IN THIS ISSUE

182 COVER STORY
The Quest for Quality
Navigating the Changing Landscape of Healthcare Technology Regulations
Chris Hayhurst

FEATURES
192 Methodology for Ensuring Accuracy and Validity of Infusion Pump Alarm Data
Catherine Schuster and Rachel R. Vitoux

199 Verification Testing of Biological Indicators for Moist Heat Sterilization
Patrick J. McCormick, Michael J. Schoene, Deanna Pedeville, James J. Kaiser, and Julie Conyer

208 CASE STUDY
Continuous Bedside Capnography Monitoring of High-Risk Patients Receiving Opioids
Paul E. Milligan, Yao Zhang, and Sally Graver

208 CASE STUDY
Developing an In-House Magnetic Resonance Imaging Maintenance Program
Mark R. Asbil, Bernard Boland, Martin Dussault, Wendy Rabbie, Marie-Ange Janvier, Y. Rachel Zhang, and Kim Greenwood

DEPARTMENTS
172 FRONTLINES
174 THE ROUNDUP
179 DID YOU SEE?
180 TEN QUESTIONS WITH...
181 PEOPLE ARE SAYING

223 ROUNDTABLE DISCUSSION
HTM: A Career Field Rich with Opportunities and Challenges

229 VIEW FROM THE TOP
The Next Big Step: Highlighting the Most Relevant Data Points for Patient Care

232 BRIGHT IDEAS
Adding IT to the HTM Toolkit
Gavin Stern

236 CYBERINSIGHTS
The Times They Are a-Changin’: Part Two
Axel Wirth

241 STERILIZATION STRAIGHT TALK
Sparking a Learning Revolution in Your Sterile Processing Department
Weston Balch

243 SETTING STANDARDS
Homing in on Common Terminology and Requirements for Luer-Activated Valves
Ravi Narayanan and Srinath Lingutla

245 TROUBLESHOOT IT
Verifying Skin Temperature Control Is Vital When Testing Infant Warmers
Becky Crossley

246 OBSERVATIONS AND INSIGHTS
Places Where HTM Can Find Money in the Hospital
Patrick K. Lynch

248 FINAL WORD
As Low as Reasonably Practicable: An Approach to Managing Device Risk
Tom Shoup

Navigating the Changing Landscape of Healthcare Technology Regulations

Biomedical Instrumentation & Technology (ISSN 0899-8205) is published bimonthly by the Association for the Advancement of Medical Instrumentation, 4301 North Fairfax Drive, Suite 301, Arlington, VA 22203. © 2018, Association for the Advancement of Medical Instrumentation. Publishing services provided by Allen Press, Inc.

Membership: AAMI members receive a complimentary subscription. Contact membership at AAMI: (800) 332-2264 ext. 1214.

Subscription rates (yearly): Individuals: online only, $190; U.S. print & online, $220; non-U.S. print & online, $272.

Institutional: online only, $242; U.S. print and online, $272; non-U.S. print & online, $315.

Single back issues (when available): $34 (US) and $38 (International). Subscriptions are available on a calendar-year basis only. Send orders and remittances to Biomedical Instrumentation & Technology, 810 E. 10th Street, P.O. Box 1897, Lawrence, KS 66044, (800) 627-0326 ext. 404.

Editorial: Visit www.aami.org/publications/BIT/guidelines.html to view the complete author guidelines. Send general correspondence to the Publications Department, AAMI, 4301 North Fairfax Drive, Suite 301, Arlington, VA 22203; (703) 525-4890, ext. 1225.

Advertising: Send correspondence to Tom Lasch (email: tlasch@aami.org; phone: 440-247-1060). General AAMI advertising information available at www.aami.org/advertising.

Index, Archive: Biomedical Instrumentation & Technology is indexed, archived, or listed by the following: CINAHL Info Systems, Crossref, DeepDyve, Ebsco, Embase, Index Medicus, PubMed/Medline, Referativnyi Zhurnal, and Thomson Reuters.

Photocopies: Authorization to photocopy items for internal or personal use, or the internal or personal use of specific clients, is granted by Allen Press, Inc. for libraries and other users registered with the Copyright Clearance Center (CCC) Transaction Reporting Service, 222 Rosewood Drive, Danvers, MA 01923.

Periodical postage is paid at Arlington, VA, and additional mailing offices.

Visit AAMI on the web at aami.org