

IEC 60601-1 With National Deviations (UL 60601-1, CSA C22.2 No. 601.1, EN 60601-1)



Company:		Contact:	
Model(s):		Phone:	
Intended Use:		Email:	
Ratings:	V, Hz, A/VA/W; Batteries:		
Accessories:			
Power Supply:	Type: [Internal] / [External] Manufacturer:	Model:	
Client Needs:	[Evaluation] [Testing] [MECA Compliance Report] [NRTL Safety Mark (UL, TUV, etc.)] [CB Report] [EMC]		
<input type="checkbox"/>	Client submits Device Information		
<input type="checkbox"/>	Determine if collateral or particular standards are required (See list of Collateral & Particular Standards)		
<input type="checkbox"/>	MECA Project Proposal (Quote)		
<input type="checkbox"/>	PO # from Client to open project:		
<input type="checkbox"/>	Anticipated date samples will be ready for testing:		
<input type="checkbox"/>	Anticipated equipment production date:		
<input type="checkbox"/>	For NRTL Project: Agency Agreements		
<input type="checkbox"/>	Receive PO#, Required Deposit		
<input type="checkbox"/>	<u>Preliminary Evaluation :</u>		
<input type="checkbox"/>	<i>Examine equipment, discuss its use, accessories, interconnection to other equipment, construction materials</i>		
<input type="checkbox"/>	<i>Determine if collateral or particular standards are required (See list of Collateral & Particular Standards)</i>		
<input type="checkbox"/>	<i>Document Classification of equipment (Per Clause 5)</i>		
<input type="checkbox"/>	<i>Examine enclosure openings (tool required to access live parts) and potential mechanical hazards, pinch points</i>		
<input type="checkbox"/>	<i>Determine potential hazards under normal use, abnormal use, Single Fault Conditions</i>		
<input type="checkbox"/>	<u>Create Insulation Diagram</u> <i>All components that cross a barrier (per insulation diagram) must meet creepage & clearance requirements, working voltage of a barrier s</i>		
<input type="checkbox"/>	<i>Verify power supply certification, construction and required fusing for equipment</i>		
<input type="checkbox"/>	<i>Verify required spacings, per the Insulation Diagram</i>		
<input type="checkbox"/>	<i>Determine component requirements (UL Recognition, Electrical, Mechanical, Flame Ratings, etc.)</i>		
<input type="checkbox"/>	<i>Create test plan (See Testing Checklist)</i>		
<input type="checkbox"/>	<i>Review requirements for labels, user manual, if available (Per Clause 6)</i>		
<input type="checkbox"/>	<i>Address any initial noncompliances</i>		
Equipment Evaluation, Testing, Documentation (Production Equivalent Samples Received for Testing)			
<input type="checkbox"/>	Verify samples functional and noncompliances from Preliminary Evaluation corrected (as applicable)		
<input type="checkbox"/>	Conduct full construction evaluation to standard requirements, review specifications and certificates for critical components		
<input type="checkbox"/>	For NRTL Project: Open NRTL Project (File #, Project #, Control #)		
<input type="checkbox"/>	For NRTL Project: Conduct Initial Review (Construction, documentation and test plan)		
<input type="checkbox"/>	<u>Perform required testing</u> (at MECA's testing facility)		
<input type="checkbox"/>	Verify label marking and accompanying document requirements		
<input type="checkbox"/>	Review Biocompatibility on patient contact parts, as applicable (supplier's biocompatibility information acceptable) [ISO 10993 -1]		
<input type="checkbox"/>	Take photographs of equipment for report (1200 x 1600 pixels minimum)		
<input type="checkbox"/>	Create critical component list, including all components needed to pass tests and meet the requirements of the standard		
<input type="checkbox"/>	Write Compliance Informative Test Report (MECA and/or NRTL Report)		
<input type="checkbox"/>	For NRTL Project: Final review with NRTL, Address Review Comments, NRTL issues Authorization to apply their Safety Mark		

INSULATION DIAGRAM

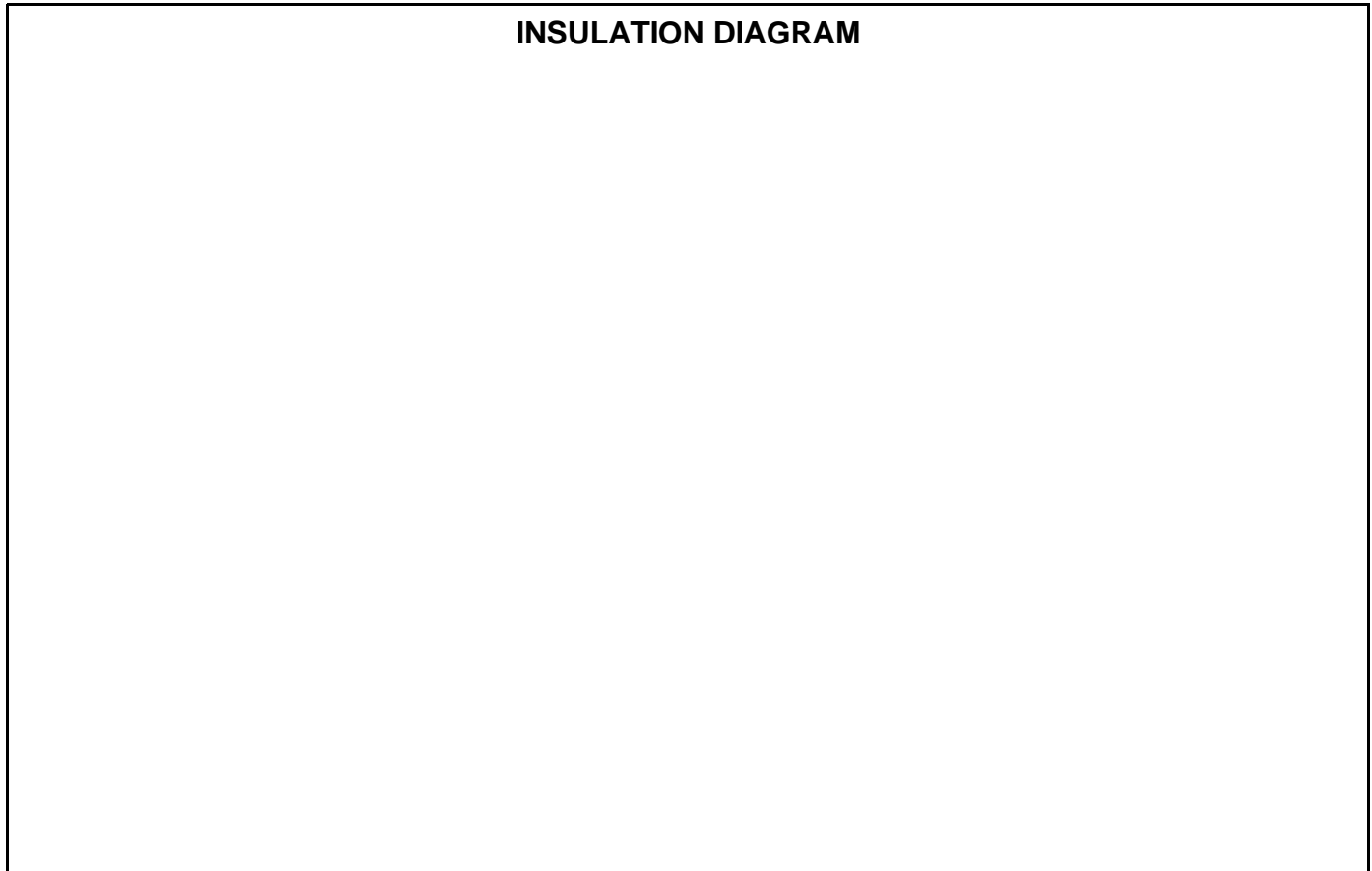


Table: to insulation diagram

Area	Insulation BOP, BI, SI, DI/RI	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Dielectric Voltage (kV)	Remarks
A								
B								
C								
D								
E								
F								
G								
H								
I								
J								
K								
L								
M								
N								
O								
P								
Q								
R								
S								
T								

IEC/UL/CSA/EN 60601-1 TEST CHECKLIST

All Tests Conducted at 90 – 110 % Voltage Ratings, Except Power Input Test (Conducted at Rated Voltage)

Test #	CLAUSE	TEST
<input type="checkbox"/> T0		CONSTRUCTION EVALUATION Required Spacings per Insulation Diagram, Construction Requirements, Critical Components <i>[Tape Measure, Caliper, Probes]</i>
<input type="checkbox"/> T1	6.1	MARKING DURABILITY Rub cotton rag 15 seconds on Labels/markings with each <i>[Distilled Water, Denatured Alcohol (Methylated spirits), Isopropyl alcohol]</i>
<input type="checkbox"/> T2	7.1	POWER INPUT <u>At rated voltage</u> , stabilized W, V, or VA recorded <i>[Power Analyzer - Volts, Hz, Amps/Volt Amps/Watts]</i>
<input type="checkbox"/> T3	15.b	VOLTAGE LIMITATION (PART 1) If > 0.1 μ F in mains: Voltage measured between supply pins, enclosure, and earth <i>[Oscilloscope, Switch box, L-C Meter]</i>
<input type="checkbox"/> T4	15.c	VOLTAGE LIMITATION (PART 2) Residual voltage measured on capacitors/circuits after opening enclosure if > 0.27 μ F (120 V) or > 0.07 μ F (240 V) <i>[Oscilloscope, L-C Meter]</i>
<input type="checkbox"/> T5	17.h1, 17.h2	DEFIBRILLATION-PROOF APPLIED PARTS DEFIBRILLATION-PROOF RECOVERY TIME Measurements taken per Fig. 50 or 51 (Applied to Accessible Parts) <i>[Defibrillator Simulator Fixture, Oscilloscope]</i>
<input type="checkbox"/> T6	18.f	EARTHING AND POTENTIAL EQUALIZATION IEC/UL = 25 A or 1.5 x Ratings for 5 sec. CAN = 30 A or 2 x Ratings for 2 min. <i>[25 A – 40 A (AC) Power Supply, Shunt, Volt Meter or 25 A – 40 A Ground Bond Tester]</i>
<input type="checkbox"/> T7	19	LEAKAGE CURRENT Conducted Before/After Humidity & Abnormals, conducted at 110% rated Voltage, <u>one side at ground potential</u> Earth, Enclosure, Patient, Patient Aux., Patient F, Patient SIP/SOP <i>[Power Supply for specified Voltage (+/- 10%), Frequency, True RMS Volt meter, MD network]</i>
<input type="checkbox"/> T8	20.4	DIELECTRIC VOLTAGE WITHSTAND Each Barrier of Insulation Diagram Tested, Full voltage held for 1 minute <i>[Dielectric (HiPot) tester]</i>
<input type="checkbox"/> T9	21a, 21b	ENCLOSURE MECHANICAL STRENGTH Force Test: 45 N, 625 mm ² Impact test: 0.5 J, \pm 0.05 J (or UL Ball @ 9.6 cm) Impact Test can be waived if UL mechanical abuse test conducted (1/13.5 x energy of UL ball drop) <i>[Force Gauge, Impact hammer or 0.5 j Impact Ball]</i>
<input type="checkbox"/> T10	21.c	HANDLE LOADING Load to 4 x Equipment weight for 1 min. on each handle (add 3 x equipment weight to actual equipment) <i>[Scale]</i>
<input type="checkbox"/> T11	21.3 [See 21.3] [See 21.4]	MECHANICAL STRENGTH - PATIENT SUPPORT SYSTEM (1.35 kN or spec. load) x (required safety factor); Load supported for 1 minute <i>[Scale]</i>
<input type="checkbox"/> T12	21.3	MECHANICAL STRENGTH - FOOT RESTS/CHAIRS (2.7 kN or max. load) x (safety factor 2) in 0.1 m ² surface area, Load supported for 1 minute <i>[Scale]</i>
<input type="checkbox"/> T13	21.5, 55 (US)	DROP IMPACT FOR PENDANT/HANDHELD EQUIPMENT Polymeric Enclosures: Drop 3 samples 1.22 meters (4 ft.), 3 times on tile covered cement All Others: Drop sample 1 meter, 3 times on 50 mm thick hardwood board on cement <i>[1-3 Samples, Tape Measure, Specified Surface]</i>
<input type="checkbox"/> T14 A	21.6	ROUGH HANDLING – DROP FOR PORTABLE/STATIONARY EQUIPMENT Portable Equipment: Drop sample 3 times at (\leq 10 kg = 5 cm), (10-50 kg = 3 cm), (>50 kg = 2 cm) <i>[Metric Ruler]</i>
<input type="checkbox"/> T14 B	21.6	ROUGH HANDLING – ROLL OFF STEP FOR MOBILE EQUIPMENT Mobile Equipment: Roll 0.4 m/s +/- 0.1 m/s (0.3 – 1.6 ft./s) or maximum velocity off step 20 mm high, 20 times <i>[Metric Ruler/Caliper, Speedometer]</i>
<input type="checkbox"/> T15	22 (US)	IMPACT TEST ON END STOPS Worst case intended/specified loading, Number cycles & Conditions Per Table 22.100 (US Deviations) <i>[Scale]</i>
<input type="checkbox"/> T16	24	STABILITY AND TRANSPORTABILITY 10° Tilt, least favorable position (or) 5° Tilt for normal use, 10° Tilt for transport, with Warning for correct transport position on unit, or in manual (with Symbol DI-14 on unit). <i>[Angle Finder, or Tape Measure, Caliper: (Distance Lifted) = (Width of Base)(0.173648) = 10°]</i>
<input type="checkbox"/> T17	28.3 (US) [See 21.3]	SUSPENSION SYSTEM WITH SAFETY DEVICES LOADING TEST Defeated suspension systems with maximum normal load from most adverse position No signs of damage to safety catch or restraining means <i>[Scale]</i>
<input type="checkbox"/> T18	28.4 (US) [See 21.3]	SUSPENSION SYSTEMS WITHOUT SAFETY DEVICE LOADING TEST Loaded 1 min. with the following Safety Factor No wear, corrosion, fatigue or aging = Safety Factor \geq 4 Wear, Corrosion, Fatigue, Aging = Safety Factor \geq 8 Specific elongation at break <5% = Safety Factor X 1.5 <i>[Scale]</i>

Test #	CLAUSE	TEST
<input type="checkbox"/> T19	29	X-RADIATION TEST Measured 5 cm from accessible surfaces, Detector window area approx. 10 cm ² : 0.5 mR/h max. for tubes over 5 kV <i>[Radiation Detector with entry window approx. 10 cm²]</i>
<input type="checkbox"/> T20	42.1, 42.2, 42.3	TEMPERATURE Tested at 25°C (or ambient near 25°C) until thermal stability. (Adjust ambient and measured temps for 40°C) <i>[Thermocouples, Temperature Meter, (IR Probe for placement), Stopwatch]</i>
<input type="checkbox"/> T21	44.2	OVERFLOW 15% Overfill, followed by Dielectric Withstand Test <i>[Fluid Measure container, Dielectric Tester]</i>
<input type="checkbox"/> T22	44.3	SPILLAGE 200 ml poured over equipment, followed by Dielectric Withstand Test <i>[Fluid Measure container, Dielectric Tester] (200 ml = 6.76 oz)</i>
<input type="checkbox"/> T23	44.4	LEAKAGE Water applied by pipette to seals, inspect for wetted components <i>[Pipette, Dielectric tester]</i>
<input type="checkbox"/> T24	44.5 (19.4) (20.4)	HUMIDITY PRECONDITIONING 90%-96% RH, 20° C – 32° C, (IPX0 = 48 hr), (IPX1-8 = 168 hr) Dielectric Withstand Test in chamber, Leakage Current 1 hr. after removing chamber <i>[Hum. chamber, Dielectric tester, RMS Volt meter, MD network]</i>
<input type="checkbox"/> T25	44.6	HARMFUL INGRESS OF LIQUIDS Per IEC 60529 (IP X X), followed by Dielectric Withstand Test and inspected for ingress into enclosure <i>[IP Apparatus for type of Ingress, Dielectric Tester]</i>
<input type="checkbox"/> T26	44.7	CLEANING, STERILIZATION AND DISINFECTION As specified in users manual, followed by Dielectric Withstand Test <i>[Cleaning solution per manual, Dielectric Tester]</i>
<input type="checkbox"/> T27	45.2	HYDROSTATIC PRESSURE If Pressure x Volume > 200 kPa l and Pressure > 50 kPa Max. Pressure of vessel X Ratio from Fig. 38 <i>[Pressure Gauge, Stopwatch] (50 kPa = 7.25 psi)(1 l = 61 in²)</i>
<input type="checkbox"/> T28	45.7	PRESSURE CONTROL TEST Safety release Performing rated load for 100,000 cycles <i>[Pressure Gauge, Stopwatch]</i>
<input type="checkbox"/> T29	49.2	INTERRUPTION OF THE POWER SUPPLY Pose no safety hazard <i>[Stopwatch]</i>
<input type="checkbox"/> T30	52.4.1	POWER AVAILABILITY TEST To Verify ≤ 15 W Available (to waive enclosure flammability requirements, component failure testing) <i>[Power Analyzer – (V, A, W), High Current/Wattage Variable Resistor, Stopwatch]</i>
<input type="checkbox"/> T31	52.5.2	FAILURE OF THERMOSTATS Disable thermostat (worst case), Temperatures recorded <i>[Thermocouples, Temperature Meter, Stopwatch]</i>
<input type="checkbox"/> T32	52.5.5	IMPAIRMENT OF COOLING Impair each type of cooling, one at a time (Cooling fan disabled), (Ventilation blocked) - Temperatures ≤ 1.7 x temp limits, minus 17.5°C <i>[Thermocouples, Temperature Meter, Stopwatch]</i>
<input type="checkbox"/> T33	52.5.6	LOCKING OF MOVING PARTS TEST 30 seconds: kept on by hand, 5 minutes: attended equipment, Thermal Stability: unattended equipment - Temperatures ≤ Table XII <i>[Thermocouples, Temperature Meter, Stopwatch]</i>
<input type="checkbox"/> T34	52.5.7	INTERRUPTION AND SHORT-CIRCUITING OF MOTOR CAPACITOR For unattended equipment and capacitors not evaluated to IEC252 Short circuit capacitors, open circuit capacitors, measuring motor temperatures <i>[Thermocouples, Temperature Meter, Stopwatch]</i>
<input type="checkbox"/> T35	52.5.9	FAILURE OF COMPONENTS TEST Components short circuited or opened (worst case), one at a time. Temperatures recorded <i>[Thermocouples, Temperature Meter, (IR Probe for placement), Stopwatch]</i>
<input type="checkbox"/> T36 T37	52.5.10d 56.6	HEATING ELEMENT OVERLOAD Thermostat or Thermal control short circuited, operated until thermal stability <i>[Thermocouples, Temperature Meter, (IR Probe for placement), Stopwatch]</i>
<input type="checkbox"/> T38	52.5.10f	MOTOR RUNNING OVERLOAD If remotely controlled or operated continuously while unattended, load increased until thermal stability, temperatures per 52.5.10 f <i>[Thermocouples, Temperature Meter, (IR Probe for placement), Stopwatch]</i>
<input type="checkbox"/> T39	52.5.10g	SHORT TIME MOTOR RUNNING OVERLOAD If attended equipment, not kept on by hand, normal load until thermal stability, temperatures per Table XII <i>[Thermocouples, Temperature Meter, (IR Probe for placement), Stopwatch]</i>
<input type="checkbox"/> T40	52.5.10h	OPEN PHASE PROTECTION For 3 Phase Equipment with Motors - One phase of equipment disconnected, run until thermal stability. <i>[Thermocouples, Temperature Meter, (IR Probe for placement), Stopwatch]</i>
<input type="checkbox"/> T41	55 (US)	MECHANICAL ABUSE – BALL DROP TEST For polymeric enclosures and covers only 2 inch stainless steel ball (1.18 lb.) dropped from ~1.3 meters (51 in) on equipment to give 5 ft. lbs. Impact <i>[UL Steel Ball, Tape Measure]</i>

Test #	CLAUSE	TEST
<input type="checkbox"/> T42	55 (US)	MOLD STRESS RELIEF TEST For polymeric enclosures and covers only Highest: [70°C] or [Maximum temp + 10°C] for 7 hours <i>[Air Circulating Oven, Stopwatch]</i>
<input type="checkbox"/> T43	56.7	REVERSED BATTERY CONNECTION No damage to battery or safety of equipment (waived if mechanically polarized to make connection correctly) <i>[Thermocouples, Temperature Meter]</i>
<input type="checkbox"/> T44	56.10b, 56.10c	ACTUATING PARTS OF CONTROLS For knobs > 10 mm diameter. 2 sec. force in each direction alternately, 10 times (See table XII for torque) <i>[Torque Meter]</i>
<input type="checkbox"/> T45	56.11b, 56.11d	CORD CONNECTED FOOT SWITCH - MECHANICAL STRENGTH 1350 N for 1 min. (Note - IPX8 required in wet / surgical areas) <i>[Force Meter, Stopwatch]</i>
<input type="checkbox"/> T46	57.4a	STRAIN RELIEF Conductors cut, Pull 25 times, 1 second each; Then Torque for 1 min. (≤1 kg = 30 N Pull, 0.1 Nm Torque) (1-4 kg = 60 N Pull, 0.25 Nm Torque) (>4 kg = 100 N Pull, 0.35 Nm Torque) <i>[Force, Torque Meter] (1 kg = 2.2 lb)(1 N = 0.225 lb)(1 m = 39.4 in) , Stopwatch]</i>
<input type="checkbox"/> T47	57.4b	CORD GUARD FLEXING Curvature ≥ 1.5 Diameter with weight (10 x (Diameter) ² g) hanging perpendicular (or) 5000 cycle flex test (180°) with ≥ 90 % total conductor strands not broken <i>[Weight, Cylinder of 1.5 x Diameter of cord] (1 g = 0.0022 lb)</i>
<input type="checkbox"/> T48	57.9.1	TRANSFORMER OVERHEATING TEST Each secondary short circuited and overload Overload just below temperature of thermal cut-out (increased slowly), (or) Current/Time from Table XX <i>[Thermocouples, Temp.Meter, Amp Meter, High Wattage Rheostat, Stopwatch]</i>
<input type="checkbox"/> T49	57.9.2	TRANSFORMER DIELECTRIC STRENGTH NOT Testing Barrier (see Clause 20) All Mains Transformers <500 V, Except in switch mode power supplies Humidity preconditioning, 5 x Voltage & 5 x Frequency for 1 min. (may be induced by secondary) <i>[Variable Frequency/ Voltage Power supply, Stopwatch]</i>
<input type="checkbox"/> T50	59.2	BALL PRESSURE TEST Not required for UL Classification on polymeric materials with rated RTI value of > 75. Using Apparatus in Fig. 48 for 1 hour (< 2 mm impression) Enclosures = 75 °C, Mains parts = 125°C <i>[Air Circulating Oven, Ball Pressure Apparatus, Stopwatch]</i>

	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Adhesive					Securing _____ to _____	MAGW2	(UL)		
Appliance Inlet /Outlet					Rated ____ V, ____ A minimum	AXUT2 AXUT RTRT2 ZYVZ2	UL		UL 498 IEC 60309-1 IEC 60309-2 IEC 60320-1 IEC 60320-2-2
Appliance Inlet with Filter (wi/ Fuse Holder)					Rated ____ V, ____ A minimum	FOKY2 AXUT2 AYVZ2	UL		UL 1283 UL 498
Battery (Lithium)					Rated ____ V, rated ____ max charging current. Protected by ____ and ____ (or current limiting component R/C (NWGQ2))	BBCV2	UL		UL 1642
Battery Pack (Lithium)					Rated ____ V, approximately ____ mAh Abusive Charge Current: ____ mA Abusive Charge Voltage: ____ V	BBFS(2)	UL		UL 2054
Battery (Standard) (Lead-Acid)					Rated ____ V, approximately ____ mAh	BAZR2			UL1989 UL2054
Battery Charger (Non-Medical)					Rated ____ V, ____ A	BBGQ2 BBML2 BBHZ	UL		
Bridge Rectifier					Rated ____ Vrms, ____ A	QQQX2	UL		UL 1557
Bushing						NZMT2	(UL)		
Cable Ties						ZODZ2	(UL)		UL 1565
Capacitor (X-Type, Y-Type) Y1 = Double Insulated					Rated ____ uF, ____ V	FOWX2	(UL)		UL 1414 IEC 60384-14
Capacitor (General)					Rated ____ uF, ____ V	CYWT2			
CD-ROM Drive					Rated ____ V, ____ A	NWGQ2			UL 60950 IEC 60950
Circuit Breaker (Supplementary protector)					Rated ____ V, ____ A	QVNU QVNU2	UL		UL 1077 IEC 60934
Circuit Breaker					Rated ____ V, ____ A	DIHS2 DKPU2 DKUY2	UL		
Computer (IT) Equipment And accessories					Rated ____ V, ____ A	NWGQ NWGQ2	(UL)		UL 60950 IEC 60950
Conductive Coating						QMRX2	UL		UL 746

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Conductive Coating						QMRX2	UL		UL 746
Conformal Coating						QMJU2			
Connector					Rated ____ V, ____ A	RTRT2 ECBT2 RFWV2	(UL)		
Contactors					Rated ____ V, ____ A	NRNT2	(UL)		
Crimp Connectors					Crimped-on closed-loop or spade connectors for securing under screw terminals or quick-disconnect type connectors with positive detent	ZMVV2	(UL)		UL 486
DC-DC Converter					Rated ____ V, ____ A Provided with Triple insulated wire on input/output windings of torroid (UL 1446)	PIDF2 NWGQ2 QQHM2 QQGQ2	(UL)		UL/IEC 60601-1 UL/IEC 60950
Diode					Rated ____ V, ____ A	QQQX2	(UL)		UL 1557
Enclosure (Polymeric)					Overall ____ cm by ____ cm by ____ cm, ____ mm thick. Rated minimum V- ____ flame rating.	QMFZ2	(UL)		UL 94
Enclosure (Material)					Overall ____ cm by ____ cm by ____ cm, ____ mm thick.				
Fan					Rated ____ V, ____ A, ____ CFM	GPWV2	UL		UL 507 IEC 60335 IEC 60950
Filter (EMI/RFI)					Rated ____ V, ____ A	FOKY FOKY2	UL, CENELE C		UL 1283 IEC 60384-14
Foam						QMFZ2	(UL)		
Fuse					Rated ____ A, ____ V. Provided in Line and Neutral	JDYX JDYX2	UL, CENELE C		UL 248 IEC 60127
Fuse holder					Rated ____ V, ____ A	IZLT2 JAMZ2	(UL)		UL 512 IEC 60127-6
Heater					Rated ____ V, ____ A	KSOT2	(UL)		
Heating Elements					Rated ____ V, ____ A	UBJY2	(UL)		
Insulator						QMFZ2	(UL)		

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Interconnect cable (External - ELV/SELV/TNV)						AVLV2	(UL)		UL 758
Interconnect cable (External – hazardous voltage)						AVLV2 ZJCZ	UL		UL 758 UL 62 IEC 60227 IEC 60245
Labels					Construction : (Adhesive, Base, Ink, Overlay material)	PGDQ2	UL		UL 969
Laser Module						NWGQ2	(UL)	FDA (CDRH)	UL 60950 IEC 60950 IEC 60825-1 IEC 60825-2 IEC 60601-2-22
LED					Colors _____ , Not LASER diode				IEC 60825-1 (LASER)
Monitor (LCD) (IT, Medical)					Rated ____ V, ____ A	NWGQ2 PIDF PIDF2	(UL)		UL 60950 UL 60601-1
Motor (Construction Only)						PRGY2	(UL)		UL 1004 IEC 60034
Motor (Impedance Protected)					Rated ____ V, ____ A	XEIT2	(UL)		UL 2111
Motor Start Capacitor					Rated ____ V, ____ uF	CYWT CYWT2	(UL)		
Optical isolator					Rated ____ kV dielectric minimum with at least ____ mm between pins on opposite sides of chip	FPQU2	UL		UL 1577 IEC 60747-5 VDE 884
Plugs & Socket- (Hospital Grade)						RTRT	UL		UL 498 IEC 60884 IEC 60309-1 IEC 60309-2
Power Supply (Internal) (Brick) (Direct Plug-in)					Rated: ____ V, ____ Hz, ____ A Output: ____ V, ____ A	QQHM2 PIDF PIDF2	UL		UL 60601-1 IEC/UL 60950 UL 1310
Power supply cords (US, Canada)						ELBZ	UL		UL 817
Power supply cords (International)							KAM (known agency mark)		IEC 60799 CENELEC HD- 21
Power Supply Cord (Danish)					Plugs: DK 2-1a, DK 2-1a with flat phase pin or DK 2-5a.		KAM (known agency mark)		DK 2-1a or DK 2- 5a
PTC Thermistor Device					Rated _____	XGPU2	(UL)		UL 1434
PWB						ZPMV2	UL		UL 796 IEC 60603-2

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Relay (control, manual, time delay)					Rated _____ V coil, _____ V, _____ A, (_____ HP) contact	NLDX2 NRNT2 NLRV2 NKCR2	(UL)		UL 508 IEC 60255 IEC 60730-2-10 IEC 60947 IEC 61810 IEC 61811 IEC 61812
Relay (solid state)					Rated _____ V activation, _____ V, _____ A, (_____ HP) contact	NMFT2 FPQU2	(UL)		UL 1577 IEC 60747-5
Relay Socket					Rated _____ V, _____ A	SWIV2	(UL)		
Resistor					Rated _____ Watts, _____ Ohms				
Shrink Tubing					Rated _____ V	YDPU2	(UL)		UL224
Sleeving					Rated _____ V	UZFT2	(UL)		
Solenoid					Rated _____ V, _____ A	VAIU2	(UL)		
Strain Relief						NZMT2 QCRV	UL		UL 514B
Surge Suppressor					Breakdown Voltage _____ V. Providing minimum _____ mm spacing across nonconductive body.	XUHT2			UL 1449
Switch (Interlock)					Rated _____ V, _____ A	WOYR WOYR2	UL		UL 61058 IEC 61020 IEC 61058
Switch (Power)					Rated _____ V, _____ A	WOYR WOYR2 NRNT2	UL, KAM		UL 61058 IEC 60669 IEC 61020 IEC 61058
Switch (Voltage selector)					Rated _____ V, _____ A	WOYR WOYR2	UL, KAM		UL 61058 IEC 61020 IEC 61058
Tape (Insulating)						OANZ2	(UL)		
Terminal block (Internal wiring) (Field wiring)					Rated _____ V, _____ A	XCFR2	UL		UL 1059 IEC 60947-7
Thermal cutoff (thermal-link)					Rated _____	XCMQ2	(UL)		UL 1020 IEC 60691
Thermal protector (for motors)					Rated _____	XEWR2	(UL)		IEC 60730
Thermistor					Rated _____	XGPU2	(UL)		UL 1434
Thermostat					Rated _____	XAPX2	UL		

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Transformer (Lock, Overload Protection)					Rated ____ V, ____ A	PIDF2 XPTQ2 NWGQ2 XODW2 FGQS2 XOKV2	(UL)		UL 60601 UL 506 UL 1950 IEC 60044 IEC 60076 IEC 60742 IEC 60950 IEC 60989 IEC 61050 IEC 61558
Transformer (construction only)						XORU2	(UL)		
Transient Voltage Surge Suppressor						XUHT2	UL		UL 1449
Transistor					Rated _____	QQQX2			
Triac					Rated _____	QQQX2	(UL)		UL 1557
Tubing						YDPU2	(UL)		
Valves					Rated _____	YIOZ2	(UL)		
Varistor (VOM)					Rated _____	XUHT2 FOWX2	(UL)		
Wire					Rated _____	AVLV2	(UL)		UL 758

**Harmonized Nations and National Differences Declared:**






Australia, Austria, Belgium, Brazil, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, India, Ireland, Israel, Italy, South Korea, Netherlands, Norway, Poland, Portugal, Russia, Slovakia, Slovenia, Sweden, Switzerland, Turkey, USA, United Kingdom











Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
			1, 2		SCOPE, TERMINOLOGY
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1.1, 2.2.15, 2.12.4		MEDICAL ELECTRICAL EQUIPMENT Electrical equipment, provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the <i>patient</i> under medical supervision and which makes physical or electrical contact with the <i>patient</i> and/or transfers energy to or from the <i>patient</i> and/or detects such energy transfer to or from the <i>patient</i> .
			2		Some Definitions: <u>Patient</u> = Living being (person or animal) undergoing medical investigation or treatment. <u>Applied Part</u> - Any pieces of the equipment that can intentionally or unintentionally be brought in contact with the patient <u>Creepage</u> - Spacing along a surface (as an ant crawls) <u>Clearance</u> - Spacing through the air (as a bug flies) <u>LOP</u> - Level of protection - 2 required (not defined in standard) <u>Basic Insulation (BI)</u> - Spacing or a physical insulation barrier providing 1 LOP <u>Supplemental Insulation (SI)</u> - Spacing or a physical insulation barrier providing 1 LOP <u>Double Insulation (DI)</u> - BI + SI, and provides 2 LOP <u>Reinforced Insulation (RI)</u> - Single spacing or physical insulation barrier that provides 2 LOP <u>Protective Impedance</u> - Component (such as a resistor) that provides 1 LOP <u>Protective Earth (PE)</u> - Well-grounded part that provides 1 LOP <u>Class I Equipment</u> - Equipment using PE as 1 LOP <u>Class II Equipment</u> (also known as Double Insulated) - Equipment not using PE as 1 LOP <u>SIP/SOP</u> = Signal Input Part / Signal Output Part (RS232, USB, Ethernet port, Phone jack...) <u>ITE</u> = Information Technology (IEC 60950) Equipment (eg. Computer, Monitor, Printer, ...) <u>N.C.</u> = Normal Condition, <u>S.F.C.</u> = Single Fault Condition <u>Insulation Diagram</u> = Graphic illustration of the electrical isolation (not defined in standard)
			SI (UL)		Data Port (SIP/SOP) Requirements: Reference to the accompanying documents or full specifications of connected equipment to be marked on or near the SIP/SOP connection(s) <u>IEC 60950 (ITE) connection:</u> Considered 50Vdc in N.C. and Mains (240 V) in S.F.C. <u>Phone line connection:</u> Considered 120Vac ringing voltage in N.C. and S.F.C.








Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3		GENERAL REQUIREMENTS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.1		Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.4		An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained
			3.6, 3.7 (Note)		<p><u>Normal Condition (Likely to Occur)</u></p> <ul style="list-style-type: none"> - Reverse polarity of supply mains - Failure of insulation less than basic (operational) <p><u>Single Fault Condition (Could Occur)</u></p> <ul style="list-style-type: none"> a) Interruption of protective earth conductor b) Interruption of one supply conductor c) Appearance of an external voltage on an F-Type applied part d) Appearance of an external voltage on SIP/SOPs e) Leakage of Flammable Anesthetic / Oxygen / Nitrous Oxide containers or connectors f) Failure of an electrical components, one at a time g) Failure of mechanical parts (without required safety factor) h) Failure of temperature limiting devices <ul style="list-style-type: none"> - Shorting of basic or supplemental insulation - Overload of mains supply transformers - Interruption and short circuit of motor capacitors - Locking of moving parts - Impairment of cooling (fans, vents blocked) <p><u>Conditions not evaluated (Unlikely to Occur):</u></p> <ul style="list-style-type: none"> - Total breakdown of double or reinforced insulation - Loss of protective earth on permanently installed equipment - More than one Single Fault Condition at a time - Failure of a UL Recognized optocoupler barrier - Failure of a UL Recognized Y1 capacitor, acting as a barrier
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.100.1a (USA)		Printed wiring boards comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.100.1b (USA)		Lithium batteries comply with U.S. National or internationally harmonized component standards *** Lithium Battery Packs must be UL Recognized or evaluated to UL 2054
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.100.1c (USA)		Optical isolators comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.100.1d (USA)		Wiring and tubing comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.100.1e (USA)		CRT's > 5 inches comply with U.S. National or internationally harmonized component standards
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3.101.1 (USA)		Primary circuit components up to isolation transformer meet U.S. national or international harmonized component standards
			3.100 (Note) (USA)		<p>Primary components shall be UL recognized to a UL standard or special investigation. Where required by this standard, compliance with applicable IEC standards will be required. This may be demonstrated by another agency's mark.</p> <p>Other components in secondary circuits need only comply with the standards listed in App. L, if so referenced in the base, collateral, or particular standards.</p> <p>Components that do not meet the requirements for that component are faulted (per subclause 4.4)</p>

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4		GENERAL REQUIREMENTS FOR TESTS
			4.1		Only Insulation, Components, and Constructional Features, which could produce a Safety Hazard in Normal and Single Fault Conditions shall be tested
			4.2		Tests shall not be repeated, unless otherwise specified in this standard
			4.3		Tests are made on representative samples of the equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7a (Israel)		Equipment that is to be connected to the mains is intended for one of the permitted voltages and frequencies:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7a (Israel)		a) Nominal frequency of 50 Hz
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7a (Israel)		b) Nominal voltage of 230 V, for portable and hand-held equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7a (Israel)		c) Nominal voltage of 230 V, for one phase equipment with input power not exceeding 4 kVA
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7a (Israel)		d) Nominal voltage of 400 V, for multiphase equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7b (Israel)		Other equipment is allowed to be connected to the mains if it has the following ratings:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7b (Israel)		a) Single phase equipment, for the range of 220 to 240 V
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4.7b (Israel)		b) Multiphase equipment, for the range of 380 to 440 V

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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5		CLASSIFICATION
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.1		Type of protection against electric shock
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.1		Class I equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.1		Class II equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.1		Internally powered equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.2		Degree of protection against electric shock
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.2		Type B applied part
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.2		Type BF applied part
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.2		Type CF applied part
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.2		Not classified - no applied parts
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.3		Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.4		Methods of sterilization or disinfection
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.5		Equipment not suitable for use in the presence of flammable mixtures
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.5		Category AP equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.5		Category APG equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.6		Mode of operation:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.6		-continuous operation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.6		-short-time operation, specified operation; period
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.6		-intermittent operation, specified operation; rest period
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.6		-continuous operation with short-time, stated permissible loading time
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5.6		-continuous operation with intermittent, stated permissible loading/rest time (Duty Cycle)

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6		IDENTIFICATION, MARKING AND DOCUMENTS	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (Canada)		Where written safety warnings appear as equipment markings, they should appear in French and English	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (USA)		a) All words in "CAUTION", WARNING", and "DANGER" markings at least 1.6 mm (1/16") high	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (USA)		b) Signal words "CAUTION", WARNING", and "DANGER" at least 2.8 mm (7/64")	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (USA)		c) Letters in contrast color to the background	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (USA)		Equipment capable of emitting ionizing radiation provided with warning statement	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (USA)		If equipment produced in more than one factory, factory identification marked on the equipment	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6 (USA)		Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.1		Marking on the Outside of Equipment or Equipment Parts	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1c		Markings of the specific power supply affixed	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1d		If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents [Table DI: 14]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1e		Name and/or trademark of the manufacturer or supplier	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1f		Model or type reference	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1g		Rated supply voltages or voltage range(s)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1g		Number of phases (if not single)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1g		Type of current (AC or DC) [Table DI: 1, 2, 3, 4, 5]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1g (Australia)		Insert the following between the first and second dashes: For low voltage equipment rated at 200 V or more, a voltage rating (which may be part of a range) of not less than 230 V. Supply frequency ratings which include 60 Hz must also include 50 Hz.	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1h		Rated frequency or rated frequency range(s) (Hz)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1j		Rated power input (VA, W or A) (Watts: required if power factor > 0.9)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1j (Korea)		Insert the following sub-clause between the second and third sub-clauses: Equipment for one or several RATED voltage or frequency ranges, the RATED input for 220 V, 60 Hz or if applicable for 110 V, 60 Hz shall be separately marked.	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1k		Power output of auxiliary mains socket - outlets (if provided)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1l		Class II symbol (if no Protective Earth) [Table DI: 10]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1l		Symbol for degree of protection against ingress of water provided (Marked "Ordinary Equipment" or IPX0 / IP X X Rating) [or DI: 14 with wording in manual]	IPX1, IPX2,IPX8
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1l		Symbol for protection against electric shock [Table DII: 1, 2, 3]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1l		Symbol for protection of defibrillation-proof applied parts [Table DII: 9, 10, 11]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1l		Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1l		If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1m		Mode of operation (if no marking, suitable for continuous operation)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1n		Types and rating of external accessible fuses	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.1p		Ratings of external output:	

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
○	○	○	6.1q		Symbol for physiological effect(s):
○	○	○	6.1q		- attention, consult accompanying documents [Table DI: 14] 
○	○	○	6.1q		- non-ionizing radiation, or symbols as adopted by ISO or IEC 417
○	○	○	6.1r		Anesthetic-proof symbol: AP or APG [Table DI: 4, 5] 
○	○	○	6.1s		Dangerous voltage symbol [Table DI: 6] 
○	○	○	6.1s (Korea)		HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a TOOL shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and wit the Korean language, .
○	○	○	6.1t		Special cooling requirements
○	○	○	6.1u		Limited mechanical stability
○	○	○	6.1v		Protective packing requirement(s)
○	○	○	6.1v		Marking(s) for unpacking safety hazard(s)
○	○	○	6.1v		Equipment or accessories supplied sterile, marked as sterile
○	○	○	6.1y		Potential equalization terminal [Table DI: 7] 
○	○	○	6.1y		Functional earth terminal [Table DI: 9] 
○	○	○	6.1z		Removable protective means (marked to indicate necessity for replacement)
○	○	○	6.1 (USA)		"Grounding Reliability Can Only Be Achieved When The Equipment Is Connected To An Equivalent Receptacle Marked 'Hospital Only' Or 'Hospital Grade'." (located on product or power supply cord)
T1	○	○	6.1z		Durability of marking test Distilled water, Denatured Alcohol (Methylated Spirits), Isopropyl Alcohol
Δ	Δ	Δ	6.1 (UL)	(For UL)	 <p>MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1</p> <p>XXXX</p> <p>(OR)</p>  <p>MEDICAL EQUIPMENT</p>  <p>UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1</p> <p>XXXX</p> <p>* Additional Collaterals (IEC 60601-1-X) and/or Particulars (IEC 60601-2-XX), as necessary</p>
Δ	Δ	Δ	6.1 (UL)	(For TÜV Rheinland)	
Δ	Δ	Δ	6.1 (UL)	(For TÜV SUD) (Americas/Product Service)	

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.2		Marking on the Inside of Equipment or Equipment Parts	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2a		Nominal voltage of permanently installed equipment	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2b		Maximum power loading for heating elements or holders for heating lamps	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2c		Dangerous voltage symbol [Table DI: 6]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2c (Korea)		Replace the existing subclause with the following: The presence of HIGH VOLTAGE PARTS shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DI, Symbol 6) and in the Korean language. [Table DI: 6]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2d		Type of battery and mode of insertion	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2d		- Marking referring to accompanying documents used for battery not intended to be changed by the operator	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2e		Fuses accessible with a tool identified either by type and rating or by a reference to diagram	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2f		Protective earth terminal [Table DI: 6]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2g		Functional earth terminal [Table DI: 7]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2h		Supply neutral conductor in permanently installed equipment marked (N)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2j		Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2j		- Markings comply with IEC 445	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2k		For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2l		Statement for suitable wiring materials at temperatures over 75°C	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2l (USA)		Statement for suitable wiring materials at temperatures over 60 °C	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.2n		Capacitors and/or circuit parts marked as required in Sub-clause 15c	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.3		Marking of Controls and Instruments	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3a		Mains switch clearly identified	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3a		- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light [Table DI: 15, 16, IEC Symbol, IEC Symbol]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3b		Indication of different positions of control devices and switches [Table DI: 17, 18]	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3c		Indication of the direction in which the magnitude of the function changes, or an indicating device (if change of settings could cause a hazard)	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3f		The functions of operator controls and indicators are identified	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3g		Numeric indications of parameters are in SI units except for units listed in Am. 2	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.3 (SI) (UL)		Ethernet Connectors marked "not for phone connection" or pass 1 kV Dielectric test between connectors and enclosure, other secondary circuits	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.4		Symbols	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.4		Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.5		Colors of the Insulation of Conductors
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5a		Protective earth conductor has green/yellow insulation (at least at their terminations)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5b		All insulations of internal protective earth conductors are green/yellow at least at their terminations
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5c		Only protective or functional earthing, or potential equalization conductors are green/yellow
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5d	Blue	Color of neutral conductor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5e	Brown	Colors of phase conductor(s)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5e		- Compliance with IEC 227 and IEC 245 (for phase conductor colors)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.5f		Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.6		Medical Gas Cylinders and Connections
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.6 (Australia)		Replace the existing text of Item a) with the following: a) Identification of the content of gas cylinders used in medical practice as part of electrical EQUIPMENT shall be in accordance with AS 1944, (see also sub-clause 56.3a).
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.6a		In accordance with ISO ISO/R 32
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.6a (USA)		Identification of the content of gas cylinders in accordance with the color coding requirement of ANSI/NFPA99.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.6b		Identification of connection point
			6.6 (Note)		US and Canada have CONFLICTING color coding of gas hoses; must have separate models for each country
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.7		Indicator Lights and Push-Buttons
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.7a		- Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.7a		- Yellow used to indicate caution or attention required
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.7a		- Green used to indicate ready for action
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.7b		- Color red push-buttons used only to interrupt a function in case of emergency

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.8		ACCOMPANYING DOCUMENTS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8 (USA)		Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8 (USA) (SI)		To avoid spacing requirements in mains power switch, include the following wording in manual: "The power cord is to be used for mains disconnection"
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		Equipment accompanied by documents containing at least instructions for use
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		Equipment accompanied by documents containing at least a technical description
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		Equipment accompanied by documents containing at least an address to which the user can refer
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		Classifications specified in Clause 5 included in both the instructions for use and the technical description
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		* Type of protection against electric shock: (Class I) / (Class II) / (Internally Powered) Equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		* Degree of protection against electric shock: Type (B) / (BF) / (CF) Applied Parts
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		* Degree of protection against the ingress of water: (IP__) / (Ordinary)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		* Methods of sterilization or disinfection:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		* Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Or: Category (AP) / (APG) Equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		* Mode of operation if not continuous: (Specified Period, loading, cycling...)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		Markings specified in Sub-clause 6.1 included in the accompanying documents if they <u>have not</u> been permanently affixed to equipment (See also 6.8.3)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1		Warning statements and the explanation of warning symbols provided in the accompanying documents
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.1 (Korea)		Insert the following sub-clause after the last paragraph: Language of accompanying documents shall be included in Korean.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.8.2		Instructions for Use
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		General information provided in instructions for use
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- <u>state the function and intended application of the equipment</u>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- include an explanation of: the function of controls, displays and signals
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- the sequence of operation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- the connection and disconnection of detachable parts and accessories
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- the replacement of material which is consumed during operation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- information regarding potential electromagnetic or other interference and advice regarding avoidance (See IEC 60601-1-2 Standard for EMC)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		General information provided in instructions:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- information for the safe performance or routine maintenance
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2a		- <u>explanation of figures, symbols, warning statements and abbreviations on the equipment</u>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2c		Signal output or signal input parts intended only for connection to specified equipment described
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2d		Details about acceptable cleaning, disinfection or sterilization methods included
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2e		Warning statement for mains operated equipment with additional power source
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2f		A warning to remove primary batteries if equipment is not likely to be used for some time
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6.8.2g		Instructions to ensure safe use and adequate maintenance of rechargeable batteries

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
○	○	○	6.8.2h		Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1
○	○	○	6.8.2j		Identification of any risks associated with the disposal of waste products, residues, etc.
○	○	○	6.8.2j		- Advice in minimizing these risks
○	○	○	6.8.3		Technical description
○	○	○	6.8.3a		All characteristics essential for safe operation provided (Markings used from Clause 6.1)
○	○	○	6.8.3a		* Manufacturer Name/Model
○	○	○	6.8.3a		* Voltage Range/Type of Current- AC/DC /Frequency
○	○	○	6.8.3a		* Power Input- Watts, Amps, VA
○	○	○	6.8.3a		* Aux. Mains Output Power- if provided
○	○	○	6.8.3a		* Mode of operation- if not continuous
○	○	○	6.8.3a		* Type & Ratings of External Fuses
○	○	○	6.8.3a		* Ratings of External Outputs
○	○	○	6.8.3a		* Special cooling requirements
○	○	○	6.8.3a		* Limited Mechanical Stability
○	○	○	6.8.3a		* Protective Packing Requirements / Unpacking Safety Hazards
○	○	○	6.8.3a		* Sterile Equipment & Accessories Marked Sterile
○	○	○	6.8.3b		Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment
○	○	○	6.8.3b		- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use
○	○	○	6.8.3c		Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided
○	○	○	6.8.3d		Environmental conditions for transport and storage specified in accompanying documents and marked on packaging. Ranges must stay within the following to avoid additional testing: [Temperature range within -40°C to +70°C]. [Relative humidity range within 10% to 100%]. [atmospheric pressure range within 500 to 1060 hPa].
Δ	Δ	Δ	6.8 (UL)		 <p>CLASSIFIED C UL US XXXX MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1</p> <p>* Additional Collaterals (IEC 60601-1-X) and/or Particulars (IEC 60601-2-XX), as necessary</p>
Δ	Δ	Δ	6.1 (UL)	(For TÜV Rheinland)	
Δ	Δ	Δ	6.1 (UL)	(For TÜV SUD) (Americas/Product Service)	
○	○	○	6.61 (Canada)		Point of connection of gas cylinders:
○	○	○	6.61 (Canada)		- is gas specific
○	○	○	6.61 (Canada)		- is non-interchangeable
○	○	○	6.61 (Canada)		- is identified

T 2

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7		POWER INPUT
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	7		Power Input Measurements: Cannot exceed ratings by more than (15% , ≤100W), (10% , >100W)
			8		BASIC SAFETY CATEGORIES (Moved to Appendix A.1.1)
			9		REMOVABLE PROTECTIVE MEANS (Moved to 6.1z)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10		ENVIRONMENTAL CONDITIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.1		Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer:
			10.2.1		Specified Environment: Temperature (+10°C to +40°C), Relative humidity (30% to 75%), Atmospheric pressure (700 hPa to 1060 hPa)
			10.2.1 (Note) (See 42.1)		Tables XIX and Xb give maximum temperatures at an ambient of 25°C. Table Xa gives maximum temperatures considering an ambient of 40°C. Therefore, 15°C shall be subtracted from the limits given in Table Xa at a 25°C ambient
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.2.2a		Rated voltage not exceeding 250 V for hand-held equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.2.2a		Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.2.2a		Rated voltage not exceeding 500 V for all other equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.2.2a		Rated input frequency not more than 1kHz
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.2.2a (USA)		Rated voltage not exceeding 250 Vdc or single phase ac or 600 V polyphase ac for equipment up to 4kVA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.2.2a (USA)		Rated voltage not exceeding 600 V for all other equipment
			11		NOT USED
			12		NOT USED
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13		GENERAL
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Risk of Electric Shock in Normal Use and in Single Fault Condition Shall be reduced as far as Reasonably Practicable
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14		REQUIREMENTS RELATED TO CLASSIFICATION
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14 (USA)		Fixed equipment and permanent equipment is Class I
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.4a		Class I and Class II equipment in addition to basic insulation provided with an additional protection
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.4b		Equipment supplied from external dc source of reverse polarity results in no safety hazard
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.5a		Dual classification for internally powered equipment with a means of connection to supply mains
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.5b		Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.6c		Applied parts intended for direct cardiac application are of type CF
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14 (Note)		Class II Equipment with a grounded plug - Accompanying Documents shall clearly indicate no Protective Earthing is provided

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15		LIMITATION OF VOLTAGE AND/OR ENERGY
T 3	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	15b		Voltage measured one sec after disconnection of the mains plug does not exceed 60V
T 4	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	15c		For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	15c		Marking provided for manual discharging
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	15 c (Note) (UL)		Interlock switches, if used, must pass a 10,000 cycle test
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16		ENCLOSURES AND PROTECTIVE COVERS
T 0	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	16a		Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test) Exception 5: SIP/SOPs on the back of equipment, separated from the mains by DI is acceptable
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16a		Insertion or removal of lamps - protection against contact with live parts provided
T 0	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	16b		Opening in a top cover positioned that accessibility of live parts by a test rod is prevented
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16c		Conductive parts accessible after the removal of handles, knobs, levers (without the use of a tool)
T 6	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	16c		- have a resistance of not more than 0.2 Ohm
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16c		- separated from live parts by one of the means described in Sub-clause 17g
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16d		Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16e		Removable enclosures protecting against contact with live parts
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16e		- Removal possible only with the aid of a tool
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16e		- Use of automatic device making parts not live when the enclosure is opened or removed
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16e		Exceptions: Plug-in modules, Covers of illuminated push-buttons, Covers of indicator lamps, Covers over recorder pens, Covers of battery compartments, empty lamp holders, specified not to open in the patient's vicinity - Exception 16e applied to the following parts:
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	16f		Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17		SEPARATION
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17a		Separation method of the applied part from live parts:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17a		1) basic insulation: applied part earthed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17a		2) by protectively earthed conductive part (e.g. screen)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17a		3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17a		4) by double or reinforced insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17a		5) by protective impedances limiting current to applied part
T 7	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	17a	- Additional leakage current test in single fault conditions
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17c		There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17d		Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17g		Separation method of accessible parts other than applied parts from live parts:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17g		1) basic insulation: accessible part earthed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17g		2) by protectively earthed conductive part (e.g. screen)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17g		3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17g		4) by double or reinforced insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17g		5) by protective impedances limiting current to accessible part
T 7	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	17g	- Additional leakage current test in single fault conditions
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17h		Arrangements used to isolate defibrillation-proof applied parts so designed that:
T 5	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	17h	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator
T 5	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	17h	- after defibrillation voltage exposure, the equipment continues to perform its intended function
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17 (SI - UL)		<ul style="list-style-type: none"> - Distances between conductive parts within a layer of a multi-layer PWB are subjected to the additional performance requirements 2.9.7 of UL 1950/60950 may be considered solid insulation and may be permitted to comply with the Distance Through Insulation requirements of minimum 0.4 mm for reinforced insulation. - Thermal cycling is not required for R/C printed wiring consisting of prepreg cured with epoxy resin and used at temperatures not exceeding 90°C. - Distances between conductive parts within flexible PWB's, such as multi-layer polyamide or Mylar, should be considered "uncemented" joints.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	17 (SI - UL)		For RI Insulation, minimum thickness shall be 0.4 mm, as long as it is not affected by age or hygroscopic

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18		PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18a		Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18b		Protective earth terminals suitable for connection to the protective earth conductor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18e		Potential equalization conductor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18e		- Readily accessible
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18e		- Accidental disconnection prevented in normal use
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18e		- Conductor detachable without the use of a tool
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18e		- Power supply cord does not incorporate a potential equalization conductor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18e		- Connection means marked with Symbol 9, Table DI
T 6	<input checked="" type="radio"/>	<input checked="" type="radio"/>	18f		- For equipment without power supply cord, impedance between protective earth terminal and accessible metal part ≤ 0.1 Ohm
T 6	<input checked="" type="radio"/>	<input checked="" type="radio"/>	18f		- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part ≤ 0.1 Ohm
T 6	<input checked="" type="radio"/>	<input checked="" type="radio"/>	18f		- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part ≤ 0.2 Ohm
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18g		If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ohm, the allowable value of the enclosure leakage current is not exceeded in single fault condition
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18k		Functional earth terminal not used to provide protective earthing
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18l		Class II equipment with isolated internal screens
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18l		- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18l		- functional earth terminal clearly marked
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18l		- explanation of functional earth terminal provided in the accompanying documents
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18m (USA)		Earthing of X-ray equipment: All parts operating at over 600 V ac, 850 V dc, or 850 V peak are enclosed in protectively earthed enclosures
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18m (USA)		Earthing of X-ray equipment: Connections from high-voltage equipment to other high voltage components made with high voltage shielded cables
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18n (USA)		Accessible non-current carrying conductive parts are protectively earthed (or may be Double Insulated)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	18 (Note) (UL)		If PWB traces are used for Protective Earthing, the traces must pass the UL1950 PAG No.2.5.1:002 test (CSA C22.2 No. 0.4-M1982 Sub-clause 4.3 per table 5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19		CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	19 (USA)		Enclosure and earth leakage currents comply with U.S. limits
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	19.1b		Leakage currents
T 7	<input checked="" type="radio"/>	<input checked="" type="radio"/>	19.1b		- earth leakage current (current flowing through PE ground wire)
T 7	<input checked="" type="radio"/>	<input checked="" type="radio"/>	19.1b		- enclosure leakage current (operator accessible parts to ground)
T 7	<input checked="" type="radio"/>	<input checked="" type="radio"/>	19.1b		- patient leakage current (patient applied parts to ground)
T 7	<input checked="" type="radio"/>	<input checked="" type="radio"/>	19.1b		- patient auxiliary current (current flowing between applied parts)

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20		DIELECTRIC STRENGTH
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	20		Overall compliance with Clause 20
T 8	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	20.1	<p>Dielectric strength for equipment per TABLE V</p> <p>Conducted At operating temperatures, After humidity preconditioning, After sterilization/disinfection:</p> <p>A-a₁: (BI) Between live parts and protective earthed accessible parts</p> <p>A-a₂: (DI) Between live parts and enclosure not protectively earthed</p> <p>A-b: (BI) Between live parts and conductive parts separated by BI, forming part of DI</p> <p>A-c: (SI) Between enclosure and Conductive parts separated from live by BI</p> <p>A-e: (DI) Between live parts and SIP/SOPs not protectively earthed (if SIP/SOPs > 42.4 V peak or 60 V dc)</p> <p>A-f: (BI) Between parts of opposite polarity of mains part (before mains fuse - fuses removed for testing)</p> <p>A-g: (BI or SI or RI) Between live parts and a metal enclosure lined with insulating material</p> <p>A-j: (SI) Between accessible parts non-protectively earthed and foil over power supply cord inside bushings/anchors)</p> <p>A-k: (DI) Between accessible parts non-protectively earthed and SIP/SOPs if:</p> <ul style="list-style-type: none"> a- (SIP/SOPs > 42.4 V peak or 60 V dc) b- (leakage currents > allowable values if SIP/SOP component failure) c- (SIP/SOPs not protectively earthed or separated from accessible parts) d- (SIP/SOP parts not tested with equipment and specified in manual)
T 8	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	20.2	<p>Dielectric strength for applied parts per TABLE V</p> <p>Conducted At operating temperatures, After humidity preconditioning, After sterilization/disinfection:</p> <p>B-a: (DI) Between live parts and applied parts (patient circuit)</p> <p>B-b: Between different parts - see particular standard if applicable</p> <p>B-c: (SI) Between applied parts and parts not protectively earthed and separated from live parts by BI</p> <p>B-d: (BI) Between F-type applied part and earth, enclosure, SIP/SOPs</p> <p>B-e: (DI) Between F-type applied part with stressing voltages in normal conditions and enclosure</p>
			20.1, 2 (Note)		Barriers specified in 20.1 and 20.2 are examples and are not necessarily the only required in the equipment. Any barrier that is required to mitigate a hazard (leakage current, auxiliary current, hazardous movement, etc.) is a required barrier
			20.2 (SI - UL)		F-type applied parts separation from ground does not include the operator (who may be earthed), Lead insulation is required where leads may contact earth or earthed parts (not counting patient or operator)
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	20.3	<p>Reference Voltage (U) – Voltage that the insulation is subject to in normal use, at maximum rated voltage</p> <p>- For insulation with either side floating, (U) is the sum of the highest voltages of each side</p>
			20.3 (SI - UL)		Barriers with a maximum voltage of 25 V on one side of the transformer do not need to be summed, as stated in 20.3
			20.4 (Note)		<p>Dielectric breakdown between primary and secondary through earth is not considered a failure (eg. Switching P.S.).</p> <p>Components crossing the barrier may be tested individually or the shorting earthed part may be modified as to not interfere with the dielectric test</p>

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21		MECHANICAL STRENGTH
T 9	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	21a		Sufficient rigidity of an enclosure tested by: force of 45 N
T 9	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	21b		Sufficient strength of an enclosure tested by: impact hammer
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21 a,b (SI - UL)		Impact hammer test may be waived when the ball impact test is performed on the same locations 5 ft. lbs Ball impact = 6.78 j impact energy (> 0.5 j impact energy from impact hammer) 0.5 j = 0.3688 ft. lbs. = 4.425 in. lbs: UL Ball Drop Test = 13.5 Times the Energy of the Impact Hammer
T 10	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	21c		On portable equipment carrying handles or grips withstand the requirements of the loading test
T 11 T 12	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	21.3		No damage to parts of patient support and/or immobilization system after the loading test
T 13	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	21.5		Hand held equipment or equipment parts are safe after drop test
T 14 A, B	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	21.6		Portable and mobile equipment is able to withstand rough handling
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22		MOVING PARTS
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22 (USA)		When risk of injury can occur, end stops are provided
T 15	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	22 (USA)		End stops have mechanical strength as determined by the test
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.2a		Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.2b		Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.3		Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.3		Guides or other safeguards are removable only with a tool
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.4		Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.4 (USA)		Dangerous movements of equipment parts which may cause physical injury to the patient or operator are possible only by the continuous activation by the operator
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.6		Parts of equipment subject to mechanical wear are accessible for inspection
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7		Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7		The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7		Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7		Means for stopping of movements operate as a result of one single action
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7a (USA)		Emergency off switch has red actuator
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7a (USA)		Emergency off switch: once actuated, maintains the equipment in "off" condition until action, different from that used to actuate, is performed
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7a (USA)		Emergency off switch is readily accessible to operator
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7b (USA)		Emergency off switch is marked with word "STOP" or symbol 5110 of IEC 878 in compliance with U.S. Clause 6
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.7b (USA)		Emergency off switch: separate and independent of the intended movement control
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23		SURFACES, CORNERS AND EDGES
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23		Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24		STABILITY IN NORMAL USE (see appended table 24)
T 16	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.3	Equipment overbalances when tilted through an angle of 10°
T 16	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	24.3	- does not overbalance when tilted through an angle of 5° in any position excluding transport
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.3	- carry a warning notice stating that transport should only be undertaken in a certain position
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.3	- in the position specified for transport does not overbalance when tilted to an angle of 10°
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.6a	- suitable handling devices (grips etc.), or
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.6a	- instructions for lifting and handling during assembly
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	24.6b	On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25	EXPELLED PARTS
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	25.1	Protective means are provided where expelled parts of the equipment could be a hazard
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion
			26		VIBRATION AND NOISE (No Requirements in Base Standard)
			27		PNEUMATIC AND HYDRAULIC POWER (No Requirements in Base Standard)

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28		SUSPENDED MASSES
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		Ceiling-supported EQUIPMENT
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		i. EQUIPMENT fitted with an anticrash device or have suspension cables duplicated and independently anchored.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		ii. Motorized drives designed to prevent the driven part from becoming hazardous in the event of a power failure.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		iii. Carriages, brakes, and supports designed such that any single failure will not constitute a hazard to the PATIENT.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		iv. Effective means incorporated to prevent carriages running off supporting rails.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		v. Effective means incorporated to facilitate adequate inspection of cables and anchorages.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		vi. Proximity or pressure switches may be used to minimize hazards.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2a (Australia)		vii. Ceiling-supported EQUIPMENT or parts thereof connected by electrical supply cables provided with stops (e.g. for limitation of rotation or linear movement) to restrict movement in a manner which avoids any undue strain on the wiring termination or damage to the wiring.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2b (Australia)		Floor and floor-to-ceiling supported (including mobile) EQUIPMENT.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2b (Australia)		i. Anticrash devices fitted to cable, chains, etc.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2b (Australia)		ii. Means incorporated to facilitate adequate inspection of cables and anchorages.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.2b (Australia)		iii. Cross-arms or pivots fitted with adequate stops, locknuts, grub screws, or similar devices to prevent supported masses from being dislodged.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.3		Suspension system with safety device
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.3		Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4
T 17	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	28.3	Safety device has safety factors complying with Sub-clause 28.4.2
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.3	Clear indication to the operator that the safety device has been activated after failure of suspension means
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.3 (USA)	No evidence of damage to a safety catch after test
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.3 (USA)	Safety catch marking provided
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.4	Suspension systems of metal without safety devices
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.4	1) Total load does not exceed the safe working load
T 18	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	28.4	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired
T 18	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	28.4	3) Safety factors not less than 8 where impairment is expected
T 18	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	28.4	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.4	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement
T 18	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	28.4 (USA)	No damage to structural parts as a result of loading test
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.4 (SI - UL)	A mass equal to 3 times the element's mass is added at the center of gravity of each element (for 4x safety factor). The total mass on all the elements is held for 1 minute.
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	28.4 (601-2-38) (SI - UL)	Hospital Beds: In order to be consistent when using the particular standard for beds, the same 2x safety factor requirement shall apply for support brackets and the like, as apply to the bed itself.
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29	X-RADIATION
T 19	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
			30		Alpha, BETA, GAMMA, NEUTRON RADIATION (No Requirements in Base Standard)
			31		MICROWAVE RADIATION (No Requirements in Base Standard)
			32		LIGHT RADIATION – INCLUDING LASERS (No Requirements in Base Standard)
			33		INFRA-RED RADIATION (No Requirements in Base Standard)
			34		ULTRAVIOLET RADIATION (No Requirements in Base Standard)
			35		ACOUSTICAL ENERGY – INCLUDING ULTRA-SONICS (No Requirements in Base Standard)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36		ELECTROMAGNETIC COMPATIBILITY
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	36		Equipment complies with IEC 601-1-2 (Ed.2, 2001)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37		COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	37		Requirements for category AP and APG equipment (Cl. 37 - 41) (For equipment used in the presence of Oxygen, see US Cl. 400)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	38		MARKING, ACCOMPANYING DOCUMENTS – CATEGORY AP & APG EQUIPMENT
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	39		COMMON REQUIREMENTS FOR CATEGORY AP & APG EQUIPMENT
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	40		REQUIREMENTS AND TESTS FOR CATEGORY AP EQUIPMENT
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	41		REQUIREMENTS AND TESTS FOR CATEGORY APG EQUIPMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42		EXCESSIVE TEMPERATURES
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	42 (USA)		Insulation systems with measured temperatures exceeding Class A 105°C (based on 40°C ambient) comply with UL1446
T 20	<input checked="" type="radio"/>	<input checked="" type="radio"/>	42.1		Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1
T 20	<input checked="" type="radio"/>	<input checked="" type="radio"/>	42.2		Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient
			42.1 (Note) (UL)		Test Temperatures may be adjusted to 40°C ambient by adding the difference between the testing ambient and 40°C to measured temperatures
T 20	<input checked="" type="radio"/>	<input checked="" type="radio"/>	42.3		Applied parts not intended to supply heat have surface temperatures not exceeding 41°C
	<input type="radio"/>	<input type="radio"/>	42.3 (Note) (UL)		If the specified maximum ambient temperature for equipment operation is specified as less than 40°C; and with the new ambient the applied part maximum temperature meets requirements, it is possible to exceed the 1°C rise limit of the 41°C requirement (allowed on a case by case basis)
	<input type="radio"/>	<input type="radio"/>	42.3 (Australia)		Item 2) Add the following to the first dash: For this clause only, low voltage equipment rated at greater than 200 V is regarded as having a maximum rated voltage of 230 V.
	<input type="radio"/>	<input type="radio"/>	42.5		Guards to prevent contact with hot surfaces removable only with a tool
	<input type="checkbox"/>	<input type="checkbox"/>	43		FIRE PREVENTION
T 9	<input checked="" type="radio"/>	<input checked="" type="radio"/>	43		Strength and rigidity necessary to avoid a fire hazard
	<input type="checkbox"/>	<input type="checkbox"/>	44		OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION
	<input type="radio"/>	<input type="radio"/>	44.2		Equipment contain a liquid reservoir:
T 21	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.2		- the equipment is electrically safe after 15% overfill steadily over a period of 1 min
T 21	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.2		- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)
T 22	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.3		Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)
T 23	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.4		Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard
T 24	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.5		Equipment sufficiently protected against the effects of humidity
T 25	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.6		Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529
T 26	<input checked="" type="radio"/>	<input checked="" type="radio"/>	44.7		Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45		PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE
T 27	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	45.2		Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.3		Maximum pressure does not exceed the maximum permissible working pressure for individual parts
T 28	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	45.7		Unless excessive pressure can not occur, pressure-relief device provided
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7a		a) Pressure-relief device connected as close as possible to the pressure vessel
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7b		b) Readily accessible for inspection
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7c		c) Not capable of being adjusted or rendered inoperative without a tool
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7d		d) Discharge opening located that the released material is not directed towards person
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7e		e) Discharge opening located that operation will not deposit material which may cause a safety hazard
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7f		f) Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7g		g) No shut-off valve between a pressure-relief device and the parts intended to be protected
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45.7h		h) Minimum number of cycles of operation: 100.000
				46		HUMAN ERROR (Not Used)
				47		ELECTROSTATIC CHARGES (Not Used)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	48		BIOCOMPATIBILITY
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	48		Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1 (or biocompatibility data from supplier of material in Applied Part)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	49		INTERRUPTION OF THE POWER SUPPLY
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	49.1		Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard
T 29	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	49.2		Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	49.3		Means are provided for removal of mechanical constraints on patient in case of a supply mains failure
				50		ACCURACY OF OPERATING DATA (Not Used in base standard)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	51		PROTECTION AGAINST HAZARDOUS OUTPUT
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	51.4		Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	52		ABNORMAL OPERATION AND FAULT CONDITIONS
T 30	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.1		Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	52.1 (Note)		Opening of a PWB trace is not acceptable, per 57.8b
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	52.1		The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	52.1 (SI - UL)		Evaluation to IEC 601-1-4 is only required to mitigate Fire, Shock and Mechanical Hazards (for the UL mark).
				52.4.1 (Note)		Safety Hazards: - Emission of flames, molten metal, poisonous or ignitable gas in hazardous quantities - Deformation of enclosure to such an extent that compliance with this Standard is impaired - temperatures exceeding the maximum values shown in Table XII
T 31	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.2		Failure of thermostats presents no safety hazards
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	52.5.3		Short-circuiting of either part of double insulation presents no safety hazard
T 32	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.5		Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C
T 33	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.6		Locking of moving parts presents no safety hazard
T 34	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.7		Interruption and short-circuiting of motor capacitors presents no safety hazard
T 33	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.8		Duration of motors locked rotor test in compliance with Cl. 52.5.8
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	52.5.8 (note) (Australia)		Table XII: In second row, first dash, after "if impedance protected", add "maximum value".
T 35	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.9		Failure of one component at a time presents no safety hazard
T 36 T 37	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.10		Overload of heating elements presents no safety hazard
T 38 T 39	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.10f		Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection
T 40	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	52.5.10h		Equipment with three-phase motors can safely operate with one phase disconnected
				53		ENVIRONMENTAL TESTS (Not Used - See Sub-clause 4.10 and Clause 10)
				54		GENERAL (No Requirements)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	55 (USA)		US DEVIATIONS FOR POLYMERIC ENCLOSURES
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	55 (USA)		Polymeric enclosures and external combustible surfaces
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	55 (USA)		Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C
ASTM E84, E162	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	55 (USA)		External combustible surface of more than 9.47 m ² or single dimension of 3.7 m have flame spread rating not exceeding 75 (Steiner Tunnel Test)
ASTM E84, E162	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	55 (USA)		External combustible surface of more than 4.74 m ² but not exceeding 9.47 m ² have flame spread rating not exceeding 75 (Radiant Panel or Steiner Tunnel Test)
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	55 (USA)		Polymeric enclosures for transportable equipment rated 94V-2 or better (for circuits with > 15 W available power)
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	55 (USA)		Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better
T 41	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	55 (USA)		Polymeric enclosures withstand 6.78 Nm (5 ft*lbs) impact test (UL Ball Impact)
T 42	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	55 (USA)		Polymeric enclosures: no deformation after mold stress test (for molded parts)
T 13	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	55 (USA)		Polymeric enclosures of hand-held equipment withstands 1.22 m drop test (see Clause 21.5)

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56		COMPONENTS AND GENERAL ASSEMBLY
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56		<u>List of Critical Components Required</u>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.1b		Ratings of components not in conflict with the conditions of use in equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.1b		Ratings of mains components are identified
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.1d		Components, movements of which could result in a safety hazard mounted securely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.1f		Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a		Connectors provide separation required by Sub-clause 17g
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a		Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a		Medical gas connections not interchangeable
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (Australia)		Replace the text in the third dash by the following: Medical gas connections on EQUIPMENT shall, if operating at positive pressures greater than 50 kPa in NORMAL USE, comply with AS 2472, AS 2473, or AS 2896 as appropriate.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (Canada)		Medical gas inlet connectors:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (Canada)		- are gas specific
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (Canada)		- are non-interchangeable
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (Canada)		- are DISS type complying with CGA V-5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (Canada)		- are configured to permit the supply from assemblies complying with CAN/CSA - Z305.2
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (USA)		Connector, pin, plug attached to patient connected lead or contact cannot engage any part on the equipment, including separable cord set
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3a (USA)		Connector, pin, plug attached to patient connected lead or contact cannot make contact with live parts of power receptacle outlet (if product can be used without professional supervision)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3b		Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.3c		Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.4		Connections of Capacitors
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.4		Not connected between live parts and non-protectively earthed accessible parts
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.4		If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.4		Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.4		Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.4 (SI - UL)		Y1 Capacitors per IEC 384 are considered equivalent to DI across a barrier This use is not adequate for across the line or line to ground bridging before the mains fuse(s) [Y1 = DI @ 250 Vac max; Y2, Y3, X1, X2 = BI @ 250 Vac max; Y4 = BI @ 150 Vac max; X3 = BI @ 125 Vac max] Two capacitors in series, forming DI must have identical electrical ratings.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.5		Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.6		Temperature and overload control devices
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a		Thermal cut-outs which have to be reset by a soldering not fitted in equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a		Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a		Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a		Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times (or UL Recognized)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a		Non-self resetting over-current releases operated 10 times (or UL Recognized)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a		Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6a (Canada)		Where consequential loss of function caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings provided
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6b		Thermostats with varying temperature settings clearly indicated
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.6b		Operating temperature of thermal cut-outs indicated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.7		Batteries
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.7a		Battery compartments:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.7a		- adequately ventilated
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.7a		- accidental short-circuiting is prevented
T 43	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.7b	Incorrect polarity of connection prevented
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.8		Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.8		- to indicate that equipment is energized
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.8		- to indicate the operation of non-luminous heaters if a safety hazard could result
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.8		- to indicate when output exists if a safety hazard could result
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.8		- charging mode indicator provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.10		Actuating parts of controls
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.10b		Actuating parts are adequately secured to prevent them from working loose during normal use
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.10b		Controls are secured to prevent the movement relative to scale marking (safety related only)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.10b		Detachable indicating devices are prevented from incorrect connection without the use of tool
T 44	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.10c	Stops are provided on rotating controls:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.10c		- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.10c		- to prevent damage to wiring

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.11		Cord-connected hand-held and foot-operated control devices
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.11a		Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.11 a (Note)		Higher voltages attained by stepping up through an inverter are allowable if leakage current and dielectric withstand tests are performed and if spacings are met for the higher voltage
T 13	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.11b		Hand-held control devices comply with the requirement and test of Sub-clause 21.5
T 45	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.11b		- Foot-operated control devices designed to support the weight of an adult human being
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56.11c		Devices not change their setting when inadvertently placed
T 25	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.11d		Foot-operated control devices are at least IPX 1
T 25	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.11d		- For surgical use, electrical switching parts are IPX 8
T 46	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	56.11e		Adequate strain relief at the cord entry provided

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57		MAINS PARTS, COMPONENTS AND LAYOUT
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57 (USA)		Permanently connected equipment provided with field wiring provision in accordance with NEC, ANSI/NFPA 70
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57 (Note)		Outside of transformers, a thickness of 0.4 mm is acceptable for Reinforced Insulation, provided it is suitable for the application. Insulating material shall be unaffected by aging (no hygroscopic materials or natural rubber).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.1		Isolation from supply mains
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.1a		Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously (Mains power cord plug used to isolate equipment if no mains switch)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.1a		Means for isolation incorporated in equipment or, if external, specified in the accompanying documents
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.1d		Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.1f		Mains switches not incorporated in a power supply cord
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.1h		Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.1m		Fuses and semiconductor devices not used as isolating devices
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.2		Mains connectors and appliance inlets
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2 (USA)		Power cord mains plug is "Hospital Grade" type
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2 (USA)		Grounding reliability marking provided on Equipment or on a tag attached to the supply cord: "grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade"
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2 (USA)		Plug for radiography equipment acceptable for current not less than 50 % of maximum input
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2 (USA)		Plug acceptable for use with current not less than 125 % of rated current
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2 (USA)		Plug acceptable for voltage for which the equipment is configured when shipped
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2 (USA)		Polarized plug wired such that the center contact of Edison-base lamp holder, single-pole switch or single-pole overcurrent device connected in ungrounded side
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2a (Australia)		Replace "not used" with: Supply plugs - Provision for inspection Where a supply flexible cord is fitted with a rewirable plug of a type complying with the requirements of AS 3112 for 3 pin plugs, the plug clear-backed to facilitate inspection of the cord colors and the condition of the terminations.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2e		Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2e (SI - UL)		Permanently installed equipment may be considered as an extension of the building wiring, even though it can have PE resistance up to 0.1 ohms. Products connected to the auxiliary mains socket outlet of the permanently installed equipment can have up to 0.2 ohms PE resistance.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2g		Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2g (Canada)		Mains plug of non-permanent installed equipment:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2g (Canada)		- if molded on type - hospital grade complying with CSA C22.2, No. 21
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2g (Canada)		- hospital grade disassembly type complying with CSA C22.2, No. 42
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.2g (Canada)		- if Class II equipment - polarized hospital grade CSA configuration 1-15P

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.3		Power supply cords
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3a		Not more than one connection to a particular supply mains
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3a		If alternative supply allowed, no safety hazards when more than one connection is made simultaneously
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3a		The mains plug has only one power supply cord
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3a		Non-permanently connected equipment provided with power supply cord or appliance inlet
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b		Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b		Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		Detachable power supply cords:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		- unlikely to be detached accidentally
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		- impedance of earth contacts presents no safety hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		- possibility of replacement by a cord which could make equipment hazards minimized
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		- complies with CSA C22.2 NO. 21
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		- not smaller than No. 18 AWG
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (Canada)		- minimum serviceability of Type SJ for mobile equipment or Type SV for other
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (USA)		Detachable power supply cord unlikely to become detached accidentally
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (USA)		Flexible cord is of type acceptable for application
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (USA)		Flexible cord not smaller than 18 AWG
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3b (USA)		Flexible cord complies with serviceability requirements
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3c		Nominal cross-sectional area of conductors of power supply cords not less than in Table XV
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.3d		Stranded conductors not soldered if fixed by any clamping means
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.4		Connection of power supply cords (not applicable for IEC 320 detachable cord sets)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Cord anchorages
T 46	<input checked="" type="radio"/>	<input checked="" type="radio"/>	57.4a		Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Tying the cord into a knot or tying the ends with string not used
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Cord anchorages made of metal provided with an insulating lining
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Clamping screws do not bear directly on the cord insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Screws associated with cable replacement are not used to secure other components
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4a		Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals
T 47	<input checked="" type="radio"/>	<input checked="" type="radio"/>	57.4b		Power supply cord protected against excessive bending
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.4c		Adequate space inside equipment to allow the supply cable conductors to be introduced and connected

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.5		Mains terminal devices and wiring of mains part (not applicable for IEC 320 detachable cord sets)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5		Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5		If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5		Screws and nuts which clamp external conductors not serve to fix any other component
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5b		Terminals closely grouped with any protective earth terminal
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5b		Mains terminal devices accessible only with use of a tool
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5b		Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5b (USA)		If leads are provided for connection to branch circuit, the free end is in separate compartment
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5b (USA)		If leads are provided for connection to branch circuit, the free length of leads inside field-wiring compartment is at least 152 mm long
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5c		Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.5d		Cord terminals not require special preparation of the conductor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.6		Mains fuses and overcurrent releases
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6		Fuses or over-current releases provided accordingly for Class I and Class II
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6 (SI - UL)		This waives the fuse requirement of Clause 57.6 for products with the following features/characteristics: . Separable power supply/ battery charger (Direct Plug-in or Desktop type), . Linear transformer isolated, . Rated 120 V only, . With Nameplate and Maximum output ratings less than 100 W, . Provided with double insulation between parts of opposite polarity and . Provided with double insulation between mains parts and any parts connected to ground.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6 (Note)		Fuses or over-current releases must have means of opening at a specific current (thermal cutoffs, PTCs not acceptable)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6		Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6 (Note)		Fuse ratings must be less than all component ratings up to the isolation transformer
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6		Protective earth conductor not fused
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.6		Neutral conductor not fused for permanently installed equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.8		Wiring of the Mains Part
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.8a		Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC Publications 227 or 245, treated as bare conductor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.8b		Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.8b		Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.9		Mains Supply Transformers
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9 (Canada)		Switching power supplies conform to CSA Electrical Bulletin 1402C
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.1		Overheating
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.1		External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative
T 48	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	57.9.1a	Short-circuit of secondary windings not caused excessive temperature
T 48	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	57.9.1b	Overload of secondary windings not caused excessive temperature
T 49	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.2 (SI - UL)		Transformer 5x Dielectric test can be waived for Switch Mode power supplies
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.2 (Note) (UL)		Transformer 5x Dielectric test can be waived if transformer primary and secondary winding varnish is R/C (OBS2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.9.4		Construction
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4a		Separation of primary and secondary windings
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4a		- separate bobbins or formers
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4a		- one bobbin with insulating partition
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4a		- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4a		- concentrically wound on one bobbin with windings separated by double insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4c		Means provided to prevent displacement of end turns
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4d		Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4e		Insulation between the primary and secondary in transformers with double insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4e		- 1 insulation layer having a thickness of at least 1 mm
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4e		- at least 2 insulation layers with a total thickness of at least 0.3 mm
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4e		- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4f (SI - UL)		Potted transformers – where DI required, 1 mm thick minimum is required. Evaluate areas where potting does not contribute to separation and where bonding may affect how spacings are measured.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4 f (Note) (UL)		Conformal Coating used on PWB considered to contribute 1 mm each to creepage distances for specific applications
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.9.4g		Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.10		Creepage distances and air clearances
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10 (SI - UL)		<p>Products or constructions using insulating compounds (encapsulation) to provide DI shall comply with Sub- Clause 2.9.7 of UL 1950/60950. Except that:</p> <ol style="list-style-type: none"> The minimum DTI for DI shall be 1 mm (UL 1950, Sub- Clause 2.9.4.1, 3rd and 4th dashes). This is to keep the requirements in line with those in Sub- Clause 57.9.4.e, 1st dash, The Humidity Conditioning test shall be performed per Sub- Clause 4.10 and The Dielectric Strength test shall be performed per Clause 20. <p>Note 1: UL 1950/60950 Practical Application Guidelines for this Sub- Clause can be used as appropriate.</p> <p>Note 2: Special attention is expected for the manufacturing process to ensure that production will not contain voids. Vacuum encapsulation processes with thermosetting materials such as epoxy typically provide an acceptable construction. Poured encapsulation processes with thermoplastic materials such as RTV Silicon typically do not.</p>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10 (Note) (UL)		<p>Reference Voltage (U) for Creepage distances and air clearances for insulation with either side isolated (floating)</p> <ul style="list-style-type: none"> - All transformer secondary voltages ≤ 25 V: The highest voltage of either side of the insulation - All others: Arithmetic sum of the highest voltages of each side
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10 (Note) (UL)		PWB with ≥ 0.4 mm thickness is sufficient for RI requirements
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10a		Values: compliance with at least the values of Table XVI
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10a		Creepage distances for slot insulation of motors at least 50% of the specified values
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10 a (Note)		For Voltages >1000 V, apply requirements from applicable or similar IEC 60601-2-xx standard or use IEC 664
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10b		Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57.10c		Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	58		PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.1		Clamping means of the protective earth terminal
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.1		Not be able to loosen without the aid of a tool
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.1		Screws for internal earth connections are covered or protected against loosening from outside
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.2 (Canada)		Protective earth connections comply with CSA C22.2 No. 0.4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.2 (USA)		Connections are mechanically secured in addition to soldering
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.7		Earth pin of the appliance inlet regarded as the protective earth terminal
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.8		The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.8 (Note)		Terminal may be stacked if PE is first connection and secured with lock washer/nut before other connections are made
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58.9		Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting (in Mains plug/receptacle)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59		CONSTRUCTION AND LAYOUT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59.1		Internal wiring
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1 (Canada)		Connecting cables comply with Canadian Electrical Code, Part I
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1 (USA)		Installation of connecting cords between parts of equipment in compliance with NEC
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1 (USA)		Cable type acceptable for external interconnection
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1a		Cables and wiring protected against contact with a moving part
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1a		Wiring having basic insulation only protected by additional fixed sleeving
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1a		Components are not likely to be damaged in the normal assembly or replacement of covers
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1b		Movable leads are not bent around a radius of less than five times the outer diameter of the lead
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1c		Insulating sleeving adequately secured
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1c		If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1c		Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1d		Aluminum wires of less than 16 mm ² cross-section not used
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.1f		Connecting cords between equipment parts considered as belonging to the equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59.2		Insulation
<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	59.2b		Mechanical strength and resistance to heat and fires retained by all types of insulation
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.2 b (SI - UL)		The Ball Pressure test may be waived for UL Classifications if the UL Recognition of the subcomponent covers the concerns for resistance to heat (RTI Rating > 75)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.2c		Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.2c		Parts of rubber resistant to ageing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59.3		Excessive current and voltage protection
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.3		Internal electrical power source provided with device for protection against fire hazard
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.3		Fuse elements replaceable without opening the enclosure fully enclosed in a fuse holder
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.3		Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.

T 50

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59.4		Oil Containers
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.4		Oil containers adequately sealed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.4		Container allow for the expansion of the oil
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.4		Oil containers in mobile equipment sealed to prevent the loss of oil during transport
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59.4		Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60 (Canada)		CANADA DEVIATIONS FOR DEFIBRILLATION-PROOF APPLIED PARTS
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	60 (Canada)		Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	400 (USA)		US DEVIATIONS FOR OXYGEN
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.1 (USA)		At least one of the following three requirements is satisfied:
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.1.1 (USA)		Electrical components separated by barrier per 400.2
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.1.2 (USA)		Compartments with electrical components ventilated per 400.3
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.1.3 (USA)		Electrical components comply with 400.4 so that cannot be a source of ignition
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.2 (USA)		Barrier required by 400.1 is sealed at all joints and holes
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.3 (USA)		Ventilation required by 400.1 is such that oxygen content does not exceed 4% above ambient
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.4 (USA)		Under N.C. and S.F.C. the product of the value of no load rms voltage and short circuit rms current less than 10 VA
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.4 (USA)		Surface temperature of components below 300°C in N.C. and S.F.C
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.5 (USA)		External exhaust gas outlets located at least 20 cm from any electrical component mounted on the outside
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.6 (USA)		Hospital beds intended for use with oxygen administering equipment provided with required markings
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.7 (USA)		Pendant controls on hospital beds with oxygen administering equipment marked as required
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	400.8 (USA)		Instructions for installation are in compliance with requirements of this clause
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	600.1 (USA)		US DEVIATIONS FOR SEPARATE POWER UNITS PACKED WITH EQUIPMENT
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	600.1 (USA)		Separate power units provided with correlation marking
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	600.2.1 (USA)		Direct plug-in unit construction and performance comply with required sections of UL1310
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	600.2.2 (USA)		Direct plug-in unit external temperature rise during overheating test do not exceed 65°C
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	600.2.3 (USA)		If direct plug-in unit provided with a mounting tab - unit marked as required by UL1310

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	General Deviations		General National Deviations
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Denmark)		For plug and socket outlets the National Standard SB 107-2-D1 3rd Edition applies.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Denmark)		For Class I equipment: Plugs: DK 2-1a, DK 2-1a with flat phase pin or DK 2-5a. Socket outlets: DK 1-3a
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Denmark)		For Class II equipment: Plugs: DKA 2-1a, DKA 2-1b, Clb, C5, C6 or according to EN 50075
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Korea)		National supply voltages are 110 V, 220 V and 380 V.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Korea)		Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Korea)		Instruction manuals and appliance markings related to safety, including nameplate, shall be in Korean or graphical symbols in accordance with IEC Publication 417.
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	General (Korea)		Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300). More details are available from KTL (c/o KTL) on request.

TABLE IV

LEAKAGE AND PATIENT AUXILIARY CURRENT LIMITS (in mA)							
Type of Leakage / Auxiliary Current		Type B		Type BF		Type CF	
		N.C.	S.F.C	N.C.	S.F.C	N.C.	S.F.C
EARTH*	- Class I Equipment	0.5, 0.3*	1.0	0.5, 0.3*	1.0	0.5, 0.3*	1.0
EARTH*	- All likely accessible surfaces non-conductive	0.5*	1.0	0.5*	1.0	0.5*	1.0
EARTH*	- Class II Equipment (functional earth)	0.15*	1.0	0.15*	1.0	0.15*	1.0
EARTH*	- All likely accessible surfaces non-conductive	0.25*	1.0	0.25*	1.0	0.25*	1.0
EARTH	(Permanently Installed Equip.)	5.0	10.0	5.0	10.0	5.0	10.0
EARTH	(No PE accessible, Mobile X-ray equipment)	2.5	5.0	2.5	5.0	2.5	5.0
ENCLOSURE*		0.1	0.5, 0.3*	0.1	0.5, 0.3*	0.1	0.5, 0.3*
PATIENT (ac)		0.1	0.5	0.1	0.5	0.01	0.05
PATIENT (dc)		0.01	0.05	0.01	0.05	0.01	0.05
PATIENT (Mains on SIP/SOP)		---	5.0	---	---	---	---
PATIENT (Mains on Applied Part, SIP/SOPs grounded)		---	---	---	5.0	---	0.05
PATIENT AUXILIARY CURRENT (ac)		0.1	0.5	0.1	0.5	0.1	0.5
PATIENT AUXILIARY CURRENT (dc)		0.01	0.05	0.01	0.05	0.01	0.05

* US Deviation L.C. limits: the highest voltage ratings (120 & 240 V) may be used instead of the 90 – 110% of voltage rating

TABLE V

DIELECTRIC WITHSTAND TEST VOLTAGES (in Volts)					
Reference Voltage	0 < V ≤ 50	50 < V ≤ 150	150 < V ≤ 250	250 < V ≤ 1K	1K < V ≤ 10K
BI	500	1K	1.5K	2V + 1K	V + 2K
SI	500	2K	2.5K	2V + 2K	V + 3K
DI / RI	500	3K	4K	2(2V + 1.5K)	2(V + 2.5K)

TABLE XVI

CREEPAGE & CLEARANCE REQUIREMENTS (in millimeters)											
Voltage	DC	≤15	≤36	≤75	≤150	≤300	≤450	≤600	≤800	≤900	≤1200
Voltage	AC	≤12	≤30	≤60	≤125	≤250	≤400	≤500	≤660	≤750	≤1000
BOP	Creepage	0.8	1.0	1.3	2.0	3.0	4.0	5.5	7.0	8.0	11.0
	Clearance	0.4	0.5	0.7	1.0	1.6	2.4	3.0	4.2	4.5	6.0
BI / SI	Creepage	1.7	2.0	2.3	3.0	4.0	6.0	8.0	10.5	12.0	16.0
	Clearance	0.8	1.0	1.2	1.6	2.5	3.5	4.5	6.0	6.5	9.0
DI / RI	Creepage	3.4	4.0	4.6	6.0	8.0	12.0	16.0	21.0	24.0	32.0
	Clearance	1.6	2.0	2.4	3.2	5.0	7.0	9.0	12.0	13.0	18.0

TABLE Xa

MAXIMUM ALLOWABLE TEMPERATURES (From 10°C to 40°C Ambient)				
Parts	°C	Parts	°C	
Windings – Class A	105	Operator accessible, continuously held surfaces (metal)	55	
Windings – Class B	130	Operator accessible, continuously held surfaces (porcelain/vitreous)	65	
Windings – Class E	120	Operator accessible, continuously held surfaces (rubber/wood)	75	
Windings – Class F	155	Operator accessible, surfaces held for short time (metal)	60	
Windings – Class H	180	Operator accessible, surfaces held for short time (porcelain/vitreous)	70	
Adjacent to Switches & Thermostats with T marking	T	Operator accessible, surfaces held for short time (rubber/wood)	85	
Rubber/PVC insulation of wiring/cords with T marking	T	Other op. accessible parts (except lamps, heaters/guards, handles)	85	
Motor Caps with maximum operating temperature Marked (2tc)	Tc-	Parts that may have brief contact with the Patient in normal use	50	
Parts in contact with oil having flash-point (fp)	fp-25	**Applied parts not intended to supply heat to a Patient (From Subclause 42.3)	41	

TABLE Xb

MAXIMUM ALLOWABLE TEMPERATURES (At 25°C Ambient)			
Parts	°C	Parts	°C
Appliance Inlets (hot conditions)	155	Moldings of urea- formaldehyde	90
Appliance Inlets (other conditions)	65	Polyester with glass-fiber reinforcement	135
All terminals for external conductors	85	Polytetrafluorethylene	290
Adjacent to Switches & Thermostats without T marking	55	Pure mica and tightly sintered ceramics used as RI or SI	425
Flexible cords (if flexing is likely to occur)	60	Used as thermal insulation and in contact with hot metal	-
Flexible cords (if flexing is unlikely to occur)	75	-Laminates bonded with Melamine/phenol formaldehyde resins	200
Natural rubber, used for safety (when used as RI or SI)	60	-Laminates bonded with phenol furfural resins	200
Natural rubber, used for safety (in other cases)	75	-Laminates bonded with urea formaldehyde resins	175
Cord sheaths used as SI	60	-Moldings of phenol formaldehyde with cellulose fillers	200
Impregnated or varnished textile/paper/press board, no wires	95	-Moldings of phenol formaldehyde with mineral fillers	225
Laminated bonded with melamine/phenol formaldehyde resins	110	-Moldings of melamine- formaldehyde	175
Laminated bonded with phenol furfural resins	110	-Moldings of urea- formaldehyde	175
Laminated bonded with urea- formaldehyde resins	90	Wood in general	90
Moldings of phenol formaldehyde with cellulose fillers	110	Electrolytic Capacitors, without tc marking	65
Moldings of phenol formaldehyde with mineral fillers	125	Other Capacitors, without tc marking	90
Moldings of melamine- formaldehyde	100	Supports, Walls, Ceiling, Floor of test corner	90

TABLE XIX

Transformers Under Short Circuit and Overload at 25°C	
Winding Class	Max. Temp. °C
A	150
E	165
B	175
F	190
H	210

TABLE XX

Test Current/Time for Transformer Overload		
Rating of Protector (A)	Mult. Factor	Test Duration
IEC 127/241 ≤ 4 A	2.1	IEC 127: 30 min. / IEC 241: 60 min.
IEC 127/241 > 4 – 10 A	1.9	IEC 127: 30 min. / IEC 241: 60 min.
IEC 127/241 > 10 – 25 A	1.75	IEC 127: 30 min. / IEC 241: 60 min.
IEC 127/241 > 25 A	1.6	IEC 127: 30 min. / IEC 241: 60 min.
UL Listed Fuse	1.35	60 min.
All Others	Max from Fuse Curve	30 min.

MOTOR TEMP TABLE

Motors Under Locked Rotor Test at 25°C					
Winding Class	Max. Temp. °C				
	Attended, timer, 5 min max use	Impedance Protected	Protection acts < 1 hr.	Protection acts > 1 hr.	Ave. after 1 st hr.
A	200	150	200	175	150
E	215	165	215	190	165
B	225	175	225	200	175
F	240	190	240	215	190
H	260	210	260	235	210

Minimum Gaps to Avoid Crush/Pinch Points

Requirements for Medical Electrical Equipment (Covered by IEC 60601-1)

From EN 394: Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (1993)

Crushing Zone

Zone in which the human body or parts of the human body are exposed to a crushing/pinching hazard.

This hazard will be generated if:

- two movable parts are moving towards one another;
- one movable part is moving towards a fixed Part

Methodology

- a) Identify the crushing hazards.
- b) Assess the risks from these hazards
- c) From table, select the appropriate minimum gap relating to the body part at risk
- d) If adequate safety cannot be achieved by the minimum gaps selected from the table, other or additional measures and/or means shall be used

Note: A crushing zone is considered only for powered movements or where weight or momentum may generate sufficient force to generate a crushing/pinching hazard.

The possibility of access to a crushing zone for a particular part of the body is dependent on the following:

- The gap between the parts;
- the depth of the crushing zone;
- the dimensions *c* of the opening in the protective structure and its distance *d* from the crushing zone.

Helpful Conversions

1 cm = 0.394 in. (1 m = 39.4 in)
1 in. = 2.54 cm (1 ft. = 30.48 cm)

10° tilt: (Distance One Side Lifted) = (Width of Base)(0.173648)

$F^\circ = (C^\circ \times 1.8) + 32$

$C^\circ = (F^\circ / 1.8) - 32$

1 N = 0.225 lb_f

1 kg = 2.2 lb (1 g = 0.0022 lb)

1 m/sec = 2.237 mph





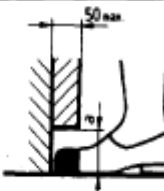



1 Nm = 141.6 in.oz = 0.7376 ft.lbs = 8.851 in.lbs

1 l = 33.8 oz (200 ml = 6.76 oz)

1 l = 61 in²

1 kPa = 0.145 psi (50 kPa = 7.25 psi)

1 psi = 6.895 kPa

Dimensions in millimetres		
Part of body	Minimum gap <i>a</i>	Illustration
Body	500	
Head (least favourable position)	300	
Leg	180	
Foot	120	
Toes	50	
Arm	120	
Hand Wrist Fist	100	
Finger	25	

Medical Standards (Updated March, 2010)**Current Base Standard (Based on Ed. 2)**IEC 60601-1 **Ed.2** (12/1998) + Am 1 (11/91) + Am. 2 (03/95).**National Deviations:**

USA: UL 60601-1 Ed.1 (4/25/2003) - for Ed.2

EU: EN 60601-1 (8/1990) + Am.1 (5/1993) + Am.2 (6/1995) + Am.11 (5/1993) + Am.12 (5/1993) + Am.13 (1/1996)

CANADA: CSA C22.2 No. 601.1-M90 (11/2003)

New Standard (Effective date June, 2012+)IEC 60601-1 (2005-12) **Ed.3**, Corr.1 (2006-12), Corr.2 (2007-12), IS1 (2008-04), Am.1 (Project)**National Deviations:**

USA: AAMI/ANSI ES60601-1 (02/05)

EU: EN 60601-1 (7/2007)

CANADA: CSA-C22.2 No.60601-1:2008

IEC 60601-1-xx

- 1: Safety Requirements for Medical Electrical Systems. Ed.2 (2000-12).
- 2: Electromagnetic Compatibility - Requirements and Tests Ed.3 (2007-03), IS1 (2010-03), Ed.2 (Project).
- 3: Gen. Requirements for Radiation Protection in Diagnostic X-ray Equipment Ed.2 (2008-01).
- 4: Programmable Electrical Medical Systems. Ed.1.1 (2000-04).
- 5: ~~Image quality and dose for X-ray equipment~~ (Cancelled).
- 6: Analysis, test and validation of human factors compatibility Ed.1 (06/04), Ed.2 (2006-12), **Ed.3: Ed.3 (2010-01)**.
- 7: ~~General requirements for multiparameter patient monitoring equipment~~ (Cancelled).
- 8: Requirements/guidelines for alarms in Medical Electrical Equipment. Ed.2 (2003-08), Ed.2 (2006-10), Am.1 (Project).
- 9: Requirements for the reduction of environmental impacts. Ed.1 (2007-07).
- 10: Process requirements for the development of therapeutic closed-loop controllers Ed.1 (2007-11).
- 11: Medical Electrical Equipment for Use in Home Care Applications (Project).

IEC 60601-2-xx

- 1: Medical Electron Accelerators in the Range 1 MeV to 50 MeV. Ed.2 (1998-06) Am.1 (2002-05), **Ed.3: Ed.3 (2009-10)**.
- 2: High Frequency Surgical Equipment. Ed.4 (2006-07), **Ed.3: Ed.5 (2009-03)**. [AAMI HF18-331].
- 3: Short-Wave Therapy Equipment. Ed. 2 (1991-06), Am.1 (1998-09), Ed.3 (Project).
- 4: Cardiac Defibrillators, Defibrillator-Monitors. Ed.2 (2002-08), Corr.1 (2004-04), Ed.3 (Project). [AAMI DF2-331].
- 5: Ultrasonic Therapy Equipment. Ed.2 (2000-07), **Ed.3: Ed.3 (2009-07)**.
- 6: Microwave Therapy Equipment.. Ed.1 (1984-01), Ed.2 (Project).
- 7: High Voltage Generators of Diagnostic X-ray Generators. Ed. 2 (1998-02).
- 8: Therapeutic X-ray Equipment in the Range 10 kV to 1 MV. Ed.1.1 Consolidated (1999-04), Ed.2 (Project).
- 9: ??? Patient Contact Dosimeters used in Radiotherapy with Electrically Connected Radiation Detectors. Ed. 2 (1996-10).
- 10: Nerve and Muscle Stimulators. Ed.1 (1987-12), Am.1 (2001-09), Corrigendum (2002-02), Ed.2 (Project).
- 11: Gamma Beam Therapy Equipment.. Ed.2 (1997-08) Am.1 (2004-07), Ed.3 (Project).
- 12: Lung Ventilators for Medical Use. Ed.2 (2001-10).
- 13: Anesthetic Machines. Ed.3 (2003-05), Am.1 (2006-05), Ed.3.1 (2009-08).
- 14: ~~Electroconvulsive Therapy Equipment (1989-03)~~ (Withdrawn).
- 15: ~~Capacitor Discharge X-ray Generators (1988-12)~~ (Withdrawn).
- 16: Hemodialysis Equipment. Ed. 3 (2008-04), Corr.1 (2008-10). [AAMI RD16-331].
- 17: Remote-Controlled Automatically-Driven Gamma-ray Afterloading Equipment. Ed..2 (2004-01), Ed.3 (Project).
- 18: Endoscopic Equipment. Ed. 2 (1996-08), Am.1 (2000-07), **Ed.3: Ed.2 (2009-02)**, **Ed.3: Ed.3 (2009-08)**.
- 19: Baby Incubators. Ed.1 (1990-12), Am.1 (1996-10), **Ed.3: Ed.2 (2009-02)**. [AAMI I136-331].
- 20: Transport Incubators. Ed.1 (12/90), Am.1 (1996-10), **Ed.3: Ed.2 (2009-02)**. [AAMI I151-331].
- 21: Infant Radiant Warmers. Ed.1 (02/94), Am.1 (1996-10), **Ed.3: Ed.2 (2009-02)**.
- 22: Diagnostic and Therapeutic Laser Equipment. Ed. 2 (1995-11), **Ed.3: Ed. 3 (2007-05)**.
- 23: Transcutaneous Partial Pressure Monitoring Equipment. Ed. 2 (1999-12), Ed.3 (Project).
- 24: Infusion Pumps and Controllers. Ed.1 (1998-02), Ed.2 (Project).
- 25: Electrocardiographs. Ed.1 (1993-03), Am.1 (1999-05), Ed.2 (Project). [AAMI EC11-331].
- 26: Electroencephalographs. Ed.2 (2002-11), Ed.3 (Project).
- 27: Electrocardiographic Monitoring Equipment. Ed.2 (2005-08), Ed.3 (Project). [AAMI EC13-331].
- 28: X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis. Ed.1 (1993-03), **Ed.3: Ed.2 (2010-03)**.
- 29: Radiotherapy Stimulators. Ed. 2 (1999-01), Ed.3 (2008-06).
- 30: Automatic Cycling Indirect Blood Pressure Monitoring Equipment. Ed.2 (1999-12) (Moving to IEC 80601-2-30). [AAMI SP10].
- 31: External Cardiac Pacemakers with Internal Power Source. Ed.1 (1994-10), Am.1 (1998-01), Ed.2 (2008-03).
- 32: Associated Equipment of X-ray Equipment. Ed.1 (1994-03).
- 33: Magnetic Resonance Equipment for Medical Diagnosis. Ed.2.1 (2006-02), Ed.2.2 (2008-04), **Ed.3: Ed.3 (2010-03)**.
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