



EUROPEAN POWER SUPPLY MANUFACTURERS ASSOCIATION
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Medical Approvals for Power Supplies

Guidelines to the standard IEC60601

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This document gives an overview of design issues, definitions and useable standards currently used in AC/DC power supplies for medical applications. It aims to provide a common understanding of which safety rules and certifications should be used depending on the final application of the standard.

Furthermore this document provides a general interpretation of how different standards - requirements are in practice realized in power supplies.

This paper does NOT intend to be a standard

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1. Introduction

The development of power supplies for medical applications requires basic knowledge of the standard IEC60601. This application note highlights the main differences between the well known IEC60950 and IEC60601.

Status of the standard:

The standard EN60601-1:1990 was replaced by the standard EN60601-1:2006. So far the European Commission has not defined a date, as to when the older version of the standard will become invalid. Therefore both standard versions are still active and approvals to both standard versions are valid.

The standard DIN EN 60601-1:2005 contains a statement, that the old version EN60601-1:1996 should not be used after 2009-Sept-12.

This application note refers to the version EN60601-1:2006 (IEC60601-1:2005) and EN60950-1:2007. This application note is applicable for Power Supplies used within medical Products or Systems and not for a medical product itself. The assumption is, that the Power Supply output is valid for operator connection and will require an additional insulation to be connected to a patient.

When a power supply is approved to the old standard IEC60601-1:1996 it is useable also for end products to be approved to the version IEC60601-1: 2005. A statement in the summary of testing in the end product should be added with the following information:

- The power supply is approved to the older version of the standard IEC(or EN) 60601-1:1996. The additional requirements of the new version of the standard were reviewed as part of the end product evaluation. The abnormal testing done at the power supply approval was accepted as method to satisfy the requirement for a risk analysis.

Overview about international standard activities:

IEC	CENELEC	DKE	Health Canada	ANSI/AAMI
IEC 60601-1:2005 --	EN 60601-1:2006	DIN EN 60601-1:2007	CAN/CSA-C22.2 No. 60601-1:08 Has to be used from 1. Juni 2012	ANSI/AAMI ES60601-1: 2005 No dow known yet.
IEC 60601-1-2: 2007 --	EN 60601-1-2:2007	DIN EN 60601-1:2007	CAN/CSA-C22.2 No. 60601-1-2:08 Has to be used from 1. Juni 2012	ANSI/AAMI ES60601-1-2: 2007 No dow known yet.

2. Summary

An main difference between the EN60601-1:1990 and EN60601-1:2006 is, that the IEC60601-1:2005 distinguished between Parts which can come in contact with the Operator and Parts which can come into contact with the Patient, as well as Applied Parts. The terms Means of Operator Protection (MOOP) and Means of Patient Protection (MOPP) were therefore introduced. The requirements for MOOP are mostly derived from the standard IEC 60950-1.

A Power Supply which is approved in accordance to IEC60950-1 fulfills all insulation requirements for IEC60601-1 operator contact (MOOP = Means of Operator Protection). If patient contact is required (MOPP = Means of Patient Protection) the requirements of EN60601 for MOPP is requested.

3. Determination of Creepage and Clearance distances

3.1 Classification in “Equipment Parts”

“Mains Part”: primary voltages

“Applied Part” part of equipment that normally comes into physical contact with the patient

- “Live”: all parts carrying voltage. Criteria: if these parts are accessible or the earth current will exceed its specified maximum values if these parts are connected to ground.
- “Signal Output/ Input Part”: part of equipment not being a “applied part” intended to deliver or receive signals (for display or recording or data processing)
- “Patient Circuit”: Circuitry applied to patient (→ applied part)
- “Accessible part”: parts other than applied parts that can be touched without use of tools (standard test finger)

IEC60601 also mentions the term “SELV”. Yet SELV is not considered as safety voltage with respect to patient circuit. The term SELV “Safety extra low voltage” covers the operator contact.

Accessible parts are seen in conjunction to maximum earth leakage current always

3.2 Calculation of the required Insulation (Isolation diagram)

- “Basic Insulation”: insulation providing basic protection against electrical shock
- “Double Insulation”: insulation comprising both Basic and Supplementary Insulation
- “Reinforce Insulation”: single insulation that provides two means of protections
- “Supplementary Insulation”: independent insulation applied in addition to Basic Insulation in order to provide protection in the event of failure of the Basic Insulation

Please note, that the standard specifies different spacing requirement for operator or patient contact. So, reinforced for operator contact based on a working voltage of 230 Vac is 5 mm creepage and 4 mm clearance for the operator (2 MOOP) and 8 mm creepage and 5 mm clearance for the patient contact (2 MOPP)

3.3 Calculation of the working voltage “reference voltage”

The working voltage is either the voltage across the respected isolation measured or the input voltage, whatever is the higher value. The RMS value is relevant for the creepage and the peak voltage for the clearance.

3.4 Determination of Creepage and Clearance Distances

Creepage and clearance distances according to tables 11 – 16 of the standard. Typically 8 mm creepage and 5 mm clearance are needed for patient protection (table 12) for double means of patient protection (MOPP) at 230V working voltage.

Alternatives for reduced creepage and clearance distances:

- The transformer is constructed with an additional shielding winding between primary and secondary. The connection of this winding to protective earth must be lower than 0.1 Ohm @ 25A.
- Tripple insulated wire: needs an approval according IEC60950 Annex U. Each Layer must be able to carry the full test voltage (HV-test).
- If the transformer is compounded (vacuum compound / sealed) only 0,4 mm is needed between primary and secondary. (8.8.2)
- If the output is reliable grounded to protection earth, the input to output has to be insulated by basic insulation
- IEC60601-1:1996 allows a reduction of creepage and clearance by 1mm within the transformer if varnished wires are used (primary and secondary are varnished wires = 2mm). IEC60601-1:2005 does not allow this anymore (see 8.9.4).

Additional requirements to a power supply approved to IEC60950-1 to be suitable for use within a medical product:

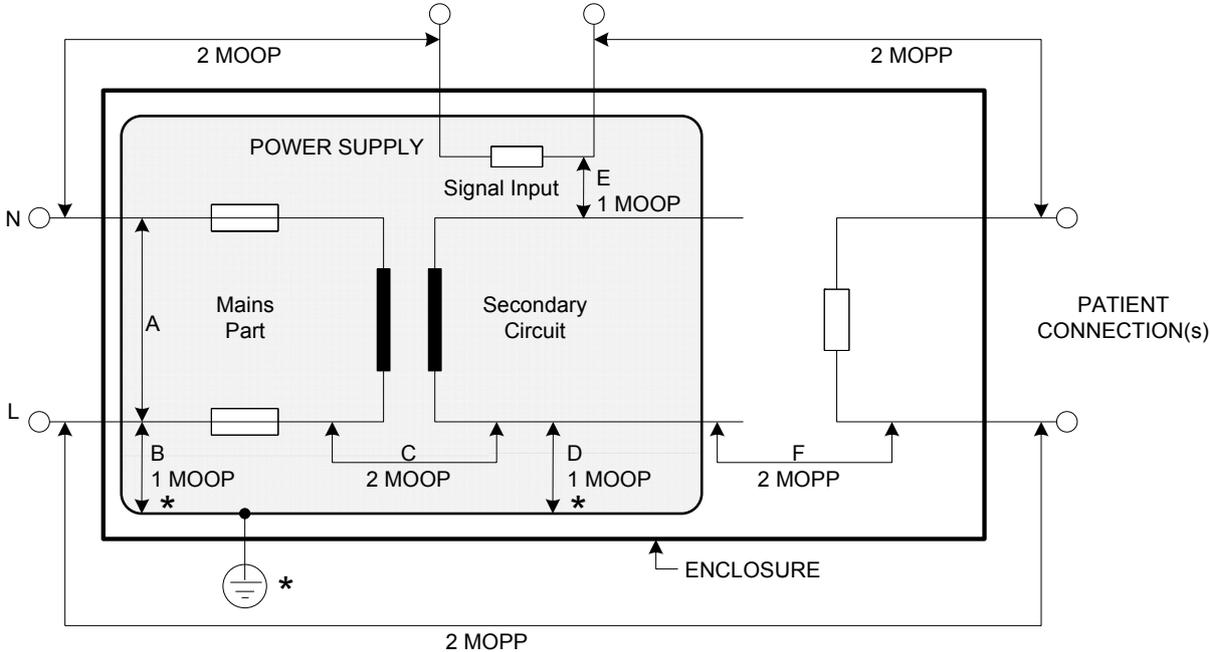
- Lower Touch current (500 μ A) for non permanent connected units. (USA 300 μ A, but center tap mains)
- Requirement for a risk analysis in accordance to ISO14971. The abnormal testing performed and a risk analysis mentioning the possible risks and the method for prevention will be acceptable as “risk analysis” for a component power supply. (A statement in the summary of testing should include that the risk analysis has to be performed in addition as part of the end product evaluation.)
- Mains voltage tolerance is min +/- 10 % (EN60950-1: +6%/ - 10% for voltage range)
- Additional requirements for identification, marking and documents (chapter 7)
- Insulation reinforced for operator protection could become bridged either by two Y2 or one Y1 capacitor.
- Mains switch or On/Off switch to be indicated by an adjacent indicator light or other ambiguous means (7.4.1). A Two Pole switch as disconnect device is mandatory.
- Units with Protection class I will require double pole fusing in Line and Neutral.

A power supply approved to IEC60950-1 fulfills (8.9.1.2) all insulation requirements to be used in a medical product and can be approved to EN60601-1: 2006 with almost no additional design changes if above additional requirements are met.

4. Construction Requirements

4.1 Insulation Diagram

General Insulation diagram for a medical product or System:



The supplementary insulation to the patient is an additional insulation outside of the power supply which generally also limits the power separated by a laser transmission. This is required outside of the power supply, because nobody would for example touch with a 24 V / 40 A power output, the open heart, without a dedicated additional separation. Because in almost all applications an additional insulation is required to the patient, in most cases it makes no sense to add reinforced insulation to the patient into the power supply.

The above block diagram describes a typical medical product. The power supply is rated for operator contact and requires therefore reinforced insulation 2 * MOOP (Means of operator protection) and 1 * MOPP (means to patient protection) = basic insulation.

Insulation F has to be a supplementary insulation to the patient.

Examples:

A: Line to Neutral: Functional insulation (according IEC/EN60950-1) or one MOOPP/ MOOP. (IEC60601-1:2005 allows to shorten the functional insulation to proof the insulation

B: Primary to earth B/I Operator protection = 1 MOOP / Patient protection = 1 * MOPP

C: Primary to Secondary: R/I Operator protection = 2 MOOP AND one MOPP.

D: Secondary to Earth: B/I Operator protection = 1 MOOP / Patient protection = 1 * MOPP

E: Secondary to Secondary: B/I Operator protection = 1 MOOP / Patient protection = 1 * MOPP

* if P/S is Class 1 (protectively earthed equipment): B, D → 1 MOOP

* if P/S is Class 2 (not protectively earthed equipment): B, D → 2 MOOP

4.2 Creepage and Clearance:

	Insulation	Voltage	Creepage (mm)	Clearance (mm)	Dielectric testing	Comment
A	Line to Neutral after fuse (functional)	230Vac	2,5	1,5	Test voltage High Pot: 1500 V	<p>According IEC60950-1 three methods are allowed to prove the insulation:</p> <ol style="list-style-type: none"> 1. Keep the spacing. The spacing for components like transistors is acceptable even smaller than the requirement, because the components are designed for the appropriate voltage and insulation. 2. Dielectric testing – would be done preferable on an empty PCB board or the external circuit breaker would have been defined. 3. Short the insulation – by defined external circuit breaker <p>See Table 11 of standard</p>

B	Primary to earthed enclosure (1 MOOP)	230Vac	2,5	2,0	Test voltage High Pot: 1500 V	Due to the TN mains the voltage Primary to earth has to be used as reference voltage or the measured operating voltage, whatever value is higher. Table 16 and 13
C	Primary to secondary (2MOOP / 1 MOPP)	230Vac	<u>5,0</u> / 4,0	<u>4,0</u> / 2,5	Test voltage High Pot: <u>3000 Vac</u> / 2500 Vac	Please note, that this is valid only for TN mains 230/400 Vac. MOOP: Table 13 and Table 16 MOPP: Table 12 Preferable the power supply should pass 4000 Vac, but is not required by the standard.
D	Secondary to earthed enclosure (1 MOOP)	24 Vdc	1,2	1,0	500 Vac	Functional insulation (see above comment) Table 15 and Table 16
E	Secondary to Secondary (Functional) 1 MOOP / 1 MOPP	24 Vdc	2,0/ 1,2	1,0/ 0,4	500 Vac	Functional insulation (see above comment) Table 15 and Table 16

4.3 Leakage current requirement

The standard defines touch current, earth leakage current and patient current. In our case the power supply is a built in product and not intended for direct patient contact. Therefore the touch current limit and the earth leakage values to clause 8.7.3 c, d have to be taken in consideration.

The leakage current has to be measured after humidity treatment and after abnormal testing is simulated. The leakage current is tested at 110 % of the rated voltage

	Normal	Single fault	Comment
Touch current	100 μ A	500 μ A	Three phase units are considered as permanent of connected with a plug Type B. The opening of PE is not considered as a single fault because of the connection. In Single phase equipment the PE open is a valid simulation of single fault. Other Single faults are
Earth leakage current	5 mA	10 mA	For permanent connected products the earth leakage current might be even higher.

Please note, the circuit to measure leakage current is different from IEC60950-1 to IEC60601-1.

The maximum patient current and patient auxiliary current is documented in table 3. The standard distinguished between patient leakage current to earth and patient leakage current produced by an external current (SIP/SOP) (see table 3 of the standard on next page).

The maximum allowable patient leakage current is 500 μ A AC and 50 μ A DC in normal operation (normal condition, NC) and 1000 μ A AC or 100 μ A DC in single failure condition (SFC).

Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION

Current in μA

Current	Description	Reference	Measuring Circuit		TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
					NC	SFC	NC	SFC	NC	SFC
PATIENT AUXILIARY CURRENT		8.7.4.8	Figure 19	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7 a)	Figure 15	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c)	Figure 17	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT ^a	With the same types of APPLIED PART connected together	8.7.4.7 a) and 8.7.4.7 h)	Figure 15 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c) and 8.7.4.7 h)	Figure 17 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
<p>Key NC = NORMAL CONDITION SFC = SINGLE FAULT CONDITION</p> <p>NOTE 1 For EARTH LEAKAGE CURRENT see 8.7.3 d). NOTE 2 For TOUCH CURRENT see 8.7.3 c).</p>										
<p>^a Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.</p>										

Type B, BF, and CF mean specific applications of the medical device, whether a part that has contact to the patient (applied part) complying with the specific requirements of this standard to provide protection against electrical shock, particularly patient leakage current and patient auxiliary current. Type CF provides highest degree of protection against electrical shock and is suitable for direct cardiac applications. Type B and BF applied parts are not suitable for direct cardiac applications, but BF provides higher degree of protection against electrical shock than type B, and is intended to deliver electrical energy or an electrophysiological signal to or from the patient.

4.4 Requirements for input stage

The input voltage range is specified for -10% to +10% of the nominal voltage (EN60950 -10% to +6%).

The Mains Switch ON/OFF needs to be an all-pole mains switch. Main switches shall have their ON/OFF positions clearly marked with the symbols (according IEC60417-5007ON or) -5008 OFF), or by an adjacent indicator light or LED.

Double pole fusing (each supply lead) is required in class I equipment except for conditions listed in section 8.11.5 of EN60601-1:2006 (IEC60601-1:2005).

4.5 Temperature measurement and requirements

The temperature measurement as IEC60950-1 can be used for a power supply. The IEC60601-1 does not require a subtraction of 10°C due to temperature measurement with the temperature sensor.

The EN60601-1 defines lower surface temperatures compared to IEC60950-1 (see table 23). This is not relevant for built in products.

The EN60601-1 defines in addition maximum temperatures for skin contact.

4.6 Requirements for the multilayer PCB board

Same as IEC60950.1 The distance for insulation thickness of 0,4 mm or three layers of insulation foil (Prepreg) are acceptable for reinforced insulation. The clause 8.9.3.1 requires a temperature cycle test even for PCB material (Multilayer with primary and secondary on one layer separated by insulation thickness). The temperature cycling test is not required for multilayer with Primary secondary insulated by three layers of prepreg and a distance between Prim-Sec on one layer related to the required creepage and clearance.

4.7 Dielectric Testing

The dielectric testing is identical to IEC60950-1 for operator contact. The dielectric testing for patient contact is higher according table 6 (4000 Vac for 230/400 V input). The dielectric testing voltage is either defined due to the mains voltage or the measured operational voltage primary to secondary.

In chapter 15 are now maximum temperatures defined for overload and short (similar to IEC60950-1 Annex C). The standard defines maximum current on primary in case transformers are protected by primary fuses to IEC60127-1.

4.8 Maximum output Energy

The IEC60601-1 does not define limited power source as IEC60950-1 2.5. For patient contacts there are energy and current limitations depending of the required patient applied part, which are not relevant for built in power supplies not intended for direct patient contact.

4.9 Enclosure and mechanical requirements

The clause 11.3 defines requirements for fire enclosure (same as IEC60950-1). In chapter 13.2 is described, that single fault conditions like melted metal should not become applied if a fire enclosure will be used to clause 11.3. Most test houses do not allow melted metal like on a PCB trace. According to IEC60601-1 melted metal is not to be used as fault criteria, if a fire enclosure is used.

5. Risk Analysis

A risk analysis is mandatory. The risk analysis is based on ISO14971. Potential risks and how they can be avoided. The risk analysis should cover the intend use of power supply, identify hazardous conditions and should cover a risk estimation for each hazardous situation. The result of the risk analysis should be used to determine which failures should be tested. A risk evaluation shall provide a risk acceptability decision. It covers the requirements of the standard EN60601-1 and the result of abnormal testing according to this standard and EN60950 as well.

6. Conditions of Acceptability

The conditions of acceptability are part of the safety report. They define under which conditions the tests were done and the product passed. An example of a possible Summary of Conditions of Acceptability is described below:

This component has been judged on the basis of the Standard for Medical electrical equipment IEC 60601:2005, EN 60601-1:2006, DIN EN 60601-1:2007, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1: 2005.

The unit is a protection class I Power Supply for built in.

The products were tested to be suitable for connection to 20 A USA branch circuit and a ≤ 16 A IEC branch circuit. The unit is approved for TN mains star connections

All secondary output circuits are separated from mains by reinforced insulation and rated SELV hazardous energy levels.

The unit is protection class I and provides one means of operator protection and one means of patient protection and a protective earth connection to metal enclosure.

The unit provides two means of operator protection between primary and secondary. For use with an equipment intended for patient connection, this power supply fulfills the requirements for one Means of Patient protection from primary to secondary. The Means of Patient Protection have to be evaluated for the end product.

A Copy of the Risk Analysis and all needed accompanying documents (manual, technical description) of the end product are stored at xxxx. Compliance of the risk management process was checked by inspection of the Risk Management File.