

ELECTRICAL LABORATORY- TEST REPORT
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Test Report N°..... ITC/ [REDACTED]
 Date of issue..... [REDACTED]
 Sample date in..... [REDACTED]
 Date of performance..... [REDACTED]
 Applicant
 Customer.....

Sample description..... LED OPERATION THEATRE LIGHT
 Sample Condition..... Ok
 Customer reference..... N/A
 Trade mark / Manufacturer..
 Model / Type / Reference..... SMART DOME
 Ratings..... 207 to 253 VAC, 50Hz, 300VA
 Test method(s)..... EN 60601-1:2006

Overall verdict **Pass**
 Fail

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60601-1	Requirements	Result/Remarks	Verdict
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4.	General requirements		
4.1	Conditions for applications to ME EQUIPMENT or ME SYSTEMS		
	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse.		P
4.2	RISK MANAGEMENT PROCESS for ME Equipment or ME Systems		
4.2.1	Introduction to RISK MANAGEMENT		-
4.2.2	General requirement for RISK MANAGEMENT		
	A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For compliance with this standard, all elements of the ISO 14971:2007	In Compliance	P
4.2.3	Evaluating RISK		
4.2.3.1	HAZARDS identified in the IEC 60601-series		
	The requirements of this standard shall be applied in the following way when evaluating RISK		
a)	Where this standard or its collateral or standards specify requirements addressing HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.	In Compliance	P
b)	These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable per the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.	In Compliance	P
c)	Where this standard or its collateral or standards identify HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements:		
	- the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS exist for the ME EQUIPMENT or ME SYSTEM, and	In Compliance	P
	- where such HAZARDS or HAZARDOUS SITUATIONS exist for the ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2.2	In Compliance	P

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4.2.3.2	HAZARDS not identified in the IEC 60601 series		
	For HAZARDS or HAZARDOUS SITUATIONS that are identified for the ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2.	In Compliance	P
4.3	Essential Performance		
	During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.	In Compliance	P
	The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.	In Compliance	P
	The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER.	In Compliance	P
	The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.	In Compliance	P
	The MANUFACTURER shall specify the methods used to verify the effectiveness of the RISK CONTROL measures. This shall include any assessment made to determine whether verification is needed.	Provided	P
4.4	Expected service life		
	The manufacturer shall state the expected service life of the ME equipment or ME system in the Risk Management file.		N/A
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS		
	Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can	Provided	P

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		earthing.	
8.6.3		Protective earthing of moving parts	
		Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connections will remain reliable during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.	P
8.6.4		Impedance and current-carrying capability	
		a) PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.	P
		For PERMANENTLY INSTALLED ME EQUIPMENT, the impedance between the PROTECTIVE EARTH TERMINAL and any part that is PROTECTIVE EARTHED shall not exceed 100 m Ω ,	N/A
		For ME EQUIPMENT with an APPLIANCE INLET the impedance between the earth pin in the appliance inlet and any part that is PROTECTIVELY EARTHED shall not exceed 100 m Ω	N/A
		For ME EQUIPMENT with a NON-DETACHABLE POWER SUPPLY cord the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 m Ω	P
		 Refer Table C	
		Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part	P



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Table A

7.1.3	Marking durability		
Marking tested		Remarks	Verdict
Rubbed by hand without undur pressure		Marking remain legible	P
Rubbed by Cloth soaked with distilled water for 15sec		Marking remain legible	P
Rubbed by Cloth soaked with 96% of ethanol for 15sec		Marking remain legible	P
Rubbed by Cloth soaked with isopropyl alcohol for 15Sec		Marking remain legible	P
Supplementary information:			

Table B

8.4.3	ME EQUIPMENT Intended to be Connected to a Power Source by Plug	P
Voltage measured between:	Measurements [V]	Remarks
	1 2 3 4 5 6 7 8 9 10	
supply pins (pin 1 & pin 2)	12 7 12 9 9 9 10 13 11.9 12.8	Less than 60V after 1s of Plug removal

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Table C

8.6.4	Impedance and current-carrying capability (Earth contact resistance test)		Result
a)	TEST CONDITIONS	TEST REQUIREMENTS	F
	Test Current: 25A Non-DETACHABLE power supply cord the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED	Resistance shall not exceed 200mΩ	Rmeas→ 88.9mΩ

Table D

8.7	Leakage Currents and Patient Auxiliary Currents			
Type of leakage current and test condition (including single faults) operating condition	Measured Value (μA)	Maximum Allowed value (mA)	Remarks	
Earth leakage current (Normal Condition)	285.6 μA	5mA	P	
Earth leakage current (Single fault Condition)	495.9 μA	10mA	P	
Earth & Enclosure leakage current (Normal condition)	Under 1μA	100μA	P	
Earth & Enclosure leakage current (single fault condition)	Under 1μA	500μA	P	
Patient leakage current	-	10 μA	N/A	
Patient auxiliary current	-	10 μA	N/A	

Abbreviations used: mA: milli-ampere, μA: micro-amperes

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Table E

8.8.3	Electric Strength			P
	For Double Insulation			
	Test voltage applied between	Voltage	Duration	Breakdown (Yes/No)
	Between live part and metal part of enclosure	1500V	60s	No

Table F

8.9	CREEPAGE DISTANCES and AIR CLEARANCES			P
	Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION			
	Creepage Distance	Required Creepage (mm)	Measured Clearance (mm)	
	one MEANS OF OPERATOR PROTECTION	4 mm	> 4 mm	
	AIR Clearance Distance	Required Clearance (mm)	Measured Creepage (mm)	
	one MEANS OF OPERATOR PROTECTION	2.5 mm	> 2.5 mm	

Table G

8.9.1	Mains Transient Voltage			P
	Nominal a.c. supply mains voltage line-to-neutral upto & including Vr.m.s.	Test voltage	Duration	Breakdown (Yes/No)
	300*	2500V**	60s	No
	*including 230/400 or 277/480 V			
	**as per overvoltage category II			