Technical Information Report

AAMI TIR130:2025

Best Practices for Designing Accessible At-Home Diagnostic Test Kits

AAMI
Advancing Safety in Healthcare Technology

Best Practices for Designing Accessible At-Home Diagnostic Test Kits

Approved 24 October 2025
AAMI

Abstract

This technical information report provides recommendations for the design of at-home diagnostic test kits to provide greater accessibility for users with no vision or low vision, a reduced range of dexterity or motor skills, and/or age-related disabilities, and to provide greater usability for all users.

Keywords

human factors, accessibility, disability, at-home diagnostics, test kits, design, usability

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Published by

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

© 2025 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 the Copyright Clearance Center.

ISBN 978-1-57020-916-1

About AAMI

The Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization founded in 1967. As the global leader in developing national and international consensus standards, AAMI has built a robust network of over 14,000+ members across more than 70 countries. This diverse and engaged membership includes industry leaders, healthcare professionals, and government representatives working together to improve patient safety and healthcare outcomes.

© 2025 Association for the Advancement of Medical Instrumentation ■ AAMI TIR130:2025

Table of Contents

Committee Representation i
Foreword iv
1 Background 1
2 Purpose 2
3 Scope 3
4 Glossary 4
5 Table of Symbols 7
6 Design Considerations 9
7 Characterizing Intended Users and User Needs 11
8 Engaging User Advocacy Groups 12
9 Assessing Usability 13
10 Instructions 14
10.1 Legibility 15
10.2 Formatting and Layout 20
10.3 Language 23
10.3.1 Plain Language 23
10.3.2 Descriptive Language 26
10.3.3 Alternative Text 29
10.3.4 Braille 30
10.4 Illustrations and Symbols 31
10.5 Printed Instructions 37
10.6 Digital Embodiment 41
10.6.1 Operating System Compatibility 41
10.6.2 Assistive Technology Compatibility 43
10.6.3 User Interface and Experience Features 46
10.6.4 Interactive Voice Response System 48
10.6.5 Video Tutorial 50
11 Physical Components 53
11.1 Outer Packaging 54
11.1.1 Labeling 54
11.1.2 Accessing Contents 60
11.2 Test Kit 63
11.2.1 Organization 63
11.2.2 Component Packaging and Internal Pouches 68
11.3 Swab 72
11.4 Fluid Vials and Sample Preparation 74
11.5 Cassette 81
11.6 Test Result Reader 86
11.7 Disposal 94
12 Test Procedure 95
12.1 Bluetooth Pairing 96
12.2 Test Result Analysis 98
12.3 Test Results Communication 99
13 References 102

© 2025 Association for the Advancement of Medical Instrumentation ■ AAMI TIR130:2025

Committee Representation

This AAMI technical information report (TR) was developed and approved by the Human Factors Engineering Committee.

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

Cochairs

Mary Beth Privitera
Molly Story

Members

Natalie Abts	Genentech, Inc
Tor Alden	HS Design, Inc.
Robert Albert	Eli Lilly & Company
Sasoon Arutyunyan	Human Factors Design Consulting, Inc.
Jahan Azizi	Getinge USA
Janey Barnes	User-View, Inc.
Alexandre Bassard	NEMERA Insight Innovation Center
Alexandra Benbadis	Sanofi
Eric D. Bergman	Fresenius Medical Care
Peter Boge	Novo Nordisk
Richard Botney	Oregon Health & Science University
Lu Bu	LivaNova, PLC
Sarah Burleton	GE HealthCare
Cathy Castro	Vested Medical, LLC
Joe Cesa	Medtronic, Inc.
Brittany Conrad	Pfizer Parenteral Center of Excellence
Kate Cox	HS Design, Inc.
Ella M. Cozmi	Intuitive Surgical, Inc.
John M. DeFoggi	Business Process & Technology Management, LLC
David A. Detmer	Veterans Administration
Wende Dewing	Usensus, LLC
Anastasia Diamond	West Pharmaceutical Services, Inc.
Shimeng Du	Medline Industries, Inc.
Evan T. Edwards	Individual
Xin Feng	Becton Dickinson & Company
Barry Fulkerson	Kuleana Technology, Inc.
Reade Harpham	Priority Designs, Inc
Jolene Hernandez	WL Gore & Associates, Inc.
Wayne Ho	Healthcare Human Factors
Nathan Hogan	Stryker
Jessie Huisinga	Eli Lilly & Company
Korey Johnson	Bold Insight, Inc.
Jeff Morang	Stratus Design
Greg M. Jung	Pelton & Crane
Madison Laskowski	Design Science Group, LLC
Michael Lau	NEMERA Insight Innovation Center
Jennifer Lehr	B. Braun of America, Inc.
Lee Leichter	P/L Biomedical
Dongping (Don) Lin	Telesair, Inc.
Beth Loring	Loring Human Factors, LLC

© 2025 Association for the Advancement of Medical Instrumentation ■ AAMI TIR130:2025

Albert Lozano-Nieto	Penn State University
Ruiqi Ma	Boston Scientific Corporation
Tanya Magana	Ecolab
Megha Mahadevan-Shah	Cardinal Health
Nicole Mason	Northwest Hospital Center
Susan Maria McDonald	Olympus America, Inc.
Cindy McGaughey	Owens & Minor
Sara McNew	Design Science Group, LLC
Christina Mendat	Eurofins Medical Device Testing
Mark Moyer	ASQ Medical Device Division
Jennifer Nalepka	STERIS Corporation
Dan Nathan-Roberts	San Jose State University
Susan Neadle	Combination Products Consulting Services, LLC
Chris Neoh	Arthrex, Inc.
Robert A. North	Human Centered Strategies
Susumu Nozawa	Siemens Healthineers
David G. Osborn	Philips
Renee Palmer	Amgen, Inc.
Joseph Pri-Paz	Individual
Mary Beth Privitera	Know Why Design, LLC / University of Cincinnati
Robert G. Radwin	University of Wisconsin
Tina Rees	Regeneron Pharmaceuticals, Inc.
Tania Reina	FDA/CDRH
Dina Sifri	Meddevsoft
Richard Allen Sit	ICU Medical, Inc.
Jennifer Soosaar	Core Human Factors, Inc.
John-Paul Stephens	Abbott Laboratories
Molly Story	Human Spectrum Design, LLC
Robert C. Sugarman	RCS Performance Systems, Inc.
Mark Swanson	Quality and Regulatory Expert Partners
Amy Trudel	Draeger Medical Systems, Inc.
Andres Uribe	Northgate Technologies
Tiffany Warner	Johnson & Johnson
Matt B. Weinger	Vanderbilt University Medical Center
Dean Wellman	Midmark Corporation
Michael E. Wiklund	UL, LLC

Alternates

Emily Borst	Stryker
Ray Boudreaux	Cook Medical - Bloomington
Joseph Cafazzo	Healthcare Human Factors
Bradley John Catalone	Getinge USA
Marshall Dean	Owens & Minor
Lynn Dixon	Boston Scientific Corporation
Thomas H. Engh	Medtronic, Inc.
Jason Flint	FDA/CDER
Denise Forkey	Clarimed, Inc.
Kathleen Gallo	Arthrex, Inc.
Michael Groendyk	West Pharmaceutical Services, Inc.
Kathryn Hansbro	Design Science Group, LLC
Merrick F. Kossack	UL, LLC
M. Dominika Kulinski	Fresenius Medical Care
Shelly Leacock	Veterans Administration
Willy Liou	Amgen, Inc.
Ben Loomis	B. Braun of America, Inc.
Natalia Mazaeva	Abbott Laboratories
Megan Moss	Pfizer Parenteral Center of Excellence
Horacio Pace Bedetti	Novo Nordisk

© 2025 Association for the Advancement of Medical Instrumentation ■ AAMI TIR130:2025

Audra Power	Avanos Medical
Michael Rakauskas	AbbVie
Prabhu Ramachandran	Siemens Healthineers
Eric Shaver	Eurofins Medical Device Testing
Kinza Shekhani	ICU Medical, Inc.
John Simpson	Becton Dickinson & Company
Kaitlin Stinson	Bold Insight, Inc.
Thomas Varricchione	Ximedica
Chelsea Wanta	GE HealthCare
Raymond Yao	Draeger Medical Systems, Inc.
Jennifer Zuba	WL Gore & Associates, Inc.

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.

Acknowledgements

The committee would like to extend its appreciation to the project leaders for their outstanding guidance, dedication, and leadership in the development of this technical information report. Their expertise and commitment were instrumental in shaping the quality and depth of the final work.

Susan Maria McDonald Olympus America, Inc.

The RADx (Rapid Acceleration of Diagnostics) team:

Samuel Dolphin
Kim Noble
Clair O'Donovan
Brian Walsh

Foreword

This technical information report (TIR) was developed by the AAMI Human Factors Engineering (HE) Committee.

The primary objective of this TIR is to provide recommendations to assist manufacturers in the design of at-home test kits that ensure greater accessibility for users that have no vision or low vision, have a reduced range of dexterity or motor skills, or age-related disabilities. More accessible test kits can also offer greater usability for all users.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

© 2025 Association for the Advancement of Medical Instrumentation ■ AAMI TIR130:2025

1 Background

In response to the COVID-19 pandemic, the National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx®) program in 2020 to speed innovation, development, commercialization, and implementation of COVID-19 testing technologies. RADx Tech, one arm of the program, was specifically designed to compress the customary technology development timeline from years down to just months. While NIH RADx Tech resulted in significant increases in available COVID-19 testing capacity in the U.S., there remained a continuing need to develop COVID-19 at-home test kits that were accessible to all users, including populations that have no vision or low vision, have a reduced range of dexterity or motor skills, and older adults.

NIH RADx Tech began committing resources to increasing accessibility of COVID-19 at-home test kits in early 2022. As a first step, the team consulted design groups and conducted research to identify existing accessible product design guidelines. However, comprehensive guidelines for manufacturers around accessible design of in vitro diagnostic (IVD) products did not exist. Consequently, the team engaged advocacy groups with deep knowledge and experience of the needs of target user populations. These advocacy groups included members of the populations they serve.

As part of this effort, NIH RADx Tech also engaged the Georgia Tech HomeLab to conduct accessibility evaluations; advocacy group partners to onboard accessibility design consultants from the target user populations; and academic centers specializing in accessibility to onboard additional subject matter experts (SMEs). SMEs provided individualized and detailed feedback on device usability and accessibility gaps and collaborated with design firms to develop potential solutions. NIH RADx Tech then worked with test kit manufacturers to bridge identified accessibility gaps on an accelerated timeline.

In 2023, the US Access Board published the program's learnings in the "Best Practices for the Design of Accessible COVID-19 Home Tests." Since that time, the NIH RADx Tech program has continued to work with companies to apply these learnings. In doing so, the team identified opportunities for improvement and made updates for clarification, which have been incorporated in this Technical Information Report (TIR).

Additional information on the RADx program's accessibility initiative that informs this TIR is available in this journal article. [1]

© 2025 Association for the Advancement of Medical Instrumentation ■ AAMI TIR130:2025