MedSun
Medical Product Safety Network

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

# November 2020

Volume 20, Issue 11

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## 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 November 2, 2020*

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 Device Correction to Reinforce Important Safety Information Regarding Cleaning Practices of all Sigma Spectrum Infusion Pumps (V6, V8 and IQ)**
**October 29, 2020**
The manufacturer issued an Urgent Device Correction to reinforce important safety information regarding cleaning practices of all Spectrum infusion pumps distributed in the United States, Canada, and the Caribbean, as deviations from the specified cleaning methods may impair infusion pump functionality and performance. Baxter previously communicated this information to customers directly in a Safety Alert on April 1, 2020 and subsequently via an Urgent Device Correction notification on August 28, 2020. Deviations from the cleaning methods described in product-specific Operator's Manuals may lead to residue buildup or corrosion of the electrical pins (e.g. depressed pins) on the infusion pump rear case and battery electrical contacts. This could result in notifications that the user should check the battery, or that batteries are not charging or holding their charge.

**Intuitive Surgical da Vinci Surgical System – Class II Recall**
**October 23, 2020**
A da Vinci Xi Endoscope Controller in the field was improperly calibrated during servicing. The result of this improper calibration may result in the tip of the endoscope may reach higher temperature causing the potential for thermal tissue injury and/or overly bright images.

**ICU Medical NanoClave Connector – Class II Recall**
**October 22, 2020**
CLAVE Neutron is a normally closed, bidirectional connector intended for use as an accessory to an Intravascular catheter placed in the vein or artery. Identification of a potential manufacturing defect on the internal surface of the NanoClave within specific lots of NanoClave sets, which may inhibit a proper seal with the NanoClave spike.

## HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during October 2020. 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.**

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| Device | Manufacturer | Problem |
|---|---|---|
| **Respirator, Surgical**<br><br>Brand: Halyard Fluidshield 3N95<br><br>Model#: AM0142811<br>Lot #: AM0142811<br>Cat #: 017308 | O&M Halyard, Inc. | The outside of the box states regular, but the box is filled with small. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Bed, Ac-powered Adjustable Hospital**<br><br>Brand: Citadel Plus | Arjohuntleigh AB | ARJO Citadel bed did not have cables installed for bed alarm. Patient fell from bed. Bed now has cables. |
| **Conserver, Oxygen**<br><br>Brand: Drive-medical Oxymizer Disposable Oxygen Conserver<br><br>Cat #: O-224 | Drive Devilbiss Healthcare | Patient was placed on the oxymizer in the intensive care unit. The patient also wore his personal glasses continuously with the oxymizer tubing around the ears. There were no prevention measures put in place for the oxymizer tubing until the pressure injuries were found, and once in place, the grey foam added to the tubing at the top of the ears didn't always stay in place. The patient developed a hospital-acquired unstageable pressure injury on the right proximal ear, stage 2 injury to the nasal septum from the sharp plastic seam of the nasal oxygen reservoir, and stage 2 to the left posterior ear from the hard stiff oxygen tubing. Patient required higher levels of oxygen and was unable to wean to softer tubing nasal cannula to minimize pressure from oxygen device.<br><br>Our Concerns Regarding Oxymizer:<br><br>1) Can cause injury under the nose related to seam. There is a seam/weld where the plastic comes together. This is a firm, slightly sharp raised edge that can cause issue if it presses into the nares/nasal septum.<br><br>2) Tubing on oxymizer is not soft and requires additional tubing added for pressure reduction, this tubing is not always reliable as an intention for pressure injury prevention since it falls down.<br><br>3) Tubing is required to be secure with the cinch at the chin in order to hold the reservoir and prongs in place in the nares. This causes the pressure to hang on the top and the back of the ears, as well as risk to secure too tight to create pressure at the nasal septum and cheeks.<br><br>Steps Taken By Facility: Created Oxymizer Best Practices to ensure oxymizer is pressure injury safe: For patients with oxymizers, make sure the respiratory device is pressure injury safe. Wrap foam tape or Mepilex around the middle seam and add grey foam pads to the ears – the tubing is not the SOFT tubing. It is okay to cover the middle vents as there will be open vents on both sides. We have also implemented the added step of placing a sticker with these instructions on a majority (but not all) of the oxymizer packages as a reminder to perform these actions. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Cylinder, Compressed Gas, And Valve**<br><br>Brand: Intelli-ox<br><br>Lot #: W0440226EE01 | Air Liquide Healthcare America Corporation | Patient was transported on a ventilator to CT when Airgas INTELLI-OX tank read oxygen failure. Patient subsequently began to desaturate into low 70% and required emergent tank switch out. The old Airgas INTELLI-OX tank still showed 75% full. |
| **Pump, Infusion**<br><br>Brand: Spectrum Iq<br><br>Model#: 3570009<br>Cat #: 3570009<br>Other #: 3568135 | Baxter International, Inc. | During correction of device recall being performed by Baxter, it was found that some of the Baxter IQ infusion pumps are unexpectedly turning off with very little movement of the pump when running on battery power. Slightly wiggling the battery module, or even picking the pump up can cause enough disturbance to turn the pump off entirely. Sometimes the pumps would turn back on right away and go to an "improper shutdown" screen with an audible alarm. Other times, it would turn back on as if the pump had been off and someone hit the power button, and would not alarm at all.<br><br>On some occasions, the pumps would get stuck in between on and off with a blank white screen, and would not turn on until the battery module is touched again. We have videos of these occurrences, however the files are too large to attach to this report. they can be sent using whatever method the reviewer of this report would like. These pumps were not in use, however after noticing this for the first time, the technicians were alerted to keep an eye out for others with this issue. of the last ~250 pumps that were handled, 5 display this issue. With Baxter's help, we have ruled out the possibility of these pumps falling under Baxter's Urgent Device Correction issued on April 1, 2020 regarding pumps being able to turn off if there is corrosion of battery terminals, or stuck pins in the backplate as none of the 5 pumps being reported have any corrosion or |
| **System, Thermal Regulating**<br><br>Brand: Arctic Sun® 5000<br><br>Model#: 50000000<br>Cat #: 50000000 | Medivance, Inc. | Patient noted to have back and thigh wounds with a mixture of superficial and deep partial thickness, and an area of full thickness burn to the left lower back, secondary to use of Arctic Sun warranting transfer to a Burn unit. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Device 1: Tubes, Gastrointestinal (And Accessories)**<br><br>Brand: Neoconnect Enteral Extension Set<br><br>Model#: PEXT-60NC<br>Lot #: 20200227<br>Cat #: PEXT-60NC<br><br>**Device 2: Tubes, Gastrointestinal (And Accessories)**<br><br>Brand: Neoconnect Enteral Extension Set<br><br>Model#: PEXT-60NC<br>Lot #: 20200110<br>Cat #: PEXT-60NC<br><br>  | NeoMed, Inc.<br><br>NeoMed, Inc. | We are reporting two failures of the same product that happened within 1 week of each other:<br><br>The feeding tubing was found to have leaked the baby's feeding. After the feeding was complete and the pump turned off, the baby was fussy and acting hungry. It was then discovered his linens soaked in formula under the tubing and NG connection. Some formula was manually pushed through the tubing and it was all leaking out of a crack at the hub. The baby was re-fed through new tubing that was not cracked or leaking (LOT# 20200227).<br><br>The feeding tube (NEOCONNECT enteral extension set with Enfit connector LOT:20200110) leaked Medolac feed where it connects to the patient's NG tube when being administered by pump. The health care provider caught the leak early so only a few mL was wasted and new tubing was obtained to deliver the remainder of the patient's feed. |
| **Ventilator, Continuous, Facility Use**<br><br>Brand: Puritan Bennett Model 840<br><br>Model#: 4-840120DIUU-US | Covidien LP | The screen on the ventilator went completely black and cut off while in use on patient.<br><br>The patient's nurse manually Ambu'ed patient while RT went to get a new ventilator for replacement. Ventilator taken out of service and tagged for biomed to pick up. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Ventilator, Continuous, Minimal Ventilatory Support, Facility Use**<br><br>Brand: Phillips Respironics<br><br>Model#: V60<br>Cat #: 1053617<br>Other #: 09074 | Respironics California, Inc. | Patient's nurse informed respiratory therapist (RT) that the internal battery alarm began flashing on Bipap machine. RT came to bedside to assess machine. The plug was moved to multiple outlets, but the alarm would not stop flashing. A replacement Bipap machine was brought to the bedside, and exchanged. The malfunctioning machine was taken out of service and tagged for Biomed to check out. |
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## 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 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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