Technical Information Report

AAMI TIR51: 2014/(R)2025

Human factors engineering—Guidance for contextual inquiry

AAMI
Advancing Safety in Health Technology

Human factors engineering—Guidance for contextual inquiry

Approved 24 October 2014 and reaffirmed 6 December 2017 and 30 September 2025 by
AAMI

Abstract: Provides guidance on conducting contextual inquiry research that is used to provide information for improving medical procedures, environments, training, and/or devices.

Keywords: human factors engineering, research, usability

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 43101 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Published by

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2014 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 978-1-57020-570-5

Contents

Page

Committee representation iv
Foreword vi
1 Definition 1
2 Purpose 1
3 Intended users of this document 2
4 Rationale 2
5 Applications 2
6 Research methodology 3
6.1 Determining roles and responsibilities of study (execution) participants 3
6.2 Conducting preliminary research and creating a research protocol 3
6.3 Determining the participants 4
6.4 Determining the sites 4
6.5 Recruiting the sites 5
6.6 Executing and documenting the research 5
7 Data analysis 7
7.1 Observational Data 7
7.2 Data Derived from Interviews 8
8 Reporting 8
8.1 Unedited video 8
8.2 Highlights video 8
8.3 Spreadsheets 8
8.4 Graphic representations 8
8.5 Reports 9
9 Integration into the design of devices, facilities, etc 9
10 Troubleshooting / What to do and not to do 9
11 Example 10
Figure 1 – Example story board format 11
Bibliography 12

Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

This AAMI Technical Information Report (TIR) was developed and approved by the AAMI Human Factors Engineering Committee.

At the time this document was published, the **AAMI Human Factors Engineering Committee** had the following members:

Cochairs: Janine A. Purcell, MS, Philips Electronics North America

Members:
Tor Alden, BS MS, HS Design Inc
Araya Amsalu, PhD, Hill-Rom Holdings
Keith B. Anderson, BSEE, Smiths Medical
Prashant Bhadri, CareFusion
Sherri Biondi, PhD, Genentech Inc
Peter Boge, Novo Nordisk
Richard Botney, MD, Oregon Health & Science University
Bill Buresh, Draeger Medical Systems Inc
Ken Catchpole, Cedars-Sinai Medical Hospital
Ella Cozmi, Hospira Worldwide Inc
Conor Curtin, Fresenius Medical Care
John M DeFoggi, DBA, Business Process & Technology Management LLC (BPTM)
Serge Dubeau, Worrell Inc
Kathi Durdon, Welch Allyn Inc
Evan T. Edwards, BSME MSSE, Kaleo Inc.
Rollin J. Fairbanks, MD MS, MedStar Washington Hospital Center
Daryle Jean Gardner-Bonneau, PhD, Bonneau and Associates
Rosemary Gonzales, Combination Product Partners
Dan Haberstich, Johnson & Johnson
R. Sean Hagen, BlackHagen Design Inc
Diane Hayman, Spacelabs Medical Inc
Wayne Ho, Healthcare Human Factors
Dean A. Hooper, HE Consulting
Shannon M. Hoste, Stryker Instruments Division
Edmond W. Israelski, PhD CHFP, Abbvie
Carolynn Johnson, PhD, Daedalus
Korey R. Johnson, MS, GFK
Mike Kasamanian, Human Factors Consulting Services Inc
Ronald D. Kaye, FDA/CDRH
James Kershner, Eli Lilly & Company
Merrick F. Kossack, MS BS, Intuitive Surgical Inc
Michael Lau, PhD, Insight Product Development
Lee Leichter, P/L Biomedical
Melissa R. Lemke, MS, Agilis Consulting Group LLC
Svetlana Lowry, PhD, National Institute of Standards & Technology
Jennifer Martin, PhD, The University of Nottingham
Marsha McArthur, Integrated Medical Systems
Cindy A. Miller, PhD, GE Healthcare
Jeffrey C. Morang, MS, Ximedica
Mark Moyer, ASQ Biomedical Division
William H. Muto, PhD, Abbott Laboratories
Dan Nathan-Roberts, University of Wisconsin (Madison)
Robert A. North, PhD, Human Centered Strategies
Edward Nuber, B Braun of America Inc
Shawn O'Connell, MS, RN, B Braun of America Inc
David G. Osborn, Philips Electronics North America
Joseph Pri-Paz, MSc, Laniado Hospital
Mary Beth Privitera, University of Cincinnati
Robert G. Radwin, PhD, University of Wisconsin

 © 2014 Association for the Advancement of Medical Instrumentation ■ AAMI TIR51:2014

Tim Reeves, PhD CHFP, Human Factors MD Inc
Arathi Sethumadhavan, PhD, Medtronic Inc WHQ Campus
Adam R. Shames, Core Human Factors Inc
Mani Shanmugham, CR Bard
Vijender Singh, Intertek
Nelson H. Soken, Baxter Healthcare Corporation
Debora Stapleton, Covidien
Robert C. Sugarman, PhD, RCS Performance Systems Inc
Matt B. Weinger, MS MD, Vanderbilt University Medical Center
Tracy Weldon, Kimberly-Clark Corporation
Steven A. White, NxStage Medical Inc
Michael E. Wiklund, PE CHFP, UL LLC
Stephen Wilcox, PhD, Design Science Consulting
Julia Yeh, Amgen Inc

Alternates:
Eric D. Bergman, PhD, Fresenius Medical Care
Barry Berson, Human Factors Consulting Services Inc
Paul A. Blowers, Abbvie
Joseph Cafazzo, Healthcare Human Factors
Joe Cesa, BA, Kimberly-Clark Corporation
Shannon Clark, Intuitive Surgical Inc
Elise Edson, Covidien
Amy Gallenberg, GE Healthcare
Stuart J. Garvin, Eli Lilly & Company
Kimberley Gibson, Johnson & Johnson
Cynthia Ann Lepak, RN, Welch Allyn Inc
Michael Rakauskas, Baxter Healthcare Corporation
Jane Lea Smith, GFK
Kathy K. Smith, Human Factors MD Inc
Joan M. Spear, MBA RM CMPR, B Braun of America Inc
Gerard Torenvliet, Medtronic Inc WHQ Campus
Tom Varricchione, Ximedica

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

Foreword

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 recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the AAMI TIR51, *Human factors engineering – Contextual inquiry* (AAMI TIR51:2014), but it does provide important information about the development and intended use of the document.

 © 2014 Association for the Advancement of Medical Instrumentation ■ AAMI TIR51:2014

Human factors engineering—Guidance for contextual inquiry

1 Definition

Contextual inquiry is the study of people, tasks, procedures, and environments in the “real world”. It applies methods from the social sciences (e.g. cultural anthropology/ethnography), to better understand real-world conditions, for example, how devices are actually used. It involves interviews and observations, often supported by video documentation, in the actual environment of use for a given product or system.

2 Purpose

In the healthcare arena, contextual inquiry is used to inform the design of devices, systems, and/or information (e.g., instructions for use—IFUs—or training). Goals include:

— Creating a deeper understanding of users, use environments, tasks and procedures than can be achieved by interview-based methods alone.

  Contextual inquiry provides a body of information about the constraints that a new device or system must operate within as well as a better understanding of met and unmet user needs.

— Identifying problems with existing devices and systems that a new design can address.

  Analyzing overall procedures in context can provide information as to the function of the device and increase knowledge for task analysis.

— Providing insight into the viewpoints of users.

  The viewpoints of those who *develop* medical devices and systems are, as a rule, different from the viewpoints of those who *use* them. One goal of contextual inquiry is to allow the developers to see things from users' points of view.

— Providing insight into user profiles including capabilities and limitations.

  Devices often have multiple users (e.g., physicians, nurses, biomeds, patients), each of which can be profiled via contextual inquiry.

— Providing insight for the purposes of determining appropriate “Instructions for Use” (IFU) and to tailor training requirements for specific users.

— Providing evidence to inform design decisions.

  Many design decisions have to take the facts of actual use into account. Contextual inquiry can provide evidence about these facts.

— Informing usability testing.

  Valid usability testing requires a set of to-be-tested tasks that closely mirrors those to be expected in real environments. Contextual inquiry can provide evidence regarding what the real tasks are and the environments in which they are performed.

— Providing information about users, use environments, and procedures that can be distributed to entire design teams.

  Design teams tend to work more effectively when all team members have equivalent information to define the to-be-solved problems. An important role of contextual inquiry is to provide information to allow

© 2014 Association for the Advancement of Medical Instrumentation ■ AAMI TIR51:2014