

# ENGINEERING, FACILITIES, EQUIPMENT AND PROCUREMENT

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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)

### 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 a SF 380 in accordance with AFMAN 23-110, Volume 5, Chapter 19. It is important that we receive documentation of equipment problems since severity and the number of separate complaints received frequently judge's impact of a materiel defect.

### *Electrocochleographs, MDC 17495, Traveler Express, Bio-logic Systems Corp.*

The Traveler Express Auditory Brainstem Response unit measures brainstem response through the use of electrodes placed on each ear and the forehead of a patient. An activity reports that during a routine test a patient felt a slight shock on the forehead from the grounding electrode. At the same time, the audiologist had turned the unit off and on in an effort to reset the unit to correct a problem. A visual check of the unit and a test procedure showed no problems. Manufacturer technical support explained that a power surge was the cause of the shock. When the unit was turned off and on with the patient connected, a non-harmful shock was felt due to a power surge and escaping residual electricity. The unit is equipped with an isolation block to prevent harmful shocks from being passed to the patient. The department was instructed not to turn the unit off and on while a patient was connected. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

### Safety Alert -Information Exchange

#### *Physiologic Monitoring Systems, MDC 12636, Solar 7000/8000 Monitors, Marquette Medical Systems, Inc.*

In a letter dated 17 Nov 97, the manufacturer states that they have become aware of a deviation identified with Solar 7000/8000 Monitors using Versions 2A 2B, 3A, 3b, and 4A software in conjunction with a Solar ECG 12SL Module.

*Problem:* The deviation affects the 12SL function when printing to laser printer or sending to the MUSES/ST Guard System. When printed or sent to MUSE or ST Guard System, the V1 lead is replaced by a true Lead III measurement. This

condition will affect the analysis performed on 12 lead ECG data and should not be relied upon. Patient treatment should not be initiated based on the 12SL analysis printout from this ECG module.

*Solution:* The manufacturer recommends **immediate discontinuance** of the 12SL function. Be aware that 12 lead ECG data stored and printed from the MUSE may be erroneous. If the 12SL function is necessary, contact your ECG Department to secure an ECG cart. The Solar ECG Module can continue to be used for normal ECG monitoring measurements. Tram modules are not affected and can continue to be used. Contact Marquette Medical Systems Customer Satisfaction Group at (800) 558-5120 extension 3478 or (414) 362-3478 to request a new revision of software and instructions for installation. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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## **Medical Equipment Management**

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

AFMLL 04-97, Attachment 1, pages 1 and 2, contains a list of all current Shared Procurement contracts and optional contracts available through the Defense Support Center Philadelphia (DSCP). 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 DSCP, and reference the contract number (from the listing) in the note section. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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