How to Handle

Electricity in Hospitals

FIRE
SHOCK
EMI

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Member

IEC - TC64: MT 3, MT 12, MT 40, MT 41, WG 43
TC81: ahG 19, MT 3, MT 14, MT 21, WG 18
SC 37 A: WG3 & WG 05
SyC LVDC WG 01

BIS - NBC-2016
ETD 20 (NEC, IS732, IS3043, IS/IEC 62305), ETD 30 & ETD50

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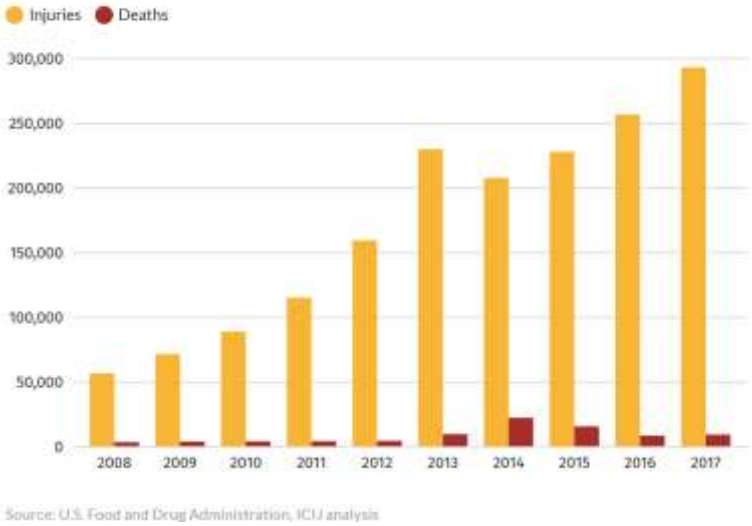
The International Consortium of Investigative Journalists

CAPE

Medical devices potentially linked to almost 83,000 deaths

ICIJ analysis of data from the United States has also found more than 1.7 million injuries potentially linked to medical devices.



Source: U.S. Food and Drug Administration, ICIJ analysis

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Examples: Electro cautery burns

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Electrical Safety in Hospitals – WHY?

- Medical electrical equipment may often be used to support or substitute vital body functions, the breakdown of which may cause a dangerous situation

DIALYSIS MACHINE

VENTILATOR

Patients may be undergoing surgery and in life support systems. Any break in electrical supply for more than few seconds could be fatal for them.

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Electrical Safety in Hospitals – WHY?

- Specific locations in medical establishments where flammable atmosphere exists, call for special treatment

ICU/CCU/MICU/NICU

OPERATION THEATRE

CATH LAB

All these areas are consists of:

1. Equipment with Conductive metal parts
2. Oxygen rich environment with ventilator, oxygen concentrators, Anesthesia Ventilators
3. Have presence of alcohol and other flammable liquids like sanitizer, alcohol rubs, spirit etc.

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Electrical Safety in Hospitals – WHY?

- Patient is unconscious / unresponsive / difficult to move
- Patient in life saving equipment / Many ill patients in the affected environment
- Severeness of the hazard environment (fire / smoke)

FIRE
Oxygen rich areas
Presence of alcohol

78% of 33 hospital fires are by electricity
(source International Journal of Community Medicine and Public Health).

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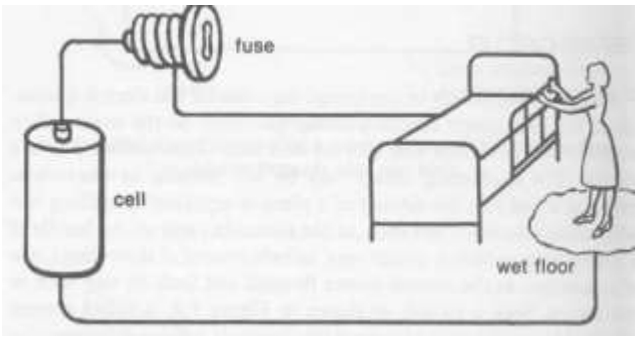
ELECTRIC SHOCK / BURNS (MIRCO / MACRO)

- Skin, is bypassed
- Conductive instruments in contact with the bloodstream or heart muscle
- WET floor

CAUTERY MACHINE

USING DEFIBRILLATOR

INTRA CARDIAC DEFIB PADDLE



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Hospitals **FIRE PREVENTION** or **FIRE PROTECTION** ??

Electrical FIRE Prevention (avoid ignition)	Electrical FIRE Prevention (Spreading)
Protection against **THERMAL EFFECT**	Active & Passive Measures
• Avoidance of Heating, Arching, • Protection from Over Current • Protection from Short Circuit • Protection from Earth fault and Leakages	• Detection • Suppression • Limit in an area • Use materials which do not spread fire

- National Electrical Code of India 2023
- IS 732: Code of practice for wiring
- IS17512: Safety in Medical Locations
- All from IEC 60364 series of standards used Globally
- The standards are aligned with all IS/IEC ISO standards referred in Hospitals (including Fire safety standards).

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Challenges

1. **Importance of Electricity / ME / MES is not seriously considered** (except the cost of equipment),
2. **Understanding on electrical classification of medical locations,**
3. **Understanding on advanced safety measures in medical locations** (expensive equipment are installed in electrically unsuitable locations / methods),
4. **Poor knowledge of equipment supplier / engineer** (lack of training / experience / knowledge),
5. **Recommended Maintenance & Calibration of ME/MES**,
6. **Misleading information from authorities** (e.g. [1] NABH guide. *The help of new technology like thermal imaging equipment can help detect loose connections in the system and thereby prevent fire incidents*), ([2] circular from government departments to hospitals),
7. **Trained Staff, Drawings, Manuals, ……..**

Safety in Medical locations need coordinated efforts from group of engineers skilled in handling different challenges.

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First Step - Identification of Risks (e.g. IEC 60513)

IEC 60513 – Fundamental aspects of electrical safety standards for medical electrical equipment

1. A device's inability to carry out its intended function,
2. Energies (electrical or thermal) delivered when functioning normally,
3. Equipment faults,
4. Fire or explosion resulting from ignition of flammable material,
5. Incorrect installation of ME equipment,
6. Incorrect selection and use of ME equipment,
7. Electromagnetic interference,
8. Release of corrosive, poisonous or hot liquids or gases, or contact with biologically unsafe materials
9. Disposal of material and byproducts resulting from the use of medical electrical equipment.

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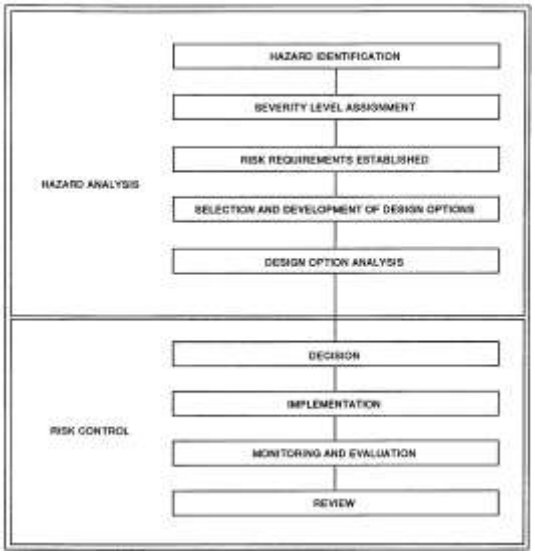
Development of systems and methods to handle the risk

IEC 60513 – Fundamental aspects of electrical safety standards for medical electrical equipment

1. Hazard identification
2. Severity level
3. Deciding on acceptable risk levels
4. Fault avoidance and control
5. Integrity levels
6. Achieving acceptable risk levels
7. Surpassing specified requirements
8. Treatment of risk in the IEC 60601 series
9. Fault conditions
10. Single fault philosophy
11. Integrity levels implied in IEC 60601-1
12. Acceptable risk levels according to IEC 60601

- Product standards
- Process standards
- Installation and environmental standards
- Application standards



Flow chart for risk management

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Safety – How??

Equipment Vs Installation

IEC 60601 (IS 13450), IS/IEC 62353 & (IEC 60364-7-710 (IS17512 / NEC 2023 (SP30))

MEDICAL ELECTRICAL EQUIPMENT & SYSTEMS ME & MES

⟺

POWER SUPPLY & DISTRIBUTION
MAINS, ALTERNATES (TRANSFORMER DG / UPS)

- Safety of the equipment depends upon the supply parameters as well, (e.g. Disconnection / Single fault condition),
- Operation of protective device used in multiple supplies, (e.g. Protective devices may work in Transformer, may not in DG, may be in UPS),

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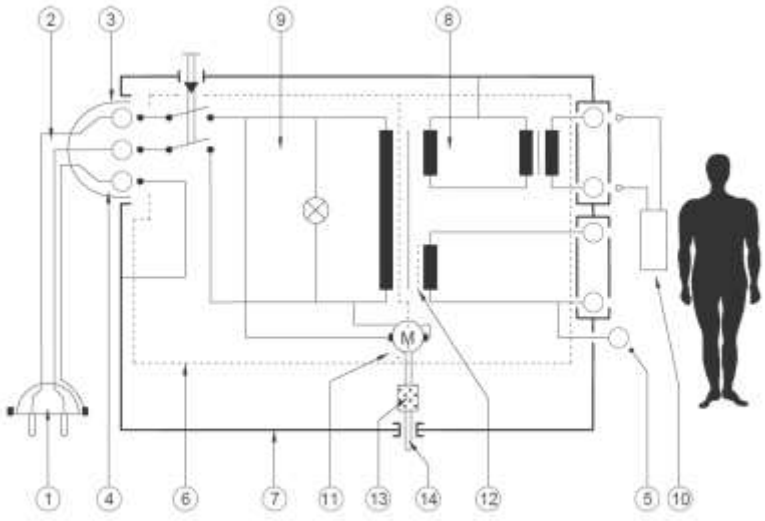
Example of a Class 1 medical equipment



Key

1. MAINS PLUG with protective earth contact
2. DETACHABLE POWER SUPPLY CORD
3. APPLIANCE COUPLER
4. Protective earth contact and pin
5. FUNCTIONAL EARTH TERMINAL
6. BASIC INSULATION
7. ENCLOSURE
8. SECONDARY CIRCUIT
9. MAINS PART
10. APPLIED PART
11. Motor
12. PROTECTIVELY EARTHED screen
13. SUPPLEMENTARY INSULATION
14. Shaft that is an ACCESSIBLE PART

Fig 3 of IEC 60601-1 (IS13450): **Medical Electrical Equipment**

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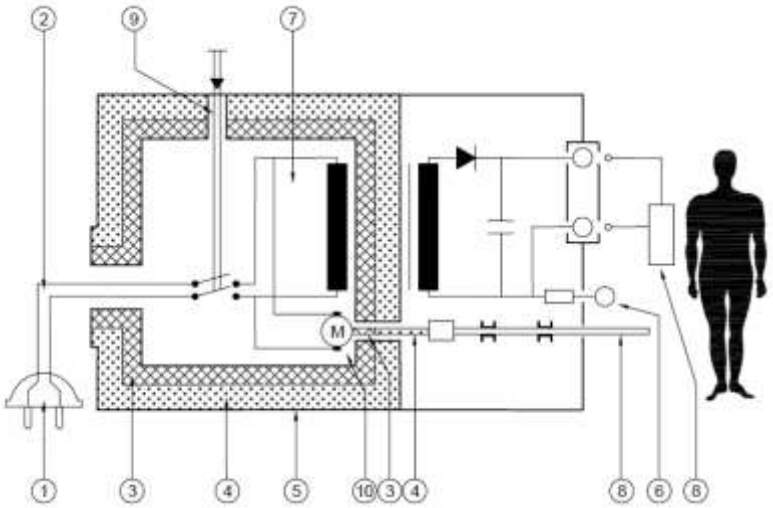
Example of a Metal Enclosed Class II Medical Electrical Equipment



Key

1. MAINS PLUG
2. POWER SUPPLY CORD
3. BASIC INSULATION
4. SUPPLEMENTARY INSULATION
5. ENCLOSURE
6. FUNCTIONAL EARTH TERMINAL
7. MAINS PART
8. APPLIED PART
9. REINFORCED INSULATION
10. Motor

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Applied part:

Part of the medical electrical equipment which in normal use:

- Necessarily comes into physical contact with the patient for the equipment to perform its function, or
- can be brought into contact with the patient, or
- needs to be touched by the patient

Applied Part	Symbol	Description
B		Earthed Part. Less safe against Earth fault
BF		Earth Insulated part (floating). Safer than B
CF		Earth Insulated part (floating) Safer than BF. Can be placed in direct contact with heart

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Medical Locations (IEC 60364-7-710 / NEC2023 / IS17512)

GROUP 0	Medical location where no applied parts are intended to be used
GROUP 1	Medical location where applied parts are intended to be used – externally – invasively to any part of the body (except group 2) *(Disconnection shall be possible with out danger to patient. Examination and treatment can be safely interrupted and repeated)*
GROUP 2	*M*edical location where applied parts are intended to be used in applications such as intra cardiac procedures, operating theatres and vital treatment. *(Discontinuity (failure) of the supply can cause danger to life)*

Intra cardiac procedure: Procedure whereby an electrical conductor is placed within the heart of a patient or is likely to come in contact with the heart, such conductor being accessible outside the patient's body. In this context, an electrical conductor includes insulated wires such as cardiac pacing electrodes or intra cardiac ECG electrodes, or insulated tubes filled with conducting fluids.

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Medical Locations

Medical Locations	Group 0	Group 1	Group 2
1. Massage room	x	X	
2. Bedrooms		X	
3. Delivery room		X	
4. ECG, EEG, EHG room		X	
5. Endoscopic room		X_b	
6. Examination or treatment room		X	
7. Urology room		X_b	
8. Radiological diagnostic and therapy room, other than mentioned under 21		X	
9. Hydrotherapy room		X	
10. Physiotherapy room		X	
11. Anesthetic room			X
12. Operating theatre			X
13. Operating preparation room		X	X
14. Operating plaster room		X	X
15. Operating recovery room		X	X
16. Heart catheterization room			X
17. Intensive care room			X
18. Angiographic examination room			X
19. Haemodialysis room		X	
20. Magnetic resonance imaging (MRI) room		X	
21. Nuclear medicine		X	
22. Premature baby room			X

[a] Luminaries and life-support medical electrical equipment which needs power supply within 0.5s or less.
[b] Not being an operating theatre.

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NEC 2023 (also in NEC 2011): **Medical IT systems**

Medical IT systems

In group 2 medical locations, a medical IT system, (including Medical Isolation Transformer and Medical insulation monitors), shall be used for final circuits and where the same final circuit is connected to ME equipment or an ME system, located within the patient environment. Exceptions can be made for final circuits for

- equipment with a rated power greater than 5 kVA,
- X-ray equipment,
- the supply of the motors of fixed operating tables.

In medical locations of group 2, the supply to final circuits for socket-outlets for ME equipment and ME systems used for life-support of the patient, shall not be automatically disconnected in the event of a first fault.

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Safety – How??

Equipment Vs Installation

IEC 60601 (IS 13450), IS/IEC 62353 & (IEC 60364-7-710 (IS17512 / NEC 2023 (SP30))

Installation

1. Medical Locations: Group 0, Group 1, Group 2
2. TN-S & IT Electric System Earthing
3. Protective equipotential bonding < 50 V in Group 0 & < 25 volt in Group 1 & 2 locations
4. Continuity of supply for Life saving equipment in Group 2 locations
5. EMI

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Challenges

CAPE

Coordination between Bio-medical and Electrical engineers

Two common misinterpretation and mistakes are compared here

1. Demand for separate earth electrode
2. Demand for low Neutral to Earth Voltage (e.g. 1 or 2) Volt.

Management of Hospitals and electrical engineers always try to meet this demand.

The above demands (e.g. 1 & 2) are against

“SCIENCE”

“STANDARDS”

“RULES & REGULATIONS”

& The main reason for accident

(Shock / fire).

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Actual Practice Vs Recommendation in Standard

e.g. Electrical Safety Audits

1. General Inspection,
2. Earth electrode resistance measurement,
3. Thermography.

No 2 is removed,

No 3 is not recognized.

Follow NEC of India 2023

- **19 Inspections**
- **11 tests (group 0)**
- **Additional (group 1 & 2)**

Note: Accreditation systems are yet to consider ELECTRICAL SAFETY MEASURES.

Instead, they give WRONG information. (e.g. NABH guide - The help of new technology like thermal imaging equipment can help detect loose connections in the system and thereby prevent fire incidents)

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Safety Audit & VERIFICATION

Standard FMS 3, of Guidebook to NABH Accreditation Standards for Hospitals (5th Edition), page number 218, which is as below:

"The intent of electrical safety audits is to minimize the electrical risks to persons and property and ensure that occurrence of fire due to short-circuiting is prevented. It shall be performed at least once a year. It could be incorporated into the electric system maintenance plan. The help of new technology like thermal imaging equipment can help detect loose connections in the system and thereby prevent fire incidents. This shall incorporate statutory requirements where applicable. National Electrical Code of India 2011 could be used as a reference document"

SAFETY IS NON-COMPROMISE

THERMOGRAPHY IS NOT RECOGNISED AS A SAFETY MEASURE IN LOW VOLTAGE ELECTRICAL INSTALLATION.

COMPLIANCE TO NEC 2023 IS A LEGAL REQUIREMENT.

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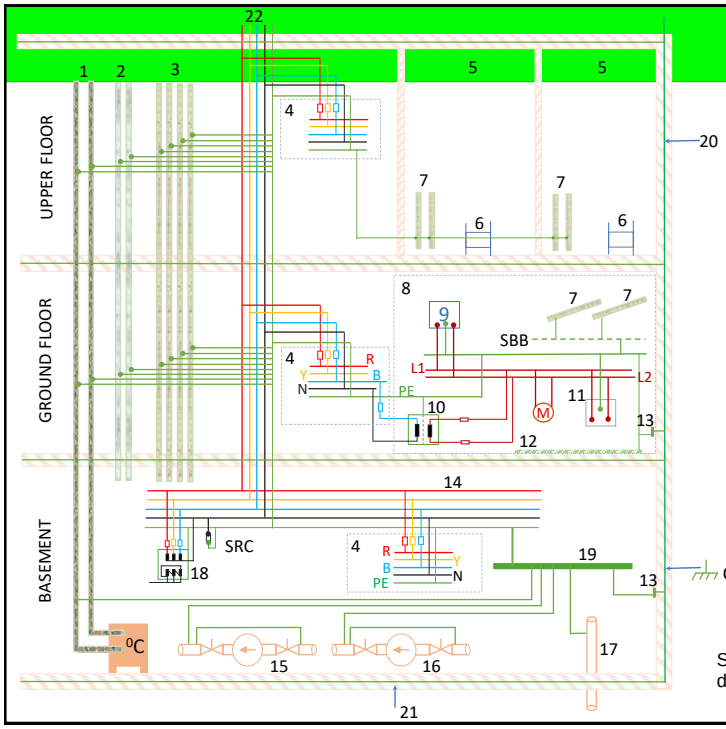

Recommended method

1 = Heating / Air condition pipes
2 = Water supply
3 = Gas supply
4 = Distribution board
5 = General ward
6 = Hospital bed
7 = Metal pipes (water, oxygen, etc)
8 = Group 2 medical location
9 = Insulation monitoring device
10 = Medical isolating transformer
11 = Socket outlet
12 = Antistatic Grid.
13 = Bonding for PME
14 = Main Distribution Board
15 = Water meter
16 = Gas meter
17 = Waste water
18 = Transformer
19 = MET
20 = Down Conductor of LPS
21 = Foundation earth
22 = Busbar trunking
R, Y, B = phase conductors
N = neutral conductors
PE = protective conductor
L1 & L2: Line conductors of medical IT
SBB = Supplementary Bonding Bar
M = Class 2 ME equipment.
SRC = System Referencing Conductor

SRC = Neutral earthing of Transformer through a disconnectable link – Preferably inside Main Distribution Board

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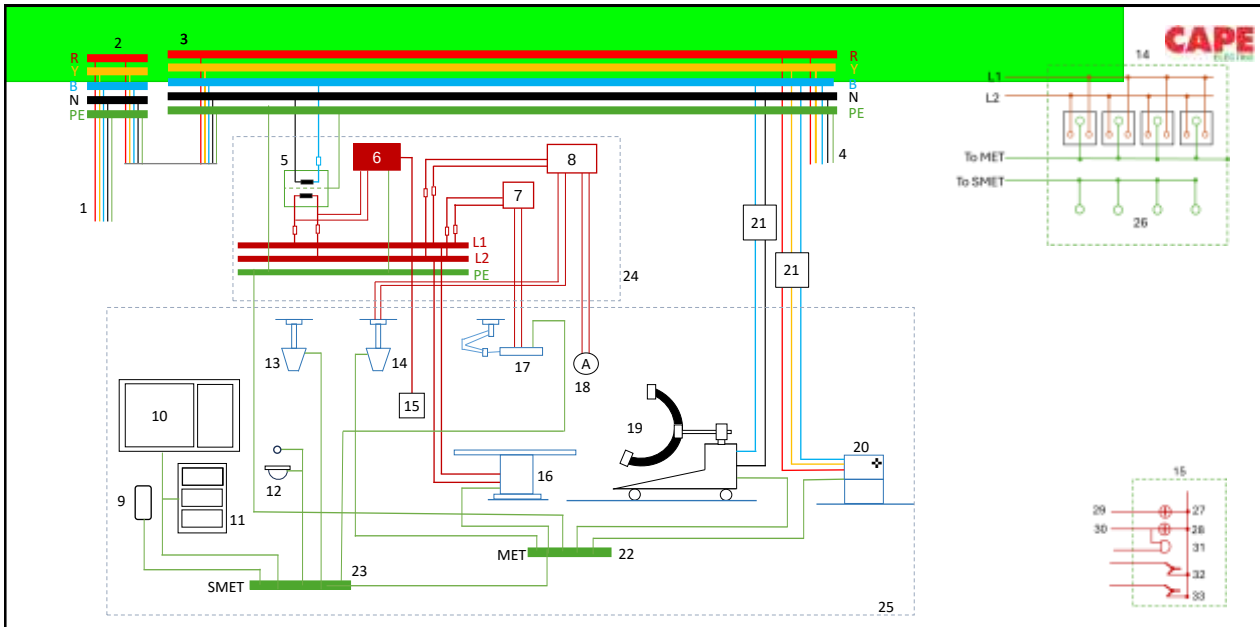

All protective and functional earthing system and conductors there of, including connections are shown in green colour

Recommended method

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1. Feeder from the main service entrance
2. Distribution of the floor supply system
3. Operating theatre distribution panel
4. Safety supply system
5. Medical isolating transformer
6. Insulation monitoring device
7. Special safety supply system E1
8. Special safety supply system E2
9. Central heating
10. Metal window-frame
11. Metal cabinet for instruments
12. Meal washing-basin and water supply
13. Ceiling stand with outlets for gas supply
14. Ceiling stand with mains socket outlets (with terminals for equipotential bonding, enclosure connected to the protective, conductor bar)
15. Alarm device for the insulation monitoring device (example)
16. Operating table (electrically driven)
17. Operating lamp
18. Ampere meter for special safety
19. X-ray equipment
20. Sterilizer
21. Residual-current protective device
22. MET: Main Earthing Terminal of the location
23. SMET: Sub earthing terminal of the location
24. Medical IT system
25. Group 2 medical location
26. Terminals for equipotential bonding
27. Operation (button)
28. Warning (button)
29. Green
30. Red
31. Buzzer
32. Stop button for buzzer
33. Test button

PE = protective conductor conductor bar)
EC = equipotential bonding
L1, L2, L3 = phase conductors
N = neutral conductor

Recommended method

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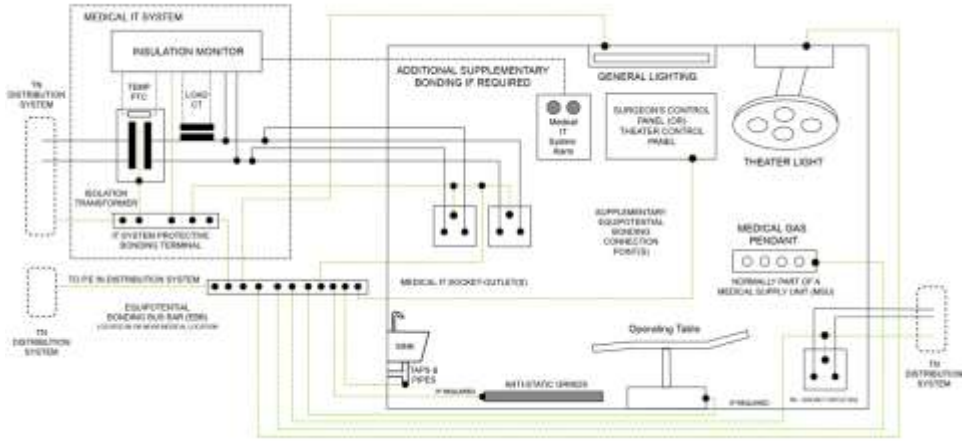
IOT panels – Group 2 locations:

Medical Isolation panels or medical IT systems in hospitals are an additional safety measure recommended in group 2 medical locations for the final equipment to ensure continuity of supply during a fault. The same final circuit is connected to multiple medical devices located within the patient environment. Several safety conditions need to be fulfilled in order to achieve the recommended safety measure by the medical IT system – Installed with in 25meters – IS17512.



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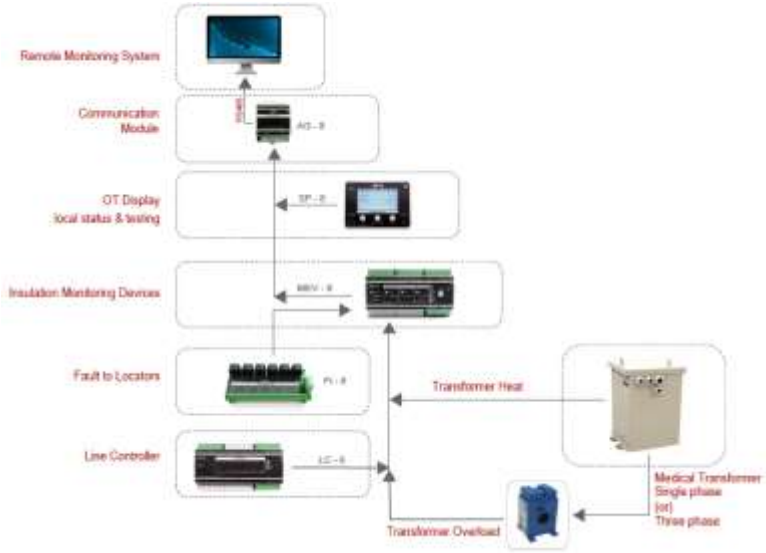
IOT panels – Group 2 locations:



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Medical Isolation Transformer:

- IEC 61558-2-15 Isolation transformers shall be used to form the medical IT systems for portable and fixed equipment and the rated output shall not be less than 0.5 kVA and shall not exceed 10 kVA.
- Three-phase loads via an IT system is also required, a separate three-phase isolation transformer shall be provided for this purpose without put line-to-line voltage not exceeding 250 V.
- The leakage current of the output winding to earth and the leakage current of the enclosure, when measured in no-load condition and the transformer supplied at rated voltage and rated frequency shall not exceed 0.5 mA.
- Range – 3.5kVA, 5.5kVA, 7.5kVA, 10kVA in both single phase & three phase.

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Medical Insulation Monitoring Device (MED-IMD) – IEC 61557-8:

MEV-8

- Monitors the insulation of a floating IT network (leakage current), transformer load (current A) and temperature (°C)
- Permanently set as a fixed value of 50 kΩ – indication (visual & sound) will take place less than specified value.
- The a.c.internal impedance shall be at least 100 kΩ
- The measuring voltage Um shall not be greater than 25 V peak.
- The measuring current Im shall not be greater than 1 mA peak, even under fault conditions.
- The response time - 5 s for an insulation resistance RF of 25 kΩ (50 % of 50 kΩ)

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FI-8 Fault Locator Unit – IEC 61557-9

- FI-8 connected with MEV-8.
- Locates any insulation faults in a floating IT network.
- system leakage capacitance is higher than 0,5 µF, response time can be longer than 5 s.

LC-8 Line Controller

- LC-8 connected with MEV-8
- Monitors the continuity of a floating IT network's protective earth.

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SP-8 Monitoring Panel

- Indicates any insulation level alarms, line controller alarms, and test lead faults as well as transformer overloading and temperature alarms
- Help of the Test button periodically testing can be done.

AG-8 Alarm transfer unit

•The AG-8 Alarm transfer unit transmits alarms to touch-screen panels and controls the room's PC programmes via the RS-485 bus.

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MED-IT system Images:

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Verification (Inspection):

1. method of protection against electric shock (see IEC 60364-4-41); (4.2)
2. presence of fire barriers and other precautions against propagation of fire and protection against thermal effects (see IEC 60364-4-42 and IEC 60364-5-52:2009, Clause 527); (4.3 & 5.2.10)
3. selection of conductors for current-carrying capacity (see IEC 60364-4-43 and IEC 60364-5-52:2009, Clauses 523); (4.4, 5.2.6 and 5.2.8)
4. single-pole switching devices connected in the line conductors (5.3.7)
5. choice, setting, selectivity and coordination of protective and monitoring devices (see IEC 60364-5-53:2001, Clause 536); (5.3.7)
6. selection, location and installation of suitable overvoltage protective devices (SPD) where specified (see IEC 60364-5-53: Clause 534); (5.3.5)
7. selection, location and installation of suitable isolating and switching devices (see IEC 60364-5-53, Clause 536); (5.3.6)
8. selection of equipment and protective measures appropriate to external influences and mechanical stresses (see IEC 60364-4-42: Clause 422, IEC 60364-5-51: 512.2 and IEC 60364-5-52: Clause 522); (4.3.2, 5.1.2.2 and 5.2.5)
9. identification of neutral and protective conductors (see IEC 60364-5-51:2005, 514.3); (5.1.4.3)
10. presence of diagrams, warning notices or similar information (see IEC 60364-5-51: 514.5); (5.1.4.5)
11. identification of circuits, overcurrent protective devices, switches, terminals etc. (see IEC 60364-5-51:2005, Clause 514); (5.1.4)
12. adequacy of termination and connection of cables and conductors (see IEC 60364-5-52:2009, Clause 526); (5.2.9)
13. selection and installation of earthing arrangements, protective conductors and their connections (see IEC 60364-5-54); (5.4)
14. accessibility of equipment for convenience of operation, identification and maintenance (see IEC 60364-5-51: Clauses 513 and 514); (5.1.3 and 5.1.4)
15. measures against electromagnetic disturbances (see IEC 60364-4-44: Clause 444); (4.5.4)
16. exposed-conductive-parts are connected to the earthing arrangement (see IEC 60364-4-41: Clause 411); (4.2.11)
17. selection and erection of the wiring systems (see IEC 60364-5-52:2009, Clauses 521 and 522). (5.2.4 & 5.2.5)
18. particular requirements for special installations or locations (IS17512:2021)
19. Compliance to IEC61000-5-1 (electronic systems and information technology equipment)

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Verification (Testing):

Tests and its sequence

1. continuity of conductors
2. insulation resistance
3. insulation resistance of SELV, PELV or electrical separation
4. floor and wall resistance/impedance
5. polarity test
6. effectiveness of automatic disconnection of supply
7. effectiveness of additional protection
8. phase sequence
9. functional tests
10. voltage drop
11. **PAT**

Note:

- Keep the sequence
- In case of failure in a test, redo from the previous test onwards after rectification
- potentially explosive atmosphere appropriate safety (IEC 60079-17) are necessary.

1	**Continuity of conductors**	Supply OFF condition
	earthing conductor, main and supplimentary bonding conductor & radial circuit	
	ring final circuits (line, neutral & earth)	
2	**Insulation resistance**	
	between live conductors	
	between live and earth condcutor	
3	**Insulation resistance of ELV**	
	Automation, BMS etc	
	earth electrode resistance test (for sl no 6)	
4	**Insulation resistance/impedance of floors and walls**	
5	**Polarity**	Supply ON condition
6	**Automatic Disconnection of Supply**	
	fault loop impedance. (line to line, line to neutral and line to earth)	
	verify the fault loop impedance with protective device	
7	**Additional protection**	
	RCD's supplimentary bonding, SPD's etc	
8	**Phase sequence**	
9	**Functional testing**	
	Switchgear including RCD's, control gear, assemblies, drives, interlocks etc	
10	**Voltage drop**	

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Additional tests for Medical locations

1. Functional test of insulation monitoring devices of medical IT systems and acoustical/visual alarm systems.
2. Measurements to verify that the supplementary equipotential bonding.
3. Verification of the integrity of the facilities for equipotential bonding.
4. Verification of the integrity of the requirements of safety services.
5. Measurements of leakage current of the output circuit and of the enclosure of medical IT transformers in no-load condition

a) functional testing of changeover devices: 12 months;
b) functional testing of insulation monitoring devices: 12 months;
c) checking, by visual inspection, settings of protective devices: 12 months;
d) measurement verifying the supplementary equipotential bonding: 36 months ;
e) verifying integrity of facilities required for equipotential bonding: 36 months;
f) monthly functional testing of:
- – safety services with batteries: 15 min;
- – safety services with combustion engines: until rated running temperature is achieved; 12 months for “endurance run”;
- – safety services with batteries: capacity test;
- – safety services with combustion engines: 60 min;

In all cases at least 50 % to 100 % of the rated power shall be taken over.
g) measurement of leakage currents of IT transformers: 36 months;
h) checking of the tripping of RCDs at *I*ΔN: not less than 12 months.

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THANK YOU

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