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The U.S. Food and Drug Administration's (FDA) MedSun program provides this monthly newsletter to inform patients and patient advocates about information from FDA on medical device related topics. The MedSun program, launched in 2002 by the FDA's Center for Devices and Radiological Health (CDRH), uses a secure online reporting system to receive medical device adverse event reports from a network of over 300 clinical facilities across the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products and play a critical role in the FDA's postmarket surveillance efforts.

Learn More About MedSun

Highlighted Recalls and Early Alerts

- Resmed Issues Correction for Astral Ventilator **7/31/2026**
- Abiomed Removes 14Fr Low Profile Introducer Kits **7/31/26**
- Argon Medical Issues Correction for Convenience Kits Containing Spectra Medical Device Lidocaine Ampules **7/30/2026**
- *Early Alert:* Percutaneous Catheter Issue from Boston Scientific **7/24/26**
- *Early Alert:* Intravascular Administration Set Issue from Baxter **7/20/26**
- Bolton Medical Removes Relay Pro System **7/17/26**
- Arrow International Issues Correction for Convenience Kits Containing Recalled Huons Lidocaine and Bupivacaine and Saline **7/16/26**
- B. Braun Medical Removes Spinal Anesthesia Kits Containing Huons Bupivacaine Hydrochloride in Dextrose Injection **7/16/26**
- Baxter Issues Correction for Volera Positive Pressure Breathing Devices **7/14/26**
- Medtronic Removes Harmony Catheter Delivery Catheter System (DCS) **7/13/26**
- *Early Alert:* Convenience Kit Issue from Medical Action Industries **7/9/26**
- *Early Alert:* Convenience Kits Issue from Medline **7/9/26**
- Fresenius Kabi Issues Correction for Ivenix Large Volume Infusion Pump **7/7/26**
- Fresenius Kabi Issues Correction for dropped or jarred Ivenix Large Volume Infusion Pumps **7/7/26**
- Windstone Medical Packaging, Inc. Issues Correction for Convenience Kit **7/6/26**
- Hamilton Medical Updates Use Instructions for Breathing Circuit Set **7/2/26**
- Insulet Removes Omnipod Pods **7/2/26**
- Abiomed Removes Impella CP Sets with SmartAssist **7/2/26**

Link to Device Recalls & Early Alerts

Announcements

FDA Offers Information on Menstrual Products

The FDA is offering information on menstrual products to help women make informed choices about their health. New web resources include information on:

- What kinds of menstrual products are available and how to use them safely.
- The benefits and risks of different options for use during menstruation.

- The FDA's activities on menstrual products, including a new scientific study describing testing conducted by FDA laboratories and a toxicological risk assessment related to metals found in tampons.

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FDA Requests Input on Certain Non-Device Software Functions and Impacts to Patient Safety

The FDA requests input on patient safety associated with certain medical software functions excluded from the medical device definition. This input will help the FDA develop the 2026 report on the risks and benefits to health of non-device software functions, which include certain software functions intended for:

- Administrative support of health care facilities,
- Encouraging a healthy lifestyle,
- Serving as electronic patient records,
- Transferring, storing, converting formats, or display of data, and
- Providing limited clinical decision support.

Please submit comments under docket number FDA-2018-N-1910 at Regulations.gov by August 13, 2026.

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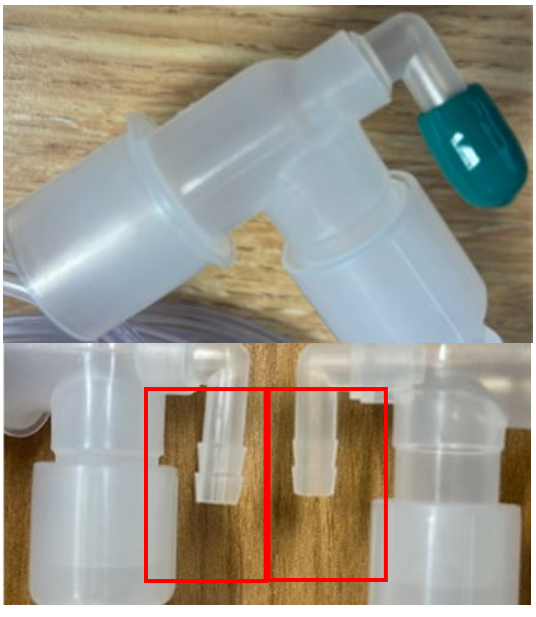
Highlighted Reports

The reports that follow represent a cross section of device related events sent by MedSun Representatives during the prior month. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and edited for clarity.

Search the MedSun Report Database

Type: General surgery tray
Manufacturer: Medline Industries, Inc. **| Brand:** Medline Industries Jackson-Rees circuit
UDI-DI: 10193489740219 **| Model/Cat:** DYNJAA246
Lot: 25IBC934, 25IBK064



Event 1: While attempting to ventilate a patient, the end cap on the circuit blew off creating significant leak. The bag could not inflate or generate positive-pressure ventilation, which poses a serious patient safety risk. An investigation found the ridges on the top valve/side port that are designed to secure the green cap, were either absent or significantly worn down on lot numbers 25IBC934 and 25IBK064. All impacted products were removed from stock at the hospital and surgery centers. The issue was reported to the manufacturer, who confirmed that within the last year they made a material change to the set, utilizing a new elbow component 153098. The manufacturer rebuilt our sets with an elbow component 121885 that does not include the side port that caused the issue.

Event 2: A Medline Jackson Rees circuit with a loose faulty piece was identified as a safety concern. This malfunction was identified, and a new design was finalized and approved for use. The original faulty design has re-entered our supply chain. Approximately four months later, circuits with the old design were found and almost used.

Top: Photo shows an opaque white ventilator circuit with a green cap on the top valve/side port.

Bottom: Photo shows two opaque ventilator circuits without the green caps. Red boxes highlight subtle design differences between the non-impacted device on the left and the impacted device on the right.

Device 1: **Type:** Analyzer, pacemaker generator function
Manufacturer: Medtronic **| Brand:** Carelink Smartsync
Device 2: **Type:** Implantable pulse generator, pacemaker (non-CRT)
Manufacturer: Boston Scientific Corporation **| Brand:** Accolad MRI EL DR **| Model/Cat:** L331
Event: We are experiencing pacemaker transmission data integrity and false positive alerts as well as incorrect patient data due to an in-office programmer issue that corrupted device data when the date was changed to four years ago. Failure to accurately generate or send clinically significant reports for patients with implantable cardiac devices for remote monitoring puts patients at risk for harm, including death.

Device 1: **Type:** Monitor, physiological, patient (without arrhythmia detection or alarms)
Manufacturer: Welch Allyn, Inc. **| Brand:** Welch Allyn **| REF:** 75CT-B
Device 2: **Type:** Oximeter
Manufacturer: Covidien LP **| Brand:** Nellcor **| Model:** DS100A
Event: We purchased over 400 bedside vital sign machines from the manufacturer and received them at the beginning of this year. Over the past few months, we have noticed an issue occurring with them. The bedside vital sign machines leave a patient's heart rate and oxygen saturation level (SpO2) on the screen after taking vital signs. This can lead to misinterpretation of values for a patient when they could have been values from a previous patient. Additionally, the issue worsens when a caregiver hits "send" to send the vital signs information into the patient's electronic medical record. It may be the wrong patient's chart receiving this information and/or it may be duplicative heart rate and SpO2 values. If you take the blood pressure and haven't cleared out the previous information, it will automatically enter the previous heart rate and SpO2 values into the patient's chart with the blood pressure but those were values from possible hours or minutes earlier. This may lead to clinicians acting on inaccurate information.

Type: Pump, infusion
Manufacturer: ICU Medical **| Brand:** Plum Duo
Event 1: This event involved an inappropriate air in line alarm. A critically ill ICU patient was receiving continuous propofol sedation via a Plum Duo infusion pump (software version 1.2.2.1). The infusion was programmed at 40 mcg/kg/min. The infusion had been running earlier in the day without documented issue. Beginning around 16:45, the pump generated an air-in-line alarm and propofol delivery was paused. Nursing staff traced the line and did not visualize any air, kinks, or occlusion. The infusion was running through a functioning central venous catheter. Despite troubleshooting by the nurse, the alarm persisted and propofol delivery was interrupted. During the sedation interruption, the patient became acutely agitated with tachycardia, tachypnea, and thrashing movements, and was attempting to self-extubate while mechanically ventilated. Nursing staff documented a RASS (Richmond Agitation-Sedation Scale) score of three. A 100-mcg Fentanyl IV bolus was administered at 17:00 to maintain sedation and patient safety. Propofol was re-primed, and infusion resumed after troubleshooting and the patient returned to baseline.
Event 2: This event involved an inappropriate downstream occlusion alarm. The IV pump infusing norepinephrine 0.14mcg/kg/min alarmed and stopped infusing. Blood pressures dropped to 50s/30s. Two nurses traced the infusion line and found no issues to explain the downstream occlusion alarm. The medication had been infusing through a central venous

catheter which was known to be functioning properly. The patient required an IV push dose of epinephrine. Staff switched to new IV pump and the patient's blood pressure recovered.

Type: Electrocardiograph
Manufacturer: Philips Medical Systems **| Brand:** Cardiac Workstation
Model: Cardiac Workstation 7000 **| Cat:** 860441
Event: Our facility has ongoing issues with the Cardiac Workstation 7000 EKG units currently in use. We have deployed a total of ten units and to date, five of them have experienced screen failures and touchscreen malfunctions. The manufacturer has been on site already and performed software updates on three of the affected devices. However, two of those units have failed again after the update. The issues observed include unresponsive touchscreens, screen freezing, and intermittent functionality, which are impacting clinical workflow. While no patient harm has been reported at this time, these failures pose a potential risk for delays in diagnostic procedures, particularly in critical care settings. The manufacturer plans to send an engineer on site to retrieve system logs and further investigate the root cause. Loaner units are being coordinated.

Type: Syringe, irrigating (non-dental)
Manufacturer: Cardinal Health **| Brand:** Dover **| Model/Cat:** 68000 **| Lot:** 2515709964
Event: A patient presented for a rectal MRI. Two 60 ml piston syringes were prepared with contrast and capped prior to the exam. The radiologist was unaware of the syringes being capped and did not see the clear (no color) caps prior to injection. Upon review of the images for angulation, an artifact was noted. The artifacts resembled the caps from the syringes. The clear syringe caps were lost in the patient's remnant rectum when rectal contrast was injected. The surgical team was unable to retrieve the caps manually due to stricture. The patient was sent for sigmoidoscopy. A foreign body was found in the rectum. The removal of two syringe caps was accomplished with rat-toothed forceps.

These reports describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations.
The FDA defines pediatric patients as those who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

Type: Attachment, breathing, positive end expiratory pressure
Manufacturer: Galemed Corporation **| Brand:** Babi Plus **| Model:** 1030 **| Lot:** 251014
Event: Pressure relief manifold for continuous positive airway pressure machine failed. The valve broke off at the T causing a leak that caused the loss of positive end-expiratory pressure to the patient. Reports indicate this happened with three different units from this lot number.

Links to FDA CDRH Databases and Other Information Sources

- Database of Registered Medical Devices and Manufacturers
- Access Global Unique Device Identification Database (GUDID)
- Medical Device Safety
- MedSun: Medical Product Safety Network
- Medical Device Recalls

Contact Us

For questions about this newsletter or to request a copy of a previous edition, please email us.

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