Technical Information Report

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Post-market surveillance of use error management

AAMI
Advancing Safety in Healthcare Technology

Post-market surveillance of use error management

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AAMI

Abstract: This document will address the issue of use error detection for medical devices from clinical, manufacturer, and regulatory perspective regarding human factors assessment. The goal is to provide guidance on how clinicians and manufacturers can best collect and leverage post-market use error data to improve product safety and usability.

Keywords: human factors, usability, hospital, clinical

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

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