



رقم المحفوظات: ٤٨/٢٥
رقم الصادر: ١٣/١٢٧١٩
بيروت، في: ٢٢ كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز دلبي

Breathing Circuits, Ventilator, Disposable Patient Circuits

الجهاز المعنى بالمتابعة:

- Breathing Circuits, Ventilator, Disposable Patient Circuits
- Trade Mark: Bunnell Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمله مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

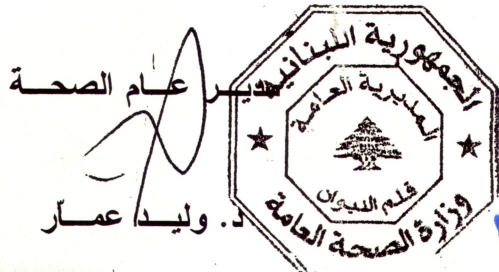
- التقرير الصادر عن وكالة ال FDA

يلف:

دائرة البرامج والمشاريع ✓

- المستشفيات الحكومية

- المحفوظات



عام الصحة
د. وليد عمار

وثيقة مطابقة للأصل
تمت في ٢٢ كانون الثاني ٢٠١٣
رئيس قسم الدروس و التضايا
و العلاقات الصحية و الدولية
عبد ضومط



U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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510(k)⁷ | Registration & Listing⁸ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ | CFR Title 21¹⁴ | Radiation-Emitting Products¹⁵ | X-Ray Assembler¹⁶ | Medsun Reports¹⁷ | CLIA¹⁸ | ITPLC¹⁹

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**Class 1 Recall
Life Pulse High Frequency
Ventilator**



Date Posted	December 14, 2012
Recall Number	Z-0514-2013
Product	Patient Circuit used with the Life Pulse High Frequency Ventilator. The Patient Circuit is a required disposable component of the Life Pulse High Frequency Ventilator. Model #(s): Individual Patient Circuit - catalog # 902 Patient Circuit Kit - catalog # 937; contains 2 circuits and 2 x 2.5 & 2 x 3.5 LifePort Adapters. Labeling states manufactured by: Bunnell Incorporated 436 Lawndale Drive, Salt Lake City, Utah 84115. 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 is to provide a conduit for the humidification, warming, and temperature monitoring of the pressurized gas. The Patient Circuit is indicated for seven day single use.
Code Information	Patient Circuit (catalog # 902) lot # on each individual patient circuit label: 12C092, 12C102, 12C115, 12C125, 12C136, 12D159, 12D172, 12D189, 12E204, 12E211, 12E224, 12F241, 12F254, 12F271, 12G279, 12G290, 12G307, 12G321, 12H330, 12H349, 12I362, 12I371, 12I397, 12J413, 12J430, 12J448, 12K457, 12K471 Patient Circuit Kit (catalog # 397) lot # on the label on outside of box: 12C099, 12C114, 12C124, 12C135, 12D152, 12D170, 12D188, 12E203, 12E210, 12E223, 12F238, 12F255, 12F274, 12G209, 12G280, 12H334, 12H341, 12I356, 12I369, 12I392, 12J411, 12J425, 12J447, 12K467, 12K479
Recalling Firm/Manufacturer	Bunnell, Inc 436 Lawndale Dr Salt Lake City, Utah 84115-2917
Reason for Recall	Customer complaints received indicate the heater wire insulation can melt, causing a short which creates sparking and smoke, in the circuit close to the humidifier cartridge. Bunnell is recalling all lots of circuits distributed between March 12, 2012 and November 30, 2012.
Action	On 12/5/12, the firm, Bunnell, Inc., issued a public press notification to their consignees. A. On or before 12-12-2012 a certified letter will be sent to all customer listed in the customer database. Specifically each customer will receive two certified letters; one directed to Director of Respiratory Therapy and a second to the Director of Biomedical Engineering. The certified letter will contain a copy of the Recall Notice and a copy of the Certificate of Medical Necessity. The Certified Letter receipts will be maintained. On the mailing date a copy of the Recall Notice will be placed on the Bunnell website. B. An Excel database will be maintained for each customer/lot #. The database will contain the current status for each. Included will be: 1. Customer Information 2. Date Certified Letter Sent 3. Date receipt received and filed 4. Date product returned or that no stock remains 5. Lot number & Quantity C. On or before 02-01-2013, a second letter will be sent to those customers who have not responded to the original certified letter. D. Data will be maintained in the database E. On or before 04-01-2013, a phone call will be placed to those customers who have not responded to either of the letters. F. Data will be maintained in the database G. On or before 04-15-2013, a second phone call will be placed to those customers who have not responded to the letters or previous phone call. H. Data will be maintained in the database I. On or before 06-07-2013, a Final Recall Notification certified letter will be sent to those customers who have not responded to either of the previous letters or phone calls. J. The Certified Letter receipt will be maintained K. Data will be maintained in the database L. When PMA for alternate heater wire is approved, steps A-K will be repeated. Dates will be determined. M. Following completion of Step L, a final review of the database will occur. Final tabulation of the status for each custo.
Quantity in Commerce	5743 patient circuits distributed in commerce
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Canada, Australia, Malaysia, and Uruguay (animal study only).

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