Technical Information Report

AAMI TIR61: 2014/(R)2019

Generating reports for human factors design validation results for external cardiac defibrillators

AAMI
Advancing Safety in Health Technology

Generating reports for human factors design validation results for external cardiac defibrillators

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Abstract: Provides guidance on the formatting and content of reports generated for the purpose of submitting human factors data for evaluation.

Keywords: defibrillation, human factors, usability, external defibrillator, automated external defibrillator

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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AAMI/DF Defibrillator Committee

This Technical Information Report was developed by the AAMI/DF Defibrillator Committee. The draft of this document was circulated to the AAMI/HE Human Factors Engineering Committee for comments. Committee approval of the Technical Information Report does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI/DF Defibrillator Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report was developed by the AAMI/DF, Defibrillator Committee. The draft of this document was circulated to the AAMI/HE, Human Factors Engineering Committee for comments. The objective is to provide guidance on the Human Factors Engineering (HFE) and usability for external cardiac defibrillators.

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NOTE—This foreword does not contain provisions of AAMI TIR61:2014, *Generating reports for human factors design validation results for external cardiac defibrillators,* but it does provide important information about the development and intended use of the document.

Introduction

External cardiac defibrillators and defibrillator/monitors (defibrillators) treat the most common cause of sudden cardiac arrest, called ventricular fibrillation (VF) and certain ventricular tachycardias by providing the only effective treatment for survival of sudden cardiac arrest (SCA): electrical energy (i.e., a shock) to the heart in order to interrupt the arrhythmia and allow the heart to reestablish a normal rhythm. Defibrillators are indicated for use on unconscious, non-responsive victims who have collapsed due to suspected SCA. The user populations for defibrillators range from untrained lay users to emergency medical services (EMS) personnel to highly trained medical professionals. Use patterns also vary widely. Defibrillators can be found in private homes, public access defibrillator (PAD) programs, corporate and industrial settings, airports, schools, emergency medical response and police vehicles, and hospitals.

Defibrillators are used in urgent, time-critical conditions. The operators, especially home users, are likely to be stressed when they must use the automated external defibrillator (AED) to save a life of a patient or family member. Defibrillators deliver a significant electrical shock and therefore must be safe for the patient bystander and the user. Some defibrillators provide automated or semi-automated defibrillation only; others may provide ECG monitoring and CPR coaching with a feedback device. Still others include additional functions, such as SpO_2, 12-lead ECG, and capnography. The complexity of the defibrillator determines the extent and type of user testing and validation activities required.

Due to the wide range of training and medical knowledge of the potential users of defibrillators, data-driven design of the user interface is key to minimizing use errors.

To achieve a successful interaction design solution, the defibrillator industry should employ human factors (HF)/user-centered design (UCD) process of the proposed defibrillator system.

The design of the defibrillator should minimize the likelihood of use-related failures. The differences in user type and use environments should be evaluated and addressed in the user interface design process. For example, if the intended user of the defibrillator is a home user, then that user might be most effectively guided by the defibrillator's functional design rather than by printed labeling (e.g., instruction manuals). The defibrillator's user interface and sequences of operation (such as voice prompts, primary controls, indicators, and labels) should consider if the users should be able to operate it without training. Further, it is recommended that, prior to validating the usability of the final design through testing, the design process should be guided through formative evaluations to ensure that by the time Human Factors validation testing is done, the design is safe and effective for its intended users and use environments.

This TIR highlights the recommended content of human factors usability validation reports. Appendix A includes recommendations and considerations for the human factors design and formative design evaluation of cardiac defibrillators.

Generating reports for human factors design validation results for external cardiac defibrillators

1 Scope

This Technical Information Report (TIR) applies to the human factors design of external cardiac defibrillators, as covered by ANSI/AAMI/IEC 60601-2-4:2010, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*. The guidance provided by this TIR is intended to be applicable to all external cardiac defibrillator/monitors, and automated external defibrillators (AEDs) including public access defibrillators (PADs).

2 Object

The object of this TIR is to provide guidance on the content of human factors validation reports for external cardiac defibrillators. The intention of providing this guidance is to ensure that the submitted report includes (or, depending on design complexity of the defibrillator, reports include) sufficient and consistent human factors validation data for external cardiac defibrillators.

Appendix A provides considerations for the formative stages of product design and development to achieve successful design and validation of defibrillators.

3 Definitions

3.1 Human factors (HF) engineering

Application of knowledge about human behavior, abilities, tendencies, limitations, and other characteristics related to the design of tools, machines, equipment, devices, systems, tasks, jobs, and environments to achieve safety and adequate usability.

3.2 Usability

Characteristics of the user interface of the defibrillator that facilitate use, specifically the users' ability to perceive information from, understand, and operate the defibrillator according to its intended use. Usability can affect a user's awareness of hazards, ability to recover from use errors, effectiveness, efficiency, learning, and user satisfaction.

3.3 User-centered design (UCD)

A type of user interface design process that provides extensive attention at each stage of the process to the needs, wants, and limitations of end users of a product. It is a problem-solving process that not only requires designers to analyze and foresee how users are likely to use a product, but also to test the validity of their assumptions with regard to user behavior and design in real-world tests with actual users. UCD explicitly optimizes product design to accommodate how users can, want, or need to use the product, rather than forcing them to change their behavior to successfully use the product.

3.4 User interface (UI)

The primary user interface (UI) of a defibrillator consists of controls (controls or switches), graphical user interface (GUI) displays, and audio prompts. Additional optional elements, such as accessories, labeling and quick reference cards, can be included in the UI to support the safe and effective use of the defibrillator. The most effective defibrillator UI varies with the device type (fully automatic, semi-automated, or manual defibrillators, with functionalities that may include ECG analysis, monitoring, and additional functions) as well as its likely use environment.