Note: Please do not reply to this e-mail, as your response will not be received.

For further information regarding Health Devices Alerts content, contact one of ECRI Institute's experts by e-mailing HDA@ecri.org or calling (610) 825-6000.

For additional important announcements from ECRI Institute, please scroll down to the bottom of this e-mail or Click Here. Announcements were updated on November 4, 2011.
Action Items - Friday, November 04, 2011

Critical Priority  A16931  ACUTRONIC-MISTRAL Jet Ventilators:
May Not Alarm if O2 Supply Fails

High Priority  H0159  Non-current Diagnostic Software in Hamilton
Medical's Hamilton-C2 Ventilators May, in Rare Cases,
Cause the Ventilator to Stop Delivering Breaths

High Priority  A16956  Medrad-Stellant Sterile Disposable Syringe Kits:
Sterility May Be Compromised

High Priority  A16954  MAKO Surgical-RIO Robotic Arm Interactive
Orthopedic Systems:
Software Error May Result in a Bone Resection

High Priority  A16948  Cincinnati Sub-Zero-Rectal/Esophageal General-
Purpose Temperature Probes:
May Display Incorrect Temperatures or Cease Operation

High Priority  A16947  Fehling Instruments-MBR-2 Aortic Deairing
Cannulae:
Tip May Break

High Priority  A16944  Philips-Various Brilliance and Ingenuity Computed
Tomography Systems:
Common Image Reconstructive System Error May Require
System Reboot; Manufacturer Provides Firmware Update

High Priority  A16942  Newdeal-2.7 x 12 mm Sterile Sufix Alpha Screws:
May Be Etched and Labeled with Incorrect Specifications

High Priority  A16940  Vascular Solutions-Povidone Iodine Products
Contained in Model 7790 and Model 7791 Vari-Lase
Procedure Packs:
May Not Have Been Tested for Microbial Contamination

High Priority A16938 Integra-CUSA EXcel and CUSA EXcel+ Ultrasonic Tissue Ablation Systems:
May Have Been Distributed without Operator’s Manual and Quick Reference Cards

High Priority A16937 HemoCue-Model 201+ Glucose Meters:
May Display Zero for Samples with High Glucose Concentrations under Certain Conditions

High Priority A16936 GE-VMX and VMX Plus Mobile X-Ray Systems:
Articulated Arm Base Casting May Develop Fatigue Cracks over Time, Potentially Allowing Components to Fall

High Priority A16934 DePuy-Sigma HP FB Tibial Tray Impactors:
May Become Fixed to Implant during Surgery

High Priority A16933 DePuy-Duraloc Polished HA Shells:
Packaging May Contain Incorrect Size Prosthesis

High Priority A16929 Stryker-Inferior Border Osteotomy Blades:
May Break during Use

High Priority A16928 Boston Scientific-Model 3120 ZOOM LATITUDE Programmers and LATITUDE Remote Monitoring System Server Software:
Shock Lead Impedance Alert Messages May Be Difficult to Interpret

High Priority A16927 GE-Revolution XRD X-Ray Diffraction Systems:
Tabletop Handgrip May Not Be Properly Adjusted, Potentially Becoming Dislodged during Use

High Priority A16926 GE-Model 3100IQ Innova Fluoroscopic Vascular X-
Ray Systems:
Monitor Suspension End-Stop May Break under Excessive Force

High Priority A16923 Philips-BV Endura, BV Pulsera, and Veradius Mobile X-Ray Systems:
Front Plate May Fracture, Potentially Causing the C-Arm to Suspend on the Single Central Bolt

High Priority A16919 Salter Labs-Adult Nebulizers and O2 Masks:
Mask May Be Obstructed, Potentially Preventing O2 Delivery

High Priority A16918 CareFusion-Nicolet C64 Stimulus Switching Unit Amplifiers, Nicolet Cortical Stimulator Control Units, and NicoletOne Software with Cortical Stimulator License:
Various Problems May Occur

High Priority A16910 Smith & Nephew-Model HD1200 Autoclavable Camera Systems:
Camera Heads May Cause Image Problems

High Priority A16896 Merz-1.5 cc RADIESSE Volumizing Filler Syringes:
Plunger May Leak, Potentially Resulting in Infection

High Priority A16883 01 Mardx-Bartels Clostridium difficile Antitoxin Reagents:
May Be Contaminated with Mold

High Priority A16868 Abbott Medical Optics-Femtosecond Laser Systems:
Discrepancy in Cut Depth May Affect Deep Corneal Incisions
High Priority A16867 Abbott-Clinical Chemistry Urea Nitrogen Reagents:
Aureobasidium Contamination May Generate Visible Matter and Cause Reagent Discoloration

High Priority A16842 Invacare-Leo Mobility Scooters:
Plastic Backrest Fixation May Break, Potentially Resulting in User or Patient Falling out of the Seat

High Priority A16781 Zimmer-Trabecular Metal Modular Acetabular System Shells without Holes:
Locking Ring Groove Depth May Prevent Corresponding Liner from Fitting into Shell as Designed

High Priority A16727 01 Drive-Model WA007 Rollators:
Front Caster Fork May Become Detached during Use

High Priority A16714 01 Nikkiso-Aquarius Hemofiltration Units:
Wheels May Break, Potentially Resulting in Unit Falling Over and Causing Injury

High Priority A16544 01 *Philips-EasyDiagnost Eleva Radiographic/Fluoroscopic Systems:
Camera May Intermittently Shut Off, Potentially Causing a Loss of Fluoroscopy [Update]

High Priority A15661 18 GE-H&P Povidone Iodine Pads Contained in Vital Signs Broselow Pediatric Emergency System Kits:
May Be Contaminated with Elizabethkingia meningoseptica

Normal Priority H0158 FDA Issues Advice on the Use of Jet Injectors to Administer Inactivated Influenza Vaccines

Normal Priority A16958 Codman-Cranial Access and Disposable ICP Kits with Xylocaine:
May Contain Outdated Xylocaine Instructions for Use

**Normal Priority**

**A16951** [eBioscience-Anti-Human CD152 (CTLA-4) Reagents]:
May Be Mislabeled with Incorrect Storage Temperature

**A16946** [KerrHawe/Metrex-Pinnacle Cure Sleeve Light Guide Covers]:
May Be Mislabeled

**A16945** [Qiagen-therascreen KRAS PCR Reagent Kits]:
Mixed Standard May Yield Out-of-Specification Results, Potentially Causing an Invalid Run

**A16943** [Newdeal-TIBIAXYS Compression Guides Used with TIBIAXYS Ankle Arthrodesis Plating Systems]:
May Break; Manufacturer Issues Surgical Caution

**A16939** [Intuitive-da Vinci Surgical Systems]:
Manufacturer Clarifies Instructions for Use

**A16932** [Coloplast-Simpla Foley Catheters]:
Packaging May Contain Incorrect Instructions for Use

**A16920** [Beckman Coulter-Gastroccult Reagent Slides]:
Quality Control Test May Yield Incorrect Color if Colored Buffer Is Used

**A16890** [Tripath-Model C4i Jouan/Thermo-Fisher Centrifuges Used with PrepStain Slide Processors]:
May Display Inaccurate G Force or RPM Readings

**A16835 01** [*Stryker-iSuite Integrated Operating Room Systems]:
Component Installation Records May Be Incomplete or
ECRI Institute News:

**November Health Devices**. In the November issue of *Health Devices*, we feature ECRI Institute's annual list of the top 10 health technology hazards. These are the potential sources of danger that we believe warrant the greatest attention for the coming year. We also feature a Guidance Article that provides an introduction to total hip replacement surgery and hip implant designs. To see the full contents of the issue, click here.
Updated HDA Help Pages: We have updated three help pages designed to help you make the most of our Health Devices Alerts services. The [HDA Help](#) page is full of commonly asked questions and answers regarding proper use and formatting of Health Devices Alerts. Check out the [Alerts Tracking Help](#) page for information on responding to assignments and basic Alerts Tracker guidance. The [Tracker Coordination Help](#) page contains numerous resources to help Alerts Tracker Coordinators with training, coordination, and configuration of your Alerts Tracker system. We invite you to check them out today!

Health Devices Web Site Training Sessions: Get the most from your ECRI Institute membership by participating in a free online training session for the Health Devices Web site. We will review all the resources that are available to you, help you better navigate the site, and show you how to use the different search capabilities. All you will need to participate in the training session is a computer with high speed internet access and a telephone to call us on a toll-free number. Sessions are held on the first Tuesday of each month from 4:00 pm to 5:00 pm Eastern time and on the third Thursday of each month from 11:00 am to 12:00 pm Eastern time. To schedule a training session, send an e-mail to our [Health Devices training coordinator](mailto:). We will send you an e-mail invitation with the necessary information for logging into the session.

For more information about Health Devices Alerts, [Click Here](#).

You have likely noticed that the Health Devices Alerts Web site and weekly e-mail notification messages have been reformatted. Changes to the system include a unified search engine, improved navigation, and an optional system for automated distribution and documentation of follow-up for hazards and recalls at your facility. For more information, see [www.ecri.org/alertstracker](http://www.ecri.org/alertstracker).

If you have questions or experience any problems or irregularities with the new system, or if you need a username and password to log into the ECRI Institute Web site, please contact the ECRI Institute Help Desk by e-mailing [HelpDesk@ecri.org](mailto:HelpDesk@ecri.org) or by calling (610) 825-6000, extension 5555.

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