

Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Draft Guidance for Industry and FDA

Draft Guidance – Not for Implementation

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Cardiac Electrophysiology and Monitoring Branch
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation**

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Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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Class II Special Controls Guidance

Document: Arrhythmia Detector and Alarm;

Draft Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Introduction

This draft guidance document was developed as a special control guidance to support the reclassification of the arrhythmia detector and alarm into class II. The device, as proposed, is intended to monitor an electrocardiogram (ECG)¹ and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia exists. This draft guidance will be issued in conjunction with a Federal Register notice announcing the proposal to reclassify this device type. This guidance is issued for comment purposes only. If a final rule to reclassify this device type is not issued, this guidance document will not be issued as a special control.

Following the effective date of a final rule reclassifying the device, any firm submitting a 510(k) premarket notification for an arrhythmia detector and alarm will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of arrhythmia

¹ An ECG is a record of the electrical activity of the heart recorded at the surface of the body. Each phase of cardiac electrical activity produces a specific wave or complex in which the basic ECG waves are labeled alphabetically beginning with the P wave (atrial depolarization). The P-QRS-T sequence represents the repetitive cycle of the electrical activity of the heart. The QRS complex represents ventricular depolarization and the cycle ends with the return of stimulated ventricular muscle to its resting state (ST segment and T wave sequence). The ST segment is usually isoelectric (i.e., flat on the baseline) but may be slightly elevated or normally depressed. Abnormal deviations of the ST segment may be indicative of some pathologic conditions, such as myocardial infarction.

1 detector and alarm devices. Thus, a manufacturer who intends to market a device of this
2 generic type should (1) conform to the general controls of the Federal Food, Drug &
3 Cosmetic Act (the Act), including the premarket notification requirements described in 21
4 CFR 807 Subpart E, (2) address the specific risks to health associated with arrhythmia
5 detector and alarm devices identified in this guidance and, (3) obtain a substantial
6 equivalence determination from FDA prior to marketing the device, unless exempt from the
7 premarket notification requirements of the Act (refer to 21 CFR 807.85).

8
9 This special control guidance document identifies the classification regulations and product
10 codes for the arrhythmia detector and alarm devices (Refer to Section 4 – **Scope**). In addition,
11 other sections of this special control guidance document list the risks to health identified by FDA
12 and describe measures that, if followed by manufacturers and combined with the general
13 controls, will generally address the risks associated with these arrhythmia detector and alarm
14 devices and lead to a timely premarket notification [510(k)] review and clearance. This
15 document supplements other FDA documents regarding the specific content requirements of a
16 premarket notification submission. You should also refer to 21 CFR 807.87 and other FDA
17 documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) -**
18 **Regulatory Requirements for Medical Devices**,
19 <http://www.fda.gov/cdrh/manual/510kprt1.html>.

20
21 Under “**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial**
22 **Equivalence in Premarket Notifications; Final Guidance**,”² a manufacturer may submit a
23 Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special
24 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of
25 demonstrating substantial equivalence for a new device, particularly once a Class II Special
26 Controls Guidance Document has been issued. Manufacturers considering modifications to their
27 own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

29 **3. The Content and Format of an Abbreviated 510(k)** 30 **Submission**

31 An Abbreviated 510(k) submission must include the required elements identified in 21 CFR
32 807.87, including the proposed labeling for the device sufficient to describe the device, its
33 intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the
34 contents of a summary report to be appropriate supporting data within the meaning of 21 CFR
35 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should
36 describe how this special control guidance document was used during the device development
37 and testing and should briefly describe the methods or tests used and a summary of the test data
38 or description of the acceptance criteria applied to address the risks identified in this document,
39 as well as any additional risks specific to your device. This section suggests information to
40 fulfill some of the requirements of 807.87 as well as some other items that we recommend you
41 include in an Abbreviated 510(k).

² <http://www.fda.gov/cdrh/ode/parad510.html>

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Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 11 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain:

- Description of the device and its intended use. We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to Section 5 for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.³
- Description of device design requirements.
- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)
- Discussion of the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.
- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 7-10 of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, or (2) describe the

³ Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

1 acceptance criteria that you will apply to your test results.⁴ (See also 21 CFR 820.30,
2 Subpart C - Design Controls for the Quality System Regulation.)
3

- 4 • If any part of the device design or testing relies on a recognized standard, (1) a
5 statement that testing will be conducted and meet specified acceptance criteria before
6 the product is marketed, or (2) a declaration of conformity to the standard.⁵ Please
7 note that testing must be completed before submitting a declaration of conformity to a
8 recognized standard. (21 USC 514(c)(2)(B)). For more information, refer to the FDA
9 guidance, **Use of Standards in Substantial Equivalence Determinations; Final**
10 **Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.
11

12 If it is not clear how you have addressed the risks identified by FDA or additional risks identified
13 through your risk analysis, we may request additional information about aspects of the device's
14 performance characteristics. We may also request additional information if we need it to assess
15 the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any
16 additional information that is necessary to reach a determination regarding substantial
17 equivalence.)
18

19 As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that
20 provides all of the information and data required under 21 CFR 807.87 and described in this
21 guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and
22 conclusions as described in Appendix I Suggested Format for Test Reports. Manufacturers
23 considering modifications to their own cleared devices should consider submitting Special
24 510(k)s.
25

26 The general discussion above applies to any device subject to a special controls guidance
27 document. The following is a specific discussion of how you should apply this special controls
28 guidance document to a premarket notification submission for arrhythmia detector and alarm
29 devices.

⁴ If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

⁵ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

4. Scope

The scope of this document is limited to the following device, classified under 21 CFR 870.1025, identified as:

An arrhythmia detector and alarm is a system that monitors the electrocardiogram (ECG) and is designed to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

FDA is proposing to identify this device under 21 CFR 870.1025(a).

Panel

Circulatory System Devices Panel (74)

Product Codes

DSI Arrhythmia Detector and Alarm

MLD Monitor, ST Segment with Alarm

MHX Patient Physiological Monitor (with arrhythmia detection or alarms)

This generic type of device includes arrhythmia monitors and alarm with or without ST segment with alarms.

The product code MHX describes patient physiological monitors that include an arrhythmia detection and alarm component. These devices contain other, non-arrhythmia-related components, such as temperature monitors, non-invasive blood pressure monitors, carbon dioxide monitors, and pulse oximeters. The arrhythmia detection and alarm component of these devices should address the specific risks to health associated with the arrhythmia detector and alarm that are identified in this guidance. You also need to demonstrate substantial equivalence of the additional components of patient physiological monitors in your 510(k) by including appropriate information (device description, bench testing, labeling, etc.) for any non-arrhythmia-related components included in your device. That information will depend on the component.

This generic type of device does **not** include:

ECG with a computerized algorithm that interprets ECG data and provides a diagnostic interpretive statement. These are class II devices under 21 CFR 870.2340 Electrocardiograph.

Devices with arrhythmia analysis algorithms intended to provide therapy, such as automated external defibrillators (AEDs). AEDs use an interpretive algorithm to identify shockable and non-shockable cardiac rhythms and are capable of delivering electrical energy in the fully automated or semi-automated mode (where additional operator steps are required). These

1 will remain class III devices (Product Code, MKJ) according to identification of AEDs that
2 FDA is proposing as 21 CFR 870.1025(b).
3

4 5. Device Description

5 You should identify your device by regulation and product code and include the following
6 information:

7
8 **Device components⁶ and theory of operation.** You should identify all components, system
9 software, and accessories within the scope of the 510(k), and any collateral devices that can
10 be connected or used with the monitor (e.g., personal computers (PCs), database management
11 software, printers).
12

13 **Photograph or drawing of the device.** You should also provide a photograph or drawing of
14 the device. You should also provide a functional block diagram (including all accessories).
15

16 **Functional performance characteristics.** You should describe the functional performance
17 characteristics of the device, including computing capability, the display or storage of
18 information, trending capability, data sampling communication (samples per second, bit
19 resolution, interface), telemetry specifications (e.g., FCC frequency bands, transmission
20 system, antenna), number of beds/patients, printer requirements, system alarms.
21

22 **Arrhythmia processor and analysis software.** You should describe the arrhythmia
23 processor and analysis software (i.e., the arrhythmia detection algorithm, including noise
24 detection and filtering techniques and computerized ST measurement capability).
25

26 **ST segment capability.** For the ST segment capability, you should provide a brief technical
27 description of the aspects of the algorithm listed below, as well as examples of all displays
28 and reports that may be generated by the device.
29

- 30 • isoelectric point determination
- 31 • J-point determination
- 32 • ST segment measurement
- 33 • noise reduction

⁶ Electrode lead wires and patient cables intended for use with arrhythmia detector devices must be in compliance with the test requirements and test methods of subclause 56.3(c) of IEC 601-1 (1998), "Medical Electrical Equipment - Part 1: General Requirements for Safety," Amendment No. 1 (1991), and Amendment No. 2 (1995) as set forth in the mandatory performance standard 21 CFR Part 898. See **Performance Standard for Electrode Lead Wires and Patient Cables**,

- 1 • ventricular and noisy beat rejection
- 2 • response to changes in heart rate

3
4 **Alarm conditions.** You should describe the alarm conditions that will produce an alarm.
5 The description should include whether they are physiologic or technical (device or system)
6 alarm conditions.

7
8 **User interface.** You should describe the user interface, including whether the device can be
9 programmed and the extent of the device’s programmability.

10
11 **Technical specifications.** You should summarize the technical specifications (i.e., product
12 specifications, such as the examples below, with ranges and/or accuracy, and any other
13 functional, physical and environmental specifications of the device).

- 14 • measurement tolerances
- 15 • operating limitations
- 16 • power source specifications
- 17 • modes or settings

18
19
20 **Patient contacting materials.** You should identify the components of the device that are
21 patient contacting. For each component, you should identify the generic material of
22 construction, its supplier, and unique material identifier.

23
24 **Comparison to the predicate device.** You should identify the legally marketed predicate
25 device by model name, number, and manufacturer, and provide the 510(k) number, if
26 available. You should also provide a table that compares your device with the predicate.
27 You should explain why any differences between them do not adversely affect safety and
28 effectiveness. The table should include all of the preceding information in section 6, except
29 for the photograph or drawing, with an emphasis on the following information:

- 30 • The patient population and intended environment of use.
- 31 • Basic technology or characteristics of the device, such as analog or digital technology,
32 electrode configuration, frequency response, input impedance, dynamic range,
33 common mode rejection ratio (CMRR), QRS detection sensitivity, pacemaker pulse
34 rejection, system noise, etc.

35
36
37

<http://www.fda.gov/cdrh/comp/leadwire.html> and the FDA guidance entitled, **Electrocardiograph (ECG) Electrode**, <http://www.fda.gov/cdrh/ode/25.pdf>.

- Level of system communication, transmission characteristics, computer interfaces and other technological features (e.g., hard-wired, radio frequency telemetry, transtelephonic and/or fax capability.).
- Heart rate indicators and alarms system (alarm levels and management) for both standalone devices and devices connected or linked to a central station.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the arrhythmia detector and alarm devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device.⁷ The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
misdiagnosis and misclassification of arrhythmias	section 7, 8, 9, 10, 11
incorrect pacemaker pulse detection	section 7, 8, 9, 10
delayed response to life threatening arrhythmias	section 7, 8, 9, 10, 11
loss of alarm at central station or bedside	section 7, 10
excessive patient leakage current	section 8

Arrhythmia detectors include parts that are applied to patients and should be considered to have prolonged contact with intact skin. We recommend that you evaluate the biocompatibility of the materials in these parts as described in the International Standard Organization (ISO) standard **ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**. We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).⁸ You should select tests appropriate for the duration

⁷ Remote, real-time arrhythmia detectors, networked systems, and ambulatory wireless systems are examples of device features that may present other risks. We encourage you to contact the review division to discuss the risk analysis and additional testing for these features.

⁸ If your device is labeled sterile, we recommend that you follow the guidance for devices intended for contact with intact skin in **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>.

1 and level of contact with your device. If *identical* materials are used in a predicate device with
2 the same type and duration of patient contact, you may identify the predicate device in lieu of
3 performing biocompatibility testing.

4 **7. Software Validation Activities**

5 Please refer to the **Guidance for the Content of Premarket Submissions for Software**
6 **Contained in Medical Devices** (hereafter, the *Software Guidance*),
7 <http://www.fda.gov/cdrh/ode/software.pdf>, for a discussion of the software documentation that
8 you should provide. As discussed in the *Software Guidance*, the "level of concern" is related to
9 the possible consequences of software failure, and may be minor, moderate, or major. The
10 software for arrhythmia detectors is generally considered a "major level of concern." If you
11 believe that the software in your arrhythmia detector should be consider a minor or moderate
12 level of concern, you should provide a clear scientific justification that discusses the possible
13 consequences of a software failure.

14
15 We encourage you to take advantage of any recognized software standards and provide
16 statements or declarations of conformity as described in FDA guidance, **Use of Standards in**
17 **Substantial Equivalence Determinations**, already cited. Please visit the following website to
18 search for the standards that have been recognized when a medical device contains software,
19 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. We have created a
20 supplemental information sheet for each software standard that we have recognized. The
21 supplemental information sheet includes a table indicating the documentation that you should
22 include in a submission when a declaration of conformity is provided.

23
24 If the device includes off-the-shelf software, you should provide the additional information as
25 recommended in the **Guidance for Industry, FDA Reviewers and Compliance on Off-the-**
26 **Shelf Software Use in Medical Devices**, <http://www.fda.gov/cdrh/ode/1252.html>.

27 **8. Electrical Safety and Environmental Handling Testing**

28 You should evaluate the electrical safety of your device as well as its ability to function after
29 exposure to environmental handling hazards. We recommend that you evaluate your device
30 according to **one or more** of the following standards:

- 31
32 • International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment
33 - Part 1: General Requirements for Safety
- 34
35 • Advancement of Medical Instrumentation (AAMI) EC 11, Diagnostic
36 Electrocardiographic Devices
- 37
38 • Underwriters Laboratory (UL) 2601-1 Amendment 1 Medical Electrical Equipment:
39 General Requirements for Safety
- 40

- 1 • American National Standards Institute (ANSI)/AAMI ES-1 Safe current limits for
2 electromedical apparatus
- 3
- 4 • IEC 60529 Degrees of protection provided by enclosures (IP Code) Consolidated Edition
- 5
- 6 • IEC 60068-2 Environmental Testing - Part 2: Test methods.
- 7

8 The features and design of your device will determine which of the above standards you should
9 use and whether other standards are appropriate in addition to or in place of these. Please contact
10 the Cardiac Electrophysiology and Monitoring Branch to discuss which standards are appropriate
11 for your device's features and design.

12 **Arrhythmia Detectors used in Transport Environments**

13
14 If your device is intended to be used in a transport environment such as an ambulance, you
15 should test your device according to the standards listed below for shock and vibration.

- 16
- 17 • IEC 68-2-6 (1982) with Amendment 1-1983 and Amendment 2-1985: Basic
18 Environmental Testing Procedures part 2: Tests. Vibration (Sinusoidal)
- 19
- 20 • IEC 68-2-6 (1982) with Amendment 1-1983 and Amendment 2-1985: Basic
21 Environmental Testing Procedures part 2: Tests. Shock
- 22
- 23 • IEC 68-2-6 (1982) with Amendment 1-1983 and Amendment 2-1985: Basic
24 Environmental Testing Procedures part 2: Tests. Random Vibration Wide Band –
25 Reproducibility Low.

26 **9. Electromagnetic Compatibility**

27 Electromagnetic compatibility (EMC) encompasses both emissions, which is interference with
28 other electronic devices and immunity, which is interference with device performance created by
29 emissions from other electronic devices. We recommend that you evaluate the EMC of your
30 device as discussed below.

31 **Emissions**

32 EMC testing should demonstrate that the device will not adversely interfere with the
33 performance of other electronic devices (*emissions*). Testing should include radio frequency
34 (RF) electromagnetic, low frequency magnetic, and conducted emissions.

35 **Immunity**

36
37 EMC testing should also demonstrate that the device will perform as expected in the presence
38 of other electrical and electronic devices or other sources of electromagnetic disturbance
39 (EMD) in the intended environment of use (*immunity*). The device should operate in an
40 acceptable manner (few EMC standards require operation within specification) during and
41 after exposure to various forms of electromagnetic disturbance. Testing should include:
42

- 1 • electrostatic discharge (ESD)
- 2 • radiated RF electromagnetic fields
- 3 • electrical fast transients and bursts
- 4 • surges
- 5 • conducted RF electromagnetic energy
- 6 • voltage dips, short interruptions, and voltage variations on power supply input lines
- 7 • low-frequency magnetic fields
- 8 • quasi-static electric fields.

9
10 We recommend that you test your device according to IEC 60601-1- 2 Medical Electrical
11 Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility --
12 Requirements and Tests (Second Edition, 2001) to demonstrate the EMC characteristics of your
13 device.

14 **Ambulatory Monitoring Systems**

15
16 If your device is intended for use as an ambulatory monitoring system, you also should test
17 your device according to AAMI EC 38-1998 Ambulatory Electrocardiographs. Part 4.2.10
18 Electromagnetic Compatibility.

19 **Arrhythmia Detectors used in Transport Environments**

20
21 FDA believes an arrhythmia detector intended for use in an ambulance should demonstrate
22 immunity to a field strength of 20 V/m or greater (rather than the 3 V/m specified in IEC
23 60601-1-2). Therefore, we recommend that you test immunity to a field strength of at least
24 20 V/m according to the method described in IEC 60601-1- 2.

25
26 As an alternative to following IEC 60601-1- 2 and, where applicable, EC 38, you should
27 identify:

- 28 • the possible sources of EMI (Electromagnetic Interference) that could affect the device
- 29
- 30 • each intended use environment (e.g., hospital general ward, hospital intensive care or
31 critical care unit, clinic, vehicle/traffic areas, emergency vehicle)
- 32
- 33 • the selected test method, and provide a justification for its use, and test reports that
34 conform to Appendix I Suggested Format for Test Reports. Testing should be applicable
35 to the environments you've identified and address emissions and immunity.
- 36

37 **10. Performance Testing**

38 The accuracy of the automated arrhythmia detection and ST segment measurement algorithms is
39 generally demonstrated by ECG waveform database testing described below. FDA believes that
40 if a device has only been tested for its accuracy in detecting specific arrhythmias or ST level
41 changes, it should be labeled only for that purpose.

1 **ECG and/or Cardiac Monitor Capabilities**

2 We recommend that you evaluate the ability of your device to perform basic cardiac
3 monitoring and ECG functions according to the following:

- 4
- 5 • AAMI EC 13-1993, Cardiac Monitors, Heart Rate Meters and Alarm.
- 6 • AAMI EC 11-1991, Diagnostic Electrocardiographic Devices.

7 If your device is intended for use as an ambulatory monitor, you should also test your device
8 according to AAMI EC 38-1998, Ambulatory Electrocardiographs.

9

10 **Algorithm Evaluation of the Automated Arrhythmia Detection Accuracy**

11 You should follow the recommendations in ANSI/AAMI-EC 57:1998, Testing and Reporting
12 Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms for
13 testing the beat-detection algorithm. If you use an alternative test method, you should
14 describe the method, objective(s) of the testing, and any limitations of the test method. You
15 should report accuracy as specificity and sensitivity. Automated test methods need to be
16 reproducible in order to be evaluated.

17

18 Most arrhythmia detectors detect abnormal beats by feature extraction/clustering, template
19 matching, or both methods in combination. Any testing needed in addition to that described
20 in AAMI EC 57 for your arrhythmia detector will vary depending on its intended use,
21 operational features, and the kind of data generated.

22

23 For all arrhythmia detectors, you should include the following basic information about
24 system accuracy in your summary report.

- 25
- 26 • An identification of the algorithm for arrhythmia detection. You should discuss the
27 over-all detection scheme employed by the arrhythmia detector.
- 28
- 29 • A list of the criteria used in the assessment of each arrhythmia. These criteria should
30 be based on empirical data that are used by electrocardiographers in making ECG
31 determinations.
- 32
- 33 • A complete description of any testing procedures and databases of tapes, if they are
34 not in EC 57.

35

36 We recommend that you evaluate the algorithm with at least two databases of tapes. The
37 database used to develop the device's algorithm should not be used to test and verify the
38 performance of the device. Annotation of the cardiac rhythms should be performed by at
39 least three qualified cardiologists. The waveforms utilized should generally be from actual
40 patient ECG recordings. Simulated tapes should only be used when existing databases do not
41 include a sufficient number of examples of a particular arrhythmia. If you use simulated
42 tapes for a particular arrhythmia, because it is too rare to obtain sufficient numbers of actual

1 patient ECGs, you should submit a brief statistical validation of its rarity. This statistical
2 validation may be based on peer-reviewed literature.

3
4 If the database of tapes used to validate the system is not in EC 57, you should provide
5 validation information supporting the use of that database. This information should describe
6 the development of the database in detail.

7 8 **ST Segment Measurement**

9 For devices with the ability to automatically measure and display or trend changes in the ST
10 segment, you should follow EC 38, 4.2.14 Automated Analysis and 4.2.15 Minimum
11 requirements for Clinical Report. You should explain if you modified or did not use the test
12 methods specified in EC 38 or if any section of EC 38 4.2.14 or 4.2.15 is not applicable to
13 your device.

14
15 EC 57 also describes testing and reporting performance results of the ST segment
16 measurement algorithms.

17 18 **Alarm System**

19 The arrhythmia system should accurately alarm for critical, life-threatening arrhythmias
20 within a few seconds of the onset of the arrhythmia. You should follow the technical
21 standards for alarms in EC 13.

22 23 **Other Standards**

24 If you choose to follow standards other than the AAMI EC standards described above, we
25 recommend that you list each requirement of the other standard. If the other standard is not
26 recognized, you should compare its requirements with the requirements described in these
27 AAMI EC standards and the identify where they differ. The list of FDA recognized
28 consensus standards is available on the web at <http://www.fda.gov/cdrh/modact/recstand.html>
29

30 31 **Clinical Studies**

32 In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997,
33 the agency will rely upon well-designed bench and/or animal testing rather than requiring
34 clinical studies for new devices unless there is a specific justification for asking for clinical
35 information to support a determination of substantial equivalence. While, in general, clinical
36 studies will not be needed for most arrhythmia detector and alarm devices, FDA may
37 recommend that you collect clinical data for arrhythmia detector and alarm devices with:

- 38 • designs dissimilar from designs previously cleared under a 510(k) such as those
39 incorporating significant new features or algorithm techniques
40
- 41 • new technology, i.e., technology different from that used in legally marketed
42 arrhythmia detectors

- indications for use dissimilar from arrhythmia detector and alarm devices of arrhythmia detectors of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. Please contact the Cardiac Electrophysiology and Monitoring Branch to discuss any clinical testing before initiating studies.

11. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).⁹

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

ST algorithm

In addition, the ST-Segment monitor labeling should disclose the following statement, or an equivalent statement: "The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician."

⁹ Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

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Appendix I Suggested Format for Test Reports

If you choose to submit a traditional 510(k) or if you use test methods not given in the standards cited in this guidance, you should submit test reports. These test reports should include the following elements, or a justification for their omission:

1. **Test protocol**, which minimally includes:
 - a. the purpose of the test,
 - b. a clear description (with schematics) of the test set-up and any device modifications,
 - c. the identification and precision of the equipment used,
 - d. step-by-step descriptions of the data collection methods and device modes used, and
 - e. the 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.

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

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