MedSun
Medical Product Safety Network

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CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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In This Issue:

In Brief..... 2

BD to Begin Remediation for BD Alaris System Software....3

Highlighted MedSun Reports..4

Links to FDA/CDRH Database and Other Information Sources.....10

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 August 26, 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

Baxter Issues Urgent Medical Device Correction for All Spectrum IQ Infusion Pumps to Reinforce Important Safety Information Regarding Best Practices for Customer-Initiated IT Network Updates
August 24, 2021
Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for all Spectrum IQ infusion pumps to reinforce important safety information when customers implement changes to their network configuration and server systems. Baxter previously communicated this information to customers via an Urgent Medical Device Correction notification on June 4, 2021 and a follow-up communication with updated information on August 2, 2021.

Cardinal Health Issues Nationwide Recall of Select Monoject Flush Prefilled Saline Syringes
August 20, 2021
Cardinal Health initiated a nationwide recall of approximately 267 million Monoject Flush Prefilled Saline Syringes (0.9% Sodium Chloride). The products have been found to reintroduce air into the syringe after the air has been expelled. This could result in injection of air into blood vessels and create the potential for air embolism, which can cause serious adverse health outcomes or death.

Customers who have affected product(s) should immediately review their inventory and quarantine and return all affected product. The recall applies to all lots of the products manufactured from July 2019 to June 2021 distributed between July 2019 and July 2021. The following SKUs have been recalled: 8881570121, 8881570123, and 8881570125.

Eco-Med Pharmaceutical Issues Voluntary Recall of Eco-Gel 200
August 4, 2021
Eco-Med Pharmaceuticals, Inc. commenced a voluntary recall of certain lots of its Eco-Gel 200 ultrasound gel due to bacterial contamination. The product is also distributed as MediChoice Ultrasound Gel by Owens and Minor and Mac Medical Supply. These ultrasound gels are non-sterile and not indicated for sterile procedures.
Eco-Med is instructing all health care facilities to identify the affected products by lot number and immediately destroy or return products from affected lots to Eco-Med.

BD to Begin Remediation for BD Alaris™ System Software

BD (Becton, Dickinson and Company) announced the company will begin remediation for the February 4, 2020 BD Alaris™ System 1 recall through a new version of software.

The February 4, 2020 voluntary recall action notified customers of the following areas where the infusion pump may not operate as expected:

- Software errors related to System Error Code 255-XX-XXX
- Delay options programming
- Low Battery Alarm Failure
- Keep vein open (KVO)/End of Infusion alarms priority
- Use errors related to Custom Concentrations Programming

Under FDA guidance, BD will release Alaris™ System software version 12.1.2 and associated ancillary software to remediate the affected software. Customers can schedule remediation by contacting the BD Recall Support Center at 1-888-562-6018. The new software, which will be available at no cost to customers, is expected to remediate the issues identified in the February 4, 2020 recall notice and provide programming, operational and cybersecurity updates to affected devices; however, this software update has not been reviewed or cleared by the FDA.

In April 2021, BD announced that the company has submitted a 510(k) submission to the FDA for the BD Alaris™ System, which is intended to bring the regulatory clearance up to date. This submission covers all modifications to the BD Alaris™ System since its last 510(k) clearance, including updated hardware features as well as software version 12.1.2. Additional details related to software version 12.1.2 and the recommended steps for BD customers can be found at https://www.bd.com/en-us/support/alerts-and-notices/recall-and-distribution-hold-of-the-bd-alaris-system.

The BD Alaris™ System allows clinicians to deliver medications, fluids and blood products through a single integrated platform that includes large volume pumps, syringe pumps and patient-controlled analgesia (PCA) modules for adult, pediatric and neonatal patients.

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

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during August 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:

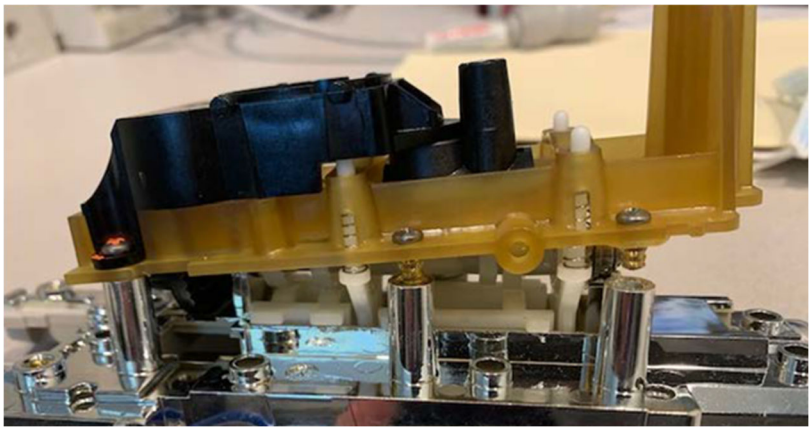
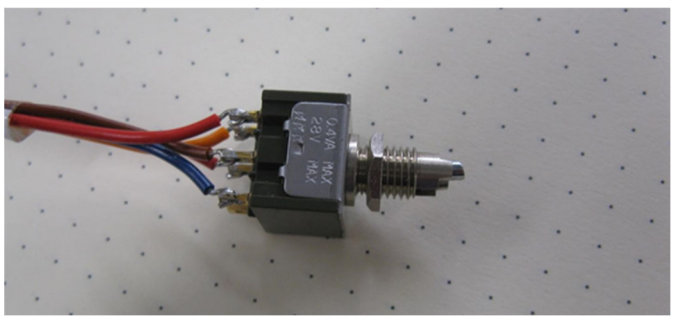
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


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
Shunt, Central Nervous System And Components Brand: Accudrain® External Csf Drainage System Cat #: INS8400	Integra Lifesciences Corporation	While walking patient to the restroom, RN heard something fall to the floor. RN got patient to toilet, then went back to look at what had fallen. RN saw EVD transducer on floor, with a trail of fluid to the toilet (CSF). RN immediately ran to EVD and clamped port off from which transducer fell from and was actively draining patient's CSF onto floor. Neurosurgery notified. Port remained clean/ uncontaminated, was appropriately cleaned and new transducer replaced. Spoke with RN who filed the event report. She states this transducer disconnected again today when ambulating to the BR. These fairly new EVD set ups are attached to a fixed point on an IV pole. When a patient is up and walking, the transducer cord has to be disconnected, which leaves the approximately 12 inch cord from the transducer swinging loose. This may produce enough torque to loosen and eventually disconnect the transducer from the buretrol. Will consult with the NICU educator to possibly add some extra teaching for this issue.
Device, Patient Transfer, Powered	Airpal, Inc.	We recently started using the AirPal mats. Several concerns regarding the mats:

Device	Manufacturer	Problem
Brand: Airpal Air-assisted Transfer Pad 34″ X 78" Model #: 34N Blue		Event 1: new AirPals are very slippery on the beds. Had a patient with mobility issues today that I was assisting to sit at the edge of the bed. When he sat and swung his legs to the side, the whole "air pal" moved with his body taking the sheet off with it. The air pal started slipping off the edge of the bed while the patient was sitting on it. He did have enough strength to stand so the mat could be removed, but this potentially could have been a fall related to the air pal and how slippery they are. Even when you wipe them clean, they slide all over the bed. Event 2: AirPal used to transfer patient from cart to bed. Individual was larger and as it was blowing up it started to sink on one side. Patient started to slide off mat. This would have resulted in a fall if RN wasn't at the side of the patient. (RN felt there was a firmness issue.) Also, when deflating it the mattress doesn't lower evenly - it wobbles. The weight does not distribute evenly. Proved to cause increased difficulty with transferring. Event 3: The new AirPal mat does not distribute weight equally. The patient fell to the right side not towards the bed and fell to the floor with mattress blown up still. The long strap on the side was stuck under the mattress and that contributed to the fall also, due to it pulling against the patient going to the bed. No injury to patient. Straps are too long and getting stuck under the matt affecting the patient when being slid onto the bed and distributing the weight unequal. Follow-up: The AirPal does not seem steady - they are very slick and do not tolerate weight adjustments. Many other staff have reported their dislike and have had near misses. There were other instances where the strap got wedged or caught in a cart. Team members tested it on a staff member after the fall and the nurse in the bed noted the firmness issue and how when deflated, it slides you in one direction fast, due to the slippery surface.
Media, Coupling, Ultrasound Brand: Medichoice Multi-purpose Ultrasound Gel Model #: M500812 Lot #: B055	Eco-Med Pharmaceutical	We have had Burkholderia cepacia in 10 cultures to date. The lot number that has been tested and is positive for Burkholderia cepacia is B055. B041 has tested negative and we continue to test other lots. An (Situation-Background-Assessment-Recommendation) SBAR was sent out on Saturday to have all lots of non-sterile Medichoice ultrasound gel pulled and replaced by another vendor. We are presuming that this is positive based on what we were told from other institutions. We did reach to distributor to make them aware. We have also been in communication with the state Department of Health and the CDC.

Device	Manufacturer	Problem
Pump, Infusion Brand: Alaris Model#: 8100	Carefusion 303, Inc.	An instance of bezel separation was discovered during inspection of an Alaris 8100 Pump Module. The bezels in question are an after-market replacement product and were installed in modules supplied by Avante Patient Monitoring (formerly Pacific Medical). The issue is similar to that described in Avante's Urgent Medical Device Recall Notification dated March 24, 2021. However, this issue differs in that instead of "cracking and/or separation of the front bezel component posts", the threaded inserts connecting the pumping mechanism frame to the bezel assembly have come loose from the component posts. The posts otherwise appear intact and have not cracked or separated. We believe the resulting risks would be the same as if the posts had cracked or separated. That is, potential issues of free flow, over infusion, under infusion, or interruption of infusion could exist if this problem were to occur. 
Ventilator, Continuous, Facility Use Brand: Base Unit Servo-u Model#: 6694800 Cat #: 6694800	Getinge/Maquet Critical Care AB	While setting up the ventilator for patient ventilation therapy, the Respiratory Care Practitioner (RCP) attempted to turn the ventilator on to perform the power on self-test. As the therapist tried to power the ventilator on the toggle lever on the switch snapped off preventing the ventilator from turning on. The ventilator was removed from service and sent to Biomedical engineering for service and reporting. This is the second incident of these switch levers snapping off. Biomedical determined that the switch design is of the locking level style in which the user is supposed to raise the switch lever about 2mm and then toggle to the On/Off position. The locking switch is designed to prevent inadvertent ventilator shut downs, but the user may be breaking the switch unaware that the switch is the locking style. 

Device	Manufacturer	Problem
Medical Gloves W/ Chemotherapy Labeling Claims -For Use W/ Chemotherapy Drugs Brand: Starmed Ultra Nitrile Exam Glove Lot #s: L074702, L076327 Other #: SMTN253	Sempermed USA, Inc.	When the StarMed Ultra nitrile exam gloves were removed from box, it was evident that they were "ripped" in box- prior to removal. Two separate events. (1) A glove was removed from the box and was ripped from the wrist all the way through the thumb. MFG Date/Lot# 2021-01 L074702 2101 size Large. The box was retained. (2) Box of medium StarMed Nitrile gloves, the first glove was found to be badly ripped and unusable. This issue has been a recurrent problem recently. Our center's glove spend has drastically increased this year and staff report it is due to high numbers of unusable gloves. MFG item number SMTN253. Date and Lot # 2021-02 L076327 2102(not saved). Sempermed USA, INC. will look into the recurrent issues.  

Device	Manufacturer	Problem
Media, Coupling, Ultrasound Brand: Ecovue Model #: 286 Lot #: 65843 Cat #: 286	HR Pharmaceuticals Inc.	Pregnant patient with continuous fetal monitoring. EcoVue ultrasound gel was being used. After 2 weeks of monitoring patient developed painful, red, and raised blister rash.
Ventricular (Assist) Bypass Brand: Thoratec® Heartmate 3 System Controller Model #: 106531US Lot #: N/A Cat #: 106531US	Thoratec Corporation/Abbott Laboratories	Day one, patient called the Left Ventricular Assist Device (LVAD) line at 1330 reporting being woken at 0230 by Low Voltage alarm while at home on MPU. On controller alarm interrogation, last low voltage alarm occurred a day before at 1639. Assumed patient experienced a Power Cable Disconnect alarm at 0230, patient presented to clinic for logfile download. Discussed with local Abbott rep, patient's Mobile Power Unit (MPU) confiscated and sent home with our loaner MPU. On review by Abbott engineers, logfiles were not available prior to 0830 from that morning as Pulsatility Index (PI) events had overwritten the alarm. On day two around 0830, patient phoned the LVAD line stating that a "blue alarm" woke him up around 0300. On controller interrogation, last alarms reveal Low Voltage alarm on day one around 1630, assumed patient experienced another Power Cable Disconnect alarm. Discussed with Physician Assistant (PA), patient to present to clinic for system controller change. International Normalized Ratio (INR) drawn prior to patient coming to clinic, logfiles downloaded and sent to Abbott engineers for review. Once INR result reviewed by medical team, patient was made comfortable lying in clinic chair for support, aware that he may feel syncopal during controller change. System controller successfully changed by Physician Assistant (PA). Patient without symptoms throughout. Once deemed medically stable, patient discharged home. System controller confiscated, will be sent to Abbott for analysis.
Media, Coupling, Ultrasound Brand: Aquasonic 100 Model #: Ultrasound transmission gel Cat #: 01-08	Parker Laboratories Inc.	Aquasonic 100 Ultrasound Transmission Gel - According to the Joint Commission "Since there is no effective way to determine whether an opened bottle of gel has been contaminated, general guidelines are that the gel should be marked to expire 28 days after opening. Using a warmer for the gel does not impact the expiration time." Our request is for the manufacturer to have an area on the gel bottle /container where the user can record the expiration date. This would improve patient safety and assist with compliance of recording expiration date.
Pump, Infusion Brand: Plum 360 Model #: Plum 360	ICU Medical	This is one MedWatch report involving many units of the same device. While preparing the infusion pump for patient use, the user would turn the infusion pump on and await the power on self-test (POST) to complete. The infusion device would report an error message on the bottom of the display stating: "! Keep Plugged into AC! Service battery/replace pump". At the same time, the pump's battery level icon would display a fully charged battery.

Device	Manufacturer	Problem
		This error would occur even on a pump that has been on charge for over 12 hours. The user would remove the pump from service and search for or request another pump from Central Equipment which would incur delays in patient care. The user would tag the pump to be repaired by Biomedical Engineering. These pumps are currently around 12 months old from new install to live date. Biomedical has been receiving these pumps at a rate of 15-20 pumps a week with this error message requiring the engineer to go into a PM service mode to reset the error. The pump is powered by a 6V 4.5Ah battery. We have a fleet of 1300 infusion pumps and we have encountered greater than 100 pumps with this error code. The clinical users are questioning the safety and efficiency of these pumps with the many battery failure messages. They are concerned that the pump will shut down while administering medications. 
Tube tracheostomy and tube cuff Brand: Shiley Flex Model #: 8CN85H Catalog #: 8CN85H	Covidien LP	Patient had an initial 8.0 Shiley placed; patient developed a persistent cuff leak and had to return to the operating room three days later to have a trach exchange to an 8.0 Bivona. Patient subsequently developed high peak airway pressures and bleeding and on bronch was found to have macerated tissue in the airway and had to have another trach change to an 8.0 distal XLT Shiley four days later.

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:
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: 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 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: 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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