Spring 2013

In This Issue

The Big Picture
6 Home Healthcare News & Products

Human Factors and Usability
20 A Question of Accessibility
Understanding Lay Users Of Medical Devices
Melissa R. Lemke and Rochelle J. Medonca

27 Conducting Home-Based Usability Tests of Home Healthcare Devices
Allison Y. Strochlic and Maureen Mulcare

31 Visual Language Can Enhance Medical Device Labeling
Danielle DeVenio

Labeling and Training
33 Guidance for Manufacturers Designing Effective Home User Labeling
Patricia A. Patterson

37 Home User Survey
Medical Device Labeling Instruction Information
Janette Collins-Mitchell, Diana Kaufman-Rivi, Simran Singh, Lisa Winstel, and Mary Weick-Brady

42 Healthcare Provider Preferences For Medical Device Labeling
Toni Stifano, Maggie Fu, Jennifer P. Alexander, Stacey A. Weger, Brian G. Southwell, Michael F. Burke, and Samruddhi Thaker

Design Considerations
43 Using Formal Methods to Improve Home-Use Medical Device Safety
Ayan Banerjee, Yi Zhang, Paul Jones, and Sandeep Gupta

49 Avoiding Conflicting Requirements Development of Home Healthcare Devices Through an Interdisciplinary Approach
Carolyn R. Johnson and R. Craig Campbell

53 Improving Patient Safety and Essential Device Performance
International Standards for Home Respiratory Care Equipment
Debra R. Milamed, Hubertus Lasthaus, and John Hedley-Whyte

58 U.S. Home Healthcare Device Standards
Jennifer Moyer

The HTM Perspective
59 A Voice of Experience
An HTM Career in the Public and Private Sectors
Reginald Cyrus

Wireless and Security
64 A Holistic Tool for Developing A Wireless Home-Based Health Monitoring System
Priyanka Bagade, Ayan Banerjee, Sunit Verma, Joseph Milazzo, and Sandeep K.S. Gupta

72 Medical Device Security—A New Frontier
Arnab Ray, Paul Jones, and Yi Zhang

AAMI President
Mary Logan, JD, CAE

Chief Marketing and Communications Officer
Steve Campbell

Director of Publications
Sean Loughlin

Managing Editor
Erika Hatva

News Editor
Elizabeth Hollis

Graphic Designer
Kristin Blair

Copy Editor
Barbara Saxton

Editorial Board
Chuck Parker
Continua Health Alliance
Daryle Gardner-Bonneau
Bonneau & Associates
Dave Osborn
Philips

Denny Treu
NxStage Medical
Elizabeth Howard
Team ACT
Jack Winters
Marquette University
James Keller
ECRI Institute
James Mueller
Verizon
Lisa Winstel
Caregiver Action Network
Mary Weick-Brady
U.S. Food and Drug Administration
Nancy Kramer
National Home Infusion Association
Reginald Cyrus
Old Dominion University Research Foundation
Robert Schumacher
User Centric

Scott Thiel
Connected Health Operations
Vicki R. Lewis
National Center for Human Factors Engineering in Healthcare
Wendy Rogers
Georgia Institute of Technology

Horizons is a supplement to Biomedical Instrumentation & Technology (ISSN 0899-8205) and is published twice a year by the Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633; +1-703-525-4890. © 2013, Association for the Advancement of Medical Instrumentation. Publishing services provided by Allen Press Publishing Services, a division of Allen Press Inc.

Membership: AAMI members receive a complimentary subscription. Contact membership at AAMI at +1-800-332-2264, ext. 1214.


Advertising and Business: Send correspondence to Allen Press, Inc., 810 E. 10th Street, Lawrence, KS 66044-8897, advertising manager Judy Riling, +1-800-627-0326, ext. 249, email: jriling@allenpress.com.

Mention of any commercial product, process, or service by trade name, trademark, manufacturer, or otherwise in Horizons does not constitute or imply endorsement or recommendation by AAMI. The views and opinions of the authors in Horizons do not state or reflect the opinion of AAMI.

POSTMASTER: Send address changes to BIRT, 810 E. 10th Street, P.O. Box 1897, Lawrence, KS 66044-8897. AAMI members send changes to AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633; +1-703-525-4890. Nonmembers send changes to Kansas address above.

Visit AAMI on the web at www.aami.org