Class I Medical Device Recall: Bunnell Incorporated, Life Pulse High-Frequency Ventilator Patient Circuits

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: November 19, 2012

Products: Life Pulse High-Frequency Ventilator Patient Circuits

Catalog Number 902 (individual Patient Circuit) and **Catalog Number** 937 (Patient Circuit Kit); Part Number 00238-07, 00238-09

Lot Numbers: See the affected lot numbers below. They can also be found on Bunnell's website, www.bunl.com [1] (See "Recall Notification & Certificate of Medical Necessity."). The patient circuit lot number can be found on a label attached to the humidifier cartridge of each individual circuit.

DO NOT reference the Lot # on the outside of the circuit box.

Recalled Patient Circuit Lot #'s
12C092 12E211 12H330 12C102 12E224 12H349 12C115 12F241 2I362 12C125 12F254 12I371 12C136 12F271 12I397 12D159 12G279 12J413 12D172 12G290 12J430 12D189 12G307 12J448 12E204 12G321 12K457 12K471

Bunnell is recalling these patient circuits that were distributed after March 19, 2012 through October, 2012. They were manufactured from March, 2012 through September, 2012.

Use: Patient circuits are used for ventilating critically ill infants with pulmonary interstitial emphysema and infants with respiratory distress syndrome complicated by pulmonary air leaks, who are, in the opinion of their physicians, failing on conventional ventilation. The patient circuit provides a conduit for humidifying, warming, and temperature monitoring of the pressurized gas. The patient circuit is indicated for a seven-day single use.

Recalling Firm:

Bunnell Inc.
436 Lawndale Drive
Salt Lake City, Utah 84115-2917

Reason for Recall: This product has been found to have heater wire insulation that can melt, causing sparking and smoke, close to the humidifier cartridge. This can cause serious adverse consequences, including death.

Public Contact: Customers with questions should contact Bunnell at 1-800-800-4358 ext. 6 between 8:00 AM and 4:00 PM (Mountain Standard Time) Monday through Friday or by email at plattdr@bunl.com [2].

FDA District: Denver District Office

FDA Comments: On November 19, 2012, Bunnell sent its customers an URGENT: MEDICAL DEVICE RECALL NOTIFICATION letter by certified mail. The letter included the reason for recall, the potential risk to health, and actions to be taken by the customer/user. The letter also stated that although this is a recall, the firm is not replacing these circuits at this time.

Actions to be taken by the Customer/User:

1- Each user should consider the likelihood and severity of the potential risks of using the affected circuits, as well as the medical necessity of using High Frequency "Jet" Ventilation, to determine whether it would be in their patients' best interests to use the affected circuits or not. Despite the risks noted above, **if a decision is made to continue use** of the High Frequency "Jet" Ventilator system, including the Patient Circuit, the **Certificate of Medical Necessity MUST be completed and returned to Bunnell. Bunnell cannot ship circuits to any hospital without receiving a signed copy of the Certificate of Medical Necessity**.

2- If a customer/user wants the affected circuits returned and a credit issued, please contact Bunnell Inc. for return authorization. Replacement circuits offering a greater protection against the failure mode noted above are not yet available. Circuits returned for credit should be sent to the following address:

Bunnell Incorporated
Attn: Recall Coordinator
436 Lawndale Drive
Salt Lake City, UT 84115

3- If it is determined that the patient's needs are best served through use of the High Frequency "Jet" Ventilator system, using the recalled circuits, the following actions will reduce the likelihood of this type of failure occurring.

a. Position the circuit so air cannot blow directly on or across the circuit, especially the thermistor/portion of circuit near the patient box.

b. Visually inspect both the circuit and the internal heating wire (red) every 30-60

minutes for thermal damage (that is, sections of exposed wire without insulation, melting or substantial discoloration). Specifically examine the red wires near the humidification chamber. Immediately replace the circuit if thermal damage is present.

c. Replace the circuit if a Circuit Low Temp activates unexpectedly and the low temperature condition is not resolved within 5 minutes after following appropriate troubleshooting contained within the operator's manual.

d. Replace the circuit if displayed temperature is noted to be below the set temperature for more than 5 minutes.

For any questions about this recall, see Public Contact above.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [3] either online, by regular mail or by FAX.

Additional Information:

- Firm Press Release [4]

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http://www.mdtmag.com/news/2012/12/class-i-medical-device-recall-bunnell-incorporated-life-pulse-high-frequency-ventilator-patient-circuits?qt-recent_content=0

Links:
[1] http://www.bunl.com/
[2] http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/mailto:plattdr@bunl.com
[3] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[4] http://www.fda.gov/Safety/Recalls/ucm330842.htm