Doc: MHD 07 (26391) P
Aug 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

इलेक्ट्रोकन्वल्सिव थेरेपी मशीन के लिए विशिष्टता

Draft Indian Standard

Specification for Electroconvulsive Therapy Machine

ICS: 11.040.01

Neurosurgery Instruments, Implants & Accessories Sectional Committee MHD 07	Last date for comments: 20 **Sep 2024**

FOREWORD

(Formal clause will be added later)

This Indian Standard specifies the general functional requirements of "Electroconvulsive Therapy Machine". These devices are provided with stimulus generators, Seizure Monitoring Equipment, Data Recording, Storage, and Control Panels. Mainly used for the treatment of depression, and for mania and schizophrenia.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded-off value should be same as that of the specified value in this standard.

1 SCOPE

This Indian Standard provides general functional requirements of an ECT machine. It applies to portable ECT with Stimulus Generators, Seizure Monitoring Equipment, Data Recording, Storage, and Control Panels.
Second-line treatment for the patient who does not respond to drugs.

2 REFERENCES

The standards given below contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

IS No./ Other Publication	***Title***
IS/ISO 13485 : 2016	Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes (First Revision)
IS 13450 (Part 1/Sec 2) : 2024	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 2 Electromagnetic disturbances Requirements and tests (Second Revision)
IS 17922 (Part 1) : 2023/ IEC 62366-1: 2015 CSV	Medical Devices Part 1: Application of Usability Engineering
IS 17932 (Part 1) : 2023/ ISO 10993-1 : 2018, MOD	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)
IS 13450 (Part 2/Sec 26) : 2021/ IEC 80601-2-26 : 2019	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 26 Electroencephalographs
IS/ISO 62304 : 2015	Medical device software - Software life cycle processes
IS 13450 (Part 1) : 2024	Medical electrical equipment Part 1 General requirements for basic safety and essential performance (Third Revision)
IS/ISO 14971 : 2019	Medical devices - Application of risk management to medical devices First Revision

3 TERMS AND DEFINITIONS: -

For this standard, the following terms and definitions shall apply.

3.1. Electrodes: These electrodes shall be easily positioned on the patient's scalp and securely connected to the machine to deliver electric currents properly.

3.2 Electroencephalogram (EEG): It is a method to record an electro gram of the spontaneous

electrical activity of the brain.

3.3 Software: The acquisition software should be provided with all the features to easily configure electrical parameters for ECT administration and to configure parameters, acquire and visualize for EEG/ECG.

3.4 Power Supply: ECT machines require a stable and reliable power supply. They may need to be plugged into a standard electrical outlet or have a reliable power source to ensure proper functioning during the procedure.

3.5 Stimulation Parameters: Electrode placement: Electrode placements in current ECT practice: bilateral (BL), also known as bitemporal (BT); right unilateral (RUL); and bifrontal (BF). Pulse width: The time elapsed from the beginning to the end of all phases plus the interphase interval within one pulse.

3.5.3 Pulse frequency: For monophasic waveforms, the frequency is the number of pulses per second for biphasic waveforms; the frequency is the number of pulse pairs per second. The unit of measure is Hertz (HZ).

4 GENERAL REQUIREMENT

Electrode Lead Wires and Patient Cables construction, materials, and connections between the stimulator device and the electrodes.

4.1 The user interface, including user controls, displays, and functions. Stimulation is initiated and controlled and describes individual output stimulus parameters (e.g., amplitude, pulse width, frequency, train duration).

4.2 Electrodes of the device that come into human contact must be biocompatible.

4.3 Use of EEG monitoring until seizure termination.

4.4 Electrode gel is used to assure excellent and uniform skin conductivity.

4.5 Facility to monitor real-time dynamic impedance during the procedure & static impedance.

4.6 Physiological monitoring and treatment data may be stored for later analysis, dosing management, or treatment assessment.

4.7 Close monitoring of the vital signs, airway patency, and seizure duration should always be performed during the ECT procedure.

4.9 First the patient should the patient anesthesia then the ECT process on the patient should be started.

5 FUNCTIONAL REQUIREMENT

5.1 Device Body: The Body shall have rigid enclosures to house the display screen, the electrical circuit to power the LED, the ECG output, the control panel, and the battery.

5.2 Displays should describe how stimulation is initiated and controlled and describe whether individual output stimulus parameters (e.g., amplitude, pulse widths, frequency, train duration) can be adjusted by the user.

5.3 The device shall comply with the general and electromagnetic compatibility requirements of IS 13450 (part / IEC 60601-1 and IS 13450 (part 1 /Sec 2)/ IEC 60601-1-

5.4 It shall be provided with the controls for frequency, pulse width, duration, energy, current, Impedance check, Brief pulse, Sin Mode, and Run.

5.5 Recommend that you demonstrate the electrical and mechanical safety of the device by performing electrical and mechanical safety testing as described in the IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance, or by an equivalent method.

5.6 GENERAL TECHNICAL PARAMETERS:

Parameters	Range
Modes	Brief Pulse Mode And Sine Mode

5.7 BRIEF PULSE MODE: In This Mode Frequency, duration, pulse width, and current are user selectable. Energy is calculated automatically by taking into consideration of the head impedance of the patient and the parameters set.

Parameters	Range
Frequency	Selectable 10Hz-140 Hz in 15 steps of 10Hz each
Pulse Width	Selectable 0.10 ms -2.0 ms in 20 steps of .10 ms each
Duration	Selectable 0.10 s to 5.0 s in 50 steps of 0.10 s each
Current	500 mA - 800mA in 7 steps of 50 mA each

5.8 SINE MODE : The energy is calculated according to the formula E=I^2 RT

Parameters	Range
Frequency	The fixed current of 650 mA
Duration	50 Hz(fixed)
Current	0.5 ms

6 ACCESSORIES

6.1 EEG Electrodes: is a test that measures electrical activity in the brain using small, metal discs (electrodes) attached to the scalp.

6.2 ELECTRODE GEL: Reduce resistance between skin and electrodes.

6.3 Electrode Lead Wires and Patient Cables.

6.4 Mouth Gag.

7 LABELING

Labeling must include adequate information for practitioners to safely and correctly use the device; this information should include indications, effects, routes, methods, frequency, and duration of administration, and any relevant hazards, contraindications, side effects, and precautions.

7.1 Instructions for Use: The labeling should include an operator's manual (Instructions for Use) with clear and concise instructions that delineate the technological features of the specific device and how the ECT device is to be used. Instructions should encourage the use of local/institutional training programs approved by the relevant institutional and professional organizations.

7.2 Warnings:

7.2.1 ECT can be an effective treatment for certain mental health conditions, but it may also cause side effects such as temporary memory loss, confusion, headache, and muscle aches.

7.2.2 Do not allow the conductive parts of the electrode and connectors to contact other surfaces of the ground.

7.2.3 Do not turn on any power until all cables have been properly connected and verified.

7.3 Patient Labeling:

The proposed special controls would require patient labeling to provide prospective patients with information that will assist them in understanding who may benefit from treatment with the device, what those potential benefits are, relevant contraindications, warnings, precautions, adverse effects/complications, how the device operates, the typical course of treatment, and other available treatments. Providing such information to the patient prior to scheduling treatment is an important

tool to help ensure effective communication between the patient and practitioner concerning the safe use of the device and the purposes for which it is intended. Each patient should have access to clear information in plain language to assist with forming realistic expectations of the treatment and its potential complications. Clearly, written patient labeling can help patients understand which types of potential side effects, e.g., disorientation, confusion, and memory problems, may be important to report to their healthcare provider.

7.3.1 Purpose of the device and indications for use:

In order to demonstrate compliance with special controls, the patient labeling for the medical device must include essential information about the device itself, its intended use, and the patient population it is designed for. It should also outline contraindications, indicating situations when the device should not be used. Additionally, the labeling should incorporate relevant data from clinical studies, describing suitable candidates for the procedure.

Furthermore, the patient labeling should explain in simple terms how the device works to achieve its effects and provide an overview of the typical treatment process. For instance, it can state that the device applies a controlled electric current, ensuring it remains within specified limits set by the manufacturer. This controlled electric current leads to a 'convulsion' or 'seizure,' which is the desired therapeutic effect of the treatment.

The patient labeling should emphasize that multiple treatments with the ECT device might be necessary for it to be effective. Patients should consult their physicians to understand the number of treatments and the treatment schedule. Continuing with the recommended follow-up treatments is vital to help prevent depression from recurring. It should also highlight that the effects of ECT are often temporary, and patients may need to continue other forms of depression therapy in conjunction with ECT.

8 TEST AND SAFETY

8.1 ELECTRODES:

8.1.1 Conductivity Test: To test the conductivity of the electrode, you can use a multimeter or a conductivity tester.

8.1.2. Biocompatibility tests appropriate for the duration and nature of contact with your device.

8.2 Performance Tests:

8.2.1 Pulse duration testing: Verify that the ECT machine delivers pulses of the specified duration.

8.2.2 Pulse frequency testing: Ensure the machine provides pulses at the required frequency.

8.2.3 Seizure threshold testing: Test the accuracy of the machine in determining the individual patient's seizure threshold.

8.2.4 Impedance monitoring: Check if the machine monitors impedance during treatment to ensure proper electrode contact.

8.2.5 Output intensity verification: Confirm that the ECT machine delivers the specified output intensity accurately.

8. 3 Basic Electrical Safety and Performance Testing

8.3.1 Leakage Current test this test is performed to make sure that the leakage current flowing through the device does not exceed a certain limit. For the purpose of this standard, the test procedures as described in IS 13450.

8.3.2 Ground Resistance Test the Ground Resistance test is used to evaluate the quality of the electrical connection between the grounding systems.

8.3.3 Ground Continuity Test: Check the integrity of the ground connection to prevent electrical shocks.

8.3.4 Power Cord and Plug Examination: Inspect the power cord and plug for damage or loose connections.

8.3.5 Protection against Electric Shock: Verify that the device incorporates appropriate measures to protect against electric shock.

8.4 Environmental Tests:

8.4.1 Temperature and Humidity: Temperature Test: This test assesses how the medical device performs under various temperature conditions. It involves subjecting the device to different temperature levels, such as high and low temperatures, to ensure its functionality and safety within the specified operating range. Humidity Test: Humidity testing evaluates the device's ability to withstand varying humidity levels. It is essential, especially for devices that may be used in environments with high humidity or varying moisture levels.

8.4.2 Vibration and Shock: Vibration Test: Vibration testing is carried out to determine the device's resistance to vibrations that may occur during transportation or use. The test simulates various vibration frequencies and intensities that the device might encounter during its lifecycle. Shock Test: Shock testing assesses the medical device's ability to endure sudden impacts or shocks. It is crucial for devices that could be dropped or experience abrupt movements during use or handling.

8.5 General Equipment Safety: This standard is used to guide the device design and protect against electrical and mechanical hazards. The discussion should include specific criteria such as:
8.5.1 power supply – supply type, rated voltage, rated current, frequency, etc.;

8.5.2 Accuracy of controls and protection from delivering hazardous outputs;

8.5.3 Protection under fault conditions;

8.5.4 Protection against unwanted or excessive radiation;

8.5.5 Excessive temperature;

8.5.6 Mechanical hazards associated with moving parts and overall device construction;

8.5.7 Protection from leakage current under normal and single-fault conditions.

8.6 Device-Specific Safety Features:

8.6.1 Disabling or limiting runaway pulse trains

8.6.2 Patient isolation from line currents

8.6.3 Preventing unintended DC current

8.6.4 Limiting maximum output

8.6.5 Provide shut-offs for high or low impedance with dynamic impedance monitoring

8.6.6 Visual and/or audible indicators for stimulus delivery.

8.6.7 Manual abort treatment capability

8.7 Software Life Cycle and Risk Management: The level of concern is related to the risks associated with software failure. The software used to operate an ECT device presents a "major level of concern" because a failure or latent design flaw could either directly result in major injury to the patient or could indirectly result in major injury to the patient through incorrect or Delayed information or through the action of a care provider. Refer to ISO 16085:2021.

9 MARKING

9.1 Each ECT machine shall be marked with the following:

a) Manufacturer's name/ trademark,

b) Name and address of the manufacturer,

c) Name and address of the marketer,

d) Month and Year of manufacture, and

e) Unique Device Identification / serial number

10 BIS CERTIFICATION

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.

11 PACKING

11.1 The device and its accessories shall be packed in a case in such a way that they are intact the case. The case for the device shall be made of a suitable material. It shall be designed in such a way that when the device and accessories are kept in position and the lid is closed; there shall be no rattling inside the case.

11.2 The device and the accessories shall be packed keeping in mind the packaging standards and regulations for medical devices to ensure compliance and product integrity.