

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST  
CERTIFICATES FOR ELECTRICAL EQUIPMENT  
(IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE  
CERTIFICATS D'ESSAIS DES EQUIPEMENTS  
ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE  
CERTIFICAT D'ESSAI OC

Product  
Produit

Switching Power Supply

Name and address of the applicant  
Nom et adresse du demandeur

Zippy Technology Corp.  
10F, No. 50, Ming Chyuan Rd.  
23120 Shin Tien City, Taipei Hsien, Taiwan

Name and address of the manufacturer  
Nom et adresse du fabricant

Zippy Technology Corp.  
10F, No. 50, Ming Chyuan Rd.  
23120 Shin Tien City, Taipei Hsien, Taiwan

Name and address of the factory  
Nom et adresse de l'usine

Zippy Technology Corp.  
2F, No. 123, Lane 235, Pao-Chiao Rd.  
23120 Shin Tien City, Taipei Hsien, Taiwan

Note: When more than one factory, please report on page 2  
Note: Lorsque il y a plus d'une usine, veuillez utiliser la 2<sup>ème</sup> page

Ratings and principal characteristics  
Valeurs nominales et caractéristiques principales

AC 100-240V; 47-63Hz; 8-4A (for model MHG2-6400P) or  
7-3.5A (for models MHG2-6350P and MHG2-6300P); Class I;  
for output ratings refer to test report page 6

Trade mark (if any)  
Marque de fabrique (si elle existe)

EMACS

Model/type Ref.  
Ref. de type

MHG2-6400P; MHG2-6350P; MHG2-6300P

Additional information (if necessary may also be  
reported on page 2)  
Les informations complémentaires (si nécessaire,  
peuvent être indiquées sur la 2<sup>ème</sup> page)

Models differ in model name, input and output ratings, DC  
fan, storage capacitor (C42) and choke (T2).

A sample of the product was tested and found  
to be in conformity with  
Un échantillon de ce produit a été essayé et a été  
considéré conforme à la

IEC 60601-1:1988+A1+A2  
for national deviations see test report

As shown in the Test Report Ref. No. which forms part  
of this Certificate  
Comme indiqué dans le Rapport d'essais numéro de  
référence qui constitue une partie de ce Certificat

11011453 001

This CB Test Certificate is issued by the National Certification Body  
Ce Certificat d'essai OC est établi par l'Organisme National de Certification



TÜVRheinland®


TÜV Rheinland Product Safety GmbH  
Am Grauen Stein · D-51105 Köln  
Phone + 49 221 806-1400  
Fax + 49 221 806-2095  
Mail: cert-validity@de.tuv.com  
Web: www.tuv.com



Date: 17.12.2007

Signature:

Dipl.-Ing

TEST REPORT	
IEC 601 -1	
Medical electrical equipment	
Part 1: General requirements for safety	
Report reference No. ....	11011453 001
Compiled by (+ signature) .....	<i>Atan Huang</i>
Reviewed by (+ signature) .....	<i>Angel Dela Cruz</i>
Approved by (+ signature) .....	N/A
Date of issue .....	Dec. 13, 2007
Testing laboratory .....	TÜV Rheinland Taiwan, Taichung Laboratory
Address .....	10F, No. 219, Min-Chuan Road, Taichung 403, Taiwan
Testing location .....	TÜV Rheinland Taiwan, Taichung Laboratory
Applicant .....	Zippy Technology Corp.
Address .....	10F., No. 50, Min Chyuan Rd., Shin Tien City, Taipei 231 Taiwan
Standard .....	IEC 60601-1: 1988 + A1:1991 + A2:1995 EN 60601-1 : 1990 + A1:1993 + A2:1995 +A13:1996
Test Report Form No. ....	I601-1_C/97-04
TRF Originator .....	Underwriters Laboratories Inc.
Master TRF .....	dated 97-04
Copyright blank test report .....	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure .....	CB Scheme
Procedure deviation .....	N/A
Non-standard test method .....	N/A
Type of test object .....	Switching Power Supply
Trademark .....	
Model/type reference .....	MHG2-6400P, MHG2-6350P, MHG2-6300P
Manufacturer .....	Same as applicant
Address .....	Same as applicant
Rating .....	Input: AC 100-240V, 47-63Hz, 8-4A for model MHG2-6400P, 7-3.5A for models MHG2-6350P and MHG2-6300P  Output: Refer to page 6

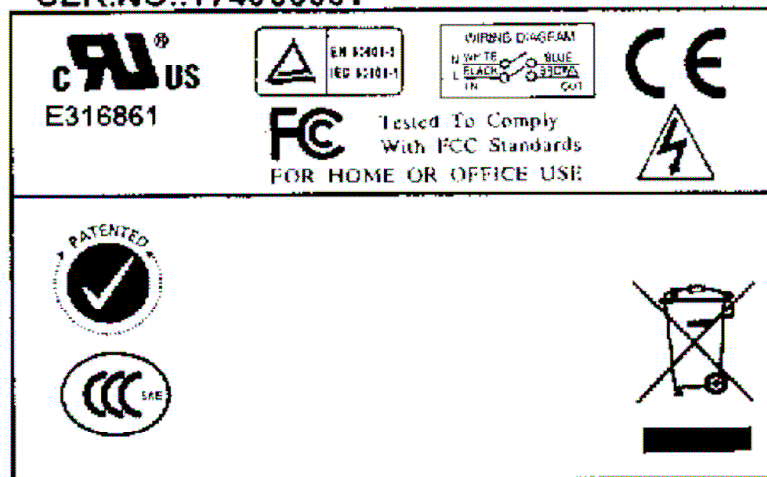
Copy of the marking plate:



**MODEL: MHG2-6400P**  
**AC INPUT: 100-240V 47-63Hz 8-4A**  
**FUSE RATING : 8A/250V**  
**DC OUTPUT: 400W (MAX)**  
**+5V 35A +12V 30A +3.3V 0-28A**  
**-5V 0-0.5A -12V 0-0.8A +5VSB 0-2A**  
**+5V AND +3.3V TOTAL MAX:45A**

**CAUTION:** Do not remove this power supply cover under any circumstances

**SER.NO.:T74000001**



**MADE IN TAIWAN 台灣製造 www.zippy.com.tw MC**

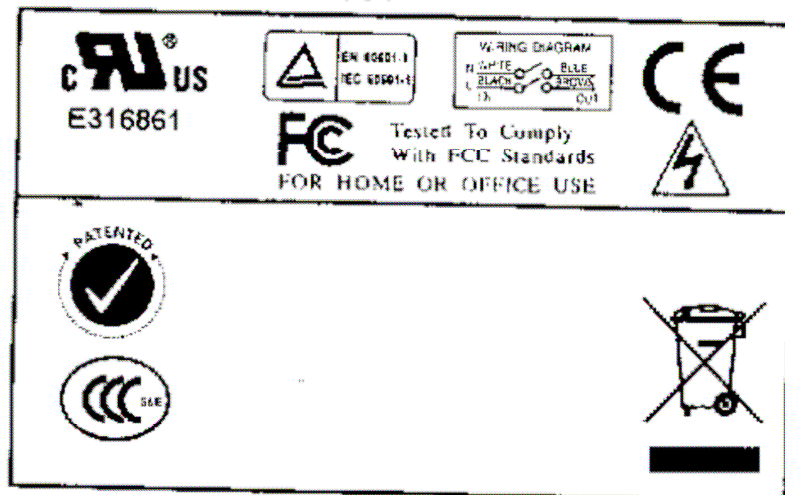
Copy of the marking plate:



**MODEL: MHG2-6350P**  
**AC INPUT: 100-240V 47-63Hz 7-3.5A**  
**FUSE RATING : 8A/250V**  
**DC OUTPUT: 350W (MAX)**  
**+5V 35A +12V 26A +3.3V 0-28A**  
**-5V 0-0.5A -12V 0-0.8A +5VSB 0-2A**  
**+5V AND +3.3V TOTAL MAX:45A**

**CAUTION:** Do not remove this power supply cover under any circumstances.

**SER.NO.: T73500001**



MADE IN TAIWAN 台湾制造 [www.zippy.com.tw](http://www.zippy.com.tw) MC



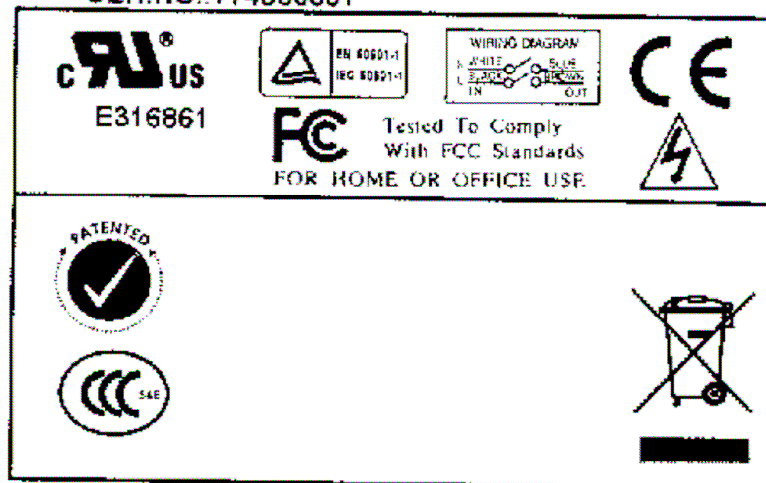
Copy of the marking plate:



**MODEL: MHG2-6300P**  
**AC INPUT: 100-240V 47-63Hz 7-3.5A**  
**FUSE RATING : 8A/250V**  
**DC OUTPUT: 300W (MAX)**  
**+5V 35A +12V 22A +3.3V 0-28A**  
**-5V 0-0.5A -12V 0-0.8A +5VSB 0-2A**  
**+5V AND +3.3V TOTAL MAX:45A**

**CAUTION:** Do not remove this power supply cover under any circumstances

SER.NO.: T74300001



MADE IN TAIWAN 台灣製造 [www.zippy.com.tw](http://www.zippy.com.tw) MC

## GENERAL INFORMATION

Test item particulars (see also clause 5):

Classification of installation and use ..... : Class I and building-in type

Supply connection ..... : AC inlet

Accessories and detachable parts included in the evaluation : None

Options included ..... : None

Possible test case verdicts:

- test case does not apply to the test object .....:N/A
- test object does meet the requirement.....:Pass
- test object does not meet the requirement.....:Fail

Abbreviations used in the report:

- |  |                                       |
|--|---------------------------------------|
| - normal condition .....:N.C.                                  | - single fault condition .....:S.F.C. |
| - operational insulation .....:OP                              | - basic insulation .....:BI           |
| - basic insulation between parts of opposite polarity.....:BOP | - supplementary insulation.....:SI    |
| - double insulation .....:DI                                   | - reinforced insulation .....:RI      |

General remarks:

**"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IEC 60335-1-2".**

"(see Attachment #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

The tests results presented in this report relate only to the object tested.

This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review.

Summary of compliance with National Differences (for explanation of codes see below):

AT, AU, BE, BR, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IE, IL, IN, IT, KE, KR, NL, NO, PL, PT, RS, RU, SE, SG, SI, SK, TR, UA, US

AT = Austria, AU = Australia, BE = Belgium, BR = Brazil, CA = Canada, CH = Switzerland, CZ = The Czech Republic, DE = Germany, DK = Denmark, FI = Finland, FR = France, GB = United Kingdom, GR = Greece, HU = Hungary, IE = Ireland, IL = Israel, IN = India, IT = Italy, KE = Kenya, KR = Korea, NL = The Netherlands, NO = Norway, PL = Poland, PT = Portugal, RS = Serbia, RU = Russian Federation, SG = Singapore, SE = Sweden, SI = Slovenia, SK = Slovakia, TR = Turkey, UA = Ukraine, US = United States

Factory:

Zippy Technology Corp.

2F, No. 123, Lane 235, Pao-Chiao Rd., Shin Tien City, Taipei Hsien 231 Taiwan

**General product information and considerations:**

- The equipment is a Switching Power Supply intended for supplying medical electrical apparatus.
- The all models are similar except for:
  1. Model name
  2. Rated input current rating and output ratings, for detail see pages 1 and 6.
  3. Components: DC fan, storage capacitor (C42) and choke (T2), for detail see appended table 56.1.
- The equipment is full voltage-range design.
- Insulation between mains part and secondary: Double or reinforced insulation;  
Insulation between mains part and protective earth: Basic insulation;  
Insulation between secondary and protective earth: Functional insulation.

**Summary of testing:**

- Pre-production samples without serial numbers and the mass of equipment is 1.98kg.
- Compliance with the requirements of IEC/EN 60601-1-2 (EMC) shall be evaluated for the final system configuration.
- The equipment does not have circuits for direct connection to the patient and is not intended for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide
- Unless otherwise specified, the tests were performed on model MHG2-6400P to represent other similar model.
- Specified maximum ambient temperature for operation is +50°C.
- Model MHG2-6400P load conditions:
  1. Condition A: DC +5V/ 17A, +12V/ 16.71A, +3.3V/ 28A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
  2. Condition B: DC +5V/ 35A, +12V/ 14.16A, +3.3V/ 10A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
  3. Condition C: DC +5V/ 0A, +12V/ 30A, +3.3V/ 5.42A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
- Model MHG2-6350P load conditions:
  1. Condition A: DC +5V/ 17A, +12V/ 12.54A, +3.3V/ 28A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
  2. Condition B: DC +5V/ 35A, +12V/ 9.99A, +3.3V/ 10A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
  3. Condition C: DC +5V/ 0A, +12V/ 26A, +3.3V/ 4.82A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
- Model MHG2-6300P load conditions;
  1. Condition A: DC +5V/ 17A, +12V/ 8.38A, +3.3V/ 28A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
  2. Condition B: DC +5V/ 35A, +12V/ 5.83A, +3.3V/ 10A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A
  3. Condition C: DC +5V/ 0A, +12V/ 22A, +3.3V/ 4.21A, -5V/ 0.5A, -12V/ 0.8A, +5VSB/ 2A

DC output ratings								
Model	Output current (A)							Output power (W)
	+5V	+12V	+3.3V	-5V	-12V	+5VSB	Combined +3.3V & +5V	Total Output
MHG2-6400P	35	30	0-28	0-0.5	0-0.8	0-2.0	45	400
MHG2-6350P	35	26	0-28	0-0.5	0-0.8	0-2.0	45	350
MHG2-6300P	35	22	0-28	0-0.5	0-0.8	0-2.0	45	300

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

<b>3</b>	<b>GENERAL REQUIREMENTS</b>		Pass
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained		N/A

<b>5</b>	<b>CLASSIFICATION</b>		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		Pass
	Class II equipment	Connection to protective earth is required.	N/A
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		Pass
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified – no applied parts	No applied parts.	Pass
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1).....:	Equipment for building-in.	N/A
5.4	Methods of sterilization or disinfection		N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Suitable warning is provided in the installation instructions.	Pass
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	- continuous operation	Equipment intended for continuous operation.	Pass
	- short-time operation, specified operation; period :		N/A
	- intermittent operation, specified operation; rest period .....		N/A
	- continuous operation with short-time, stated		N/A





IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	permissible loading time .....		
	- continuous operation with intermittent, stated permissible loading/rest time .....		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

### INSULATION DIAGRAM

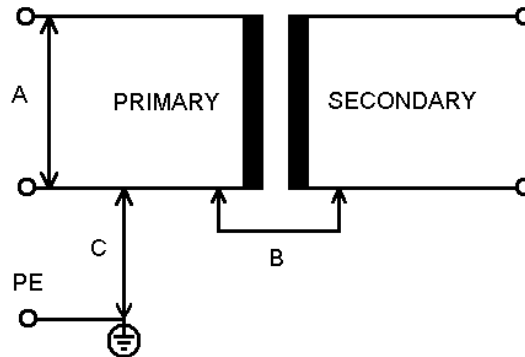


Table: to insulation diagram							Pass
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
For main board							
Primary to primary part (BI)							
A	A-f	250	3.0	1.6	5.6	5.6	Under fuse F1
Primary to secondary or accessible part (RI/DI)							
B	A-a2	250	8.0	5.0	12.5	6.8	Primary component C2 to secondary component C37 <sup>1.</sup>
B	A-a2	278	8.8	7.0	14.3	8.5	Primary trace C2 to secondary trace R47 <sup>1.</sup>
B	A-a2	250	8.0	5.0	10.2	8.5	Primary trace C3 to secondary trace U6 <sup>1.</sup>
B	A-a2	264	8.4	7.0	8.4	8.4	Primary trace LF2 to secondary trace C25 <sup>1.</sup>
B	A-a2	264	8.4	7.0	8.7	8.7	Primary trace LF2 to secondary trace R48
B	A-a2	250	8.0	5.0	8.1	5.1	Primary trace CY3 to secondary trace U2 <sup>2.</sup>
B	A-a2	250	8.0	5.0	8.0	5.1	Primary trace LF1 to secondary trace U2 <sup>2.</sup>

IEC 601+ Am. 1 & 2							
Clause	Requirement + Test			Result - Remark			Verdict
B	A-a2	250	8.0	5.0	8.0	5.0	Primary trace F1 to secondary trace U2 <sup>3.</sup>
B	A-a2	250	8.0	5.0	10.2	8.4	Primary trace R72 to secondary trace U6 <sup>1.</sup>
B	A-a2	250	8.0	5.0	11.2	6.2	Primary trace to secondary trace under U6 <sup>1.</sup>
B	A-a2	250	8.0	5.0	8.1	8.1	Primary trace to secondary trace under U7, U8
B	A-a2	287	9.0	7.0	11.3	9.3	Between transformer T4 pins <sup>4.</sup>
B	A-a2	250	8.0	5.0	13.8	9.8	Primary trace C36 to secondary trace R57 (under T3) <sup>5.</sup>
Primary to PE part (BI)							
C	A-a1	250	4.0	2.5	4.2	3.5	Primary component C1 to PE metal chassis
C	A-a1	250	4.0	2.5	9.6	7.2	Primary component H1 to PE metal chassis
C	A-a1	250	4.0	2.5	5.2	5.2	Primary trace U8 to metal chassis <sup>8.</sup>
C	A-a1	250	4.0	2.5	4.0	4.0	Primary trace to PE trace under CY3
C	A-a1	250	4.0	2.5	4.1	4.1	Primary trace to PE trace under CY4
C	A-a1	250	4.0	2.5	4.6	4.6	Primary trace to PE trace under CY5
C	A-a1	250	4.0	2.5	4.0	4.0	Primary trace LF1 to PE trace
For EMI board							
Primary to primary part (BI)							
A	A-f	250	3.0	1.6	5.5	5.5	L to N in front of fuse FN
A	A-f	250	3.0	1.6	11.5	11.5	Under fuse FN
Primary to secondary or accessible part (RI/DI)							
B	A-a2	250	8.0	5.0	12.3	8.6	Primary component CX2 to secondary component H4
Primary to PE part (BI)							
C	A-a1	250	4.0	2.5	4.2	2.7	Primary trace CY2 to PE

IEC 601+ Am. 1 & 2							
Clause	Requirement + Test				Result - Remark		Verdict
							metal chassis
C	A-a1	250	4.0	2.5	4.0	3.6	Primary trace L to PE metal chassis
C	A-a1	250	4.0	2.5	4.8	4.8	Primary trace to PE trace under CY1, CY2
<p>Notes:</p> <ul style="list-style-type: none"> <li>- The following reference voltages (see table 7.1 for the load conditions) were considered relevant for the evaluation of the separation system. If not otherwise specified the reference voltage used for the calculation of the relevant separation was 250V.</li> <li>- Working voltage information: <ul style="list-style-type: none"> <li>• T3 and T4: see following description of transformer for detail.</li> <li>• Primary trace C2 to secondary trace R47: Up-p= 784V, Urms= 245V, Uref= 278V</li> <li>• Primary trace LF2 to secondary trace C25: Up-p= 744V, Urms= 246V, Uref= 264V</li> <li>• The maximum working voltages are measured at model MHG2-6400P with load condition A.</li> </ul> </li> </ul>							
<p>Supplementary information:</p> <ol style="list-style-type: none"> <li>1. There is a "L" shape slot between the components and add a mylar sheet through the slot. The slot size is 43.0 x 1.2mm, the mylar sheet size is 28.0 x 28.0mm.</li> <li>2. There is a slot between the components, the size is 26.0 x 1.2mm.</li> <li>3. There is a slot between the components, the size is 11.3 x 1.2mm.</li> <li>4. There is a slot under the T4, the size is 36.0 x 1.2mm.</li> <li>5. There is a slot under the T3, the size is 39.0 x 1.2mm.</li> <li>6. Glued component: all internal wires on PCB, R1, F1, LF1, LD1, LF2, C1, C25, U5, C37, C36, L8, R14, R16, C13, R17, D13, R68A, C37A, C26, C27, D30, D12, D12A, R36, D11, R100, C87, CY5 + R19.</li> <li>7. Tubed components: wires of DC fan, F1, FN,</li> <li>8. There is a "U" shape mylar sheet between PCB and metal chassis, the size is 145 x 82 x 110mm.</li> <li>9. Insulation definition: FI: functional insulation BI: basic insulation DI/RI: double/reinforced insulation SI: supplementary insulation</li> </ol>							
Transformer position..... : T3 Type ..... : Refer to appended table 56.1 Manufacturer..... : Refer to appended table 56.1							

IEC 601+ Am. 1 & 2				
Clause	Requirement + Test		Result - Remark	Verdict
Non-sinusoidal peak-peak working voltage .....: 1200V      Location (from – to): pins 8 – 1/2				
Sinusoidal r.m.s. working voltage .....: 387V      Location (from – to): pins 8 – 1/2				
Reference working voltage.....: 425V      Note 2 of table V considered				
Required creepage distance [mm]: 13.0 (RI)			Required air clearance [mm]: 9.0 (RI)	
Measured creepage distance:			Measured air clearance:	
A – a2	Inside [mm]	17.0 (primary to secondary)	Inside [mm]	17.0 (primary to secondary)
A – a2	Outside [mm]	13.2 (primary to secondary)	Outside [mm]	13.2 (primary to secondary)
A – b	Inside [mm]	9.0 (primary to core)	Inside [mm]	9.0 (primary to core)
A – b	Outside [mm]	9.0 (primary to core)	Outside [mm]	9.0 (primary to core)
A – c	Inside [mm]	9.0 (secondary to core)	Inside [mm]	9.0 (secondary to core)
A – c	Outside [mm]	9.0 (secondary to core)	Outside [mm]	9.0 (secondary to core)
BI – basic insulation; RI – reinforced insulation				
Construction details:				
<ul style="list-style-type: none"><li>- Concentric windings on ERL-35 size core.</li><li>- Triple insulated wires are used in primary windings N1, N6 and secondary winding N4.</li><li>- The primary windings N2, N5 are covered by two layers insulation tape and overlap 5.0mm min. (as BI) and with margin tape 4.0mm on both sides.</li><li>- The secondary winding N3 is covered by two layers insulation tape and overlap 8.0mm min.</li><li>- The core is considered as floating part.</li><li>- Outer winding is primary, three layers insulation tape around outer winding and three layers tape between primary and secondary windings.</li><li>- Winding ends additionally fixed with tape.</li><li>- One layer insulation tape covered all bottom core.</li></ul>				
Materials:				
<ul style="list-style-type: none"><li>- Bobbin: type FR-530 of Dupont, PET, 155°C, V-0</li><li>- Insulation tape: No. 92 of 3M, 155°C</li><li>- Margin tape: No. Super 20 of 3M, 155°C</li></ul>				
Primary pins: 12-11-10, 14-N2/N5			Secondary pins: 1/2-5, 6/7-3-4	



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

Transformer position..... : T4			
Type ..... : Refer to appended table 56.1			
Manufacturer..... : Refer to appended table 56.1			
Non-sinusoidal peak-peak working voltage ....: 810V		Location (from – to): pins 1-8	
Sinusoidal r.m.s. working voltage .....: 285V		Location (from – to): pins 2-8	
Reference working voltage.....: 287V		Note 2 of table V considered	
Required creepage distance [mm]: 9.0 (RI)		Required air clearance [mm]: 7.0 (RI)	
Measured creepage distance:		Measured air clearance:	
A – a2	Inside [mm] 13.6 (primary to secondary)	Inside [mm] 13.6 (primary to secondary)	
A – a2	Outside [mm] 12.4 (primary to secondary)	Outside [mm] 12.4 (primary to secondary)	
A – b	Inside [mm] 7.5 (primary to core)	Inside [mm] 7.5 (primary to core)	
A – b	Outside [mm] 6.2 (primary to core)	Outside [mm] 6.2 (primary to core)	
A – c	Inside [mm] -- (secondary to core, triple wire used)	Inside [mm] -- (secondary to core, triple wire used)	
A – c	Outside [mm] 6.2 (secondary to core)	Outside [mm] 6.2 (secondary to core)	
BI – basic insulation; RI – reinforced insulation			
Construction details:			
<ul style="list-style-type: none"><li>- Concentric windings on ERL-19 size core.</li><li>- Triple insulated wires are used in primary windings N1, N6, N7 and secondary windings N3, N4.</li><li>- The primary windings N2, N5 are covered by two layers insulation tape and overlap 4.0mm min. and with margin tape 3.5mm on top side and 5.0mm on pin side.</li><li>- The core is considered as floating part.</li><li>- Outer winding is primary, three layers insulation tape around outer winding and three layers tape between primary and secondary windings.</li><li>- Winding ends additionally fixed with tape.</li><li>- Two layers insulation tape covered all bottom core.</li></ul>			
Materials:			
<ul style="list-style-type: none"><li>- Bobbin: type FR-530 of Dupont, PET, 155°C, V-0</li><li>- Insulation tape: No. 92 of 3M, 155°C</li></ul>			

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
- Margin tape: No. Super 20 of 3M, 155°C			
Primary pins: 6-8, 7-5, 7-10, 10-N2/N5		Secondary pins: 2-1-4	

### INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optical isolators, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
<b>6</b>	<b>IDENTIFICATION, MARKING AND DOCUMENTS</b>		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
	c) Markings of the specific power supply affixed		N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N/A
	e) Name and/or trademark of the manufacturer or supplier .....	See the copy of marking plate.	Pass
	f) Model or type reference .....	See the copy of marking plate.	Pass
	g) Rated supply voltages or voltage range(s)	See the copy of marking plate.	Pass
	Number of phases .....	Single phase equipment	N/A
	Type of current .....	AC	Pass
	h) Rated frequency or rated frequency range(s) (Hz) .....	See the copy of marking plate.	Pass
	j) Rated power input (VA, W or A) .....	See the copy of marking plate.	Pass
	k) Power output of auxiliary mains socket-outlets	No outlets.	N/A
	l) Class II symbol	Class I equipment.	N/A
	Symbol for degree of protection against ingress of water provided .....	IPX0	N/A
	Symbol for protection against electric shock .....		N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets	No applied parts.	N/A
	Symbol for protection of defibrillation-proof applied parts	Same as above.	N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	Same as above.	N/A
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous operation.	N/A
	n) Types and rating of external accessible fuses .....	Built-in type power supply. To be evaluated for the final system assembly.	N/A
	p) Ratings of external output .....	See the copy of marking plate.	Pass
	q) Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	r) Anaesthetic-proof symbol: AP or APG.....:	Not AP or APG type.	N/A
	s) Dangerous voltage symbol	Not generated.	N/A
	t) Special cooling requirements	No special conditions.	N/A
	u) Limited mechanical stability		N/A
	v) Protective packing requirement(s)	No special conditions.	N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal	Not provided.	N/A
	- Functional earth terminal		N/A
	z) Removable protective means	No application where removal of the protective means is necessary, however, to be evaluated for the final system assembly.	N/A
	Durability of marking test	See appended table 6.1.	Pass
6.2	Marking on the inside of equipment or equipment parts		Pass
	a) Nominal voltage of permanently installed equipment	To be evaluated for the final system assembly.	N/A
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements or lamps.	N/A
	c) Dangerous voltage symbol	No such voltages generated.	N/A
	d) Type of battery and mode of insertion	None.	N/A
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	The fuses are identified accordingly on the PCB and in the circuit diagram. However, to be evaluated for the final system assembly.	N/A
	f) Protective earth terminal	AC inlet provided. Built-in type power supply. To be evaluated for the final system assembly.	N/A
	g) Functional earth terminal	Not provided.	N/A
	h) Supply neutral conductor in permanently installed equipment (N)		N/A
	j) Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed	No such marking required.	N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Markings comply with IEC 445		N/A
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	To evaluated for the final system assembly.	N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C		N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c	See sub-clause 15c.	N/A
6.3	Marking of controls and instruments		N/A
	a) Mains switch clearly identified		N/A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		N/A
	b) Indication of different positions of control devices and switches		N/A
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
	f) The functions of operator controls and indicators are identified		N/A
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	In compliance with Appendix D.	Pass
6.5	Colors of the insulation of conductors		Pass
	a) Protective earth conductor has green/yellow insulation		N/A
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	Green/yellow wire used.	Pass
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	Compliance.	Pass
	d) Color of neutral conductor .....		N/A
	e) Colors of phase conductor(s) .....		N/A
	- Compliance with IEC 227 and IEC 245		N/A
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.6	Medical gas cylinders and connections		N/A
	a) In accordance with ISO ISO/R 32		N/A
	b) Identification of connection point		N/A
6.7	Indicator lights and push-buttons		N/A
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N/A
	- Yellow used to indicate caution or attention required		N/A
	- Green used to indicate ready for action		N/A
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
6.8	ACCOMPANYING DOCUMENTS		Pass
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Installation instructions provided.	Pass
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Provided.	Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents		N/A
6.8.2	Instructions for use		Pass
	a) General information provided in instructions for use	Provided.	Pass
	- state the function and intended application of the equipment	Same as above.	Pass
	- include an explanation of: the function of controls, displays and signals		N/A
	- the sequence of operation		N/A
	- the connection and disconnection of detachable parts and accessories		N/A
	- the replacement of material which is consumed during operation		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Notification that EMC compliance is to be evaluated for the final system approval is provided.	N/A
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N/A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Equipment for building-in.	N/A
	General information provided in instructions:		Pass
	- information for the safe performance or routine maintenance	Instructions for proper installation into a final system assembly are provided.	Pass
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		N/A
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		N/A
	c) Signal output or signal input parts intended only for connection to specified equipment described	Built-in type equipment. To be evaluated for the final system assembly.	N/A
	d) Details about acceptable cleaning, disinfection or sterilization methods included		N/A
	e) Warning statement for mains operated equipment with additional power source		N/A
	f) A warning to remove primary batteries if equipment is not likely to be used for some time		N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		N/A
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		Pass
	a) All characteristics essential for safe operation provided	Provided.	Pass
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		N/A
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Provided.	Pass
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Provided.	Pass

<b>7</b>	<b>POWER INPUT</b>		Pass
	Power Input Measurements	Refer to appended table.	Pass

<b>10</b>	<b>ENVIRONMENTAL CONDITIONS</b>		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	On manufacturer declaration: Transport conditions: -20°C to +85°C at R.H. 5% to 95% Storage conditions: -20°C to +65°C at R.H. 5% to 95%	Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment		N/A
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz		Pass
10.2.2b	Internal replaceable electrical power source specified		N/A

<b>14</b>	<b>REQUIREMENTS RELATED TO CLASSIFICATION</b>		Pass
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IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Class I equipment. The protection against electric shock hazards rely on basic insulation between live and earthed parts as well as double/reinforced insulation between live and secondary circuit.	Pass
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		N/A
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		N/A
14.6c	Applied parts intended for direct cardiac application are of type CF		N/A

<b>15</b>	<b>LIMITATION OF VOLTAGE AND/OR ENERGY</b>		Pass
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	Refer to appended table.	Pass
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging		N/A

<b>16</b>	<b>ENCLOSURES AND PROTECTIVE COVERS</b>		N/A
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	Equipment for building-in. Compliance is to be evaluated for the final system assembly.	N/A
	Insertion or removal of lamps - protection against contact with live parts provided		N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented		N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 $\Omega$		N/A
	- separated from live parts by one of the means described in Sub-clause 17g		N/A
	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16e	Removable enclosures protecting against contact with live parts		N/A
	- Removal possible only with the aid of a tool		N/A
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts.....:		N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N/A

<b>17</b>	<b>SEPARATION</b>		Pass
17a	Separation method of the applied part from live parts:		N/A
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		N/A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17g	Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed	Evaluated between live and earthed parts. Accessibility to be evaluated for the final system assembly.	Pass
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	4) by double or reinforced insulation	Double/reinforced insulation is provided by the separation transformer, optical isolator and the PCB.	Pass
	5) by protective impedances limiting current to accessible part	See below.	Pass
	- Additional leakage current test in single fault conditions	Refer to appended table 19.	Pass
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A

<b>18</b>	<b>PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION</b>		Pass
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	The equipment is a building-in type power supply that is provided with inlet or screw terminal for connection of the protective earthing conductor. It shall be earthed in the final system assembly.	Pass
18b	Protective earth terminals suitable for connection to the protective earth conductor	Approved AC inlet used.	Pass
18e	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table DI		N/A
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$		N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$	Refer to appended table 18.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$		N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds $0.1 \Omega$ , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N/A
18k	Functional earth terminal not used to provide protective earthing		N/A
18l	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

<b>19</b>	<b>CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS</b>		Pass
19.1b	Leakage currents	See below.	Pass
	- earth leakage current	Refer to appended table.	Pass
	- enclosure leakage current	Same as above.	Pass
	- patient leakage current		N/A
	- patient auxiliary current		N/A

<b>20</b>	<b>DIELECTRIC STRENGTH</b>		Pass
	Overall compliance with Clause 20	Refer to appended table	Pass

<b>21</b>	<b>MECHANICAL STRENGTH</b>		Pass
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	Perform on DC fan side, compliance.	Pass
21b	Sufficient strength of an enclosure tested by: impact hammer	Perform on DC fan side, complied.	Pass
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test		N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test		N/A
21.5	Hand held equipment or equipment parts are safe after drop test		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

21.6	Portable and mobile equipment is able to withstand rough handling		N/A
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<b>22</b>	<b>MOVING PARTS</b>		Pass
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	The DC fan was enclosed by metal chassis and fan guard.	Pass
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N/A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or other safeguards are removable only with a tool		N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A

<b>23</b>	<b>SURFACES, CORNERS AND EDGES</b>		N/A
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	Equipment for building-in. It shall be evaluated in final system.	N/A

<b>24</b>	<b>STABILITY IN NORMAL USE</b> (see appended table 24)		N/A
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IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	Equipment for building-in. It shall be evaluated in final system.	N/A
24.3	Equipment overbalances when tilted through an angle of 10°		N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or		N/A
	- instructions for lifting and handling during assembly		N/A
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N/A

<b>25</b>	<b>EXPULSED PARTS</b>		N/A
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A

<b>28</b>	<b>SUSPENDED MASSES</b>		N/A
28.3	Suspension system with safety device		N/A
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4		N/A
	Safety device has safety factors complying with Sub-clause 28.4.2		N/A
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N/A
28.4	Suspension systems of metal without safety devices		N/A
	1) Total load does not exceed the safe working load		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N/A
	3) Safety factors not less than 8 where impairment is expected		N/A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N/A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N/A
<b>29</b>	<b>X-RADIATION</b>		N/A
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure $\leq 130$ nC/kg (0.5 mR)		N/A
<b>36</b>	<b>ELECTROMAGNETIC COMPATIBILITY</b>		N/A
	Equipment complies with IEC 601-1-2		N/A
<b>37</b>	<b>COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT</b>		N/A
	Requirements for category AP and APG equipment (Cl. 37 - 41)	Equipment not classified as category AP and APG.	N/A
<b>42</b>	<b>EXCESSIVE TEMPERATURES</b>		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	Refer to appended table.	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient	Same as above.	Pass
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N/A
<b>43</b>	<b>FIRE PREVENTION</b>		N/A



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	Strength and rigidity necessary to avoid a fire hazard	The fire enclosure is necessary. However, the equipment for building-in and it shall be evaluated in final system.	N/A
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<b>44</b>	<b>OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION</b>		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overflow steadily over a period of 1 min		N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity	Refer to appended table.	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		N/A

<b>45</b>	<b>PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE</b>		N/A
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure		N/A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N/A
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N/A
45.7b	Readily accessible for inspection		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N/A
45.7d	Discharge opening located that the released material is not directed towards person		N/A
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	Minimum number of cycles of operation: 100.000		N/A
<b>48</b>	<b>BIOCOMPATIBILITY</b>		N/A
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1		N/A
<b>49</b>	<b>INTERRUPTION OF THE POWER SUPPLY</b>		N/A
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No such components provided.	N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	Equipment for building-in. It shall be evaluated in final system.	N/A
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	See above.	N/A
<b>51</b>	<b>PROTECTION AGAINST HAZARDOUS OUTPUT</b>		N/A
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	No such outputs.	N/A
<b>52</b>	<b>ABNORMAL OPERATION AND FAULT CONDITIONS</b>		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	Refer to appended table.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		N/A
52.5.2	Failure of thermostats presents no safety hazards		N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	Refer to appended table.	Pass
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	Refer to appended table.	Pass
52.5.6	Locking of moving parts presents no safety hazard	DC fan used, refer to appended table.	Pass
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	Refer to appended table.	Pass
52.5.10	Overload of heating elements presents no safety hazard		N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected		N/A

<b>56</b>	<b>COMPONENTS AND GENERAL ASSEMBLY</b>		Pass
	List of critical components	Refer to appended table 56.1.	Pass
56.1b	Ratings of components not in conflict with the conditions of use in equipment	All components rated accordingly.	Pass
	Ratings of mains components are identified	Refer to appended table 56.1.	Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely	All relevant components/conductors are reliably secured.	Pass
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	All relevant conductors are additionally secured reliably by solder, glue or mechanical fixing.	Pass
56.3a	Connectors provide separation required by Sub-clause 17g	No such connectors.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		N/A
	Medical gas connections not interchangeable	No such connections.	N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	No such cord.	N/A
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		N/A
56.4	Connections of capacitors		Pass
	Not connected between live parts and non-protectively earthed accessible parts	Refer to sub-clause 17g 5).	Pass
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14	All sources of class Y capacitors are in compliance with IEC 60384-14:1993.	Pass
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	Compliance.	Pass
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such devices used.	Pass
56.6	Temperature and overload control devices		N/A
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
56.6b	Thermostats with varying temperature settings clearly indicated		N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		N/A
	a) Battery compartments:		N/A
	- adequately ventilated		N/A
	- accidentally short-circuiting is prevented		N/A
	b) Incorrect polarity of connection prevented		N/A
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		N/A
	- to indicate that equipment is energized	To be evaluated for the final system assembly.	N/A
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		N/A
56.10	Actuating parts of controls		N/A
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N/A
56.10c	Stops are provided on rotating controls:		N/A
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		N/A
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N/A
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Devices not change their setting when inadvertently placed		N/A
	d) Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
	e) Adequate strain relief at the cord entry provided		N/A

<b>57</b>	<b>MAINS PARTS, COMPONENTS AND LAYOUT</b>		Pass
57.1	Isolation from supply mains		Pass
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	AC inlet provided.	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Same as above.	N/A
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N/A
	f) Mains switches not incorporated in a power supply cord		N/A
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a	Refer to sub-clause 57.1a.	Pass
	m) Fuses and semiconductor devices not used as isolating devices	Not used.	Pass
57.2	Mains connectors and appliance inlets		N/A
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	Not used.	N/A
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	Class I equipment.	N/A
57.3	Power supply cords		Pass
	a) Not more than one connection to a particular supply mains	No power supply cord provided.	N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Non-permanently connected equipment provided with power supply cord or appliance inlet	AC inlet provided.	Pass
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		N/A
	d) Stranded conductors not soldered if fixed by any clamping means		N/A
57.4	Connection of power supply cords		N/A
57.4a	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods	AC inlet used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
	b) Terminals closely grouped with any protective earth terminal		N/A
	Mains terminal devices accessible only with use of a tool		N/A
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N/A
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
	d) Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		Pass
	Fuses or over-current releases provided accordingly for Class I and Class II	Double pole fusing is used.	Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Compliance. Fuses (F1, FN) rated F8.0A 250V.	Pass
	Protective earth conductor not fused	Compliance.	Pass
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		Pass
	a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or 245, treated as bare conductor		N/A
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord	Compliance.	Pass
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		N/A
57.9	Mains supply transformers		Pass



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Clause	Requirement + Test	Result - Remark	Verdict
57.9.1	Overheating	Protection circuit against overheating in case of short-circuit or overload is provided.	Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	Refer to appended table.	Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	Same as above.	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	Same as above.	Pass
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N/A
57.9.4	Construction		Pass
	a) Separation of primary and secondary windings		N/A
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation	Triple insulated wire or double insulated copper bands are used.	Pass
	c) Means provided to prevent displacement of end turns	The winding ends are additionally fixed by tape.	Pass
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
	e) Insulation between the primary and secondary in transformers with double insulation		Pass
	- 1 insulation layer with thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation	Triple insulated wire is used or three layers of insulation tape is provided for double/reinforced insulation.	Pass
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

57.10	Creepage distances and air clearances		Pass
	a) Values: compliance with at least the values of Table XVI	Compliance.	Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard	Sufficient separation is provided.	Pass
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N/A

<b>58</b>	<b>PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS</b>		Pass
58.1	Clamping means of the protective earth terminal		N/A
	Not be able to loosen without the aid of a tool		N/A
	Screws for internal earth connections are covered or protected against loosening from outside		N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	Compliance.	Pass
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N/A
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	Approved AC inlet used.	Pass

<b>59</b>	<b>CONSTRUCTION AND LAYOUT</b>		Pass
59.1	Internal wiring		Pass
	a) Cables and wiring protected against contact with a moving part	No such moving part.	N/A
	Wiring having basic insulation only protected by additional fixed sleeving	The wire of DC fan is tubed complete by a adequate length tubing.	Pass
	Components are not likely to be damaged in the normal assembly or replacement of covers	To be evaluated for the final system assembly.	N/A
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Insulating sleeving adequately secured	Adequate length tubing is used.	Pass
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	Tubing rated 105°C.	Pass
	d) Aluminum wires of less than 16 mm <sup>2</sup> cross-section not used	Not used.	N/A
	f) Connecting cords between equipment parts considered as belonging to the equipment		N/A
59.2	Insulation		Pass
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Phenolic material used and no further tests are necessary. See appended table: additional tests for the others.	Pass
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts	No such likelihood.	Pass
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard		N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed		N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

6.1	TABLE: marking durability		Pass
Marking tested		Remarks	
Product rating label		Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol.	
Supplementary information:			

7	TABLE: power input					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Model MHG2-6300P						
Load condition A		90	47	5.05	454	
Same as above		90	63	5.06	454	
Same as above		100	47	4.47	447	Rated 7.0A
Same as above		100	63	4.47	447	Rated 7.0A
Same as above		240	47	1.77	421	Rated 3.5A
Same as above		240	63	1.78	422	Rated 3.5A
Same as above		254	47	1.68	420	
Same as above		254	63	1.69	420	
Same as above		264	47	1.61	420	
Same as above		264	63	1.62	420	
Load condition B		90	47	4.72	428	
Same as above		90	63	4.77	430	
Same as above		100	47	4.22	422	Rated 7.0A
Same as above		100	63	4.22	422	Rated 7.0A
Same as above		240	47	1.68	400	Rated 3.5A
Same as above		240	63	1.69	400	Rated 3.5A
Same as above		254	47	1.60	400	
Same as above		254	63	1.60	400	
Same as above		264	47	1.53	399	
Same as above		264	63	1.54	399	

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Clause	Requirement + Test			Result - Remark	Verdict

Load condition C	90	47	4.52	407	
Same as above	90	63	4.52	407	
Same as above	100	47	4.00	400	Rated 7.0A
Same as above	100	63	4.00	400	Rated 7.0A
Same as above	240	47	1.60	380	Rated 3.5A
Same as above	240	63	1.61	380	Rated 3.5A
Same as above	254	47	1.52	380	
Same as above	254	63	1.52	380	
Same as above	264	47	1.46	379	
Same as above	264	63	1.47	379	
Model MHG2-6350P					
Load condition A	90	47	5.85	527	
Same as above	90	63	5.87	528	
Same as above	100	47	5.18	518	Rated 7.0A
Same as above	100	63	5.18	518	Rated 7.0A
Same as above	240	47	2.04	486	Rated 3.5A
Same as above	240	63	2.05	486	Rated 3.5A
Same as above	254	47	1.93	484	
Same as above	254	63	1.93	485	
Same as above	264	47	1.85	484	
Same as above	264	63	1.86	484	
Load condition B	90	47	5.60	503	
Same as above	90	63	5.60	503	
Same as above	100	47	4.95	495	Rated 7.0A
Same as above	100	63	4.95	495	Rated 7.0A
Same as above	240	47	1.95	465	Rated 3.5A
Same as above	240	63	1.96	466	Rated 3.5A
Same as above	254	47	1.85	465	
Same as above	254	63	1.86	465	
Same as above	264	47	1.78	464	
Same as above	264	63	1.79	464	
Load condition C	90	47	5.31	477	
Same as above	90	63	5.31	478	

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Clause	Requirement + Test			Result - Remark	Verdict

Same as above	100	47	4.70	470	Rated 7.0A
Same as above	100	63	4.70	470	Rated 7.0A
Same as above	240	47	1.86	443	Rated 3.5A
Same as above	240	63	1.87	443	Rated 3.5A
Same as above	254	47	1.76	442	
Same as above	254	63	1.77	442	
Same as above	264	47	1.70	442	
Same as above	264	63	1.70	442	
Model MHG2-6400P					
Load condition A	90	47	6.69	602	
Same as above	90	63	6.66	599	
Same as above	100	47	5.90	590	Rated 8.0A
Same as above	100	63	5.90	590	Rated 8.0A
Same as above	240	47	2.32	551	Rated 4.0A
Same as above	240	63	2.31	551	Rated 4.0A
Same as above	254	47	2.19	550	
Same as above	254	63	2.19	550	
Same as above	264	47	2.10	550	
Same as above	264	63	2.10	550	
Load condition B	90	47	6.46	580	
Same as above	90	63	6.44	579	
Same as above	100	47	5.70	570	Rated 8.0A
Same as above	100	63	5.70	570	Rated 8.0A
Same as above	240	47	2.24	532	Rated 4.0A
Same as above	240	63	2.23	532	Rated 4.0A
Same as above	254	47	2.12	532	
Same as above	254	63	2.11	532	
Same as above	264	47	2.04	531	
Same as above	264	63	2.03	531	
Load condition C	90	47	6.13	551	
Same as above	90	63	6.12	550	
Same as above	100	47	5.41	541	Rated 8.0A
Same as above	100	63	5.41	541	Rated 8.0A

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Clause	Requirement + Test	Result - Remark	Verdict

Same as above	240	47	2.14	507	Rated 4.0A
Same as above	240	63	2.13	507	Rated 4.0A
Same as above	254	47	2.02	507	
Same as above	254	63	2.01	507	
Same as above	264	47	1.95	506	
Same as above	264	63	1.94	506	

Supplementary information:

1. Test condition: see the General product information and considerations for load conditions.

15b	TABLE: residual voltage in attachment plug										Pass
Voltage measured between:		Measurements [ V ]									Remarks
		1	2	3	4	5	6	7	8	9	
Normal condition											
Supply pins (L-N)	12	20	18	20	2	16	6	20	22	18	Limit = 60V
L-earth	0	0	0	0	0	0	0	0	2	0	Limit = 60V
N-earth	0	0	0	0	0	0	0	2	1	0	Limit = 60V
Fuse (F1) opened											
Supply pins (L-N)	10	8	14	12	8	10	11	10	10	6	Limit = 60V
L-earth	0	0	0	0	0	0	0	0	0	0	Limit = 60V
N-earth	0	0	0	0	0	0	0	0	0	0	Limit = 60V
Fuse (FN) opened											
Supply pins (L-N)	28	36	22	24	24	20	18	28	16	14	Limit = 60V
L-earth	0	0	0	0	0	0	0	0	0	0	Limit = 60V
N-earth	0	0	0	0	0	0	0	0	0	0	Limit = 60V
Supplementary information:											
1. Test condition: No load and i/p is 264Vac, 63Hz											
2. Overall capacitance and discharge resistor: see appended table 56.1.											

15c	TABLE: residual voltage or energy in capacitors					N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (μF)	Residual energy (mJ)	Remarks	
Supplementary information:						

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Clause	Requirement + Test	Result - Remark	Verdict

17h1	TABLE: defibrillation-proof applied parts					N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks	
Supplementary information:						

17h2	TABLE: defibrillation-proof recovery time					N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks		
Supplementary information:						

18	TABLE: protective earthing					Pass
Test location	Test current (A)	Measured voltage (V)	Resistance (mΩ)	Remarks		
PE of inlet to metal chassis	25	0.10	4	Tested for 1 min.		
PE of inlet to metal chassis	40	0.12	3	Tested for 2 min.		
PE of inlet to PE trace of CY3	25	0.05	2	Tested for 1 min.		
PE of inlet to PE trace of CY3	40	0.12	3	Tested for 2 min.		
Supplementary information:						

19	TABLE: leakage current					Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks		
<u>Before humidity conditioning</u>						
ER, N.C. (limit = 0.5mA)	264	63	134	S1= 1, S5= 0 or 1		
ER, S.F.C (limit = 1.0mA)	264	63	250	S1= 0, S5= 0 or 1		
EN, N.C. (limit = 0.1mA)	264	63	0.1	S1= 1, S5= 0 or 1, S7= 1		
EN, S.F.C. (limit = 0.5mA)	264	63	0.1	S1= 0, S5= 0 or 1,		



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Clause	Requirement + Test		Result - Remark	Verdict
				S7= 1
EN, S.F.C. (limit = 0.5mA)	264	63	145	S1= 1, S5= 0 or 1, S7= 0
<u>After humidity conditioning</u>				
ER, N.C. (limit = 0.5mA)	264	63	150	S1= 1, S5= 0 or 1
ER, S.F.C (limit = 1.0mA)	264	63	258	S1= 0, S5= 0 or 1
EN, N.C. (limit = 0.1mA)	264	63	0.1	S1= 1, S5= 0 or 1, S7= 1
EN, S.F.C. (limit = 0.5mA)	264	63	0.1	S1= 0, S5= 0 or 1, S7= 1
EN, S.F.C. (limit = 0.5mA)	264	63	148	S1= 1, S5= 0 or 1, S7= 0
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).				
Supplementary information:				
1. Overall capacity: Refer to appended table 56.1.				
2. All tests were performed with R19 short-circuit.				
<u>Abbreviations used:</u>				
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity N.C. - Normal condition S.F.C. - Single fault condition	

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational/ BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (Va.c.)	Test voltage (Va.c.)	Remarks	
Before humidity conditioning					
A	BI (A-f)	250	1500	Primary to primary for unit	
B	RI/DI (A-a2)	425	4700	Primary to secondary for unit	
C	BI (A-a1)	425	1850	Primary to Earth for unit	
B	RI/DI (A-a2)	425	4700	Primary to secondary for T3	
B	BI (A-b)	425	1850	Primary to core for T3	
B	SI (A-c)	425	2850	Secondary to core for T3	

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Clause	Requirement + Test	Result - Remark		Verdict
B	RI/DI (A-a2)	287	4148	Primary to secondary for T4
B	BI (A-b)	287	1574	Primary to core for T4
B	SI (A-c)	287	2574	Secondary to core for T4
B	RI/DI (A-a2)	425	4700	Two layers insulation tape
B	RI/DI (A-a2)	425	4700	One layer insulation tape
<u>After humidity conditioning</u>				
A	BI (A-f)	250	1500	Primary to primary for unit
B	RI/DI (A-a2)	425	4700	Primary to secondary for unit
C	BI (A-a1)	425	1850	Primary to Earth for unit
B	RI/DI (A-a2)	425	4700	Primary to secondary for T3
B	BI (A-b)	425	1850	Primary to core for T3
B	SI (A-c)	425	2850	Secondary to core for T3
B	RI/DI (A-a2)	287	4148	Primary to secondary for T4
B	BI (A-b)	287	1574	Primary to core for T4
B	SI (A-c)	287	2574	Secondary to core for T4
B	RI/DI (A-a2)	425	4700	Two layers insulation tape
B	RI/DI (A-a2)	425	4700	One layer insulation tape
Supplementary information:				

21	TABLE: mechanical strength		Pass
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
DC fan side of metal chassis		Steady force test	
DC fan side of metal chassis		Impact test	
Supplementary information:			

24	TABLE: - stability		N/A
Part under test		Test condition	Remarks
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

29	TABLE: X - radiation			N/A
Part under test		Test condition	Measured radiation (mR)	Remarks
Supplementary information:				

42	TABLE: normal temperature			Pass
Supply voltage . . . . .:	See below	Test Condition: Placed on the test bench. See below for further details.		
Ambient temperature.....:	See below			
Measuring location		Measured temperature [°C]	Remarks (allowed Tmax [°C])	
For model MHG2-6300P				
1. Load condition A, 90Vac/63Hz, DC fan air-flow inward				
2. Load condition A, 264Vac/63Hz, DC fan air-flow inward				
Test condition	1.	2.	--	
AC inlet	61.6	53.9	70	
Internal mains supply wire	65.4	54.1	105	
LF	81.0	55.5	105	
CX1	71.4	55.5	85	
CY2	62.4	54.0	85	
CY1 (on inlet)	61.9	53.0	85	
CX (on inlet)	62.3	54.5	85	
LD1	82.7	57.0	130	
LF1	86.4	59.3	105	
CY3	70.3	55.8	100	
C1	55.4	50.8	100	
LF2	65.4	52.9	105	
C2	69.0	55.0	85	
PCB under BD1	65.4	54.1	130	
T2	73.1	56.4	105	
C42	56.5	52.7	105	
L8	114	108	130	
T3 primary coil	95.3	89.0	145	
T3 secondary coil	107	100	145	

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Clause	Requirement + Test	Result - Remark	Verdict

T3 core	87.3	81.3	145
T4 primary coil	80.2	74.7	145
T4 secondary coil	83.0	77.6	145
T4 core	75.2	68.8	145
U6	59.2	53.6	110
L4	110	103	130
L7	98.0	82.2	130
H2 near D8 (touch PCB)	74.6	67.9	130
U7	78.3	71.4	110
Metal chassis	53.2	50.1	--
Ambient	50.0	50.0	--

3. Load condition B, 90Vac/63Hz, DC fan air-flow inward

4. Load condition C, 90Vac/63Hz, DC fan air-flow inward

Test condition	3.	4.	--
AC inlet	61.3	59.7	70
Internal mains supply wire	65.1	63.4	105
LF	78.4	75.1	105
CX1	70.1	67.9	85
CY2	62.5	60.6	85
CY1 (on inlet)	61.7	59.7	85
CX (on inlet)	62.3	60.2	85
LD1	80.2	77.5	130
LF1	83.5	80.8	105
CY3	69.3	67.0	100
C1	55.8	54.1	100
LF2	64.7	62.4	105
C2	68.4	66.1	85
PCB under BD1	64.8	63.0	130
T2	71.3	67.0	105
C42	56.4	54.2	105
L8	96.5	87.8	130
T3 primary coil	90.0	84.6	145
T3 secondary coil	100	91.7	145

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

T3 core	83.4	78.3	145
T4 primary coil	77.9	76.5	145
T4 secondary coil	80.7	79.2	145
T4 core	73.4	71.3	145
U6	59.0	57.4	110
L4	117	122	130
L7	81.7	79.0	130
H2 near D8 (touch PCB)	69.3	67.5	130
U7	74.0	70.6	110
Metal chassis	53.1	51.3	--
Ambient	50.0	50.0	--

5. Load condition A, 90Vac/63Hz, DC fan air-flow outward

6. Load condition C, 90Vac/63Hz, DC fan air-flow outward

Test condition	5.	6.	--
AC inlet	61.4	58.6	70
Internal mains supply wire	65.8	62.6	105
LF	75.0	69.0	105
CX1	77.8	72.5	85
CY2	67.2	63.6	85
CY1 (on inlet)	63.0	59.9	85
CX (on inlet)	63.2	60.0	85
LD1	85.1	78.0	130
LF1	71.3	66.5	105
CY3	85.8	80.7	100
C1	74.3	69.9	100
LF2	78.3	72.4	105
C2	82.0	77.1	85
PCB under BD1	90.0	81.7	130
T2	71.3	66.4	105
C42	61.2	58.7	105
L8	72.2	59.5	130
T3 primary coil	68.7	63.2	145
T3 secondary coil	74.3	67.1	145

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

T3 core	68.0	62.3	145
T4 primary coil	95.1	86.2	145
T4 secondary coil	100	90.0	145
T4 core	89.8	81.6	145
U6	91.7	82.0	110
L4	82.4	83.3	130
L7	61.4	51.0	130
H2 near D8 (touch PCB)	67.2	60.4	130
U7	56.2	53.4	110
Metal chassis	56.5	54.4	--
Ambient	50.0	50.0	--

## For model MHG2-6400P

1. Load condition A, 90Vac/63Hz, DC fan air-flow inward
2. Load condition A, 264Vac/63Hz, DC fan air-flow inward

Test condition	1.	2.	--
AC inlet	65.3	52.5	70
Internal mains supply wire	71.9	54.9	105
LF	76.7	54.8	105
CX1	70.5	54.5	85
CY2	60.9	53.1	85
CY1 (on inlet)	70.8	55.4	85
CX (on inlet)	71.0	56.7	85
LD1	94.3	58.7	130
LF1	90.7	58.1	105
CY3	80.1	56.6	100
C1	65.5	53.9	100
LF2	78.4	55.2	105
C2	60.3	52.3	85
PCB under BD1	57.2	51.2	130
T2	71.0	55.5	105
C42	55.6	52.6	105
L8	113	109	130
T3 primary coil	118	113	145

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

T3 secondary coil	118	112	145
T3 core	106	102	145
T4 primary coil	67.1	62.3	145
T4 secondary coil	65.1	61.1	145
T4 core	65.8	61.0	145
U6	54.3	50.4	110
L4	105	98.4	130
L7	121	115	130
H2 near D8 (touch PCB)	89.1	84.3	130
U7	70.1	65.2	110
Metal chassis	51.9	50.5	--
C3	64.4	--	105
U1 (touch PCB)	66.6	--	130
C42	56.8	--	105
Q3 (touch PCB)	78.4	--	130
PCB under R1	80.8	--	130
Ambient	50.0	50.0	--

3. Load condition B, 90Vac/63Hz, DC fan air-flow inward

4. Load condition C, 264Vac/63Hz, DC fan air-flow inward

Test condition	3.	4.	--
AC inlet	64.5	64.6	70
Internal mains supply wire	69.1	68.2	105
LF	73.0	71.6	105
CX1	67.8	66.9	85
CY2	59.4	59.0	85
CY1 (on inlet)	68.2	67.8	85
CX (on inlet)	68.4	67.8	85
LD1	88.7	86.2	130
LF1	85.6	83.8	105
CY3	76.7	75.2	100
C1	63.4	63.4	100
LF2	74.7	73.5	105
C2	58.8	58.9	85

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

PCB under BD1	55.6	55.9	130
T2	68.0	67.2	105
C42	54.3	54.1	105
L8	96.5	91.5	130
T3 primary coil	111	105	145
T3 secondary coil	110	103	145
T3 core	100	94.8	145
T4 primary coil	64.7	64.8	145
T4 secondary coil	63.1	63.6	145
T4 core	63.7	63.9	145
U6	52.9	53.3	110
L4	114	128	130
L7	88.3	88.5	130
H2 near D8 (touch PCB)	81.2	80.8	130
U7	65.8	64.6	110
Metal chassis	57.0	56.8	--
Ambient	50.0	50.0	--

5. Load condition A, 90Vac/63Hz, DC fan air-flow outward

6. Load condition C, 90Vac/63Hz, DC fan air-flow outward

Test condition	5.	6.	--
AC inlet	68.7	67.4	70
Internal mains supply wire	69.5	69.4	105
LF	72.4	72.9	105
CX1	65.8	68.1	85
CY2	60.8	61.1	85
CY1 (on inlet)	73.3	72.3	85
CX (on inlet)	70.8	69.4	85
LD1	100	93.4	130
LF1	85.4	83.8	105
CY3	94.8	86.3	100
C1	90.0	84.6	100
LF2	84.5	80.7	105
C2	75.2	75.1	85



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
PCB under BD1	95.8	92.8	130
T2	81.4	79.6	105
C42	59.5	59.5	105
L8	77.5	68.6	130
T3 primary coil	95.3	88.3	145
T3 secondary coil	86.9	81.2	145
T3 core	89.3	81.7	145
T4 primary coil	91.8	87.5	145
T4 secondary coil	95.6	90.9	145
T4 core	87.6	83.9	145
U6	95.6	92.4	110
L4	83.0	99.5	130
L7	75.1	58.9	130
H2 near D8 (touch PCB)	75.0	73.8	130
U7	52.2	56.2	110
Metal chassis	54.2	62.5	--
Ambient	50.0	50.0	--
C3	93.3	92.5	105
U1 (touch PCB)	64.9	63.5	130
C42	59.2	--	105
Q3 (touch PCB)	70.9	--	130
PCB under R1	102	--	130
Ambient	50.0	50.0	--
7. Load condition A, 90Vac/63Hz, stand-by mode			
Test condition	7.	--	--
Q3 (touch PCB)	61.9	--	130
T4 coil	80.4	--	145
U5	56.8	--	100
U6	76.6	--	100
Ambient	50.0	--	--
Supplementary information:			
1. Unit specified with maximum of 50°C ambient temperature. Winding components (providing safety isolation): - Class F $T_{max} = 155 - 10^2 = 145^{\circ}\text{C}$			

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

2. Thermocouple method used for measuring the temperatures and an asterisk indicates 10K reduction as compensation.
3. Smallest air-flow of DC fan used during the tests, see appended table 56.1 for detail.

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		Pass
Test type and condition		Part under test	Remarks
Humidity treatment for 120hrs, 95%, 40°C		Unit.	No breakdown after dielectric strength test
Supplementary information:			

45	TABLE: hydrostatic pressure and pressure-relief device cycling test		N/A
Test type and condition		Test pressure	Remarks
Supplementary information:			

52	TABLE: abnormal operation		Pass
Test type, condition and clause reference		Observed results	Remarks
For model MHG2-6300P			
Ventilation openings blocked	Unit shut down except for +5VSB. No component damaged. No hazards. T3= 117°C, T4= 109°C, ambient= 27.7°C.		Input: 264Vac/63Hz, Test time: 2hrs
For model MHG2-6400P			
Ventilation openings blocked	Unit cycle protection. No component damaged. No hazards. T3= 122°C, T4= 108°C, ambient= 26.3°C.		Input: 264Vac/63Hz, Test time: 3hrs
DC fan locked	Unit shut down except for +5VSB. No component damaged. No hazards. T3= 140°C, T4= 82°C, ambient= 25.6°C.		Input: 264Vac/63Hz, Test time: 3hrs
U6 primary pins s-c	Unit shut down except for +5VSB. No component damaged. No hazards.		Input: 264Vac/63Hz, 0.18A Test time: 10mins
U6 secondary pins s-c	Unit cycle protection. No component damaged. No hazards.		Input: 264Vac/63Hz, 0.16-0.30A Test time: 10mins

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Clause	Requirement + Test	Result - Remark	Verdict

U7 primary pins s-c	Unit shut down except for +5VSB. No component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins
U7 secondary pins s-c	Unit shut down except for +5VSB. No component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins
U8 primary pins s-c	Unit normal operation. No component damaged. No hazards.	Input: 264Vac/63Hz, 1.95A Test time: 10mins
U8 secondary pins s-c	Unit shut down except for +5VSB. No component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins
Q6 (G-S) s-c	Unit normal operation. No component damaged. No hazards.	Input: 264Vac/63Hz, 1.95A Test time: 2hrs
Q6 (S-D) s-c	Unit shut down. F1, FN, Q6, Q7 damaged, no hazards.	Input: 264Vac/63Hz Test time: 10mins
Q6 (D-G) s-c	Unit shut down. F1, FN, Q6, Q7 damaged, no hazards.	Input: 264Vac/63Hz Test time: 10mins
Q3 (D-C) s-c	Unit shut down. R36 damaged, no hazards.	Input: 264Vac/63Hz, 0.05A Test time: 10mins
Q3 (D-G) s-c	Unit shut down. R36 damaged, no hazards.	Input: 264Vac/63Hz, 0.05A Test time: 10mins
C3 s-c	Unit shut down. F1, FN damaged, no hazards.	Input: 264Vac/63Hz Test time: 10mins
L to N trace before fuse (F1) s-c	Unit shut down. FN damaged, no hazards.	Input: 264Vac/63Hz Test time: 10mins
C42 s-c	Unit shut down. F1, FN damaged, no hazards.	Input: 264Vac/63Hz Test time: 10mins
BD1 (AC to +) s-c	Unit shut down. F1, FN damaged, no hazards.	Input: 264Vac/63Hz Test time: 10mins
+3.3V output s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins
+5V output s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins

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Clause	Requirement + Test	Result - Remark	Verdict
+12V output s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
-5V output s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
-12V output s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+5VSB output s-c	Unit shut down within 1sec. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.16A Test time: 10mins	
+5V - +12V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+5V - +3.3V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+5V - -5V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+5V - -12V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+5V - +5VSB s-c	Unit shut down within 1sec. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.16A Test time: 10mins	
+12V - +3.3V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+12V - -5V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+12V - -12V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+12V - +5VSB s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+3.3V - -5V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
+3.3V - -12V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A	

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
			Test time: 10mins
+3.3V - +5VSB s-c	Unit shut down within 1sec. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.16A Test time: 10mins	
-5V - -12V s-c	Unit shut down within 1sec except for +5VSB. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.21A Test time: 10mins	
-5V - +5VSB s-c	Unit shut down within 1sec. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.16A Test time: 10mins	
-12V - +5VSB s-c	Unit shut down within 1sec. No other component damaged. No hazards.	Input: 264Vac/63Hz, 0.16A Test time: 10mins	
+3.3V output o-l	Overload to 33A then unit shut down. D15 damaged. No hazards. T3= 128°C, T4= 75°C, ambient= 25.0°C.	Input: 264Vac/63Hz Test time: 3hr	
+5V output o-l	Overload to 39A then unit shut down. D15 damaged. No hazards. T3= 123°C, T4= 65°C, ambient= 22.3°C.	Input: 264Vac/63Hz Test time: 2hr	
+12V output o-l	Overload to 37A then unit shut down. D15 damaged. No hazards. T3= 144°C, T4= 69°C, ambient= 29.0°C.	Input: 264Vac/63Hz Test time: 4hr	
-5V output o-l	Overload to 1.7A then unit shut down. No hazards. T3= 110°C, T4= 48.6°C, ambient= 28.3°C.	Input: 264Vac/63Hz Test time: 2hr	
-12V output o-l	Overload to 1.2A then unit shut down. No hazards. T3= 132°C, T4= 59.6°C, ambient= 27.2°C.	Input: 264Vac/63Hz Test time: 2hr	
+5VSB output o-l	Overload to 4.5A then unit shut down. No hazards. T3= 116°C, T4= 74.0°C, ambient= 23.8°C.	Input: 264Vac/63Hz Test time: 4hr Air-flow inward	
+5VSB output o-l	Overload to 4.5A then unit shut down. No hazards. T3= 74°C, T4= 85.0°C, ambient= 22.6°C.	Input: 264Vac/63Hz Test time: 4hr Air-flow outward	
+5VSB output o-l	Overload to 4.5A then unit shut down. No hazards. T4= 82.0°C, ambient= 26.1°C.	Input: 264Vac/63Hz Test time: 2hr Stand-by mode	

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1. Used abbreviations: s-c=short circuit, o-l=overload.
2. The dielectric strength test performed after fault condition test and see appended table 20.4 for detailed test conditions.
3. Maximum permitted temperature of transformers class F: Tmax = 190°C - (50-25)°C= 165°C.
4. The dielectric strength test was performed at 4000Vac/150°C for all sources of photocoupler, no insulation breakdown.
5. For fuse opened conditions, same result came out for each source of fuse used.

56.1	TABLE: lists of critical component parts					Pass
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity	
Chassis	Various	Metal	Minimum 1.0mm thick	--	--	
Appliance Inlet	Rong Feng	SS-7B, SS-120	10A, 250V	IEC/EN 60320-1	VDE, UL	
	Solteam	ST-01	10A, 250V	IEC/EN 60320-1	VDE, UL	
PCB Material	Various	Various	V-0 or better, min.130°C	UL 94	UL	
DC Fan (8 cm) Air flow direction: inward or outward (For Models MHG2-6300P)	Sanyo Denki Co., Ltd.	9A0812F4XX(1) XX= 01-99, (1)= 1 or blank	12 V, 0.11A, 32.4 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	
(For Models MHG2-6300P )	Sanyo Denki Co., Ltd.	9A0812H4XX(1) XX= 01-99, (1)= 1 or blank	12 V, 0.13A, 36.3 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	
(For Models MHG2-6300P)	NMB	3110KL-04W-B40	12 V, 0.26A, 35.3 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	
(For Models MHG2-6300P)	Nidec Taiwan Corp.	D08T-12PG	12 V, 0.15A, 37 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	
(For Models MHG2-6300P)	Delta Electronics Inc.	AFB0812H	12 V, 0.24A, 35.31 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	
(For Models MHG2-6300P)	Delta Electronics Inc.	AFB0812HH	12 V, 0.30A, 37.43 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	
(For Models MHG2-6300P)	Delta Electronics Inc.	EFB0812H	12 V, 0.1A, 33.20 CFM.	IEC/EN 60950-1: 2001	UL, TÜV	

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
(For Models MHG2-6300P)	Delta Electronics Inc.	EFB0812HH	12 V, 0.13A, 36.83 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For Models MHG2-6300P)	Protechnic Electric Co., Ltd.	MGA8012HB-O25	12 V, 0.24A, 37.65 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Sanyo Denki Co., Ltd.	9A0812S4XX(1), where XX= 01-99, (1)= 1 or blank	12 V, 0.18A, 42.3 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	NMB	3110GL-B4W-B54	12 V, 0.3A, 38.3 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	NMB	3110KL-04W-B50	12 V, 0.3A, 38.8 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Nidec Taiwan Corp.	D08T-12PU	12 V, 0.24A, 42 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Delta Electronics Inc.	AFB0812VH	12 V, 0.41A, 42.02 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Delta Electronics Inc.	EFB0812VH	12 V, 0.15A, 40.75 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Delta Electronics Inc.	EFB0812EH	12 V, 0.28A, 52.01 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Protechnic Electric Co., Ltd.	MGA8012XB-O25	12 V, 0.39A, 40.67CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Protechnic Electric Co., Ltd.	MGA8012YB-O25	12 V, 0.42A, 48.95 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Protechnic Electric Co., Ltd.	MGA8012ZB-O25	12 V, 0.54A, 52.71 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
(For all models)	Protechnic Electric Co., Ltd.	MGA8012UB-O25	12 V, 0.66A, 60.24 CFM.	IEC/EN 60950-1: 2001	UL, TÜV
Fuse (FN, F1) (FN on EMI Board)	Conquer	GFP	F8A, 250V	--	UL, CSA

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
	Conquer	UBM-A	F8A, 250V	IEC/EN 60127-2	UL, VDE
X-Capacitors (CX, CX1, CX2, C1, C2) (Optional)  CX on Inlet, max. 0.68µF  CX1, CX2 on EMI board, max. 0.1µF  C1, C2 on Main board, max. 0.47µF  C1 rated min. 100°C	Philips	PCX2 335	Minimum. 250V, 85°C	IEC 60384-14: 1993	VDE, UL
	Taishing	MPX	275V, 100°C	IEC 60384-14: 1993	VDE, UL
	Arcotronics	R46	275V, 125°C	IEC 60384-14: 1993	ENEC, UL
	Matsushita	ECQ-UV	Minimum. 250V, 85°C	IEC 60384-14: 1993	VDE, UL
	Iskra	KNB1530	275V, 100°C	IEC 60384-14: 1993	VDE, UL
	Okaya	RE-series, PA	275V, 100°C	IEC 60384-14: 1993	VDE, UL
	Ultra Tech	HQX	275V, 100°C	IEC 60384-14: 1993	VDE, UL
	Carli	MPX	275V, 100°C	IEC 60384-14: 1993	VDE, UL
	Board-Tech	MEX	Minimum. 250V, 85°C	IEC 60384-14: 1993	VDE, UL
	Teapo	XG-VP, XG-VS	Minimum. 250V, 85°C	IEC 60384-14: 1993	VDE, UL
	Pilkor	PCX2 335M	275V, 105°C	IEC 60384-14: 1993	ENEC, UL
	Thomson	QX	275V, 100°C	IEC 60384-14: 1993	VDE, UL
	Shiny Space	SX1	300V, 100°C	IEC 60384-14: 1993	VDE, UL
	Cheng Tung	CTX	300V, 100°C	IEC 60384-14: 1993	VDE, UL
Thermistor (R1)	--	--	2.5 Ω , min. 9A	--	--



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

			at 25°C		
Bridge Diode (BD1)	--	--	600V, 10A	--	--
Bleeder Resistor (RX) (On Inlet)	Pilkor	SR37	Carbon type, 510k $\Omega$ , 0.5W	EN 60065:2002	VDE
	Futaba	RM-series	Carbon type, 510k $\Omega$ , 0.5W	EN 60065:2002	Semko
	Tai Electronic Co Ltd	RD	Carbon type, 510k $\Omega$ , 0.5W	EN 60065:2002	Nemko
Bleeder Resistor (R2) (On main board)	--	--	Carbon type, 470k $\Omega$ , 1/2W	--	--
Bleeder Resistor (RX1, RX2) (On EMI Board)	--	--	Carbon type, 1M $\Omega$ , 1/4W	--	--
Y-Capacitors (CY1, CY2, CY5) (optional) (Y2 type min.) CY1, CY2 on EMI Board, max. 220pF CY1, CY2 on Inlet, max. 220pF CY5 on Main Board, max. 100pF	Matsushita	NS-A, TS	Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Matsushita	RS	Minimum 250Vac, 85°C	IEC 60384-14: 1993	VDE, UL
	Murata	KC	Minimum 250Vac, 85°C	IEC 60384-14: 1993	VDE, UL
	Murata	KH	Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Walsin (Pan Overseas)	AC	Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Samwha	SC	Minimum 250Vac, 85°C	IEC 60384-14: 1993	VDE, UL
	Welson	KL	Minimum	IEC 60384-14:	VDE, UL

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
			250Vac, 125°C	1993	
	TDK	CS	Minimum 250Vac, 85°C	IEC 60384-14: 1993	VDE, UL
	TDK	CD	Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Samsung	AA, AD	Minimum 250Vac, 85°C	IEC 60384-14: 1993	VDE, UL
	Iskra	KNB2520	Minimum 250Vac, 100°C	IEC 60384-14: 1993	VDE, UL
	Siemens	B81122 series	Minimum 250Vac, 100°C	IEC 60384-14: 1993	VDE, UL
	Jya-Nay Co Ltd	JY	Minimum 250Vac, 85°C	IEC 60384-14: 1993	VDE, UL
	Success Electronics Co Ltd	SE	Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
Y-Capacitors (CY3, CY4) (optional) (Y2 type min.)	Matsushita	NS-A, TS	Maximum 220pF, Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Murata	KH	Maximum 220pF, Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Walsin (Pan Overseas)	AC	Maximum 220pF, Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Welson	KL	Maximum 220pF, Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	TDK	CD	Maximum 220pF, Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
	Iskra	KNB2520	Maximum 220pF, Minimum 250Vac, 100°C	IEC 60384-14: 1993	VDE, UL
	Siemens	B81122 series	Maximum 220pF, Minimum 250Vac, 100°C	IEC 60384-14: 1993	VDE, UL

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
	Success Electronics Co Ltd	SE	Maximum 220pF, Minimum 250Vac, 125°C	IEC 60384-14: 1993	VDE, UL
Varistor (V1, V2)	Ceramate Technical Co Ltd	GNR-07D471K	300Vac, 385Vdc	--	UL
	Joyin Co., Ltd.	JVR07N471K	300Vac, 385Vdc	--	UL
	Nippon Chemi-Con Corp (Marcon Electronics Co., Ltd.)	TNR9G471K	300Vac, 385Vdc	--	UL
	Nippon Chemi-Con Corp (Marcon Electronics Co., Ltd.)	TND14V471K	300Vac, 385Vdc	--	UL
	Matsushita Electric Ind. Co., Ltd.	V7 471U	300Vac, 385Vdc	--	UL
	Sino-American Silicon Products Inc. (Song Long Electronics Co Ltd)	SAS-471KD07	300Vac, 385Vdc	--	UL
	Wujin Thinking Electronic Co., Ltd. (Thinking Electronic Industrial Co Ltd)	TVR07D471, TVR10D471	300Vac, 385Vdc	--	UL
	EPCOS CO LTD	S14k300	300Vac, 385Vdc	--	UL
	Thinking Electronic Industrial Co., Ltd	TVR 07471K	300Vac, 385Vdc	--	UL
Transistors (Q6, Q7)	--	--	Min. 9A, min. 900V	--	--

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test			Result - Remark	Verdict
Storage Capacitor (C42) (For models MHG2-6400P, MHG2-6350P)	Various	Electrolytic type	270 $\mu$ F, min. 400V, min. 105°C	--	--
(For Model MHG2-6300P)	Various	Electrolytic type	220 $\mu$ F, min. 400V, min. 105°C	--	--
Photo coupler (U6, U7, U8)	Toshiba Corp.	TLP421, TLP421F	Di=0.4mm Ext. dcr=8mm Thermal cycle test 110°C	EN 60747-5-2 IEC 60950-1: 2001	VDE, UL, FI
Choke (LF) (Optional) (On EMI Board)	Li Chieh	EMR-269	105°C	--	--
Choke (LF1) (Optional)	Li Chieh	EMR-257	105°C	--	--
	Chief Superior	EMR-257	105°C	--	--
Choke (LD1) (optional)	Li Chieh	EMR-167	130°C	--	--
	Chief Superior	EMR-167	130°C	--	--
Choke (LF2) (Optional)	Li Chieh	13-052-023	105°C	--	--
	I-MAG	13-052-023	105°C	--	--
	Sz Fong	13-052-023	105°C	--	--
	Chu Yang	13-052-023	105°C	--	--
Choke (T2) (Optional) (For models MHG2-6400P, MHG2-6350P)	Main Power	EMR-180	105°C	--	--
Choke (T2) (Optional) (For Model MHG2-6300P)	Li Chieh	EMR-178	105°C		
Choke (L2) (Optional)	Xingda	R6x20	150°C	--	--
	Main Power	R6x20	150°C	--	--
Choke (L4) (Optional)	Li Chieh	EMR-175	130°C	--	--

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	Main Power	EMR-175	130°C	--	--
Choke (L7) (Optional)	Main Power	EMR-174	130°C	--	--
	Li Chieh	EMR-174	130°C	--	--
Choke (L8) (Optional)	Jez Ho	EMR-176	130°C	--	--
	Aitiou	EMR-176	130°C	--	--
Transformer (T3)	Li Chieh	EMT-158(V2)	Class F	--	--
- Bobbin	DU PONT Co., Ltd.	FR-530	V-0, 150°C	UL94	UL
- Triple Wire	Rubadue	TCA3	155°C	IEC 60601-1: 1998 EN 60601-1:1990	VDE
Transformer (T4)	Li Chieh	EMT-157(V1)	Class F	--	--
- Bobbin	DU PONT Co., Ltd.	FR-530	V-0, 150°C	UL94	UL
- Triple Wire	Rubadue	TCA3	155°C	IEC 60601-1: 1998 EN 60601-1:1990	VDE
Mylar Sheet	--	--	V-1 or better, Min. 0.4 mm thick	UL 94	UL
Capacitor (C3)	--	--	Rated 0.47µF, 630Vac, 105°C	--	--

Supplementary information:

1. Di= distance through insulation and dcr= creepage distance.

56.10	TABLE: actuating parts and controls		N/A
Part under test		Torque applied	Remarks
Supplementary information:			

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

56.11b	TABLE: foot operated control devices-loading		N/A
Part under test		Observed results	Remarks
Supplementary information:			

57.4	TABLE: cord anchorages					N/A
Cord under test		Mass of equipment	Pull	Torque	Remarks	Verdict
Supplementary information:						

57.4b	TABLE: cord bending			N/A
Cord under test		Test mass	Measured curvature	Remarks
Supplementary information:				

57.9.1a	TABLE: transformer short circuit					Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
T3 (1-5)	Circuit design	-- 1.	-- 1.	25	10mins	Input: 264Vac/60Hz, 0.21A Unit shut down except +5VSB. No other component damaged. No hazards.
T3 (3-6)	Circuit design	-- 1.	-- 1.	25	10mins	Input: 264Vac/60Hz, 0.21A Unit shut down except +5VSB. No other component damaged. No hazards.
T4 (1-2)	Circuit design	-- 1.	-- 1.	25	10mins	Input: 264Vac/60Hz, 0.16A Unit shut down. No other component damaged. No hazards.
T4 (1-4)	Circuit design	-- 1.	-- 1.	25	10mins	Input: 264Vac/60Hz, 0.16A Unit shut down. No other component damaged. No

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

						hazards.
T4 (5-7)	Circuit design	-- <sup>1.</sup>	-- <sup>1.</sup>	25	10mins	Input: 264Vac/60Hz, 0.16A Unit shut down. No other component damaged. No hazards.
T4 (7-10)	Circuit design	-- <sup>1.</sup>	-- <sup>1.</sup>	25	10mins	Input: 264Vac/60Hz, 0.16A Unit shut down. No other component damaged. No hazards.

Supplementary information:

1. The input current is lower than normal condition. Therefore, the heating measurement is skipped.

57.9.1b	TABLE: overload						Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cut-out temp.	Remarks
		Primary	Secondary	Ambient			
T3 (5) after D7	Circuit design	122	142	24.4	4hrs	2.45A	Input: 264Vac/63Hz Overload to 36A then unit shut down. No hazards.
T3 (5) after D8	Circuit design	146	153	24.9	5hrs	2.73A	Input: 264Vac/63Hz Overload to 55A then unit shut down. No hazards.
T3 (1) after D9	Circuit design	154	160	24.5	3hrs	2.93A	Input: 264Vac/63Hz Overload to 37A then unit shut down. No hazards.
T4 (1) after D13	Circuit design	74	76	28.7	5.5hrs	2.45A	Input: 264Vac/63Hz Overload to 4.5A then unit shut down. No hazards.
T4 (4) after D15	Circuit design	81.5	84.1	25.5	2hrs	2.45A	Input: 264Vac/63Hz Overload to 0.5A then unit shut down. No hazards.

Supplementary information:

1. Maximum permitted temperature of transformers class F:  $T_{max} = 190^{\circ}\text{C} - (50-25)^{\circ}\text{C} = 165^{\circ}\text{C}$ .
2. The dielectric strength test was performed at 4000Vac/150°C for all sources of photocoupler, no insulation breakdown.

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

57.9.2	TABLE: transformer dielectric strength			N/A
Transformer under test	Test voltage applied to	Test voltage (V)	Test frequency (Hz)	Remarks
Supplementary information:				
The electrical insulation between primary windings and other windings and the core of transformers has been investigated by the tests performed as described in clause 20. Result see table 20.				

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
59.2	Ball pressure test at 125°C for base of Choke (LF2)(mfr.: CHISSO, type: 2654)	The impression diameter= 0.9mm	Pass
59.2	Ball pressure test at 186°C for bobbin of transformer (T3, T4)(material see appended table 56.1)	The impression diameter= 1.74mm	Pass
Tests according to IEC 60950-1: 2001			
2.2.2/2.2.3	SELV measurement	The Vpeak= 62.4V at T3 (1-earth), Vpeak= 44.8V after D9. The output voltage is 0V (unit shutdown) for D9 shorted.	Pass
2.2.2/2.2.3	SELV measurement	The Vpeak= 25.6V at T3 (5-earth)	Pass
2.2.2/2.2.3	SELV measurement	The Vpeak= 30.4V at T4 (1-earth)	Pass
2.2.2/2.2.3	SELV measurement	The Vpeak= 59.4V at T4 (4-earth)	Pass
Supplementary information:			



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

**SUMMARY OF CONTENTS:**

The equipment has been tested according to standards IEC 60601-1 (1998) and amendments A1 and A2, and EN 60601-1 (1990) and amendments A1, A2 and A13.

All applicable tests according to the above specified standard(s) have been carried out.

These tests fulfill the requirements of standard EN ISO 17025 (replaced the obsolete EN45001).

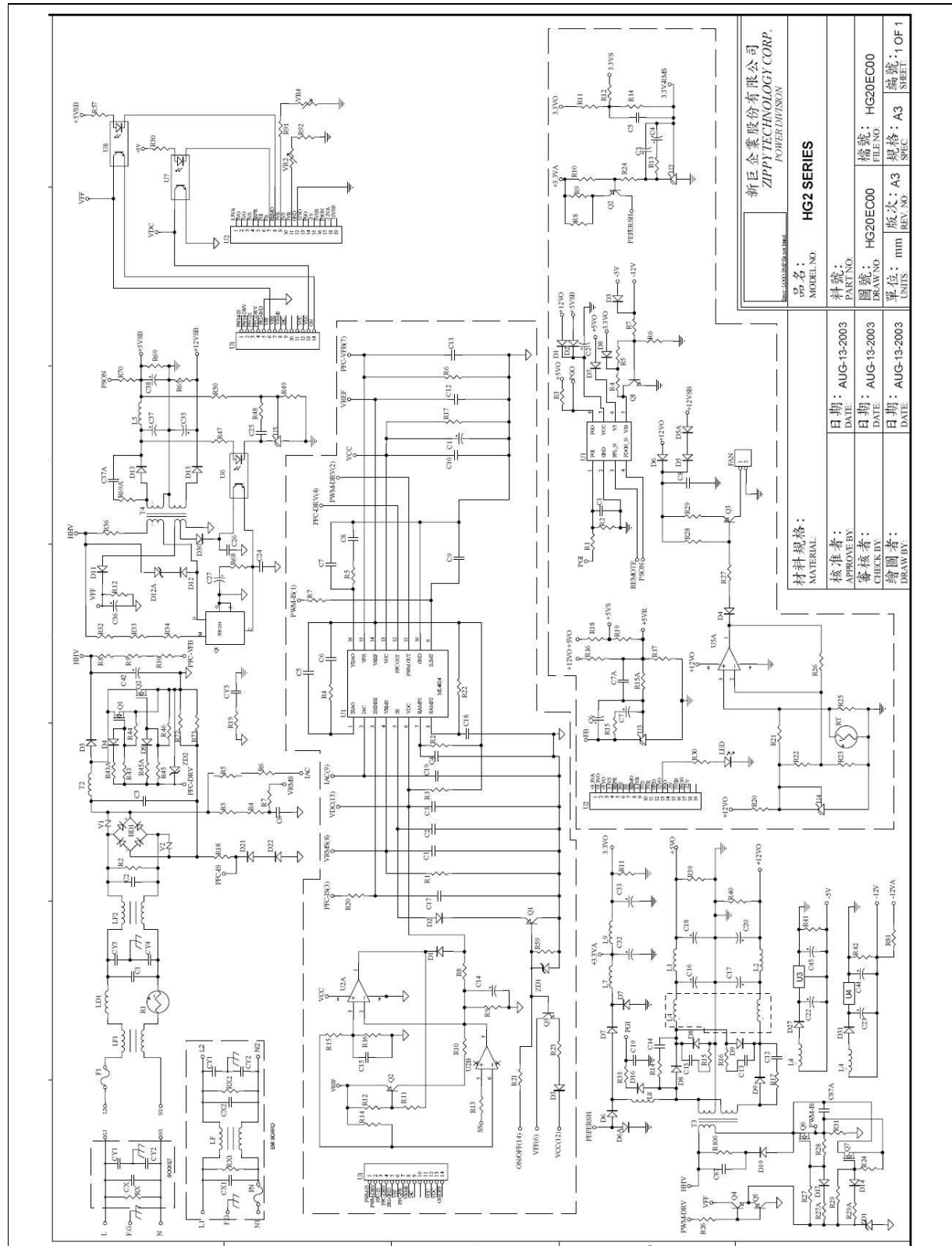
This test report comprises 68 pages of CB Test Report, 14 pages of National Differences and the following Attachments:

Attachment #	Description	Pages
1	Circuit diagrams	69
2	PCB layouts	70-72

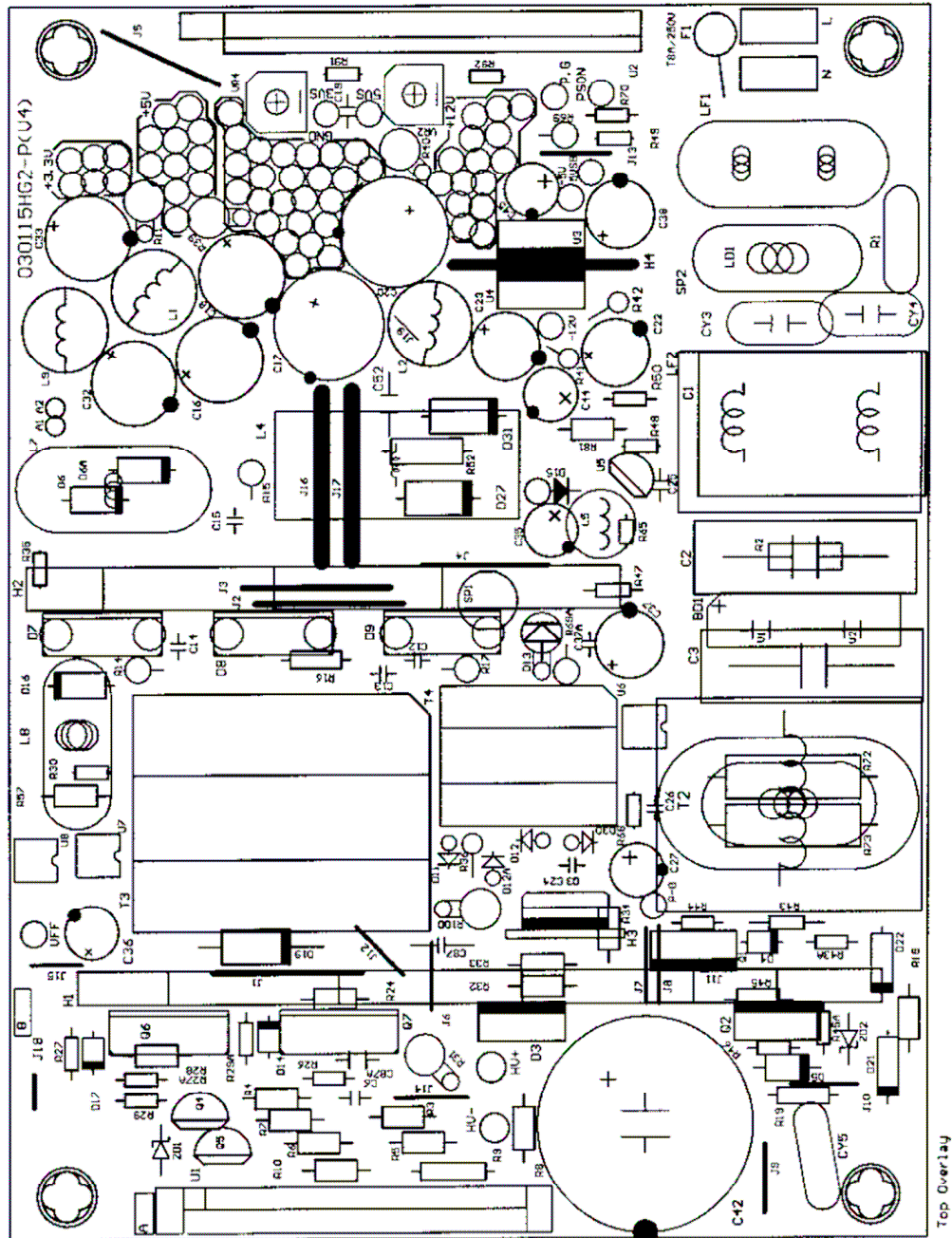
**Note:**

Attachments may include Schematics, Components information, Component test Reports, Particular Standard test Reports, Standard test Reports, Information from accompanying documents and similar.

Attachment 1

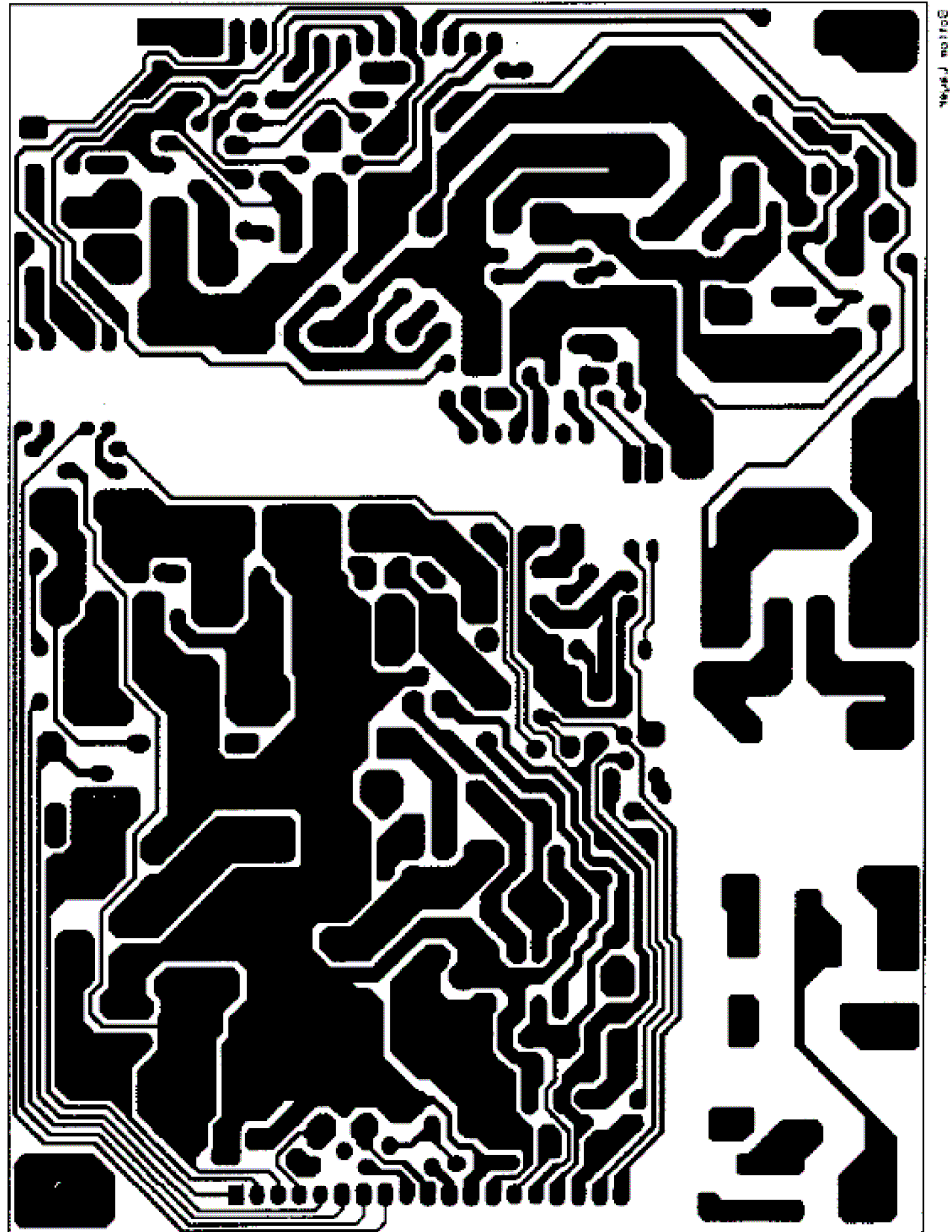


Attachment 2



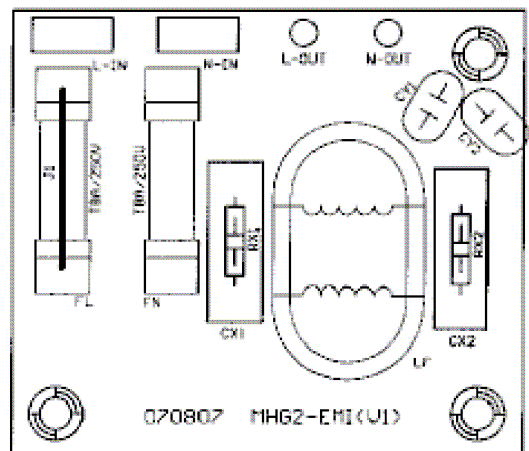
Main board

Attachment 2

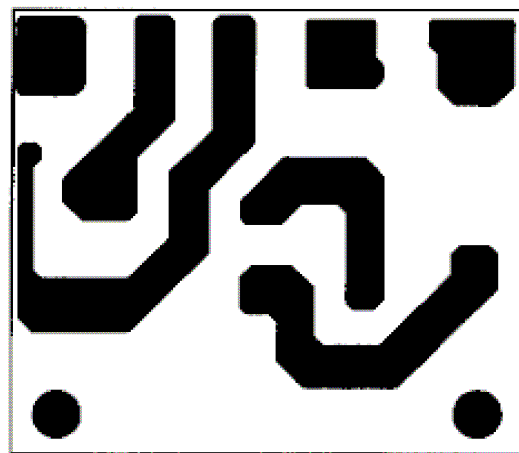


Main board

Attachment 2



Top Overlay



Bottom Overlay

EMI board

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Australian National Differences according to CB Bulletin No. 112A, December 2006 (AS/NZS 3200-1-0:1998) (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
6.1 g)	Insert the following sub-clause between the first and second dashes:	Inserted.	Pass
	For low voltage equipment rated at 200V or more, voltage marking (which may be part of a voltage range) of not less than 230V. Supply frequency ratings which include 60Hz must also include 50Hz.	Included in the rated voltage/frequency range.	Pass
6.6	Replace the existing text of item a) with the following: a) Identification of the contents of gas cylinders used in medical practice as part of electrical EQUIPMENT shall be in accordance with AS 1944, (see also Sub-clause 56.3a).	No medical gas cylinders.	N/A
28.2	Replace the existing text with the following:	Replaced.	N/A
	Support (a) Ceiling-supported EQUIPMENT EQUIPMENT shall comply with the following requirements: (i) EQUIPMENT shall be fitted with an anticrash device or have suspension cables duplicated and independently anchored. (ii) Motorized drives shall be designed to prevent the driven part from becoming hazardous in the event of a power failure. (iii) Carriages, brakes and supports shall be design such that any single failure will not constitute a hazard to the PATIENT. (iv) Effective means shall be incorporated to prevent carriages running off supporting rails. (v) Effective means shall be incorporated to facilitate adequate inspection of cables and anchorages. (vi) Proximity or pressure switches may be used to minimize hazards. (vii) Ceiling-supported EQUIPMENT or parts thereof connected by electrical supply cables shall be provided with stops (e.g. for limitation of rotation or linear movement) to restrict movement in a manner which avoids any		N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
	<p>undue strain on the wiring termination or damage to the wiring.</p> <p>(b) Floor and floor-to-ceiling supported (including mobile) EQUIPMENT</p> <p>EQUIPMENT shall comply with the following requirements:</p> <p>(i) Anticrash devices shall be fitted to cable, chains, etc.</p> <p>(ii) Means shall be incorporated to facilities adequate inspection of cables and anchorages.</p> <p>(iii) Cross-arms or pivots shall be fitted with adequate stops, locknuts, grub screws or similar devices to prevent supported masses being dislodged.</p>		
42.3	<p>Item 2) Add the following prior to the first dash:</p> <p>For this clause only, low voltage equipment rated at greater than 200V is regarded as having a maximum rated voltage of 230V.</p>	No applied parts.	N/A
Table XII	In second row, first dash, after 'if impedance protected' add 'maximum value'.	Added.	N/A
51.2 a)	<p>Replace "not used" with:</p> <p>Supply plugs – Provision for inspection</p> <p>Where a supply flexible cord is fitted with a rewirable plug of a type complying with the requirements of AS 3112 for 3-pin plugs, the plug shall be clear-backed to facilitate inspection of the core colours and the condition the terminations.</p>	No supply flexible cord provided.	N/A
56.3 a)	<p>Replace the text in the 3<sup>rd</sup> dash by the following:</p> <p>Medical gas connections on EQUIPMENT shall, if operating at positive pressures greater than 50 kPa in NORMAL USE comply with AS 2472, AS 2473, or AS 2896, as appropriate.</p>	No medical gas connections.	N/A



National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Canadian National Differences according to CB Bulletin No. 112A, December 2006 (CAN/CSA 22.2 No. 601.1-M90) (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
6	Where written safety warnings appears as equipment markings, they should appear in French and English.	It should be evaluated in national approval.	N/A
6.61	The point connection of gas cylinders to equipment is gas specific.  The point of connection of gas cylinders to equipment is non-interchangeable.  The point of connection of gas cylinders to equipment is identified.	No gas cylinders.	N/A
56.3 a	Medical gas inlet connectors on equipment are specific.  Medical gas inlet connectors on equipment are non-interchangeable.  Medical gas inlet connectors on equipment are DISS type complying with CGA V-5  Medical gas inlet connectors on equipment are configured to permit the supply from assemblies complying with CAN/CSA – Z305.2.	No gas connections.	N/A
56.6 a	Where consequential loss of function caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings provided.	To be evaluated for the final system assembly.	N/A
57.2 g	Mains plug of non-permanents installed equipment:  - if molded on type – hospital grade complying with CSA C22.2, No. 21  Mains plug of non-permanent installed equipment:  - hospital grade disassembly type complying with CSA C22.2, No. 42  Mains plug of non-permanent installed equipment:  - if Class II equipment – polarized hospital grade CSA configuration 1-15P	No mains plug provided.	N/A



National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
57.3 b	<p>Detachable power supply cord is unlikely to be detached accidentally.</p> <p>Detachable power supply cord impedance of earth contracts presents no safety hazard.</p> <p>Detachable power supply cord: possibility of replacement by a cord which could make equipment hazards minimized.</p> <p>Detachable power supply cord complies with CSA C 22.2 No.21.</p> <p>Detachable power supply cord not smaller than No. 18 AWG</p> <p>Detachable power supply cord minimum serviceability of type SJ for mobile equipment of Type SV for other.</p>	No power supply core provided.	N/A
57.9	Switching power supplies conform to CSA Electrical Bulletin 1402C.	It should be evaluated in national approval.	N/A
58.2	Protective earth connections comply with CSA C 22.2 No.04	It should be evaluated in national approval.	N/A
59.1	Connecting cables comply with Canadian Electrical Code, Part I.	It should be evaluated in national approval.	N/A
60	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts.	No such parts.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Danish National Differences according to CB Bulletin No. 112A, December 2006 (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
	For plugs and socket outlets the National Standard SB 107-2-D1 3 <sup>rd</sup> ed. Applies.	See below.	N/A
	For Class I equipment: Plugs: DK 2-1a, DK 2-1a with flat phasepin or DK 2- 5a Socket outlets: DK 1-3a	No plug provided.	N/A
	For Class II equipment: Plugs: DKA 2-1a, DKA 2-1b Clb, C5, C6 or according to EN 50075	No plug provided.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Israeli National Differences according to CB Bulletin No. 112A, December 2006 (SI 1011) IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
	Clause 4.7 – Supply and mains voltages:	See below.	Pass
A.	Equipment that is to be connected to the mains, shall be intended for one of the following voltages and frequencies:  Nominal frequency of 50Hz.  Nominal voltage of 230V for portable and hand-held equipment.  Nominal voltage 230V, for one phase equipment with input power not exceeding 4kVA.  Nominal voltage 400V, for multiphase equipment.	Included in the rated voltage/frequency range.	Pass
B.	It is allowed to connect to the mains other equipment, with the following ratings:  One phase equipment, for the range of 220 to 240 Volts.  Multiphase equipment, for the range of 380 to 440 Volts.  The equipment shall comply with all the requirements of the standard, while being connected to the above mentioned mains frequencies and voltages, as if it was marked for 50Hz and 230 or 400 Volts.	Same as above.	Pass
36.	Change clause 36. – EMC – to:  The equipment shall comply with the equipments of SI 1011 part 1.2 (IEC 60601-1-2).	To be evaluated for the final system configuration.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Korean National Differences according to CB Bulletin No. 112A, December 2006 (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
	LIMITATIONS	See below.	Pass
	<Supply voltage rating> National supply voltages are 110, 220V and 380V	Included in the rated voltage/frequency range.	Pass
	<Frequency> Only appliances having supply frequency of 60Hz or a frequency range including 60Hz are accepted.	Included in the rated voltage/frequency range.	Pass
	<Instruction> Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417.  Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300)  More details are available from KTL (c/o KTL) on request.	It should be evaluated in national approval.	N/A
	DEVIATIONS	See below.	Pass
6.1 j)	Insert the following sub-clause between the second and third sub-clauses:  Equipment for one or several RATED voltage or frequency ranges, the RATED input for 220V, 60Hz or if applicable for 110V, 60Hz shall be separately marked.	Marked as voltage and frequency range.	Pass
6.1 s)	HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a TOOL shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and with the Korean language, <b>고압주의</b> .	No high voltage parts.	N/A
6.2 c)	Replace the existing sub-clause with the following:  The presence of HIGH VOLTAGE PARTS shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and with the Korean language, <b>고압주의</b> .	See above.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
6.8.1	Insert the following sub-clause after the last paragraph: Language of accompanying documents shall be included Korean.	It should be evaluated in national approval.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Singaporean National Differences according to CB Bulletin No. 112A, December 2006 (SS 481 Part 1:2000) IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
4.10	<p>Replace the following in the sixth and seventh paragraph:</p> <p>“91% to 95%” with “90% to 95%”,</p> <p>“within 2°C of any convenient value t in the range +20°C to +32°C” with “at 40°C ± 1°C”,</p> <p>“2 days (48h)” with “5 days (120h)”</p> <p>Explanation: This national standard modifies the requirements of the humidity preconditioning treatment to reflect better the weather conditions of high temperatures and humidity.</p>	Replaced. Humidity treatment at 40°C, 93% R.H. for 120 hours.	Pass
6.1 g)	<p>Add between the first and second items</p> <p>“The following voltage requirements shall be used:</p> <p>Single-phase: 230V ± 6%, 50Hz ± 1Hz;</p> <p>Three phase: 400V ± 6%, 50Hz ± 1Hz (phase to phase)”</p> <p>Explanation: The addition has been made to reflect the local power requirements.</p>	Included in the rated voltage/frequency range.	Pass
28.2	<p>Replace the existing text with the following:</p> <p>Support</p> <p>a) Ceiling-supported EQUIPMENT</p> <p>EQUIPMENT shall comply with the following requirements:</p> <p>(i) EQUIPMENT shall be fitted with an anticrash device or have suspension cables duplicated and independently anchored.</p> <p>(ii) Motorized drives shall be designed to prevent the driven part from becoming hazardous in the event of a power failure.</p> <p>(iii) Carriages, brakes and supports shall be designed such that any single failure will not constitute a hazard to the PATIENT.</p> <p>(iv) Effective means shall be incorporated to prevent carriages running off supporting rails.</p> <p>(v) Effective means shall be incorporated to</p>	No suspended masses.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
	<p>facilitate adequate inspection of cables and anchorages.</p> <p>(vi) Proximity of pressure switches may be used to minimize hazards.</p> <p>(vii) Ceiling-supported EQUIPMENT or parts thereof connected by electrical supply cables shall be provided with stops (e.g. for limitation of rotation or linear movement) to restrict movement in a manner which avoids any undue strain on the wiring termination or damage to the wiring</p> <p>(b) Floor and floor-to-ceiling supported (including mobile) EQUIPMENT</p> <p>EQUIPMENT shall comply with the following requirement:</p> <p>(i) Anticrash devices shall be fitted to cable, chains, etc.</p> <p>(ii) Means shall be incorporated to facilitate adequate inspection of cables and anchorages.</p> <p>(iii) Cross-arms or pivots shall be fitted with adequate stops, locknuts, grub screws or similar devices to prevent supported masses being dislodged.</p> <p>Explanation: The addition has been made to cover the safety aspects for patients, operators as well as equipment.</p>		
42.3 Item 2	<p>Add the following prior to the first item</p> <p>“The following voltage requirements shall be used:</p> <p>Single-phase: 230V ± 6%, 50Hz ± 1Hz;</p> <p>Three phase: 400V ± 6%, 50Hz ± 1Hz (phase to phase)”</p> <p>Explanation: The addition has been made to reflect the local power requirements.</p>	Included in the rated voltage/frequency range.	Pass
52.5.8	<p>Table XII</p> <p>Add “maximum value”, in the second row, first item, after “if impedance protected”.</p> <p>Explanation: The addition has been made to correct typographical error.</p>	Not motor operated equipment.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
57.3 a)	<p>Add the following after the third item:</p> <p>“Plugs used shall be rough-use type, marked with ‘SS145/A’.”</p> <p>Explanation: The addition has been made to reflect the local requirements of the 3 pin plugs.</p>	No power supply cord provided.	N/A



National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	US National Differences according to CB Bulletin No. 112A, December 2006 (UL 2601-1/IEC 60601-1-1) (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
The following US National differences are based on requirements in the US National Electrical Code (NEC), ANSI/NFPA 70-1993.			
2.4.1, 2.10.100 (new), 2.10.101 (new) c) 10.2.2	High voltage X-ray installations Long Time and Momentary ratings definitions Clause 6, 6.2 and product markings shall agree with the NEC.	No X-ray source.	N/A
6.21	Replace 70°C with 60°C	Not applicable.	N/A
Clause 14, clause 18	The class of high voltage parts of equipment shall be in accordance with the provisions of NEC.	No high voltage parts.	N/A
57	All equipment installations are required to be in accordance with NEC.	To be evaluated when submitted for national approval.	N/A
57.2	“Hospital Grade” or “Hospital Only” mains plugs required on cord connected equipment marking/instructions regarding grounding reliability is to be provided. Radiographic control disconnect mains plugs shall be acceptable for a current not less than 50 per cent of the maximum input current measured. Except for X-Ray equipment mains plugs shall be rated no less than 125 percent of the rated current of the equipment. Where polarized mains plugs are used in edison base lampholders and any single pole protective device shall be connected in the ungrounded side of the line, except if it is in addition to the one in the ungrounded side.	Not a cord connected equipment.	N/A
57.3, 59.1	Power supply cords and internal wiring including interconnection cords between equipment shall meet the requirements of NEC. A detachable power supply cord for non-permanently installed equipment shall be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety hazard.	Same as above.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
The following US National deviations are based on requirements other than the US National Electrical Code (NEC)			
1.1, Section 5	Safety hazards resulting from intended physiological function of and ionizing radiation resulting from equipment covered by this standard are not considered. Such equipment is subject to US FDA requirements and US Federal Radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.	Not applicable.	N/A
2.12.100 (new) 2.12. 101 new, 19	In addition to the requirements in the base standard, equipment shall comply with ANSI/AAMI Safety Current Limits (SCL) and ANSI/NFPA 99 Health Care Facilities Standards. X-Ray equipment need only comply with the Clause 19 requirements in UL 2601-1.	No X-ray source.	N/A
3 (new sub-clause 3.100, 3.100.1, 3.101, 3.101.1, 3.101.2, 3.102) and 57.5	In addition to compliance with this standard, primary connected components, printed wiring boards, lithium batteries, optical isolators, wiring and tubing, and cathode ray tubes exceeding 5 inches maximum dimensions shall meet US nationally recognized standards, such as ANSI/UL standards or internationally harmonized component standards. Components shall be used in accordance with their intended use and in consideration of their inherent limitations.	Considered. See appended table 56.1.	Pass
6	“CAUTION”, “WARNING” or “DANGER” markings shall be in contrasting color to the background. The signal word letters shall be minimum 2.8 mm high, all others minimum 1.6 mm high. A “WARNING” statement is required for ionizing radiation producing equipment.		N/A
22 and 28	In addition to the requirements and basic standard, equipment shall be found to be in compliance with the Standard for X-Ray equipment, ANSI/UL 187, 5 <sup>th</sup> edition, Sections 31 and 34 with respect to the movement control and supported masses.	No X-ray source.	N/A
42	In addition, to the basic requirements in this standard, insulating systems operating at greater than Class 105°C limits during normal use and normal condition shall comply with the requirements of the Standard for Systems of Insulating Materials - General (UL 1446).	Insulation system incorporated.	Pass

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
55	The flaking or peeling of a conductive coating is not to contribute to safety hazard. External combustible materials having a surface area of more than 4.74 square meters shall have controlled flame spread characteristics. Polymetric enclosures and covers shall be considered for flammability characteristics and be resistant to mold stress relief and impact/drop safety hazards consistent with their use.		N/A
56.3	The likelihood of a patient connected lead or part being misused so as to introduce a safety hazard shall be investigated.		N/A
58.2	Connections shall be made mechanically secure as well as being soldered.		N/A
400 (new)	For equipment which uses oxygen or recommends use with oxygen, special safety hazards associated with use of oxygen should be addressed in accordance with Clause 400. These requirements are based on oxygen-related requirements from IEC 601-2-19, particular requirements for the safety of baby incubators.	This equipment does not generate or use oxygen.	N/A
600 (new)	A separate power unit employing a separable connector for supplying the equipment shall be packaged with the equipment or be referenced to by the marking on the equipment. Direct plug-in units shall comply with the mechanical assembly, enclosure, input connections, accessibility of live parts, grounding, marking and performance requirements in the Standard for Class 2 Power Units, UL 1310.	Not Direct plug-in unit.	N/A

Product: Switching Power Supply

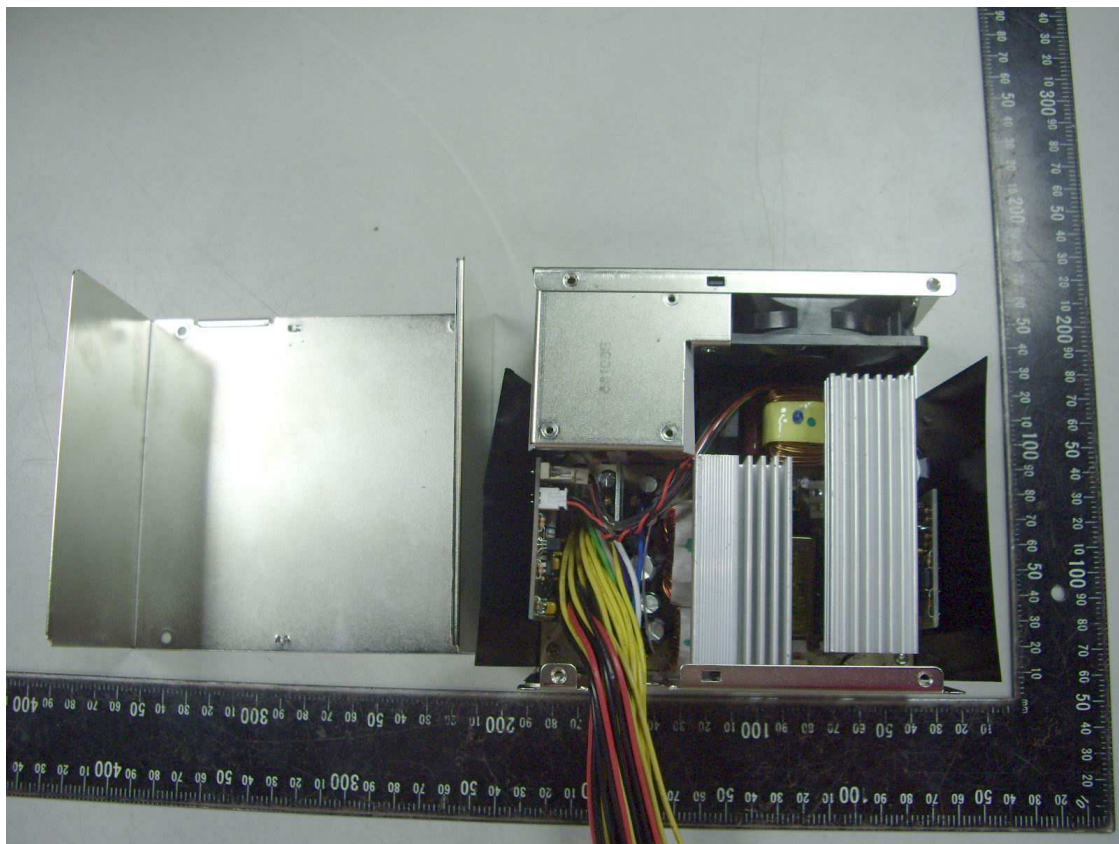
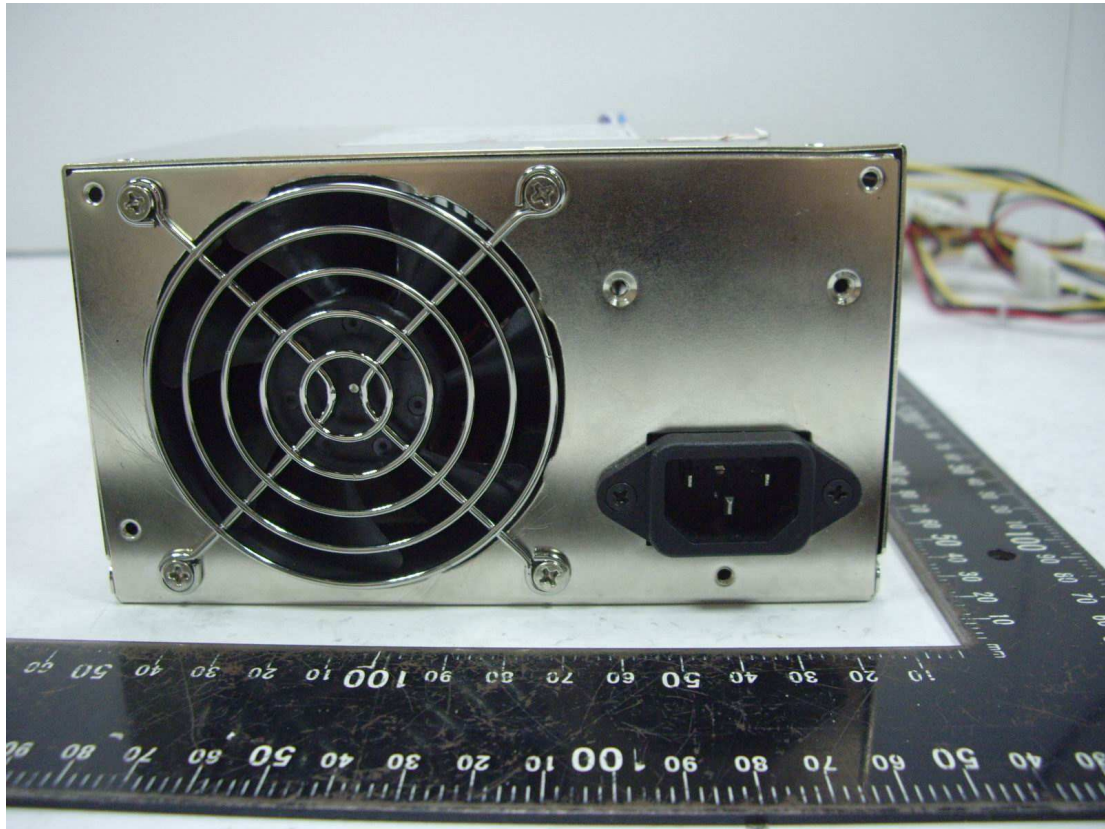
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Product: Switching Power Supply

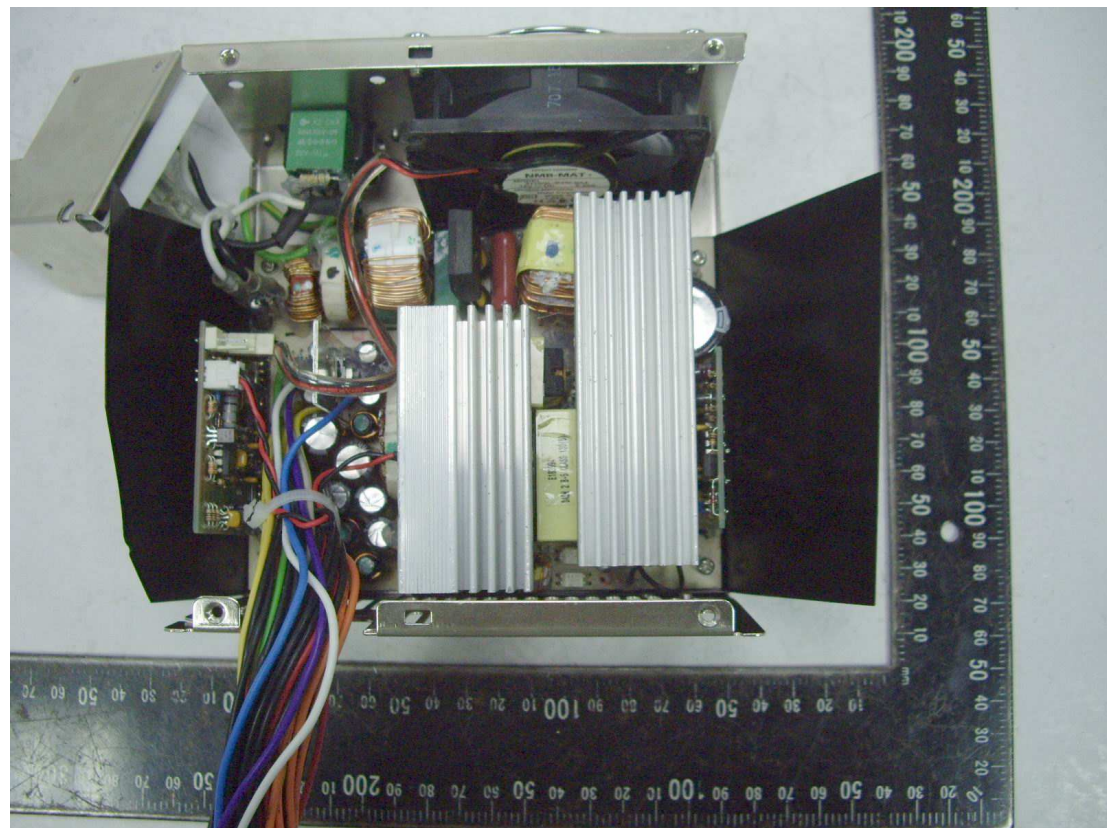
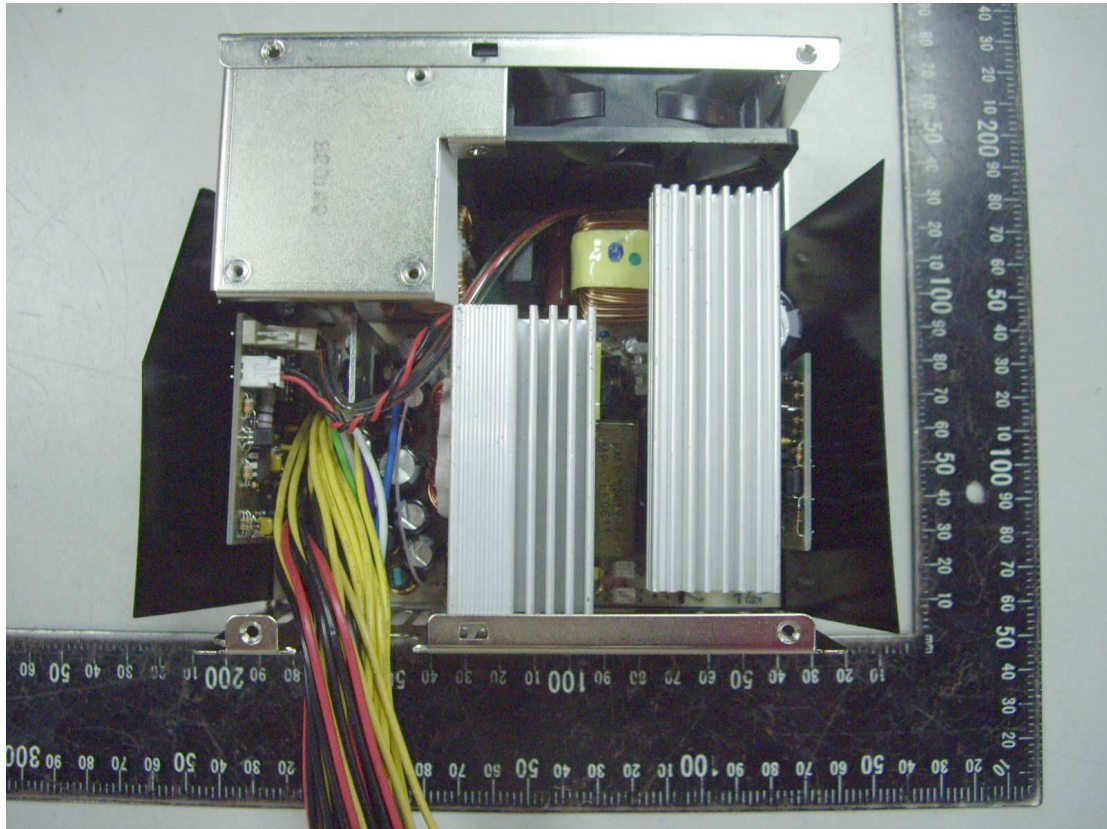
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Product: Switching Power Supply

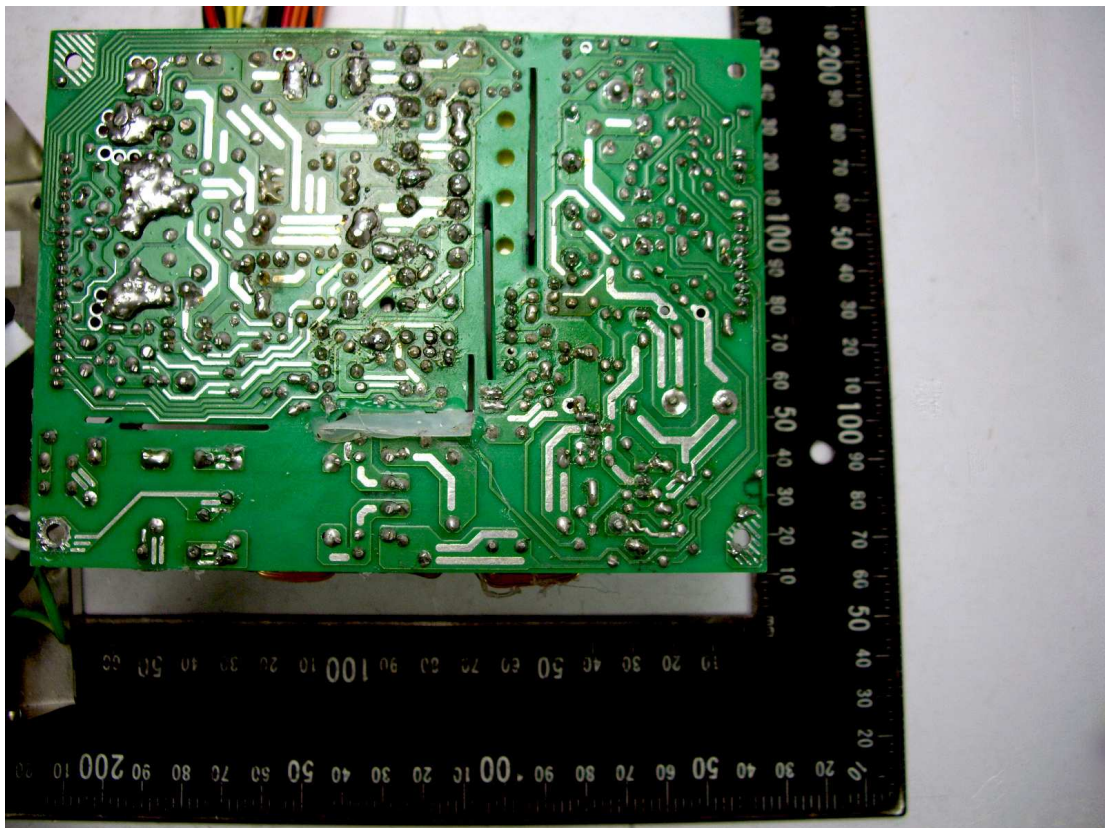
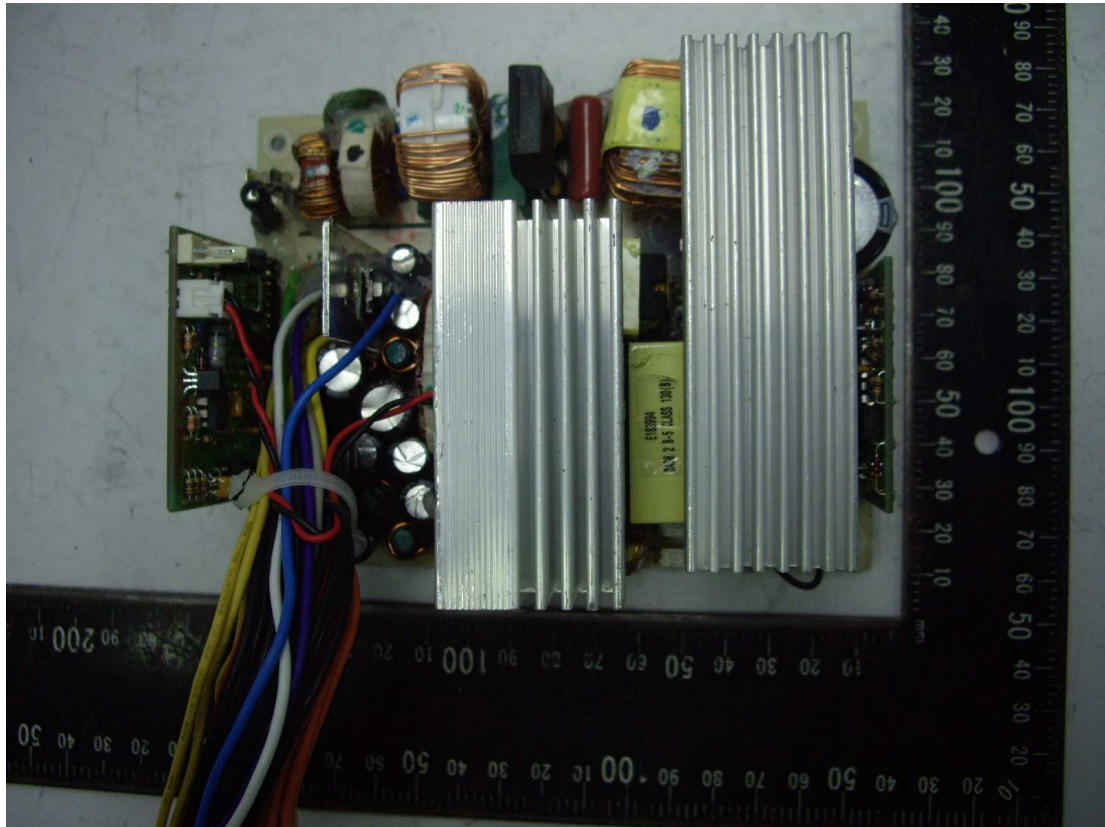
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Product: Switching Power Supply

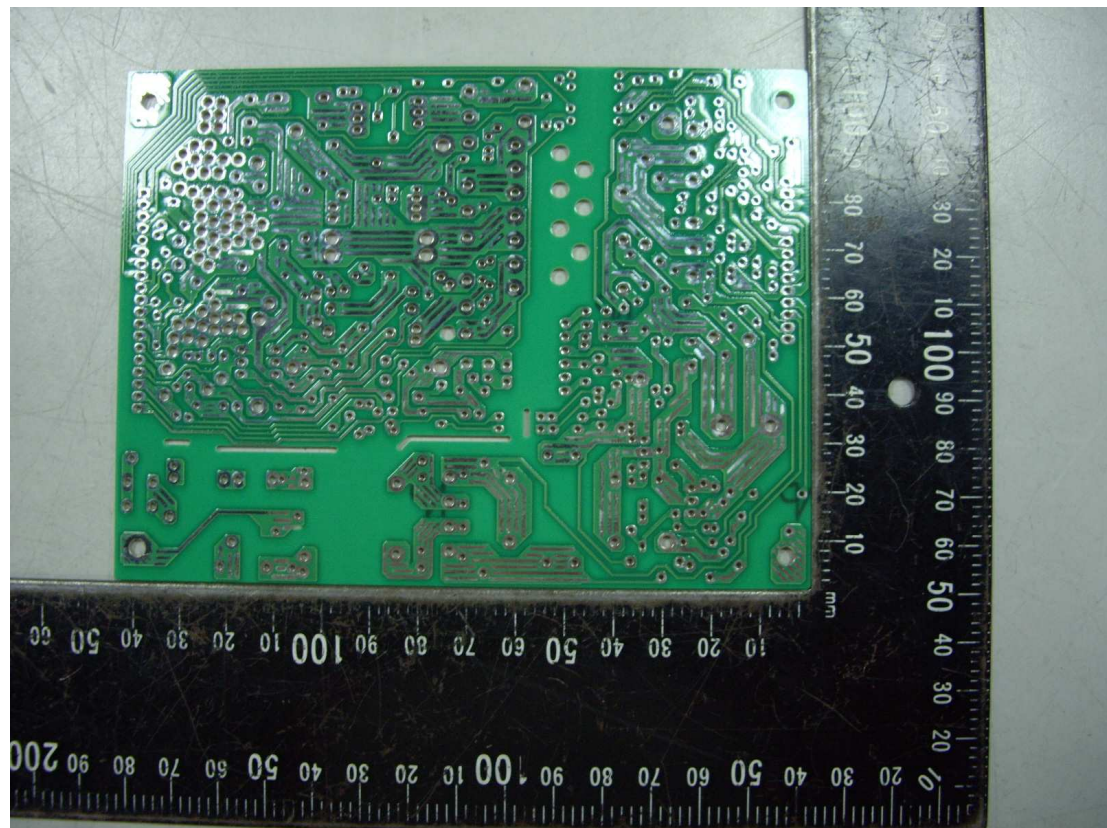
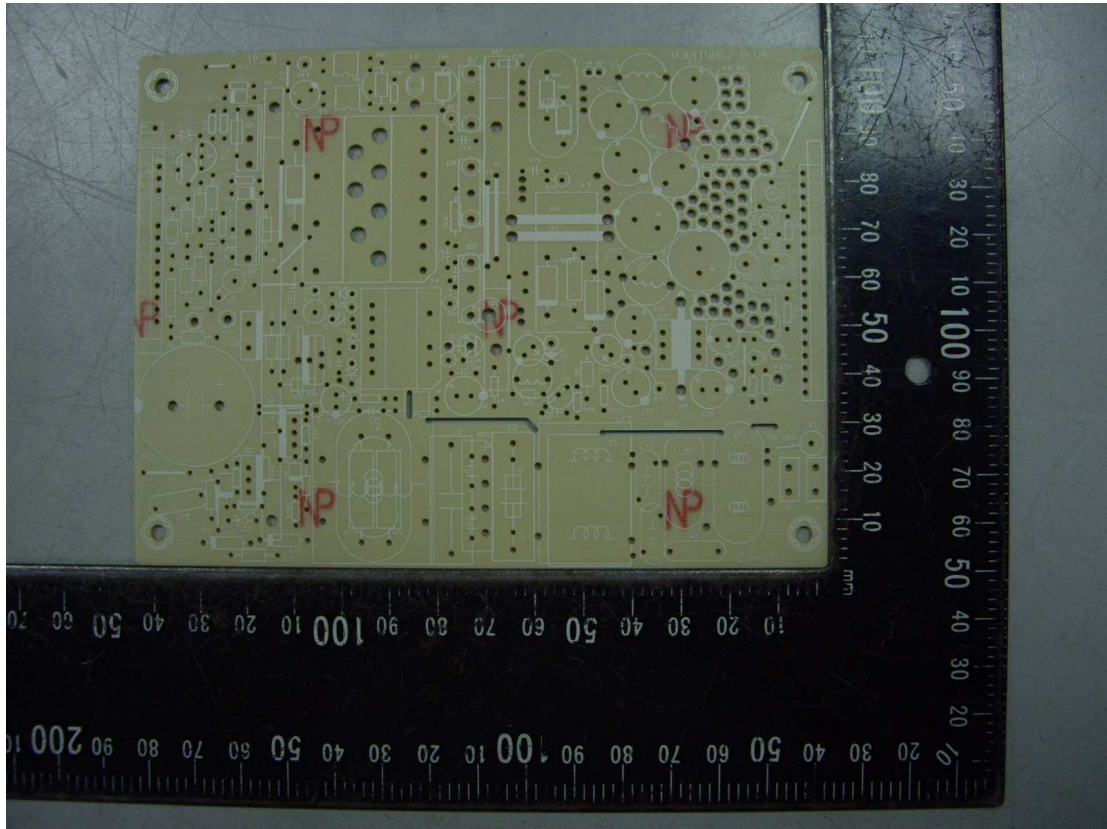
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Product: Switching Power Supply

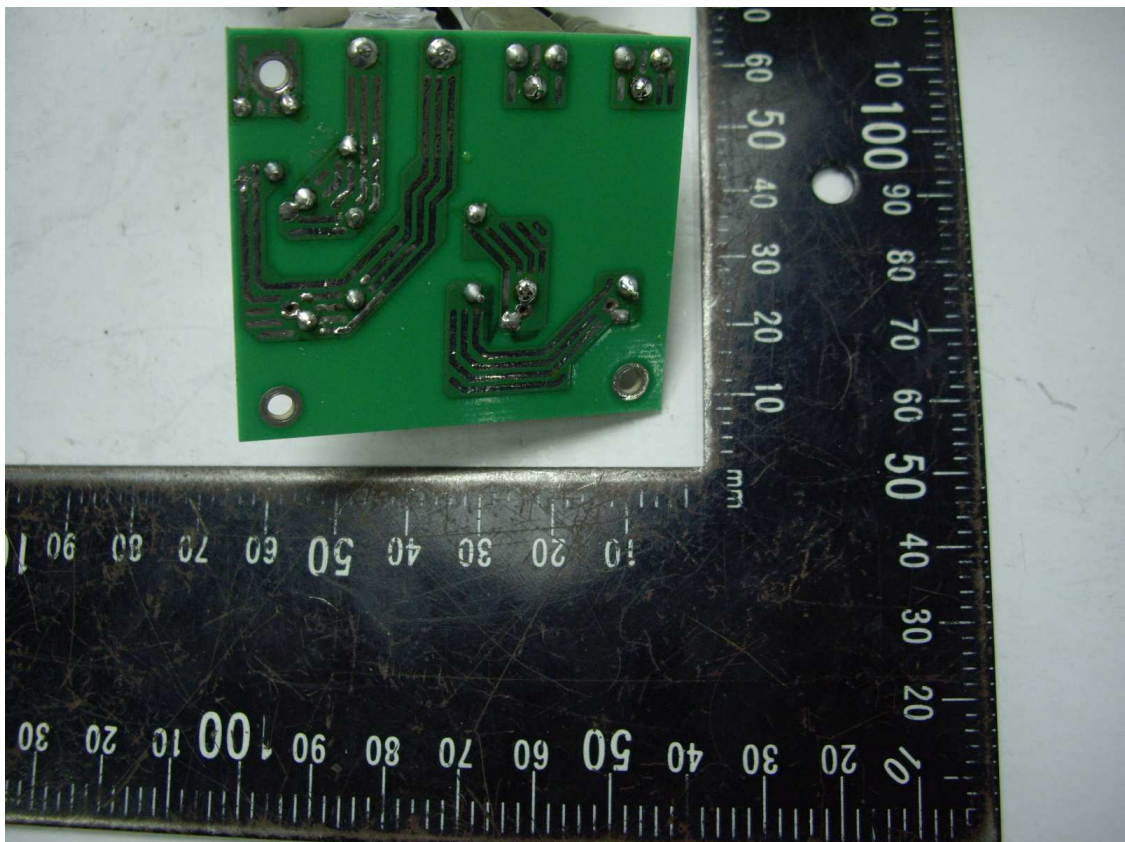
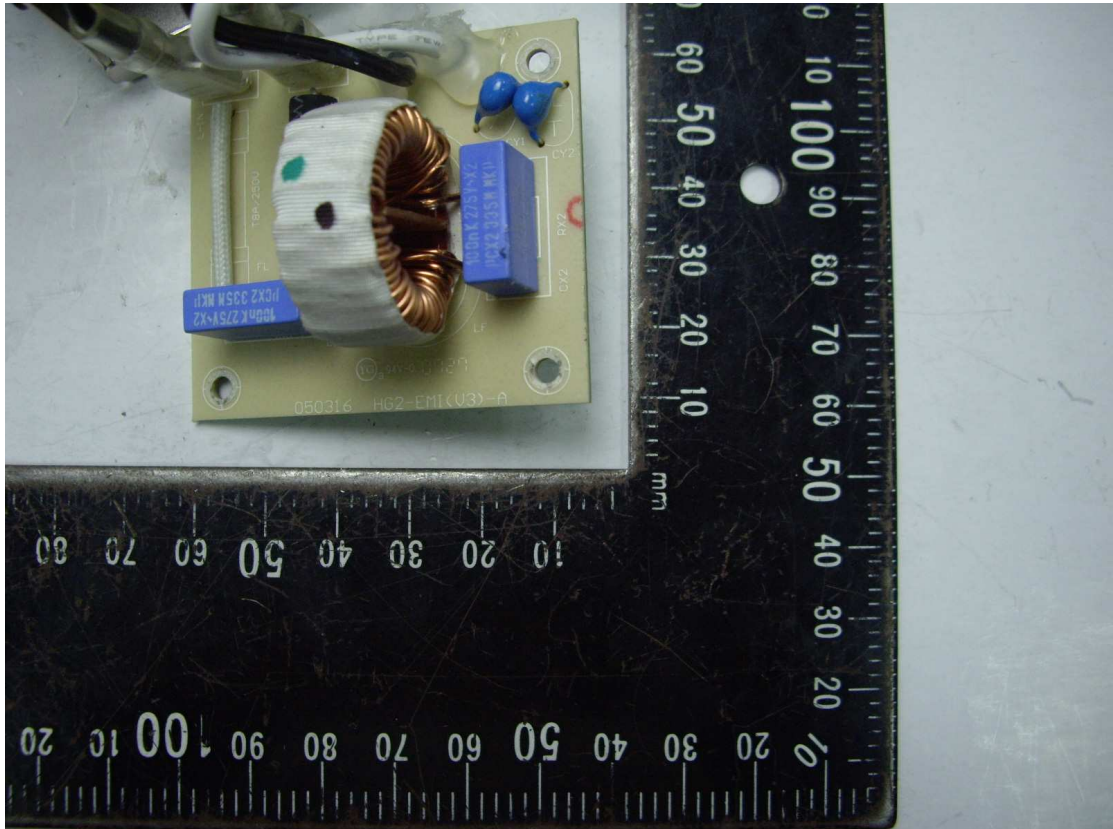
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Product: Switching Power Supply

Type Designation: MHG2-6400P, MHG2-6350P, MHG2-6300P





Product: Switching Power Supply

Type Designation: MHG2-6400P, MHG2-6350P, MHG2-6300P

