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 August 2, 2019

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

FDA Takes Action to Protect Patients from Risk of Certain Textured Breast Implants; Requests Allergan Voluntarily Recall Certain Breast Implants and Tissue Expanders from the Market: FDA Safety Communication
July 25, 2019
To protect individuals from the increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), associated with Allergan BIOCELL textured breast implants, FDA requested that Allergan recall its BIOCELL textured breast implants and tissue expanders. Allergan agreed and is removing these products from the global market. The FDA requested that Allergan recall all BIOCELL textured breast implants and tissue expanders marketed in the U.S. based on newly submitted Medical Device Reports (MDRs) reporting worldwide cases of BIA-ALCL and BIA-ALCL-related deaths associated with these devices. Allergan has notified the FDA that it will recall its BIOCELL textured breast implants and tissue expanders from the global market.

Datascope/Getinge Recalls Cardiosave Hybrid, Cardiosave Rescue, CS300 and CS100/100i Intra-Aortic Balloon Pumps (IABP) Due to Potential Battery Failure
July 24, 2019
Maquet/Datascope is recalling all IABPs due to reports of the IABP batteries failing to hold a charge, stopping unexpectedly, and having a shortened run-time which may cause the device to stop working when being operated by battery only. This recall is being conducted to ensure that all IABP users and servicers follow each device's Operating Instructions Manual for recommendations on usage, charging, maintenance and storage of the batteries, as battery run times and discharge cycles vary between IABP models. If battery maintenance is not performed per the Operating Instructions Manual for each IABP, the battery may not provide the expected minimum run time of operating power.

Becton Dickinson (BD) Recalls Alaris Infusion Sets for the Alaris Pump Model 8100 Due to Potential for Tube Collapse that May Cause Unintended Delivery or Faster than Expected Delivery of Medication
July 18, 2019
BD is recalling Alaris Infusion Sets, due to the potential for faster than expected delivery of medication (over-infusion) or an unintended delivery that occurs while the pump is not in a "running status." The firm has determined that the silicone segment of the affected administration set has non-uniform thickness. Non-uniform wall thickness can lead to non-uniform tubing collapse and can contribute to a failure to fully occlude the tubing. This recall has been associated with MDR reports, several of which are associated with serious injuries.

FDA Offers Tips about Medical Devices and Hurricane Disasters

Severe storms, power outages, hurricanes, and other natural disasters can strike during the summer months. This **FDA resource** provides tips to healthcare facilities on keeping their devices safe and properly working during these occurrences. Along with the general device safety tips below FDA also provides information on how to potentially mitigate water contamination, sterility, and heat and humidity issues that may affect devices in different ways.

General Device Safety Tips:

- Keep your device and supplies clean and dry.
- If you depend on your device to keep you alive, seek emergency services immediately. If possible, notify your local Public Health Authority to request evacuation prior to adverse weather events.
- Always use battery powered flashlights or lanterns rather than gas lights or torches when oxygen is in use (to minimize the risk of fire).
- If your device appears to be damaged, or if you need a back-up device, contact your distributor or device manufacturer.
- Check all power cords and batteries to make sure they are not wet or damaged by water. If electrical circuits and electrical equipment have gotten wet, turn off the power at the main breaker.
- Maintain your device only in a well-lit area so you can assess your device's performance (e.g., refilling your insulin pump, checking your glucose meter).
- Keep your device in as clean and secure location as possible: off the ground, away from animals or crowded areas.
- Always check your device for pests before you use it (e.g., syringes, mechanical devices).

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during July 2019. 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

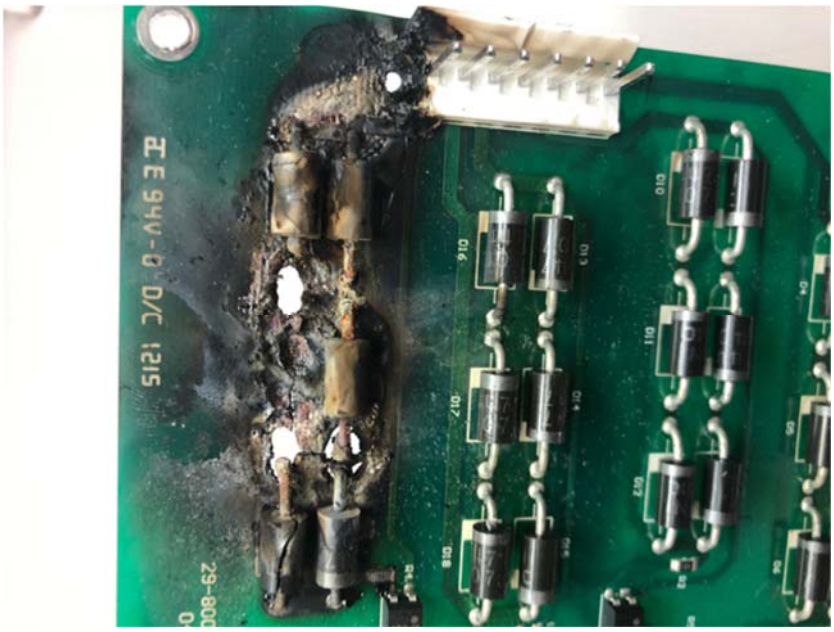
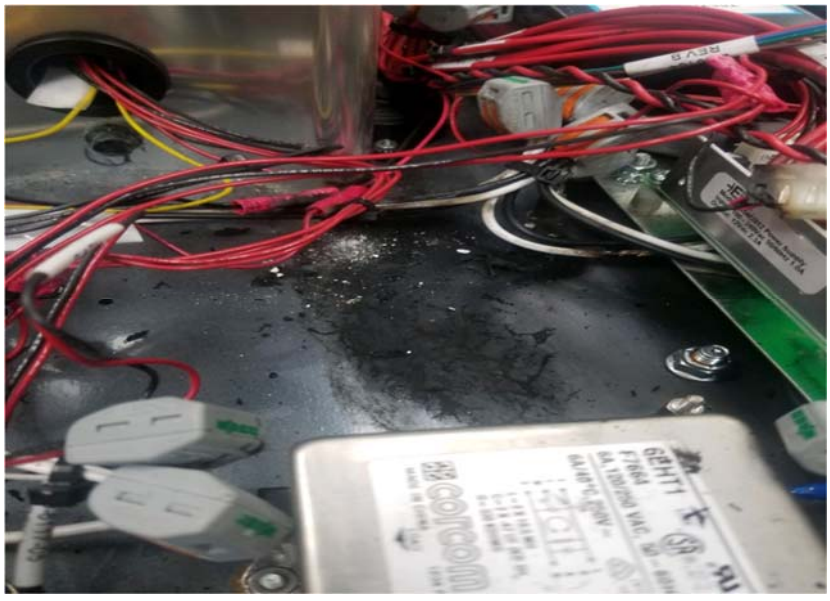
 Special Note:

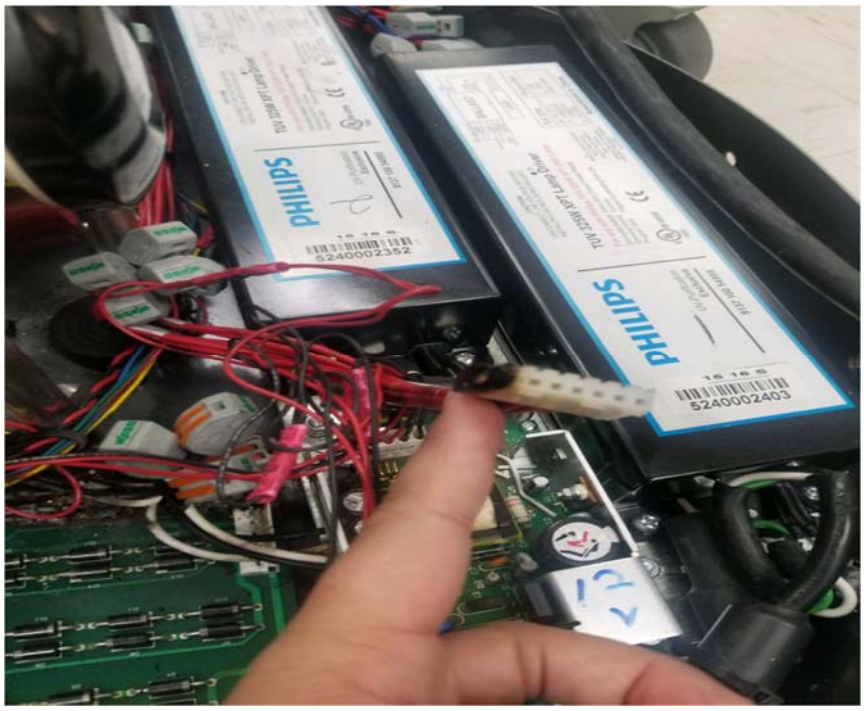
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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
Warmer, Infant Radiant Brand: Giraffe Model#: M1118179 Other #: CEID11011834 	Datex-Ohmeda, Inc	Upon doing safety check assessment of side rails, the side rail clip malfunctioned. It was found to be broken/cracked similar to another bed that resulted in a serious injury to the infant.

Device	Manufacturer	Problem
Accessories, Cleaning Brushes, Brand: Control Head /valve Cleaning Brush Cat #: 00711610 Other #: UPN H 9130071161001	Healthmark Industries Co., Inc.	After processing to ensure proper cleaning was the source of contamination from the culture. Per infection control, every week the duodenoscopes are cultured after processing. The department completes a brush culture and a flush culture. The past four weeks the brush culture has been positive for a bacillus species (<10 CFU) with no growth after 48 hours. The scopes were taken out of service and reprocessed. In addition, at the same time new scopes were acquired as a planned replacement. In early June, Infection Control queried the manufacturer to validate the brushes were sterile as it is not indicated on the packaging. The manufacturer indicated that the brushes go through a ethylene oxide sterilization process. The company indicates that they are not to be used in sterile procedures involving patient care and therefore they do not place the word sterile on the wrapper. In order to better determine the source, the brushes were cultured immediately after removal from the packaging. The brush culture was positive for probable bacillus species (<10 CFU). Consequently, the brushes were removed from use and a replacement is being sought. Upon further review, the hospital acknowledges that they purchased the incorrect non-sterile brush and are concerned about the labeling of the sterile cleaning brush product verses the non-sterile cleaning brush. The only distinction between the sterile brush and the non-sterile brush is the "S" at the end of the catalog number for both products.
Pump, Infusion Brand: Alaris Model#: 8015	Carefusion 303, Inc.	This report is to bring to attention the design of drug selection when programing the BD CareFusion Alaris infusion pumps, how accessible and how easy it is to select and program the pump in basic infusion that provides no safety protections against errors while creating high risk for manual errors. First selection screen lists 3 choices: Guardrails Drugs, Guardrails fluids, and Basic infusion. This design makes it easy to select and naming " basic" often gets confused with basic IV/saline infusion. Having the selection of the main screen, as one of only 3 choices, makes it easy and fast to program infusion in basic mode (just enter rate and volume), without any alerts, limits, information about medication infusing. It is even easier than programing correctly using Guardrails library. We understand that the need for quick infusion for emergency purposes is beneficial, but the design, ease of access and naming, make it really easy to abuse and incorrectly use this option. Also when this option is used to program, not only it does not provide safety limits and alerts, it also provides no history of infusion, as it does not have drug name programed, and makes it incompatible with Interoperability.

Device	Manufacturer	Problem
Device 1: Blood Pressure Cuff Brand: Disposable Blood Pressure Cuff Lot #: 19-122 Cat #: 901044	Welch Allyn, Inc.	Disposable blood pressure cuffs are ripping or developing a hole when inflating.
Device 2: Blood Pressure Cuff Brand: Disposable Blood Pressure Cuff Lot #: 19-141 Cat #: 901044	Welch Allyn, Inc.	
Device 3: Blood Pressure Cuff Brand: Disposable Blood Pressure Cuff Lot #: 19-157 Cat #: 901044	Welch Allyn, Inc.	
Device 4: Blood Pressure Cuff Brand: Disposable Blood Pressure Cuff Lot #: 19-127 Cat #: 901044	Welch Allyn, Inc.	

Device	Manufacturer	Problem
UV Disinfection Tower Model#: 29-5100	Clorox Healthcare	Clinical Engineering received a call indicating that a circuit breaker kept tripping when the UV tower was plugged in. While inspecting the device, it was noted that one of the circuit boards appeared to have been on fire. Significant burn damage was noted on the circuit board and associated connector. Also noted 1)the electronics for this device are all located in the base and there does not appear to be a fluid barrier on this device 2) every other relay on the printed circuit board appears to have excessive residue on the insides of the relays (this is true of the relays on all devices that were inspected.) This event happened in the OR, which of course is an oxygen enriched environment, making this event especially concerning. Per hospital, the vendor came on site and inspected all devices. Please see pictures below:  

Device	Manufacturer	Problem
		 

Device	Manufacturer	Problem
Pump, Infusion Brand: Alaris Model#: 8110 	Carefusion 303, Inc.	This is to report design and configuration of BD Alaris (model 8110) pressure settings. The design is such that the default and the max pressure setting are the same. And this is true for both with or without use of pressure sensing disk(provides more accurate pressure readings and more accurate alarms). The options for pressure selection are low (~200mmHg), medium (~500mmHg), and high (~900mmHg). If default is set to low, it is also the MAX so it does not allow selection of medium or high. This creates a problem specifically in our when these devices are used in neonatal population (NICU) and Pediatric ICU. They need to have low pressure setting to alert occlusion in timely manner, but every once in while a larger baby will need higher pressure settings or if ECMO is run, they have to change profiles to accommodate those children. We have been forced to spend a lot hours to understand the system, the ins and outs of pressure settings and options, to create workarounds for our staff, to be able to protect the smallest population of our patients (NICU preemies),but also be able to provide appropriate care to larger/full term neonates or deliver ECMO therapy (high pressure circuit). If pressure is set to medium to accommodate those, then the smallest population is without protection or nurses have to change pressure setting manually every single time they program the pump (unrealistic, impossible and unsafe). Same design is used for their pressure sensing disk (supply item, tubing with pressure sensing disk to provide accurate pressure reading in the line). Again, the maximum pressure setting is the default or starting point once the infusion is programed. The end user is supposed to go behind screen, into options, pressure settings, and then select "Auto-pressure" to enable auto pressure feature to adjust the limit to pressure in the line or to a manually programed limit. Again, this is unrealistic workflow for bedside clinician, to depend on them remembering turning on this feature every time, especially when a NICU or PICU patient can have over 10 infusions running. And if they forget, the default becomes automatically value chosen as the max allowed pressure, which is a highly unsafe condition. Being able to separate default pressure setting from a maximum setting would provide maximum safety and protection for most critical patient population (neonates and pediatric) where even the smallest of volumes or delays can have lasting or negative impact.

Device	Manufacturer	Problem
Tubes, Gastro-intestinal (And Accessories) Brand: Qora Aeon Stool Management Kit Model#: MG-12015-002 Other #: HEMM # 513769	Consure Medical Private Limited	Registered nurse (RN) noted bloody output in fecal containment device and around the device. Large amount of bleeding continued. Device was removed at bedside. A digital rectal exam revealed a defect anteriorly in the rectal mucosa. Patient was taken to OR emergently for examination under anesthesia and ligation of the rectal bleed. Multiple blood products transfused. Operative findings: Large anterior rectal ulcer, ischemic appearing, about 8cm from anal verge, running stitch proximally, figure of eight placed distally, 15cc of 2% lido with epi injected. Patient developed recurrent bleeding postoperatively. Initial OR repair with suture placed was followed by re-bleeding episode and vessel ligation was performed. Patient again bled with OR suture placed, and rectum packed. Given that additional intervention would cause bowel ischemia, family transitioned patient to comfort-care measures only. Pt expired. *When staff attempted to withdrawal the Qora by pulling the string to collapse the device the string would only move about an inch and then resistance was felt and unable to further collapse the device. Able to remove the device through the rectum. Once the tube was removed a large clot was found to be encasing the entire cage-like aspect of the rectal tube device. On review of device-related complication, clinical team expressed that patient's death was primarily caused by bleeding complications associated with use of the device.
Ventricular (Assisst) By-pass Brand: Thoratec Heartmate 3 Model#: 106523US Cat #: 106523US	Thoratec Corporation	A structural defect was identified in the body of the pump after multiple episodes of significant air embolism arising from the inflow cannula of the pump was noted. One of the clasps that secures the inflow cannula to the apical connector was identified to be loose and did not properly lock to the cuff and provide an air-tight seal.
Set, Administration, Intravascular Brand: Maxzero Model#: MZ9267 Cat #: MZ9267	CAREFUSION 303, INC.	Leak identified when using BD 3ml Syringe (Luer-Lok Tip) with BD MaxZero (Microbore extension set, IV connector). Leak not present when using other sized syringes. This is a recurring problem with these two devices regardless of the lot number of either device.

Device	Manufacturer	Problem
Stopcock, I. V. Set Brand: ICU Medical Model#: MC33904 Lot #: 4065904	ICU Medical, Inc.	While performing cares it was noted that blood was backing up in the blue lumen of patient's UVC. Attempt to flush line normal saline syringe was unsuccessful. Another RN was immediately called to come to the bedside and assess. Before the other RN arrived, all clamps and lines rechecked to make sure all were appropriate and no problems were found. TPN was changed a few hours prior to noted blood backing up and clamps were double checked immediately after TPN change with 2nd RN. Red tape was applied to clamps of syringes not being infused. The doctor was also at bedside. Other RN attempted to flush the blue lumen without success. Together we flushed the TPN line infusing in the blue lumen to find it was cracked just before the filter and was infusing fluid out of the crack of the tubing. We removed the tubing and placed all fluid to be infused in the remaining white lumen. We also changed the rate to the appropriate rate. Unable to re-create how tubing could have been compromised by clamp.
Syringe, Piston Brand: Bd Luer-lok Model#: 309657 Cat #: 309657	BECTON, DICKINSON AND COMPANY	Leak identified when using BD 3ml Syringe (Luer-Lok Tip) with BD MaxZero (Microbore extension set, IV connector). Leak not present when using other sized syringes. This is a recurring problem with these two devices regardless of the lot number of either device.

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: http://www.fda.gov/medsun/
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 August 2019 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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