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/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of March 5, 2021

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

Improper Use of Thermal Imaging Devices: FDA Safety Communication
March 4, 2021
FDA is alerting consumers, health care providers and other users of thermal imaging systems intended to measure human body temperature that improper use of these systems may provide inaccurate temperature readings. These devices are also known as telethermographic systems, infrared thermographs, thermal cameras, and "fever cameras." We understand thermal imaging systems are currently being used for initial temperature assessment and triage of individuals for elevated temperatures in public areas (such as airports, workplaces, grocery stores, schools) and that such systems can be used as part of a larger approach to pandemic risk management, such as in combination with social distancing, wearing masks, and frequent hand washing. To help mitigate these risks, the FDA is providing important recommendations to consumers, health care providers and other users about the proper and improper use of these systems.

Medtronic Recalls HVAD Pump Implant Kits Due to Delayed or Failed Restart After the Pump is Stopped
March 1, 2021

The device may fail to initially start, restart, or have a delay in restarting after the pump was stopped. These delays or failures to start or restart have occurred during preimplant testing, during the implant, or in a variety of post-implant situations. If the device has delays or fails to start or restart, this could cause serious patient harm including a heart attack, worsening heart failure, the need for additional procedures and hospitalizations, or death. There have been 29 complaints about this device issue, which include 19 serious injuries and 8 cases of patients who had a life-threatening event but recovered without long term effects. Two deaths have been reported.

Boston Scientific Corporation Recalls EMBLEM S-ICD (Subcutaneous Implantable Cardioverter Defibrillator) System Due to Risk of Short-Circuit
February 19, 2021
A manufacturing process may allow moisture to get inside the defibrillator and cause a short-circuit when it tries to deliver high voltage shocks. If this happens during use, patients may experience less shock than intended or may not receive a shock at all. The device may also beep, not respond to a device check in, and issue battery alerts. A device with this error may delay or prevent the device from delivering a lifesaving electrical shock to a person in cardiac arrest (tachycardia) and lead to serious injury or death. Additional surgeries may also be needed to replace failed devices.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during February 2021. The reports are displayed within clinical specialty areas based on analysis of the information submitted. 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:

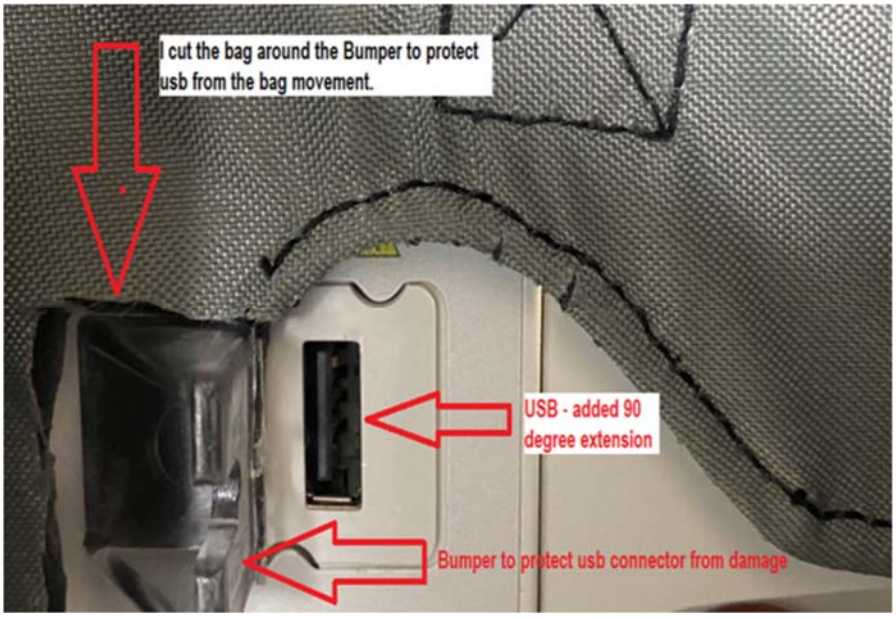
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


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
Ventilator, Continuous, Facility Use Brand: ZVent Model#: 799-EGB2-01-01	Zoll Medical Corporation	ZOLL ventilator would not pass the pre-use check, it would not pressurize, failed to work. Ventilator had to be switched out for transport. Manufacturer response for VENTILATOR, CONTINUOUS, FACILITY USE, Z Vent (per site reporter) We are having weekly updates with no resolution to the frequent failures of these Zoll transport ventilators. The company has identified a spring valve that is failing but not the reason behind. We continue to have weekly meetings and they have supported with loaner ventilators (which have also failed).

Device	Manufacturer	Problem
Applicator, Absorbent Tipped, Sterile Brand: Chloraprep One-step Hi-lite Orange Model#: 260815 Lot #: 0328213 Cat #: 260815	Becton Dickinson	Upon getting ready to prep patient for procedure using chloraprep syringe, Tech opened package and top of syringe fell off and both glass vials inside landed on floor and shattered. This is not first incident of top falling off these applicators. BD chloraprep hi-lite orange 26ml applicators lot # 0328213. No patient harm. Applicator saved however the packaging was not saved.
Applicator, Absorbent Tipped, Sterile Brand: Chloraprep One-step Hi-lite Orange Model#: 260815 Lot #: 0328213 Cat #: 260815	Becton Dickinson	During preparation of patient the chlora-prep wand must be bent to break the inside glass vials to release the chlora-prep solution. As I was bending the stick the end flew off and shards of glass exited the end of the prep stick. Shards of glass were collected and removed from the patient's upper shoulder and chest. No injury to the patient or staff. Wand was saved but packaging was discarded prior to incident.
Applicator, Absorbent Tipped, Sterile Brand: Chloraprep Hi-lite Orange 26-ml Applicator Lot #: 0328213 Cat #: 930815	Becton Dickinson	During surgical preparation of patient's chest with Chloraprep, the user of the item had already activated the solution by pressing the handle into the stick of the prep. At the time was ready to use, user gently shaken the prep stick for the solution to move into the sponge. While that was happening, the end of the prep stick (not the sponge side) flew off with small fragments of glass that landed on the patient's chest and floor. The pieces that were visible were removed from the patient's skin. No injuries sustained.

Device	Manufacturer	Problem
Applicator, Absorbent Tipped, Sterile Brand: Chloraprep Hi-lite Orange 26-ml Applicator Lot #: #0328213, #0327867 Cat #: 930815	Becton Dickinson	Occurrence involved the malfunction of a chlorhexidine surgical prep devise. The "BD ChloraPrep" devise came apart while preforming the surgical prep. While in use the end cap fell off the bottom of the prep stick. Next, the 2 plastic inner ampules fell out of the stick, These 2 ampules are very fragile and shatter very easily. All the broken pieces were collected. This prep was being done prior to the patient being draped. The sterile field was not compromised, we reprepped with another Chloraprep stick. No harm to the patient. All affected lots have been removed.
Automated External Defibrillator (Non Wearable) Brand: Zoll XSeries Defibrillator/monitor Model#: X Series	Zoll Medical Corporation	Since replacement of our monitors/defibrillators in June 2020 with Zoll X Series monitors/defibrillators, there have been multiple reports of broken USB ports that has only been a problem since replacing our old Zoll monitors/defibrillators. Three of the events were described in previous MedSun report. We continue to have issues with broken USB ports and Zoll has not come up with a solution to the USB connector issue. The cost for having Zoll make the necessary repairs is quite expensive. One of our Biomedical Technicians has made a plastic bumper in an attempt to alleviate the USB connector breakage issue. Biomed has thus far installed the bumper on ten of the Zoll X monitors that have been sent to Biomed recently, and so far Biomed has not received any of these ones back with an USB issue. A large quantity with a request to install them on all X series monitors. Please see picture below: 

Device	Manufacturer	Problem
Medical Gas Flowmeter, Thorpe Tube Brand: Flowmeter 15lpm Us Oxy Ohmeda Pt Swivel Model#: FM-15UO-OHPT-S Cat #: FM-15UO-OHPT-S	Ohio Medical, LLC	During transport, the patient's oxygen saturation was 90% and higher, Heart Rate (HR) 68 while being hand ventilated on 100% FIO2. Upon arrival to new bed, the transport ventilator (Hamilton)'s oxygen source (E-Tank) was connected to the wall oxygen outlet. This was done via flowmeter using the 50 PSI valve. Alarm began signaling "Oxygen failure." The oxygen was immediately disconnected and reconnected to an adjacent bed's wall oxygen outlet via flowmeter. Approximately 1-2 minutes later, alarm signaled "oxygen failure." The oxygen was then immediately disconnected and reconnected to the E-tank. The alarm no longer signaled "oxygen failure." The patient's oxygen saturation dropped to 30-49%, the patient was removed from ventilator and bagging began with 100% FIO2. The patient's heart rate dropped in the 40's bpm. Code blue was initiated, before patient’s death.
Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms) Brand: Suresigns Vs4	Phillips Medical Systems	Since 2015, we have purchased numerous Philips SureSigns VS4 vital signs monitors. Each monitor comes with shock absorbing rubber feet on the bottom of the monitors. The shock absorbing rubber feet have been melting due high heat produced by the battery, thus becoming a glue-like substance that once it sticks to the floor or fingers, it's very hard to clean or peel off from the skin. We have purchased several batteries and replaced them, but the issue has not been resolved as it is continue to occur.
Oximeter Brand: Radical 7Pulse Co-oximeter Model#: RADICAL 7 Other #: 404191006 CONTROL #	Masimo Corporation	Masimo in bed space Y not communicating with the Spacelab, thus not communicating with central monitoring system. We checked all plug connections and even tried replacing them. Removed equipment from service and replaced with Masimo from bed space A. Equipment was recognized and removed before an adverse event could occur. No patient harm. Per Biomed Tech: After troubleshooting with tech support, we’ve determined the Masimo docking station and Spacelabs monitor are operating correctly, but the Masimo module that the SPO2 comes from has a software issue that must be reprogrammed by Masimo. It is covered under an extended warranty. I will be sending the unit off for reprogramming today.

Device	Manufacturer	Problem
Device 1: Needle, Hypodermic, Single Lumen Brand: BD Safetyglide Model#: 305916 Lot #: 0205090 Cat #: 305916 **Device 2: Needle, Hypodermic, Single Lumen** Brand: BD Safetyglide Model#: 305916 Lot #: 0775206 Cat #: 305916	Becton Dickinson and Company Becton Dickinson and Company	We have had two separate issues with the BD SafetyGlide Single-Use Hypodermic Needle (Model # 305916). December, 2020. Medical assistant (MA) was giving a immunization to a patient using a BD SafetyGlide 25g needle. After the injection, MA pulled the needle out of the arm and the needle came loose from the safety device and stuck in the arm of the patient. MA then had to pull the used needle out of the arm of the patient, and being extra careful that she did not get stuck. The BD SafetyGlide syringe/needle was discarded after the incident. The numeric identifiers for the BD SafetyGlide Needle are as follows: Lot # 0175206, Expiration Date 06/30/25, Reference/Catalog # 305916. January, 2021. The MA was giving a shot to a patient and when attempting to pull the needle out it stayed in the patient's leg. The needle detached itself from the safety device. This is the second time that this has happened. BD 25g needle with 3mL syringe. The faulty BD SafetyGlide syringe/needle was saved and returned to Becton Dickson on February, 2021. The numeric identifiers are as follows: Lot # 0205090, Expiration Date 07/31/2025, Reference/ Catalog # 305916.
Prosthesis, Mitral Valve, Percutaneously Delivered Brand: Edwards Sapien 3Transcatheter Heart Valve (Thv)	Edwards Lifesciences LLC	The Edwards SAPIEN 3 Transcatheter Heart Valve System was delivered via the left-side groin. Upon deployment of the valve the C -Arm, of the Siemens Healthcare GmbH Artis Zeego, blanked out and there was no image, therefore it was a blind deployment. Once image was able to be seen the valve had migrated to the descending thoracic aorta. During valve deployment, the fluoroscopy monitor went dark in the middle of valve deployment (10 seconds); therefore, exact positioning of the valve was unclear during mid-to-late deployment. By the monitor image returned, the valve had clearly migrated above the native aortic valve and was beyond the point of recovery and had to be deployed. Once image was able to be seen, the Edwards SAPIEN 3 transcatheter heart valve had migrated to the descending thoracic aorta. Unfortunately, root angiography at this point showed evidence of an descending aortic dissection.
System, X-ray, Angiographic GmbH Brand: Artis Icono Model#: ARTIS icono Other #: Functional Location # 400-658512	Siemens Healthcare	Siemens Icono Bi-Plane angio-suite had major software malfunction during start of Acute Stroke Treatment. Physician unable to review prior DSA runs to evaluate vessels. Physician unable to view imaging of DYNA CT acquire to determine if hemorrhage has occurred or not to determine next course of treatment. Tech unable to view/ film/adjust any images/exposure factors in control room (Control Room system completely locked). These factors directly affected patient care throughout the case. Unable to view prior images required physician to view/ memorize imaging. CT data would have shown MD a bleed which would have changed MD course of action.

Device	Manufacturer	Problem
System, Nuclear Magnetic Resonance Imaging GmbH Brand: Magnetom Avanto 1. 5t Other #: 129028	Siemens Healthcare	Patient's finger was pinched in table trolley system on MR28 during lowering of the scanner bed after completion of scanning. Patient was sitting upright and their fingers were in the gap, and subsequently injured. Left 3rd digit tip was degloved. Patient sent to ED w/wife via ambulance for further evaluation and treatment (amputated part sent with patient in sterile container on ice). Please see pictures below: **CORRECT POSITIONING OF PATIENT WHILE LOWERING THE TABLE:** • Patient in a supine position with their arms/hands resting on their chest or abdomen • **Effective immediately, ALL patients must remain in the supine position while the table is being lowered to the trolley and it must be ensured that no body part is at risk of being caught in that closing gap.**  **INCORRECT POSITIONING OF PATIENT WHILE LOWERING THE TABLE:** • Patient sitting in an upright position with their hands holding onto the table • This introduces a very high risk that the patients fingers will be pinched in the table because they have nothing to hold onto while the table is lowering.

Device	Manufacturer	Problem
System, X-ray, Angiographic GmbH Brand: Artis Icono Model#: ARTIS icono Other #: Functional Location # 400-658512	Siemens Healthcare	Siemens Icono Bi-Plane angio-suite had major software malfunction during start of Acute Stroke Treatment. Physician unable to review prior DSA runs to evaluate vessels. Physician unable to view imaging of DYNA CT acquire to determine if hemorrhage has occurred or not to determine next course of treatment. Tech unable to view/ film/adjust any images/exposure factors in control room (Control Room system completely locked). These factors directly affected patient care throughout the case. Unable to view prior images required physician to view/ memorize imaging. CT data would have shown MD a bleed which would have changed MD course of action.
System, X-ray, Angiographic GmbH Brand: Artis Zeego Lot #: 1261137	Siemens Healthcare	The Edwards SAPIEN 3 Transcatheter Heart Valve System was delivered via the left-side groin. Upon deployment of the valve the C -Arm, of the Siemens Healthcare GmbH Artis Zeego, blanked out and there was no image, therefore it was a blind deployment. Once image was able to be seen the valve had migrated to the descending thoracic aorta. During valve deployment, the fluoroscopy monitor went dark in the middle of valve deployment (10 seconds); therefore, exact positioning of the valve was unclear during mid-to-late deployment. By the monitor image returned, the valve had clearly migrated above the native aortic valve and was beyond the point of recovery and had to be deployed. Once image was able to be seen, the Edwards SAPIEN 3 transcatheter heart valve had migrated to the descending thoracic aorta. Unfortunately, root angiography at this point showed evidence of an descending aortic dissection.
Transmitters And Receivers, Physiological Signal, Radiofrequency Brand: Na Model#: ORG-9110A Cat #: ORG-9110A	NIHON KOHDEN AMERICA, INC.	It was discovered on [date redacted] at 13:02 that the arrhythmia recall was not recording or updating on cardiac monitors. Then on [date redacted] at 11:04, we were notified that Prefense was not storing non-invasive blood pressure (NIBP) readings. Last evening, [date redacted], notified that Prefense was not storing any information. After reboot the issue was corrected, but the device was still not saving NIBP readings. Made Nihon Kohden aware on [date redacted] of issues related to the WMTS digital telemetry receiver system. The manufacturer was also updated on [date redacted] related to Prefense issues. Followed up with them multiple times. Learned that this is a nationwide issue, and that it will require a software update that they need to build. The company report that they are working on it but will still be several weeks. They did provide a work around to this in the interim but it is cumbersome and not ideal for the folks using the system or working with and monitoring the patients.

Device	Manufacturer	Problem
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: V60 Ventilator Model#: V60	Philips-Respironics	V60 ventilator stopped while on the patient, the following alarms were noted: 1. PATIENT CIRCUIT OCCLUDED 2. CHECK VENT: 35 V SUPPLY FAILED 3. CHECK VENT: AUX SUPPLY FAILED 4. CHECK VENT: BACKUP ALARM FAILED 5. CHECK VENT: VENTILATOR RESTARTED 6. CHECK VENT: BLOWER STALLED We received the Field Safety Notice regarding the above stated failure mode of the V60 ventilator after this event occurred.
Device 1: Bottle, Collection, Vacuum Brand: Oasis Model#: 3600-100 Cat #: 3600-100 **Device 2: Bottle, Collection, Vacuum** Brand: Oasis Model#: 3612-100 	Atrium Medical Corporation Atrium Medical Corporation	Infant had chest tube placed. Chamber stocked on the unit was not the neonatal chest tube chamber and because of lookalike packaging this was not immediately recognized. Please change packaging to help better differentiate between neonatal/pediatric chamber and "adult" chamber.

Device	Manufacturer	Problem
Pack, Hot Or Cold, Disposable Brand: Infatherm Transport Mattress Model#: 989805616831 Lot #: 061820, 100520, 061920 Cat #: 1015 	Phillips North America LLC.	In evening, neonatal nurse practitioner (NNP) uncovered infant to access umbilical lines and noticed that there was no blanket between infant and chemical warmer. The infant was not under lights and was on the warmer for a total of 3.5 hours. Dayshift RN lifted baby, NNP held ETT, and RN added blanket under infant. The duration of contact (without blanket in between) was about 20 minutes. RN, Dayshift RN, NNP, and Resident assessed infant. No redness was seen at this time. About one hour later, neonatal nurse practitioner (NNP) was removing sterile field and both she and RN noticed redness and blistering present across buttocks and right leg. NNP and resident contacted dermatology, as wound was not available. The patient had 10% of total body surface area partial thickness thermal contact burns. The infant was cleaned with warm, spay water and then Xeroform was applied coated with Bacitracin twice a day to burn wounds, and changed, as needed. Chemical mattress suspected to have contributed to significant burn that patient suffered. On review, this infant transport mattress has a stated maximum temperature of 117°F which is significantly higher than many other mattresses on the market (104-105°F) Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) guidelines for neonatal bath water say no higher than 104°F which would be the closest guideline to this product. Specific mattress used in this injury is unavailable as it was discarded. Lot numbers have been pulled from current stock on the shelf and removed from patient use. This is all the information available.

Links to FDA/CDRH Databases and Other Information Sources

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.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
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: http://www.fda.gov/medicaldevices/safety/default.htm
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 Ill 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: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
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

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