Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design

U.S. Food & Drug Administration

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When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

Preface

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Applying Human Factors and Usability Engineering to Medical Devices to Optimize Safety and Effectiveness in Design

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page of this guidance.

AAMI/ANSI/ISO 14971:2007, *Medical Devices ––Application of risk management to medical devices*. International Organization for Standardization. Geneva, Switzerland.

AAMI/ANSI HE75:2009, *Human Factors Engineering – Design of Medical Devices.*

Bahr, N., *System safety engineering and risk assessment: A practical approach*. Washington DC: Taylor and Francis; 1997

Chapanis, A., *The business case for human factors in informatics*. In: Shackel and Richardson (eds.). Human Factors for Informatics Usability. New York: John Wiley & Sons; 1994.

Chapanis, A., *Human factors in systems engineering*. New York: John Wiley & Sons; 1996.

Cooper, J., *Preventable anesthesia mishaps: A study of human factors*. Anesthesiology 1978, 49:399-406.

Cooper, J., *An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection.* Anesthesiology 1984, 60:34-42.

Dekker, S. (2011). *Patient Safety: A Human Factors Approach.* CRC Press.

Dhillon, B. S. (2003). *Human Reliability and Error in Medical System.* River Edge: World Scientific Publishing Co. Pte. Ltd.

Dumas, J., and Redish, J., *A Practical Guide to Usability Testing*. Ablex, New Jersey, 1993.

Faulkner, L. (2003). Beyond the five-user assumption: Benefits of increased sample sizes in usability testing. *Behavior Research Methods, Instruments, and Computers, 35*(3), 379-383.

FDA, *Design Control Guidance for Medical Device Manufacturers.* March 11, 1997.

FDA, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* May 29, 1998.

FDA, *Quality system regulation (current good manufacturing practice (CGMP) final rule)*. October 7, 1996.

Goodstein, L., Anderson, H. and Olson, S., *Tasks, errors, and mental models*. New York: Taylor and Francis; 1988.

ISO/IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General*

requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. Geneva , International Electrotechnical Commission.

ISO/IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices.* Geneva , International Electrotechnical Commission.

Kirwan, B., and Ainsworth, L.K., *A guide to task analysis*. London: Taylor & Francis Ltd; 1992.

Kohn, L., and Corrigan, J., (eds.), *Building a Safer Health System.* Institute of Medicine (IOM), Committee on Quality of Health Care in America. Washington, D.C.: National Academy Press; 1999.

Landauer, T. K. (1999). *The Trouble with Computers: Usefulness, Usability, and Productivity.* Cambridge: The MIT Press.

Leape, L., *Error in Medicine.* Journal of American Medical Association, 1994 Dec; 21(3) 272.

Meister, D., *Human factors testing and evaluation*. Amsterdam: Elsevier; 1986.

MIL-STD-1472F, Change Notice 1, *Human engineering*. Washington, D.C.: Department of Defense, 12-05-2003.

Nielsen, J. (1993). *Usability Engineering.* Boston: AP Professional.

Norman, D., *The Design of Everyday Things*. New York: Doubleday; 1988.

O'Brien, T., and Charlton, S., *Handbook of Human Factors Testing and Evaluation*, New Jersey: Lawrence Erlbaum Assoc; 1996.

Reason, J., *Human Error.* Cambridge, Mass: Cambridge University Press; 1992.

Redmill, F. and Rajan, J. (1997). *Human Factors in Safety-Critical Systems.* Oxford: Butterworth-Heinemann.

Rubin, J., *Handbook of Usability Testing*. New York: John Wiley and Sons, Inc; 1994.

Salvendy, G. (ed.), *Handbook of Human Factors and Ergonomics.* New York: John Wiley and Sons, Inc; 1997.

Sanders, M., and McCormick E., *Human Factors in Engineering and Design*. New York: McGraw Hill; 1993.

Shneiderman, B., Plaisant, C., Cohen, M. and Jacobs, S. (2010). *Designing the User Interface: Strategies for Effective Human-Computer Interaction.* (5 th ed.). Menlo Park, CA: Addison Wesley.

Trautman, K., *The FDA and Worldwide Quality Systems Requirements Guidebook for Medical Devices*. ASQC Press; 1997.

Virzi, R.A. (1992). Refining the rest phase of usability evaluation: How many subjects is enough? *Human Factors,* 34, 457-468.

Weinger, M. B., Wiklund, M. E. and Gardner-Bonneau, D. J. (2011). *Handbook of Human Factors in Medical Device Design.* CRC Press.

Weinstock, C. B. and Goodenough, J. B. (2009). *Towards an Assurance Case Practice for Medical Devices.* Pittsburgh: Carnegie Mellon.

Wickens, C. D., Gordon, S. E., and Liu, Y., *An Introduction to Human Factors Engineering*. Addison-Wesley (Longman Imprint): New York, NY; 1998.

Wickens, C. D. and Hollands, J. G. (2000). *Engineering Psychology and Human Performance* (3 rd Edition). Upper Saddle River: Prentice Hall.

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[1] 21 CFR 820.30

[2] See Draft Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions *[19]*, released on April 23, 2010. When final, this will represent FDA's guidance on this topic.

[3] 21 CFR §820.250

[4] Clinical studies must comply with the Investigational Device Exemption requirements set out in 21 CFR §812.

[5] e.g., Virzi, 1992; Nielsen, 1993

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