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# Technical Information Report

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## AAMI TIR51: 2014/(R)2017

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Human factors engineering  
—Guidance for contextual  
inquiry

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**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

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## 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.

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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.

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# 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