TEST REPORT

IEC 60601-1:2005+AMD1:2012+AMD2:2020
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report reference No..... :	2206013
Approved by (+ signature)..... :	Kunal Deshpande
Date of issue ..... :	20.06.2022
Testing laboratory ..... :	Astute Labs Pvt. Ltd.
Address ..... :	Office # 01A, B Wing, Siddhesh Optimus,Opp. Lunkad Queensland, S. No. 211, Viman Nagar, Pune – 411014, Maharashtra, India.
Testing location ..... :	Sr. No. 82/1, Bajirao Dhawade Patil Industrial Estate, NDA Road, Shivane, Pune-411023, Maharashtra, India
Applicant ..... :	Heka Medicals India Pvt. Ltd.
Address ..... :	First Floor, S H Arcade Monippally P O, Kottayam PIN -686636
Standard..... :	IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Test procedure ..... :	According to IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
Procedure deviation ..... :	N/A
Non-standard test method ..... :	N/A
Discipline/ Group..... :	Electronics / Safety Testing Facility
Type of test object..... :	HekaFlo
Trademark..... :	HekaFlo
Model/type reference ..... :	HM-P-500
Manufacturer ..... :	Heka Medicals India Pvt. Ltd.
Address ..... :	First Floor, S H Arcade Monippally P O, Kottayam PIN -686636
Ratings ..... :	Input: 1) Supplied by AC mains: 220-240VAC, 50Hz, 3.2A, or 2) Supplied by external adapter: NA or 3) Supplied by internal electric power source: N/A

ASTUTE LABS PRIVATE LIMITED PUNE

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	Complies	Pass
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	Refer:- Risk management file HM/RMF/001	Pass
4.2.1	**Introduction to RISK MANAGEMENT** Sub clause 4.2 specifies the RISK MANAGEMENT PROCESS that is required for compliance with this standard. This RISK MANAGEMENT PROCESS is intended to serve the following purposes:	Complies	Pass
	a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the HAZARDS associated with the particular ME EQUIPMENT or ME SYSTEM under consideration.	Complies	Pass
	b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME EQUIPMENT or ME SYSTEM.	Complies	Pass
	c) To identify whether particular HAZARDS or HAZARDOUS SITUATIONS for which this standard does not provide specific acceptance criteria result in any RISKS for a particular ME EQUIPMENT or ME SYSTEM, and, if so, to establish acceptable RISK levels and evaluate The RESIDUAL RISKS.	Complies	Pass
	d) To evaluate the acceptability of alternative RISK CONTROL strategies by comparing RESIDUAL RISK with that achieved by applying the full requirements of this standard.	Complies	Pass
	Although the RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971, it is not as extensive as and does not include all of the elements required for compliance with ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this standard does not include the production and postproduction monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.	Complies	Pass
4.2.2	**General requirement for RISK MANAGEMENT** A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For	Complies	Pass

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	compliance with this standard, all elements of the ISO 14971:2007 RISK MANAGEMENT PROCESS shall be applied except: – the planning for and execution of production and post-production monitoring (sub clause 3.1, fourth dash, sub clause 3.4, item f), and Clause 9 of ISO 14971:2007), and – periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (sub clause 3.2, fourth dash, of ISO 14971:2007). When applying any of the requirements of ISO 14971: – the term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM; and – the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.		
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 particular standards specify requirements addressing particular 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. b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria defined in the RISK MANAGEMENT plan. These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan. c) Where this standard or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements: – the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS	Complies	Pass

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	exist for the particular ME EQUIPMENT or ME SYSTEM, and – where such HAZARDS or HAZARDOUS SITUATIONS exist for the particular 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.		
4.2.3.2	**HAZARDS not identified in the IEC 60601 series** For HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular 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.	Complies	Pass
4.3	ESSENTIAL PERFORMANCE	RM File Reference to Essential performance: Risk management file HM/RMF/001	Pass
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.	Device expected service life is 5 Years	-
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	No Such method.	N/A
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	See Appended Insulation Diagram	Pass
4. 7	SINGLE FAULT CONDITION for ME EQUIPMENT	Complies	Pass
4.8	Components of ME EQUIPMENT They shall comply with one of the following (see also 4.5): a) the applicable safety requirements of a relevant IEC or ISO standard; b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.	See Appended Table 8.10	Pass
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	Not applicable	N/A
4.10	Power supply		
4.10.1	Source of power for ME EQUIPMENT	Suitable for connection to a Supply mains.	Pass
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded: – 250 V for HAND-HELD ME EQUIPMENT;	Rated Voltage 220-240 VAC, 50HZ, single phase SUPPLY MAINS connection	Pass

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	– 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS		
4.11	Power input: The steady-state measured input of the ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating by more than 10 % (see 7.2.7).	See Appended Table 4.11	Pass
5	General requirements for testing ME EQUIPMENT	Complies	Pass
5.1	TYPE TESTS	All the applicable tests were conducted.	Pass
5.2	Number of samples	01 Nos. Serial No.BC6399AF of EUT	-
5.3	Ambient temperature, humidity, atmospheric pressure Complies according to 5.7 and 7.9.3.1	Complies	Pass
5.4	Other conditions, Tested under the least favorable working conditions as specified in the instructions and during risk analysis.	Complies	Pass
5.5	Supply voltages, type of current, nature of supply, frequency (according to 5.7 and 7.9.3.1)	AC 220-240vac, 50Hz	Pass
5.6	Repairs and modifications	No failures. No repairs / modifications required	Pass
5.7	Humidity preconditioning treatment	Pre-condition performed: T = 25°C & Humidity 93%.Time 168H	Pass
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS	Type BF applied part	Pass
5.9.2	ACCESSIBLE PARTS		
5.9.2.1	Test finger	There was no live part accessible to the patient or operator	Pass
5.9.2.2	Test hook ME EQUIPMENT openings are mechanically tested by means of the test hook	The test hook does not cause damage to opening.	Pass
5.9.2.3	Actuating mechanisms See 15.4.6.1.	There is no actuating mechanism	N/A
6	**Classification of ME EQUIPMENT and ME SYSTEMS**		
6.2	**Protection against electric shock** ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT (see 7.2.6). Other ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT. INTERNALLY POWERED ME EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT while so connected, and with the requirements for INTERNALLY	Complies	Pass