

Wende Dewing



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Summary

More than 17 years of rich and diverse Human Factors experience in medical device, military, commercial aviation, and home automation domains. Seasoned practitioner in all phases of product development from user needs to user interface design to validation and post-market monitoring. Well versed in regulatory guidance and industry standards for Human Factors in medical device development. Successful cross-functional interactions based on a strong reputation for relationship building and personal integrity.

Education

1998 | **PhD, Human Factors**, Virginia Polytechnic Institute & State University, Blacksburg, VA
1995 | **MS, Industrial Engineering-Human Factors**, University of Minnesota, Minneapolis, MN
1989 | **BA, Mathematics & Studio Arts**, Macalester College, St. Paul, MN

Work Experience

CEO, Usensus, LLC 2014 – Present

Established a consulting company to provide Human Factors professional services to the medical device community.

Senior Human Factors Manager, Neuromodulation, Medtronic, Inc. 2011 – 2014

Principal Human Factors Scientist, Neuromodulation, Medtronic, Inc. 2008 – 2011

Senior Human Factors Scientist & Manager, Neuromodulation, Medtronic, Inc. 2005 – 2008

Provided leadership to the Neuromodulation Human Factors team and applied user-centered design methodologies across the product development lifecycle for implantable medical devices, clinician instrumentation, patient instrumentation, and instructions for use. Contributed to the development of a dozen market-released products including a first of its kind hand-held clinician programmer that utilized touchscreen technology. Accomplishments included:

- Founded a Human Factors team for the Neuromodulation division and built a 12-member center of excellence.
- Created procedures for Human Factors activities based on industry standards (IEC62366, AAMI HE75, ISO 14791) and FDA guidance. Integrated Human Factors activities with those of other disciplines – software, systems, mechanical, quality, risk management, technical communications – and institutionalized them within the organization's quality management system.
- Advised project teams and functional leaders across Neuromodulation and other Medtronic divisions on the interpretation of new regulatory guidance and industry standards for Human Factors in medical device development.
- Worked with project leadership to determine appropriate Human Factors activities for all projects then planned the labor and expenses necessary to accomplish the activities.
- Established best practices for Human Factors activities. Provided coaching for continuous improvement of technical skills among Human Factors team members. Helped team members learn how to balance Human Factors activities and user needs with business needs.

- Represented the Human Factors function during submission-related meetings with FDA and TUV reviewers. Presented Human Factors evidence during audits with FDA and TUV inspectors.
- Reviewed intellectual property submissions with regard to patentability and alignment with business priorities through service as a member of the Neuromodulation software patent review board.
- Conducted contextual inquiry and observational research to identify user needs and document task flows. Translated user needs into engineering requirements and user interface design concepts that were enthusiastically received by customers.
- Analyzed task flows and user interface designs for potential sources of use error. Assessed risk, generated mitigation options, and evaluated mitigations for effectiveness.
- Employed formative usability methods to identify and correct potential sources of use error, user performance issues, and low user acceptance.
- Conducted summative usability validation for implantable products, clinician programmer software, patient instruments, and instruction manuals. Established best practices for the validation of instruction manuals.
- Analyzed customer complaint data to identify sources of use error and identify unmet user needs.

Senior Human Factors Scientist, Cardiac Rhythm Management, Medtronic, Inc. 2002 – 2005

Applied user-centered design methodologies across the product development lifecycle for clinician and patient instrumentation, including a patient remote control for delivery of Atrial Fibrillation therapy and the introduction of concurrent applications to the clinician instrument platform. Accomplishments included:

- Innovative software user interface designs that improved user performance and satisfaction.
- Application of iterative user testing methods to reduce usability issues and programming errors prior to market release.
- Strong user-centered focus maintained through productive relationships with patients, clinicians, and Medtronic field personnel.

Senior Research Scientist, Honeywell Laboratories, Honeywell, Inc. 1998 – 2002

Applied user-centered design methodologies across multiple stages of research and development in aviation, medical device, military, and home automation domains.

Accomplishments included:

- Conducted contextual research to understand Naval Watchstander needs for a Windows-based application to remotely monitor and diagnose power generation, hull structure, personnel, and environmental conditions aboard a destroyer.
- Created an innovative new natural language-based Flight Management System user interface for commercial aviation flight-decks.
- Applied iterative design and evaluation methods for a web-based homeowner interface to remotely control lights, appliances, thermostats, and security system.
- Created a novel new clinician programmer software user interface for the Medtronic, Inc. Restore spinal cord stimulation platform.
- Managed a 7-member Human-Centered Systems team for a 2.5 year, \$5M NIST-sponsored Advanced Technology Program. Directed strategic technical approach for overall program, built community awareness of the technology through presentations, lectures, and selection of business partners.

- Developed a resource library to teach developers how to integrate user-centered design processes into their current software development process.
- Managed internship program, including recruiting and mentoring of 3 Human Factors students per year.

Associate Human Factors Scientist, Eastman Kodak Company

1997 – 1998

Human Factors Intern, Eastman Kodak Company

1995 – 1997

Planned and managed research efforts to explore subjective image quality and colorimetric issues associated with the color rendering differences between softcopy and hardcopy media. Accomplishments included:

- Researched the effect of cathode-ray tube (CRT) display color balance on pre-processing image adjustments made by consumers.
- Measured the effect of pre-processing color adjustments on perceived post-processing image quality.
- Designed and tested a web-based, visual, CRT display color characterization tool.

Affiliations

1993 | [Human Factors & Ergonomics Society](#)

2012 | [Association for the Advancement of Medical Instrumentation \(AAMI\)](#), Human Factors Standards Committee

Patents

System and method for automatically generating an alert message with supplemental information

United States 7,145,462 | Issued December 5, 2006

System and method for assessing the functional ability or medical condition of an actor

United States 7,244,231 | Issued July 17, 2007

Guided programming with feedback

United States 8,010,203 | Issued August 30, 2011

Characterization of electrical stimulation electrodes using post-implant imaging

United States 8,160,328 | Issued April 17, 2012

User interface with toolbar for programming electrical stimulation therapy

United States 8,255,060 | Issued August 28, 2012

User interface with toolbar for programming electrical stimulation therapy

United States 8,321,808 | Issued November 27, 2012

Implantable therapeutic substance delivery device with septum guide and method of use

United States 8,348,909 | Issued January 8, 2013

Programming therapy delivered by implantable medical device

United States 8,352,039 | Issued January 8, 2013

Guided Programming with feedback

United States 8,527,059 | Issued September 3, 2013

Publications & Presentations

- Dewing, W.L., Duley, J.A., & Hancock, P.A. (1993, October). *The Role of Vehicle Type, Velocity, and Gap Size on Drivers' Left Turn Decisions*. Poster presented at the Thirty-Seventh Annual Meeting of the Human Factors and Ergonomics Society. Seattle, WA.
- Hancock, P.A., Dewing, W.L., & Parasuraman, R. (1993, May). *A Driver Centered System Architecture for IVHS Implementation*. Paper presented at the Fourth Annual Center for Transportation Studies Transportation Research Conference, Minneapolis, MN.
- Hancock, P.A., Dewing, W.L., and Parasuraman, R. (1993, April). *The Human Factors of Intelligent Travel Systems*. *Ergonomics In Design*, 1 (2), pp. 12-15.
- Levitan, L., Burrus, M., Dewing, W.L., Reinhart, W., Vora, P., & Llaneras, R. (1994). *Preliminary Human Factors Guidelines For Automated Highway System Designers*. (Contract No. DTFH61-92-C-00100). Washington, DC: Federal Highway Administration.
- Dewing, W.L. & Stackhouse, S.P. (1994). *Following Advice From Traffic Advisories*. (Tech. Report MN/RC-94/29). Saint Paul, MN: Minnesota Department of Transportation.
- Dewing, W.L., Stackhouse, S.P., & Hancock, P.A. (1994, May). *Willingness of Travelers to Accept Information and Advice*. Paper presented at the Fifth Annual Center for Transportation Studies Transportation Research Conference. Minneapolis, MN.
- Dewing, W.L., Johnson, S.M., & Stackhouse, S.P. (1995). *The Interaction of Nondriving Tasks with Driving*. (Tech. Report MN/PR-95/20). Saint Paul, MN: Minnesota Department of Transportation.
- Dewing, W.L. & Miller, M.E. (1996). *User Acceptance of Hardcopy Digital Images When Edited on a Miscalibrated CRT*. Kodak Technical Report No. 301036Q. Rochester, NY: Eastman Kodak Company.
- Dewing, W.L. (1999). *Softcopy Image Manipulation and Its Influence on Perceived Color Quality of Printed Output*. Paper presented at the Forty-Second Annual Meeting of the Human Factors and Ergonomics Society. Houston, TX.
- Dewing, W.L. (2001). *Automation as Caregiver*. Panel presentation at the Forty-Fifth Annual Meeting of the Human Factors and Ergonomics Society. Minneapolis, MN.
- Ververs, P.M., Dorneich, M.C., Good, M.D., Rye, J., Downs, J., Niehus, G., and Dewing, W. (2001). *Alerting and Notification of Conditions Outside the Aircraft (ANCOA): Final Report*. Technical Report prepared for NASA Langley Research Center under contract NAS1-00107, Honeywell Laboratories, November 30, 2001