EE-511 Sensors in medical instrumentation

Chapter 3 – BASIC SAFETY OF ME EQUIPMENT

MEDICAL ELECTRICAL

3.1 Safety assurance
3.2 MEANS OF PROTECTION (against electric shock)
3.3 Leakage current protection
3.4 Defibrillation-proof protection

Objectives

understand:

- regulations, medical devices vs. ME EQUIPMENT, standard family 60601
- classification
- MOP, MOPP, MOOP
- ENCLOSURE, touch connection, APPLIED PART, PATIENT CONNECTION
- LEAKAGE CURRENT, AUXILIARY CURRENT
- defibrillator-proof

Section 3.1 – SAFETY ASSURANCE

3.1.1 EU regulations

3.1.2 Medical device

3.1.3 Standards for ME EQUIPMENT

3.1.4 Definition/scope of ME EQUIPMENT

~~3.1.5 Definition/scope of ME SYSTEM~~

3.1.6 Definition of APPLIED PART

3.1.7 Protection against electric shock

3.1.8 Protection against ingress of dust and water

3.1.9 RISK MANAGEMENT PROCESS

3.1.10 NORMAL and SINGLE FAULT CONDITIONS

3.1.1 EU Regulations

- Manufacturers who wish to place a medical device onto the European market must apply the CE mark to their device to indicate compliance with the Medical Device Regulations (MDR).
- Compliance with **state-of-the-art standards** is the preferred method of demonstrating compliance with the applicable General Safety and Performance Requirements (GSPR) of the Medical Devices Regulation (MDR) (EU) 2017/745.
- To find out which harmonized medical standards and version (date of issue) are applicable, visit eur-lex.europa.eu.

3.1.2 Medical device (definition)

- any instrument, software, implant, material, etc. intended by the manufacturer to be used for human beings for:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of **disease**
  - diagnosis, monitoring, treatment, alleviation of, or compensation for, an **injury or disability**
  - investigation, replacement, or modification of the **anatomy** or of a physiological or pathological **process or state**
  - providing information by means of **in vitro examination of specimens** derived from the human body, including organ, blood, and tissue donations

  and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means.

3.1.2 Medical device (classification)

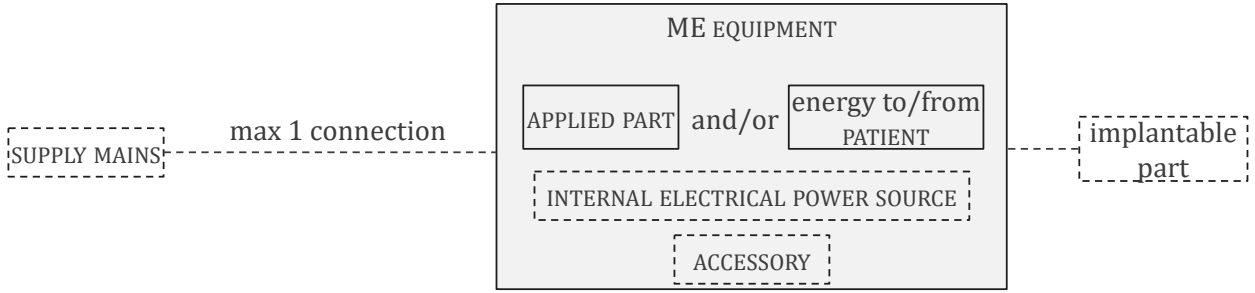
- The class of a medical device shall consider its *intended purpose*. There are four classes of medical devices:
  - **class I** (e.g., non-invasive everyday low-risk devices: bandages, walking aids, etc.)
  - **class IIa** (e.g., hearing-aids, catheter, diagnosis/monitoring devices for signals that will not be used to detect an immediate danger to the patient)
  - **class IIb** (e.g., ventilators, ICU equipment, diagnosis/monitoring devices for signals that are used to detect an immediate danger to the patient)
  - **class III** (e.g., high risk devices: heart valves, pacemakers, etc.)

3.1.3 Standards for ME EQUIPMENT (IEC 60601-1)

- **IEC**: International Electrotechnical Commission, **ISO**: International Organization for Standardization, **EN**: European Norm, **UL**: US
- 60601-1: **General requirements** for:
  - **BASIC SAFETY**
  - **ESSENTIAL PERFORMANCE**
    "Delivery of energy or therapeutic substances, processes and displays of physiological data have an impact on the PATIENT"
- 60601-**1-XX**: **Collateral** standards for ME EQUIPMENT
- **6**0601/**8**0601-**2-XX**: **Particular** standards for particular types of ME EQUIPMENT

3.1.4 Definition of ME EQUIPMENT

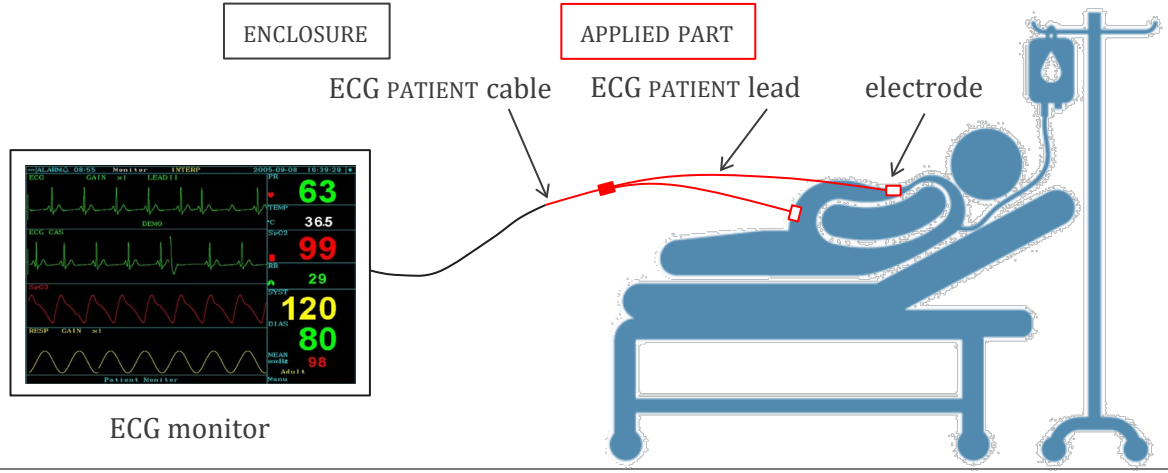
- must contain an **APPLIED PART**, and/or **transfer energy** to/from a PATIENT
- MUST HAVE NO MORE THAN ONE CONNECTION TO SUPPLY MAINS
- MUST BE INTENDED BY ITS MANUFACTURER TO BE USED:
  - in the diagnosis, treatment, and/or monitoring of PATIENT, and/or
  - compensation or alleviation of disease, injury, or disability
- must not include any implantable part (covered by ISO 14708-1)



3.1.6 Definition of APPLIED PART

- parts in contact with PATIENT
  (or potentially in contact, or from where a current can flow to/from the PATIENT)

→ stringent requirements (e.g., temperature, LEAKAGE CURRENT)



ECG monitor

3.1.7 Protection against electric shock

- ME EQUIPMENT
  - CLASS I
  - CLASS II 
  - INTERALLY POWERED ME EQUIPMENT
- APPLIED PART

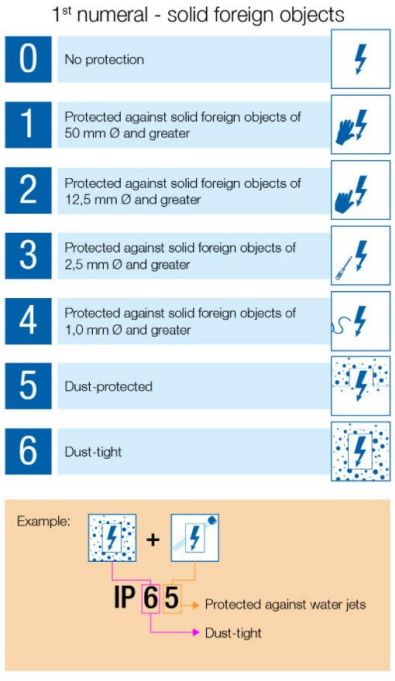
		DEFIBRIALLATION-PROOF
TYPE B		
TYPE BF		
TYPE CF		

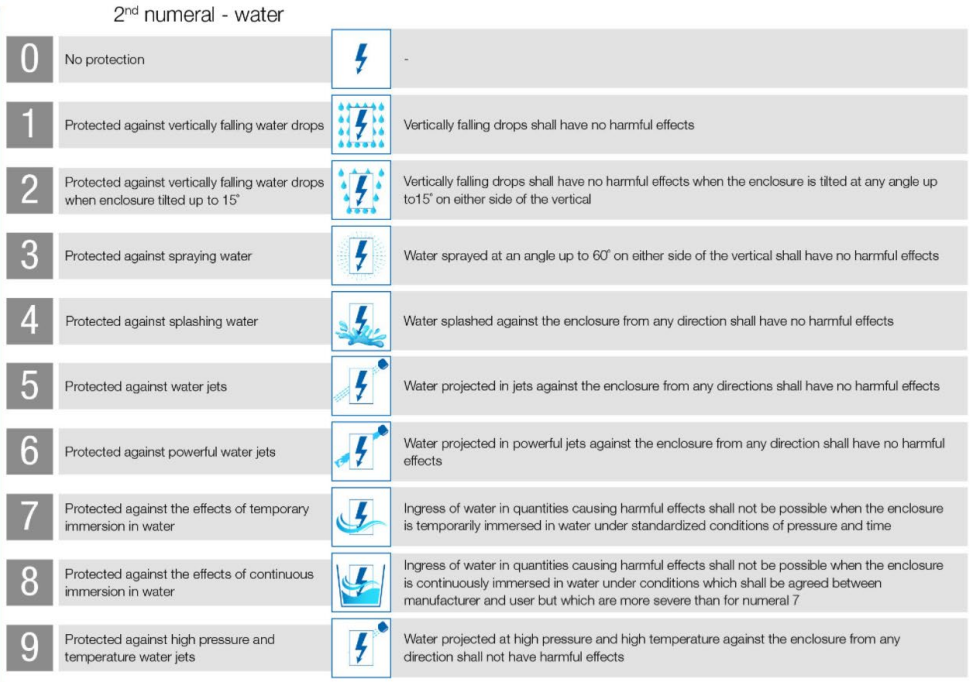
class I, II *ME EQUIPMENT* must not to be confused with class I, IIa, IIb, III *medical devices*

3.1.8 Protection against ingress of dust and water

- IEC 60529
- IP X4, IP 3X

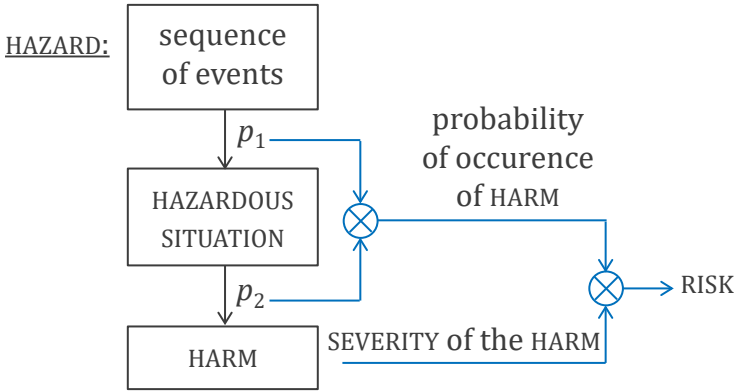
X means:
insufficient data to
claim a given level protection

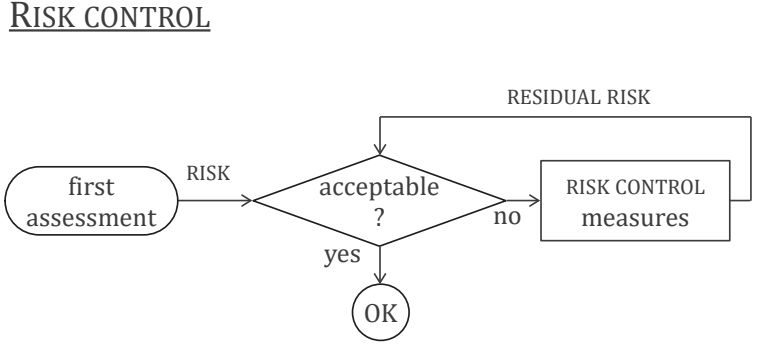




3.1.9 RISK MANAGEMENT PROCESS

- ME EQUIPMENT shall be designed and manufactured to be SINGLE FAULT SAFE so that two independent faults have a negligible probability of occurring during the EXPECTED SERVICE LIFE.
- Rating or RISKS:





3.1.10 NORMAL and SINGLE FAULT CONDITIONS

- NORMAL CONDITION: “all means to reduce RISK are intact”
- SINGLE FAULT CONDITION:
  - “a single means of reducing a RISK is defective” or
  - “a single abnormal condition exists”

Section 3.2 – MEANS OF PROTECTION (against electric shock)

3.2.1 MOP, MOPP, MOOP

3.2.2 PATIENT CONNECTION

3.2.3 BASIC SAFETY

3.2.4 Insulation

3.2.5 PROTECTIVE EARTH CONNECTION

3.2.6 AIR CLEARANCE and CREEPAGE DISTANCE

3.2.7 Component impedance

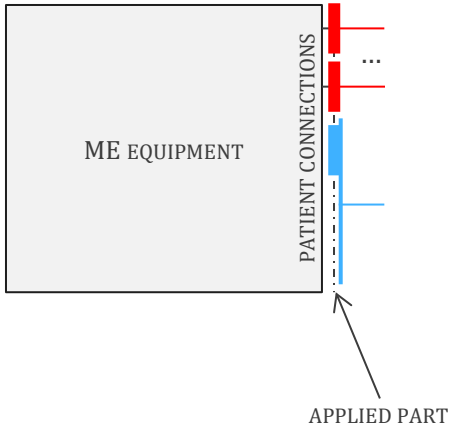
3.2.1 MOP (MEANS OF PROTECTION)

- MOPP: MEANS OF PATIENT PROTECTION
- MOOP: MEANS OF OPERATOR PROTECTION

- MOPs include:
  - solid insulation
  - PROTECTIVE EARTH CONNECTION
  - AIR CLEARANCE and CREEPING DISTANCE
  - component impedance

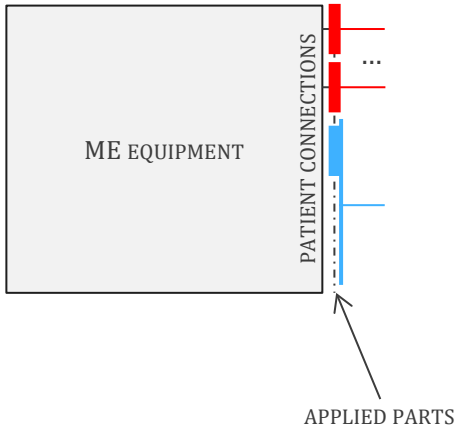
3.2.2 PATIENT CONNECTION

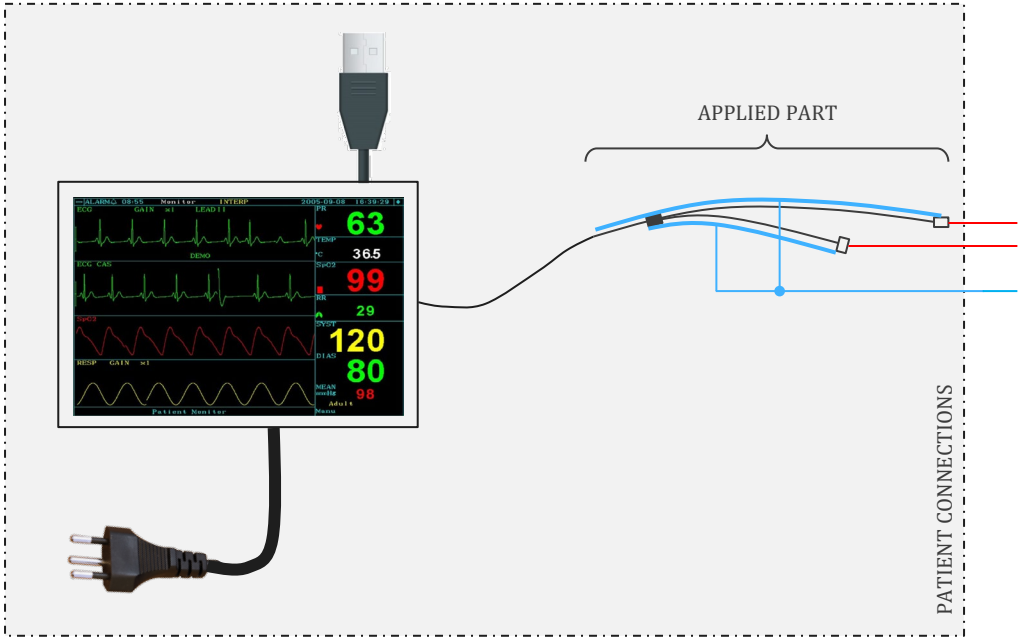
- PATIENT CONNECTIONS are areas of APPLIED PART:
  - one for each conductive area (~~MOPP~~)
    (e.g., electrode, intra-vascular fluid line, sheet, sweat)
  - one for all non-conductive areas (MOPP)
    (covered by a metallic foil or immerged in saline)



3.2.2 PATIENT CONNECTION

- Example:



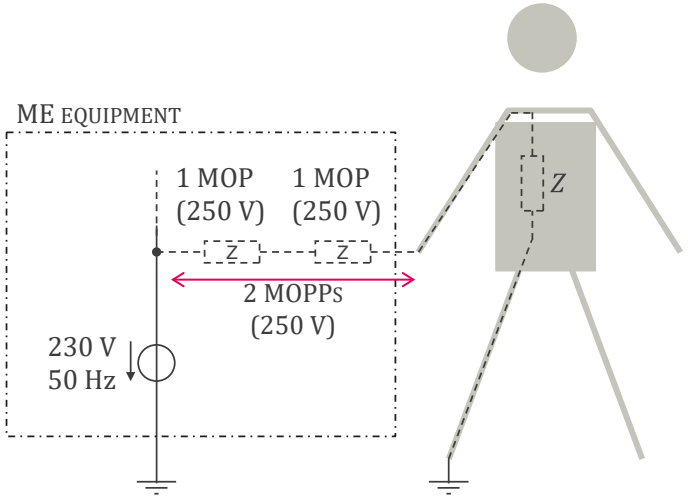


3.2.3 BASIC SAFETY

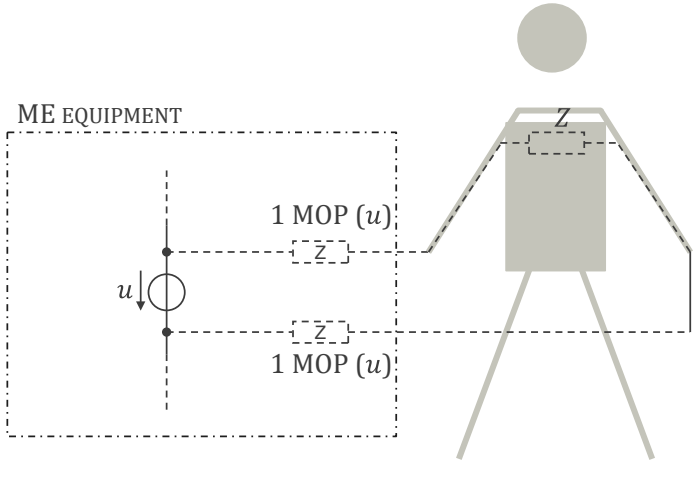
- BASIC SAFETY:
  - limits currents not intended to produce physiological effects, to avoid:
    - d.c. (< 0.1 Hz): tissue necrosis
    - a.c. (≥ 0.1 Hz): ventricular fibrillation or interference with heart pumping action
    - $i \geq 10$ mA: burns
  - 2 MOPs

1 MOP: NORMAL CONDITION	(WORKING VOLTAGE)
1 MOP: SINGLE-FAULT CONDITION	(failure of first MOP or unexpected voltage)

3.2.3 BASIC SAFETY (continued)



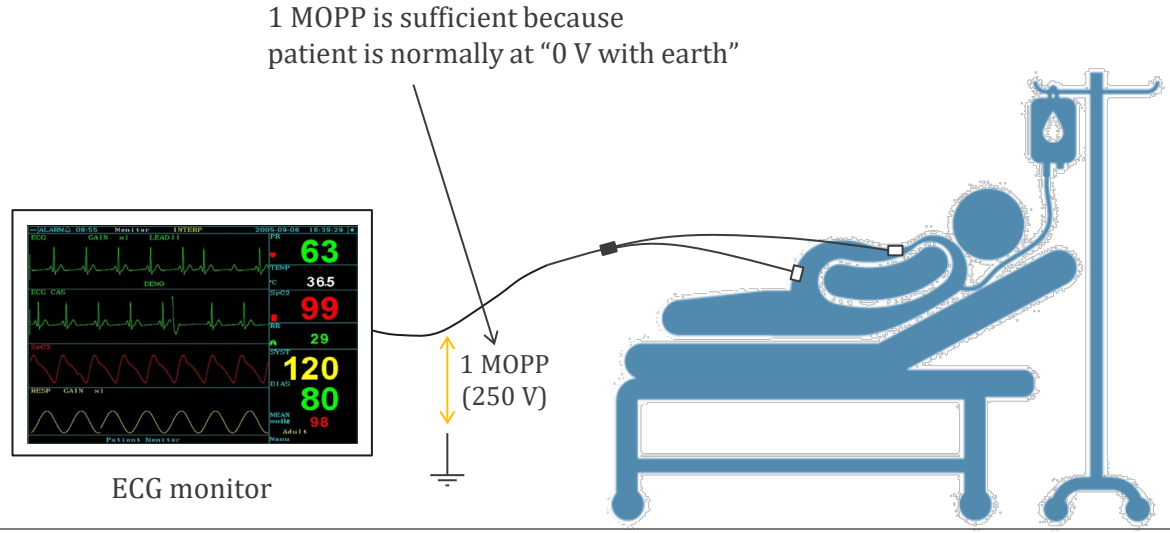
MAXIMUM MAINS VOLTAGE (250 V)



floating voltage (u)

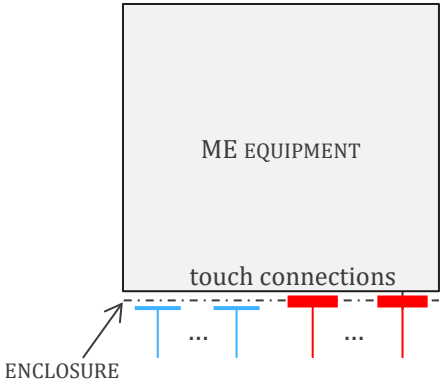
3.2.3 BASIC SAFETY (continued)

- One MOP (250 V) for PATIENT cable and leads



3.2.3 BASIC SAFETY (continued)

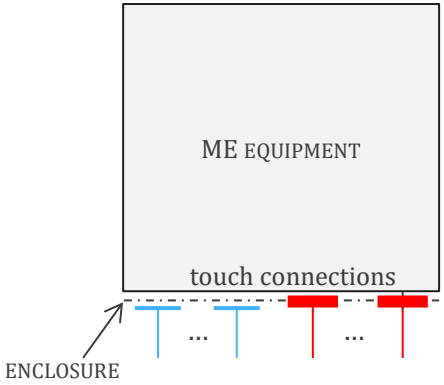
- ENCLOSURE is the exterior surface of ME EQUIPMENT
- touch connections are areas of ENCLOSURE:
  - one for each conductive ACCESSIBLE PART (~~MOP~~)

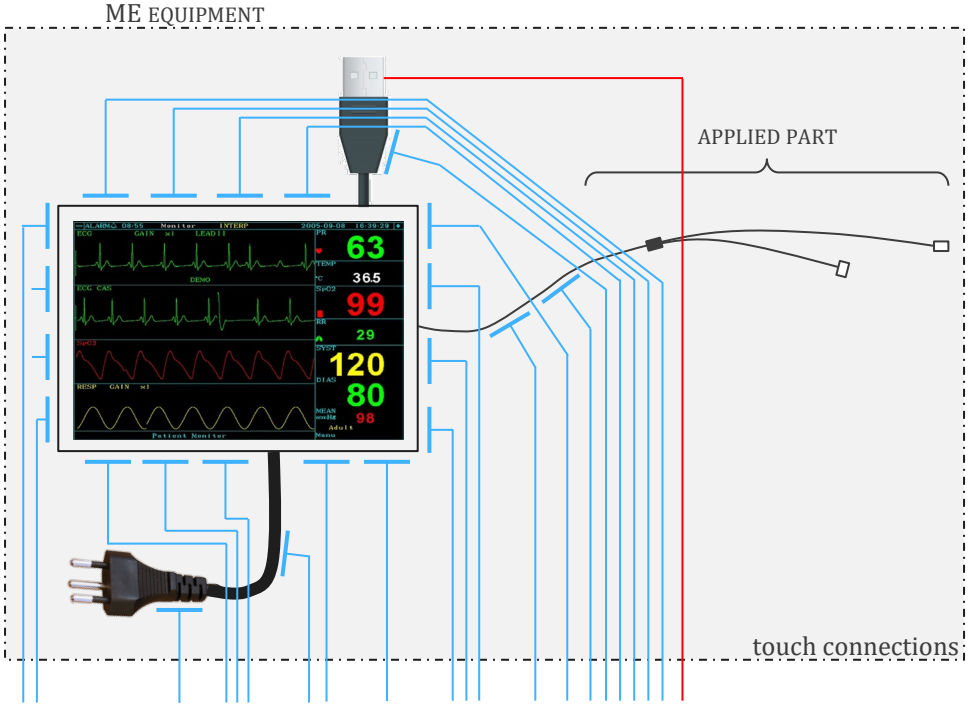


  - one for every non-conductive areas (MOP)
    covered by a metallic foil of 20×10 cm^2 ('hand' model)
    (larger areas if OPERATOR may contact ENCLOSURE with a larger body part than hand)

3.2.3 BASIC SAFETY (continued)

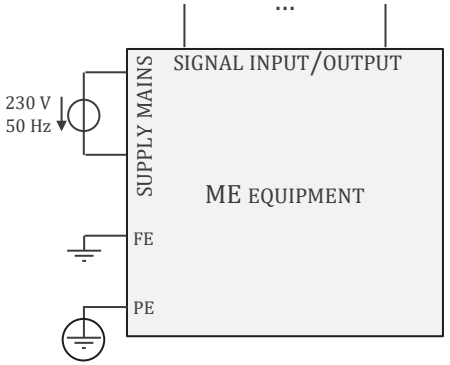
- Example:





3.2.3 Basic safety (continued)

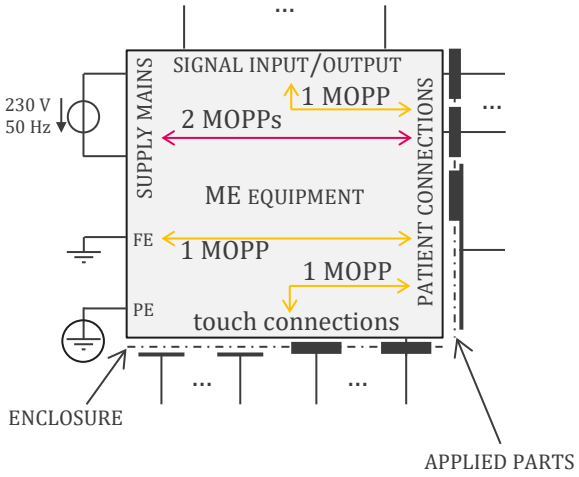
- Supply mains
- Functional earth
- Protective earth

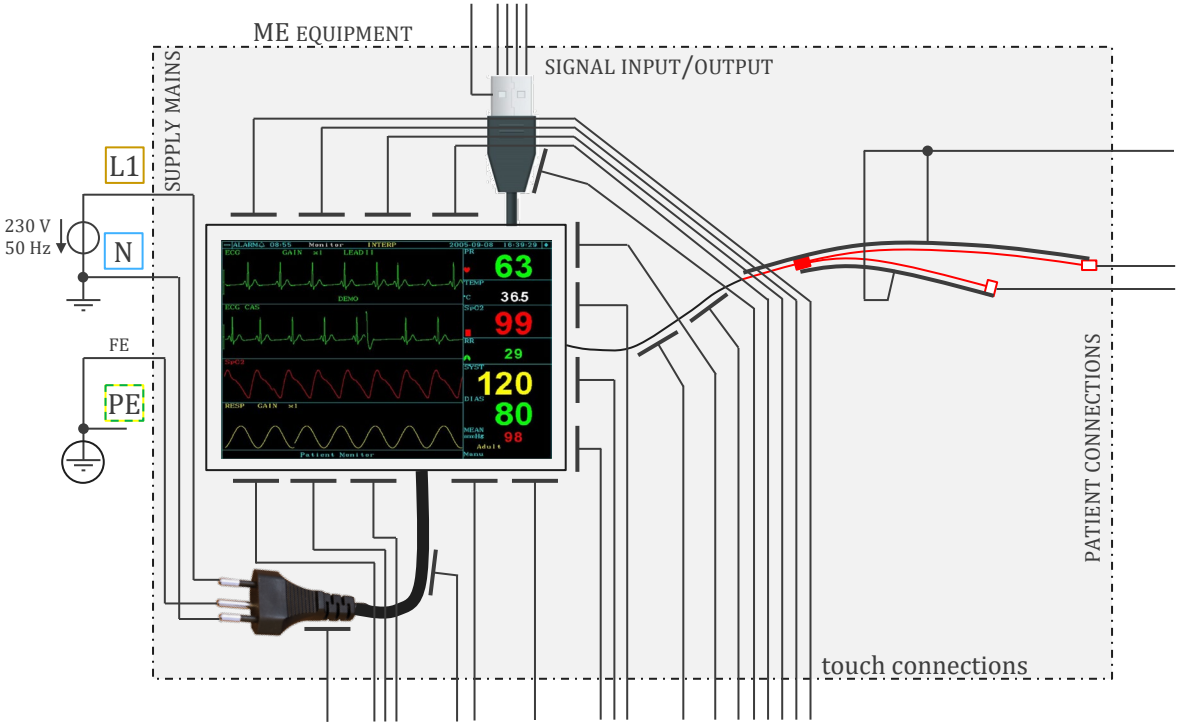


- Signal input/output (e.g., USB)

3.2.3 BASIC SAFETY (continued)

- Example:





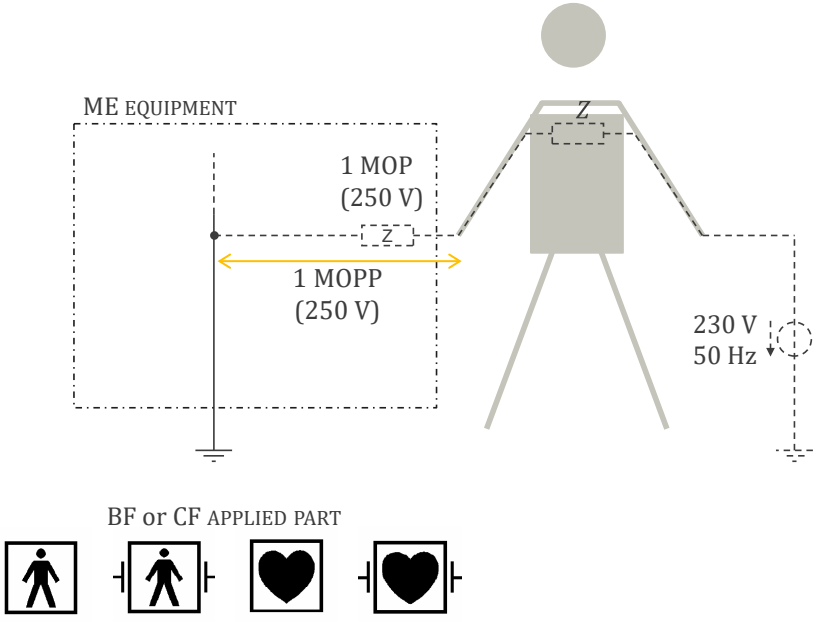
3.2.3 BASIC SAFETY (continued)

	APPLIED PART	DEFIBRILLATION-PROOF APPLIED PART
• TYPE-B APPLIED PARTS (= ~~MOPP~~ with earth)		

- TYPE-F APPLIED PARTS (= MOPP with earth)
  'unintended voltage between PATIENT and earth ⇒ low PATIENT LEAKAGE CURRENT'
  - TYPE-BF APPLIED PARTS
    (e.g., if electrodes)
    
    
  - TYPE-CF APPLIED PARTS
    (e.g., if DIRECT CARDIAC APPLICATION, ECG electrodes)
    
    

3.2.3 BASIC SAFETY (continued)

- One MOP (250 V) to earth for BF or CF APPLIED PART

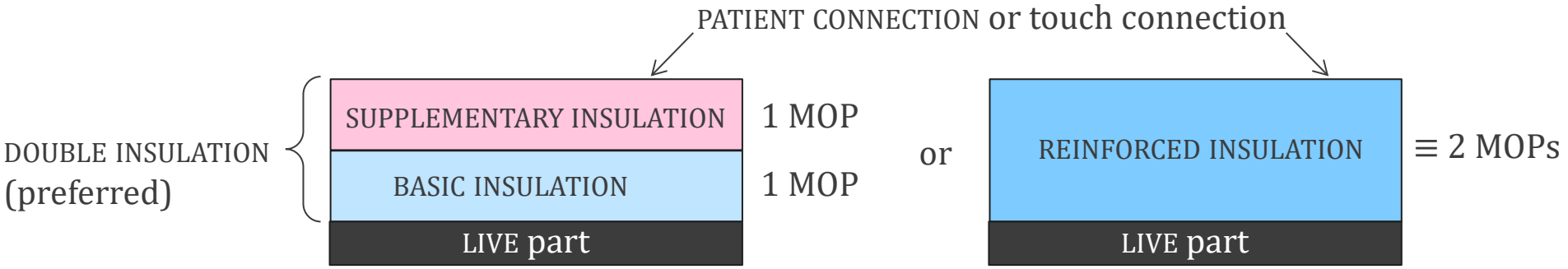


3.2.4 Insulation

- (solid) insulation

  e.g., CLASS II ME EQUIPMENT ⧈

MAINS PART (250 V)	dielectric strength for at least 1 min (V rms ac)	SECONDARY CIRCUITS (≤ 60 V dc)	dielectric strength for at least 1 min (V rms ac)
1 MOOP	1500	1 MOOP	—
2 MOOP	3000	2 MOOP	—
1 MOPP	1500	1 MOPP	500
2 MOPP	4000	2 MOPP	1000



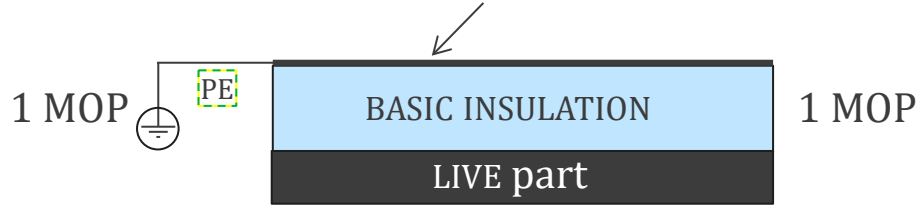
3.2.5 PROTECTIVE EARTH CONNECTION

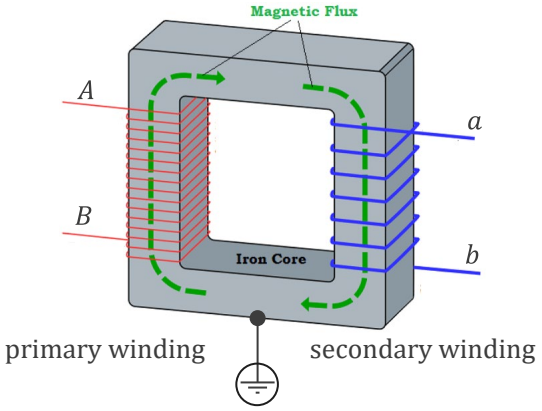
- PROTECTIVE EARTH CONNECTION

  e.g., CLASS I ME EQUIPMENT

MAINS PART (250 V)	dielectric strength for at least 1 min (V rms ac)	SECONDARY CIRCUITS (≤ 34 V dc)	dielectric strength for at least 1 min (V rms ac)
1 MOOP	1500	1 MOOP	500
1 MOPP	1500	1 MOPP	1500

metallic PATIENT CONNECTION or touch connection





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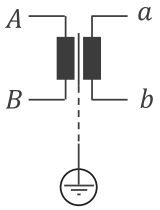


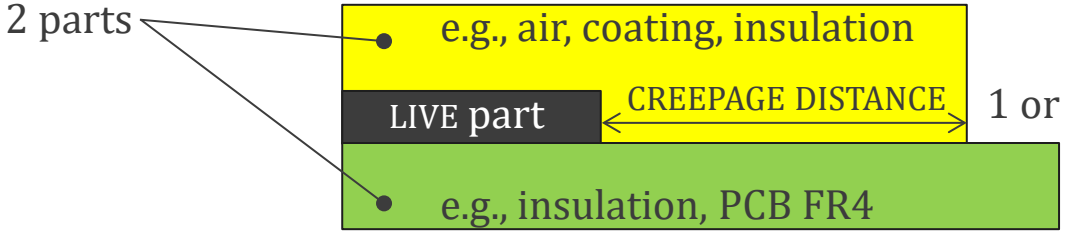
3.2.6 AIR CLEARANCE and CREEPAGE DISTANCE

- AIR CLEARANCE

1 or 2 MOPs

MAINS PART (250 V)	AIR CLEARANCE (mm)	CREEPAGE DISTANCE (mm)
1 MOOP	2	4
2 MOOP	4	8
1 MOPP	2.5	4
2 MOPP	5	8

- CREEPAGE DISTANCE



1 or 2 MOPs

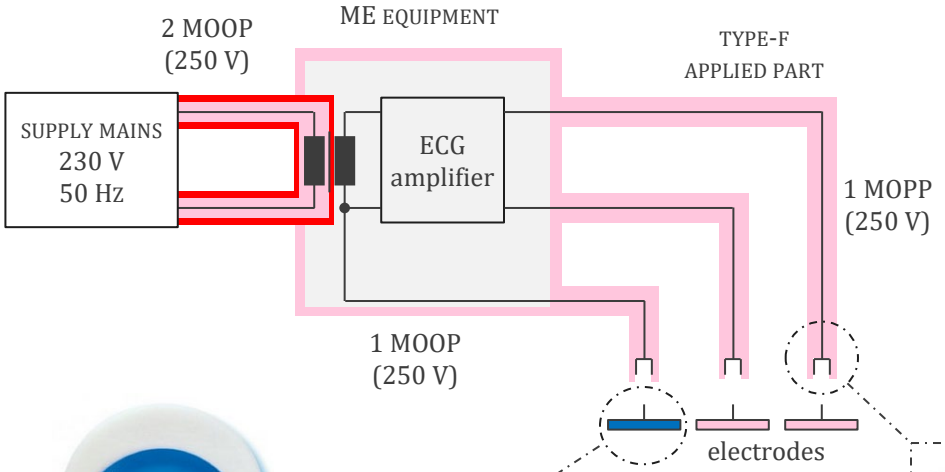
SECONDARY CIRCUITS (≤ 17 V dc)	AIR CLEARANCE (mm)	CREEPAGE DISTANCE (mm)
1 MOOP	0.8	1.7
2 MOOP	1.6	3.4
1 MOPP	0.8	1.7
2 MOPP	1.6	3.4

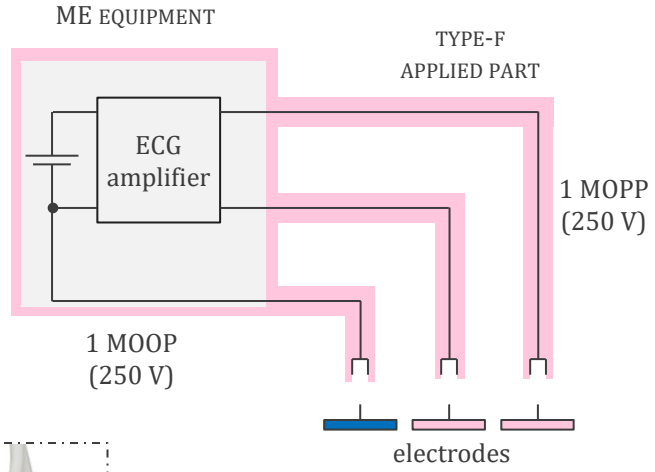
3.2.7 Component impedance

- impedance (COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS = 2 MOP)

  - Y1 capacitors (500 V a.c. WORKING VOLTAGE, withstand voltages up to 4 kV a.c.)
    2 MOOP (250 V) or 1 MOPP (250 V)
  - Y2 capacitors (300 V working voltage, withstand voltages up to 2.5 kV)
    1 MOOP (250 V)

Examples





at least 0.5 mm AIR CLEARANCE with flat surface

Section 3.3 – Leakage current protection

3.3.1 EARTH LEAKAGE CURRENT

3.3.2 TOUCH CURRENT

3.3.3 PATIENT LEAKAGE CURRENT—energized PATIENT

3.3.4 PATIENT LEAKAGE CURRENT—energized SIGNAL INPUT/OUTPUT

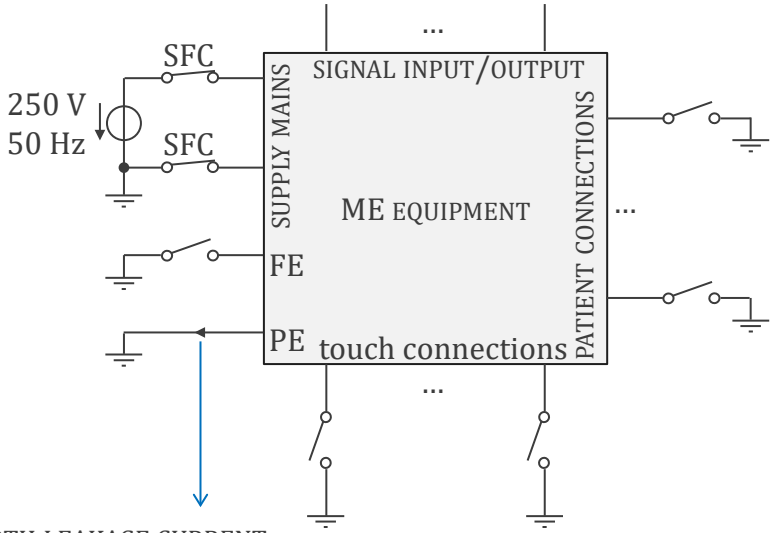
3.3.5 PATIENT LEAKAGE CURRENT—energized ENCLOSURE

3.3.6 PATIENT LEAKAGE CURRENT—energized SUPPLY MAINS

3.3.7 PATIENT AUXILIARY CURRENT

3.3.1 EARTH LEAKAGE CURRENT (PE current)

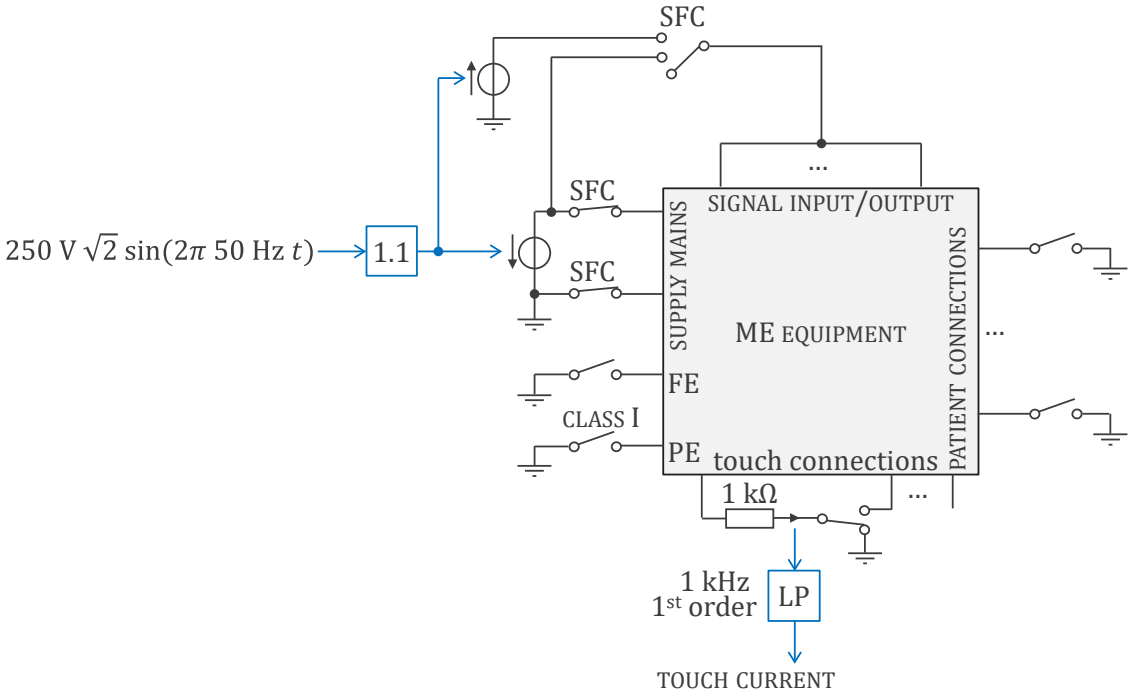
- CLASS I ME EQUIPMENT



EARTH LEAKAGE CURRENT
(max value for any switch position)

TYPE		d.c. (µA)	a.c. (µA)
B	NC	5000	5000
	SFC	10000	10000
BF	NC	5000	5000
	SFC	10000	10000
CF	NC	5000	5000
	SFC	10000	10000

3.2.2 TOUCH CURRENT (ENCLOSURE leakage)

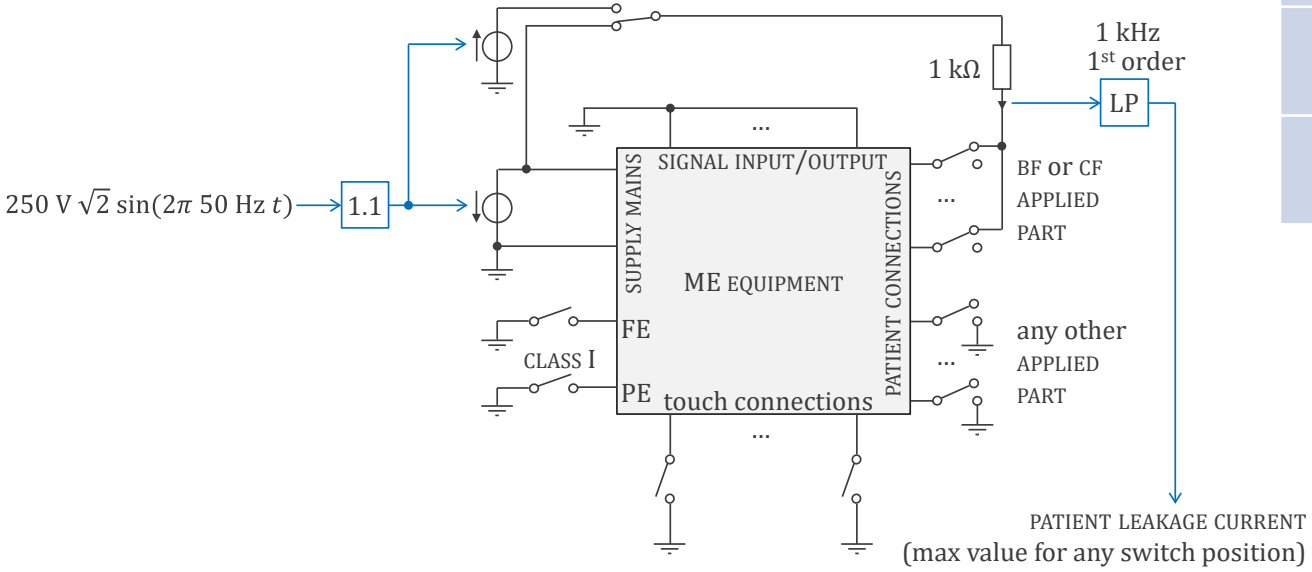


(max value for any switch position and any combination of touch connections)

TYPE		d.c. (µA)	a.c. (µA)
B	NC	100	100
	SFC	500	500
BF	NC	100	100
	SFC	500	500
CF	NC	100	100
	SFC	500	500

without LP: 10000

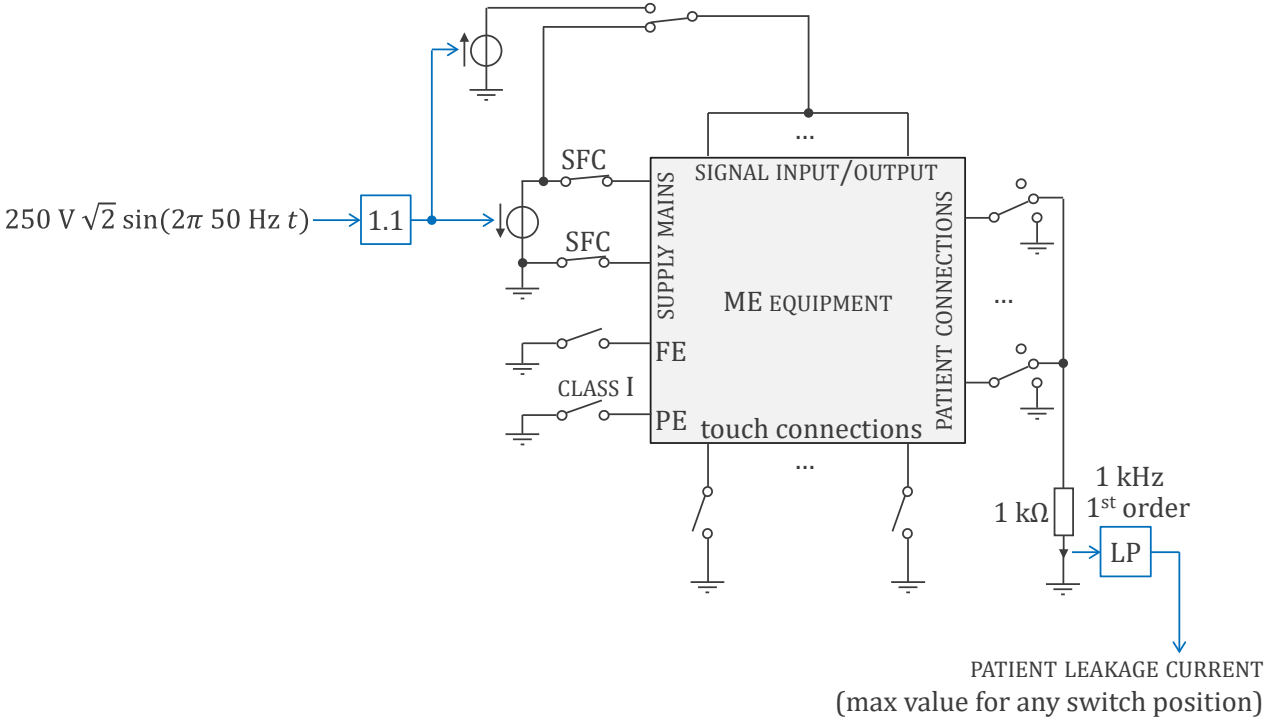
3.3.3 PATIENT LEAKAGE CURRENT—energized PATIENT



TYPE		d.c. (µA)	a.c. (µA)
B			
	SFC	—	—
BF			
	SFC	5000 (5000)	5000 (5000)
CF			
	SFC	50 (100)	50 (100)

without LP: 10000
(Total): all APPLIED PARTS together

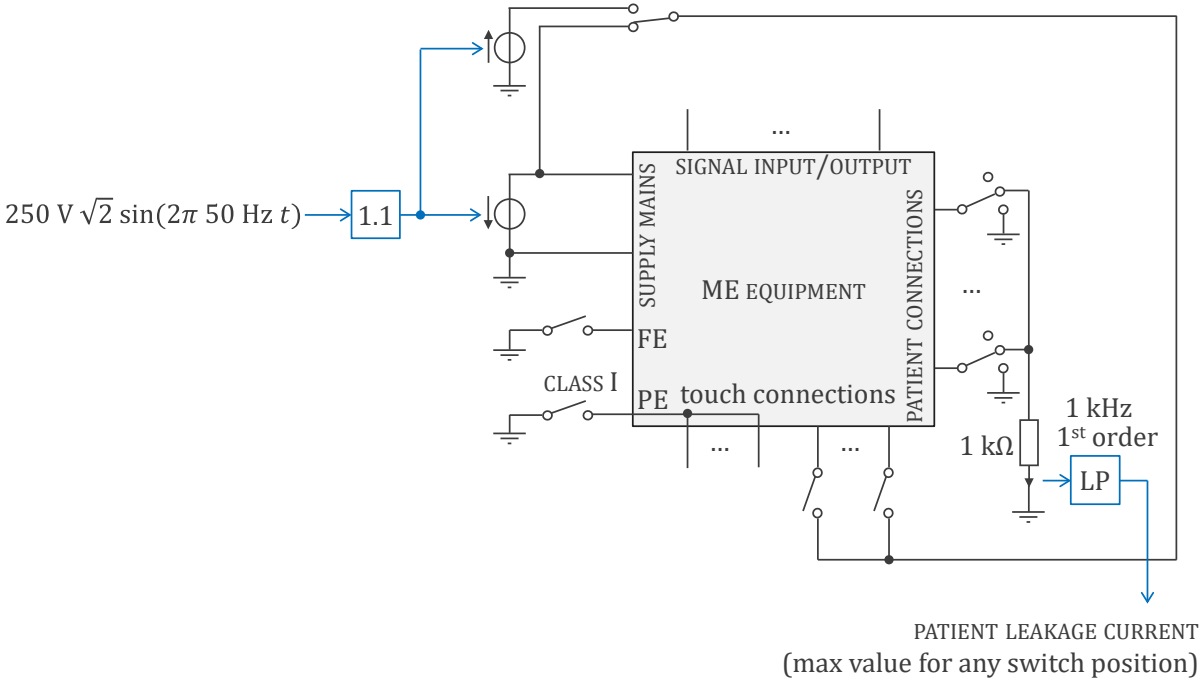
3.3.4 PATIENT LEAKAGE CURRENT—energized SIG. INPUT/OUTPUT



TYPE		d.c. (µA)	a.c. (µA)
B	NC	10 (50)	100 (500)
	SFC	50 (100)	500 (1000)
BF	NC	10 (50)	100 (500)
	SFC	50 (100)	500 (1000)
CF	NC	10 (50)	10 (50)
	SFC	50 (100)	50 (100)

without LP: 10000
(Total): all APPLIED PARTS together

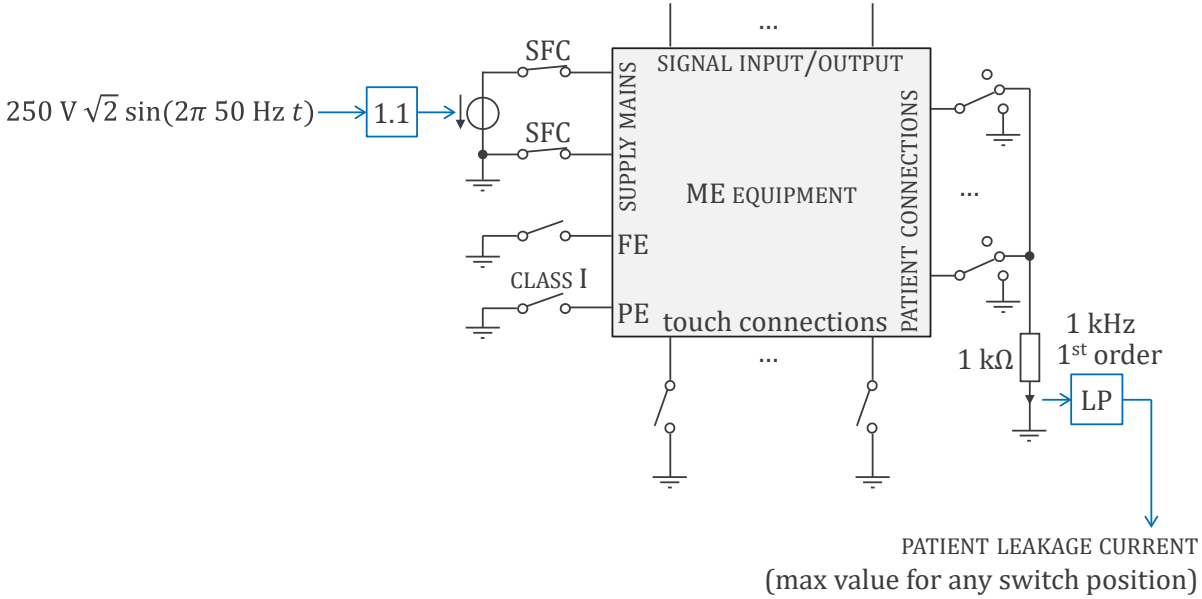
3.3.5 PATIENT LEAKAGE CURRENT—energized ENCLOSURE



TYPE		d.c. (µA)	a.c. (µA)
B			
	SFC	500 (1000)	500 (1000)
BF			
	SFC	500 (1000)	500 (1000)
CF			
	SFC	50 (100)	50 (100)

without LP: 10000
(Total): all APPLIED PARTS together

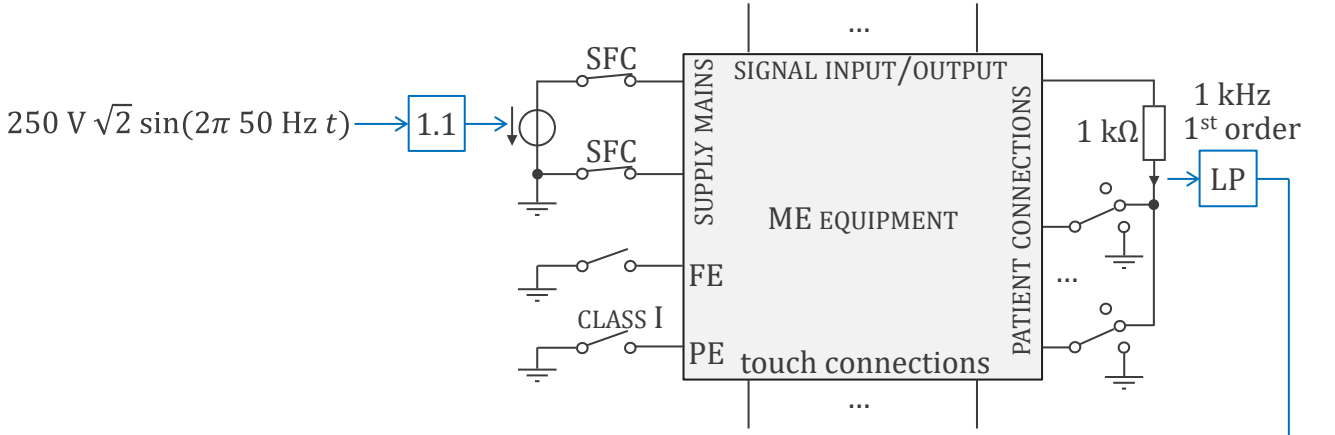
3.3.6 PATIENT LEAKAGE CURRENT—energized SUPPLY MAINS



TYPE		d.c. (µA)	a.c. (µA)
B	NC	10 (50)	100 (500)
	SFC	50 (100)	500 (1000)
BF	NC	10 (50)	100 (500)
	SFC	50 (100)	500 (1000)
CF	NC	10 (50)	10 (50)
	SFC	50 (100)	50 (100)

without LP: 10000
(Total): all APPLIED PARTS together

3.3.7 AUXILIARY CURRENT



TYPE		d.c. (µA)	a.c. (µA)
B	NC	10	100
	SFC	50	500
BF	NC	10	100
	SFC	50	500
CF	NC	10	10
	SFC	50	50

without LP: 10000

Section 3.4 – Defibrillation-proof protection

3.4.1 Operator protection test

3.4.2 Energy reduction test

~~3.4.3 Integrity test~~

DEFIBRILLATION-PROOF APPLIED PART

TYPE-B

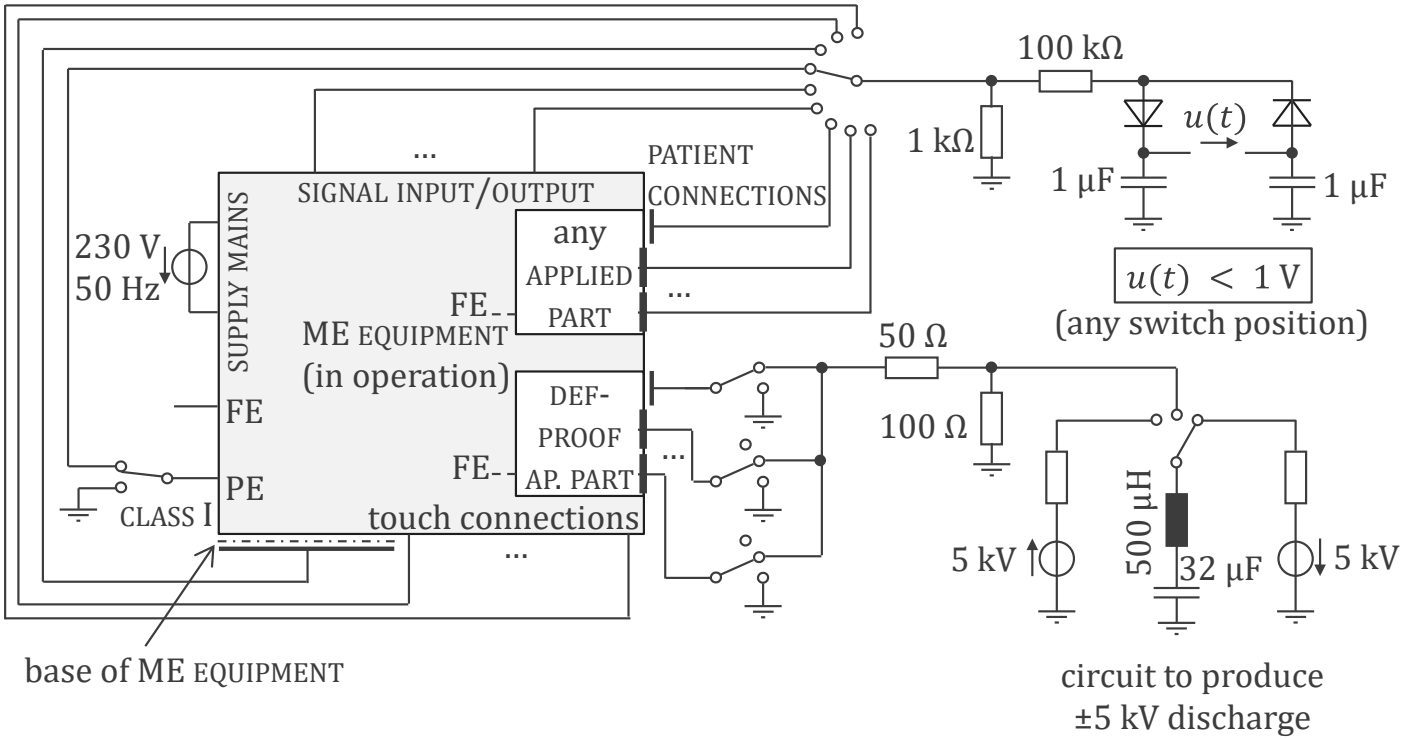
TYPE-BF

TYPE-CF

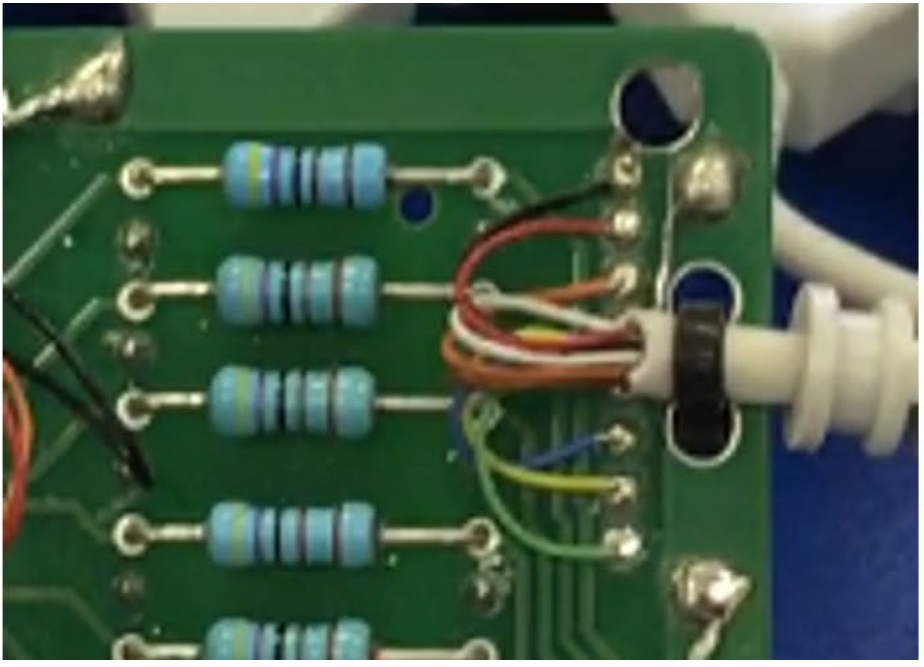
- recovery time: as stated in ACCOMPANYING DOCUMENTS

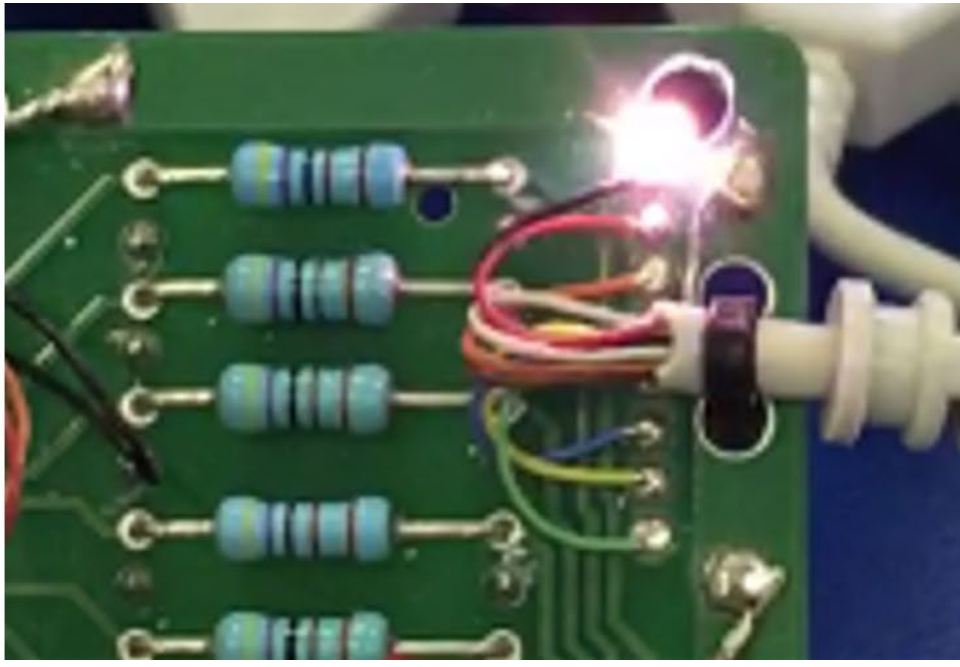
- AIR CLEARANCE: 4 mm
- CREEPAGE DISTANCE: 4 mm

3.4.1 Operator protection test

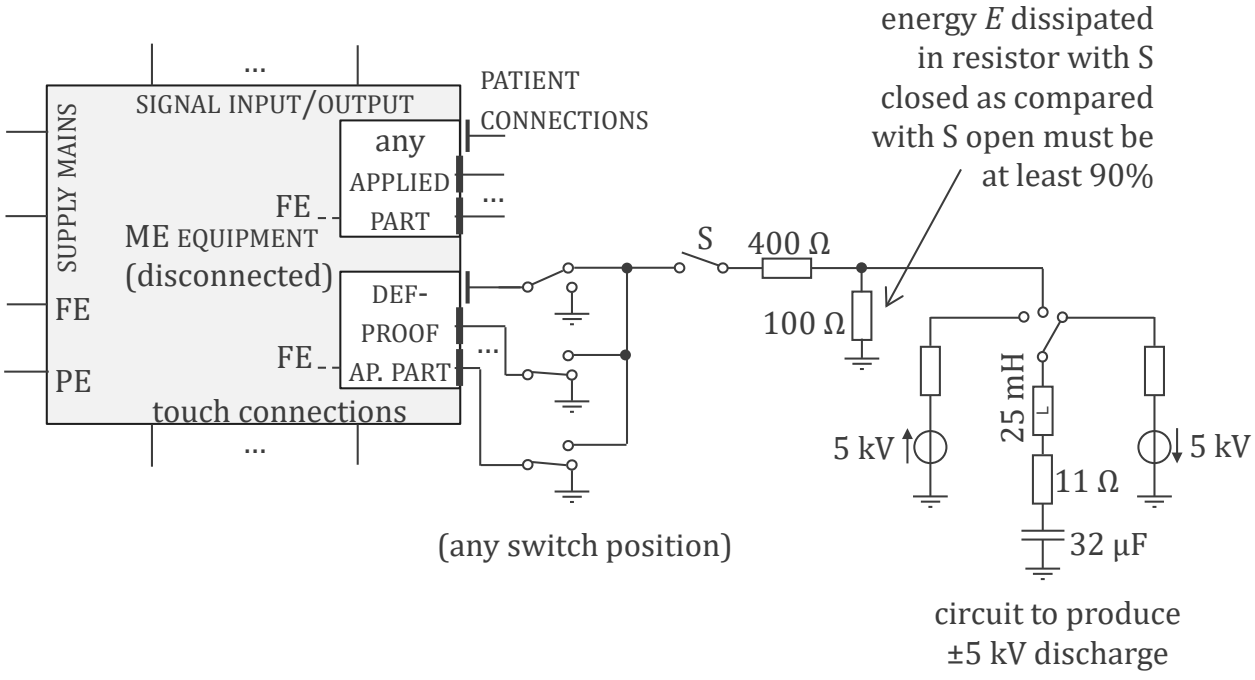


Example (of failed test)





3.4.2 Energy reduction test

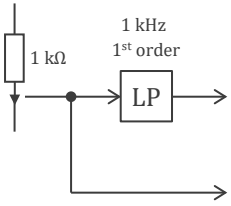


Summary (example: TYPE CF)

AUXILIARY CURRENT: between PATIENT CONNECTIONS

PATIENT LEAKAGE CURRENT: between PATIENT CONNECTIONS and

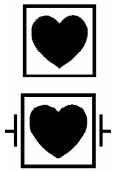
- earth
- SIGNAL INPUTS/OUTPUTS
- ENCLOSURE
- SUPPLY MAINS



	d.c. (µA)	a.c. (µA)
NC	≤ 10	≤ 10
SFC	≤ 50	≤ 50

- d.c. (< 0.1 Hz) tissue necrosis
- a.c. (≥ 0.1 Hz) ventricular fibrillation or interference with heart pumping action
- a.c. (≤ 10 mA) burns

NC: normal condition, SFC: single-fault condition

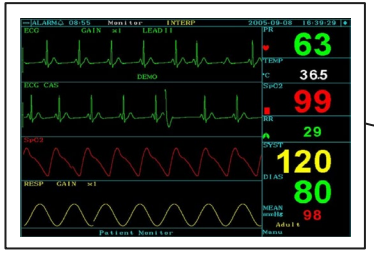


TYPE-CF APPLIED PART

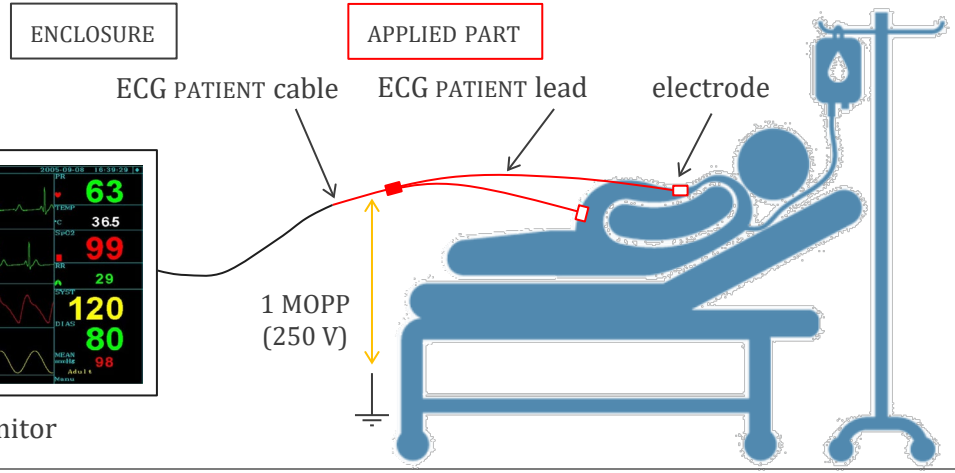
DEFIBRILLATION-PROOF TYPE-CF APPLIED PART

PATIENT CONNECTIONS:

- electrodes
- all other parts of APPLIED PART together



ECG monitor



Quiz

This symbol means

- ☐ do no enter
- ☐ TYPE-BF APPLIED PART
- ☐ Faraday cage
- ☐ use antistatic clothing

This symbol indicates

- ☐ CLASS I ME EQUIPMENT
- ☐ high accuracy
- ☐ high protection
- ☐ not PROTECTIVELY EARTHED

The AUXILIARY CURRENT is a current

- ☐ from PATIENT to earth
- ☐ supplied by a SIGNAL OUTPUT
- ☐ that is optional
- ☐ between two PATIENT CONNECTIONS

Medical electrical equipment

- ☐ must comply with IEC60601-1
- ☐ must comply with ISO14708-1
- ☐ must comply with UL9001
- ☐ must comply with ISO81060-3

A patient lead must be protected by

- ☐ 2 MOPPs (for 250 V)
- ☐ 1 MOPP (for 250 V)
- ☐ 2 MOOPs (for 3.7 V)
- ☐ 1 MOOP (for 3.7 V)

A risk is measured with

- ☐ its HARM probability
- ☐ its HARM SEVERITY
- ☐ the sum of HARM prob. and sev.
- ☐ the product of HARM prob. and sev.

IP 60 marked on a device means

- ☐ Intellectual Property, clause 6.0
- ☐ address 60 of internet protocol
- ☐ 60 steps from initial point
- ☐ dust-tight, no water protection

In the IEC60601-1 family, SMALL CAPITALS are used to

- ☐ indicate terms that has been defined
- ☐ emphasize words
- ☐ indicate mandatory measure
- ☐ highlight important concepts