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DCRND

Electrocardiograph (ECG) Surface Electrode Tester

Version 1.0

This Document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Office of Device Evaluation
Division of Cardiovascular, Respiratory and Neurological Devices
Anesthesiology and Defibrillator Devices Group

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

Guidance Document
Device: Electrocardiograph Surface Electrode Tester

Overview

This Draft Guidance Document provides information directed to the review of electrocardiograph surface electrode testers (ECG electrode testers). This guidance should assist in determining whether the device submission has addressed design, testing, and labeling issues sufficiently to establish a basic level of safety, effectiveness, and substantial equivalence to predicate devices.

There are no formal performance standards for an "ECG electrode tester". As discussed in the information that follows, the ANSI/AMMI EC12-1991 Disposable ECG Electrodes (EC12) standard recommends tests and procedures in which the electrical performance of electrodes is measured by connecting a pair of electrodes gel-to-gel, that is aligned with their conductive foam material in direct contact. These test methods appear to be more readily implemented with a discrete test apparatus (current sources, oscilloscopes, etc.) and bread boarded test circuits, rather than an integrated commercial device. The predicate ECG electrode testers currently on file determine the impedance (ohms) and DC offset potential while attached to the patient's skin and not in the gel-to-gel setup.

I. Device Description

Common Name:	Electrocardiograph surface electrode tester (ECG electrode tester)
Class:	II
Classification panel:	74
Product code:	KRC
Regulation number:	870.2360

An ECG electrode tester is a device used to test the function and application of electrocardiograph electrodes.

There are two primary parameters used to characterize the electrical behavior or functioning of ECG electrodes - AC impedance and DC offset. An ECG electrode tester is an electrical meter that measures the AC impedance (resistance in ohms) and DC offset (DC voltage in millivolts) of an electrode.

If impedance and offset are too high, faulty electrodes or poor skin contact may obscure surface signal potentials, and introduce measurement bias and inaccuracies.

II. Indications for Use

To provide a means of verifying the electrical performance and safety of disposable ECG electrodes

In "skin prep" applications the device is intended to measure the impedance and offset voltage of the electrode and electrode and skin surface interface. This may assist in determining if the electrode and contact impedance is low enough to proceed with a desired clinical procedure, or if the skin surface preparation or placement is poor, or if the electrode itself is defective.

If indicated for Gel-to-Gel measurements, the device should measure AC impedance, DC offset, and include defibrillation overload recovery, combined offset instability and internal noise, and bias current tolerance measurements.

III. Preclinical (bench) Specifications/Testing

A tester labeled to measure the contact impedance of an electrode to the patient's skin should foremost be concerned that the patient is properly isolated from the AC line voltage in any AC powered devices and that the total patient risk current for either AC or DC powered devices complies with ANSI/AAMI ES1 Safe Current Limits for Electromedical Apparatus -1993. The limit for total risk current in most circumstances is 10 microamps. The electrode tester should generate a test AC current frequency of 10 Hertz. If other frequencies are used, a rational and justification should be provided. The range of Impedance in ohms should, at a minimum, be 0-60K ohms at ± 2%. Any display indicator for "good", "fair", or "poor" or "good/bad" electrode contact must have performance validation data and results and the resistance threshold criteria used should be discussed(see clinical section of this document).

A device labeled for gel-to-gel measurements should include the following specifications as recommended in Section 4 of EC-12:

- The device should have a means of generating a sinusoidal current of 10 Hertz. The generated current should be limited to 100 microamps peak to peak. This would enable the ECG electrode tester to perform the AC impedance test as specified in EC-12.

- The device should have volt/ohm meter having a minimum input impedance of 10 megaohms and a resolution of 1 millivolt or better. The device should apply a bias current less than 10 nanoamps to the pair of electrodes connected gel-to-gel. This would enable the ECG electrode tester to perform the DC offset voltage test as specified in EC-12.

Gel-to-Gel testing should be performed at 23°C ± 5°C, and 40 ± 1% relative humidity.

The EC-12 standard states that a gel-to-gel pair of electrodes should not have an AC impedance exceeding 3K ohms and a DC offset exceeding 100 millivolts.

The ECG electrode tester should also have the capability to test the defibrillation overload recovery, combined offset instability and internal noise, and bias current tolerance. These tests are detailed in EC-12. If test circuitry is built into the ECG electrode tester rather than bread boarded, then equivalent circuitry and component tolerances to the circuits outlined in sections 4.2.2.3 - 4.2.2.5 of EC-12 should be used.

IV. Clinical Data

In the case of electrode prep checker, analyzers, etc., testing on the patient's skin at the intended locations on the patient's body should be provided. If the electrode tester offers indicators (status lights, alarms, or table in the device labeling) to assess the "quality" of the electrode/patient contact, then the clinical basis for the impedance or offset threshold values used by these "quality indicators" should be provided.

V. Software/Hardware Information

The electrode tester can be an entirely analog meter with analog test outputs. In this case, the device would have no software. If the device contains analog and digital circuitry, then any software or firmware should comply with the Reviewer Guidance for Computer Controlled Medical Devices. Any device displays and/or readout should be clearly labeled with measurement units, for example, ohms and millivolts.

VI. Examples of Predicate Devices

1. K874327 Skin Prep Analyzer
2. K830878 Prep-Check
3. K830823 Z View Meter
4. K813358 Gerard Medical Electrode Tester

VII. Biocompatibility/Sterility Information

Since the electrode tester does not come in contact with the patient, either directly or indirectly, biocompatibility and sterility information is not applicable.

VIII. Labeling

(See checklist items at end of this guidance document)

References

ANSI/AMMI EC12-1991 Disposable ECG Electrodes

ANSI/AMMI ES1 Safe Current Limits for Electromedical Apparatus - 1993

ANSI/AMMI EC53-1995 ECG Cables and Lead Wires

Reviewer Guidance for Premarket Notification Submissions, November 1993

Reviewer Guidance for Computer Controlled Medical Devices (if applicable)

Check List for ECG Electrode Tester

Information for the following items should be provided in the 510(k) submission:

1. Intended Use: all applications, environments of use, etc.

2. Hardware Information:
   a) User Displays: Impedance(ohms) Display and DC Offset
   b) A circuit diagram and description of current limiting features
   c) Power Source: AC, battery, or both
   d) Identification of any test leads or fixtures provided with the device

3. Software Information (if applicable)

4. Labeling Information
   a) Device Specifications which includes the following:
      - Range and Accuracy of ohm and volt meter
      - Maximum output peak-to peak current and AC current frequency
      - Threshold values for any stratification of "quality" of electrode impedance/contact readings or DC offsets

   b) Identification of all measurement output displays, and controls and switches

   c) Instructions for Use:
   - How to properly connect and test the electrodes
   - How the device selects the reference electrode
   - Cautions and warnings

5. Bench Testing
   a) Performance validation for the full range of the Ohm/Volt meter using reference and test electrodes
   b) Verification of patient risk current
   c) Verification of output signal frequency and stability
   d) Environmental testing consistent with indications
   e) Device calibration

6. Clinical

If the Electrode tester offers indicators (status lights, alarms, or table in the device labeling) to assess the "quality" of the electrode/patient contact, then the clinical basis for the impedance or offset values(thresholds) used by these "quality indicators" should be provided.