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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 Surfix 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 A16951 [eBioscience-Anti-Human CD152 \(CTLA-4\)](#)
Priority [Reagents](#):

May Be Mislabeled with Incorrect Storage Temperature

Normal A16946 [KerrHawe/Metrex-Pinnacle Cure Sleeve Light](#)
Priority [Guide Covers](#):

May Be Mislabeled

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

Normal A16943 [Newdeal-TIBIAXYS Compression Guides Used](#)
Priority [with TIBIAXYS Ankle Arthrodesis Plating Systems](#):

May Break; Manufacturer Issues Surgical Caution

Normal A16939 [Intuitive-da Vinci Surgical Systems](#):
Priority Manufacturer Clarifies Instructions for Use

Normal A16932 [Coloplast-Simpla Foley Catheters](#):
Priority Packaging May Contain Incorrect Instructions for Use

Normal A16920 [Beckman Coulter-Gastrocult Reagent Slides](#):
Priority Quality Control Test May Yield Incorrect Color if Colored
Buffer Is Used

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

Normal A16835 01 [*Stryker-iSuite Integrated Operating Room](#)
Priority [Systems](#):
Component Installation Records May Be Incomplete or

Inadequate [Update]

Normal Priority A16700 01 [Drive-Nimbo Pediatric Walkers:](#)
Use over Unsuitable Outdoor Environments May Reduce
Wheel and Fastener Lifespan

No Priority A16941 [LeMaitre-AlboGraft Polyester Vascular Grafts:](#)
May Exhibit Surface Extravasation after Implantation

No Priority A16925 [Baxter-Model 6301 Flo-Guard Volumetric Infusion
Pumps:](#)
May Have Been Released with Out-of-Specification Air-in-
Tubing Test Air Sensor Calibration Values

No Priority A16913 [Carl Zeiss-OPMI VARIO 700 Surgical
Microscopes:](#)
Spring Assembly May Contain Incorrect Nut and Bolt Set

No Priority A16855 [Exalenz-IDkit:](#)
HPTWO Pylori Breath Test Kits: May Not Have Received
FDA Clearance

No Priority A16696 01 [*Philips-Ingenia 1.5 T and 3.0 T Magnetic
Resonance Systems:](#)
Patient Skin May Redden during Scanning [Update]

To view the entire issue, [Click Here.](#)

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](#). We will send you an e-mail invitation with the necessary information for logging into the session.

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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.

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 or by calling (610) 825-6000, extension 5555.

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