

ENGINEERING, FACILITIES, EQUIPMENT AND PROCUREMENT

Quality Assurance

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 an 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 judges impact of a materiel defect.

Note: Similar incidents were reported in AFMLLs 20-88, 4-90, and 14-90. A FDA Medical Device Safety Alert for this device was published in AFMLL 16-90.

Oximeters, Pulse, MDC 17148, Model 3700, Ohmeda Inc. Medical Systems Division

Complaint: An activity reports a patient received a minor burn to the index finger when a sensor for Physio-Control LIFESTAT 1600 was used with the Ohmeda 3700. The patient required no treatment for the burn. It was possible for the staff to mix leads because the plugs for the probes used on each unit are physically compatible. However, the pin-outs for these oximeters have different voltages that caused the sensor to carry significantly more current than usual, thus causing the probe to get very hot. A facility where this incident previously occurred tested a set of intentionally interchanged leads and determined that in two to three seconds, the probe reached a temperature of 200 degrees Fahrenheit. When the Physio-Control sensor is connected to the Ohmeda oximeter, no readings are displayed, and the oximeter may provide error messages. The sensor, however, continues to heat while attached to the oximeter and must be removed from the patient to prevent burns. Please notify all appropriate personnel to use only Physio-Control sensors with Physio-Control pulse oximeters, and that patient burns are possible if sensors are used with other manufacturers' oximeters. If you have either of these oximeters, contact the manufacturer and obtain warning labels for both the sensors and the oximeters, and affix them to the equipment. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

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 DSCP. 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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