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

MECA Medical Equipment Compliance Associates, LLC

Company:		Contact:	
Product Type:		Phone:	
Model:		Email:	
Ratings:	V, Hz, A, W VA Bat.		

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								

EVALUATION PROCEDURE:	
○	Overall equipment description, accessories to equipment, area(s) equipment will be used , intended power supply, overall objectives
○	MECA Project Proposal (Quote)
○	PO # from Client to open project
○	Preliminary investigation
○	Anticipated date samples will be ready for testing
○	Anticipated equipment production date
○	UL L-37 & L-40 forms signed
Conduct Preliminary Evaluation to Identify Potential Noncompliances and Determine Critical Components and Test Plan	
○	Examine equipment, discuss its use, accessories, interconnection to other equipment, construction materials
○	Determine if collateral or particular standards are required *(See list of Collateral & Particular Standards)*
○	Document Classification of equipment *(Per Clause 5)*
○	Examine enclosure openings (tool required to access live parts) and potential mechanical hazards, pinch points
○	Determine potential hazards under normal use, abnormal use, Single Fault Conditions
○	Create Insulation Diagram All components that cross a barrier (per insulation diagram) must meet creepage & clearance requirements - The working voltage of a barrier is determined by measurement - If either/both sides of barrier are floating, the highest voltages on either side of barrier are summed (except where one side ≤ 25 V)
○	Verify power supply certification, construction and required fusing for equipment
○	Verify required spacings, per the Insulation Diagram
○	Determine component requirements (UL Recognition, Electrical, Mechanical, Flame Ratings, etc.)
○	Create test plan *(See Testing Checklist)*
○	Review requirements for labels, user manual *(Per Clause 6)*
○	Address any initial noncompliances
○	Schedule UL testing dates
○	Open UL Project (UL File #, UL Project #, UL Control #)
○	Samples ready for testing
Equipment Evaluation, Testing, Documentation	
○	Verify corrected noncompliances from Preliminary Evaluation (as applicable)
○	Conduct full construction evaluation to standard requirements, review specifications and certificates for critical components
○	Conduct Initial Review with Underwriters Laboratories (Construction, documentation and test plan)
○	Perform required testing at MECA's UL witness testing facility (or UL, when required)
○	Verify label marking requirements
○	Verify accompanying document requirements
○	Review Biocompatibility on patient contact parts, as applicable (supplier's biocompatibility information acceptable) [ISO 10993-1]
○	Software evaluation [IEC60601-1-4 + ISO/IEC12207 + ANSI/UL1998, 2nd Edition]. - Required if mitigating fire, shock, or mechanical hazards in N.C. and S.F.C; or if required by applicable particular standard(s)
○	Take photographs of equipment for report (1200 x 1600 pixels minimum)
○	Create critical component list, including all components needed to pass tests and meet the requirements of the standard
○	Write UL Informative Test Report (CB-Style) for UL / C-UL (for US and Canada) Classification
○	Final review with Underwriters Laboratories
○	UL Issue Authorization to apply the UL Mark and provides UL Report
❑	EMC testing (Optional in US for UL Mark, required for Europe by the MDD) [IEC60601-1-2]
❑	CB Report (Optional - Required only for obtaining other Safety Marks – VDE, TUV, NEMKO, SEMKO, etc.) (Not required for CE Marking)
❑	Optional CE Marking services for sale in the European Union - Assist with your compliance documentation for the Medical Device Directive (MDD), work with your Notified Body, as necessary

IEC 60601-1 / UL 2601-1 TEST CHECKLIST

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

Test #	CLAUSE	TEST
☐ T0		**CONSTRUCTION EVALUATION** Required Spacings per Insulation Diagram, Construction Requirements, Critical Components *[Caliper]*
☐ T1	6.1	**MARKING DURABILITY** Rub cotton rag 15 seconds on Labels/markings with each *[Distilled Water, Denatured Alcohol (Methylated spirits), Isopropyl alcohol]*
☐ T2	7.1	**POWER INPUT** At rated voltage, stabilized W, V, or VA recorded *[Power Analyzer - Volts, Amps, Watts]*
☐ T3	15.b	**VOLTAGE LIMITATION (PART 1)** If > 0.1 µF in mains: Voltage measured between supply pins, enclosure, and earth *[Oscilloscope, or 1 sec. Switch box + Volt Meter with max.]*
☐ T4	15.c	**VOLTAGE LIMITATION (PART 2)** Residual voltage measured on capacitors/circuits after opening enclosure if > 0.27 µF (120 V) or > 0.07 µF (240 V) *[Oscilloscope]*
☐ T5	17.h1, 17.h2	**DEFIBRILLATION-PROOF APPLIED PARTS** **DEFIBRILLATION-PROOF RECOVERY TIME** Measurements taken per Fig. 50 or 51 (Applied to Accessible Parts) *[Oscilloscope]*
☐ 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. *[30 A (AC) Power Supply, Shunt, Volt Meter or Ground Bond Tester]*
☐ T7	19	**LEAKAGE CURRENT** Conducted Before/After Humidity & Abnormals, conducted at 110% rated Voltage, one side at ground potential Earth, Enclosure, Patient, Patient Aux., Patient F, Patient SIP/SOP *[True RMS Volt meter, MD network]*
☐ T8	20.4	**DIELECTRIC VOLTAGE WITHSTAND** Each Barrier of Insulation Diagram Tested, Full voltage held for 1 minute *[Dielectric (HiPot) tester]*
☐ T9	21a, 21b	**ENCLOSURE MECHANICAL STRENGTH** Force Test: 45 N, 625 mm^2 Impact: Impact Hammer: 0.5 J, ± 0.05 J (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) *[Force Gauge, Impact hammer or UL Ball]*
☐ 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) *[Scale]*
☐ 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 *[Scale]*
☐ 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 *[Scale]*
☐ 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 *[1-3 Samples, Tape Measure, Specified Surface]*
☐ T14 A	21.6	**ROUGH HANDLING – DROP FOR PORTABLE/STATIONARY EQUIPMENT** Portable Equipment: Drop sample 3 times at (≤10 kg = 5 cm), (10-50 kg = 3 cm), (>50 kg = 2 cm) *[Metric Ruler]*
☐ T14 B	21.6	**ROUGH HANDLING – ROLL OFF STEP FOR MOBILE EQUIPMENT** Mobile Equipment: Roll 0.4 m/s +/- 0.1 m/s (60 - 98 ft./s) or maximum velocity off step 20 mm high, 20 times *[Metric Ruler]*
☐ T15	22 (US)	**IMPACT TEST ON END STOPS** Worst case intended/specified loading, Number cycles & Conditions Per Table 22.100 (US Deviations) *[Scale]*
☐ T16	24	**STABILITY AND TRANSPORTA BILITY** 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). *[Tape Measure: (Distance Lifted) = (Width of Base)(0.173648) = 10°]*
☐ 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 *[None]*
☐ 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 ≥ 4 Wear, Corrosion, Fatigue, Aging = Safety Factor ≥ 8 Specific elongation at break <5% = Safety Factor X 1.5 *[Scale]*

Test #	CLAUSE	TEST
☐ 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 *[Radiation Detector with entry window approx. 10 cm^2]*
☐ 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) *[Thermocouples, Temperature Meter]*
☐ T21	44.2	**OVERFLOW** 15% Overfill, followed by Dielectric Withstand Test *[Fluid Measure container, Dielectric Tester]*
☐ T22	44.3	**SPILLAGE** 200 ml poured over equipment, followed by Dielectric Withstand Test *[Fluid Measure container, Dielectric Tester] (200 ml = 6.76 oz)*
☐ T23	44.4	**LEAKAGE** Water applied by pipette to seals, inspect for wetted components *[Pipette, Dielectric tester]*
☐ T24	44.5 (19.4) (20.4)	**HUMIDITY PRECONDITIONING** 91%-95% RH, 20° C – 32° C, (IPX0 = 48 hr), (IPX1-8 = 168 hr) Dielectric Withstand Test in chamber, Leakage Current 1 hr. after removing chamber *[Hum. chamber, Dielectric tester, RMS Volt meter, MD network]*
☐ T25	44.6	**HARMFUL INGRESS OF LIQUIDS** Per IEC 60529 (IP X X), followed by Dielectric Withstand Test and inspected for ingress into enclosure *[IP Apparatus for type of Ingress, Dielectric Tester]*
☐ T26	44.7	**CLEANING, STERILIZATION AND DISINFECTION** As specified in users manual, followed by Dielectric Withstand Test *[Cleaning solution per manual, Dielectric Tester]*
☐ 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 *[Pressure or Load Source] (50 kPa = 7.25 psi)(1 l = 61 in^2)*
☐ T28	45.7	**PRESSURE CONTROL TEST** Safety release Performing rated load for 100,000 cycles *[Pressure or Load Source]*
☐ T29	49.2	**INTERRUPTION OF THE POWER SUPPLY** Pose no safety hazard *[None]*
☐ T30	52.4.1	**POWER AVAILABILITY TEST** To Verify ≤ 15 W Available (to waive enclosure flammability requirements, component failure testing) *[Power Analyzer – (V, A, W), High Wattage Variable Resistor]*
☐ T31	52.5.2	**FAILURE OF THERMOSTATS** Disable thermostat (worst case), Temperatures recorded *[Thermocouples, Temperature Meter]*
☐ 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 *[Thermocouples, Temperature Meter]*
☐ 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 *[Thermocouples, Temperature Meter]*
☐ 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 *[Thermocouples, Temperature Meter]*
☐ T35	52.5.9	**FAILURE OF COMPONENTS TEST** Components short circuited or opened (worst case), one at a time. Temperatures recorded *[Thermocouples, Temperature Meter]*
☐ T36 T37	52.5.10d 56.6	**HEATING ELEMENT OVERLOAD** Thermostat or Thermal control short circuited, operated until thermal stability *[Thermocouples, Temperature Meter]*
☐ 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 *[Thermocouples, Temperature Meter]*
☐ 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 *[Thermocouples, Temperature Meter]*
☐ T40	52.5.10h	**OPEN PHASE PROTECTION** For 3 Phase Equipment with Motors - One phase of equipment disconnected, run until thermal stability. *[Thermocouples, Temperature Meter]*
☐ 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 *[UL Steel Ball]*

Test #	CLAUSE	TEST
☐ T42	55 (US)	**MOLD STRESS RELIEF TEST** For polymeric enclosures and covers only Highest: [70°C] or [Maximum temp + 10°C] for 7 hours *[Air Circulating Oven]*
☐ T43	56.7	**REVERSED BATTERY CONNECTION** No damage to battery or safety of equipment (waived if mechanically polarized to make connection correctly) *[Thermocouples, Temperature Meter]*
☐ 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) *[Torque Meter]*
☐ T45	56.11b, 56.11d	**CORD CONNECTED FOOT SWITCH - MECHANICAL STRENGTH** 1350 N for 1 min. (IP X7 required in wet / surgical areas) *[Force Meter]*
☐ 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) *[Force, Torque Meter] (1 kg = 2.2 lb)(1 N = 0.225 lb_f)(1 m = 39.4 in)*
☐ 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 *[Weight, Cylinder of 1.5 x Diameter of cord] (1 g = 0.0022 lb)*
☐ 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 *[Thermocouples, Temp.Meter, Amp Meter, High Wattage Rheostat]*
☐ 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) *[Variable Frequency/ Voltage Power supply]*
☐ 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 *[Air Circulating Oven, Ball Pressure Apparatus]*

#	Resolved	Issues, Noncompliances

	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 AYVZ2	UL		
Battery (Lithium)					Rated _____ V, rated _____ max charging current. Protected by _____ and _____ (or current limiting component R/C (NWGQ2) _____)	BBCV2	UL		UL 1642
Battery (Standard) (Lead-Acid)					Rated _____ V, approximately _____ mAh	BAZR2			UL1989 UL1642 UL2054
Battery Pack					Rated _____ V, approximately _____ mAh	BBFS			
Battery Charger (Non-Medical)					Rated ____ V, _____ A	BBGQ2 BBML2 BBHZ	UL		
Bridge Rectifier					Rated _____ Vrms, _____ A	QQQX2 QQFU2	UL		
Bushing						NZMT2	(UL)		
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 (Accessories)					Rated ____ V, _____ A	DIHS2	UL		
Circuit Breaker (Adjustable Trip)					Rated ____ V, _____ A	DKPU2	UL		
Circuit Breaker (GFCI)					Rated ____ V, _____ A	DKUY2	UL		
Computer					Rated ____ V, _____ A	NWGQ	(UL)		UL 60950 IEC 60950

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)		
CRT					Rated ____ V, _____ A	NCQI2	UL		UL 1418 IEC 60065
DC-DC Converter						QQGQ2 PIDF2 QQHM2	(UL)		UL 1950 UL 2601-1 IEC 60601 IEC 60950
Enclosure (Polymeric)					Overall _____ cm by _____ cm by _____ cm, _____ mm thick. Rated minimum V-____ flame rating.	QMFZ2	(UL)		UL 94
Enclosure					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, CENELEC		UL 1283 IEC 60384-14
Floppy disk drive					Rated ____ V, _____ A	NWGQ2			UL 60950 IEC 60950
Foam						QMFZ2	(UL)		
Fuse (Mains)					Rated _____A, _____ V. Provided in Line and Neutral	JDYX JDYX2	UL, CENELEC		UL 248 IEC 60127
Fuse (DC)					Rated ____ V, _____ A	JDYX JDYX2 FHXT	(UL)		UL 248 IEC 60127 UL 198G
Fuse holder					Rated ____ V, _____ A	IZLT2 JAMZ2	(UL)		UL 512 IEC 60127-6
Hard disk drive					Rated ____ V, _____ A	NWGQ2			UL 60950 IEC 60950

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Heater					Rated ____ V, _____ A	KSOT2	(UL)		
Heating Elements					Rated ____ V, _____ A	UBJY2	(UL)		
Insulator						QMFZ2	(UL)		
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
Keyboard						NWGQ2			UL 60950 IEC 60950
Labels						PGDQ2	UL		UL 969
Laser Module						NWGQ2	(UL)		UL 60950 CDRH IEC 60950 IEC 60825-1 IEC 60825-2 IEC 60601-2-22
LED					Colors _____ , Not LASER diode				IEC 60825-1 (LASER)
Modem					Rated ____ V, _____ A	NWGQ2	(UL)		UL 60950 IEC 60950
Monitor (LCD)					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)		
Mouse						NWGQ2			UL 60950 IEC 60950
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

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Plugs & Socket-(Hospital Grade)						RTRT	UL		UL 498 IEC 60884 IEC 60309-1 IEC 60309-2
Power Supply (Direct Plug-in) (Brick)						PIDF PIDF2 QQHM2 QQFU2	UL		UL 60601-1 IEC 60950 UL 1310 UL 60950 IEC 60950
Power supply cords (US, Canada)						ELBZ	UL		UL 817
Power supply cords (International)							KAM		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		DK 2-1a or DK 2-5a
Printer					Rated ____ V, _____ A	NWGQ NWGQ2	(UL)		UL 60950 IEC 60950
PTC Thermistor Device					Rated _____	XGPU2	(UL)		UL 1434
PWB						ZPMV2	UL		UL 796 IEC 60603-2
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)		UL 224
Sleeving					Rated ____ V	UZFT2	(UL)		
Solenoid					Rated ____ V, _____ A	VAIU2	(UL)		

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
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		
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			

Object/Part	UL	IEC	Manufacturer	Model/Type	Technical Data, Ratings, etc.	UL CCN	Req. Marks	Other Marks	Standards
Tubing						YDPU2	(UL)		
Valves					Rated _____	YIOZ2	(UL)		
Varistor (VOM)					Rated _____	XUHT2 FOWX2	(UL)		
Wire					Rated _____	AVLV2	(UL)		

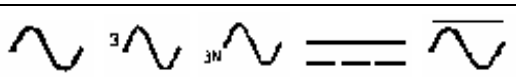
MECA
Medical Equipment Compliance Associates, LLC

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
			1, 2		SCOPE, TERMINOLOGY
☑	☐	☐	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 *patient* under medical supervision and which makes physical or electrical contact with the *patient* and/or transfers energy to or from the *patient* and/or detects such energy transfer to or from the *patient*.
			2		**Some Definitions:** Patient = Living being (person or animal) undergoing medical investigation or treatment. Applied Part - Any pieces of the equipment that can intentionally or unintentionally be brought in contact with the patient Creepage - Spacing along a surface (as an ant crawls) Clearance - Spacing through the air (as a bug flies) LOP - Level of protection - 2 required (not defined in standard) Basic Insulation (BI) - Spacing or a physical insulation barrier providing 1 LOP Supplemental Insulation (SI) - Spacing or a physical insulation barrier providing 1 LOP Double Insulation (DI) - BI + SI, and provides 2 LOP Reinforced Insulation (RI) - Single spacing or physical insulation barrier that provides 2 LOP Protective Impedance - Component (such as a resistor) that provides 1 LOP Protective Earth (PE) - Well-grounded part that provides 1 LOP Class I Equipment – Equipment using PE as 1 LOP Class II Equipment (also known as Double Insulated) - Equipment not using PE as 1 LOP SIP/SOP = Signal Input Part / Signal Output Part (RS232, USB, Ethernet port, Phone jack…) ITE = Information Technology (IEC 60950) Equipment (eg. Computer, Monitor, Printer, …) N.C. = Normal Condition, S.F.C. = Single Fault Condition Insulation Diagram = 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) IEC 60950 (ITE) connection: Considered 50Vdc in N.C. and Mains (240 V) in S.F.C. Phone line connection: Considered 120Vac ringing voltage in N.C. and S.F.C.

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	3		GENERAL REQUIREMENTS
○	○	○	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.)
○	○	○	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)		Normal Condition (Likely to Occur) - Reverse polarity of supply mains - Failure of insulation less than basic (operational) Single Fault Condition (Could Occur) 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 - 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) Conditions not evaluated (Unlikely to Occur): - 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
○	○	○	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.
○	○	○	3.100.1b (USA)		Lithium batteries comply with U.S. National or internationally harmonized component standards
○	○	○	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.
○	○	○	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.
○	○	○	3.100.1e (USA)		CRT's > 5 inches comply with U.S. National or internationally harmonized component standards
○	○	○	3.101.1 (USA)		Primary circuit components up to isolation transformer meet U.S. national or international harmonized component standards
			3.100 (Note) (USA)		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. 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. Components that do not meet the requirements for that component are faulted (per subclause 4.4)

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	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
○	○	○	4.7a (Israel)		Equipment that is to be connected to the mains is intended for one of the permitted voltages and frequencies:
○	○	○	4.7a (Israel)		a) Nominal frequency of 50 Hz
○	○	○	4.7a (Israel)		b) Nominal voltage of 230 V, for portable and hand-held equipment
○	○	○	4.7a (Israel)		c) Nominal voltage of 230 V, for one phase equipment with input power not exceeding 4 kVA
○	○	○	4.7a (Israel)		d) Nominal voltage of 400 V, for multiphase equipment
○	○	○	4.7b (Israel)		Other equipment is allowed to be connected to the mains if it has the following ratings:
○	○	○	4.7b (Israel)		a) Single phase equipment, for the range of 220 to 240 V
○	○	○	4.7b (Israel)		b) Multiphase equipment, for the range of 380 to 440 V

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	5		CLASSIFICATION
○	○	○	5.1		Type of protection against electric shock
○	○	○	5.1		Class I equipment
○	○	○	5.1		Class II equipment
○	○	○	5.1		Internally powered equipment
○	○	○	5.2		Degree of protection against electric shock
○	○	○	5.2		Type B applied part
○	○	○	5.2		Type BF applied part
○	○	○	5.2		Type CF applied part
○	○	○	5.2		Not classified - no applied parts
○	○	○	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)
○	○	○	5.4		Methods of sterilization or disinfection
○	○	○	5.5		Equipment not suitable for use in the presence of flammable mixtures
○	○	○	5.5		Category AP equipment
○	○	○	5.5		Category APG equipment
○	○	○	5.6		Mode of operation:
○	○	○	5.6		-continuous operation
○	○	○	5.6		-short-time operation, specified operation; period
○	○	○	5.6		-intermittent operation, specified operation; rest period
○	○	○	5.6		-continuous operation with short-time, stated permissible loading time
○	○	○	5.6		-continuous operation with intermittent, stated permissible loading/rest time

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	6		IDENTIFICATION, MARKING AND DOCUMENTS
○	○	○	6 (Canada)		Where written safety warnings appear as equipment markings, they should appear in French and English
○	○	○	6 (USA)		a) All words in "CAUTION", WARNING", and "DANGER" markings at least 1.6 mm (1/16") high
○	○	○	6 (USA)		b) Signal words "CAUTION", WARNING", and "DANGER" at least 2.8 mm (7/64")
○	○	○	6 (USA)		c) Letters in contrast color to the background
○	○	○	6 (USA)		Equipment capable of emitting ionizing radiation provided with warning statement
○	○	○	6 (USA)		If equipment produced in more than one factory, factory identification marked on the equipment
○	○	○	6 (USA)		Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped
☐	☐	☐	6.1		Marking on the Outside of Equipment or Equipment Parts
○	○	○	6.1c		Markings of the specific power supply affixed
○	○	○	6.1d		If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents [Table DI: 14] 
○	○	○	6.1e		Name and/or trademark of the manufacturer or supplier
○	○	○	6.1f		Model or type reference
○	○	○	6.1g		Rated supply voltages or voltage range(s)
○	○	○	6.1g		Number of phases (if not single)
○	○	○	6.1g		Type of current (AC or DC) [Table DI: 1, 2, 3, 4, 5] 
○	○	○	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.
○	○	○	6.1h		Rated frequency or rated frequency range(s) (Hz)
○	○	○	6.1j		Rated power input (VA, W or A) (Watts: required if power factor > 0.9)
○	○	○	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.
○	○	○	6.1k		Power output of auxiliary mains socket - outlets (if provided)
○	○	○	6.1l		Class II symbol (if no Protective Earth) [Table DI: 10] 
○	○	○	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**
○	○	○	6.1l		Symbol for protection against electric shock [Table DII: 1, 2, 3] 
○	○	○	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
○	○	○	6.1l		Symbol for protection of defibrillation-proof applied parts [Table DII: 9, 10, 11] 
○	○	○	6.1l		Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable
○	○	○	6.1m		Mode of operation (if no marking, suitable for continuous operation)
○	○	○	6.1n		Types and rating of external accessible fuses

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
○	○	○	6.1p		Ratings of external output:
○	○	○	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)
D	D	D	6.1 (UL)		 **Medical Equipment** With Respect to Electric Shock, Fire, and Mechanical Hazards Only, In Accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, and IEC 60601-1 **(OR)**   UL 60601-1, IEC 60601-1, CAN/CSA C22.2 No. 601.1 *** Additional Collaterals (IEC 60601-1-X) and/or Particulars (IEC 60601-2-XX), as necessary**
T1 ○	○	○	6.1z		Durability of marking test Distilled water, Denatured Alcohol (Methylated Spirits), Isopropyl Alcohol

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	6.2		Marking on the Inside of Equipment or Equipment Parts
○	○	○	6.2a		Nominal voltage of permanently installed equipment
○	○	○	6.2b		Maximum power loading for heating elements or holders for heating lamps
○	○	○	6.2c		Dangerous voltage symbol [Table DI: 6] 
○	○	○	6.2c (Korea)		Replace the existing subclause wit the following: The presence of HIGH VOLTAGE PARTS shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and in the Korean language. [Table DI: 6] 
○	○	○	6.2d		Type of battery and mode of insertion
○	○	○	6.2d		- Marking referring to accompanying documents used for battery not intended to be changed by the operator 
○	○	○	6.2e		Fuses accessible with a tool identified either by type and rating or by a reference to diagram
○	○	○	6.2f		Protective earth terminal [Table DI: 6] 
○	○	○	6.2g		Functional earth terminal [Table DI: 7] 
○	○	○	6.2h		Supply neutral conductor in permanently installed equipment marked (N)
○	○	○	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
○	○	○	6.2j		- Markings comply with IEC 445
○	○	○	6.2k		For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)
○	○	○	6.2l		Statement for suitable wiring materials at temperatures over 75°C
○	○	○	6.2l (USA)		Statement for suitable wiring materials at temperature s over 60 ºC
○	○	○	6.2n		Capacitors and/or circuit parts marked as required in Sub-clause 15c
☐	☐	☐	6.3		Marking of Controls and Instruments
○	○	○	6.3a		Mains switch clearly identified
○	○	○	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] 
○	○	○	6.3b		Indication of different positions of control devices and switches [Table DI: 17, 18] 
○	○	○	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)
○	○	○	6.3f		The functions of operator controls and indicators are identified
○	○	○	6.3g		Numeric indications of parameters are in SI units except for units listed in Am. 2
○	○	○	6.3 (SI) (UL)		Ethernet Connectors marked “not for phone connection” or pass 1 kV Dielectric test between connectors and enclosure, other secondary circuits
☐	☐	☐	6.4		Symbols
○	○	○	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
☐	☐	☐	6.5		Colors of the Insulation of Conductors
○	○	○	6.5a		Protective earth conductor has green/yellow insulation (at least at their terminations)
○	○	○	6.5b		All insulations of internal protective earth conductors are green/yellow at least at their terminations
○	○	○	6.5c		Only protective or functional earthing, or potential equalization conductors are green/yellow
○	○	○	6.5d		Color of neutral conductor is Blue (Not Applicable with UL Listed or KAM detachable cord sets)
○	○	○	6.5e		Colors of phase conductor(s) if not single phase
○	○	○	6.5e		- Compliance with IEC 227 and IEC 245 (for phase conductor colors)
○	○	○	6.5f		Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors
☐	☐	☐	6.6		Medical Gas Cylinders and Connections
○	○	○	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).
○	○	○	6.6a		In accordance with ISO ISO/R 32
○	○	○	6.6a (USA)		Identification of the content of gas cylinders in accordance with the color coding requirement of ANSI/NFPA99.
○	○	○	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
☐	☐	☐	6.7		Indicator Lights and Push-Buttons
○	○	○	6.7a		- Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action
○	○	○	6.7a		- Yellow used to indicate caution or attention required
○	○	○	6.7a		- Green used to indicate ready for action
○	○	○	6.7b		- Color red push-buttons used only to interrupt a function in case of emergency

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	6.8		ACCOMPANYING DOCUMENTS
○	○	○	6.8 (USA)		Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage
○	○	○	6.8.1		Equipment accompanied by documents containing at least instructions for use
○	○	○	6.8.1		Equipment accompanied by documents containing at least a technical description
○	○	○	6.8.1		Equipment accompanied by documents containing at least an address to which the user can refer
○	○	○	6.8.1		Classifications specified in Clause 5 included in both the instructions for use and the technical description
○	○	○	6.8.1		* Type of protection against electric shock: (Class I) / (Class II) / (Internally Powered) Equipment
○	○	○	6.8.1		* Degree of protection against electric shock: Type (B) / (BF) / (CF) Applied Parts
○	○	○	6.8.1		* Degree of protection against the ingress of water: (IP__ __) / (Ordinary)
○	○	○	6.8.1		* Methods of sterilization or disinfection:
○	○	○	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
○	○	○	6.8.1		* Mode of operation if not continuous: (Specified Period, loading, cycling…)
○	○	○	6.8.1		Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment (See also 6.8.3)
○	○	○	6.8.1		Warning statements and the explanation of warning symbols provided in the accompanying documents
○	○	○	6.8.1 (Korea)		Insert the following sub-clause after the last paragraph: Language of accompanying documents shall be included in Korean.
☐	☐	☐	6.8.2		Instructions for Use
○	○	○	6.8.2a		General information provided in instructions for use
○	○	○	6.8.2a		- state the function and intended application of the equipment
○	○	○	6.8.2a		- include an explanation of: the function of controls, displays and signals
○	○	○	6.8.2a		- the sequence of operation
○	○	○	6.8.2a		- the connection and disconnection of detachable parts and accessories
○	○	○	6.8.2a		- the replacement of material which is consumed during operation
○	○	○	6.8.2a		- *information regarding potential electromagnetic or other interference and advice regarding avoidance*
○	○	○	6.8.2a		- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety
○	○	○	6.8.2a		- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance
○	○	○	6.8.2a		General information provided in instructions:
○	○	○	6.8.2a		- information for the safe performance or routine maintenance
○	○	○	6.8.2a		- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied
○	○	○	6.8.2a		- explanation of figures, symbols, warning statements and abbreviations on the equipment
○	○	○	6.8.2c		Signal output or signal input parts intended only for connection to specified equipment described
○	○	○	6.8.2d		Details about acceptable cleaning, disinfection or sterilization methods included
○	○	○	6.8.2e		Warning statement for mains operated equipment with additional power source
○	○	○	6.8.2f		A warning to remove primary batteries if equipment is not likely to be used for some time
○	○	○	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 i n 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 -40ºC to +70ºC]. [Relative humidity range within 10% to 100%]. [atmospheric pressure range within 500 to 1060 hPa].
D	D	D	6.8 (UL)		 **Medical Equipment** With Respect to Electric Shock, Fire, and Mechanical Hazards Only, In Accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, and IEC 60601-1 *** Additional Collaterals (IEC 60601-1-X) and/or Particulars (IEC 60601-2-XX), as necessary**
○	○	○	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

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	7		POWER INPUT
T 2 ○	○	○	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)
☐	☐	☐	10		ENVIRONMENTAL CONDITIONS
○	○	○	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 when using a 25°C ambient.
○	○	○	10.2.2a		Rated voltage not exceeding 250 V for hand-held equipment
○	○	○	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
○	○	○	10.2.2a		Rated voltage not exceeding 500 V for all other equipment
○	○	○	10.2.2a		Rated input frequency not more than 1kHz
○	○	○	10.2.2a (USA)		Rated voltage not exceeding 250 Vdc or single phase ac or 600 V polyphase ac for equipment up to 4kVA
○	○	○	10.2.2a (USA)		Rated voltage not exceeding 600 V for all other equipment
○	○	○	10.2.2b (USA)		Internal replaceable electrical power source specified
			11		NOT USED
			12		NOT USED
☐	☐	☐	13		GENERAL
○	○	○			Risk of Electric Shock in Normal Use and in Single Fault Condition Shall be reduced as far as Reasonably Practicable
☐	☐	☐	14		REQUIREMENTS RELATED TO CLASSIFICATION
○	○	○	14 (USA)		Fixed equipment and permanent equipment is Class I
○	○	○	14.4a		Class I and Class II equipment in addition to basic insulation provided with an additional protection
○	○	○	14.4b		Equipment supplied from external dc source of reverse polarity results in no safety hazard
○	○	○	14.5a		Dual classification for internally powered equipment with a means of connection to supply mains
○	○	○	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
○	○	○	14.6c		Applied parts intended for direct cardiac application are of type CF
○	○	○	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
	☐	☐	☐	15		LIMITATION OF VOLTAGE AND/OR ENERGY
T3	○	○	○	15b		Voltage measured one sec after disconnection of the mains plug does not exceed 60V
T4	○	○	○	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
	○	○	○	15c		Marking provided for manual discharging
	○	○	○	15 c (Note) (UL)		Interlock switches, if used, must pass a 10,000 cycle test
	☐	☐	☐	16		ENCLOSURES AND PROTECTIVE COVERS
T0	○	○	○	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
	○	○	○	16a		Insertion or removal of lamps - protection against contact with live parts provided
T0	○	○	○	16b		Opening in a top cover positioned that accessibility of live parts by a test rod is prevented
	○	○	○	16c		Conductive parts accessible after the removal of handles, knobs, levers (without the use of a tool)
T6	○	○	○	16c		- have a resistance of not more than 0.2 Ohm
	○	○	○	16c		- separated from live parts by one of the means described in Sub-clause 17g
	○	○	○	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
	○	○	○	16e		Removable enclosures protecting against contact with live parts
	○	○	○	16e		- Removal possible only with the aid of a tool
	○	○	○	16e		- Use of automatic device making parts not live when the enclosure is opened or removed
	○	○	○	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
	○	○	○	16e		- Exception 16e applied to the following parts :
	○	○	○	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
	☐	☐	☐	17		SEPARATION
	○	○	○	17a		Separation method of the applied part from live parts:
	○	○	○	17a		1) basic insulation: applied part earthed
	○	○	○	17a		2) by protectively earthed conductive part (e.g. screen)
	○	○	○	17a		3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure
	○	○	○	17a		4) by double or reinforced insulation
	○	○	○	17a		5) by protective impedances limiting current to applied part
T7	○	○	○	17a		- Additional leakage current test in single fault conditions
	○	○	○	17c		There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed
	○	○	○	17d		Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)
	○	○	○	17g		Separation method of accessible parts other than applied parts from live parts:
	○	○	○	17g		1) basic insulation: accessible part earthed
	○	○	○	17g		2) by protectively earthed conductive part (e.g. screen)
	○	○	○	17g		3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure
	○	○	○	17g		4) by double or reinforced insulation
	○	○	○	17g		5) by protective impedances limiting current to accessible part
T7	○	○	○	17g		- Additional leakage current test in single fault conditions
	○	○	○	17h		Arrangements used to isolate defibrillation-proof applied parts so designed that:
T5	○	○	○	17h		- no hazardous electrical energies appear during a discharge of a cardiac defibrillator
T5	○	○	○	17h		- after exposure to the defibrillation voltage, the equipment continues to perform its intended function
	○	○	○	17 (SI - UL)		- 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 prepeg 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.
	○	○	○	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
	☐	☐	☐	18		PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION
	○	○	○	18a		Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal
	○	○	○	18b		Protective earth terminals suitable for connection to the protective earth conductor
	○	○	○	18e		Potential equalization conductor
	○	○	○	18e		- Readily accessible
	○	○	○	18e		- Accidental disconnection prevented in normal use
	○	○	○	18e		- Conductor detachable without the use of a tool
	○	○	○	18e		- Power supply cord does not incorporate a potential equalization conductor
	○	○	○	18e		- Connection means marked with Symbol 9, Table DI
T 6	○	○	○	18f		- For equipment without power supply cord, impedance between protective earth terminal and accessible metal part <= 0.1 Ohm
T 6	○	○	○	18f		- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part <= 0.1 Ohm
T 6	○	○	○	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
	○	○	○	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
	○	○	○	18k		Functional earth terminal not used to provide protective earthing
	○	○	○	18l		Class II equipment with isolated internal screens
	○	○	○	18l		- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation
	○	○	○	18l		- functional earth terminal clearly marked
	○	○	○	18l		- explanation of functional earth terminal provided in the accompanying documents
	○	○	○	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
	○	○	○	18m (USA)		Earthing of X-ray equipment: Connections from high-voltage equipment to other high voltage components made with high voltage shielded cables
	○	○	○	18n (USA)		Accessible non-current carrying conductive parts are protectively earthed (or may be Double Insulated)
	○	○	○	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)
	☐	☐	☐	19		CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS
	○	○	○	19 (USA)		Enclosure and earth leakage currents comply with U.S. limits
	○	○	○	19.1b		Leakage currents
T 7	○	○	○	19.1b		- earth leakage current
T 7	○	○	○	19.1b		- enclosure leakage current
T 7	○	○	○	19.1b		- patient leakage current
T 7	○	○	○	19.1b		- patient auxiliary current

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	☐	☐	☐	20		DIELECTRIC STRENGTH
	○	○	○	20		Overall compliance with Clause 20
T 8	○	○	○	20.1		Dielectric strength for equipment per TABLE V Conducted At operating temperatures, After humidity preconditioning, After sterilization/disinfection: A-a_1: (BI) Between live parts and protective earthed accessible parts A-a_2: (DI) Between live parts and enclosure not protectively earthed A-b: (BI) Between live parts and conductive parts separated by BI, forming part of DI A-c: (SI) Between enclosure and Conductive parts separated from live by BI A-e: (DI) Between live parts and SIP/SOPs not protectively earthed (if SIP/SOPs > 42.4 V peak or 60 V dc) A-f: (BI) Between parts of opposite polarity of mains part (before mains fuse - fuses removed for testing) A-g: (BI or SI or RI) Between live parts and a metal enclosure lined with insulating material A-j: (SI) Between accessible parts non-protectively earthed and foil over power supply cord inside bushings/anchors) A-k: (DI) Between accessible parts non-protectively earthed and SIP/SOPs if: 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	○	○	○	20.2		Dielectric strength for applied parts per TABLE V Conducted At operating temperatures, After humidity preconditioning, After sterilization/disinfection: B-a: (DI) Between live parts and applied parts (patient circuit) B-b: Between different parts - see particular standard if applicable B-c: (SI) Between applied parts and parts not protectively earthed and separated from live parts by BI B-d: (BI) Between F-type applied part and earth, enclosure, SIP/SOPs B-e: (DI) Between F-type applied part with stressing voltages in normal conditions and enclosure
				20.1, 2 (Note)		Barriers specifi ed 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)
	○	○	○	20.3		Reference Voltage (U) – Voltage that the insulation is subject to in normal use, at maximum rated voltage - For insulation with either side isolated (floating), (U) is the sum of the highest voltages of each side
				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)		Dielectric breakdown between primary and secondary through earth is not considered a failure (eg. Switching P.S.). Components crossing the barrier may be tested individually or the shorting earthed part may be modified as to not interfere with the dielectric test

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	☐	☐	☐	21		MECHANICAL STRENGTH
T 9	○	○	○	21a		Sufficient rigidity of an enclosure tested by: force of 45 N
T 9	○	○	○	21b		Sufficient strength of an enclosure tested by: impact hammer
	○	○	○	21 a,b (SI - UL)		The impact hammer test may be waived when the ball impact test is performed on the same test 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	○	○	○	21c		On portable equipment carrying handles or grips withstand the requirements of the loading test
T 11 T 12	○	○	○	21.3		No damage to parts of patient support and/or immobilization system after the loading test
T 13	○	○	○	21.5		Hand held equipment or equipment parts are safe after drop test
T 14 A, B	○	○	○	21.6		Portable and mobile equipment is able to withstand rough handling
	☐	☐	☐	22		MOVING PARTS
	○	○	○	22 (USA)		When risk of injury can occur, end stops are provided
T 15	○	○	○	22 (USA)		End stops have mechanical strength as determined by the test
	○	○	○	22.2a		Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment
	○	○	○	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
	○	○	○	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
	○	○	○	22.3		Guides or other safeguards are removable only with a tool
	○	○	○	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
	○	○	○	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
	○	○	○	22.6		Parts of equipment subject to mechanical wear are accessible for inspection
	○	○	○	22.7		Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard
	○	○	○	22.7		The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard
	○	○	○	22.7		Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents
	○	○	○	22.7		Means for stopping of movements operate as a result of one single action
	○	○	○	22.7a (USA)		Emergency off switch has red actuator
	○	○	○	22.7a (USA)		Emergency off switch: once actuated, maintains the equipment in "off" condition until action, different from that used to actuate, is performed
	○	○	○	22.7a (USA)		Emergency off switch is readily accessible to operator
	○	○	○	22.7b (USA)		Emergency off switch is marked with word "STOP" or symbol 5110 of IEC 878 in compliance with U.S. Clause 6
	○	○	○	22.7b (USA)		Emergency off switch: separate and independent of the intended movement control
	☐	☐	☐	23		SURFACES, CORNERS AND EDGES
	○	○	○	23		Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	☐	☐	☐	24		STABILITY IN NORMAL USE (see appended table 24)
T 16	○	○	○	24.1		Equipment does not overbalance during normal use when tilted through an angle of 10°
	○	○	○	24.3		Equipment overbalances when tilted through an angle of 10°
T 16	○	○	○	24.3		- does not overbalance when tilted through an angle of 5° in any position exduding transport
	○	○	○	24.3		- carry a warning notice stating that transport should only be undertaken in a certain position
	○	○	○	24.3		- in the position specified for transport does not overbalance when tilted to an angle of 10°
	○	○	○	24.6a		Equipment or its parts with a mass of more than 20 kg is provided with:
	○	○	○	24.6a		- suitable handling devices (grips etc.), or
	○	○	○	24.6a		- instructions for lifting and handling during assembly
	○	○	○	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
	☐	☐	☐	25		EXPELLED PARTS
	○	○	○	25.1		Protective means are provided where expelled parts of the equipment could be a hazard
	○	○	○	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
	☐	☐	☐	28		SUSPENDED MASSES
	○	○	○	28.2a (Australia)		Ceiling-supported EQUIPMENT
	○	○	○	28.2a (Australia)		i. EQUIPMENT fitted with an anticrash device or have suspension cables duplicated and independently anchored.
	○	○	○	28.2a (Australia)		ii. Motorized drives designed to prevent the driven part from becoming hazardous in the event of a power failure.
	○	○	○	28.2a (Australia)		iii. Carriages, brakes, and supports designed such that any single failure will not constitute a hazard to the PATIENT.
	○	○	○	28.2a (Australia)		iv. Effective means incorporated to prevent carriages running off supporting rails.
	○	○	○	28.2a (Australia)		v. Effective means incorporated to facilitate adequate inspection of cables and anchorages.
	○	○	○	28.2a (Australia)		vi. Proximity or pressure switches may be used to minimize hazards.
	○	○	○	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.
	○	○	○	28.2b (Australia)		Floor and floor-to-ceiling supported (including mobile) EQUIPMENT.
	○	○	○	28.2b (Australia)		i. Anticrash devices fitted to cable, chains, etc.
	○	○	○	28.2b (Australia)		ii. Means incorporated to facilitate adequate inspection of cables and anchorages.
	○	○	○	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.
	○	○	○	28.3		Suspension system with safety device
	○	○	○	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	○	○	○	28.3		Safety device has safety factors complying with Sub-clause 28.4.2
	○	○	○	28.3		Clear indication to the operator that the safety device has been activated after failure of suspension means
	○	○	○	28.3 (USA)		No evidence of damage to a safety catch after test
	○	○	○	28.3 (USA)		Safety catch marking provided
	○	○	○	28.4		Suspension systems of metal without safety devices
	○	○	○	28.4		1) Total load does not exceed the safe working load
T 18	○	○	○	28.4		2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired
T 18	○	○	○	28.4		3) Safety factors not less than 8 where impairment is expected
T 18	○	○	○	28.4		4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%
	○	○	○	28.4		5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement
T 18	○	○	○	28.4 (USA)		No damage to structural parts as a result of loading test
	○	○	○	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.
	○	○	○	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.
	☐	☐	☐	29		X-RADIATION
T 19	○	○	○	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)
	☐	☐	☐	36		ELECTROMAGNETIC COMPATIBILITY
	○	○	○	36		Equipment complies with IEC 601-1-2 (Ed.2, 2001)
	☐	☐	☐	37		COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT
	○	○	○	37		Requirements for category AP and APG equipment (Cl. 37 - 41) (For equipment used in the presence of Oxygen, see US Cl. 400)
	☐	☒	☐	38		MARKING, ACCOMPANYING DOCUMENTS – CATEGORY AP & APG EQUIPMENT
	☐	☒	☐	39		COMMON REQUIREMENTS FOR CATEGORY AP & APG EQUIPMENT
	☐	☒	☐	40		REQUIREMENTS AND TESTS FOR CATEGORY AP EQUIPMENT
	☐	☒	☐	41		REQUIREMENTS AND TESTS FOR CATEGORY APG EQUIPMENT
	☐	☒	☐	42		EXCESSIVE TEMPERATURES
	○	○	○	42 (USA)		Insulation systems with measured temperatures exceeding Class A 105°C (based on 40°C ambient) comply with UL1446
T 20	○	○	○	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	○	○	○	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	○	○	○	42.3		Applied parts not intended to supply heat have surface temperatures not exceeding 41°C
	○	○	○	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)
	○	○	○	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.
	○	○	○	42.5		Guards to prevent contact with hot surfaces removable only with a tool
	☐	☐	☐	43		FIRE PREVENTION
T 9	○	○	○	43		Strength and rigidity necessary to avoid a fire hazard
	☐	☐	☐	44		OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION
	○	○	○	44.2		Equipment contain a liquid reservoir:
T 21	○	○	○	44.2		- the equipment is electrically safe after 15% overfill steadily over a period of 1 min
T 21	○	○	○	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	○	○	○	44.3		Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)
T 23	○	○	○	44.4		Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard
T 24	○	○	○	44.5		Equipment sufficiently protected against the effects of humidity
T 25	○	○	○	44.6		Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529
T 26	○	○	○	44.7		Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	☐	☐	☐	45		PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE
T 27	○	○	○	45.2		Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure
	○	○	○	45.3		Maximum pressure does not exceed the maximum permissible working pressure for individual parts
T 28	○	○	○	45.7		Unless excessive pressure can not occur, pressure-relief device provided
	○	○	○	45.7a		a) Pressure-relief device connected as close as possible to the pressure vessel
	○	○	○	45.7b		b) Readily accessible for inspection
	○	○	○	45.7c		c) Not capable of being adjusted or rendered inoperative without a tool
	○	○	○	45.7d		d) Discharge opening located that the released material is not directed towards person
	○	○	○	45.7e		e) Discharge opening located that operation will not deposit material which may cause a safety hazard
	○	○	○	45.7f		f) Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure
	○	○	○	45.7g		g) No shut-off valve between a pressure-relief device and the parts intended to be protected
	○	○	○	45.7h		h) Minimum number of cycles of operation: 100.000
				46		HUMAN ERROR (Not Used)
				47		ELECTROSTATIC CHARGES (Not Used)
	☐	☐	☐	48		BIOCOMPATIBILITY
	○	○	○	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)
	☐	☐	☐	49		INTERRUPTION OF THE POWER SUPPLY
	○	○	○	49.1		Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard
T 29	○	○	○	49.2		Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function
	○	○	○	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)
	☐	☐	☐	51		PROTECTION AGAINST HAZARDOUS OUTPUT
	○	○	○	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
	☐	☐	☐	52		ABNORMAL OPERATION AND FAULT CONDITIONS
T 30	○	○	○	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)
	○	○	○	52.1 (Note)		Opening of a PWB trace is not acceptable, per 57.8b
	○	○	○	52.1		The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4
	○	○	○	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	○	○	○	52.5.2		Failure of thermostats presents no safety hazards
	○	○	○	52.5.3		Short-circuiting of either part of double insulation presents no safety hazard
T 32	○	○	○	52.5.5		Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C
T 33	○	○	○	52.5.6		Locking of moving parts presents no safety hazard
T 34	○	○	○	52.5.7		Interruption and short-circuiting of motor capacitors presents no safety hazard
T 33	○	○	○	52.5.8		Duration of motors locked rotor test in compliance with Cl. 52.5.8
	○	○	○	52.5.8 (Australia)		Table XII: In second row, first dash, after "if impedance protected", add "maximum value".
T 35	○	○	○	52.5.9		Failure of one component at a time presents no safety hazard
T 36 T 37	○	○	○	52.5.10		Overload of heating elements presents no safety hazard
T 38 T 39	○	○	○	52.5.10f		Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection
T 40	○	○	○	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)
	☐	☐	☐	55 (USA)		US DEVIATIONS FOR POLYMERIC ENCLOSURES
	○	○	○	55 (USA)		Polymeric enclosures and external combustible surfaces
	○	○	○	55 (USA)		Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C
ASTM E84, E162	○	○	○	55 (USA)		External combustible surface of more than 9.47 m2 or single dimension of 3.7 m have flame spread rating not exceeding 75 (Steiner Tunnel Test)
ASTM E84, E162	○	○	○	55 (USA)		External combustible surface of more than 4.74 m2 but not exceeding 9.47 m2 have flame spread rating not exceeding 75 (Radiant Panel or Steiner Tunnel Test)
	○	○	○	55 (USA)		Polymeric enclosures for transportable equipment rated 94V-2 or better (for circuits with > 15 W available power)
	○	○	○	55 (USA)		Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better
T 41	○	○	○	55 (USA)		Polymeric enclosures withstand 6.78 Nm (5 ft*lbs) impact test (UL Ball Impact)
T 42	○	○	○	55 (USA)		Polymeric enclosures: no deformation after mold stress test (for molded parts)
T 13	○	○	○	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
☐	☐	☐	56		COMPONENTS AND GENERAL ASSEMBLY
○	○	○	56		List of Critical Components Required
○	○	○	56.1b		Ratings of components not in conflict with the conditions of use in equipment
○	○	○	56.1b		Ratings of mains components are identified
○	○	○	56.1d		Components, movements of which could result in a safety hazard mounted securely
○	○	○	56.1f		Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard
○	○	○	56.3a		Connectors provide separation required by Sub-clause 17g
○	○	○	56.3a		Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment
○	○	○	56.3a		Medical gas connections not interchangeable
○	○	○	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.
○	○	○	56.3a (Canada)		Medical gas inlet connectors:
○	○	○	56.3a (Canada)		- are gas specific
○	○	○	56.3a (Canada)		- are non-interchangeable
○	○	○	56.3a (Canada)		- are DISS type complying with CGA V-5
○	○	○	56.3a (Canada)		- are configured to permit the supply from assemblies complying with CAN/CSA - Z305.2
○	○	○	56.3a (USA)		Connector, pin, plug attached to patient connected lead or contact cannot engage any part on the equipment, including separable cord set
○	○	○	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)
○	○	○	56.3b		Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken
○	○	○	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
	☐	☐	☐	56.4		Connections of Capacitors
	○	○	○	56.4		Not connected between live parts and non-protectively earthed accessible parts
	○	○	○	56.4		If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14
	○	○	○	56.4		Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts
	○	○	○	56.4		Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs
	○	○	○	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.
	○	○	○	56.5		Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment
	○	○	○	56.6		Temperature and overload control devices
	○	○	○	56.6a		Thermal cut-outs which have to be reset by a soldering not fitted in equipment
	○	○	○	56.6a		Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits
	○	○	○	56.6a		Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard
	○	○	○	56.6a		Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times (or UL Recognized)
	○	○	○	56.6a		Non-self resetting over-current releases operated 10 times (or UL Recognized)
	○	○	○	56.6a		Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard
	○	○	○	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
	○	○	○	56.6b		Thermostats with varying temperature settings clearly indicated
	○	○	○	56.6b		Operating temperature of thermal cut-outs indicated
	☐	☐	☐	56.7		Batteries
	○	○	○	56.7a		Battery compartments:
	○	○	○	56.7a		- adequately ventilated
	○	○	○	56.7a		- accidental short-circuiting is prevented
T 43	○	○	○	56.7b		Incorrect polarity of connection prevented
	○	○	○	56.8		Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):
	○	○	○	56.8		- to indicate that equipment is energized
	○	○	○	56.8		- to indicate the operation of non-luminous heaters if a safety hazard could result
	○	○	○	56.8		- to indicate when output exists if a safety hazard could result
	○	○	○	56.8		- charging mode indicator provided
T 44	○	○	○	56.10		Actuating parts of controls
	○	○	○	56.10b		Actuating parts are adequately secured to prevent them from working loose during normal use
	○	○	○	56.10b		Controls are secured to prevent the movement relative to scale marking (safety related only)
	○	○	○	56.10b		Detachable indicating devices are prevented from incorrect connection without the use of tool
	○	○	○	56.10c		Stops are provided on rotating controls:
	○	○	○	56.10c		- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard
	○	○	○	56.10c		- to prevent damage to wiring

	Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
	☐	☐	☐	56.11		Cord-connected hand-held and foot-operated control devices
	○	○	○	56.11a		Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g
	○	○	○	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	○	○	○	56.11b		Hand-held control devices comply with the requirement and test of Sub-clause 21.5
T 45	○	○	○	56.11b		- Foot-operated control devices designed to support the weight of an adult human being
	○	○	○	56.11c		Devices not change their setting when inadvertently placed
T 25	○	○	○	56.11d		Foot-operated control devices are at least IPX 1
T 25	○	○	○	56.11d		- For surgical use, electrical switching parts are IPX 8
T 46	○	○	○	56.11e		Adequate strain relief at the cord entry provided

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	57		MAINS PARTS, COMPONENTS AND LAYOUT
○	○	○	57 (USA)		Permanently connected equipment provided with field wiring provision in accordance with NEC, ANSI/NFPA 70
○	○	○	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).
☐	☐	☐	57.1		Isolation from supply mains
○	○	○	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)
○	○	○	57.1a		Means for isolation incorporated in equipment or, if external, specified in the accompanying documents
○	○	○	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
○	○	○	57.1f		Mains switches not incorporated in a power supply cord
○	○	○	57.1h		Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a
○	○	○	57.1m		Fuses and semiconductor devices not used as isolating devices
☐	☐	☐	57.2		Mains connectors and appliance inlets
○	○	○	57.2 (USA)		Power cord mains plug is "Hospital Grade" type
○	○	○	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"
○	○	○	57.2 (USA)		Plug for radiography equipment acceptable for current not less than 50 % of maximum input
○	○	○	57.2 (USA)		Plug acceptable for use with current not less than 125 % of rated current
○	○	○	57.2 (USA)		Plug acceptable for voltage for which the equipment is configured when shipped
○	○	○	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
○	○	○	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.
○	○	○	57.2e		Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug
○	○	○	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.
○	○	○	57.2g		Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment
○	○	○	57.2g (Canada)		Mains plug of non-permanent installed equipment:
○	○	○	57.2g (Canada)		- if molded on type - hospital grade complying with CSA C22.2, No. 21
○	○	○	57.2g (Canada)		- hospital grade disassembly type complying with CSA C22.2, No. 42
○	○	○	57.2g (Canada)		- if Class II equipment - polarized hospital grade CSA configuration 1-15P

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

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	57.5		Mains terminal devices and wiring of mains part (not applicable for IEC 320 detachable cord sets)
○	○	○	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
○	○	○	57.5		If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced
○	○	○	57.5		Screws and nuts which clamp external conductors not serve to fix any other component
○	○	○	57.5b		Terminals closely grouped with any protective earth terminal
○	○	○	57.5b		Mains terminal devices accessible only with use of a tool
○	○	○	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
○	○	○	57.5b (USA)		If leads are provided for connection to branch circuit, the free end is in separate compartment
○	○	○	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
○	○	○	57.5c		Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened
○	○	○	57.5d		Cord terminals not require special preparation of the conductor
☐	☐	☐	57.6		Mains fuses and overcurrent releases
○	○	○	57.6		Fuses or over-current releases provided accordingly for Class I and Class II
○	○	○	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.
○	○	○	57.6 (Note)		Fuses or over-current releases must have means of opening at a specific current (thermal cutoffs, PTCs not acceptable)
○	○	○	57.6		Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current
○	○	○	57.6 (Note)		Fuse ratings must be less than all component ratings up to the isolation transformer
○	○	○	57.6		Protective earth conductor not fused
○	○	○	57.6		Neutral conductor not fused for permanently installed equipment
☐	☐	☐	57.8		Wiring of the Mains Part
○	○	○	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
○	○	○	57.8b		Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord
○	○	○	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
	☐	☐	☐	57.9		Mains Supply Transformers
	○	○	○	57.9 (Canada)		Switching power supplies conform to CSA Electrical Bulletin 1402C
	○	○	○	57.9.1		Overheating
	○	○	○	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	○	○	○	57.9.1a		Short-circuit of secondary windings not caused excessive temperature
T 48	○	○	○	57.9.1b		Overload of secondary windings not caused excessive temperature
T 49	○	○	○	57.9.2		The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests
	○	○	○	57.9.2 (SI - UL)		Transformer 5x Dielectric test can be waived for Switch Mode power supplies
	○	○	○	57.9.2 (Note) (UL)		Transformer 5x Dielectric test can be waived if transformer primary and secondary winding varnish is R/C (OBJS2)
	☐	☐	☐	57.9.4		Construction
	○	○	○	57.9.4a		Separation of primary and secondary windings
	○	○	○	57.9.4a		- separate bobbins or formers
	○	○	○	57.9.4a		- one bobbin with insulating partition
	○	○	○	57.9.4a		- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm
	○	○	○	57.9.4a		- concentrically wound on one bobbin with windings separated by double insulation
	○	○	○	57.9.4c		Means provided to prevent displacement of end turns
	○	○	○	57.9.4d		Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn
	○	○	○	57.9.4e		Insulation between the primary and secondary in transformers with double insulation
	○	○	○	57.9.4e		- 1 insulation layer having a thickness of at least 1 mm
	○	○	○	57.9.4e		- at least 2 insulation layers with a total thickness of at least 0.3 mm
	○	○	○	57.9.4e		- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation
	○	○	○	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.
	○	○	○	57.9.4 f (Note) (UL)		Conformal Coating used on PWB considered to contribute 1 mm each to creepage distances for specific applications
	○	○	○	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
☐	☐	☐	57.10		Creepage distances and air clearances
○	○	○	57.10 (SI - UL)		Products or constructions using insulating compounds (encapsulation) to provide DI shall comply with Sub-Clause 2.9.7 of UL 1950/60950. Except that: 1. 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, 2. The Humidity Conditioning test shall be performed per Sub-Clause 4.10 and 3. The Dielectric Strength test shall be performed per Clause 20. Note 1: UL 1950/60950 Practical Application Guidelines for this Sub-Clause can be used as appropriate. 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.
○	○	○	57.10 (Note) (UL)		Reference Voltage (U) for Creepage distances and air clearances for insulation with either side isolated (floating) - 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
○	○	○	57.10 (Note) (UL)		PWB with ≥ 0.4 mm thickness is sufficient for RI requirements
○	○	○	57.10a		Values: compliance with at least the values of Table XVI
○	○	○	57.10a		Creepage distances for slot insulation of motors at least 50% of the specified values
○	○	○	57.10 a (Note)		For Voltages >1000 V, apply requirements from applicable or similar IEC 60601-2-xx standard or use IEC 664
○	○	○	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
○	○	○	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
☐	☐	☐	58		PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS
○	○	○	58.1		Clamping means of the protective earth terminal
○	○	○	58.1		Not be able to loosen without the aid of a tool
○	○	○	58.1		Screws for internal earth connections are covered or protected against loosening from outside
○	○	○	58.2 (Canada)		Protective earth connections comply with CSA C22.2 No. 0.4
○	○	○	58.2 (USA)		Connections are mechanically secured in addition to soldering
○	○	○	58.7		Earth pin of the appliance inlet regarded as the protective earth terminal
○	○	○	58.8		The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing
○	○	○	58.8 (Note)		Terminal may be stacked if PE is first connection and secured with lock washer/nut before other connections are made
○	○	○	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)
☐	☐	☐	59		CONSTRUCTION AND LAYOUT
☐	☐	☐	59.1		Internal wiring
○	○	○	59.1 (Canada)		Connecting cables comply with Canadian Electrical Code, Part I
○	○	○	59.1 (USA)		Installation of connecting cords between parts of equipment in compliance with NEC
○	○	○	59.1 (USA)		Cable type acceptable for external interconnection
○	○	○	59.1a		Cables and wiring protected against contact with a moving part
○	○	○	59.1a		Wiring having basic insulation only protected by additional fixed sleeving
○	○	○	59.1a		Components are not likely to be damaged in the normal assembly or replacement of covers
○	○	○	59.1b		Movable leads are not bent around a radius of less than five times the outer diameter of the lead
○	○	○	59.1c		Insulating sleeving adequately secured
○	○	○	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
○	○	○	59.1c		Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material
○	○	○	59.1d		Aluminum wires of less than 16 mm2 cross-section not used
○	○	○	59.1f		Connecting cords between equipment parts considered as belonging to the equipment
☐	☐	☐	59.2		Insulation
T 50 ○	○	○	59.2b		Mechanical strength and resistance to heat and fires retained by all types of insulation
○	○	○	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)
○	○	○	59.2c		Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts
○	○	○	59.2c		Parts of rubber resistant to ageing
☐	☐	☐	59.3		Excessive current and voltage protection
○	○	○	59.3		Internal electrical power source provided with device for protection against fire hazard
○	○	○	59.3		Fuse elements replaceable without opening the enclosure fully enclosed in a fuse holder
○	○	○	59.3		Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.

Pass	N/A	Fail	CLAUSE	COMMENTS	REQUIREMENT
☐	☐	☐	59.4		Oil Containers
○	○	○	59.4		Oil containers adequately sealed
○	○	○	59.4		Container allow for the expansion of the oil
○	○	○	59.4		Oil containers in mobile equipment sealed to prevent the loss of oil during transport
○	○	○	59.4		Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level
☐	☐	☐	60 (Canada)		CANADA DEVIATIONS FOR DEFIBRILLATION-PROOF APPLIED PARTS
○	○	○	60 (Canada)		Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts.
☐	☐	☐	400 (USA)		US DEVIATIONS FOR OXYGEN
○	○	○	400.1 (USA)		At least one of the following three requirements is satisfied:
○	○	○	400.1.1 (USA)		Electrical components separated by barrier per 400.2
○	○	○	400.1.2 (USA)		Compartments with electrical components ventilated per 400.3
○	○	○	400.1.3 (USA)		Electrical components comply with 400.4 so that cannot be a source of ignition
○	○	○	400.2 (USA)		Barrier required by 400.1 is sealed at all joints and holes
○	○	○	400.3 (USA)		Ventilation required by 400.1 is such that oxygen content does not exceed 4% above ambient
○	○	○	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
○	○	○	400.4 (USA)		Surface temperature of components below 300°C in N.C. and S.F.C
○	○	○	400.5 (USA)		External exhaust gas outlets located at least 20 cm from any electrical component mounted on the outside
○	○	○	400.6 (USA)		Hospital beds intended for use with oxygen administering equipment provided with required markings
○	○	○	400.7 (USA)		Pendant controls on hospital beds with oxygen administering equipment marked as required
○	○	○	400.8 (USA)		Instructions for installation are in compliance with requirements of this clause
☐	☐	☐	600.1 (USA)		US DEVIATIONS FOR SEPARATE POWER UNITS PACKED WITH EQUIPMENT
○	○	○	600.1 (USA)		Separate power units provided with correlation marking
○	○	○	600.2.1 (USA)		Direct plug-in unit construction and performance comply with required sections of UL1310
○	○	○	600.2.2 (USA)		Direct plug-in unit external temperature rise during overheating test do not exceed 65°C
○	○	○	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
☐	☐	☐	General Deviations		General National Deviations
○	○	○	General (Denmark)		For plug and socket outlets the National Standard SB 107-2-D1 3rd Edition applies.
○	○	○	General (Denmark)		For Class I equipment: Plugs: DK 2-la, DK 2-la with flat phase pin or DK 2-5a. Socket outlets: DK 1-3a
○	○	○	General (Denmark)		For Class II equipment: Plugs: DKA 2-la, DKA 2-1b, Clb, C5, C6 or according to EN 50075
○	○	○	General (Korea)		National supply voltages are 110 V, 220 V and 380 V.
○	○	○	General (Korea)		Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.
○	○	○	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.
○	○	○	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	5.9	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	Max. Temp. °C				
Winding Class	Attended, timer, 5 min max use	Impedance Protected	Protection acts < 1 hr.	Protection acts > 1 hr.	Ave. after 1st 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

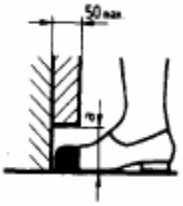
Methodology

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.

Dimensions in millimetres

Part of body	Minimum gap *a*	Illustration
Body	500	
Head (least favourable position)	300	
Leg	180	
Foot	120	
Toes	50	
Arm	120	
Hand Wrist Fist	100	
Finger	25	

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° = (C° x 1.8) + 32
C° = (F° / 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 in^2

1 kPa = 0.145 psi (50 kPa = 7.25 psi)
1 psi = 6.895 kPa

Medical Standards (Updated May 1, 2005)

IEC 60601-1 Ed.2 (12/98) Medical Electrical Equipment
= IEC 601-1 (1988) + Am 1 (11/91) + Am. 2 (03/95).
[Ed. 3 will be published near end of 2005]

National Deviations:
USA: UL 60601-1 Ed.1 (4/25/2003)
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)
Japan: JSA JIS T0601-1 (12/27/1999).

IEC 60601-1-xx

1: Safety Requirements for Medical Electrical Systems (06/92), Am.1 (11/95), Ed.2 (12/00).

2: Electromagnetic Compatibility - Requirements and Tests (04/93), Ed.2 (09/01), Am.1 (09/04), Ed. 2.1 (11/04).

3: Gen. Requirements for Radiation Protection in Diagnostic X-ray Equipment (07/94).

4: Programmable Electrical Medical Systems (05/96), Am.1 (10/99), Ed.1.1 Consolidated (04/00).

5: Image quality and dose for X-ray equipment (Project).

6: Analysis, test and validation of human factors compatibility Ed.1 (06/04).

7: General requirements for multiparameter patient monitoring equipment (Project ?).

8: General requirements and guidelines for the application of alarms in Medical Electrical Equipment (08/03).

IEC 60601-2-xx

1: Medical Electron Accelerators in the Range 1 MeV to 50 MeV Ed.2 (06/98) Am.1 (05/02).

2: High Frequency Surgical Equipment Ed. 3 (09/98) Ed.4 (Project). [AAMI HF18-331].

3: Short-Wave Therapy Equipment Ed. 2 (06/91), Am.1 (09/98) Ed.2 (Project).

4: Cardiac Defibrillators and Cardiac Defibrillator-Monitors (01/83), Ed.2 (08/02), Corr.1 (04/04). [AAMI DF2-331].

5: Ultrasonic Therapy Equipment (01/84), Ed.2 (07/00).

6: Microwave Therapy Equipment (01/84).

7: High Voltage Generators of Diagnostic X-ray Generators Ed. 2 (02/98).

8: Therapeutic X-ray Equipment Operating in the Range 10 kV to 1 MV (04/87), Am.1 (08/97), Ed.1.1 Consolidated (04/99).

9: Patient Contact Dosimeters used in Radiotherapy with Electrically Connected Radiation Detectors Ed. 2 (10/96).

10: Nerve and Muscle Stimulators (12/87), Am.1 (09/01), Corrigendum (02/02).

11: Gamma Beam Therapy Equipment (08/97) Am.1 (07/04).

12: Lung Ventilators for Medical Use (12/88), Ed.2 (10/01).

13: Anesthetic Machines Ed.2 (05/98), Ed.3 (05/03), Am.1 (Project).

14: ~~Electroconvulsive Therapy Equipment (03/89)~~ (Withdrawn).

15: ~~Capacitor Discharge X-ray Generators (12/88)~~ (Withdrawn).

16: Haemodialysis Equipment Ed. 2 (02/98). [AAMI RD16-331].

17: Remote-Controlled Automatically-Driven Gamma-ray Afterloading Equipment (09/89), Am.1 (03/96), Ed..2 (01/04).

18: Endoscopic Equipment Ed. 2 (08/96), Am.1 (07/00).

19: Baby Incubators (12/90), Am.1 (10/96). [AAMI II36-331].

20: Transport Incubators (12/90), Am.1 (10/96). [AAMI II51-331].

21: Infant Radiant Warmers (02/94), Am.1 (10/96).

22: Diagnostic and Therapeutic Laser Equipment Ed. 2 (11/95), Ed. 3 (Project).

23: Transcutaneous Partial Pressure Monitoring Equipment (09/93), Including essential performance Ed. 2 (12/99).

24: Infusion Pumps and Controllers (02/98).

25: Electrocardiographs (03/93), Am.1 (05/99). [AAMI EC11-331].

26: Electroencephalographs (04/94), Ed.2 (11/02), Ed.2 Bilingual (12/03).

27: Electrocardiographic Monitoring Equipment (04/94), Ed.2 (Project). [AAMI EC13-331].

28: X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis (03/93).

29: Radiotherapy Stimulators (04/93), Am.1 (11/96), Consolidated Ed. 2 (01/99).

30: Automatic Cycling Indirect Blood Pressure Monitoring Equipment (03/95), Ed.2 (12/99). [AAMI SP10-331].

31: External Cardiac Pacemakers with Internal Power Source (10/94), Am. 1 (01/98).

32: Associated Equipment of X-ray Equipment (03/94).

33: Magnetic Resonance Equipment for Medical Diagnosis (07/95), Ed.2 (05/02), Am.1 (Project).

34: Direct Blood Pressure Monitoring Equipment (12/94), Ed.2 (10/00). [AAMI BP22-331]. [AAMI SP9-331].

35: Blankets, Pads and Mattresses Intended for Heating in Medical Use (11/96).

36: Extracorporeally Induced Lithotripsy (03/97).

37: Ultrasonic Medical Diagnostic and Monitoring Equipment (07/01), Am.1 (08/04), Ed.1.1 (10/04), Am.2 (Project).

38: Electrically Operated Hospital Beds (10/96), Am.1 (12/99), Ed. 2 (Project).

39: Peritoneal Dislysis Equipment (06/99) Ed.1 Bilingual (12/03).

40: Electromyographs and Evoked Response Equipment (02/98).

41: Surgical Luminaires and Luminaires for Diagnosis (02/00).

42: ~~Automatic or Advisory External Defibrillators~~ (Incorporated into IEC 60601-2-4).

43: X-ray Equipment for Interventional Procedures (06/00).

44: X-ray Equipment for Computed Tomography (02/99), Ed.2 (06/01), Am.1 (09/02) Ed.2.1 (11/02).

45: Mammographic X-ray Equipment and Mammographic Stereotactic Devices (09/98), Ed.2 (05/01).

46: Operating Tables (06/98).

47: Ambulatory Electrocardiographic Monitors [Holter Monitors] (07/01).

48: Canceled

49: Multiparameter Patient Monitoring Equipment (07/01).

50: Infant phototherapy equipment (07/00), Corrigendum 1 (03/01).

51: Recording and analyzing single and Multichannel electrocardiographs (02/03).

52: Safety of Medical Beds (To replace IEC 60601-2-38) Ed.1 (Project).

53: Computer Assisted Electrocardiography Communication Protocol (Project).

54: Pulse Oximeters (Project?).

55: Respiratory Gas Monitoring Equipment (Project?).

IEC 60601-3-xx (Requirements Incorporated Into Particular Standards)

~~1: Performance of Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment (09/96).~~

~~2: Performance of Recording and Analyzing Single Channel and Multichannel Electrocardiographs (Project).~~

Other Related Standards:

IEC 60529: Protection provided by Enclosures - IPXX Rating Ed.2 (11/89), Am.1 (11/99), Ed.2.1 (02/01).

ISO 10993-1: Biological Evaluation of Medical Devices [Biocompatibility] (08/03).

IEC 60825-1: Safety of LASER Products - Part 1. Ed. 1.2 (08/01).

ANSI / UL1998: Software in Programmable Components Ed.2 (05/98), Am.1 (05/00), Rev.1 (05/04)

ISO 14971: Medical Devices - Application of Risk Management to Medical Devices (12/00), Am.1 (03/03).

CSA C22.2 No. 0.4-M1982: Bonding and Grounding of Electrical Equipment (Protective Grounding) (12/82).

IEC 60878: Graphic Symbols for Electrical Equipment in Medical Practice Ed.2 (07/03).

ASTM F2196-02: Circulating Liquid and Forced Air Patient Temperature Management Devices (10/02).

UL 544: Medical and Dental Equipment (Equipment Freeze Date 1/1/2005), (Standard Withdraw Date 1/1/2010)

UL 187: X-Ray Equipment (Equipment Freeze Date 1/1/2005), (Standard Withdraw Date 1/1/2010)