)
mGPSA-360 series: compliant scheduled in summer 2009
mGPSA-750 series: during preparation

● Low leakage current
0.3mA or less (at AC 264V input)

● Input huses
mounted on both L (live) and N (neutral) line

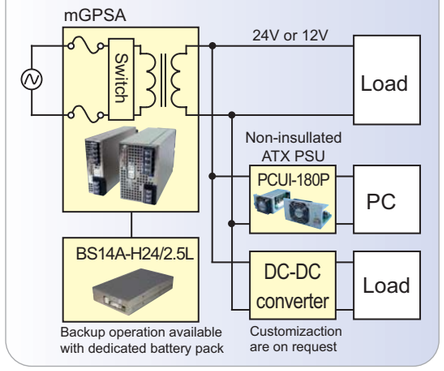
● Double and reinforced insulation
When applying for medical standard for your equipment, you will not need to connect fuse and breaker, or set up supplementary insulation outside the power supply.

Previously...



Medical insulating transformer (image)

From now on...



Backup operation available with dedicated battery pack

Customization are on request

Line-up and Input/output specification

Series	Output voltage		+12V	+24V
mPSA-360 series	Rated output current		30A	15A
	Peak output current	AC100V	40A	20.8A
		AC200V	40A	25A
mPSA-750 series	Rated output current		56A	30A
	Peak output current	AC100V	70A	37.5A
		AC200V	80A	50A
Input voltage	AC85~264V			

Features

- **Conducted emission class B compliant**
  Low leakage current spec, and satisfies conducted emission class B.
- **Convenient size for loading system rack**
  Hight 3U, width 1U/2U sized rack embedded size.
- **12V standby power supply output**
  0.3A output is possible as auxiliary power (stanby output).
- **Blackout detection signal available**
  24V output type is available backup operation when connected to dedicated battery pack.

Applicable examples

Ultrasonograph
ePCSA-650P-E2S
eNSP-300P-S20-11S

Operation microscope
mGPSA-360-24-TP
BS14A-H24/2.5L

PC for MRI/CT
ePCSA-500P-X2S

Immunoanalytical system
mGPSA-750-12-TP

Ultrasonograph for overseas
mGPSA-360-12-TP

PC for medical analyzer
PCTF-220P-X2S

Security camera for tensive unit
mPCSA-500P-X2S

Medical DVR
PCTF-220P-X2S

(images)

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