Technical Information Report

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Human factors engineering for processing medical devices

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Human factors engineering for processing medical devices

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Abstract: Provides guidance on the application of human factors engineering principles to instructions provided by manufacturers for cleaning medical devices.

Keywords: human factors engineering; instructions for use; medical device; processing

AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

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Contents

Page

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www.aami.org/standards/glossary.pdf

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Association for the Advancement of Medical Instrumentation

Human Factors for Device Reprocessing Working Group

This standard was developed by the AAMI Human Factors for Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the **AAMI Human Factors for Device Reprocessing Working Group** had the following members:

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

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Foreword

This technical information report (TIR) was developed by the Human Factors for Device Reprocessing Working Group under the purview of the AAMI Sterilization Standards Committee.

Human factors engineering plays a significant role in the successful processing of medical devices. The objective of this TIR is to provide guidance to medical device manufacturers from a human factors perspective on the aspects of product design; design of processing instructions for use (IFU); education and training design; and development, verification, and validation of the device processing process to meet the needs of personnel working in a health care facility processing environment.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the TIR. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Human factors engineering for processing medical devices

Introduction

Human factors engineering plays a significant role in the successful processing of medical devices. Understanding the full lifecycle of a reusable device from initial use through processing to subsequent use, and the limitations introduced by the intended use environments where processing occurs, could help implement design features to address the device usability and safety. Considering the volume and variety of devices processed in a health care facility, the broad spectrum of device manufacturers, and device similarities existing among manufacturers, a standardized approach to the development of processing instructions for use and subsequent education and training materials is needed to help ensure the processing function can be executed accurately, completely, and consistently.

1 Scope

This document provides guidance to medical device manufacturers from a human factors perspective on the aspects of product design; design of processing instructions for use (IFU); education and training design; and development, verification, and validation of the device processing process to meet the needs of personnel working in a health care facility processing environment. Limitations and challenges on human factors imposed by processing environments have a direct impact on the effectiveness of product designs, processing, IFU, and the processing procedure. The processing lifecycle of the device is considered to be from the point-of-use at the end of a patient procedure to delivery to the point-of-use prior to the next patient procedure.

1.1 Inclusions

This technical information report (TIR) addresses processing as a design element; product design; processing procedures; the development of the IFU; education, training, and competency assessment; and validation from a human factors engineering perspective.

1.2 Exclusions

This TIR does not address processing requirements for devices (see ANSI/AAMI ST79); requirements for the manufacturer on what information should be provided to the user (see ANSI/AAMI ST81 and AAMI TIR12); or the processing of single-use devices.

2 Definitions and abbreviations

2.1 cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

2.2 cleaning validation: Documented evidence of obtaining, recording, and interpreting the results required to establish that a cleaning process will consistently yield product complying with predetermined specifications.

2.3 color coding: (1) Assigning colors to different versions of a like object, typically with the purpose of using the inherent associated meaning of a color to help the user distinguish between the versions (e.g., stop lights, warnings, and error software messages). (2) Use of design elements, such as shape, color, texture, and placement, to communicate information, such as the priority of an alarm condition, or to differentiate user-interface components, such as pushbuttons.

2.4 competency verification: An activity designed to substantiate or confirm the ability of an individual to successfully complete a particular skill, task, complex series of tasks, or behavior necessary to perform effectively.