

DEAN A HOOPER

19860 Swallow St, Oak Grove, MN | 763 639 4576 | dean.hooper@heconsultingllc.com

EDUCATION

New Mexico State University, Las Cruces NM

M.A. (ABD) Cognitive Psychology

1995

Thesis: Phonological Information as a Determinant in Performance of a Word Superiority Task

Washington State University, Pullman WA

BA – Psychology

1991

3.98 GPA

Summa cum Laude

Phi Beta Kappa

AWARDS AND GRANTS

Medtronic Research Grant (\$50,000)

2005

Investigated the feasibility of creating a software tool so that any development team without human factors expertise can conduct a use error analysis for their respective projects.

Innovation and Creativity Award, Medtronic, Inc

2004

Leadless ECG feature integration into implantable defibrillator platform

Graduate Research Grant, New Mexico State University

1993

Initial research concerning the influence of linguistic history on reading competence of deaf children

TEACHING EXPERIENCE

AdvaMed – Medical Technology Learning Institute

Seminar Instructor - Design and Manufacturing Principles: Integrating Design in Human Factors to Meet Regulatory Requirements and User Needs.

2011

Medical Design and Manufacturing

Seminar Instructor – Identifying and Assessing Use Error during Product Development

2012

Shaw University

Instructor – Introduction to Psychology, Survey of Social Systems, Neuro-psychology, Senior Seminar in Cognition

1996-1999

Developed and administered curricula.

Faculty advisor for non-traditional student organization.

Dona Ana Community College, Dona Ana, NM

1994

Adjunct Instructor – Introduction to Psychology

Developed syllabus and overall course structure, and administered all grades.

New Mexico State University, Las Cruces, NM

Lab Instructor – Sensation and Perception

1992-1993

Designed and implemented lab demonstrations, activities, and lessons.

RELATED EXPERIENCE

HE Consulting LLC

2013

Principal

HE consulting provides human factors and user research capabilities to manufacturers of FDA and EU regulated medical devices. Expertise spans the product life cycle from concept to post market surveillance and all facets of the development program; whether providing user needs and design inputs to engineering teams or consulting on user and patient safety related regulatory guidelines and quality initiatives. Our consultants can also help your organization establish user-centered practices, as mandated by IEC standards, that naturally lead to a more complete FDA submission and, above all, a safe and easy to use product.

Ximedica

2011 – 2013

Principal Human Factors Scientist

Contribute to the design of efficacious, safe, and easy to use medical device products through user and customer centered activities. Through sound research and team collaboration I have delivered to our clients user needs, user requirements, user profiles, task analyses, usability specifications as outlined in IEC62366, usability validation study results and reports that have been successfully reviewed by the FDA, empirically derived, design direction for engineering teams, use error analyses, etc. I have also provided project management services and consulted on the establishment of human factors programs to address FDA and CE pressures to demonstrate user centered design practices. Data analyses have included parametric and non-parametric assessment of error rates, inter-rater reliability evaluation, consumer preferences and descriptive statistical analyses.

Stereotaxis, Inc.

2007 – 2011

Human Factors Engineer

Responsible for building and maintaining the corporate human factors program for robotic cardiac surgical and information display systems development.

- Designed, implemented, and managed the company's human factors program based on FDA guidelines and IEC/ISO 62366 and 14971 standards for medical device manufacturers. Integrated program into Quality and Regulatory processes.
- Member of regulatory team that re-defined and established company-wide risk management processes.
- Created and maintained the corporate software standards and style guide to define the look and feel of all software products.
- Designed and led a large outcomes study to identify and define system enhancements and new features for inclusion in product revisions.
- Designed and led a heuristic analysis on software applications. Findings drove new design activities for next generation of products.
- Supported numerous development project teams utilizing user-centered design processes; including project planning, user needs assessment, user requirement generation, initial design of concepts, formative testing, design iteration, and summative testing of both hardware and software products.
- Collaborated with the validation group to ensure processes conform to user centered guidelines. Designed product validation studies to assess overall system safety (i.e. test against user requirements) with the Validation and Verification Group. Results were fed into the Regulatory Design Control process.
- Led a monthly human factor/advanced concepts update meeting to keep the development organization abreast of user-centered activities.
- Trained graphics designers, development engineers and field personnel on user- centered data collection methodologies and techniques.
- Analyzed a large data set of clinical data to determine which aspects of the clinical procedure most influenced case time. Using a multiple regression, model reduction technique, it was discovered that specific catheter navigation techniques and staff roles most influenced case times. An additional software tool was developed and training curricula modified to increase use efficiency.

Medtronic, Inc.

2000 – 2007

Human Factors Engineer

Responsible for feature level human factors input to all phases of software and hardware development projects for implantable cardiac devices and associated instruments in a regulatory environment.

- Created a use error analysis process to identify potential use errors and their respective causes; meeting and surpassing current FDA guidelines. Influenced the design of 3 systems with the process.
- Researched and discovered unforeseen user needs for an additional ECG amplifier in an implantable device given the interaction of system features.
- Led Human Factors effort to allow physicians to treat heart failure through cardiac resynchronization therapies. Through participatory design and structured interviews, unmet clinical needs were discovered. The project team re-defined the feature and re-scoped the development effort based on this research.
- Managed a Human Factors team in software development for a hand-held neurological instrument. Team developed a menu hierarchy to incorporate a set of new features. New design was adopted across neurological business units.
- Set up and maintained a monthly discussion group that brought together user interface professionals from various business units within Medtronic to share knowledge and experiences.
- Designed and tested system behaviors that allow physicians to alter the state of a device to make it MRI compatible. This included research on patient flow and general care.
- Designed and conducted research into the intrusiveness of wireless telemetry in the surgical and clinic settings. Potential hazards and work flow modifications were identified and mitigations developed.

Additional Experience

1995 – 2000

Human Factors Engineer

User-centered techniques, design principles, and product development process knowledge were honed at Nortel Networks and Ericsson, Inc.

PUBLICATIONS AND PRESENTATIONS

Hooper D. A. (2013), Assimilating Use Error Analysis into Risk Management and Product Development. Presented at the Human Factors and Ergonomics International Healthcare Symposium. Baltimore, MD. March 10-13, 2013.

Varricchione, T Davol, P & **Hooper D. A.** (2013). Do Human Factors & Usability Studies Need IRB Review? Presented at the Human Factors and Ergonomics International Healthcare Symposium. Baltimore, MD. March 10-13, 2013.

Hooper D. A. (2012). User-Centered Design For Medical Devices: If It Isn't Documented It Doesn't Exist. <http://www.mddionline.com/print/9572>. Published September 7, 2012.

Hooper, D. A. and Simoens K. (2012). The 'Smart Bay' Optimizing Trauma Care of the Future. Proceedings of the Human Factors and Ergonomics Society Annual Meeting. September 2012 56: 816-818.

Hooper, D. A. (2012). Mapping 3D Mouse Controls to a Remotely Driven Cardiac Catheter. Presented at the Design of Medical Devices Conference. April 10-12. Minneapolis, MN.

Hooper, D. A. and Hitchens, Richard E. (2011): Use Error Analysis in a Medical Device Product Development Cycle. In: Proceedings of the Human Factors and Ergonomics Society 55th Annual Meeting 2011. pp. 1803-1807.

Hooper, D. A., & Paap, K. R. (1997). The use of assembled phonology during performance of a letter recognition task and its dependence on the presence and proportion of word stimuli. *Journal of Memory and Language*, 37(2), 167-189.

Hooper, D. A. & Perea, M (1995). Phonological mediation in letter recognition of non-words. Paper presented at the Sixty-fifth annual convention of the Rocky Mountain Psychological Association, Boulder, Colorado.

Perea, M., Paap, K. R., Gotor, A., **Hooper, D. A.,** & Algarabel, S. (1995). "Some neighbors are more equal than others". Paper presented at the Sixty-fifth annual convention of the rocky mountain psychological association, Boulder, Colorado.

Paap, K. R., Johansen, L., & **Hooper, D. A.,** (1992). Talking Heads: How To Be A Head Of Your Time In The Naming Task. Paper presented at the 33rd annual meeting of the Psychonomic Society. November 14th, 1992. St Louis, MO.

PATENTS AND CURRENT APPLICATIONS

Blahe, Eric V.; Ericksen, James H.; **Hooper, Dean A.**; Masoud, Javid, & Zimmerman, James A. (2012) METHOD AND APPARATUS FOR PROVIDING SAFE LONG-RANGE TELEMETRY WITH IMPLANTABLE MEDICAL DEVICES. US patent number: 8229568. Filed: March 24, 2009. Issued: July 24, 2012

Blahe, Eric V., Ericksen, James H., **Hooper, Dean A.,** Masoud, Javid, & Zimmerman, James A. (2009). METHOD AND APPARATUS FOR PROVIDING SAFE LONG-RANGE TELEMETRY WITH IMPLANTABLE MEDICAL DEVICES. US patent number: 7528094. Filed: October 25, 2004. Issued: May 5, 2009

Gordon, Paul G.; Masoud, Javid; Ball, James J., Vitense, Holly S., Willenbring, James E., Vandanacker, John P., McAdams, Sean B., & **Hooper, Dean A.** (2007). ALERT SYSTEM AND METHOD FOR AN IMPLANTABLE MEDICAL DEVICE. US patent number: 7265676. Filed: October 29, 2004. Issued: September 4, 2007

Hooper, Dean; Ford, Christine, & LeDuc, Sheryl (2012). METHOD FOR MANAGING NON-OVERLAPPING WINDOWS. US application number 20130047118. Filed: August 23, 2012 Issued: February 21, 2013

Nelson, Shannon; **Hooper, Dean;** Ericson, Eric; Swanberg, Paul; Haerle, Mark; Echols, Lori; & Crandall, Kathleen (2006) SYSTEM AND METHOD FOR OPERATING AN IMPLANTABLE MEDICAL DEVICE IN A DISRUPTIVE ENERGY FIELD. US application number: 20060167496

MEMBERSHIPS

Association for the Advancement of Medical Instrumentation
Human Factors and Ergonomics Society