

# Technical Information Report

## AAMI TIR51: 2014/(R)2017

Human factors engineering  
—Guidance for contextual  
inquiry

**AAMI**

Advancing Safety in Healthcare Technology

## Human factors engineering—Guidance for contextual inquiry

Approved 24 October 2014 and reaffirmed 6 December 2017 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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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](http://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) 525-4600; Fax: (703) 525-1067.

Printed in the United States of America

**ISBN 978-1-57020-570-5**

# Contents

Page

Committee representation.....	iv
Foreword.....	vi
<b>1</b> Definition.....	1
<b>2</b> Purpose.....	1
<b>3</b> Intended users of this document.....	2
<b>4</b> Rationale.....	2
<b>5</b> Applications.....	
<b>6</b> Research methodology.....	3
<b>6.1</b> Determining roles and responsibilities of study (execution) participants.....	3
<b>6.2</b> Conducting preliminary research and creating a research protocol.....	3
<b>6.3</b> Determining the participants.....	4
<b>6.4</b> Determining the sites.....	4
<b>6.5</b> Recruiting the sites.....	5
<b>6.6</b> Executing and documenting the research.....	5
<b>7</b> Data analysis.....	7
7.1 Observational Data.....	7
7.2 Data Derived from Interviews.....	8
<b>8</b> 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
<b>9</b> Integration into the design of devices, facilities, etc.....	9
<b>10</b> Troubleshooting / What to do and how to do.....	9
<b>11</b> 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 Haberstick, 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, C. E. F., Abbvie  
Carolynn Johnson, PhD, D. Odalus  
Korey R. Johnson, MSc, FK  
Mike Kasamarian, Human Factors Consulting Services Inc  
Ronald D. Kave, FDA/CDRH  
James Kerstner, Lilly & Company  
Merrick F. Kosciak, 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  
Jonathan 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

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  
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, Ximeda

*Alternates:*

---

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.

---

# 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, biomed, 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

members of device design teams to be able to work from the same information regarding the actual facts of use.

- Identifying success with existing devices and systems that should be preserved in a new design.

### 3 Intended users of this document

This document is prepared for anyone involved in medical device development particularly the "front end" or pre-design-control phase. This may include engineers, designers, researchers, and marketing and regulatory professionals.

### 4 Rationale

So why is it necessary to conduct contextual inquiry instead of simply relying upon interview-based methods to determine the characteristics of users, use environments, and procedures? One big reason is to improve factual accuracy. There is enormous evidence that what people say is not always factually accurate (cf., Holmström, et al., 1993; Appleton, 1995). Thus, relying exclusively on interview methods without "real-world" observation, design teams may pursue solutions that do not meet the needs of the majority of users. In fact, there is enormous evidence that what people say is not always factually accurate.

Some information (e.g., timing details) is unknown by users because obtaining it requires measurements that are not taken. Other information cannot be articulated because much of human conduct is largely unconscious. This absence of consciousness particularly characterizes highly skilled behavior (e.g., suturing by experienced surgeons). Another problem is that, when interviewed, various motivations (e.g., agreeing with others, telling people what they expect to hear) undermine accuracy. Also, obtaining some relevant information requires expertise that users do not have—e.g., the frequency of clinically significant errors or injury-inducing postures.

In addition to improving factual accuracy, relative to interviews, contextual inquiry is a tool for bridging the "cultural gap" between system users and system developers. When the two are together for a period of time in the user's environment, the interviewee has a chance to learn more fully what the researcher is asking, and the researcher has a chance to learn more fully what the interviewee means by a given answer. A contextual setting can provide the interviewee with familiar cues to allow for a more productive and interactive observations when compared to a simulated setting. Often, participants will demonstrate device use and recall important considerations when they are in their own environments of use.

### 5 Applications

Contextual inquiry is a tool for (and frequently used for) designing better devices, systems, processes and information-based materials, such as IFUs; however, as discussed below, it also has other applications. It generally takes place at the beginning of a design project, since it provides input to the design process, including the development of design requirements. The applications include:

- Supporting benchmarking activities by providing information about existing/competitive systems and their use in the same intended environment.
- Supporting risk analysis by providing objective information about use errors or conditions that can lead to use errors and/or outcomes that can lead to patient (or user) harm.
- Providing input to the development of training programs, including the capture of examples to be incorporated into training.
- Supporting the development of improved procedures by finding errors and/or inefficiencies that can be eliminated.
- Providing information about who performs tasks in order to determine screening criteria for later usability testing.
- Developing user profiles.
- Enabling detailed task analysis and functional analysis.
- Verifying key use cases, critical decision points, pain-points (dis-satisfiers), points of satisfaction (satisfiers), and areas of design opportunity to optimize use and aid decision-making.