Guidance for Industry

Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm)

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U.S. Department Of Health And Human Services
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Pacing Devices Branch
Division of Cardiovascular and Respiratory Devices
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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.

Additional Copies

World Wide Web/CDRH home page: http://www.fda.gov/cdrh/ode/cmonitor.pdf, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2233when prompted for the document shelf number.

CARDIAC MONITOR GUIDANCE[1] (INCLUDING CARDIOTACHOMETER AND RATE ALARM)

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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.

CARDIAC MONITOR GUIDANCE (INCLUDING CARDIOTACHOMETER AND RATE ALARM)

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 §870.2300, Cardiac Monitor (including cardiotachometer and rate alarm)
Class:	II
Panel:	Circulatory System Devices Panel (74)
Product Code:	DRT

This guidance applies to most of the cardiac monitors covered by the ANSI/AAMI EC13-1992 standard for Cardiac Monitors, Heart Rate Meters, and Alarms (EC13 standard). Included in the EC13 standard are ECG devices intended for monitoring purposes; diagnostic ECG devices are addressed by EC11, and are discussed in further detail in the FDA guidance "Diagnostic ECG Devices."

Note that this guidance does **not** apply to the following cardiac monitors, which are classified elsewhere, and excluded by the EC13 standard:

- devices for fetal heart rate monitoring
- pulse plethysomographic devices
- devices that use invasive catheters or sensors
- devices for monitoring ambulatory ECG

Sometimes, the cardiac monitor acts only as a signal acquisition device, and transmits via radio frequency telemetry (or hardwire) the detected ECG waveforms to a central station for processing. If the processing at the central station is only for generating heart rate alarms, the cardiac monitor remains in regulatory Class II (as 74 DRT/II). However, if the processing at the central station involves real-time arrhythmia detection and alarms, the cardiac monitor and the central station are both placed into Class III (as 74 DSI/III), and are not covered by this guidance document.

NOTE: This guidance does not address issues specific to *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., measures heart rate and sounds an alarm when the heart rate falls outside of preset limits, 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

- alarm management for both stand-alone devices and devices networked to a central station.

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 EC13 standard, or 3) conformance to any other standard which meets or exceeds the requirements of the EC13 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 EC13 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 EC13 standard, i.e., a testing issue identified in the EC13 standard is usually (but not always) relevant to the safety and effectiveness of a device. The EC13 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, a 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. EC13 Standard Testing

To show conformance to the EC13 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 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 EC13 standard may be necessary.

If the EC13 standard is chosen by the manufacturer, conformance to the entire standard should be demonstrated. Conformance to 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. Other Standards

If the manufacturer chooses to conform to a standard other than the EC13, it is recommended that they list each requirement of the EC13 standard, compare the other standard to the EC13 requirements, and clearly identify where the other standard does not meet the requirements of the EC13 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.

4. 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

[2] If EC 13 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 on the Recognition and Use of Consensus Standards'). Refer to the CDRH Web page for the most recent list of Recognized Standards.

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 EC13, 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, cardiac monitors 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 EC13 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 EC13 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 EC13-1992, "Cardiac monitors, heart rate meters, and alarms"

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.

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