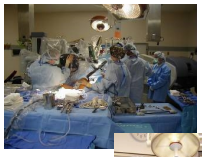
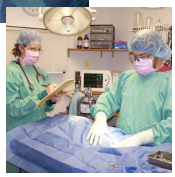
XP Power

XPerts in Power - Module 17
Medical Safety

Diana Izvorska

Agenda





- Introduction
- Conformance Route – Europe, USA
- Structure of 60601-1
- General Philosophy
- Electric Shock and Harm
- Terminology
- Insulation diagram
- Requirements
- Differences between 60601 and 60950
- What is new in 3rd edition
- 2nd edition vs 3rd edition
- Risk Management and 60601
- MOP and Impact on PSU
- XP Position on 3rd edition
- How We Have Addressed Risk Management

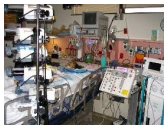
Where does Healthcare Equipment get used?

LABORATORY PRODUCTS

HOSPITALS, PHARMCEUTICAL RESEARCH, OUTSIDE DIAGNOSTIC LABS

PATIENT VICINITY PRODUCTS

HOSPITALS, OUT PATIENT CLINICS, DOCTOR'S OFFICES, HOMES, SHOPPING MALLS, AIRCRAFT, ETC



World Governing Bodies

- USA - Food and Drug Administration (FDA)
- Europe - European Union Medical Devices Directive (MDD 93/42/EEC)
- Japan - Ministry of Health, Labor and Welfare (MHLW)
- Canada - Therapeutic Product Directive

FDA

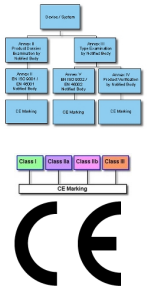
CE
EN455

厚生労働省許可
特定保健用食品

Canada
Health Canada

Conformance Route – Europe

Class I Devices - Generally, require just Internal Control of Production and compilation of a Technical File. The Technical File then has to be held in case of a request by a Competent Authority. The final step is Self Certification and Registration with a Competent Authority.
Class IIa Devices - Require a Quality Management System to ISO 13485:2003 or ISO 9001:2000 or Annex V and compilation of a Technical File. The final step is an audit by a Notified Body.
Class IIb Devices - Require a Quality Management System to ISO 13485:2003 and compilation of a Technical File. The final step is an audit by a Notified Body.
Class III Devices - Being the highest risk devices, it is necessary to implement a Quality Management System to ISO 13485:2003 and compilation of a Design Dossier which is a more detailed Technical File. The final step is an audit by a Notified Body.



CE

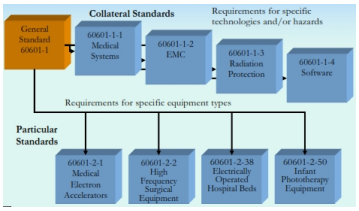
Conformance Route – USA

FDA Medical Device Regulatory Classification System

Classification System	Risk Level	% of All Devices	Regulatory Hurdle	Example Devices
Class I	Low	46%	No 510k* or PMA** needed	Dental floss, wheelchairs, thermometers, manual surgical instruments, research diagnostics
Class II	Moderate	47%	510k*	Facial implants, sutures, vascular clamps, urologic catheters, clinical diagnostics
Class III	Moderate to High	7%	PMA** needed as new indications are being claimed	Breast implants, pacemakers, stents, vascular grafts

* 510k must demonstrate intended use, performance data, labeling, sterilization and packaging as well as compliance with special controls and substantial equivalence to a predicate device.
** PMA must show reasonable assurances of safety and effectiveness and where the safety outweighs the probable risks. The efficacy has to be demonstrated in a target population with clinically significant results.

Structure of 60601-1



IEC60601-1: EU EN60601-1:2006, US ANSI/AAMI ES60601-1:2005, CAN CSA-C22.2 No60601-1:08

General Philosophy – Two Means of Protection

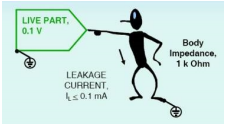
- Requires product to have two Means of Protection (MOP) to meet requirements.
- IEC60601-1 permits three building blocks to meet two MOPs. These are insulation, protective earthing and protective impedance.
- IEC60601-1 is based on same concept as risk management. It uses one or more of the following risk-control measures:
  - Forces inherent safety design
  - Imposes protective measures in medical device

Abbreviation	Earth Type	LOP
FE	Functional earth	0
PE	Protective earth	1

Abbreviation	Insulation Type	LOP
OP	Operational	0
BOP	Basic opposite polarity	0
B	Basic	1
S	Supplementary	1
D	Double	2
R	Reinforced	2

Protection against Electrical Shock

- Electrical current passing through the body can cause electric shock. This is dependent on the voltage and the body impedance.
- The fundamental principle is to limit the accessible current, therefore protecting against shock.
- This is achieved by placing high impedance (insulation) in the current path, or limiting the accessible voltage (earthling).



Electric Shock Harm

Harm	Thresholds (not limits)
Startle reaction:	0.5mA, 50/60Hz (Hand)
Inability to let-go:	10mA, 15-100Hz (Arm)
Ventricular fibrillation:	35mA, 15-100Hz (hand-foot)
	0.01mA, 50/60Hz (Heart, direct)

Body impedance is normally 1000 ohms (dry hand-to-hand body impedance)

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Terminology – Electrical Classification

- Class 1 Equipment - Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for the connection of the equipment to the protective earth connector in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

- Class II Equipment - Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

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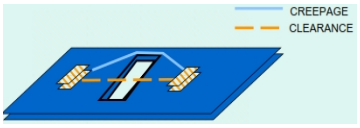
Terminology – Creepage and Clearance



- Creepage Distance - This is the shortest path along the surface on insulating material between two conductive parts.
- Air-clearance Distance - This is the shortest path in air between two conductive parts.

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Terminology - Fault Conditions

- Normal Condition (NC) is an event considered likely to happen ,i.e. reverse polarity of supply mains
- Single Fault Condition (SFC) is a single event that could occur, i.e. interruption of protective earth.

LIKELY TO OCCUR (NORMAL CONDITION)
Reverse polarity of supply mains
Failure of insulation less than basic
COULD OCCUR (SINGLE-FAULT CONDITION)
Interruption of protective earth
Interruption of one supply conductor
Mains voltage on floating (F-type) applied part(s)
Mains voltage on communication ports
Failure of electrical components, one at a time
Failure of mechanical parts, one at a time
Failure of temperature-limiting devices, one at a time
Shorting of basic or supplemental insulation
Overload of mains supply transformers
Interruption and short circuit of motor capacitors
Locking and moving parts
Impairment of cooling (fans, vents)
UNLIKELY TO OCCUR (NOT EVALUATED)
Total breakdown of double or reinforced insulation
Loss of protective earth on permanently installed equipment
More then one single-fault condition at a time
Failure of a UL-recognized Y1 capacitor, acting as a barrier

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Terminology – Dielectric Strength

- Also known as withstand voltage, it is the amount of voltage an insulation barrier will withstand before it breaks down. It is based on the working voltage used in the product, for example a PSU operating at 230VAC will have a primary to secondary withstand voltage of 4000VACrms

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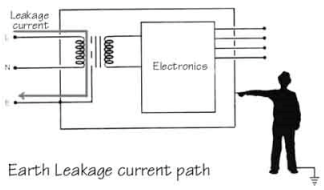
Terminology – Leakage Current

- *Earth Leakage Current* - Current flowing from the mains parts through or across the insulation into the protective earth conductor"



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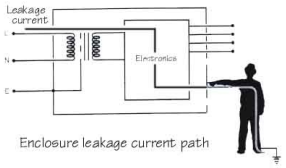
Terminology – Leakage Current

Enclosure Leakage Current - Current flowing from the enclosure, or parts thereof, excluding applied parts, accessible to the operator or patient in normal use, through an external conductive connection other than the protective earth conductor to earth or to another part of the enclosure



Enclosure leakage current path

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Terminology – Leakage Current

- *Patient Leakage Current* - Current flowing from the applied part via the patient to earth, originating from the unintended appearance of a voltage from an external source on the patient.

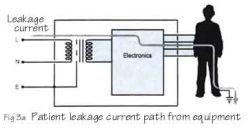

Fig 3a Patient leakage current path from equipment

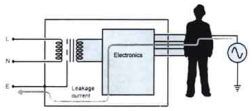

Fig 3b Patient leakage current path to equipment

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Terminology – Patient Vicinity

- Patient Vicinity - An area in which patients are normally cared for, the patient vicinity is the space with surfaces likely to be contacted by the patient or an attendant who can touch the patient. This encloses a space within the room 6 ft beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 7.5ft above the floor. (UL60601-1 definition).

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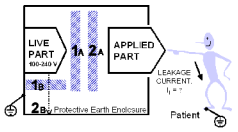
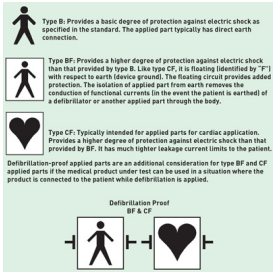
Terminology – Applied Parts

- Applied Part – Entirety of all parts of equipment including the patient leads which come intentionally into contact with the patient to be examined or treated.
- Patient circuit – Electrical circuit of which the patient forms a part.
- F – type Applied Part – Floating, isolated applied part which is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when voltage equals to 1.1 times the highest rated mains voltage is applied between the applied part and earth.

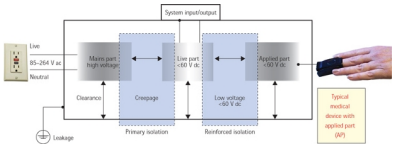


Terminology – Applied Parts



Insulation Diagrams

- These are used to identify:
  - Insulation types, earthing types and reference voltages
  - Physical requirements such as creepage and clearance
  - Dielectric strength values (test requirements)
  - Alternative constructions



Creepage and Clearance - Requirements

Table XVI
CREEPAGE DISTANCES and AIR CLEARANCES in millimetres[1)]

	d.c. voltage	15	36	75	150	300	450	600	800	900	1 200	
	a.c. voltage	12	30	60	125	250	400	500	660	750	1 000	
Equivalent to BASIC INSULATION between parts of opposite polarity	A-f	0,4	0,5	0,7	1	1,6	2,4	3	4	4,5	6	AIR CLEARANCES
		0,8	1	1,3	2	3	4	5,5	7	8	11	CREEPAGE DISTANCES
BASIC INSULATION OF SUPPLEMENTARY INSULATION	A-a1, A-b, A-c, A-j	0,8	1	1,2	1,6	2,5	3,5	4,5	6	6,5	9	AIR CLEARANCES
	B-d, B-c	1,7	2	2,3	3	4	6	8	10,5	12	16	CREEPAGE DISTANCES
DOUBLE INSULATION OR REINFORCED INSULATION	A-a2, A-e, A-k	1,6	2	2,4	3,2	5	7	9	12	13	18	AIR CLEARANCES
	B-a, B-e	3,4	4	4,6	6	8	12	16	21	24	32	CREEPAGE DISTANCES

1) This table replaces Tables XVI and XVII of the first edition.

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Leakage Current - Requirements

Table IV
***Allowable values of continuous LEAKAGE and PATIENT AUXILIARY CURRENTS, in milliamperes**

Current		Type B		Type BF		Type CF	
		N.C.	S.F.C.	N.C.	S.F.C.	N.C.	S.F.C.
EARTH LEAKAGE CURRENT general		0,5	1[1)]	0,5	1[1)]	0,5	1[1)]
EARTH LEAKAGE CURRENT for EQUIPMENT according to notes 2) and 5)		2,5	5[1)]	2,5	5[1)]	2,5	5[1)]
EARTH LEAKAGE CURRENT for EQUIPMENT according to note 3)		5	10[1)]	5	10[1)]	5	10[1)]
ENCLOSURE LEAKAGE CURRENT		0,1	0,5	0,1	0,5	0,1	0,5
PATIENT LEAKAGE CURRENT according to note 5)	d.c.	0,01	0,05	0,01	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5	0,01	0,05
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the SIGNAL INPUT PART OF SIGNAL OUTPUT PART)		–	5	–	–	–	–
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)		–	–	–	5	–	0,05
PATIENT AUXILIARY CURRENT according to note 5)	d.c.	0,01	0,05	0,01	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5	0,01	0,05

N.C.: NORMAL CONDITION
S.F.C.: SINGLE FAULT CONDITION

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Dielectric Strength - Requirements

Table V
Test voltages

Insulation to be tested	Test voltages for reference voltage (*U*/V)					
	U≤50	50<*U* ≤150	150<*U* ≤250	250<*U* ≤1 000	1 000<*U* ≤10 000	10 000<*U*
BASIC INSULATION	500	1 000	1 500	2*U* + 1 000	*U* + 2 000	1)
SUPPLEMENTARY INSULATION	500	2 000	2 500	2*U* + 2 000	*U* + 3 000	1)
REINFORCED and DOUBLE INSULATION	500	3 000	4 000	2(2*U* + 1 500)	2(*U* + 2 500)	1)

1) If necessary, to be prescribed by Particular Standards.

NOTES

1 Tables VI and VII, not used.

2 Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal a.c., the test may be performed using a sinusoidal 50 Hz test voltage. In this case the value of the test voltage shall be determined from table V using a reference voltage (*U*) equal to the measured peak-to-peak voltage divided by 2√2.

*See rationale for 20.3

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Difference between IEC60601 and IEC60950

Insulation Type	Reference Voltage	IEC 60601-1			IEC 60950[a]		
		CR (mm)	CL (mm)	DS (kV)	CR (mm)	CL (mm)	DS (kV)
B	120	3	1.6	1	1.5	1	1
S	120	3	1.6	2	1.5	1	1
D/R	120	6	3.2	3	3	2	2
B	240	4	2.5	1.5	2.5	2	1.5
S	240	4	2.5	2.5	2.5	2	1.5
D/R	240	8	5	4	5	4	3

[a] Assumes typical Installation Category II, Pollution Degree 2, and Material Grade IIIb.

	IEC 60601-1		IEC 60950	
	Normal (mA)	Single fault (mA)	Normal (mA)	Single fault (mA)
Earth leakage	0.5 (U.S. dev. 0.3)	1	3.5[a]	N/A
Enclosure leakage	0.1	0.5 (U.S. dev. 0.3)	N/A	3.5[a]

IEC 60950	IEC 60601-1
Likely fault	Single-fault condition
Hazardous voltage	Mains part, live part
Safety extra low voltage (SELV)	Signal input part (SIP), signal output part (SOP)
N/A	Applied part (AP), patient connection
Insulation grade: Basic Supplementary Double Reinforced	Insulation type: Basic Supplementary Double Reinforced
Air clearance (CL)	Air clearance
Creepage distance (CR)	Creepage distance
Electric strength	Dielectric strength (DS)
Distance through insulation (DTI)	Transformer layer insulation
Working voltage: RMS or dc for CR; RMS/peak for CL/peak, or dc for electric strength	Reference voltage: RMS or dc for CR, CL, DS, (some peak exceptions for DS)
Protective conductor current Defined in 3rd edition (1999-04); in current CSA/UL and CENELEC requirements, protective conductor current is referred to as earth leakage current	Earth leakage current
Touch current Defined in 3rd Edition (1999-04); in current CSA/UL and CENELEC requirements, touch current is not defined.	Enclosure leakage current

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What's new in 3rd edition

- Revolutionary new device standard, first published in December 2005
- Introduction of Mean of Patient Protection (MOPP) and Means of Operator Protection (MOOP)
- Safety broadened from Basic Safety to Essential Performance
- Require application of Risk Management and RM process needs to be defined according to ISO14971
- Terminology brought in line with IEC60950
- Altitude multiplication factors included

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2nd Edition vs 3rd Edition

- Noise and vibration limits introduced
- Temperature of accessible parts more detailed, with time limit included
- Earth leakage current has changed. 2nd edition limits were 0.5mA NC, 1mA SFC, 3rd edition is 5mA NC, 10mA SFC
- Touch current introduced – this was enclosure leakage current. Requirements are unchanged.
- Total patient leakage current introduced
- MOOP and MOPP introduced - MOOP follows IEC60950 requirements and MOPP follows IEC60601-1 2nd edition requirements
- Insulation & dielectric strength and creepage and clearance distances changed.
- Fire enclosure requirements changed
- Use of Y1 and Y2 capacitors has changed

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Risk Management and 60601

- 3rd edition states:

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

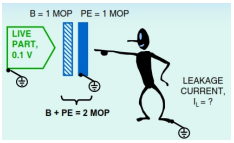
A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.

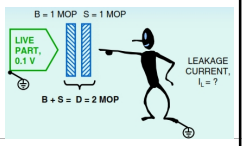
Compliance is checked by inspection of the RISK MANAGEMENT FILE. The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:

- *established a RISK MANAGEMENT PROCESS;*
- *established acceptable levels of RISK; and*
- *demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).*

What is Means of Protection (MOP)

- 60601 Safety Philosophy: Medical equipment shall be single fault safe, i.e. free of unacceptable risk under single fault conditions
- Means between hazardous voltages and patient/operator must be two MOP in normal conditions
- MOP divided into two categories:
  - MOOP – means of operator protection (follows 60950)
  - MOPP – means of patient protection (follows 60601-1 2nd edition)
- Philosophy of two means of protection has not changed – known as Level of Protection (LOP) in 2nd edition





Impact on PSUs

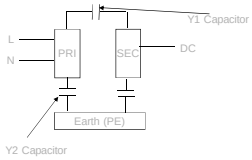
- Biggest impacts are:
  - MOOP vs MOPP – effects, separation and dielectrics
  - Risk management File required for every product
  - Type of Y capacitors used for EMI suppression
- From section 8.5.1.2 :

A Y1 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION provided that it will pass the dielectric strength test for two MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance.

- From section 8.5.1.3 :

A Y2 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF OPERATOR PROTECTION provided that it will pass the dielectric strength test for one MEANS OF OPERATOR PROTECTION. A Y1 capacitor complying with IEC 60384-14 is considered equivalent to two MEANS OF OPERATOR PROTECTION provided that it will pass the dielectric strength test for two MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance.

How does this relate to Power Supplies?



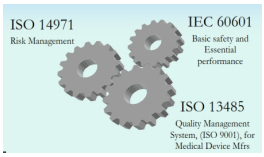
- Under 2nd edition this would be acceptable as it provides 2 x LOPs.
- Under 3rd edition this would provide 1 x MOPP between input and output and 0 x MOPP between input and earth, although it would provide 2 x MOOP between input and output and 1 x MOOP between input and ground.
- To ensure output can be considered 2 x MOPP and input is 1 x MOPP then Y2 capacitor must be changed to a Y1 and 2 x Y1 capacitors must be used to bridge primary and secondary.

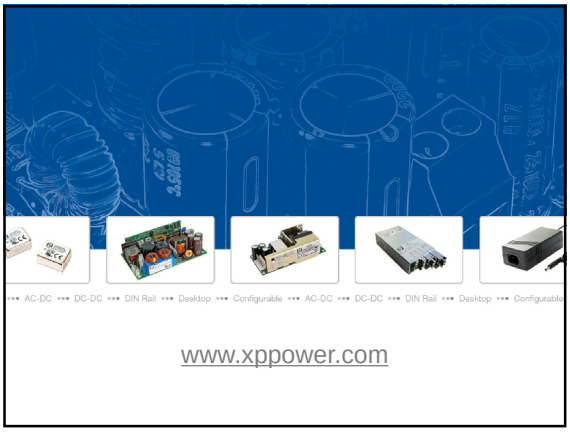
XP's Position on 3rd Edition

- Our goal is to comply with 2 x MOPP.
- All products to be updated to 3rd edition provided it makes economic sense.
- New products to be designed so that input to output is considered 2 x MOPP and input to ground is considered 1 x MOPP.
- FMEA is being performed on all new products to help with risk management.
- Risk Management process established and RMF for each product

How we have addressed Risk Management

- To satisfy with 3rd edition requirements risk management process is incorporated into design process
- Based around ISO14971
- Risk management file consists of approximately 14 pages
- Process developed with guidance from UL
- Factory certified to ISO13485





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