



**Additional Test Report
according to
EN 60601-1:1990
for switching power supplies**

Tested by: Hofmann, Signature: [Signature], Date: 09. Nov. 98
Checked by: [Signature], Signature: [Signature], Date: 10. Nov 98

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General:

manufacturer	Grzelka Elektronik GmbH,	D-41812 Erkelenz
unit	Switch mode power supplies for building in	
type/model	GP-235 TXS, GP-235 TX, GP-250 TXS, GP-250 TX	
ratings	See labels Attachment III	
class		
	Not for direct patient contact.	

Table of Attachments

Attachment / Title	Version/date	Pages
additional test data for EN 60601	14.10.1998 Attachment I	1
installation manual	14.10.1998 Attachment II	6
samples of model labels	14.10.1998 Attachment III	1
separation, creepage and clearance	14.10.1998 Attachment IV	15
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DE 1-7141



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Clause	Document/ Requirement	Comments	Result
6	Marking		
	1. Reference to accompanying document	use symbol # 14, of appendix D, table DI	N/A
	2. if there are secondary circuits suitable for direct patient contacts, statement needed for type of applied part	statement: installation manual must state which applied part symbol for the end use product may be use.(see also 6.8 item 1 of this report) (patient leakage current, and separation of this circuit has to be investigated)	N/A
6.8	Documentation		
	1. direct patient contact unit or normal unit	„Not for direct patient contact“.	Pass See manual Attachment III
	2. symbols used on unit outside	symbols used on the outside of the unit shall be explained in the installation manual	N/A
	3. simultaneously disconnection from mains is done by power supply cord	statement in installation manual is needed when power supply cord is used for this purpose. „The simultaneously disconnection from mains can only be achieved by removed the power supply cord.“	Pass
	4. class 1 equipment without two fuses, (not for fixed equipment)	Unit has two fuses	Pass
5. the conditions of installation must be specified: a.) unit only for installation in fixed medical equipment b.) when using the unit in medical electrical equipment the requirements of EN 60601-1 must be considered, especially the particular standards which are applicable for the end use product. c.) other conditions	conditions of the installation for medical electrical equipment	Pass Pass	

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Clause	Document/ Requirement	Comments	Result
19	Leakage currents tests	(use the IEC 601 measurement circuitry)	
	1. earth leakage current for fixed equipment	Limit: NC: 5 mA, SFC: 10 mA	N/A
	2. earth leakage current	Limit: NC: 0.5 mA, SFC: 1 mA	Pass *
	3. enclosure leakage current	Limit: NC: 0.1 mA , SFC: 0.5 mA	Pass *
	4. patient leakage current for type B and BF applied part	Limit: NC: 0.1 mA, SFC: 0.5 mA, only for direct patient contact circuitry	N/A
20	Separation	Attention: voltage > 250V r.m.s one has more strengthen requirements	
	1. for a reference voltage between 150 V to 250 V a test voltage of 4000V must be used (based on double isolation)	primary to secondary insulation: double/reinforced insulation: 5/8 mm, 4000V See also Attachment IV.	Pass
	2. reference voltage has to be measured with normal load of the unit	measured reference voltage: 245 V r.m.s maximum, See also Main Test Report, Addendum 6	Pass
	3. primary to secondary (DI)	test voltage base of measured reference voltage: AC 4000V	Pass
	4. SELV needs double insulation from primary and basic insulation from earth or earthed parts	SELV: measured - V dc/ac Not considered as SELV ; Secondary is earthed.	N/A
42	Normal Temperature Test		
	1. has to be conducted at rated voltage +/- 10% depending of the maximum power input	voltage used in test: e.g.: AC 253 V or AC 207 V or AC 230 V AC 90V - AC 132 V and AC 180V - AC 264 V See also Main Test Report ; Addendum 6	Pass
	2. 2.5 h or thermal equilibrium	test time: _____ thermal equilibrium	Pass
56.8	Indicators		
	1. to indicate that unit is energised	built in equipment, fulfilled by tested unit or must be investigated in end use product	N/A

* See also enclosed Attachment I ; Measurement of the Earth Leakage Current



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Clause	Document/ Requirement	Comments	Result
57.1	Separation from mains		
	1. by mains switch (3 mm distances at contact, 2 pole)	requirement fulfilled in tested unit or must be investigated in end use product, mains switch is not required, but when one is used the marking „O“ and „I“ is needed	N/A N/A
	2. by power supply cord	statement needed see 6.8 item 3 of this report	Pass
57.2	Mains auxiliary receptacles		
	1. labelling of output rating	AC 100 - 120V AC 200 - 240V / 2,5 A	Pass
	2. ordinary mains plug cannot be connected	appliance outlet (IEC-type) used	Pass
57.6	Mains fuses and overcurrent protection		
	1. class 1 unit: two fuses or statement in installation manual	2 fuses provided	Pass
	2. fixed installed class 1 unit: one fuse	- fuses provided, note: neutral shall not be fused	N/A
	3. class 2 unit: min one fuse in supply line	- fuses provided	N/A
57.8	Wiring of mains part		
	1. isolation of wire must be electrical equivalent to individual conductors of flexible supply cords complying with IEC 227 or 245	primary wiring is approved with equipment under test	Pass
	2. wiring before the fuse must have 0.75 mm ² up to rating 6 A 1 mm ² up to rating 10 A 1.5 mm ² up to rating 16 A 2.5 mm ² up to rating 25 A	1 mm ²	Pass
57.10	Creepage and clearances		
	1. see values in standard		Pass
	2. for 250 V the values are 8/5 mm	See Attachment IV	Pass

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APPENDIX 1 : Sub-clause 19.4.f :

MEASUREMENT OF THE EARTH LEAKAGE CURRENT

- Notes:
- 1.) The secondary output of the power supply is internal connected to protective earth, so that a switch position S12 = 0 is not applicable.
 - 2.) Primary and secondary circuits are always separated by reinforced insulation. All fault conditions are not able to decrease the effectiveness of the reinforced insulation.

Switch positions			NC (S1 = 1) measured μ A		SFC (S1 = 0) measured μ A		Addit. SFC (S1 = 1) measured in μ A *)	
S5	S10	S12	before	after	before	after	before 2.)	after 2.)
1	1	1	5,69	5,94	6,89	7,43	5,69	5,94
1	1	0	1.)		1.)		1.)	
1	0	1	254,0	278,0	496,0	524,0	254,0	278,0
1	0	0	1.)		1.)		1.)	
0	1	1	5,47	5,72	6,88	7,36	5,47	5,72
0	1	0	1.)		1.)		1.)	
0	0	1	247,0	269,0	494,0	516,0	247,0	2,69
0	0	0	1.)		1.)		1.)	

Remarks: S7 not used for classII equipment.

- NC = Normal condition
 SFC = Single fault condition
 1 = Switch closed
 0 = Switch open
 *) = describe additional SFC according to sub-clause 17a in notes above.

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