Guidance for Industry

Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement)

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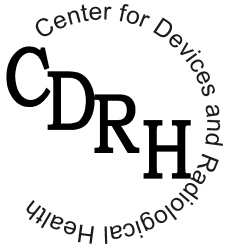

U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Pacing Devices Branch
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to James Cheng, Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact James Cheng at 301-443-8517.

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DIAGNOSTIC ECG GUIDANCE[1] (INCLUDING NON-ALARMING ST SEGMENT MEASUREMENT)

Version 1.0

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[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

DIAGNOSTIC ECG GUIDANCE (INCLUDING NON-ALARMING ST SEGMENT MEASUREMENT)

Version 1.0

I. Scope

This guidance is intended to aid in the preparation or review of premarket notification (510(k)) applications for the devices regulated under:

CFR Section:	21 CFR §870.2340, Electrocardiograph
Class:	II
Panel:	Circulatory System Devices Panel (74)
Product Codes:	DPS (electrocardiograph)
	MLC (non-alarming ST segment monitor)

This guidance applies to most of the diagnostic electrocardiographs covered by the ANSI/AAMI EC11-1991 standard for Electrocardiographs (EC-11 standard). Included in the EC-11 standard are ECG devices intended for diagnostic purposes. Cardiac Monitor devices, including cardiotachometers and alarms, are addressed by EC13, and are discussed in further detail in the FDA guidance on "Cardiac Monitor Devices (Including Cardiotachometers and Alarms)." Also included in this standard are devices which detect and measure ST segment level changes, but which do not alarm based on ST segment level changes.

Note that this guidance does **not** apply to the following cardiac monitors, which are classified elsewhere, and are excluded by the EC11 standard:

- devices that collect ECG data from locations other than the external surface of the body
- devices for interpretation or pattern recognition (e.g., QRS detectors, alarm circuits, rate meters, diagnostic algorithms)
- fetal ECG monitors
- ambulatory monitoring electrocardiographic devices, including ECG recorders and associated scanning and readout devices
- devices for fetal heart rate monitoring
- vectorcardiographs, that is, the display of loops
- pulse plethysomographic devices
- electrocardiographs used in other medical devices (e.g., patient monitors, defibrillators, stress testing devices)

NOTE: This guidance does not address issues specific to *automation (interpretation, classification, and diagnosis of ECGs), central monitoring stations, networked devices, or devices that use telemetry or transtelephonic communication.* Please contact the Division

for additional guidance on additional information that should be included in a submission for these types of devices.

This guidance is complementary to the requirements of 21 CFR § 807.87. Other information not identified in this guidance may be required in a 510(k) application. This guidance is subordinate to all other applicable statutes, regulations, and policies.

II. Recommended Information and Testing

A. Device Description

The description should include sufficient information to define the design, capabilities, and function of the device, and the scope of the 510(k) submission. Minimal information includes:

1. intended use (an explicit description of all clinical functions performed by the device, e.g., acquires and records 12 channel electrocardiographic waveforms, measures ST segment level changes, etc.),

2. contraindications and indications for use (describe when and where the device is or is not to be clinically used, and the intended patient population),

3. photographs or drawings of the device with all accessories included in the submission,

4. functional block diagram, including all accessories,

5. identification of all components and accessories included in the 510(k), and any collateral devices which can be connected or used with the monitor (e.g., personal computers (PCs), printers, database management software),

6. material descriptions for all patient contacting materials,

7. product specifications with ranges and/or accuracy (e.g., measurement limits, operating limitations, power source specifications, available modes or settings, and any other functional or physical limitation of the device),

8. discussion of the functional performance characteristics of the device, including any new or unique features,

9. an explanation of how the device interacts with the user, including whether the device can be programmed and to what extent.

B. Comparison to Predicate

Identify the legally-marketed predicate device by name, manufacturer, and 510(k) number (if available). Provide a table that lists the similarities and differences between your device and the predicate devices, and justify why any differences do not affect

safety and effectiveness. The table should include the items listed above, with emphasis on the following:

- indications for use, including patient population and intended use environment;

- basic technological characteristics, such as the number of electrodes employed, bandwidth, input dynamic range, storage of recorded signals, and analog or digital technology;

- other technological features such as radio frequency telemetry, and transtelephonic transmission (including FAX capabilities if applicable); and

If the 510(k) application is for a modification to an existing device, the manufacturer should provide the specifications for the original device along with a detailed and complete description of the similarities and differences between the two versions of the device.

C. Performance Testing

Substantial equivalence can be demonstrated by showing either 1) sufficient comparison testing with a legally-marketed predicate device, 2) conformance to the EC11 standard and to relevant portions of EC38 for ST segment measurement, or 3) conformance to any other standard which meets or exceeds the requirements of the EC11 standard. ***NOTE: If the device incorporates significant new features, additional testing may be necessary. Please contact the Division for further guidance.***

1. Comparison Testing

It is recommended that substantial equivalence be demonstrated by showing conformance to the EC11 standard. However, if the manufacturer chooses to provide comparative testing (i.e., to a predicate device), the provided data should meet the Suggested Format for Test Reports (listed below) and account for the following:

a) The manufacturer should identify all of the safety and effectiveness issues for their device. These issues can be identified independently or in parallel with the EC11 standard, i.e., a testing issue identified in the EC11 standard is usually (but not always) relevant to the safety and effectiveness of a device. The EC11 standard may not be sufficient, however, if the device incorporates a significant new feature;

b) There should be sufficient comparison testing provided to encompass each safety and effectiveness issue related to the device. Usually, should be conducted if it is capable of evaluating a failure mode, functional limitation, or a labeling claim for the device;

c) Provide sound scientific justification for the test methods and pass/fail criteria that were used. Note that the test method should evaluate the device in worst

case and normal operating conditions, and the pass/fail criteria should demonstrate equal or better performance as compared to the predicate device.

2. EC11 Standard Testing

To show conformance to the EC11 standard, the manufacturer should list each of the requirements of the standard and describe how the device conforms to each requirement[2] . For every requirement of the standard which necessitates in-vitro testing, test data and analysis should be provided and clearly identified (see the **Data and Results** section of "Suggested Format for Test Reports", below) . If the test method specified in the standard was not used or was modified, or if a section of the standard is not applicable to the device, an appropriate justification should be provided. For devices with unique features or intended uses, additional testing beyond the EC11 standard may be necessary.

If the EC11 standard is chosen by the manufacturer, conformance to the entire standard should be demonstrated. Conformance to only portions of the standard is usually insufficient to permit the standard's use or to allow a labeling claim of conformance to the standard. Therefore, if only part of the standard is met, the manufacturer should refer to the Comparison Testing section of this guidance.

3. ST Segment Measurement

For devices which have the ability to automatically measure and display or trend changes in the ST segment (without alarms), the manufacturer should show conformance to the applicable portions of the EC38 standard which concern ST segment measurement. The manufacturer should list each of the relevant requirements of the standard and describe how the device conforms to each of these requirements. For every requirement which necessitates in-vitro testing, the test protocol, test data and results, and analysis should be provided and clearly identified (see the **Data and Results** section of "Suggested Format for Test Reports," below). If the test method specified in the standard was not used or was modified, or if a section of the standard is not applicable to the device, an appropriate justification should be provided. For devices with unique features or intended uses, additional testing beyond the relevant portions of the EC38 standard may be necessary.

4. Other Standards

If the manufacturer chooses to conform to a standard other than the EC11, it is recommended that they list each requirement of the EC11 standard, compare the other standard to the EC11 requirements, and clearly identify where the other standard does not meet the requirements of the EC11 standard (if at all). Justification for any differences should be based on valid scientific or statistical analyses and supported by testing if necessary. Test reports should meet the Suggested Format for Test Reports, as listed below.

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2 Note: If EC11 becomes a "Recognized Standard", it will not be necessary to submit the test report. Instead, a "Declaration of Conformity" should be submitted (see the "Guidance of the Recognition and Use of Consensus Standards"). Refer to the CDRH Web page for the most recent list of Recognized Standards.

5. Suggested Format for Test Reports

The test report should include the following elements, or a justification for their omission:

a) **Test protocol**, which minimally includes:
- the purpose of the test,
- a clear description (with schematics) of the test set-up and any device modifications,
- the identification and precision of the equipment used,
- step-by-step descriptions of the data collection methods and device modes used, and
- justification for the testing parameters (e.g., testing temperature, length of test, the selection of device modes, etc.) and the pass/fail criteria. The testing parameters and pass/fail criteria should be conservative and based on the extreme clinical use of the device, according to the intended use or applicable standard. Depending on the test, it may be appropriate to base the testing parameters on the normal use of the device. However, if an extreme exists, it should be explored.

b) **Data and results**, which minimally include:
- clearly labeled data with the appropriate units,
- the data should be easily associated with the methods described in the protocol,
- for any graph, a table listing each data point shown on the graph is necessary, and
- for any calculated values, the calculated values should be obvious and calculated according to formulae presented in the protocol.

c) **Analysis**, which minimally includes:
- an evaluation of the test data according to the pass/fail criteria and purpose defined in the test protocol,
- identification of the inadequacies and accuracy of the test,
- evaluation of the need for additional testing, and a clear conclusion which is within the scope of the particular test.

D. In-Vitro Safety Testing

1. Environmental Testing

The manufacturer should evaluate the ability of the device to function after exposure to the environmental hazards expected when used by an abusive user. Tests for some of these hazards may be found in EC11, IEC 601-1, UL 2601, IEC 68-2, and IEC 529.

If a device is intended to be used outside of the hospital environment (e.g., those indicated for use in a transport environment such as an ambulance or helicopter), it may require additional testing. For example, devices intended for use in an ambulance should generally meet an appropriate shock/vibration test (e.g., see the

IEC 68-2 series), and should demonstrate immunity to a field strength of 20 V/m (rather than the 3 V/m typically needed). Additional testing is necessary for use in helicopters and aircraft – contact the Division for guidance.

2. Software

Depending on the proposed indications for use, cardiac monitors may be considered to have a level of concern ranging from minor to moderate. Refer to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for additional information about software documentation for a 510(k).

3. Electrical Safety

Any appropriate standard for electrical safety (e.g., ANSI/AAMI ES-1, IEC 601-1) may be used. If the EC11 standard is used, the manufacturer should conform to the standard's requirements or justify any deviation from the standard.

4. Electromagnetic Compatibility

Electromagnetic compatibility (EMC) testing should be done to demonstrate that the device will not adversely interfere with the performance of other electronic devices (emissions), and will perform as expected in the presence of other electronic devices or other sources of electromagnetic interference (EMI) in the intended environment of use (immunity).
NOTE: If the device is intended for use outside the hospital environment, additional testing may be necessary. See Environmental Testing, above, for details.

To demonstrate EMC for the device, one of the following options may be chosen:

a) Provide test data demonstrating conformance to part 3.2.10 (Electromagnetic Compatibility) of ANSI/AAMI EC38-1994 (Ambulatory Electrocardiographs). List each requirement of the standard and describe how the device conforms to it. For every requirement which necessitates in-vitro testing, test data and analysis should be provided and clearly identified (see the **Data and Results** section of "Suggested Format for Test Reports", above) . If the test method specified in the standard was not used or was modified, or if a section of the standard is not applicable to the device, an appropriate justification should be provided.

b) Provide a Declaration of Conformity to IEC 601-1-2 (refer to "Guidance for the Recognition and Use of Consensus Standards" for additional details on how to prepare a declaration of conformity); or

c) Provide the following information:
- Identification of every intended environment in which the device will be used, e.g., hospital general ward, hospital ICU/CCU, clinic, vehicle/traffic areas, emergency vehicle (including aircraft), operating room, home. This description should identify the possible sources of EMI which could affect the device.

- Identification of the selected standard, justification for its use, and test reports which conform to the "Suggested Format for Test Reports". Testing should be applicable to the intended environments described above and should address the following as appropriate for the device:
  - Emissions: radiated and conducted electromagnetic fields, and
  - Immunity: radiated electromagnetic fields, electrostatic discharge, electrical fast transients/bursts, ands surges.

Any omitted tests or deviations from the requirements of the chosen standard should be accompanied by appropriate justification.

E. Labeling

Conformance to the labeling regulations and policies is necessary (see 21 CFR 807.87(e)). Appropriate labeling guidances are available through the Division of Small Manufacturers Assistance (DSMA) at its toll-free number (800) 638-2041 or at its internet address: http://www.fda.gov/cdrh//dsma/dsmamain.html.

If the EC11 standard is used, the labeling requirements of the standard should be included or justification provided for any modifications.

F. Regulatory Requirements

Either a Summary of Safety and Effectiveness or a 510(k) Statement is necessary as described in 21 CFR § 807.92 and 21 CFR § 807.93, respectively.

A "Truthful and Accuracy Statement" is necessary according to 21 CFR §807.87 (j).

An "Indications for Use Statement" is necessary according to Office of Device Evaluation policy. A format for this statement can be provided to the manufacturer by DSMA.

G. References

ANSI/AAMI EC11-1991, "Diagnostic Electrocardiographic Devices"

ANSI/AAMI EC38-1994, "Ambulatory Electrocardiographs"

ANSI/AAMI ES1-1993, "Safe current limits for electromedical apparatus

IEC 60601-1-2 (1993), "Medical Electrical Equipment- Part 1: General Requirements for Safety; 2. Collateral Standard: Electromagnetic Compatibility- Requirements and Tests".

IEC 68-2-6 1982) with Amendment 1-1983 and Amendment 2-1985: Basic Environmental Testing Procedures part 2: Tests. Test Fc and Guidance: Vibration (Sinusoidal).
IEC 68-2-6 1982) with Amendment 1-1983 and Amendment 2-1985: Basic Environmental Testing Procedures part 2: Tests. Test Ea and Guidance: Shock.

IEC 68-2-6 1982) with Amendment 1-1983 and Amendment 2-1985: Basic Environmental Testing Procedures part 2: Tests. Test Fdc and Guidance: Random Vibration Wide Band – Reproducibility Low.

IEC 529 (1989): Classification of Degrees of Protection Provided by Enclosures.

FDA, guidance entitled, "(Draft) Guidance for the Content of 510(k) Submissions for Electrocardiographs", ### date.

FDA, guidance entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 29, 1998

FDA, Blue Book memorandum #K97-1 entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device".

FDA, "Premarket Notification 510(k), Regulatory Requirements for Medical Devices", FDA 95-4158.

FDA, guidance entitled, "Reviewer Guidance for Premarket Notification Submissions", November 1993.

FDA, guidance entitled, "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", March 20, 1998.

FDA, guidance entitled, "Guidance on the Recognition and Use of Consensus Standards", February 19, 1998.

Acknowledgements:

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