

# ENGINEERING, FACILITIES AND EQUIPMENT

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## Quality Assurance

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### Food and Drug Administration (FDA) Recalls/Alert Notices

**Attachment 2**, paragraph 1, provides information on FDA medical equipment recalls and alerts. Personnel from clinical engineering, biomedical equipment maintenance, quality assurance, and safety should follow the guidance provided to ensure the effective maintenance and management of medical equipment. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

### Safety Alert -- Multiple Medical Gas Monitors, Respired/Anesthetic, MDC 17445, Model 1100 Multiple Medical Gas Monitors, Criticare Systems Inc.

Reference ECRI *Health Devices Alerts* Number 1996-A36, 6 September 1996, Accession No. A3109. ECRI reports that a unit did not display gas concentrations after warm-up and autocalibration, rendering the monitor useless. The manufacturer discovered that the problem was caused by wear of a moving part in the CO<sub>2</sub> electronic subsystem and replaced the affected part. The firm states that it has since improved the subsystem in units with serial numbers above 493000000 manufactured since October 1993. If your Criticare Model 1100 fails to display gas concentrations, contact Criticare for an upgrade. The upgrade costs \$593. Criticare also notes that tilting up the front face of the system will shift the load on the bearings, thereby extending the bearing

life of the problem component. For further information, contact Criticare or your local Criticare representative.

### Safety Alert -- Ventilators, Portable, MDC 17423, LP6 Portable Volume Ventilator, Aequitron Medical Inc.

Reference ECRI *Health Devices Alerts* Number 1996-A36, 6 September 1996, Accession No. A3110. ECRI reports that as of 1 September 1998, Aequitron will no longer recertify or provide replacement parts for the LP6 ventilator. Aequitron recommends that customers consider purchasing new units. The firm notified customers of record of this decision by letter dated 18 September 1995. All affected activities should verify receipt of the 18 September 1995 letter from Aequitron and plan to replace these devices with newer units. If it is not practical to replace the units, ECRI believes that these devices can continue to be safely used beyond the manufacturer's recertification period provided **all** of the following conditions are met:

- (1) The units pass a performance verification every six months.
- (2) Performance verification and service are provided by qualified technical service personnel with experience in inspecting and servicing these ventilators.
- (3) When needed, components of the same brand, rating, model number, etc., as those supplied with the original equipment are used for repairs or replacement.
- (4) Users take precautions to minimize the risk of high delivered pressure if the exhalation pathway becomes blocked.

ECRI recommends that an external pressure-relief valve be used. If these conditions can not be met,

the units should be replaced as soon as possible. The manufacturer recommends that the units not be used beyond 1 September 1998.

**Safety Alert --  
Monitor Systems, Physiologic,  
MDC 12636, Tram 250SL, 450SL,  
650SL, 850SL, and 850A Modules,  
Marquette Medical Systems, Inc.**

The manufacturer notified customers in a letter with a reply card dated 30 August 1996 that a possible component anomaly has been identified in the above units. The component is part of the Pulse Oximetry board. If there is such an occurrence, the module will no longer function. The manufacturer has an upgrade available that will reduce the likelihood of this anomaly. This upgrade can be performed either by the Hospital Biomedical Department or scheduled with a Marquette Service Engineer on a "first-come, first-serve" basis. The upgrade is estimated to take approximately ten minutes and will be performed at no cost to the facility. Activities should ensure they received the 30 August 1996 letter from the manufacturer. If you are experiencing problems, suspect a problem, or require additional information, contact Marquette Service at 1-800-558-7822.

**Type III Materiel Complaints -  
Information Exchange**

A summary of the most recent medical materiel complaints involving medical equipment is listed below. This summary is provided for information only. Please note the complaints *are not validated*. They do not constitute a recall, nor do they require you to perform the sort of inspection and reporting associated with equipment hazards. If you have experienced a similar problem locally, please submit an SF 380 in accordance with AFMAN 23-110, Vol. 5, Chap. 19. It is important that we receive documentation of equipment problems since

severity and impact of a materiel defect is frequently judged by the number of separate complaints received.

**Mammographic System, Diagnostic, Athena HF,  
Fischer Imaging Corporation**

An activity reports the unit is causing exam/study delays due to unreliable operation. The first recurring problem was with faint grid lines. The company made numerous repairs and determined a different bucky was required. In the seven months since the bucky problem was resolved, the unit has been "down" a total of 32 days, 23 percent of available business hours. Service requests have been requested for error codes 26, 24, and 21, as well as inconsistent density, slow MAS, image cutoff, and an adjustment of the automatic exposure control. The unit is stated to be so unreliable that the user is not able to schedule patients or fully utilize the equipment or personnel.

**Defibrillator Battery Support System,  
Models 801807-12 and 801807-21,  
Physio Control Corporation**

A using activity reports a switch interface board in the Physio Control LIFEPAK 10 Battery Support System becomes excessively hot around resistors R1, R9, R17, and R13. This burns the circuit board and discolors the membrane panel on the top of the unit which makes it difficult to read the Ready, Charging, and Faulty readouts. The LED light bars are also stated to become hot and melt. Circuit boards found to be affected are part numbers 801894-01 and 804894-10. The units found to be affected are stated to be between two to five years old. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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## **Medical Equipment Management**

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### **Shared Procurement Equipment Items Currently Available**

AFMLL 16-96, Attachment 1, page 1, contains a list of all current Shared Procurement contracts and optional contracts available through the Defense Personnel Support Center (DPSC). If you plan to order any of these items for your facility, use the specific ordering instructions and overall program guidance contained in AFMLL 04-96, pages CE-4 and CE-5. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

### **“Piggyback” Contracts Currently Available**

AFMLL 16-96, Attachment 1, pages 4 and 5, contains a list of all current “piggyback” contracts currently available through DPSC. These contracts will allow facilities to “piggyback” requirements onto existing orders placed for specific quantities. Many of these contracts are designed to buy large quantities at reduced prices, and are written with the option of buying additional quantities at the same price. The list includes available quantities and “Order By” dates. To order, send your MILSTRIP requisitions to DPSC, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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