MedSun
Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):

https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Premarket Approval Final Decisions:
https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals

510(k)s Final Decisions:
https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

In Brief

As of June 28, 2022

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to
http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Class I Recall - GE Healthcare Recalls CARESCAPE R860 Ventilator Due to Early Failure of Backup Batteries that May Cause Unexpected Ventilator Shut Down

June 28, 2022

GE Healthcare is recalling CARESCAPE R860 ventilator backup batteries, including replacement backup batteries, manufactured on or after April 1, 2019, because the batteries may run out before they are expected to do so. If the ventilator is running on battery power only when the battery fails, ventilation could stop completely, preventing the patient from receiving oxygen and breathing support.
Lack of oxygen (hypoxia), especially if it occurs over a long period, can cause serious injury and death. There have been 1,553 complaints, one injury, and no deaths associated with the use of this device.

Class I Recall - Baxter Healthcare Corporation Recalls Volara System For Risk Of Respiratory Distress In Ventilated Patients During Home Use

June 23, 2022

Baxter Healthcare Corporation, and its subsidiary company Hillrom, are recalling the Volara system because the in-line ventilator adaptor may prevent home-use patients from getting enough oxygen from their ventilators. The risks to affected patients include:

- Choking on mucus or other airway secretions
- An infection in the lungs (pneumonia) that prevents oxygen from getting to the blood (respiratory failure)
- Brain injury caused by lack of oxygen to the brain (hypoxia)
- Death

The risk of serious injury or death is more significant in home-care settings if the caregivers are not trained properly, the device is not connected properly, or if the caregiver is not prepared to address any issues that may arise caused by use of this device. There has been one complaint and one injury, as well as two deaths, associated with the use of this device.

Class I Recall - Draeger, Inc Recalls SafeStar 55 Breathing System Filters for Possible Obstructions That May Block Oxygen Flow To Patients

June 21, 2022

Draeger, Inc is recalling a specific lot (LT2103) of the SafeStar 55 Breathing System Filter because a manual inspection process led to some defective filters, including some that may be partially obstructed, to be inadvertently distributed instead of destroyed.
If the filter on a ventilator or breathing system is obstructed, oxygen may not flow properly to the patient. That lack of oxygen (hypoxia) can have serious effects including death. There has been one complaint and one injury associated with the use of this device. There have been no reported deaths.

Pulse Oximeter Accuracy and Limitations: FDA Safety Communication

The Coronavirus Disease 2019 (COVID-19) pandemic has caused an increase in the use of pulse oximeters, and a recent report (Sjoding et al.) suggests that the devices may be less accurate in people with dark skin pigmentation. The FDA is informing patients and health care providers that although pulse oximetry is useful for estimating blood oxygen levels, pulse oximeters have limitations and a risk of inaccuracy under certain circumstances that should be considered. Patients with conditions such as COVID-19 who monitor their condition at home should pay attention to all signs and symptoms of their condition and communicate any concerns to their health care provider.

Recommendation for Health Care Providers

- Be aware multiple factors can affect the accuracy of a pulse oximeter reading, such as poor circulation, skin pigmentation, skin thickness, skin temperature, current tobacco use, and fingernail polish. The full communication has additional information on how accuracy is calculated and interpreted.
- Refer to the device labeling or the manufacturer's website to understand the accuracy of a particular brand of pulse oximeter and sensor. Different brands of pulse oximeters and even different sensors (finger clip vs. adhesive) may have a different accuracy level. Pulse oximeters are least accurate when oxygen saturations are <80%.
- Consider accuracy limitations when using the pulse oximeter to assist in diagnosis and treatment decisions.
    - Use pulse oximeter readings as an estimate of blood oxygen saturation, e.g., a pulse oximeter saturation of 90% may represent an arterial blood saturation of 86-94%.
    - When possible, make diagnosis and treatment decisions based on trends in pulse oximeter readings over time, rather than absolute thresholds.

JUNE 21, 2022 UPDATE

The FDA continues to evaluate all available information pertaining to factors that may affect pulse oximeter accuracy and performance. Because of ongoing concerns that these products may be less accurate in individuals with darker skin pigmentations, the FDA is planning to convene a public meeting of the Medical Devices Advisory Committee later this year to discuss the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, the amount and type of data that should be provided by manufacturers to assess pulse oximeter accuracy, and to guide other regulatory actions as needed. Further details concerning the agenda, timing, and location of the Advisory Committee meeting will be announced in the coming weeks.

To read the full safety communication, please visit FDA's website.

Illumina Cybersecurity Vulnerability May Present Risks for Patient Results and Customer Networks: Letter to Health Care Providers

The FDA is informing laboratory personnel and health care providers about a cybersecurity vulnerability affecting software in the Illumina NextSeq 550Dx, the MiSeqDx, the NextSeq 500, NextSeq 550, MiSeq, iSeq, and MiniSeq, next generation sequencing instruments. These instruments are medical devices that may be specified either for clinical diagnostic use in sequencing a person's DNA or testing for various genetic conditions, or for research use only (RUO). Some of these instruments have a dual boot mode that allows a user to operate them in either clinical diagnostic mode or RUO mode. Devices intended for RUO are typically in a development stage and must be labeled "For Research Use Only. Not for use in diagnostic procedures." – though many laboratories may be using them with tests for clinical diagnostic use.

The cybersecurity vulnerability affects the Local Run Manager (LRM) software. An unauthorized user could exploit the vulnerability by:

- taking control of the instrument remotely;
- operating the system to alter settings, configurations, software, or data on the instrument or a customer's network; or
- impacting patient test results in the instruments intended for clinical diagnosis, including providing no results or incorrect results, altering results, or a potentially breaching data.
- Illumina has developed a software patch to protect against the exploitation of this vulnerability and is working to provide a permanent software fix for current and future instruments. The FDA wants laboratory personnel and health care providers to be aware of the required actions to mitigate these cybersecurity risks.

Recommendations

- Review the Urgent Safety Notification or Product Quality Notification (for RUO Customers) sent by Illumina on May 3, 2022 to affected customers. If you did not receive a notification from Illumina, but believe you should have, please contact techsupport@illumina.com.
- Immediately download and install the software patch (Dx mode and RUO mode) on every affected instrument, including in each stand-alone instance of the off-instrument LRM for RUO mode on the Dx instruments, while connected to the internet.
- Contact techsupport@illumina.com for instructions about other ways to install the software patch, if you are not connected to the internet.
- Immediately contact techsupport@illumina.com if you suspect your instrument may have been compromised by an unauthorized user.

For more information about Illumina's cybersecurity vulnerability, see the Cybersecurity and Infrastructure Security Agency (CISA) published advisory, ICSA-22-153-02.

To read the full recall notification, please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during June 2022. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

Special Note:

The lollipop icon distinguishes highlighted reports that 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. 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.

Device	Manufacturer	Problem
Accelerator, Linear, Medical Brand: Redifoam Two-part Foaming Agent Model#: MTFA41B Lot #: M160049 Cat #: MTFA41B	Medtec, Inc.	After construction of the patient's body mold and simulation, therapists noticed Redifoam mix was not hardening like it usually does (it dimpled to the touch). After roughly 24 hours, therapists noticed patient's body mold began to shrink and lose its form or shape which could cause misalignment of radiation treatment. A new simulation and body mold had to be created which could have caused a delay in the patient's cancer treatments.
Aid, Transfer Brand: Posey Gait Belt Model#: 6556 Lot #: 2005T371 Cat #: 6556	TIDI Products, LLC	Occupational therapist working with patient using walker and gait belt in hallway stairs. Patient's knees buckled on stairs. Gait belt "slipped" and patient was assisted to the ground. Gait belt evaluated and compared to other gait belts with same lot number and brand. Gait belt that slipped noted to be thinner. Suspected cause of "slipping" may be related to lack of belt thickness for material to grip against buckle teeth.

Device	Manufacturer	Problem
Insufflator, Laparoscopic Brand: Pneumoclear Smoke Evacuation High-flow Tube Set Model#: 0620050250 Lot #: 4025383 4024006 K21N334 K22A009 4023461 4023621 K21H210 K21K234 4020970	W.O.M. World of Medicine GmbH	We were made aware of a sterility issue by the Stryker representative about contamination in the packaging of the Pneumoclear Smoke Evaluation High Flow Tube Set (Stryker--Insufflation Tubing).
Ligator, Esophageal Brand: Speedband Superview Super 7 Model#: M00542250 Lot #: 28552592 Cat #: M00542250	Boston Scientific Corporation	Bander placed on scope like normal. When the doctor went to fire a band on the esophagus, it did not deploy. The bands all scrunched up and would not come off.
Needle, Hypodermic, Single Lumen Brand: Arrow Ez-io 45mm Needle Set Model#: IP-N917347 Cat #: 9079-VC-005 Other #: 651501646975	Teleflex, Inc.	The patient experienced a cardiac arrest and the patient did not have vascular access. The team assessed the situation and decided the patient would benefit from an intraosseous needle. The critical care nurse used the EZ-IO power driver and placed an EZ-IO 45 mm needle in the patient's proximal tibia. The RN followed the manufacturer's instructions for placement. Approximately 5 hours later, the patient's status changed and the IO was no longer needed. The critical care nurse began the removal procedure per the manufacturer's instructions for removal. After the needle was removed, the RN noticed the needle was not intact and over one inch of the needle remained in the patient's tibia. The needle had broken approximately 0.125 inches below the yellow hub. I contacted the local rep regarding the issue and the rep was forwarding the information to the appropriate parties and these parties would circle back.
Syringe, Antistick Brand: Vanishpoint Syringe Lot #: G210955	Retractable Technologies, Inc.	Plunger would not inject any medication or move at all when trying to administer immunization during intramuscular injection. Patient "poked" again with a new needle, syringe, and immunization after first one didn't work. (Medication was only injected once). I used the vanishing syringe and needle.

Device	Manufacturer	Problem
		Multiple instances of numerous problems with the vanishing needle not retracting while in the patient's arm without having to apply an unreasonable amount of pressure to the syringe, causing patients more pain. In this case, I have to remove the needle from the patient's arm, hold the needle away, and press down firmly on the plunger to get the needle to retract. I don't feel that this is safe for the nurses or the patients.
Humidifier, Respiratory Gas, (Direct Patient Interface) Brand: Myairvo 2Heated Breathing Tube And Chamber Kit Model#: 900PT561 Lot #: 2101249702 2101308307 Cat #: 900PT561	Fisher & Paykel Limited Healthcare	Staff found high flow device circuit (tubing) melted on patient's bed. There were signs of the heat marks on the side of the bed. Suspected tubing may have become trapped in the side rail and was being pinched up against the bed. Pinch may have led to pressure buildup of heat which could have caused circuit to melt. There was no patient contact and therefore, no injury to patient. Concern for potential burns/fire. The high flow unit was removed from service and sent for review and vendor was notified of the event.
Aortic Valve, Prosthesis, Percutaneously Delivered Brand: Sapien 3Ultra System Model#: 9750CM26 Lot #: 64009600 Cat #: 9750CM26A	Edwards Lifesciences LLC	Cardiologist's explanation: Under ultrasonic guidance, with the use of micropuncture needle, an access was made in right common femoral artery, and a 6 French sheath was inserted. Over the wire 2 Perclose sutures were placed and with the help of Amplatzer extra stiff wire, a 14 French e-sheath+ was inserted. The valve was advanced through the 14 French sheath and positioned at the aortic annulus under fluoroscopic guidance. The valve was positioned and replaced using standard technique. During valve deployment, there was rupture of the balloon which was immediately identified. The balloon was attempted to be retrieved into the sheath but there was flaring of the esheath+. Therefore, we removed the sheath and the ruptured balloon en mass. We exchanged for a stiffer Lunderquist wire and continued slowly removing the sheath and it got stuck at the femoral access site. Thereafter a cutdown was performed. Cardiac surgeon's explanation. Ultrasound guided percutaneous access was obtained on the right common femoral artery. The right common femoral artery was "preclosed" with 2 Per Close devices, and using standard techniques, a 14 French hemostatic sheath was secured in place. Anticoagulation was initiated with heparin. The aortic valve was crossed and with a series of exchanges a Safari wire was advanced to the LV apex. After confirmation of correct orientation of the 26 mm S3 Ultra valve on the delivery catheter, the valve was crimped and loaded onto the delivery catheter which was then advanced over the exchange wire into the descending aorta. Proper alignment with the valve and balloon on the delivery catheter was achieved. The valve was advanced across the aortic valve. With rapid pacing and under fluoroscopic guidance, the valve was positioned precisely across the aortic valve, and the valve was deployed.

Device	Manufacturer	Problem
		Unfortunately the balloon ruptured just at full deployment. Rapid pacing was ceased, and the balloon and delivery system were retracted into the descending aorta without issue. At this point, the delivery system was able to be retracted to the distal external iliac without issue; however, it was not able to be pulled out of the artery. A cutdown on the right femoral artery was done to retrieve it. Days after surgery, an Echo showed normal ejection fraction, and a well-functioning valve.
Cardiac Ablation Percutaneous Catheter Brand: Thermocool Smarttouch Sf Model#: D134804 Lot #: 30589230L Cat #: D134804	Biosense Webster, Inc.	Device was prepped and flushed with heparinized saline but when it was plugged into the generator an error appeared as a force sensor error. A new cable was tried, and device was unplugged and plugged back in and flushed again, but the same error came up. So, a new device was used (same lot number) and worked fine. The patient was not affected.
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Intellivue Mx40 Wlan Model#: MX40-WL3 Cat #: 865352	Philips Medical Systems Hsg	The patient reported to nursing staff that the black EKG lead wire set on fire while she was wearing the device. She was in the bathroom and smelled something strange. She looked down and saw the black wire melting and then a little flame appeared. She used a wet towel to put it out. The patient reported no injury and nursing staff verified no burn. The patient reported earlier in the night she had noticed that the telemetry monitor box felt hot in her gown pocket. She took it out of her gown and laid it on the bed to cool off. The patient stated the box fell off the bed onto the ground at one point that evening. The telemetry box and leads were sequestered and delivered to Biomedical Engineering for evaluation.
Indicator, Physical/ chemical Sterilization Process Brand: 3m Attest Model#: 1243RE Lot #: TA032024 FF022024 SS022023 Cat #: 1243RE	3M COMPANY	A few months ago we noted on our 3M Steam Chemical Integrator (CI) strips where the extender was not attached to glue section & glue could stick to our surgical instruments. 3M was involved straightaway with their response to the issue and we have a letter of involvement since we informed them when the issue was first observed. Now (from the first observation of this issue) we have seen more issues arising from the CI ref# 1243R (the CIs we typically get has the extender). But in these CIs, we see that the extender is not attached to the glue section. The glue could stick to our surgical instruments inside the tray, which could be a patient safety issue. The other two indicators are, issues with the move forward bead, again. The middle one has no white sheet and only the metal backing, with the bead exposed as well and not seated correctly. In the bottom device, a piece of the white sheet is not seated properly and we see that the piece is sticking behind the window. Without the white sheet, one will not be able to see the bead move into the acceptance range.

Device	Manufacturer	Problem
		Recently, all of the CIs are from the same lot - TA032024. This lot is what we have stocked on our workstations and in our warehouse inventory. We have directed our staff to check each CI prior to placing them in the sets and verify the bead is present, the white strip is present, the glue is not exposed and the bead is seated in the correct position. Note: Our warehouse in supply chain has removed the current lot (TA032024) from the shelf. No patient harms. Our Sterile Processing Manager continues to be in communication with 3M.
Protector, Skin Pressure Brand: Static Iar Seat Cushion Lot #: 21470010 Cat #: 1400106	Molnlycke Health Care	Waffle Cushion deflated while patient was using cushion in chair. The chair cushion is utilized for pressure reduction for skin care. If this product is deflated, it increased the risk for hospital acquired pressure injuries. Thus, it has the potential for skin integrity impairment.
Set, Administration, Intravascular Brand: Cadd Administration Set Model#: 21-7322-24	Smiths Medical MD, Inc.	Over a four-month period, there have been reports (12 or so) of the medication volume with PCA (patient-controlled analgesia) administration being greater than expected when volumes are checked when PCA is discontinued, or pump reset. This discrepancy includes allowance for priming and bag overfill. In some instances, the PCA pumps were examined and determined to be functioning properly. The concern is that this has led to underdosing of patient pain medication. The problem appears to be occurring with priming.
Warmer, Infant Radiant Brand: Giraffe Omnibed Carestation 	General Electric Co.	Nurse said she was always at the left side of the Isolette, (so facing it) she went to the left. She changed the infant and had the left side down. At that time, she needed to retrieve more blankets and bent down and moved the side upward to reach into the drawer. She pulled the drawer toward her to retrieve a blanket and that is when she heard the loud noise - the right side disengaged and went down, patient followed and fell to the floor.
Prosthesis, Hip, Semi-constrained, Metal/ ceramic/ polymer, Cemented Or Non-porous Brand: Vivacit-e Model#: 110031013 Lot #: 64689634	Zimmer, Inc.	The patient had a bilateral Total Hip Arthroplasty (THA) done a few years back and had done well. Patient, subsequently, had an extensive lumbosacral fusion, after which point the patient dislocating total hip replacement anteriorly. CT scans and engineers analyzed patient's hips in the sitting and standing position and gave recommendations for the ideal location of the acetabular component. Surgical/clinical staff then went ahead and did that acetabular revision approximately eight weeks ago. Patient had done well and at her six-week postoperative visit, patient expressed absolutely no pain and everything was doing very, very well. About one week ago, something happened and patient dislocated her hip. There was some concern that there may have been more going on than what the patient said initially. However, she said that she flexed her hip past 90 degrees in the shower, rotated internally and then adducted her femur. This caused the first

Device	Manufacturer	Problem
Cat #: 110031013 **Prosthesis, Hip, Semi-constrained, Metal/ ceramic/ polymer, Cemented Or Non-porous** Brand: Oxinium Model#: 71342804 Cat #: 71342804	Smith Nephew, Inc.	dislocation. Over one week she had two subsequent dislocations. Because of this, we decided to do a revision. Description of catastrophic failure of the Dual Mobility construct: after the fascia was opened, surgical team found the polyethylene large ball sitting in the soft tissues independent of the OXINIUM femoral head, which was still affixed superiorly to the trunnion. The representative in the room was asked what the reported incidence of this was and he was aware that there had been one reported incidence of this.

Links to FDA/CDRH Databases and Other Information Sources

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Global Unique Device Identification Database (GUDID):
https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid
This is a searchable database administered by the FDA that will serve as a reference catalog for every device with a unique device identifier (UDI).

Human Factors Website: **https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices**
This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Medical Device Connection Website:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-connectors
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: **https://www.fda.gov/medical-devices/medical-device-safety**
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: https://medsun.fda.gov/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: **https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters**
This database contains the most recent manufacturer warning letters.

To access additional newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

Contact the MedSun Program Staff:

Telephone: 800-859-9821
Fax: 800-859-1292
E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993