Writing

Human Factors Plans & Reports

for Medical Technology Development

Michael Wiklund
Laura Birmingham
Stephanie Alpert Larsen
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This publication is intended to be a helpful resource, and reflects the expert advice and views of the authors. It is not to be construed as legal or regulatory advice.

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It has been widely reported that preventable medical error by clinicians was the third leading cause of death in the United States in 2015, claiming over a quarter million people's lives that year and trailing only heart disease and cancer in terms of lethality. These reports were based on a conclusion derived from a Johns Hopkins University School of Medicine study, published in The BMJ in May 2016. The study quotes Professor of Surgery Martin Makary, stating, “...researchers examined four separate studies that analyzed medical death rate data from 2000 to 2008. Then, using hospital admission rates from 2013, they extrapolated that, based on a total of 35,416,020 hospitalizations, 251,454 deaths stemmed from a medical error, which the researchers say now translates to 9.5% of all deaths each year in the U.S.” (Figure F-1)

This troubling finding updated the equally widely reported finding, published in the Institute of Medicine’s publication To Err Is Human: Building a Safer Health System in 1999, that between 44,000 and 98,000 people in the United States died in hospitals as the consequence of the same problem—healthcare providers making mistakes. Evidently, the more researchers study the problem in the United States and recognize how many deaths have been incorrectly categorized, the more the reported magnitude of medical error seems to increase. The magnitude of error-related deaths in the United States suggests that researchers would discover the same situation in many other countries, with death rates varying to some extent because of the level of medical care provided and the types of medical technology in use.

The pressing question for human factors engineering (HFE) specialists is: How many medical errors are what human factors specialists call “use errors,” committed while interacting with medical technology (e.g., infusion pumps, dialysis machines, defibrillators, glucose meters, nebulizers, pen injectors) that induced the error? The research tells us that the broad term medical error covers such failures as misdiagnoses, wrong-site surgeries, surgical blunders, administering medication to the wrong patient, and not responding to alarms in a timely manner. But, we do not know the degree to which the mistakes are induced by user...

Figure F-1. Medical death rate from 2000 to 2008. Source: National Center for Health Statistics, The BMJ.
interface (UI) design flaws: defects at the points where people interact with medical technology. In 2008, when delivering the keynote speech at the annual Human Factors and Ergonomics Society meeting, Peter Carstensen, the Food and Drug Administration’s (FDA’s) human factors team founder and leader, grossly estimated, based on adverse event reports, that 10% to 15% of medical errors—and potentially more—might have this root cause.

Years later, our sense for the magnitude of deaths related specifically to UI shortcomings, as compared to deaths generally caused by medical error, is not much better; but we can make the simplifying assumption that the magnitude of UI-related deaths is significant, perhaps in the tens of thousands. Therefore, we and many other HFE specialists believe that applying HFE to medical devices to improve safety, and by extension effectiveness and usability, is a worthwhile pursuit. Of course, regulatory bodies have already drawn this conclusion, dating back to 1996 when the U.S. government changed the Quality System Regulation, calling for medical device developers to closely consider users’ needs when designing a medical device and then to verify and validate that users’ needs have been met.

Today, medical technology developers must apply HFE comprehensively and demonstrate to regulators that devices are unlikely to induce potentially harmful use errors. Specifically, those seeking approval or clearance to market certain types of Class II and III devices in the United States must meet the FDA’s HFE guidance, which calls for manufacturers to submit an HFE report that summarizes their HFE approach and results. Those who intend to sell devices in many other countries must demonstrate compliance with the International Electrotechnical Commission (IEC) standard on usability engineering (another term for HFE). This standard has been adopted in the United States as ANSI/AAMI/IEC 62366-1:2015, Medical devices—Part 1: Application of usability engineering to medical devices.

Regulators’ actions and the moral imperative to make medical technology safer have led to widespread adoption of HFE by companies that only now are gaining experience with the discipline. This is where this book’s content can be helpful.

As covered in the Introduction to follow, we intend this book’s content to give companies a head start on the important tasks of defining the elements of an HFE project plan, planning and reporting the results of usability tests, and reporting HFE research results to the FDA in particular. Note that this book is less focused on helping companies conform to 62366-1. Specific guidance for this standard is provided in the IEC Technical Information Report IEC TR 62366-2:2016, Medical devices—Part 2: Guidance on the application of usability engineering to medical devices (adopted in the United States as AAMI/IEC TIR62366-2:2016).

Naturally, it is distressing that people receiving medical care can be hurt or killed by the same medical technology intended to help them. It is also distressing to consider the consequences for healthcare professionals and home caregivers taking care of a dependent who are induced to err by a device with a flawed UI.

Over the course of many years of HFE practice and to date, we have identified UI shortcomings (i.e., flaws) in all manner of medical technology, including large capital equipment (e.g., ventilators, computed tomography [CT] scanners, heart-lung machines) down to hand-held devices purchased over-the-counter (e.g., glucose meters, pen injectors, inhalers). The flaws have been as fundamental

Figure F-2. People in every stage of life might need to use medical devices and should not be at risk of death due to mistakes induced by the device’s user interface. Note that the products shown simply depict medical devices in use and are not presented as flawed devices that caused use errors.
as the assignment of system monitoring and calibration functions to human operators—who are not particularly good at performing tedious tasks perfectly and exactly on time—instead of automating them. The flaws have been as seemingly superficial and trivial as placing two push buttons too close together or labeling them with confusing terms. Fortunately, we discovered the flaws through HFE research and have worked with our clients to fix them. Just as fortunately, resolving them did not require magic or even a startling level of brilliance. Rather, it required diligence, the diligence to apply HFE in a quality-conscious, comprehensive manner throughout device development, which included taking time to perform activities such as a proper formative usability test of a prototype medical device. We hope this book’s content helps many of you do the same.

Finally, we wish all readers success at integrating HFE into their device development efforts, as we work in broad collaboration to address the epidemic of medical errors.
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The authors thank the following individuals for their support during the book-writing process.

Thanks to our families and friends

- Michael Wiklund thanks his wife, Amy, for her generous support during the book-writing effort.
- Laura Birmingham thanks her family and friends for their advice and feedback throughout the development of this book, and her parents, in particular, for their encouragement and support over the years.
- Stephanie Alpert Larsen thanks her husband, David, and her parents for their never-ending love and support.

Thanks to our colleagues at UL-Wiklund

- Our HFE colleagues offered informal editorial support and had a helping hand in the development of UL-Wiklund’s work product templates upon which we based the plans and reports presented in this book. Special thanks go to Jonathan Kendler, Allison Strochlic, Jon Tilliss, Andrea Dwyer, Erin Davis, Rachel Aronchick, Echo Kirk, and Cory Costantino, colleagues who have been with the team for many years and helped shape our HFE practice.
- Jonathan Kendler provided extraordinary visual design support (including multiple book illustrations), and both designed and coordinated the 3-D modeling of the hypothetical intravenous (IV) infusion pump that serves as the focus of our sample work products.
- UL senior managers “green lighted” our proposal to share sample HFE work products that otherwise could be viewed as the organization’s intellectual property and not suitable for release. They understood the value to industry of sharing our property and the potential it had to improve healthcare quality, which is consistent with UL’s mission to make the world a safer place. Special thanks go to Upayan Sengupta, Anil N. Patel, and Hiroshi Yamaki (retired from UL).

Thanks to Gil Molho

- Gil Molho, an industrial designer based in Eindhoven, NL enthusiastically embraced the task of interpreting and expanding upon Jonathan Kendler’s hypothetical infusion pump design and then creating a 3-D model—the source of the IV infusion pump illustrations within the book.

Thanks to Shannon Hoste

- The authors express their appreciation to Shannon Hoste, MSSE, MSM, RAC for her review and comments on our book. Shannon Hoste is a human factors engineer leading the Human Factors Premarket Evaluation Team of the Food and Drug Administration’s (FDA’s) Center for Devices and Radiological Health (CDRH). Prior to joining the FDA in January 2015, Shannon spent 18 years in the medical device industry as a device development engineer and R&D manager. Over this time she has worked within and directed project teams in all phases of product development from front-end research to postmarket support, as well as architecting new product development processes, including the incorporation of human factors and usability into the product development lifecycle. Shannon has a BS in mechanical engineering, an MS in cognitive systems engineering, and an MS in management. Generously, the FDA granted her request to review and comment on our book, but required her to provide this support while off duty and working on a peer-to-peer basis in an unofficial capacity. Neither the FDA nor the U.S. government has officially sanctioned the book’s content, and the FDA has neither recognized nor endorsed the book.
ACKNOWLEDGMENTS

Thanks to AAMI

- Melissa Coates, special projects editor, welcomed our proposal to write this book and provided helpful project management and manuscript editing support.

- Steve Campbell, chief operating officer, also encouraged the book-writing project and got us off to a rapid start on the project by streamlining the approval process.

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About the Authors

Stephanie Alpert Larsen (left), Laura Birmingham (center), and Michael Wiklund (right).

Michael Wiklund

Michael has worked in the HFE profession for more than 30 years as a consultant and educator.

He received his master’s degree in engineering design (specializing in HFE) from Tufts University, where he has subsequently taught UI design for three decades. He has a professional engineering license and is a board-certified human factors professional.

He joined the profession in the mid-1980s, a time when microprocessor technology started to change the fundamental nature of medical technologies. Originally trained to make machines safe and user friendly, his early work was focused on “knobs and dials” but soon transitioned to making software UIs more comprehensible to users.

Today, he helps optimize the design of hardware, software, and hybrid devices as well as instructional media, such as quick reference guides, user manuals, and online resources.

In 1997, the Food and Drug Administration (FDA) engaged Michael to write a guide to applying HFE in medical device development in a manner that was consistent with the (then) new guidance of the agency on the topic. Later, the FDA provided the guide to the Human Factors Engineering Committee at AAMI, which used it as a basis for writing ANSI/AAMI HE74:2001, Human factors design process for medical devices. HE74 ultimately became the basis for the current standard of the International Electrotechnical Commission (IEC) on the topic (IEC 62366-1:2015, adopted in the United States as ANSI/AAMI/IEC 62366-1:2015).

In 2005, Michael cofounded Wiklund Research & Design, Inc. with the goal of providing comprehensive HFE services to industry—medical device manufacturers in particular. In the ensuing years, the firm has provided user research, UI development, and usability testing services to more than 100 clients based in multiple countries. In 2012, UL acquired Wiklund R&D to expand the renowned safety organization’s portfolio of advisory services. Now, as general manager of HFE at UL, Michael manages the work of HFE specialists based in multiple countries while still serving as a technical contributor on special projects.

Michael's other books include Usability in Practice (editor), Medical Device and Equipment Design: Designing Usability into Medical Products (co-author), and Handbook of Human Factors in Medical Device Design (co-editor).
He has published more than 70 articles in *Medical Device & Diagnostic Industry* (MD&DI) magazine that promote the application of HFE in medical device development and provide practical tips. He has been an invited speaker at multiple professional conferences and universities, where he has described HFE as an imperative in the medical industry and a path toward ensuring device safety and commercial success owing to its effectiveness, usability, and appeal.

He has served as a voting member of the AAMI Human Factors Engineering Committee for over 20 years. He has also served on the Human Factors Committee of the IEC and as chair of the Industrial Designers Society of America—Medical Section.

**Laura Birmingham**

Laura received her BS degree in engineering psychology from Tufts University and has worked in the field for six years.

Laura serves as a managing human factors specialist at UL-Wiklund. In this role, she participates in a wide range of the HFE consulting group's activities, including conducting user research, performing known problems analyses, analyzing use-related risks, evaluating preliminary UI designs, and conducting various types of usability tests (e.g., formative, summative, comparison). Laura's responsibilities extend to working with clients to determine project requirements, defining technical approaches to HFE activities, and general project management.

Laura's HFE portfolio includes a wide range of therapeutic and diagnostic devices, such as dialysis machines, patient monitoring devices, insulin pumps, a computer-controlled prosthetic limb, and left-ventricular-assist devices. She has also worked on a wide variety of combination products, including pen injectors, inhalation systems and inhalers, and auto-injectors. These and many more medical technologies have included UIs of various forms, including hardware, software, and documentation.

Laura has been a lead author of each type of work product discussed and exemplified in this book.

**Stephanie Alpert Larsen**

Stephanie received BA degrees in both mathematics and psychology from Binghamton University, and received an MS in human factors engineering and ergonomics from Virginia Polytechnic Institute and State University. She has worked in the field for four years.

Stephanie serves as a senior human factors specialist at UL-Wiklund. In this role she participates in a wide range of the HFE consulting group's activities, including conducting user research, task analyses, and known problems analyses; analyzing use-related risks; evaluating preliminary UI designs; and conducting various types of usability tests (e.g., formative, summative, comparison, benchmark).

Her HFE portfolio includes many combination products, including prefilled syringes, pen injectors, auto-injectors, and inhalers. It also includes web and smartphone applications, as well as computerized systems that process various medical samples. Stephanie's usability testing work has involved a large variety of users including children, adolescents, adults, and seniors; clinicians and laypersons; people with impairments associated with the medical condition addressed by the device being tested; and people with limited education and low literacy.
This book is based on HFE documents developed and refined over many years of HFE practice at UL-Wiklund, as well as essential inputs received from members of the book-writing project’s advisors.

UL (formerly named Underwriters Laboratories) is a global independent safety science company with more than a century of expertise innovating safety solutions—from the public adoption of electricity in the past century to helping medical technology developers bring safe and effective devices to market.

UL's mission guides everything the organization does. UL conscientiously advances safety science through careful research and investigation, applies its efforts to prevent or reduce loss of life and property, and promotes safe living and working environments for all people.

UL-Wiklund is UL’s HFE practice, created when UL acquired Wiklund Research & Design in 2012. The HFE practice concentrates on helping medical technology developers bring safe, effective, usable, and satisfying devices to market through the comprehensive application of HFE. However, it often applies its expertise to help develop other kinds of technology, including consumer products, commercial and industrial products, and enterprise software applications.

William Henry Merrill founded UL in 1894 to conduct product safety tests on behalf of insurance underwriters. The UL certification mark quickly became a trusted symbol of product safety. In the more than 120 years since its founding, UL has certified the safety of over one billion products and driven the creation of innumerable safety standards. Photos reprinted with permission.

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About UL-Wiklund

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Advisory Panel

The authors thank the following members of our advisory panel for providing their insights and editorial suggestions throughout the book-writing effort. Each member reviewed preliminary book content from the perspectives of highly accomplished and hands-on HFE practitioners who are members of AAMI’s Human Factors Engineering Committee.

Wayne Ho, MEng is managing director of Healthcare Human Factors, a design and human factors consultancy affiliated with Toronto General Hospital. In the past 20 years, he has focused on the interaction between people and technology as an interaction designer and usability specialist. He is passionate about improving the design of software, devices, and processes in healthcare. Wayne is an active researcher and designer for healthcare systems, devices, and software from radiotherapy systems to infusion pumps. He is also a member of the AAMI Human Factors Engineering Committee and the IEC/ISO joint working group on usability of medical devices. Wayne holds a MEng in industrial engineering from the University of Toronto, specializing in human factors, and a BASc in systems design engineering from the University of Waterloo.

Edmond Israelski, PhD, CHFP recently retired from corporate life but remains involved in human factors as an independent consultant. Previously, he served for 15 years as director of human factors at AbbVie, a biopharmaceutical company. At AbbVie, he led a cross-company team to imbed best-practice HFE design methods into all of the company’s products to ensure safety and usability. He is a past cochair of the AAMI Human Factors Engineering Committee and continues to serve as convener for IEC and ISO ergonomic committees that develop international standards for medical devices. As a certified human factors professional, Ed has authored 15 book chapters and numerous articles in the area of human factors, and holds 30 patents. He is a fellow of the Human Factors and Ergonomics Society and a member of the American Psychological Association, the User Experience Professionals Association, and the National Academy of Sciences Board on Human-System Integration. He has served as a juror for the Medical Design Excellence Awards.

Merrick Kossack, MS, CHFP serves as research director at UL-Wiklund. In this role, he works with medical technology developers to understand their HFE needs and then plan and deliver HFE services to meet those needs. His client engagements have involved technologies ranging from medical robotics to diagnostic and therapeutic devices to combination products. He manages UL-Wiklund’s HFE services based in the Chicago area and supports the work based in the consulting group’s other offices in Concord, Massachusetts, Utrecht, and Tokyo. Previously and when he first joined the advisory panel, Merrick served as principal human factors engineer at Intuitive Surgical, where he led the HFE efforts developing the da Vinci Surgical System. His responsibilities ranged from integrating HFE into the organization’s established design and development processes, to conducting usability studies, to providing the overall human factors strategy for each project. Merrick taught human factors in medical device development at the University of California–Santa Cruz. He received his MS in human–machine systems research from the Georgia Institute of Technology and his BS in industrial engineering from the University of Illinois.
Mary Beth Privitera, PhD

is a principal human factors engineer at HS Design and an associate professor of biomedical engineering/industrial design and director of the Medical Device Innovation and Entrepreneurship Program (MDIEP) at the University of Cincinnati. MDIEP is a group of multidisciplinary teams of faculty and students who work collaboratively to solve challenges within the medical field. Mary Beth also serves as the cochair of AAMI’s Human Factors Engineering Committee. She is the author of Contextual Inquiry for Medical Device Design and a contributing author of AAMI TIR51:2014, Human factors engineering—Guidance for contextual inquiry. Additionally, she serves as AAMI faculty for the Advanced Human Factors course. Mary Beth has a PhD in design from Loughborough University and has current research in design process (formative evaluations, user collaborations) and in the clinical areas of endovascular neurosurgery, deep brain stimulation, general and vascular surgery, wound healing, temperature management, and central access devices.

Tim Reeves, PhD, CHFP

is the managing director of Human Factors MD and founded the company in early 2001. He has 20 years of commercial experience evaluating and designing usable, effective, and safe medical devices. He is a certified human factors professional and a member of the AAMI’s Human Factors Engineering Committee. He has been an invited speaker at several professional meetings, including the AAMI/FDA sponsored conference on Human Factors and Patient Safety for Medical Devices and the first IBC conference on Human Factors and Combination Products. Tim is also a member of the teaching faculty for AAMI’s popular Human Factors for Medical Device Design course. Tim has a PhD in cognitive psychology and human factors from the University of Toronto.
Who Could Use This Book

Practitioners
This book is principally intended for use by people who apply HFE to medical technology and have some degree of responsibility for meeting regulators’ HFE-related expectations. Such individuals include the following:

• Accident investigators
• HFE practitioners
• Learning tool developers
• Product liability attorneys
• Project and product managers
• Quality managers
• Research and development managers
• Risk managers
• UI designers

People working in associated organizations
In addition to being of interest to the medical device development community, the book’s contents might also interest people working in the following types of organizations:

• Authorities having jurisdiction (AHJs)
• Healthcare organizations concerned with improving healthcare and patient safety through the application of HFE
• Regulatory policy developers and analysts
• Universities offering HFE degrees and courses

Students
We also believe that the book content will be of interest to people studying the following topics:

• Biomedical engineering
• Human factors engineering
• Industrial design
• Industrial engineering
• Information design
• Product liability law
• Project management
• Quality management
• Rehabilitation engineering
• Risk management

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1. Please consider the sample HFE work products and associated job aids presented in this book as a starting point for shaping your own HFE approaches and work products. We give this advice with the knowledge that project-specific work products will be unique even though they might contain common content—what some people term “boilerplate.”

For example, HFE project plans can vary widely among developers because of (1) a product developer’s internal processes (e.g., research and development process, quality management procedures) and (2) a product developer’s resources (e.g., development time, budget, staffing). You can also factor in differences related to the need for more or less intensive HFE based on a device’s complexity and risk profile.

2. This book presents HFE work products that we consider to be comprehensive for the sake of providing maximum guidance to readers. However, based on the many factors listed above, practitioners might choose to scale up or scale down their documents. We will simply state that conciseness is a virtue, especially when a work product will be reviewed by someone other than the developer, such as a reviewer from a regulatory body. For example, a shorter, more concise HFE report might be best in some reviewers’ eyes. However, a drive toward conciseness should not place a manufacturer at risk of excluding important information that could lead reviewers to seek additional information, thereby extending the review process.

3. Ultimately, the responsibility remains with each medical technology developer to review and interpret current regulatory guidance for the appropriate jurisdictions and to assess industry standard practice to confirm the suitability of its HFE approaches and end products.

4. Note that standards of HFE practice continually evolve, along with requirements and guidance established by authorities having jurisdiction. Therefore, the sample work products and guidance presented in this book are bound to “drift” from the prevailing standard of care at any point in the future. Therefore, look to other sources in addition to the book to ensure that work products are contemporary. Also, take into consideration that some regulators’ expectations might still be aligned with older guidance, such as that presented in IEC 62366:2007 (adopted in the United States as ANSI/AAMI/IEC 62366:2007) and other versions prior to the issuance of yet-to-be-harmonized IEC 62366-1:2015 (adopted in the United States as ANSI/AAMI/IEC 62366-1:2015). The guidance presented in this book is based on the most recently available information when we wrote this book. That said, we believe that the basic elements of our sample work products and our guidance should be generally relevant for a long time.

5. The authors, advisory panel members, and AAMI offer no warranty and assume no liability for the HFE approaches and end products that could be influenced by this book’s contents. The contents are presented to readers only for their consideration and use at their own risk.

6. Any similarities between the hypothetical product development company (InfusaMed) and the hypothetical product (Infusatron 2600) with actual companies and products are purely coincidental.
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We wrote this book to fill a perceived gap in the guidance available to medical technology developers who seek to apply HFE effectively to produce safe and effective devices and, in parallel, to satisfy regulators’ requirements and expectations. In our view, the pre-existing guidance has delineated the HFE process and described how to perform specific HFE techniques. For example, the guidance has called for performing and reporting the results of a summative (i.e., validation) usability test to demonstrate that intended users can use a device safety and effectively. However, the guidance has not gone so far as to provide sample work products (e.g., test plans, test reports), which revealed to us an unmet need.

We acknowledge that there are various HFE work products available for review, but they are not specifically tailored to the evaluation of medical technology, nor are they optimally aligned with regulatory body (e.g., FDA) expectations. For example, the National Institute of Standards and Technology (NIST) has published several good exemplars, but ones that are applicable to a wide range of products and other items with a UI (e.g., consumer electronic devices, software applications, websites) rather than focused on medical device safety and effectiveness. Therefore, we consider the NIST documents and equivalents to be valuable inputs to HFE practitioners working in the medical industry, but believe that this book’s content fills in a gap.

Now, we will say a few more words about our motivations to create this book. Quite frequently, medical technology developers have asked our consulting group (UL-Wiklund) if we could provide sample HFE work products, such as a summative usability test plan and report, which they could then use as a basis for writing their own. We have responded that our work products are normally client-confidential items and are based on templates that we regard to be our company’s intellectual property. But, we have sorely wished we could share our work products in the spirit of helping others and promoting better HFE practice.

This book became possible when we and our parent organization (UL) concluded that sharing our work products could (1) have a positive influence on HFE practice, and (2) help to improve healthcare safety in view of the present-day scourge of medical error, which we cited earlier as the third leading cause of death in the United States and certainly a major problem in other geographic regions. We recognize that this all sounds a bit lofty, but our intentions are quite down-to-earth. We sincerely hope that this book’s content helps readers apply HFE more effectively and efficiently in the spirit of increasing the relevance of HFE in medical technology development and the quality of the work.

This book contains sample work products (exemplars) of the following six documents:

- HFE Project Plan
- Formative Usability Test Plan (i.e., Protocol)
- Formative Usability Test Report
- Summative Usability Test Plan (i.e., Protocol)
- Summative Usability Test Report
- HFE Report