entela

Entela Canada Inc.
Presents:

Medical Equipment and Systems:
Designing for Compliance to IEC 60601

including National Deviations

US: UL 2601-1

Canada: CAN/CSA C22.2 No. 601.1

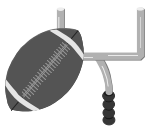
Europe: EN 60601-1

IEC 60601 Seminar

ICEBREAKERS

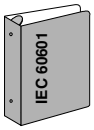
Introduction of Attendees

Expectations of Attendees



Contents of Participant Manual

MODULE 1 Role of IEC 60601
MODULE 2 Structure of IEC 60601 and UL 2601
MODULE 3 General Philosophy of IEC 60601
MODULE 4 Protection Against Electric Shock
- Insulation Diagrams
MODULE 5 Protection Against Electric Shock
- Requirements



Contents of Participant Manual

MODULE 6 Protection Against Electric Shock
- Compliance (Design & Construction)
MODULE 7 Protection Against Electric Shock
- Compliance (Testing)
MODULE 8 Protection Against Mechanical Hazards
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MODULE 10 Construction
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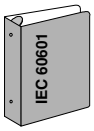


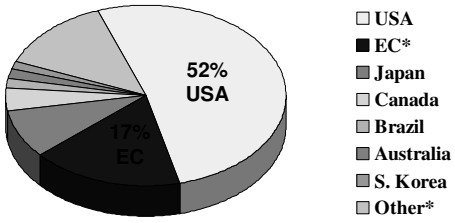
1. Role of IEC 60601

1. Objectives

- ✓Identify key safety requirements for medical electrical equipment
- ✓Explain the worldwide benefits of designing a product to IEC 60601, including national deviations such as UL 2601-1, EN 60601-1, and CAN/CSA C22.2 No. 601.1

Medical Device Marketplace

U.S. Electromedical Factory Sales



*Source: U.S. Dept. of Commerce. Export data is 1995. *EC includes only top 5 countries. Remaining 10 included in Other. Total 1995 factory sales estimated from 1994 data (only available) by adding 7% (average growth over last 10 years).*

FDA Requirements

- ✓Medical devices must be “Safe and Effective…” (Federal Food, Drug and Cosmetic Act)
- ✓“Design validation shall include…risk analysis...” (QSR: 21 CFR 820.30(g)

European Community Requirements

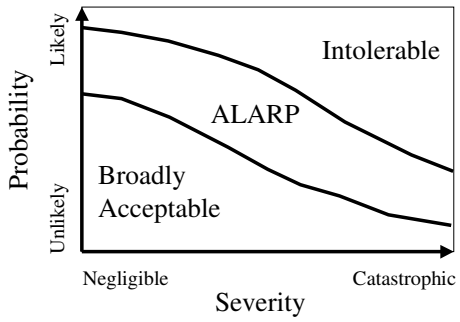
- ✓Medical devices “must meet the essential requirements” (MDD: 93/42/EEC, Article 3)
- ✓Risk analysis needed to describe solutions adopted to meet essential requirements (MDD: 93/42/EEC, Article 3; Annex I, ER 1; Annexes II, III, VII)

Risk Analysis - Key Terms

- ✓Hazard: “A potential source of harm”
- ✓Risk = Probability * Severity
- ✓Harm: “Physical injury or damage to health or property”

ISO 14971-1

Risk Regions



ALARP = As Low As Reasonably Practicable

Role of Standards

- ✓Consensus documents
- ✓Define "Broadly Acceptable" region
  - Or in some cases, "ALARP"
- ✓Considered minimal level of safety

FDA Requirements

- ✓FDA recognized consensus standards can be used to support declaration of conformity (New 510(k) Paradigm, "Abbreviated 510(k)")
  - IEC 60601 + national deviations (UL 2601) is a recognized consensus standard

European Community Requirements

- ✓Compliance is presumed by conformity to the harmonized standards in the Official Journal of the EC (93/42/EEC, Article 5)
  - IEC 60601 + regional deviations (EN 60601) is a harmonized standard

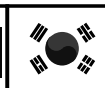
Rest of World Requirements

- ✓IEC 60601 forms basis for national medical product safety standards in many countries
  - Japan, Canada, Brazil, Australia, S. Korea, others

IEC 60601 Based Standards

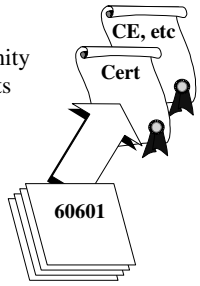
				
National Safety Standard	**UL 2601-1**	**EN 60601-1**	**JIS T1001, 1002**	**CAN/CSA C22.2 No. 601.1**

IEC 60601 Based Standards -- con't

			
National Safety Standard	Based on IEC 60601-1	AS/NZS 3200-1-0	IEC 60601-1

Worldwide Benefits of Compliance with IEC 60601

- ✓Facilitate legal market *access*
  - Supports declaration of conformity to regulatory safety requirements
- ✓Facilitate market *acceptance*
  - Supports obtaining 3rd Party Marks



IEC 60601 Based 3rd Party Marks

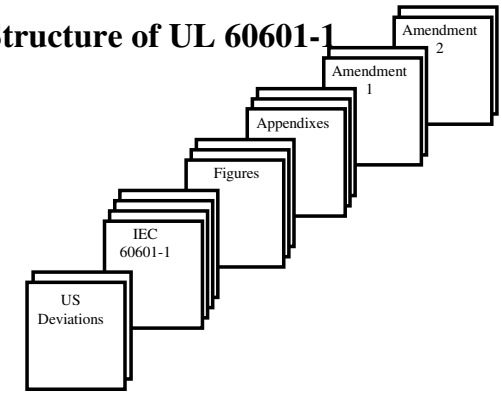
- ✓IECEE NCB Scheme (Medical)
  - Members agree to exchange IEC 60601 compliance documents
  - Supports obtaining 3rd party certification marks
  - Participating members include: Australia, Austria, Canada, Czech Republic, Denmark, Finland, France, Germany, Hungary, India, Israel, Italy, Netherlands, Norway, Sweden, United States (as of 11/24/98)

2. Structure of IEC 60601

2. Objectives

- ✓Explain the structure of IEC 60601-1: General Requirements for Safety
- ✓Explain the role of amendments, collateral standards, particular standards and national deviations

Structure of UL 60601-1



UL 60601-1, U.S. Deviations

- ✓Located in the front of UL 2601-1, page 8
- ✓Address U.S. national concerns
  - Resulting from National Electrical Code® (NEC®)
    - » Electrical supply installation differences
  - Other national deviations
    - » Component differences, Supplement A
  - Rationale statement
    - » Explanatory Information, Appendix B

National Electrical Code and NEC are registered trademarks of National Fire Protection Association

IEC 60601-1: General Requirements for Safety, Part 1

- ✓Included in the body of UL 2601-1, page 40
- ✓Applies to all equipment that falls within the scope of the standard
- ✓Contains the primary safety requirements for this type of electrical equipment
- ✓Organized by hazard

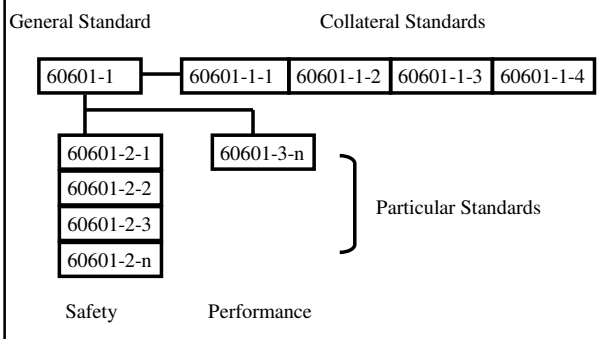
IEC 60601-1 Print Type

- ✓Requirements appear in roman type
- ✓Explanations appear in smaller type
- ✓Test specifications appear in *italic type*
- ✓Key terminology appear in CAPITAL LETTERS
- ✓Requirements with rationale in Appendix A are preceded with an *

IEC 60601-1 Amendments

- ✓Amendments 1 and 2 to IEC 60601-1 are included at the end of UL 2601-1, pages 251, 277
- ✓Revisions to the Standard

IEC 60601 Series of Standards



Collateral Standards

- ✓Identified as IEC 60601-1-X
- ✓Horizontal standards
  - Requirements for specific technologies and/or hazards
  - Apply to all equipment
- ✓Must be used in addition to the Part 1 requirements
- ✓Revisions are issued as Amendments

IEC 60601-1-X: Collateral Standards

Standard	Subject
IEC 60601-1-1	Medical Systems
IEC 60601-1-2	EMC
IEC 60601-1-3	X-Radiation
IEC 60601-1-4	Programmable Electric Medical Systems (Software)

Particular Standards

- ✓Identified as IEC 60601-2-XX
- ✓Vertical standards
  - Requirements for specific equipment types
- ✓Must be used in addition to the Part 1 requirements
- ✓Revisions are issued as Amendments

IEC 60601-2-X: Particular Standards

Standard	Subject
IEC 60601-2-2	High Frequency Surgical Equipment
IEC 60601-2-18	Endoscopic Equipment
IEC 60601-2-25	Electrocardiographs
IEC 60601-2-32	Associated Equipment of X-ray Equipment

Partial List of Particular Standards
For up-to-date list check IEC Web Page (www.iec.ch)

US Deviations

- ✓Collateral Standards optional
- ✓Applicable Particular Standards required
  - If < 2 years old, compliance optional
- ✓Most efficacy requirements addressed by FDA

3. General Philosophy

3. Objectives

- ✓Define MEDICAL ELECTRICAL EQUIPMENT
- ✓Identify relevant requirements based on equipment hazards
- ✓Explain the underlying principles behind IEC 60601

MEDICAL ELECTRICAL EQUIPMENT - Definition

- ✓See Clause 2.2.15 in Part 1, and Amendment 2, pages 50, 281

Electrical EQUIPMENT, provided with not more than one connection to a particular SUPPLY MAINS and intended to diagnose, treat, or monitor the PATIENT under medical supervision and which makes physical or electrical contact with the PATIENT and/or transfers energy to or from the PATIENT and/or detects such energy transfer to or from the PATIENT.

The EQUIPMENT include those ACCESSORIES as defined by the manufacturer which are necessary to enable the NORMAL USE of the EQUIPMENT

ACCESSORY - Definition

✓See Clause 2.1.3 in Part 1, page 48

Optional component necessary and/or suitable to be used with EQUIPMENT in order to enable, facilitate or improve the intended use of EQUIPMENT or to integrate additional functions.

Exercise 3.1

✓Identify whether the following Equipment falls within the scope of IEC 60601-1

Equipment	Intended Use	Yes/No
Tongue depressor	Visually inspect pharynx	**No Not Electric**
Endoscopic camera	Inspect pipe, but doctors see medical applications	
ECG Monitor	Monitor and allow diagnosis of heart beat rhythm	
Computer	Diagnostic image capture and enhancement hard/software	
Cart with isolation transformer and powertap	Power ITE connected to diagnostic equipment	

Hazards Addressed by IEC 60601

✓See table of Contents, page 40

Electric Shock Hazard -- Section Three

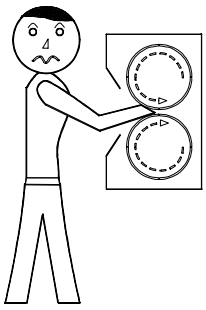
✓Hazard
- Electric current passing through the human body

✓Harm
- startle reaction
- inability to let-go
- ventricular fibrillation
- cell damage
- burn hazard (high frequency)

Mechanical Hazard -- Section Four

✓Hazard
- Moving parts/instability
- Sharp edges and corners
- Flying particles
- Suspended Masses

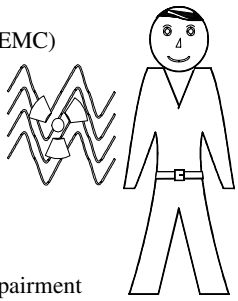
✓Harm
- Cuts, laceration, puncture
- Contusion, abrasion
- Crushing, fracture



Radiation Hazard -- Section Five

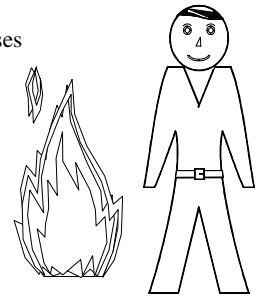
✓Hazard
- Electromagnetic radiation (EMC)
- Laser (light) radiation
- X-radiation
- Ultraviolet (UV) light

✓Harm
- Visual Impairment
- Burns, Genetic Defects
- Equipment Malfunction/Impairment



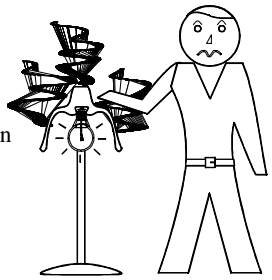
Flammable Anaestectics Hazard -- Section Six

- ✓Hazard
  - Ignition of flammable gases
- ✓Harm
  - Burns
  - Smoke inhalation
  - Equipment damage



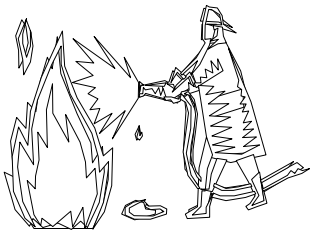
Excessive Temperature Hazard -- Section Seven

- ✓Hazard
  - High temperatures
- ✓Harm
  - Burns, Insulation/ Component degradation
  - Ignition of flammable materials
  - Flying projectiles



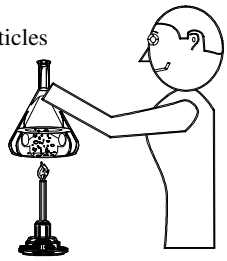
Fire Hazard -- Section Seven

- ✓Hazard
  - Fire
- ✓Harm
  - Smoke Inhalation
  - Burn
  - Water Damage



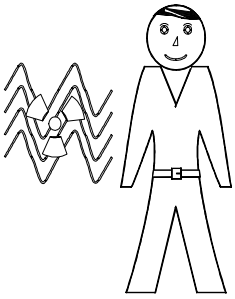
Other Hazards -- Section Seven

- ✓Hazards
  - Pressure Vessels/Flying particles
  - Wetting of parts
  - Biocompatibility
- ✓Harm
  - Cuts, laceration, puncture
  - shock/degradation
  - Skin Irritation, poisoning, reproductive/developmental impairment



Accuracy and Output Hazards -- Section Eight

- ✓Hazards
  - Inaccurate Operating Data
  - Hazardous Output
- ✓Harm
  - Misdiagnosis
  - Patient Injury



Abnormal Ops & Fault Hazard -- Section Nine

- ✓Hazards
  - emission of flames/gases
  - ENCLOSURE deformation
  - Excessive Temps
- ✓Harm
  - Irritation, poisoning
  - Electric Shock (Accessibility)
  - Burns

Exercise 3.2

✓For an Electrocardiograph (ECG), identify Hazards, possible Harm and relevant Section providing safety requirements

Hazard	Harm	Section
Electric Shock	Ventricular Fibrillation	3

"Broadly Acceptable" Level of Risk -- Background

✓IEC 60601-1, Appendix A, page 200
- General Guidance and Rationale

✓IEC 60513
- Basic Aspects of the Safety Philosophy of Electrical Equipment used in Medical Practice

"Broadly Acceptable" Level of Risk -- Requirement

✓IEC 60601-1, Clause 3.1, page 59

✓Single fault tolerance/Two levels of protection

EQUIPMENT shall, when transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, cause no SAFETY HAZARD which could reasonably be foreseen and which is not connected with its intended application, in NORMAL CONDITION and in SINGLE FAULT CONDITION.

“Likely” SINGLE FAULT CONDITIONS

✓IEC 60601-1, Clause 3.6, page 59

a) Interruption of PROTECTIVE EARTH
b) Interruption of one supply conductor
c) External voltage on F-TYPE APPLIED PART
d) External voltage on SIP/SOP
e) Leakage FLAM. ANAESTHETIC MIX.
f) Leakage of liquid
g) Failure of electrical component
h) Failure of mechanical parts
j) Failure of temperature limiting devices

“Unlikely” SINGLE FAULT CONDITIONS

✓IEC 60601-1, Clause 3.7, page 60

a) Breakdown of DOUBLE INSULATION
b) Breakdown of REINFORCED INSULATION
c) Interruption of permanently installed PROTECTIVE EARTH

4. Protection Against Electric Shock

Insulation Diagrams

4. Objectives

- ✓Explain acceptable current and voltage levels for protection against Electric Shock Hazards
- ✓Construct Insulation Diagrams to define insulation types, earthing, and reference voltages, providing 2 levels of protection against Electric Shock Hazards

Electric Shock Hazard -- Section Three

- ✓Hazard
  - Unintended electric current passing through the human body = LEAKAGE CURRENT

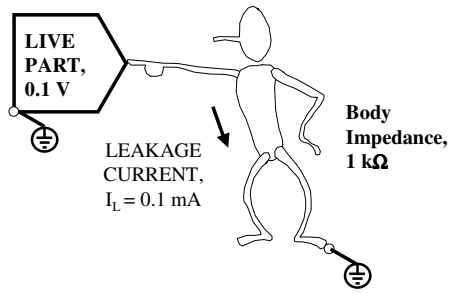
Electric Shock Harm

Harm	Thresholds (not limits)
startle reaction:	0.5 mA, 50/60 Hz (Hand)
inability to let-go:	10 mA, 15-100 Hz (Arm)
ventricular fibrillation:	35 mA, 15-100 Hz (Hand-Foot)
	0.01 mA, 50/60 Hz (Heart, direct)

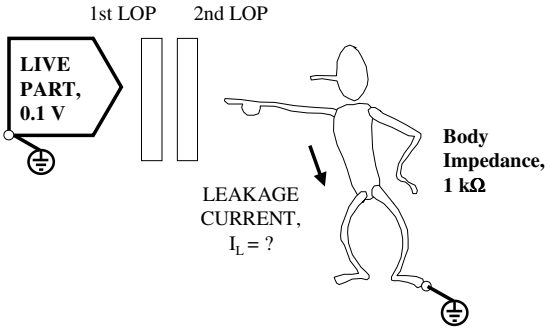
Body Impedance is nominally 1000 ohms
(dry hand-to-hand body impedance)

Source: IEC-60479 TR & 60601-1 Appendix A

Electrical Shock Hazard



2 Levels of Protection (LOP)

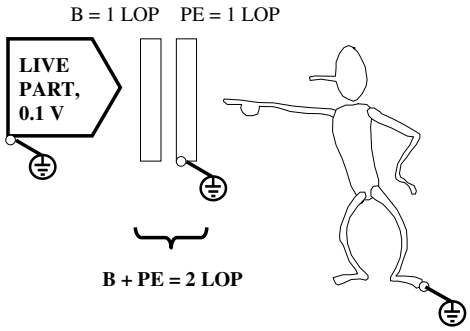


Protection Against Electrical Shock

Abbr.	Earth Type	LOP
FE	FUNCTIONAL EARTH	**0**
PE	PROTECTIVE EARTH	**1**

Abbr.	Insulation Type	LOP
OP	Operational	**0**
BOP	BASIC Opposite Polarity	**0**
B	BASIC	**1**
S	SUPPLEMENTARY	**1**
D	DOUBLE	**2**
R	REINFORCED	**2**

2 Levels of Protection (LOP)



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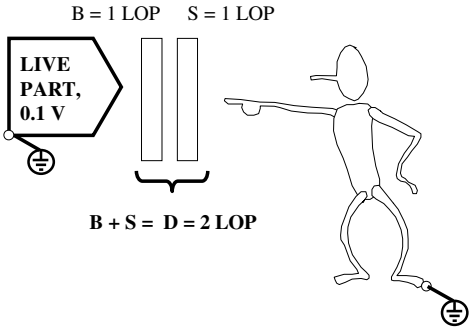

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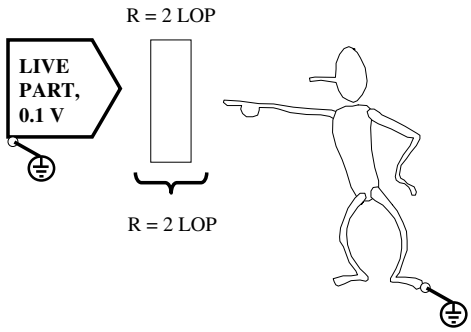
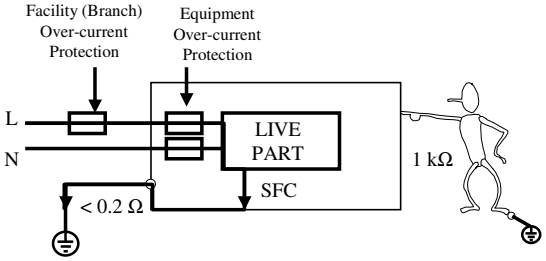


PROTECTIVE EARTH -- 1 LOP

- ✓High current carrying capacity and low impedance
  - Over-current protection is cleared in event of SFC
  - ACCESSIBLE METAL PARTS remain at earth potential

PROTECTIVE EARTH -- 1 LOP



Insulation

- ✓ Clause 57.10, Table XVI, page 154

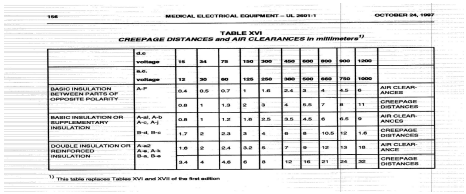


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TABLE XVI
CREEPAGE DISTANCES and AIR CLEARANCES in millimeters[1]

	a.c. voltage	15	34	75	150	300	450	600	900	1000	
	d.c. voltage	15	30	60	125	250	380	500	750	1000	
BASIC INSULATION OR SUPPLEMENTARY INSULATION OF OPPOSITE POLARITY	A-F	0.4	0.5	0.7	1	1.6	2.4	3	4.5	6	AIR CLEARANCES
		0.8	1	1.3	2	3	4	5.5	7	8	11	CREEPAGE DISTANCES
BASIC INSULATION OR SUPPLEMENTARY INSULATION	A-al, A-b A-c, A-j	0.8	1	1.2	1.8	2.5	3.5	4.5	6	6.5	9	AIR CLEARANCES
	B-al, B-c	1.7	2	2.3	3	4	5	8	10.5	12	1.6	CREEPAGE DISTANCES
DOUBLE INSULATION OR REINFORCED INSULATION	A-a2 A-a, A-b B-a, B-c	1.6	2	2.4	3.2	5	7	9	12	13	18	AIR CLEARANCE
		3.4	4	4.8	6	8	10	16	21	24	32	CREEPAGE DISTANCES

[1] This table replaces Tables XVI and XVII of the first edition

Clause 20, Table V, page 95
Dielectric Strength

TABLE V
Test voltages

Insulation to be tested	Test voltages for reference voltage U (V)					
	U ≤	50 < U ≤ 150	150 < U ≤ 250	250 < U ≤ 10000	1000 < U ≤ 10000	10000< U
BASIC INSULATION	500	1000	1500	2U+1000	U + 2000	1)
SUPPLEMENTARY INSULATION	500	2000	2500	2U+2000	U + 3000	1)
REINFORCED AND DOUBLE INSULATION	500	3000	4000	2(2U+1500)	2(U + 2500)	1)

1) If necessary, to be prescribed by Particular Standards.
Note – Tables VI and VII, not used.

Insulation Parameters

- ✓Type
  - Operational, BASIC, SUPPLEMENTARY, DOUBLE, REINFORCED
- ✓Reference Voltage
  - Clause 20.3, page 97
    - » "Voltage to which the relevant insulation is subjected in NORMAL USE and at RATED supply voltage…"
    - » V RMS, or V dc

Insulation -- Typical Values

	Reference Voltage		
	250 V ac		
Insulation Type	CREEPAGE mm	CLEARANCE mm	Dielectric Strength kV
B	4	2.5	1.5
S	4	2.5	2.5
D/R	8	5	4.0

Reviewing values for 250 V, one can see that B + B ≠ 2 LOP

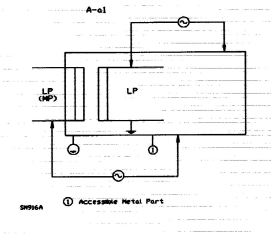
Insulation Diagrams

✓Used in product design to graphically:

- Identify insulation types, reference voltages, and earthing types
- Determine required CREEPAGE, CLEARANCE, and Dielectric Strength values
- Identify alternative constructions
- Convey design criteria to production staff, vendors, and others

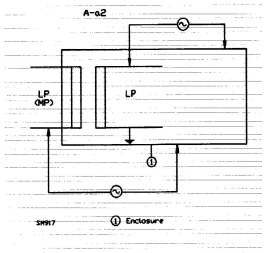
Isolation systems Appendix E

Type A-a1: Mains to grounded enclosure



Type A-a2

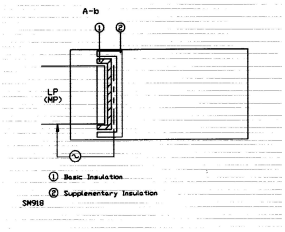
Mains to ungrounded accessible enclosure



Type A- b

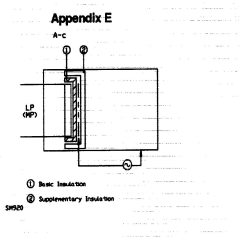
DOUBLE insulation equipment

Between LIVE PARTS and conductive parts isolated from LIVE PARTS by BASIC insulation only forming part of the Double insulation



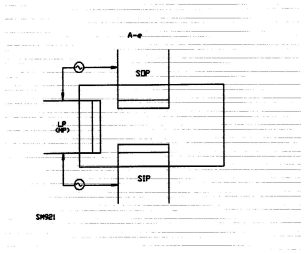
Type A-c

- ✓ DOUBLE INSULATED EQUIPMENT
- ✓ Supplementary insulation between ACCESSIBLE PART and conductive part isolated for LIVE PART by BASIC insulation only forming part of DOUBLE insulation



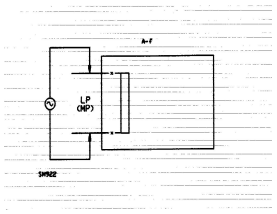
Type A-e

Isolation between LIVE PART and SIP/SOP



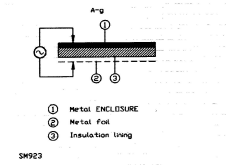
Type A-f

- ✓ ISOLATION between LIVE PARTS of opposite polarity



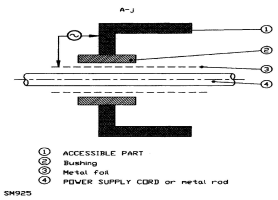
Type A-g

- ✓ Isolation between accessible enclosure and internal enclosure were an internal isolation lining is used.



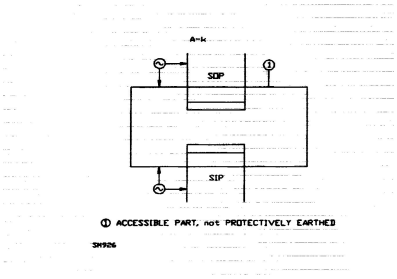
Type A-j

- ✓ Isolation between enclosure and power supply cord jacketing for fixed wired equipment at cord entry.



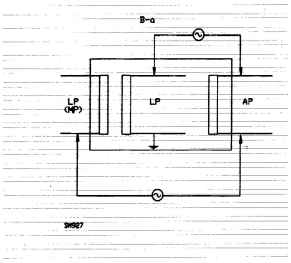
Type A-k

Isolation between ACCESSIBLE ENCLOSURE and SIP/SOP



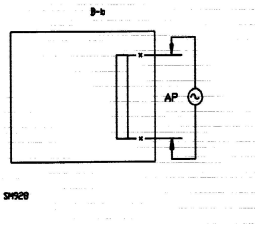
Type B-a

Isolation between LIVE PARTS and PATIENT APPLIED PART



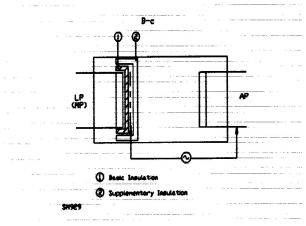
Type B-b

✓ Isolation between PATIENT APPLIED PARTS



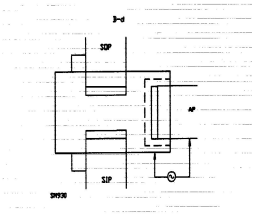
Type B-c

- ✓ Supplementary Isolation between conductive part isolated from LIVE PARTS by BASIC only and the PATIENT APPLIED PART



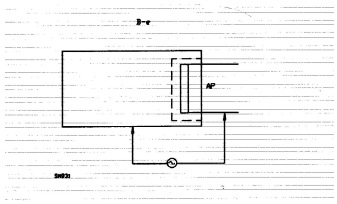
Type B-d

- ✓ Isolation between PATIENT APPLIED PART and ACCESSIBLE ENCLOSURE and SIP/SOP



Type B-e

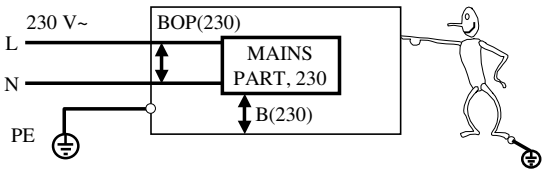
- ✓ Isolation between PATIENT APPLIED PART and ACCESSIBLE Enclosure were there is voltage on the APPLIED PART



CLASS I EQUIPMENT

✓Clause 2.2.4, page 50

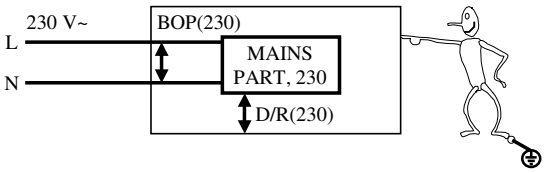
Provides protection against fire



B + PE provides 2 LOP's
against electric shock

CLASS II EQUIPMENT

✓Clause 2.2.5, page 50

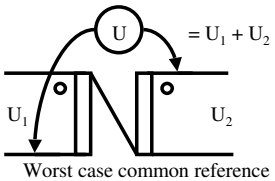


D/R provide 2 LOP's
against electric shock

Determining Reference Voltage

✓ Clause 20.3, page 98.

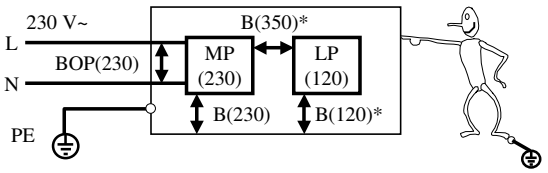
"For insulation between two isolated parts or between an isolated part and an earthed part, the reference voltage (U) is equal to the arithmetic sum of the highest voltages between any two points within both parts."



Worst case common reference

Equipment with Multiple Voltages

✓Isolation Diagram Example



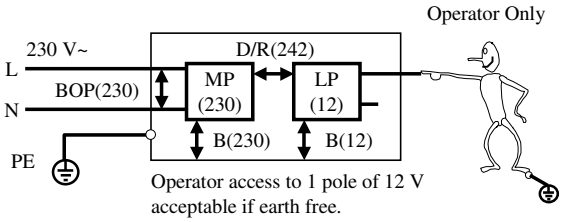
*Other combinations possible

Maximum Voltage -- OPERATOR (only)

- ✓Operator contact with patient unlikely
- ✓≤ 25 V ac, ≤ 60 V dc
- ✓D/R INSULATED from higher voltages
- ✓Clause 16.a.5, page 79
  - Earth Free/Medical SELV (page 52)
- ✓- OR- Clause 16.e.1, page 81
  - Must remove enclosure/equipment parts

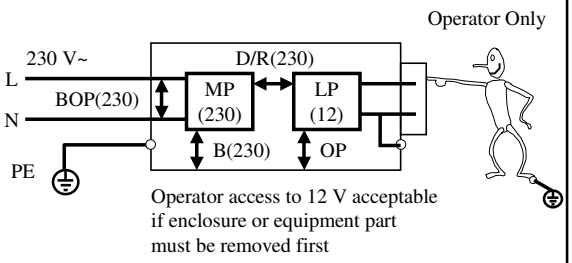
SIGNAL INPUT PART/SIGNAL OUTPUT PART - (16.a.5)

✓Clause 2.1.18, 2.1.19, page 49



Operator access to 1 pole of 12 V acceptable if earth free.

SIGNAL INPUT PART/SIGNAL OUTPUT PART - (16.e.1)



Operator access to 12 V acceptable if enclosure or equipment part must be removed first

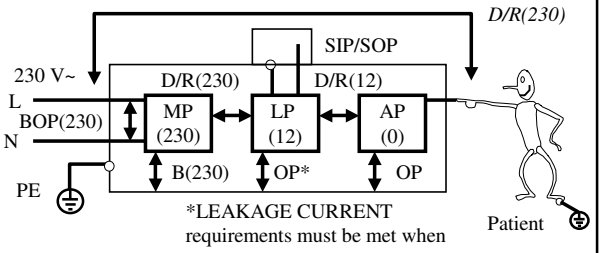
General requirements for all types of EQUIPMENT

✓Clause 20.1, page 95

- A-a1 (LIVE parts to Accessible PE parts)
- A-a2 (LIVE parts to Accessible non-PE parts)
- A-e (LIVE non-SIP/SOP parts to SIP/SOP parts)
- A-f (Between parts of opposite polarity of MAINS PART)

TYPE B APPLIED PART

✓Clause 2.2.24, page 51



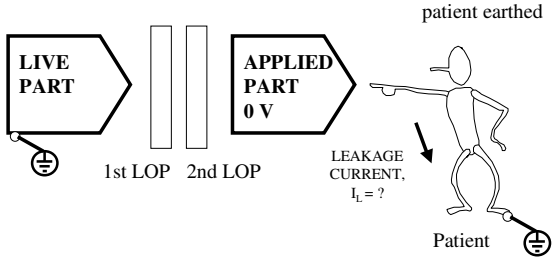
*LEAKAGE CURRENT requirements must be met when shorted (Clause 17g)

TYPE BF or CF APPLIED PART

Example 1 - No voltage on AP

✓Clause 2.2.25, 2.2.26, page 51

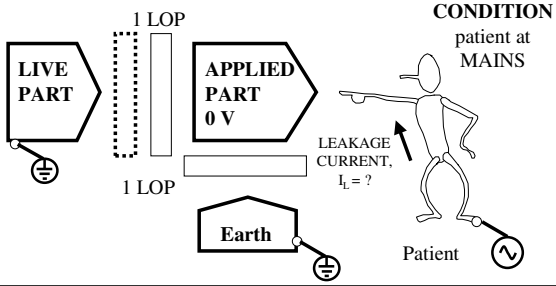
NORMAL CONDITION
patient earthed



TYPE BF or CF APPLIED PART

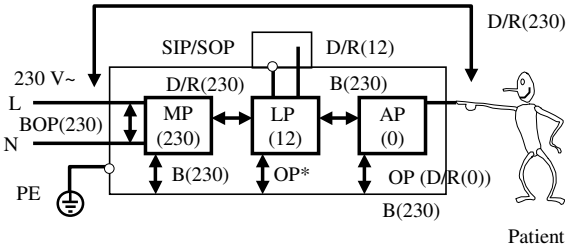
Example 1 - No voltage on AP

SINGLE FAULT CONDITION
patient at MAINS



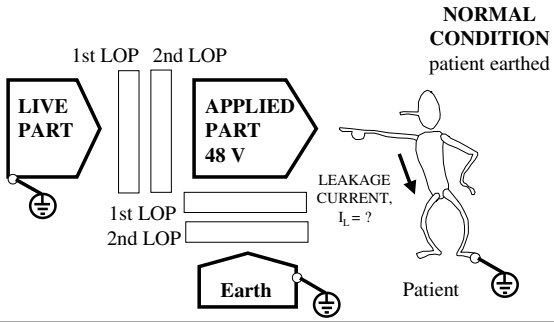
TYPE BF or CF APPLIED PART

Example 1 - No voltage on AP



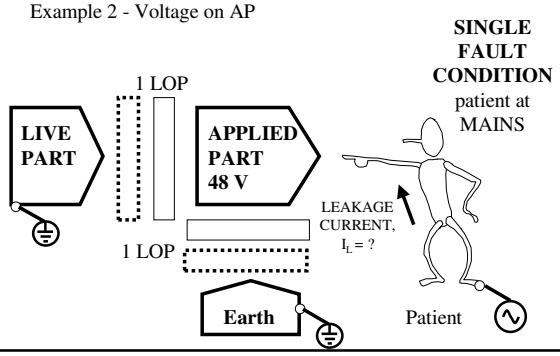
TYPE BF or CF APPLIED PART

Example 2 - Voltage on AP



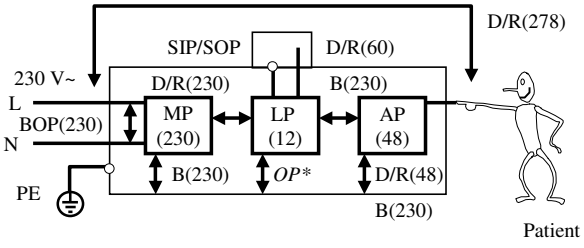
TYPE BF or CF APPLIED PART

Example 2 - Voltage on AP



TYPE BF or CF APPLIED PART

Example 2 - Voltage on AP

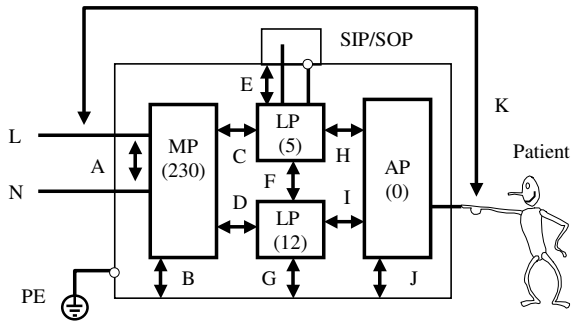


Requirements for EQUIPMENT with an APPLIED PART

✓Clause 20.2, page 97

- B-a (APPLIED PART to LIVE parts)
- B-d (F-TYPE APPLIED PART to ENCLOSURE including SIP/SOP)
- B-e (F-TYPE APPLIED PART with Voltage to ENCLOSURE)

Exercise 4.2 -- F TYPE AP



Exercise 4.2 -- Work Sheet

Enter Insulation type and reference voltage

Area	Insulation type	Reference voltage (V)
A		
B		
C		
D	BASIC	242
E		
F		
G		
H		
I		
J		
K		

Exercise 4.2 -- Answers

Area	Insulation type	Reference voltage (V)
A	BOP	230
B	BASIC	230
C	D/R	230
D	BASIC	242
E	OP	5
F	SUPP.	242
G	OP	12

Exercise 4.2 -- Answers (cont.)

Area	Insulation type	Reference voltage (V)
H	D/R	5
	BASIC	230
I	D/R	12
	SUPP.	242
	BASIC	230
J	OP (D/R)	0
	BASIC	230
K	D/R	230

5. Protection Against Electric Shock

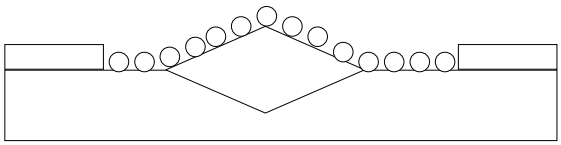
Requirements

5. Objectives

- ✓Determine requirements for Creepage distances, Clearance distances, Dielectric Strength voltages and Leakage current based on an Insulation Diagram

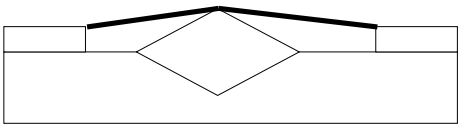
CREEPAGE DISTANCE

- ✓Clause 2.3.3, page 52
- ✓Shortest path along the surface of insulating material between two conductive parts
- ✓Sometimes called “over-surface spacing”

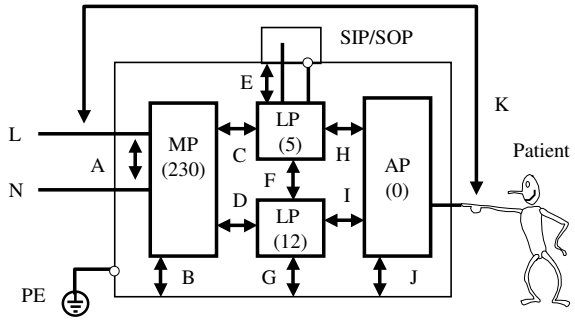


AIR CLEARANCE

- ✓Clause 2.3.1, page 52
- ✓The shortest path in air between two conductive parts
- ✓Sometimes called “through-air spacing”



Exercise 4.2 -- Revisited



CREEPAGE DISTANCE, AIR CLEARANCE

✓Consider insulation diagram from Exercise 4.2 and Table XVI, page 156

Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)
A	BOP	230	3	1.6
B	BASIC	230	4	2.5
C	D/R	230	8	5
D	BASIC	242	4	2.5

Exercise 5.1 -- CREEPAGE DISTANCE, AIR CLEARANCE

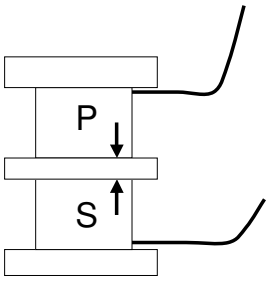
Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)
E	OP	5		
F	SUPP.	242		
G	OP	12		
H	D/R	5		
	BASIC	230		
I	D/R	12		
	SUPP.	242		
	BASIC	230		
J	OP (D/R)	0		
	BASIC	230		
K	D/R	230		

Exercise 5.1 -- Answers

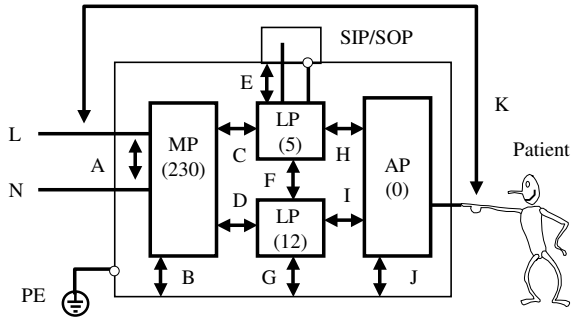
Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)
E	OP	5	NA	NA
F	SUPP.	242	4	2.5
G	OP	12	NA	NA
H	D/R	5	3.4	1.6
	BASIC	230	4	2.5
I	D/R	12	3.4	1.6
	SUPP.	242	4	2.5
	BASIC	230	4	2.5
J	OP (D/R)	0	NA	NA
	BASIC	230	4	2.5
K	D/R	230	8	5

Dielectric Strength

- ✓Clause 20.3, page 97
- ✓Insulation shall withstand a Test Voltage



Exercise 4.2 -- Revisited



Dielectric Strength

✓Consider insulation diagram from Exercise 4.2

Area	Insulation type	Reference voltage (V)	Test Voltage
A	BOP	230	Usually NA*
B	BASIC	230	1500
C	D/R	230	4000
D	BASIC	242	1500

* Clause 20.1 A-f, page 95

Exercise 5.2 -- Dielectric Strength

Area	Insulation type	Reference voltage (V)	Test Voltage
E	OP	5	
F	SUPP.	242	
G	OP	12	
H	D/R BASIC	5 230	
I	D/R SUPP. BASIC	12 242 230	
J	OP (D/R) BASIC	0 230	
K	D/R	230	

Exercise 5.2 -- Answers

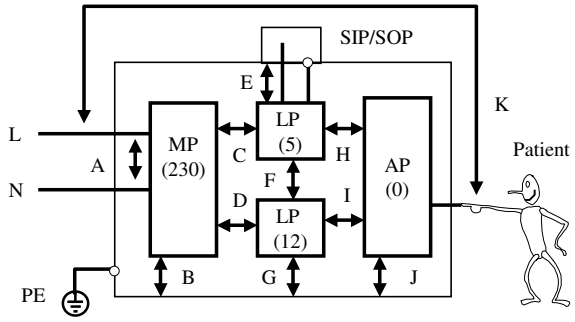
Area	Insulation type	Reference voltage (V)	Test Voltage
E	OP	5	NA
F	SUPP.	242	2500
G	OP	12	NA
H	D/R	5	500
	BASIC	230	1500
I	D/R	12	500
	SUPP.	242	2500
	BASIC	230	1500
J	OP (D/R)	0	NA
	BASIC	230	1500
K	D/R	230	4000

LEAKAGE CURRENT

- ✓Clause 19.1, page 85

  "Electrical insulation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the specified values"

Exercise 4.2 -- Revisited



LEAKAGE CURRENT

✓ Clause 19.3, Table IV, page 88

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 [4]	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	0.1	0.5	0.1	0.5	0.01	0.05
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the SIGNAL INPUT PART OR SIGNAL OUTPUT PART)	-	5	-	-	-	-
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)	-	-	-	5	-	0.05
* PATIENT AUXILIARY CURRENT 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

LEAKAGE CURRENT

✓Table 19.100, page 12, Class I

Current	Type BF	
	N.C.	S.F.C.
EARTH LEAKAGE CURRENT	0.3	-
ENCLOSURE LEAKAGE CURRENT	-	0.3*

* Does not include opening line conductor

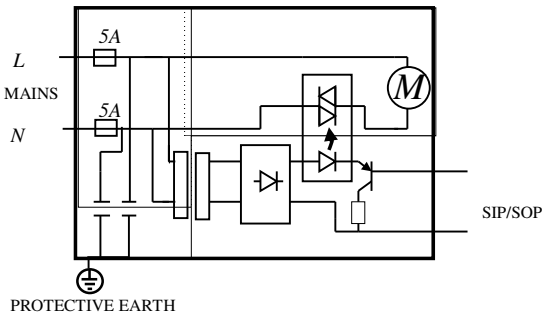
6. Protection Against Electric Shock

Compliance --Design and Construction

6. Objectives

- ✓Identify circuit blocks and insulating components in a product
- ✓Measure Creepage and Clearance distances and evaluate against requirements

Circuit Blocks



Insulating Components

✓MAINS to PROTECTIVE EARTH

- Appliance Inlet
- Fuse holders
- Y Capacitors
- Transformer
- Motor (enclosure earthed)
- Printed Wiring Board
- Wire Insulation

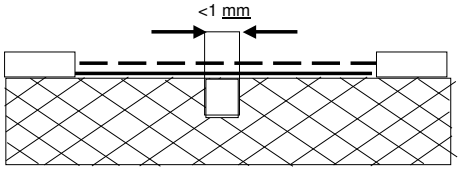
Insulating Components

✓MAINS to SIP/SOP

- Transformer
- Opto-coupler
- Relay
- Printed Wiring Board
- Wire Insulation

Measuring CREEPAGE & CLEARANCE

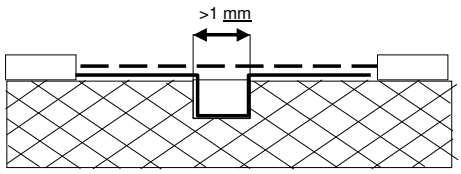
Clearance
Creepage



Path under consideration includes a parallel or converging -sided groove of any depth with width less than 1 mm.
CREEPAGE DISTANCE & AIR CLEARANCE are measured directly across the groove as shown

Figure 39. - Example 1, page 192

Measuring CREEPAGE & CLEARANCE

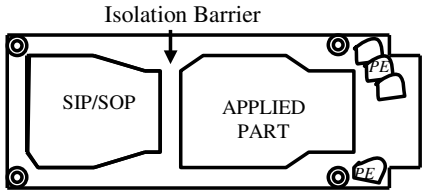


Path under consideration includes a parallel-sided groove of any depth, equal to or more than 1 mm wide.
AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove

Figure 40. - Example 2, page 192

Exercise 6.1 -- Printed Wiring Board

- ✓Consider Exercise 4.2 and printed wiring board containing circuitry from SIP/SOP and AP



Exercise 6.1 -- Printed Wiring Board

- ✓Fill in observed distances

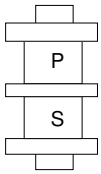
Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)
H	D/R	5	3.4	1.6		
	BASIC	230	4	2.5		
J	OP (D/R)	0	NA	NA		
	BASIC	230	4	2.5		

Exercise 6.1 -- Answers

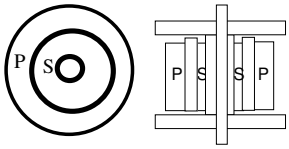
Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)
H	D/R BASIC	5 230	3.4 4	1.6 2.5		
J	D/R BASIC	0 230	NA 4	NA 2.5		

Transformer Separation

✓Clause 57.9.4 a, page 153



Bobbin with
insulating partition



Concentrically
Wound

Insulating Partition,
Copper Screen >0.13 mm,
or D/R Insulation

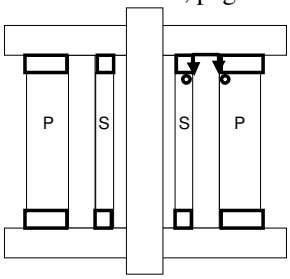
Transformer Construction

✓Clause 57.9.4, page 153

- c) end turns
- d) earthed screen
- e) REINFORCED layers and/or thickness

Transformer CREEPAGE

✓Clause 57.9.4 f, page 154



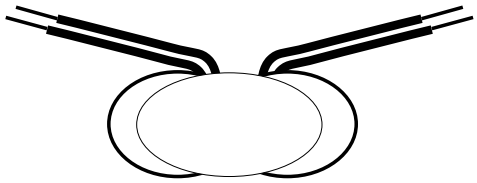
D (margin tape)

CR = 1 mm (enamel) +
1 mm (enamel) + D + D

Transformer Construction

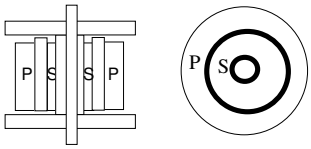
✓Clause 57.9.4, page 153

- g) Toroidal exit wires

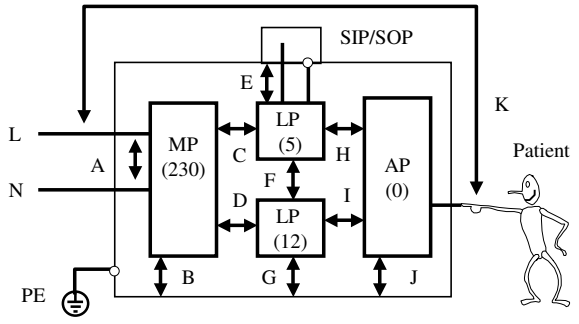


Exercise 6.2 -- Transformer

✓Consider Exercise 4.2 and power transformer containing circuitry from Mains and SIP/SOP



Exercise 4.2 -- Revisited



Exercise 6 .2 -- Transformer

✓Fill in observed distances

Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)
B	BASIC	230	4	2.5		
C	D/R	230	8	5		
E	OP	5	NA	NA		

Exercise 6.2 -- Answers

Area	Insulation type	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)
B	BASIC	230	4	2.5		
C	D/R	230	8	5		
F	OP	5	NA	NA		

7. Protection Against Electric Shock Hazards

Compliance -- Testing

7. Objectives

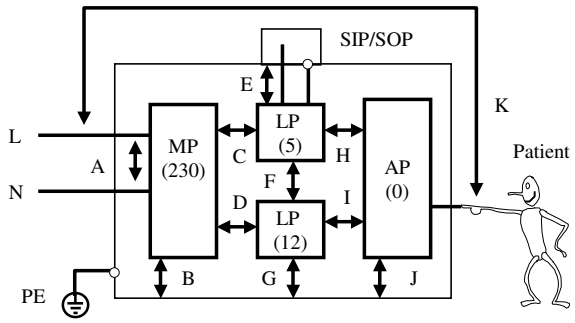
- ✓Perform Dielectric Strength testing to evaluate insulation
- ✓Perform PROTECTIVE EARTHING testing to evaluate PE impedance
- ✓Perform LEAKAGE CURRENT testing to determine that accessible currents are acceptable in NORMAL and SINGLE FAULT CONDITIONS

Dielectric Strength Test

✓Clause 20.4, page 99

✓No flashover or breakdown shall occur

Exercise 4.2 -- Revisited



Dielectric Strength

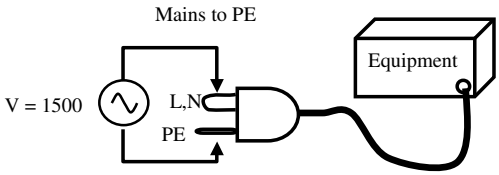
✓Requirements from Exercise 4.2

Area	Insulation type	Reference voltage (V)	Test Voltage
A	BOP	230	Usually NA*
B	BASIC	230	1500
C	D/R	230	4000
D	BASIC	242	1500

* Clause 20.1 A-f, page 95

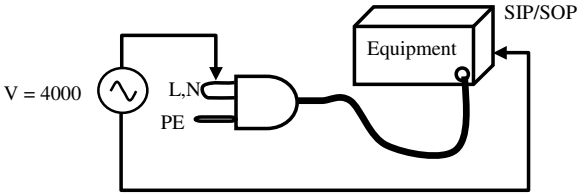
Dielectric Strength Test

✓B(230)
- MAINS to PROTECTIVE EARTH



Dielectric Strength Test

✓D(235)
- MAINS to SIP/SOP



Protective Earthing Test

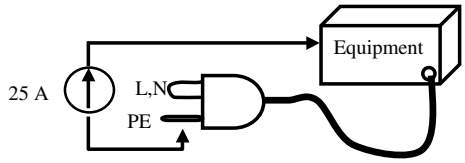
✓Clause 18f, page 84

✓ACCESSIBLE PARTS connected by sufficiently low impedance to the PROTECTIVE EARTH TERMINAL

✓Test Current
- 25 A or 1.5*rated current, 5 s
  - » 30 A, 2 min (assuming 15 A branch protection)

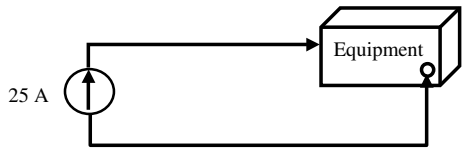
Protective Earthing Test

- ✓Non-detachable power supply cord
- ✓Impedance < 0.2 Ω



Protective Earthing Test

- ✓Detachable power supply cord
- ✓Impedance < 0.1 Ω



Leakage Current Tests - General Requirements

- ✓Clause 19.1, page 85
- ✓Measured values shall not exceed allowable values

Leakage Current Tests - Conditions

✓NORMAL CONDITION
- » S5=0, S5=1, S1=1

✓SINGLE FAULT CONDITION
- Clause 19.2, page 86
  - » S1=0, S7=0
  - » Mains on SIP/SOP
    - – Not needed if equipment is evaluated
  - » Mains on F Type AP

Leakage Current Tests - Supply Circuit

✓Clause 19.4a & b, page 89
- a) 110% RATED MAINS VOLTAGE
- b) Supply circuit, Figs. 10-14, page 167

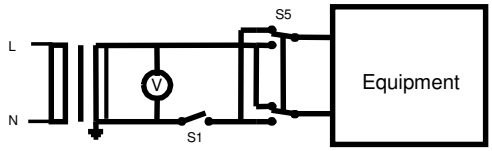
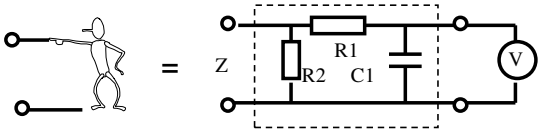


Fig. 10

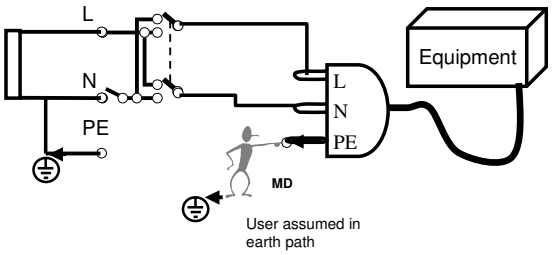
Leakage Current Tests - Measuring Device

✓Clause 19.4e, page 90, Fig. 15, page 171
- Measuring Device (MD)
  - » Simulates human body impedance
  - » For frequencies > 20 kHz appropriateness of MD must be determined due to absolute 10 mA limit



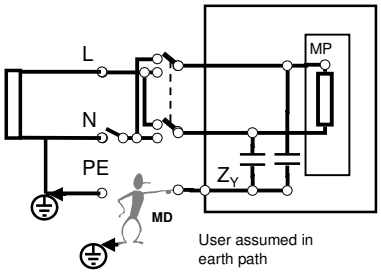
Leakage Current Tests - EARTH LEAKAGE

✓Clause 19.4f, page 91



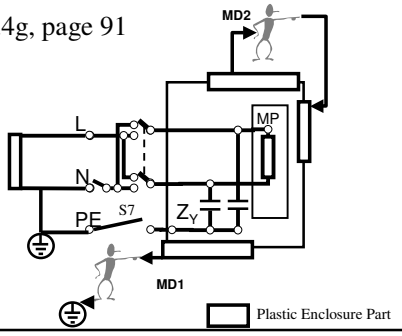
Leakage Current Tests - EARTH LEAKAGE

✓Clause 19.4f, page 91



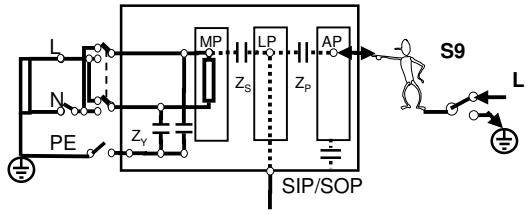
Leakage Current Tests - ENCLOSURE LEAKAGE

✓Clause 19.4g, page 91



Leakage Current Tests - PATIENT LEAKAGE

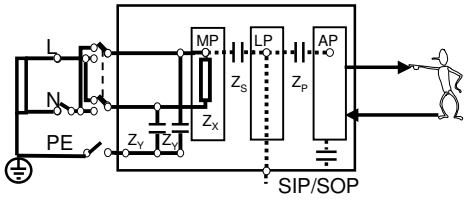
✓Clause 19.4h, page 92



Leakage Current Tests - PATIENT AUXILIARY LEAKAGE

✓Clause 19.4j, page 92

» Fig. 26, pg 182, App. K, pg 243



Medical Systems

✓Medical Equipment interconnected with non-medical equipment

» Printers, monitors, computers, others

✓IEC 60601-1-1

- Connection Requirements

» Isolation transformer, redundant PE, others

- Enclosure Leakage Tests

8. Protection against Mechanical Hazards

OBJECTIVES

- ✓ Apply hierarchy of mitigation techniques to address Mechanical Hazards.
- ✓ Determine requirements for mechanical strength of materials.
- ✓ Determine requirements for moving parts of equipment.
- ✓ Determine requirements for mechanical stability.
- ✓ Determine requirements for suspended masses.

MECHANICAL HAZARDS

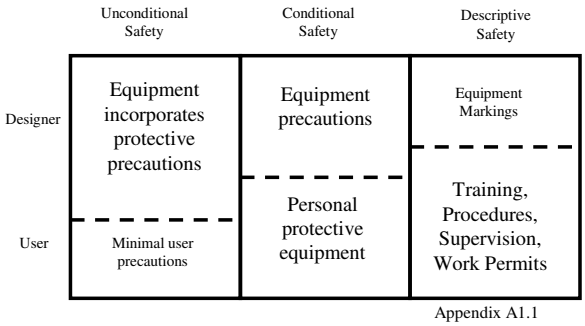
✓ *Hazard*

- Moving parts/Equipment instability
- Sharp edges and corners
- Flying particles
- Suspended masses

✓ *Harm*

- Cuts, laceration, puncture
- Contusion, abrasion
- Crushing, fracture

Hierarchy of Mitigation

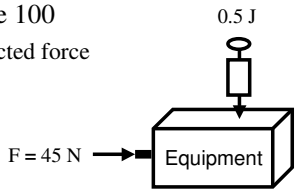


Appendix A1.1

Mechanical Strength

✓Clause 21, page 100

- a) Inward directed force
- b) Impact test

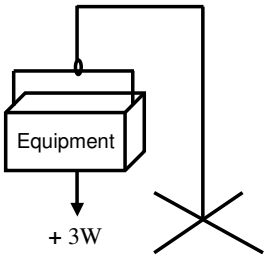


Clause 55, page 22 (polymeric enclosures)
Single impact
6.78 N-m

Mechanical Strength

✓Clause 21, page 101

- c) Handle test

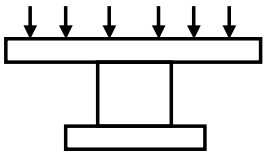


Mechanical Strength

✓Clause 21.3, page 102

- Patient support system

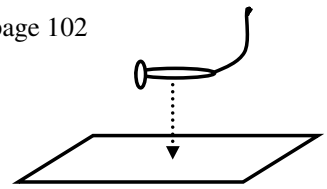
F = SAFETY FACTOR * normal load (1.35 kN)



Mechanical Strength

✓Clause 21.5, page 102

- Drop Test

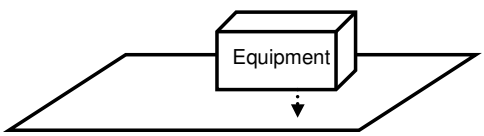


Clause 55, page 22
Tile covered concrete surface
Number of samples

Mechanical Strength

✓Clause 21.6, page 102

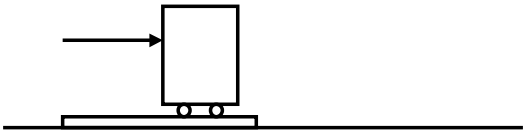
- Rough Handling



Mechanical Strength

✓Clause 21, page 102, Am 1, page 260

- Mobile "Step" Test



U.S. Deviations

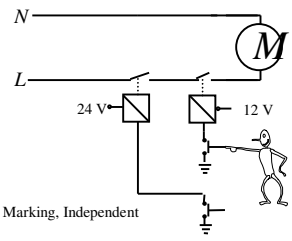
✓Clause 55, page 22

- Mold stress relief test for polymeric enclosures

Moving Parts

✓Clause 22.4, 22.7, page 103

- Continuous Activation
- Independent Emergency Stop

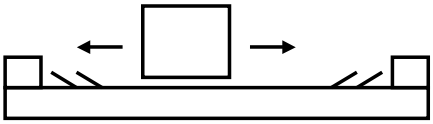


Color, Action, Location, Marking, Independent

End Stops

✓Clause 22, page 14

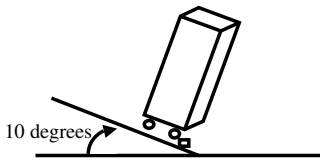
- Travel limiting means
- Test cycles dependent on limit system and drive method



Mechanical Stability

✓Clause 24, page 104

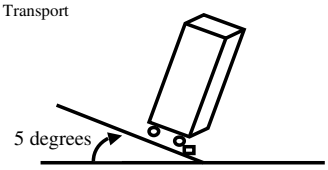
- Normal Use



Mechanical Stability

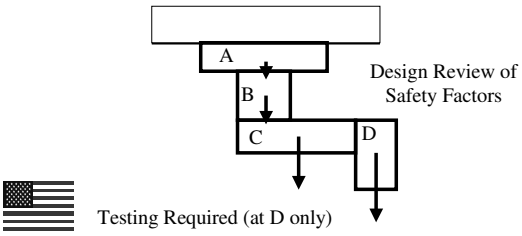
✓Clause 24, page 104

- If overbalances at 10 degrees
  - » 5 degree test - Normal Op.
  - » warning notice
  - » 10 degree test - Transport



Suspended Masses

✓Clause 28, page 106



9. Protection Against Excessive Temperatures & Fire

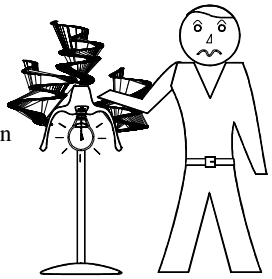
OBJECTIVES

✓Determine requirements for fire enclosures

✓Determine testing required to demonstrate allowable temperatures are not exceeded in NORMAL and SINGLE FAULT CONDITIONS

Excessive Temperature Hazard

- ✓Hazard
  - High temperatures
- ✓Harm
  - Burns, Insulation/ Component degradation
  - Ignition of flammable materials
  - Flying projectiles



Fire Hazard

- ✓Hazard
  - Fire
- ✓Harm
  - Smoke Inhalation
  - Burn
  - Water Damage

General Philosophy

- ✓Avoid high temperatures
- ✓Avoid temperatures above the ignition point of materials
- ✓Restrict accessibility
- ✓Limit risk of propagation
- ✓Provide overcurrent/overtemperature protection

Normal Temperatures

✓Clause 42, page 117

- Operating conditions
  - » Accompanying Documents
- Temperature limits

Abnormal Operation

✓Clause 52.1, page 129

The introduction of any of the SINGLE FAULT CONDITIONS described in Sub-clause 52.5, one at a time, does not lead to any of the SAFETY HAZARDS described in Sub-clause 52.4

✓15 Watt Exception, page 130

SAFETY HAZARDS

✓Clause 52.4, page 129

- Emission of flames
- Deformation of ENCLOSURES
- Temperatures exceeding maximum values

SINGLE FAULT CONDITIONS

✓Clause 52.5, page 131
- Overload of mains supply transformers
- Failure of THERMOSTATS
- Short circuiting parts of DOUBLE INSUL.
- Interruption of PROTECTIVE EARTH
- Impairment of cooling
- Locking of moving parts

SFC - Continued

✓Clause 52.5, page 132
- Interruption and s.c. of motor capacitors
- Add. tests for motor operated EQUIPMENT
- Failure of components
- Overload

Enclosure Flammability Requirements

✓Transportable equipment
- Minimum of V-2 rating

✓Fixed or Stationary equipment
- Minimum of 94V-0 rating

✓ Large Surfaces
- Steiner Tunnel Test
- Radiant panel Test

Flammability Ratings

- ✓Flammability ratings
  - material other than metal and ceramic
  - according to their ignition and burning resistance characteristics

94-5VA or B
94V-O
94V-1
94V-2
94HB

Increasing Flammability Rating

10. Construction

OBJECTIVES

- ✓Incorporate the following component requirements into product design:
  - Rewirable, non-detachable power supply cords
  - Fuses and Over-current Devices
  - Protective Earth Terminal
  - Capacitor
- ✓Design for compliance with US component requirements.

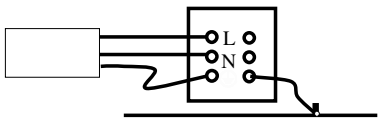
Capacitors

✓Connection
- Clause 56.4, page 138
- Mains to Earth, IEC 384-14
- Mains to SIP/SOP, not allowed

Rewirable, Non-detachable POWER SUPPLY CORDS

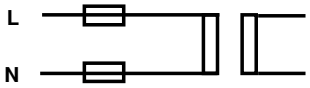
✓MAINS TERMINAL DEVICES
- Clause 57.5, page 147

✓Colors of insulation
- Clause 6.5, page 70



Mains Fuses and Over-current Devices

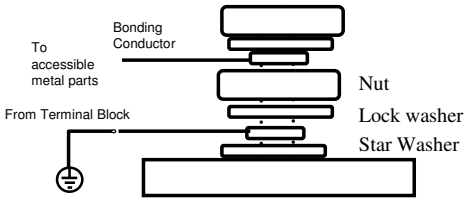
✓Clause 57.6, page 148
- One in each supply lead for CLASS I & CLASS II with functional earth



- In at least one supply lead for CLASS II

Protective Grounding Terminal

- ✓First earthing connection to chassis
- ✓Clause 58.2 (CAN/CSA C22.2 No. 601-1)
  - C22.2 No. 0.4



Components

- ✓Clause 3.100, page 9
  - Printed Wiring Boards, Lithium Batteries, Optical Isolators, Wiring And Tubing, CRTs > 5 inches
  - MAINS components

11. Markings and Accompanying Documents

OBJECTIVES

- ✓Determine EQUIPMENT classification
- ✓Determine required Equipment markings
- ✓Incorporate ACCOMPANYING DOCUMENT requirements into product literature.

Classification

- ✓Clause 5.1, page 63
  - Type of protection against electric shock
    - » Class I
    - » Class II
    - » Internally Powered

Classification

✓Clause 5.2, page 63, 284

- Degree of protection against electric shock
  - » Type B APPLIED PART
  - » TYPE BF APPLIED PART
  - » TYPE CF APPLIED PART

Classification

✓Clause 5.3, page 63, 284

- Degree of protection against ingress of water
  - » No protection
  - » IPX1 (DRIP-PROOF)
  - » IPX4 (SPLASH-PROOF)
  - » IPX7 (WATERTIGHT)

Classification

✓Clause 5.4, page 63

- Method of sterilization or disinfection

Classification

✓Clause 5.5, page 64

- Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
  - » Not suitable
  - » Category AP
  - » Category APG

Classification

✓Clause 5.6, page 64

- Mode of operation
  - » CONTINUOUS OPERATION
  - » SHORT-TIME OPERATION
  - » INTERMITTENT OPERATION
  - » CONTINUOUS OPERATION WITH SHORT TIME LOADING
  - » CONTINUOUS OPERATION WITH INTERMITTENT LOADING

Exercise 11.1

✓Determine the appropriate classification for an ECG recorder

Type of Protection against Electric Shock	
Degree of protection against Electric Shock	
Degree of Protection against Ingress of Water	
Method of Sterilization	
Degree of safety in presence of flammable gas	
Mode of Operation	

Markings

✓Clause 6.1, page 64
- On outside of EQUIPMENT
- Table II, page 65

Markings

✓Clause 6.2, page 68
- On inside of EQUIPMENT or EQUIPMENT parts

Markings

✓Clause 6.3, page 69
- Of controls and instruments

Markings

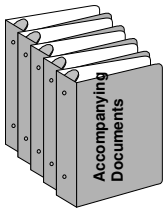
✓Clauses 6.4 - 6.7, page 70

- Symbols
  - » Appendix D, page 233
- Colors of insulation of conductors
- Identification of medical gas cylinders
- Indicator lights and push-buttons

ACCOMPANYING DOCUMENTS

✓Clause 6.8.1, page 71

- General



ACCOMPANYING DOCUMENTS

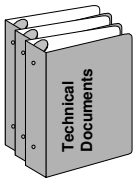
✓Clause 6.8.2, page 71

- Instructions for use

ACCOMPANYING DOCUMENTS

✓Clause 6.8.2, page 73

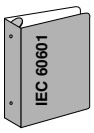
- Technical Description



Summary and Concluding Remarks

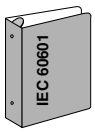
Summary

MODULE 1	Role of IEC 60601
MODULE 2	Structure of IEC 60601 and UL 2601
MODULE 3	General Philosophy of IEC 60601
MODULE 4	Protection Against Electric Shock - Insulation Diagrams
MODULE 5	Protection Against Electric Shock - Requirements

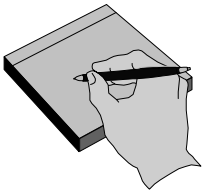


Summary

MODULE 6	Protection Against Electric Shock - Compliance (Design & Construction)
MODULE 7	Protection Against Electric Shock - Compliance (Testing)
MODULE 8	Protection Against Mechanical Hazards
MODULE 9	Protection Against Excessive Temperatures & Fire
MODULE 10	Construction
MODULE 11	Marking & Acc. Doc's



THANK YOU FOR ATTENDING



Please complete an evaluation form and return it to the podium

ITEMS NEEDED FOR INVESTIGATION

✓ ***Schematics***

- Essential to investigation
- Degree of schematics
  - » Primary (mains) circuitry
  - » Hazardous voltage circuitry
  - » Possibly others, such as d.c. to d.c. converters circuitry
- Level of detail may vary
- If a component is already Recognized, the schematic for that component generally is not necessary

ITEMS NEEDED FOR INVESTIGATION

✓Critical components

- Components that affect the safety of the unit
- Components in the mains are critical
- Provide a list of general information:
  - » Part number
  - » Manufacturer(s)
  - » Ratings (not mandatory but recommended)
  - » Tested by/publications
  - » Information on safety certifications done on that product

ITEMS NEEDED FOR INVESTIGATION

✓***Samples***

- Entela will work with client to use minimum number possible
- The number of samples required depends on:
  - » Time
  - » Expense of sample
  - » Alternate constructions
  - » Use of component level samples

ITEMS NEEDED FOR INVESTIGATION

✓Accompanying Documents:

- Clause 6 contains requirements for information that must be in the user and service manual
- Should provide warnings about hazards associated with using and servicing the equipment
- Should specify the intended use of a product
- Entela often reviews draft level documents

ITEMS NEEDED FOR INVESTIGATION

✓Drafts of markings and labels

- Provide if markings and labels are not already on the sample

ITEMS NEEDED FOR INVESTIGATION

✓Marketing information:

- Reviewed for how the product's intended use is addressed
- Can affect how and what requirements are applied
- By specifying targeted markets, Entela can plan investigation to address all of the services that you may need

ITEMS NEEDED FOR INVESTIGATION

✓Draft Entela/CB report (optional)

- This option may be considered by more experienced clients to speed up the process

ITEMS NEEDED FOR INVESTIGATION

✓Production line testing considerations

- Dielectric tests
- Earthing continuity tests for mains-connected Class I products

Marketing/Sales Info

✓MDS Brochure

✓seminar list

- EMC seminar
- Software seminar
- ISO 9000
- MDD

Submitting Products to Entela

✓Quote Request Form

✓CB Test Report Form

CB Test Report

- ✓General
- ✓Deviations
- ✓Particular