



**Medtronic**

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Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

CC: Dr. Oscar Tovar, FDA Office of Device Evaluation

Subject: Reclassification of Automated External Defibrillators (AEDs)  
[Docket No. 1994N-0418]

Dear Dr. Tovar:

We are writing in response to your letter of July 13, 2005. You requested additional information in the following areas:

**(1) Please comment on the need for usability testing, particularly as these devices may now be considered for over-the-counter status. Please comment on what aspects of usability are considered most critical. Please offer a proposal for how to appropriately conduct these studies in terms of methodology, sample size, and pass fail criteria.**

#### **The Need for Usability Testing**

Medtronic Emergency Response Systems believes that usability testing is an important part of the human factors engineering process and a critical step for validating the design of automated external defibrillators, whether they are prescription or over-the-counter. The Quality System Regulation Design Controls regulation requires testing of the products under "actual or simulated use conditions". Usability testing requirements should be applied to demonstrate the product can be safely and effectively used by the intended users, regardless of the prescription status of the device.

#### **Aspects Considered Most Critical**

It is important that usability testing be integrated with risk analysis, both to identify use errors and to validate risk mitigations. With respect to AEDs, usability testing should include simulations that exercise all the normal operational modes of the product. The usability test should ensure actual use scenarios are integrated into the test procedure, that the appropriate user groups are included, and that environmental influences are addressed in the procedure. Critical steps in the use of AEDs include preparing the AED for use (ensuring readiness), applying the electrodes, refraining from moving or touching the

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patient during analysis or shock, and delivering a shock, if needed, within a critical time period (3-5 minutes). When a usability test is designed to simulate the use of the AED on a cardiac arrest victim, these critical steps should be measured and made part of the pass/fail criteria.

Another important aspect, especially for the minimally trained user, is validating the adequacy of the training materials. Usability testing should demonstrate that the materials provided with the product adequately transfer knowledge to the user about the safe and effective use of the product.

### **Methodology, Sample Size, and Pass/Fail Criteria**

There are several guidance and standards documents that speak to usability and human factors.<sup>1, 2, 3</sup> These documents generally apply to all medical devices and not specifically to AEDs.

In concert with the IEC usability standard the rigor of the usability effort should be determined on a case-by-case basis, depending on the newness of the device, the complexity of the user interface and the risk for use error. For example, if an AED product introduces an entirely new technology, method or user interface, more evaluations and testing with more users should be done than would be necessary for an AED design that is similar to other marketed devices.

In certain circumstances, the usability test sample size should be statistically based, for example, if the product is intended to be used by a new user group for which there is little field experience. In other circumstances sample sizes between 5 – 20 users would be adequate, e.g. validation of a minor change to a currently marketed AED or focused usability tasks such as validating electrode replacement instructions, or assembling supplies in a carry case. When multiple iterations of a design have been tested, final validation with as little as 5 users (of a homogenous user group) may be sufficient.<sup>4</sup>

Pass/fail criteria should be determined by either (a) the level of risk to the patient and user should the task under test not be met or (b) the lower confidence level desired when statistical approaches are used. When non-statistical approaches are used, pass criteria may be 80, 90 or 100% of user success, again dependent on the criticality of the task(s). Rationale for the pass/fail criteria should be provided in the documentation of the test procedure.

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<sup>1</sup> IEC 60601-1-6 Medical electrical equipment – Part 1-6: General Requirements for safety – Collateral Standard: Usability

<sup>2</sup> US DHHS Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management; July 19, 2000.

<sup>3</sup> ANSI/AAMI HE74:2001 Human Factors Design Process for Medical Devices

<sup>4</sup> Virzi (1990), Proceedings of the Human Factors Society 34th Annual Meeting

## **Conclusion**

Medtronic Emergency Response Systems believes that usability testing is a critical aspect of design validation. The approach to conducting a usability test is dependent on the product, the objectives of the test, and the intended users. At a minimum, a simulated use test that exercises the normal operating modes of the AED with the intended users should be conducted. Labeling validation should also be conducted. Additional user testing and pass/fail criteria should be based on the risk analysis and analysis of critical tasks.

**(2) Identify all the risks associated with a device and the ways in which special controls can be used to mitigate those risks. Assess risks associated with the use of AEDs and the ways in which special controls can be used to mitigate them. Comment on whether OTC status of these devices raises new risks, and if so how they would be mitigated by special controls.**

On August 14, 1996 Advamed (then HIMA) submitted a petition to FDA on behalf of its members requesting that AEDs be reclassified. The petition and related correspondence provided extensive information about the risks associated with AEDs and the ways in which Special Controls can be used to mitigate those risks.

## **Risks**

Medtronic ERS is not aware of any risks associated with AEDs beyond those identified in the 1996 Advamed petition. These risks are consistent with those of other similar Class II devices and do not justify a Class III designation. Medtronic ERS believes there are no new hazards presented by over-the-counter status. OTC status does not change the intended user or the intended use environment. As stated above, usability testing requirements should be applied to demonstrate the product can be safely and effectively used by the intended users, regardless of the prescription status of the device. Medtronic ERS has been manufacturing home-use, lay user AEDs since 1986.

## **Special Controls**

In recent years standards committees, industry, and the medical community have done extensive work in the area of international standards and guidelines applicable to AEDs. These new standards and guidelines for usability, design, performance and safety risk management can be used by FDA as special controls to effectively regulate AEDs.

## **Defibrillator Standards**

The primary international standard for external defibrillators is the International Electrotechnical Commission (IEC) document 60601-2-4, Medical Electrical Equipment, Part 2-4, Particular requirements for the safety of cardiac defibrillators. The second edition of this standard was published in 2002. This standard amends and supplements IEC 60601-1 (second edition, 1988): Medical electrical equipment – Part 1: General

requirements for safety, an FDA-recognized standard. Improvements from the first edition include new and improved safety requirements for AEDs.

Recently, the Defibrillator Standard Committee of the Association for the Advancement of Medical Instrumentation (AAMI) approved the adoption of IEC 60601-2-4 as the new American Standard for external defibrillators. The new standard, AAMI DF80, maintains the full content of IEC 60601-2-4:2002 and also includes additional requirements that the AAMI Defibrillator Committee deemed important for standardization for self-adhesive defibrillation electrodes and external pacemakers (as applicable). The new standard replaces the previous AAMI standards, ANSI/AAMI DF2:1996 for manually operated external defibrillators and ANSI/AAMI DF39:1993 for automated external defibrillators (AEDs).

### **Safety Risk Management Standards**

The international standard for Safety Risk Management, ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices, establishes the requirements for a comprehensive safety risk management approach to the development of medical devices. It is being adapted into the third edition of IEC 60601-1 and should be followed by all AED manufacturers.

### **Usability Standards**

Usability standards and guidelines are discussed above. The IEC International Standard for Usability<sup>1</sup> would be a useful special control for AEDs.

### **Guidelines**

Resuscitation experts have been actively involved in developing guidelines for cardiopulmonary resuscitation and emergency cardiovascular care using an evidence-based evaluation process.

For example, the American Heart Association (AHA) published *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, International Consensus on Science*, Circulation, 2000; 102(Supplement I). Part 4 of the guidelines, “Automated External Defibrillator, Key Link in the Chain of Survival” provides extensive background, discussion and clinical literature references regarding AEDs and is the most definitive reference on the subject today. *Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care* is expected to be published in December 2005.

AHA has also addressed the requirements for essential performance of AED ECG rhythm recognition detectors. This topic has been the object of considerable clinical/industry collaboration recently, and has resulted in useful, insightful, and statistically meaningful methods of specifying the performance of such systems. The new IEC and AAMI

standards have adopted the results of these efforts. AHA published the recommendations in the following reference:

“Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety, A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy”

This reference may be accessed via the internet at  
<http://www.americanheart.org/presenter.jhtml?identifier=1656>

### **Conclusion**

As you can see, standards committees, industry and the medical community have been very active in the creation and international harmonization of standards and guidelines. These new standards now provide manufacturers, health care providers and regulators with a cohesive set of requirements for standardized control of key safety and performance aspects of both manual and automated external defibrillators.

Medtronic ERS believes that Special Controls are available for FDA to support the reclassification of AEDs to Class II. We are not aware of risks associated with AEDs beyond those identified in the 1996 AdvaMed petition. Such risks are consistent with those of other similar devices classified in Class II and do not justify a Class III designation.

### **(3) Justify why pre-approval review and inspections of Quality System information are not necessary to control risks**

Since 1996 the FDA has required manufacturers of class II and III devices to develop product designs in conformance with design control requirements of 21 CFR 820. The FDA Quality System Inspection Technique (QSIT) is incorporated into the FDA facility inspections, internal assessments and other 3rd party reviews. The Design Control subsystem is part of this inspection technique.

Manufacturers of Class II and class III devices are subject to inspection by FDA at any time. The primary distinction between the inspections for Class II and III PMA devices is that inspection of Class III PMA devices must take place before the approval. Although as you state, “A Class II 510(k) device does not require premarket review of Quality System information, does not require pre-approval inspections and may potentially be inspected with less frequency than a Class III PMA device” the timing and frequency of inspections of Class II devices is still completely subject to FDA discretion. In this way the FDA has adequate tools at its disposal to effectively regulate the design control systems of AED manufacturing if these devices are regulated under the Class II designation.

Historically FDA has inspected our facility at least every two years and at times, more frequently. During these inspections, FDA has the opportunity to review the adequacy of design control and design change processes and systems. This frequency of facility inspection already provides a current assessment and status of Quality System information.

Product recalls and field actions are individually reviewed with FDA. Corrective and preventive action plans associated with these field actions are also reviewed by FDA with effectiveness reviews being performed at the end of the recall.

The pre-approval inspections required by the Class III process would add no additional value to FDA's regulatory oversight of AEDs, given that the Class II paradigm provides FDA with ample authority to inspect as necessary. Therefore, the significant additional burdens imposed by a Class III designation both for FDA and industry would not be appropriate.

Regards,

MEDTRONIC EMERGENCY RESPONSE SYSTEMS



James W. Dennison  
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