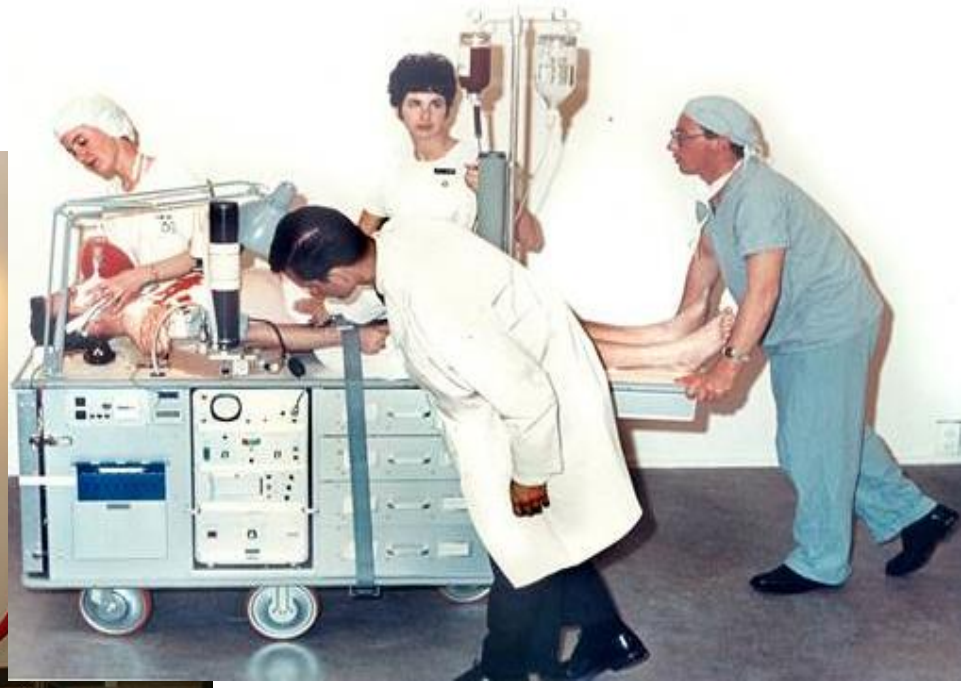
Top 10 Health Technology Hazards for 2023

Selected Hazards related to Medical Devices

How ECRI Started

Dr. Joel J. Nobel (1934-2014)



"Anger is a great source of energy. I focused it on improving technology and patient safety."

- Joel J. Nobel, MD, Founder of ECRI

Over 50 Years of Safe and Effective Healthcare

INDEPENDENT TESTING & EVALUATION LAB

The only independent medical device testing and evaluation lab in North America and Asia Pacific

PATIENT SAFETY ORGANIZATION

Listed by the U.S. Department of Health & Human Services and now one of the largest in the U.S

EVIDENCE-BASED PRACTICE CENTER

Designated as an Evidence-Based Practice Center by the U.S. Agency for Healthcare Research & Quality

Outline

- **Purpose** of the List
- What the List **Includes**
- The **2023** List at a Glance
- A Closer Look at the **Hazards**
- **Q&A**

Purpose of the List

- Annual report identifying high-impact health technology hazards

Health technology hazards are device or system faults, design features, or methods of use that might, under certain circumstances, place patients or users at risk.

- Produced by ECRI's Health Devices Group to:
  - Shine a light on health technology safety issues that have the clear potential to:
    - Cause death or serious injury
    - Adversely affect patient care
  - Provide healthcare professionals with a tool they can use to:
    - Set patient safety priorities — We identify topics that warrant attention for the coming year
    - Implement effective changes to help prevent harm — We provide recommendations for action

What the List Includes

- Topics derive from
  - Known events (e.g., problem reports)
  - Emerging issues — predictive (e.g., from our testing or investigations)
- Criteria for inclusion:
  - Baseline criteria—all hazards on the list are:
    - Technology-related, generic (not model-specific)
    - Preventable — Healthcare organizations can prevent harm by being proactive

Additional criteria—one or more may apply:

Severity

How serious would the harm to patients be if this safety concern were to occur?

Frequency

How likely is it that the safety concern will occur?

Breadth

If the safety concern were to occur, how many patients would it affect?

Insidiousness

Is the problem difficult to recognize or challenging to rectify if it occurs?

Profile

Would the safety concern place a lot of pressure on the organization?

The 2023 List at a Glance

1. Gaps In Recalls For At-home Medical Devices Cause Patient Confusion And Harm
2. Growing Number Of Defective Single-use Medical Devices Puts Patients At Risk
3. Inappropriate Use Of Automated Dispensing Cabinet Overrides Can Result In Medication Errors
4. Undetected Venous Needle Dislodgement Or Access-bloodline Separation During Hemodialysis Can Lead To Death
5. Failure To Manage Cybersecurity Risks Associated With Cloud-based Clinical Systems Can Result In Care Disruptions
6. Inflatable Pressure Infusers Can Deliver Fatal Air Emboli From IV Solutions Bags
7. Confusion Surrounding Ventilator Cleaning And Disinfection Requirements Can Lead To Cross-contamination
8. Common Misconceptions About Electrosurgery Can Lead To Serious Burns
9. Overuse Of Cardiac Telemetry Can Lead To Clinician Cognitive Overload And Missed Critical Events
10. Underreporting Device-related Issues May Risk Recurrence

Underreporting Device-related Issues May Risk Recurrence

Underreporting Device-related Issues May Risk Recurrence

The Problem

- **Event reporting** can uncover problems that could negatively affect patients or contribute to serious events in the future
  - Opportunity to identify and fix/replace damaged or malfunctioning devices.
  - To identify system-based problems that may be happening in the background

Device-related problems are not always reported:

- Users may be focused on patient care and unable to interrupt a time sensitive task to submit a report.
- They may be unfamiliar with the method for reporting.
- They may see little benefit to reporting, particularly if no harm was observed.
- They may fear disciplinary action or other personal consequences

Underreporting Device-related Issues May Risk Recurrence

Recommendations

Incident Response Staff
(BMEs, Patient Safety officers, Med Safety officers)

- Develop streamlined, centralized method for reporting device-related problems.
- Reporting mechanism should be well-designed, easy to use, and readily accessible.
- Work with IT/risk management information system vendor

Leadership & Management

- Ensure staff recognize potential hazards – sharing examples, learning
- Encourage event reporting by creating incentives to report
- Review consumables usage to identify any trends of unusually high usage rate – may indicate high incidence of product failures
- **Analyze** reports

8

Common Misconceptions about Electrosurgery Can Lead to Serious Burns

Common Misconceptions about Electrosurgery Can Lead to Serious Burns

The Problem

Misconceptions associated with monopolar electrosurgery:

Using multiple ESUs simultaneously on one patient presents no added risk.	→ Burn risks increase exponentially when multiple ESUs are used.
The surgeon should activate the ESU's active electrode before its tip is in contact with the patient.	→ Doing so causes a high voltage to develop in the ESU circuit, increasing the likelihood of patient or clinician injury.
The return electrode pad can never be safely applied over an orthopedic metal implant, tattoo or piercing – may prompt users to place return electrode over a less safe part of the anatomy	→ placing the return electrode over metal objects embedded in simulated surgical tissue does not heat or burn the surrounding tissue during ESU activation.

Common Misconceptions about Electrosurgery Can Lead to Serious Burns

Recommendations

- Avoid the use of multiple ESUs simultaneously for monopolar electrosurgery
- Do not activate the active electrode until it is in contact with the target tissue
- Choose proper location for the placement of the return electrode – clean, dry, unbroken skit, on a part of the patient's body where larger muscles can aid in current dispersion (thighs, trunk)
- Avoid locations over bony prominences and where the patient would be lying on the electrode.
- Placing return electrode over a part of the body containing tattoo, metallic orthopedic implant or other non-electronic piece of metal that cannot be removed is safe.
- Be cautious if patient has an electronic metallic implant

Confusion Surrounding Ventilator Cleaning And Disinfection Requirements Can Lead To Cross-contamination

Confusion Surrounding Ventilator Cleaning And Disinfection Requirements Can Lead To Cross-contamination

The Problem

Reprocessing instructions provided by ventilator manufacturers are, in some cases, incomplete or confusing; and even guidance from regulatory authorities is not always clear.

US CDC
Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
Recommendation 3.b.,

"Provide, at a minimum, high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or nonintact skin."

Which ventilator component?

Manufacturer instructions

- Some vendors – *but not all* – recommend that after every patient, facilities perform high-level disinfection on the exhalation valve and any other components that are in the path of exhaled gases.
- Some vendors provide detailed cleaning and disinfecting information but make *no specific recommendations* on how often these tasks should be performed.
- Some vendors *informally* instruct clients that a filter in the breathing circuit, either at the patient wye or between the circuit and the exhalation valve, will be sufficient.

Confusion Surrounding Ventilator Cleaning And Disinfection Requirements Can Lead To Cross-contamination

? Do internal exhalation valves or other reusable ventilator components that come into contact with exhaled patient gas require high-level disinfection (or sterilization) between patients?

? Is the use of a filter in the breathing circuit sufficient to prevent contamination of ventilator components?

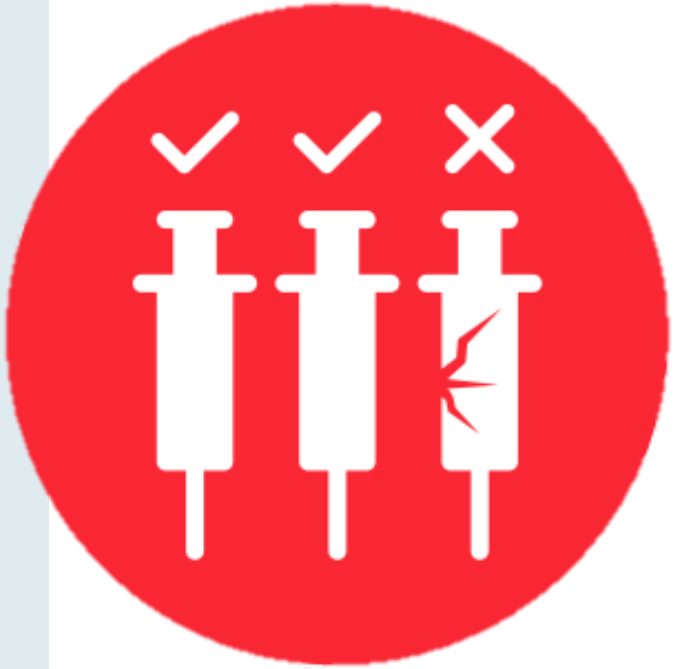
Confusion Surrounding Ventilator Cleaning And Disinfection Requirements Can Lead To Cross-contamination

Recommendations

- Use single-use items
- Use at least one appropriate filter in the breathing circuit when ventilating a patient infected with a known or suspected airborne pathogen
- Inspect filters before use and replace filters following manufacturers' instructions
- Treat any reusable components that may come into contact with the exhaled patient gas as **semicritical equipment** and reprocess accordingly; with high-level disinfection instructions (e.g., internal & external exhalation valves, reusable breathing circuits)

ECRI Challenge to Industry

Verify that their instructions for cleaning and disinfecting the various components are:
1. Complete, clear, accessible
2. Realistically achievable in the clinical environment
3. In alignment with ECRI's recommendations



2

Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk

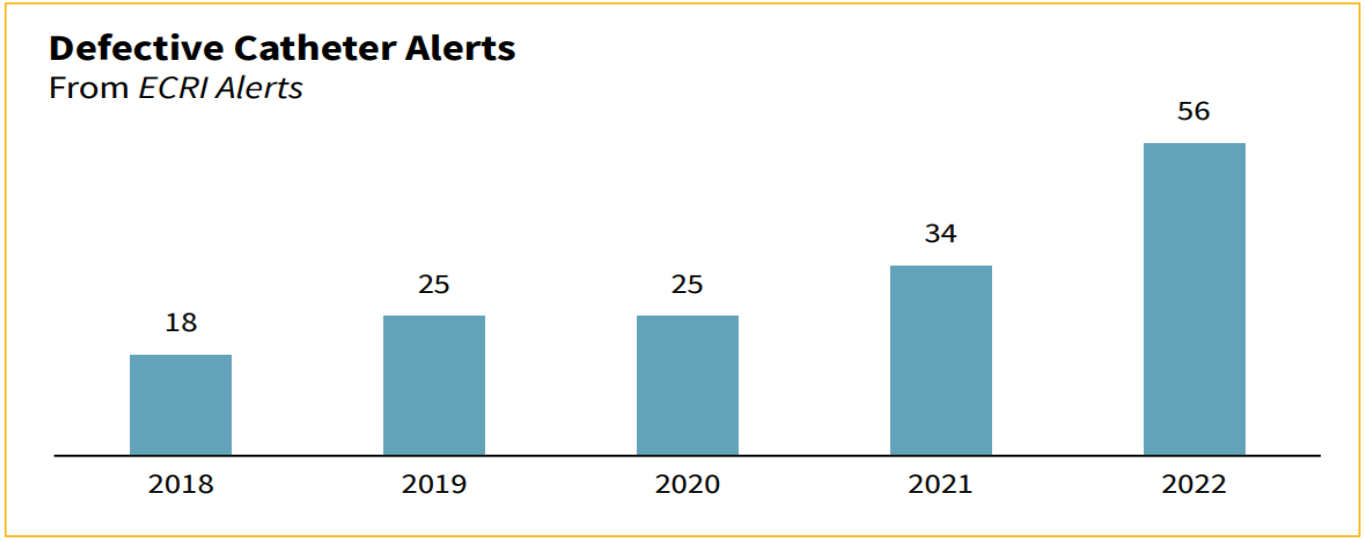
Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk

The Problem

ECRI has received reports of:

- cracked tubing and connectors
- compromised sterility of needles, catheters, and procedure kits
- incorrect product labeling

Defective single-use products can cause **delays in care, increase costs, healthcare-acquired infections, patient injury or death.**



FDA Maude August 2022 - 412 records on basic syringes
18 involved injuries, with 394 malfunctions reports:

- Breaks/cracks (73)
- Device contamination (62)
- Leaks (42)
- Failure to deliver (12)
- “Air in device” (2)

Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk

Recommendations

Healthcare Organizations

- Establish processes for reporting defective products, both internally and externally
- Track the usage of specific product types. Look for unexpected increased usage of a particular product type, which may indicate product waste due to defects .
- Maintain a list of functionally equivalent alternatives for critical products.
- Hold manufacturers accountable.

Clinical Staff

- Examine each device before use for signs of defects
- Sequester any product that have contributed to an adverse event, and report the defective products

ECRI Challenge to Industry

- Strive for zero defects in QC processes.
- Scrutinize processes when there is a change in raw materials/production location.
- Retain samples of each lot for future failure analysis, should problems arise.

Gaps In Recalls For At-home Medical Devices Cause Patient Confusion And Harm

Gaps In Recalls For At-home Medical Devices Cause Patient Confusion And Harm

The Problem

Accurate and understandable information about medical device recalls often does not reach patients using those devices in the home.

Examples of recalls in which the info was received long after the recalls were issues:

1) Recall of continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines.
2) Ventricular assist device – 15 recalls in 2021 and 2022 but not clear enough communications.

Without a clear understanding of the risks, patients may be harmed by continuing to use an unsafe device— or by inappropriately stopping use.

Device manufacturers often don't have direct communication with home care patients

Healthcare providers may not proactively contact patients about recalls

Even if patients do receive a notification, the language may be jargon-heavy, perplexing and taking time to reach patient

Gaps In Recalls For At-home Medical Devices Cause Patient Confusion And Harm

Recommendations

Healthcare Organizations

- Maintain and organize databases of device allocations, patient info.
- Educate patients on the importance of device registration with the manufacturers, explain what recall is and the actions to take if any recall is issued.

Patients

- Familiarize yourself with the manufacturers' website, including how to find product notices.
- Discuss, always communicate with your physicians

ECRI Challenge to Industry

- Provide easy-to-follow registration instructions to the labels of home care devices.
- Clear, concise, simply worded recall notices – to be easily understood and followed by patients
- Maintain up-to-date databases of device distribution and, if applicable, end users with patient contact information.
- Consider public communications

Download the executive brief at:

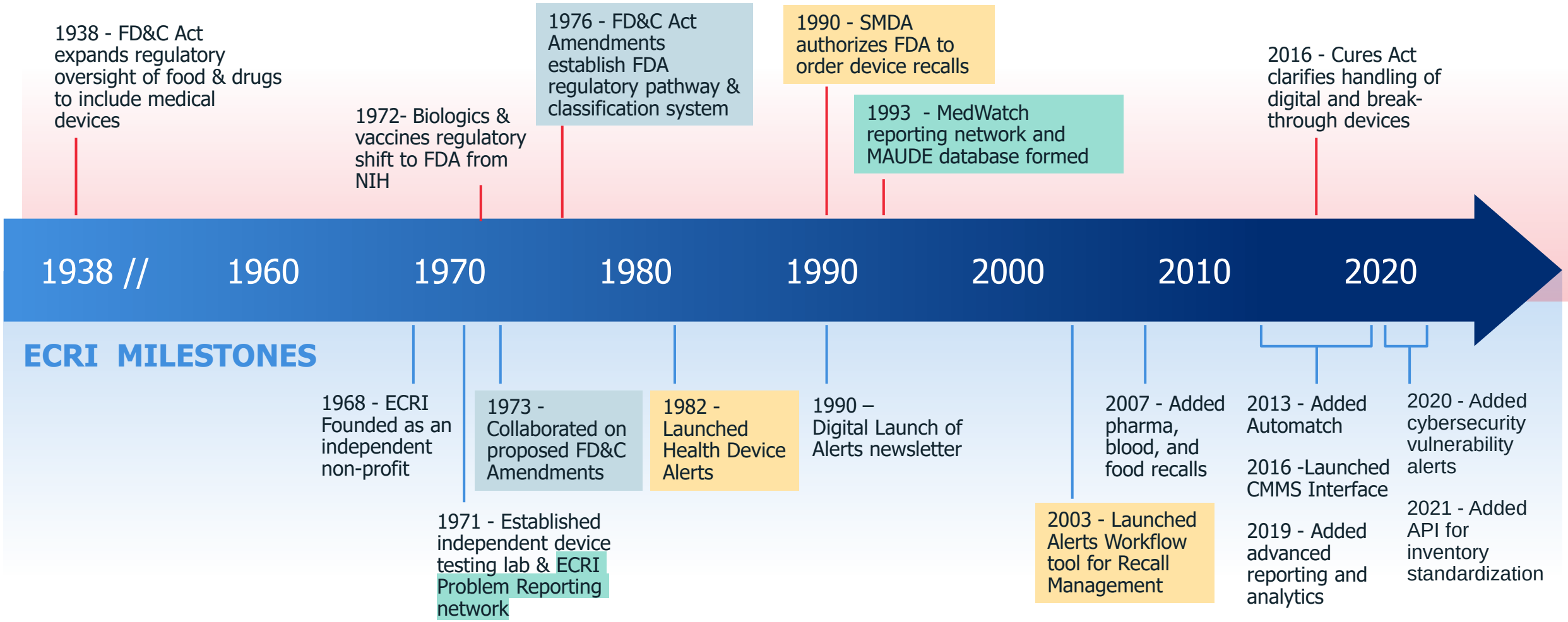
https://www.ecri.org/top-10-health-technology-hazards-2023-executive-brief

Managing Hazards and Recalls

Impact on Maintenance Management and Adverse Event Management

ECRI - Trusted Leader in Patient Safety and Recall Management

FDA / REGULATORY MILESTONES



ECRI Alerts Workflow Solution

— ECRI offers a configurable web-based alerts notification and management solution for medical technology to help mitigate safety and compliance risk

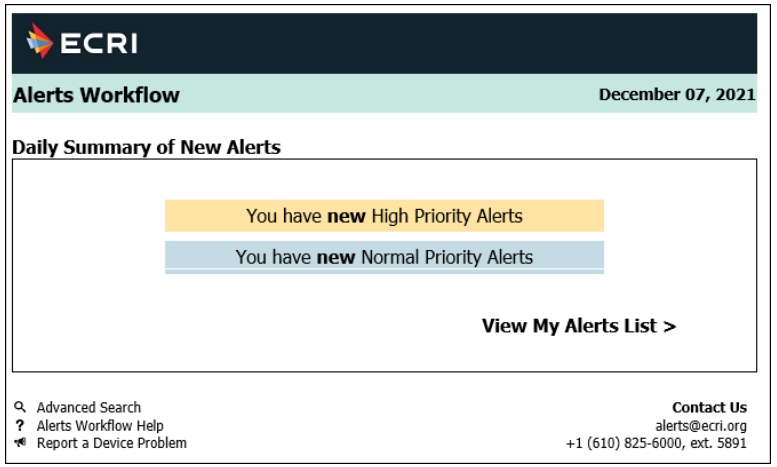
- Ensures the **right alerts get to the right people** in your organization
- Enables **timely tracking** of recalls and safety hazards.
  - Provides **early warning signals** for **timely intervention**, often before manufacturer and FDA notifications
  - **Streamlines collaboration** across hospitals, facilities, and departments to avoid adverse events
- Summarizes all manufacturer and product details along with **actionable corrective actions**.
- Provides a **single source of truth** and online system for managing all hazard and recall alerts
  - Enables hospitals to track, assign, and update status to **support ongoing accreditation and compliance**.
- Includes **advanced dashboard and reports** to drive corrective action and closure

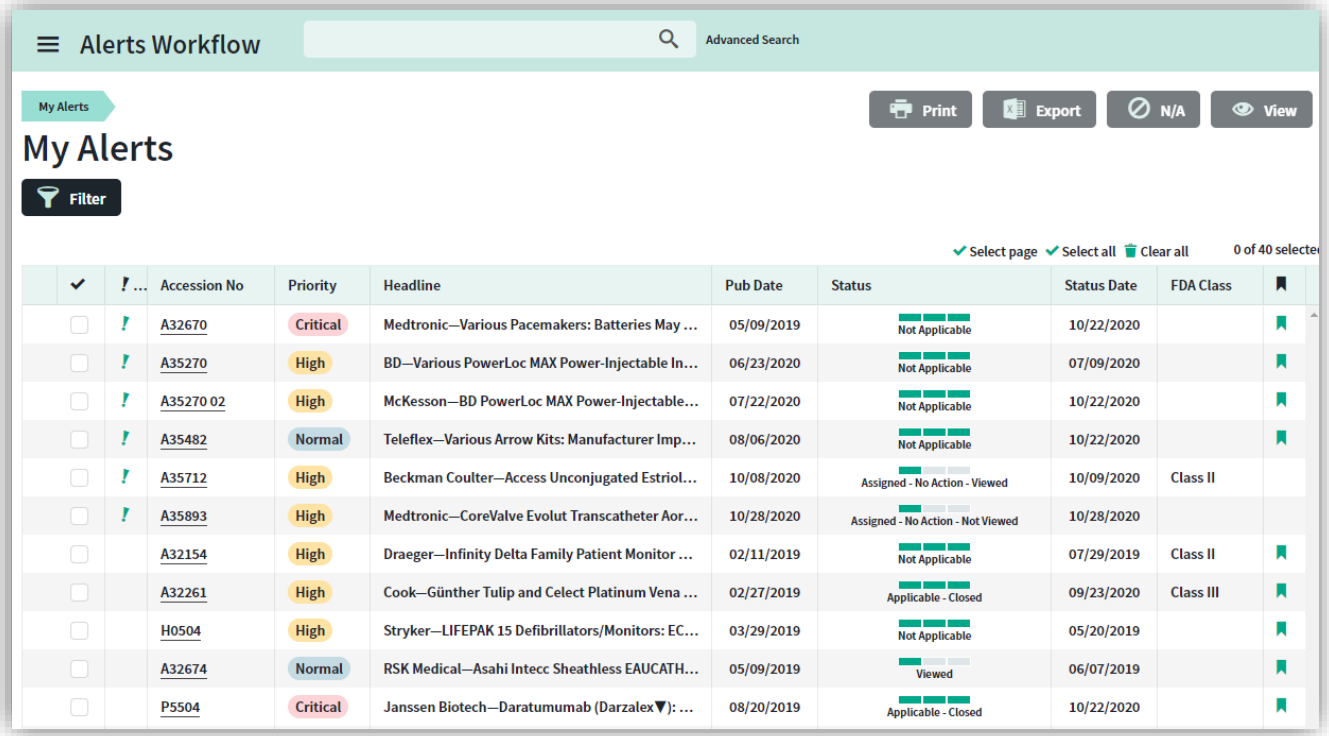
Our Global Coverage and Reach

- **ECRI In-house Resources:**
  - Local Support (North America, Europe, Asia, Middle East)
  - Independent Medical Device Testing Lab
  - In-house independent research team
- **3rd-party Resources:**
  - Regulatory Agencies and Government Authorities
    - FDA (U.S.)
    - MRHA (U.K.)
    - Health Canada
    - BfArM (Germany)
    - TGA (Australia)
  - Vendors/Manufacturers
  - ECRI's Customer Problem Reporting Network (PRN)

Our Breadth

- **Single Source of Truth**
- **4 channels and 50 categories of configurable Alerts content, including:**
  - Medical equipment
  - Medical supplies
  - Implantable devices
  - Personal Protective Equipment (PPE's)
  - Drugs
  - Biologics
  - Vaccines
  - Blood and blood products
  - Radiation-emitting products
  - Transplantable human tissue
  - Food
  - ***Plus networked medical device vulnerabilities for cybersecurity***





Surgical Lasers : Reported Problems
- *Tissue Damage*

[Not Prioritized] - 24779 : Defective laser machine and defective technique blamed for bowel/bladder fistula from laser surgery. Med Malpract Verdicts Settlements Experts 1993 Dec;9(12):15.
Medical Device Abstract

Published: Friday, January 21, 1994

UMDNS Terms:

- LASERS, SURGICAL, ND:YAG [16943]

Product Identifier:
Lasersonics 8900 Laser Machines

Geographic Regions: GeographicRegion

Manufacturer(s): Heraeus Surgical Div Heraeus Instruments Inc575 Cottonwood Dr, Milpitas CA 95035-7402

Abstract: The plaintiff underwent outpatient laser surgery in 1989 with a Lasersonics 8900 to remove superficial bladder tumors. Later, the plaintiff was diagnosed with a bowel/bladder fistula requiring a temporary colostomy. The plaintiff claimed that stress from the recuperation and resulting financial difficulties caused his heart attack in 1991 and that he suffered severe depression. The plaintiff contended that the physician was negligent in performing the procedure; that the manufacturer's device was defective, delivering twice the set energy level; and that the hospital did not properly maintain the laser unit. All 3 defending parties denied the allegations. The court returned a directed verdict for the hospital and manufacturer based on lack of evidence of product defect; a defense verdict was returned for the operating surgeon. An appeal is pending. (*Gerald Spalti, et al. v. Gregory Fouts, M.D., Mt. Diablo Medical Center; Heraeus Lasersonics, Inc., et al.* Contra Costa County {CA} Superior Court, Case No. C90-05370.)

Source: Defective laser machine and defective technique blamed for bowel/bladder fistula from laser surgery. *Med Malpract Verdicts Settlements Experts* 1993 Dec;9(12):15.

Report on AED Failures: A Reminder that Maintenance is Vital

Submitted by SCAFoundation on Mon, 08/29/2011 - 11:00pm SCA News

WASHINGTON-- More than 1,000 cardiac arrest deaths over 15 years are connected to the failure of automated external defibrillators (AEDs); battery failure accounted for almost one-quarter of the failures. The study was published online last week in Annals of Emergency Medicine ("Analysis of Automated External Defibrillator Device Failures Reported to the Food and Drug Administration" http://bit.ly/ox6YYr).

"Survival from cardiac arrest depends on the reliable operation of AEDs," said lead study author Lawrence DeLuca, MD, EdD, of the University of Arizona Department of Emergency Medicine in Tucson. "AEDs can truly be lifesavers but only if they are in good working order and people are willing to use them."

Researchers analyzed reports to the Food and Drug Administration (FDA) about all adverse events connected to use of an AED between January 1993 and October 2008. Of the 40,787 AED-related events reported to the FDA, 1,150 adverse events connected to fatalities were reported (3%). Almost half (45 percent) of failures occurred during the attempt to charge and deliver a recommended shock to the person in cardiac arrest. Problems with pads and connectors accounted for 23.7 percent of the failures and battery power problems accounted for 23.2 percent of the failures.

Defibrillators : Common Reported Problems

Philips recalls defibrillators tied to 2 patient deaths

OCTOBER 25, 2019 BY NANCY CROTTI — LEAVE A COMMENT

(Image from Philips)

Philips has issued two separate recalls for its HeartStart XL+ defibrillator/monitor which may delay therapy and endanger patients.

One recall relates to the device's potential to fail to start or to unexpectedly try to restart and affects only devices sold outside the U.S. and Canada. It is associated with 588 customer complaints since 2011 and two patient deaths.

In some cases, the problem may stem from a defect in the HeartStart's memory management software. In others, the cause may be a malfunction of the System On Module (SOM) installed on the processor printed circuit assembly (PCA). Philips said it will perform a system software upgrade and replace the processor PCA that contains the faulty SOM module.

[Critical Priority] - A33651 : Philips— HeartStart XL+ Defibrillator/Monitors: May Unexpectedly Restart or Fail to Turn On
Medical Device Ongoing Action

Published: Friday, November 8, 2019

UMDNS Terms:

- Defibrillators, External, Manual [11134]

Product Identifier:
[Capital Equipment]

Product	Philips Healthcare Model	Model No.
Defibrillator/Monitors	HeartStart XL+	861290

Geographic Regions: (Impact in specific regions has not been identified or ruled out at the time of this posting), Worldwide except Canada and U.S.

Manufacturer(s): Philips Healthcare3000 Minuteman Rd, Andover, MA 01810, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, Information Technology, EMS/Transport

Problem:
In an October 2019 Urgent Medical Device Correction letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), Philips states that the above defibrillator/monitors may fail to turn on or unexpectedly attempt to restart, rendering the devices unable to return to a ready-for-use state, potentially resulting in a delay of patient therapy. Philips also states that this problem may occur when the device is in standby mode and a user is attempting to power on the device to run a self-test. The device will then indicate that it is not ready for use. This problem may result in a delay of therapy being delivered to apatient if the defibrillator/monitor is needed for immediate use. Philips further states that it has received 588 reports of this problem occurring on the above defibrillator/monitors; two of these reports involved a patient death. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected defibrillator/monitors in your inventory. See the letter for information on how to determine whether your device is affected. If you have affected devices, verify that you have received the October 2019 Urgent Medical Device Correction letter and Customer Reply form from Philips. Complete the form, and return it to Philips using the information on the form. You may continue to use affected devices if they do not exhibit any of the above behaviors; however, if any devices in your inventory exhibit the above behaviors, remove the device from service and contact Philips. Philips will contact your facility to arrange for device repair. Philips will install a replacement system on module (SOM) and perform a software upgrade at no cost. Philips will contact your facility when replacement parts are available.
For Further Information:
Philips
Tel.: (0870) 5329741 (U.K.)
Website: Click here

Ventilator – Common Problem: Barotrauma

Accession Number:	A39239	**ECRI Priority:**	Critical	**Published:**	06/03/2022
Channel:	Devices	**FDA:**	Class I	**Last Updated:**	06/24/2022

Hillrom—Volara Systems: Oxygen Desaturation or Barotrauma May Occur When Used with In-Line Ventilator in Home Care Environment [FDA Class I]

Product Identifier(s)

[Capital Equipment]

Product	Hillrom Co Inc Model	Model No.
Respiratory Therapy Systems	Volara	M08594, M08594A, PVL1HCBA
Handset 2 Modules	OPTIMUS	M07937
Patient Circuit Kits	Volara	M08473

Manufacturer(s)

Hillrom Co Inc, 130 E Randolph St Suite 1000, Chicago, IL 60601, United Statrs

Problem

In an April 26, 2022, Urgent Medical Device Correction letter, Baxter states that a patient's or caregiver's potential lack of awareness of a possible risk of decrease in oxygen levels (oxygen desaturation) or injury may result in lung tissue damage caused by over-expansion (barotrauma) when the above systems are used in the home care environment. These potential events may occur while using the Volara device in line with a ventilator with the required Volara ventilator adapter (OPTIMUS Handset 2) or Volara patient circuit kit (OPTIMUS OLE AC Patient Circuit Kit). Hillrom also states that a home care patient or caregiver can set up their Volara device in line with a homecare ventilator for oscillation and lung expansion (OLE) therapy. The added flow and pressure from the Volara device may interfere with the accuracy of the therapy provided by the ventilator. The patient may be unaware that the interference may result in oxygen desaturation or barotrauma.

Ventilator – Common Problem: Hypoxia

Accession Number: A38612 **ECRI Priority:** High **Published:** 01/12/2022

Channel: Devices **FDA:** Class I **Last Updated:** 02/18/2022

Vyaire/imtmedical—bellavista 1000 and bellavista 1000e Ventilators: May Cease Ventilation under Certain Conditions

Product Identifier(s)

[Capital Equipment]

Product	Vyaire Medical Inc Model	Hardware Generation	Catalog No.	Software Version	Serial No.
Ventilators	bellavista 1000	G6	301.100.030	>= V6.0.1600.0	All
	bellavista 1000e	G6	301.100.130	>= V6.0.1600.0	All

Manufacturer(s)

Vyaire Medical Inc, 26125 N Riverwoods Blvd, Mettawa, IL 60045, United States
imtmedical AG, Gewerbestrasse 8, Buchs, CH-9470, Switzerland

Problem

In a December 28, 2021, Urgent Medical Device Correction letter submitted by an ECRI member hospital, Vyaire states that if the above ventilators are connected to an HL7 interface for data communication, that configuration may cause the device to cease ventilating and notify the user with an audible audio and visual alarm (technical alarm failure 305). Vyaire further states that imtmedical, the manufacturer of the above devices and a subsidiary of Vyaire, has received reports that some of the above ventilators ceased ventilation during use and ventilation monitoring waveforms and parameters became frozen on the display (display is not updated). When this occurs, the ventilator generates a continuous audible and visual high-priority alarm (technical failure 305), and ventilation is suspended until the ventilator is rebooted or replaced. For the device to cease ventilation, all the following conditions must exist:

1. Software version 6.0.1600.0 (released February 12, 2021) or above is installed, and
2. Software option "Data Communication" is installed, and
3. The data communication port is configured to "HL7" (possible only when condition 2 is fulfilled)

Suspension of ventilation may cause the patient to become hypoxic and hypercapnic, leading to a potentially critical outcome, including mortality. imtmedical's investigation determined that a conflict in memory resource allocation between software tasks causes the ventilation controller software to stop. The failure condition involves a combination of software version 6.0.1600.0 or above and the data communication port configured for HL7. Once the communication between the user interface controller (EPC) and the ventilation controller (CFB) is interrupted, the communication is re-established only after a restart of the machine. The manufacturer has not confirmed the information provided in the source material.

Accession Number:	A39617 01	**ECRI Priority:**	High	**Published:**	09/23/2022
Channel:	Devices	**FDA:**	Class II	**Last Updated:**	09/23/2022

Medtronic—Puritan Bennett 500 Series Ventilators: May Become Inoperable during Use

Product Identifier(s)

[Capital Equipment]
For affected serial numbers, see the Source Document or contact the manufacturer.

Product	Medtronic Model	Model No.	Product No.
Ventilators	Puritan Bennett 560	PB560	4096600
	Puritan Bennett 520	PB520	4098300

Manufacturer(s)

Medtronic , 710 Medtronic Pkwy, Minneapolis, MN 55432-5604, United States

Problem

Health Canada states that Medtronic has received six reports of incidents in which the low pressure alarm on the above ventilators annunciated, and the high priority indicator illuminated indicating a loss of gas supply resulting in the ventilator becoming inoperable. If a loss of gas supply resulting in an inoperable ventilator occurs, the audible and visual alarms will alert a caregiver that an alternative form of ventilation is required. Loss of ventilation can lead to a delay of treatment, potentially resulting in hypoxia, dyspnea, or death. FDA's Center for Devices and Radiologic Health (CDRH) states that Medtronic confirmed six reports from users outside the U.S. in which the above ventilators became inoperable because of a loss of gas supply caused by manufacturing error of specific turbine components. FDA's CDRH also states that the manufacturer initiated a recall by letter on August 19, 2022.

[High Priority] - A23051 01 : *Intuitive—EndoWrist Stapler 45 Instruments Used with da Vinci Si Surgical Systems: May Resist Removal from Tissue following Clamp and Firing Sequence; Manufacturer Initiates Field Recall [Update]

Medical Device Ongoing Action

Published: Monday, December 8, 2014

UMDNS Terms:

- Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Product Identifier:

EndoWrist Stapler 45 Instruments used with da Vinci Si Surgical Systems *[Capital Equipment]*
EndoWrist Stapler 45 Instrument Part/Model Nos.: 410298-05, 410298-06, 410298-07, 410298-08, 410298-09

Problem:

[December 8, 2014]
In a December 5, 2014, Medical Device Recall letter submitted by an ECRI Institute member hospital, Intuitive states that it is initiating a field recall of the above EndoWrist Stapler 45 instruments. Intuitive also states that since issuing the September 19, 2014, Stop Use Product Notice regarding the problem described below, the firm has performed extensive analysis to determine the cause of 3 field failures where the instrument remained clamped on tissue. The investigation has shown 2 separate failure modes in the clamp mechanism (a component failure in 2 instruments and an assembly failure in one instrument). Intuitive states that it has also determined that the likelihood of the component failure increased with use of cleaning and sterilization processes outside of those recommended in the instructions for use (IFU). Intuitive also states that only the above EndoWrist Stapler 45 instruments are affected by this recall; this recall does not affect or relate to any other EndoWrist instruments, accessories, or components.
[September 23, 2014]
In a September 19, 2014, Urgent Product Notice letter submitted by ECRI Institute member hospitals, Intuitive states that it is voluntarily initiating a Stop Use for the above EndoWrist Stapler 45 instruments as the result of an ongoing investigation into an inability to remove the stapler from tissue following the clamp and firing sequence, even when the Stapler Release Kit is used. Intuitive also states that if the above EndoWrist Stapler 45 instruments cannot be released from tissue during a procedure, the stapler and tissue it is grasping may need to be excised using an alternative stapling device or other intervention. Intuitive further states that this instrument malfunction constitutes a 0.023% rate of occurrence based on total firings completed during procedures using the above EndoWrist Staper 45 instruments and that in the clinical cases that prompted the firm's investigation, the procedures were completed minimally invasively with a backup stapling device. Intuitive states that only the above EndoWrist Stapler 45 instruments used with the above da Vinci Si surgical systems are affected by this problem and stop use product notice and that no other EndoWrist instruments, accessories, or components are affected.

Adverse Events Related to Surgical Robot– Device Failure/ Malfunction
System Error

Accession Number: A37971 **ECRI Priority:** Critical **Published:** 09/28/2021

Channel: Devices **FDA:** Class I **Last Updated:** 10/29/2021

Zimmer Biomet—ROSA One 3.1 Brain Systems: Software Anomaly May Lead to Inaccurate Placement of Electrode during Surgery

Product Identifier(s)

[Capital Equipment]

Product	Zimmer Biomet Model	Item No.
Surgical Systems	ROSA One 3.1 Brain	ROSAS00203

Manufacturer(s)

Zimmer Biomet, 345 E Main St, Warsaw, IN 46580, United States

Problem

In a September 22, 2021, Urgent Medical Device Correction letter submitted by an ECRI member hospital, Zimmer Biomet states that it has become aware of an event in which a software anomaly affecting the above systems led to the inaccurate placement of an electrode during a surgery. Since the installation of the affected software beginning in December 2019, there have been three global complaints related to the software anomaly out of approximately 3,600 surgeries performed. While patient injury has not been reported, an incorrect trajectory could result in serious injury or death if it goes undetected during surgery. After the registration of the patient during the ROSA One 3.1 Brain application procedure, the problem may occur when the device shuts down either manually or unexpectedly. After reboot, if the trajectory is interrupted by deactivating the pedal, the device gives the user an option to "Return to HOME," "Clear the robotic arm," or "Continue." If the user chooses to "Clear the robotic arm," the device prompts the user to perform an empty device calibration. If the user performs this step and presses start, the problem will occur, which results in the device driving to an incorrect trajectory. See Attachment 2 - Detailed sequence of events of the letter for further information along with corresponding images.

Adverse Events Related to Surgical Robot– Device Failure/ Malfunction

Broken Parts/Component

Accession Number:	A40388	**ECRI Priority:**	High	**Published:**	02/23/2023
Channel:	Devices	**FDA:**	Not Specified	**Last Updated:**	02/23/2023

Medtronic—Hugo Robotic-Assisted Surgery Monopolar Curved Shears: Cable May Break during Use [MHRA FSN 5080174]

Product Identifier(s)

[Consumable]

Product	Medtronic Ltd Model	UDI	Serial No.
Hugo Robotic-Assisted Surgery (RAS) Monopolar Curved Shears	US-MF-000028763	10884521836433	C22BAJ0710, C22BAJ0711

Manufacturer(s)

Medtronic Ltd, Building 9 Croxley Park, Watford, WD18 8WW, England

Problem

In a February 2023 Urgent Field Safety Notice letter posted by MHRA, Medtronic states that it has received 17 reports of cable break in the above devices during clinical use. A cable break may cause unintended motion of the wrist and/or jaws of the Hugo RAS monopolar curved shears in clinical cases and may also cause the device jaws to no longer move or cut tissue. A cable break does not prevent the device from being able to deliver energy. The manufacturer has not confirmed the information provided in the source material.

Action Needed

Refer to the letter for details on responding to this problem.

UMDNS Term(s)

Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Thank you

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