

- ✖ Energy
- ✖ Electrical Hazards
- ✖ Macroshock and Microshock
- ✖ Electrical Susceptible Patient
- ✖ Physiological effect of Electricity
- ✖ Leakage current
- ✖ Patient Isolator design
- ✖ Ground Fault Interrupter
- ✖ Other Protective Ckts
- ✖ Medical device Classification
- ✖ Area classification
- ✖ Power distribution

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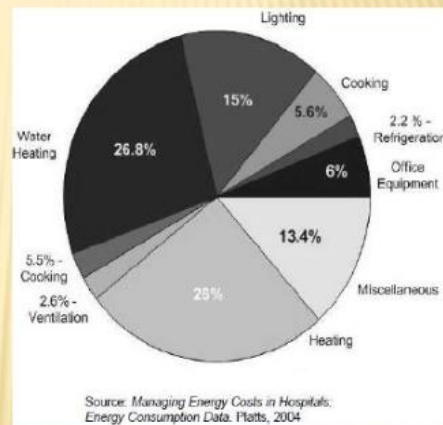
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ENERGY IN HOSPITALS

- ✖ Lighting and HVAC take up largest share of hospital energy bills
- ✖ The energy requirements in hospitals are sensitive and 24-7



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- ✖ Ignition or Explosion of flammables
- ✖ Electric shocks due to ground breaking
- ✖ Breakdown of electrical equipment
- ✖ Patient safety

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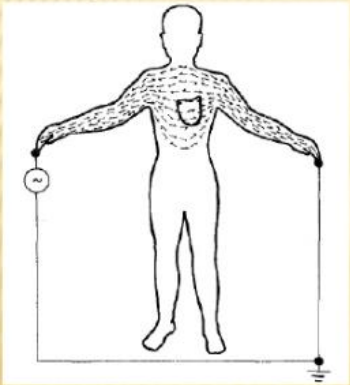
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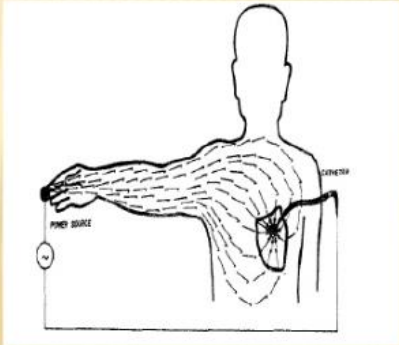
Microshock Hazards

When the point of contact is away from the heart



Macroshock Hazards


When the point of contact is on/inside/near the heart




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- ✧ Insertion of a pacemaker catheter electrode from an externally worn pacemaker.
- ✧ Use of a fluid-filled catheter
- ✧ Insertion of an electrode into one of the cardiac chambers for intracardiac ECG measurement.

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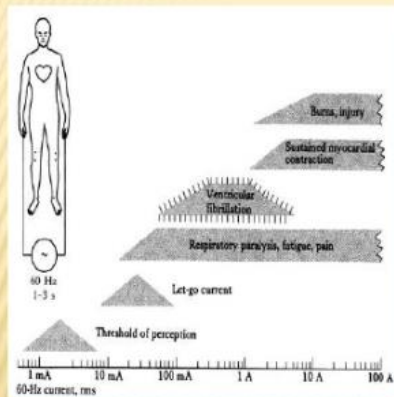
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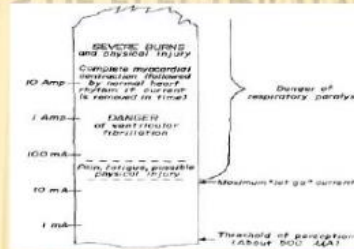
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PHYSIOLOGICAL EFFECTS OF ELECTRICITY



PHYSIOLOGICAL EFFECTS OF ELECTRICITY THRESHOLD OR ESTIMATED MEAN VALUES ARE GIVEN FOR EACH EFFECT IN A 70 KG HUMAN FOR A 1 TO 3 S EXPOSURE TO 60 HZ CURRENT APPLIED VIA COPPER WIRES GRASPED BY THE HANDS. MEDICAL INSTRUMENTATION: APPLICATION AND DESIGN, WEBSTER



- ✗ Frequency
- ✗ Skin resistance
- ✗ Let go Current
- ✗ Injury

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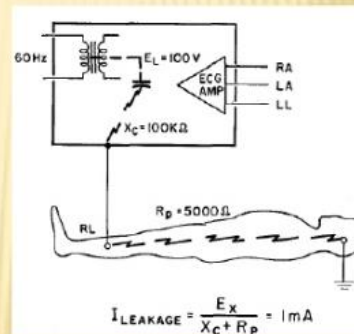
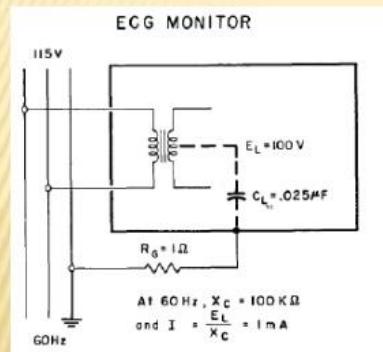
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LEAKAGE CURRENT



Capacitive coupling exists between the chasis and power line

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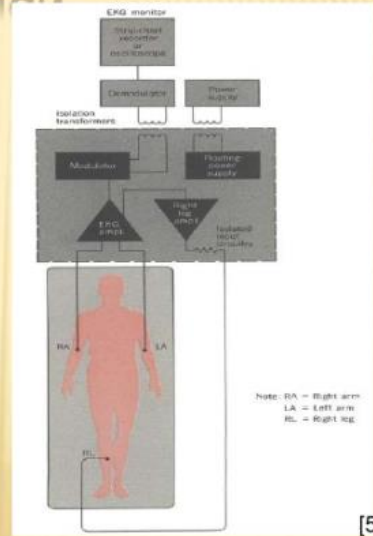
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PATIENT ISOLATOR DESIGN

- ✖ Patient in ICU/CCU have been designed to be Electrically Isolated
- ✖ No conductive path is present between isolated and other sections of the instrument



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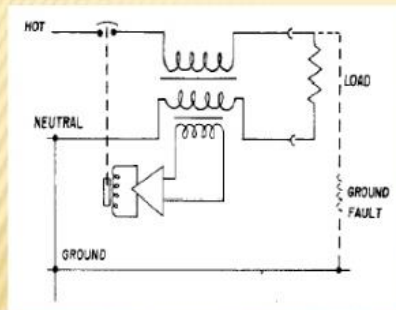
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GROUND FAULT INTERRUPTER



- ✗ Normal conditions
 $I_{\text{Neutral}} = I_{\text{hot}}$
- ✗ If the difference becomes more than a fixed value (5mA)
- ✗ The fault interrupter goes off

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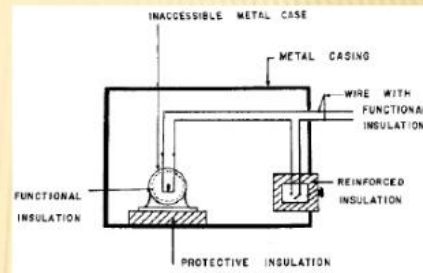
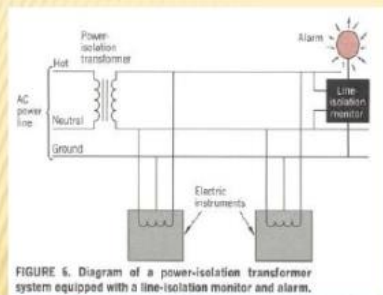


FIG. 6. Double-insulated equipment.

[3],[5]

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MEDICAL DEVICE CLASSIFICATION

Equipment Function and Risk

RELEVANCE FACTOR ASSIGNED TO THE EQUIPMENT PHYSICAL RISK	
Equipment physical risk	ρ
Patient or Operator Death	25
Patient or Operator Injury	20
Inappropriate Therapy or Misdiagnosis	15
Patient Discomfort	10
No significant Risk	5

RELEVANCE FACTOR FOR PHYSICAL RISK CLASSIFICATION

Class C ₄₁	Relevance %	ρ
Class I	55	1.0
Class II	40	0.72
Class III	5	0.09

RELEVANCE FACTOR ASSIGNED TO THE EQUIPMENT FUNCTION

Type	Equipment function	ρ
Therapeutic	Life Support	25
	Surgical and Intensive Care	23
	Physical Therapy and Treatment	20
Diagnostic	Surgical and Intensive Care Monitoring	18
	Additional Monitoring and Diagnostic	15
Analytical	Analytical Laboratory	13
	Laboratory Accessories	10
	Computer y Related	8
Misc.	Patient Related and Other	5

Risk based classification

- ✗ Class I
- ✗ Class II
- ✗ Class III

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MEDICAL DEVICE CLASSIFICATION

Classification by safety arrangements

- ✗ Type H
- ✗ Type B
- ✗ Type C

Classification by Insulation

- ✗ Class 1
- ✗ Class 2
- ✗ Class 3

TABLE 3
RELEVANCE FACTOR FOR THE DEGREE AND QUALITY CLASSIFICATION

Class C_{ij}	Relevance %	ρ
$\mu(C, B, H)$		
Type C	60	1.0
Type B	30	0.5
Type H	10	0.16

RELEVANCE FACTOR FOR INSULATION LEVEL CLASSIFICATION

Class C_{ik}	Relevance %	ρ
$k=(1,2,3)$		
Class 1	50	1.0
Class 2	40	0.8
Class 3	10	0.2

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MEDICAL DEVICE CLASSIFICATION

Based on contact with patient

- Class C
- Class S
- Class G

RELEVANCE FACTOR FOR THE EQUIPMENT CONTACT CLASSIFICATION

Class C_m	Relevance %	ρ
Class C	60	1.0
Class S	30	0.5
Class G	10	0.16

PRIORITY AND FREQUENCY TO REALIZE THE ELECTRICAL SAFETY TESTS TO MEDICAL EQUIPMENT

Priority Level	Range	Frequency
High Priority	[1, 0.60]	3 Months
Medium Priority	(0.6, 0.20]	6 Months
Low Priority	< 0.20	12 Months

TABLE 11

IPSEEM FOR THE MEDICAL EQUIPMENT IN CRITICAL AREAS

Equipment	C_1		C_2	C_3	C_4	C_5	ESPIRE	
	FE	RF	RE					
Electrosurgery Eq.	23	20	0.86	1.0	0.8	1.0	1.0	0.926
Defibrillator	20	25	0.9	0.5	0.8	1.0	0.5	0.680
Cardiotocograph	15	10	0.5	0.5	1.0	0.72	0.5	0.672
Electric Bed	5	15	0.4	0.5	1.0	0.72	0.5	0.662
Patient Monitor	18	15	0.66	0.5	0.8	0.72	0.5	0.628
Electrocardiograph	18	15	0.66	0.5	0.8	0.72	0.5	0.628
Patient Ventilator	25	25	1.0	0.16	1.0	1.0	0.16	0.580
Heart Lung Machine	23	25	0.96	0.16	1.0	1.0	0.16	0.576
Incubator	20	25	0.9	0.16	1.0	1.0	0.16	0.570
Microscope	23	5	0.56	0.16	1.0	0.09	0.16	0.445
Colposcope	23	5	0.56	0.16	1.0	0.09	0.16	0.445
Endoscope	23	5	0.56	0.16	1.0	0.09	0.16	0.445
Suction Pump	20	5	0.5	0.16	1.0	0.09	0.16	0.439
Body Weight	15	5	0.4	0.16	1.0	0.09	0.16	0.429
Negatoscope	5	5	0.2	0.16	1.0	0.09	0.16	0.409
Headlamp	0	5	0.1	0.16	1.0	0.09	0.16	0.399
Anesthesia machine*	23	15	0.76	0.16	0.2	0.72	0.16	0.288
Infusion Pump	20	15	0.7	0.16	0.2	0.09	0.16	0.219
Sphygmomanometer	15	15	0.6	0.16	0.2	0.09	0.16	0.209
Surgical Lamp*	23	5	0.56	0.16	0.2	0.09	0.16	0.205
Humidifier	20	5	0.5	0.16	0.2	0.09	0.16	0.199
Nebulizer	20	5	0.5	0.16	0.2	0.09	0.16	0.199
Digital Thermometer	15	5	0.4	0.16	0.2	0.09	0.16	0.189
Diagnostic Instr	15	5	0.4	0.16	0.2	0.09	0.16	0.189

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AREA CLASSIFICATION

Body Protected Area

- ✖ The equipment lowers the natural resistance of skin



Cardiac Protected Area

- ✖ The equipment has direct contact with Heart



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- ✦ Group 0: An allocation to this group implies that these rooms are of considerable importance to the course of medical processes.
- ✦ Group 1: includes all rooms and areas in which patients whose condition and type of medical treatment places substantial demands on the electrical installation are cared for. An unexpected interruption to the power supply does not expose the patient to immediate danger and a repetition of the examination is possible at any time.
- ✦ Group 2: In these rooms diagnoses and therapy are performed on the patient where the type of medical treatment may directly or indirectly be dangerous for the patient

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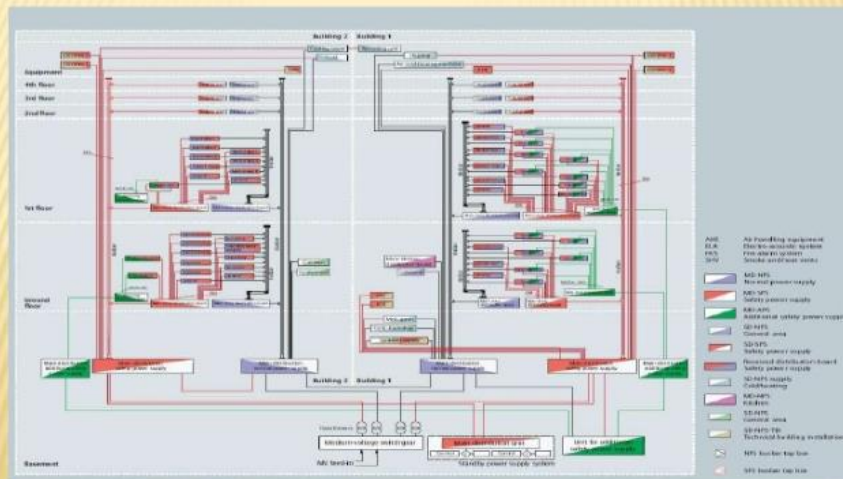
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