

Technical Information Report

AAMI TIR61: 2014/(R)2019

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

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

Approved 24 October 2014 and reaffirmed 19 September 2019 by
AAMI

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.

AAMI acknowledges the contributions of the AAMI Human Factors group in the development of this TIR.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

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Printed in the United States of America

ISBN 1-57020-568-x

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Committee representation

Association for the Advancement of Medical Instrumentation

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:

- Chairs:* Oscar Tovar-Calderon, MD, FDA/CDRH
Robert J. Zito, Physio-Control
- Members:* Joseph Basta, Spacelabs Medical Inc.
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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.
