

CLINICAL ENGINEERING

Biomedical Equipment Maintenance



Manufacturers' "P" Number Consolidated Listing, November 1995

The November 1995 edition of the Manufacturers' "P" Number Consolidated Listing was distributed to all biomedical equipment repair sections in mid-December. The new "P" number book contains all "P" numbers currently assigned, and includes all updates since the June 1993 listing. If your biomedical equipment repair section has not yet received the new "P" number book, please contact us.

If you need a "P" number for a medical manufacturer who is not listed in the current Manufacturers' "P" Number Consolidated Listing, contact us with the manufacturer's name, address, phone number(s), and equipment manufactured. After the suggested manufacturer is researched and approved, a "P" number will be assigned. All newly assigned "P" numbers are periodically published in the AFMLL. (AFMLO/FOM, TSgt Ben Allen, DSN 343-4039)

Tool Kit, Biomedical Equipment Technician (BMET), NSN 5180-00-117-3414

A suggestion to replace the current tool case with a heavy duty polyethylene transit style tool case was recently reviewed and approved. Contents of the tool kit will not be affected. BMETs will receive the new tool kits as an initial issue item. However, replacement of the current tool case is only authorized when one becomes unserviceable. If that occurs, replace it with NSN 5140-01-423-3639 to ensure your tool box is kept in line with current issue. The recommended replacement is a tool case equal to part number 117-331, sold by Contact East, (508) 682-2000.

Implementation of this suggestion is optional and the specific benefits should be evaluated locally by each base. If your facility adopts this suggestion, please complete an AF Form 1000-1, Suggestion Evaluation and Transmittal, citing the suggestion number (SHE-950028), and forward it to the originating base suggestion program office (82TRS/MOS, Sheppard AFB, TX 76311-2624). Information and guidance on the Air Force Suggestion Program can be found in AFI 38-401.

We commend 2Lt Thomas A. Stewart for this potential cost-saving idea. Recommendations or suggestions for additional tools may be forwarded to this office. (AFMLO/FOM, TSgt Ben Allen, DSN 343-4039)

Management Assistance Visit (MAV)

Each Medical Equipment Repair Center (MERC) is required by AFI 41-201, to perform annual MAVs to each active duty facility within their region. This part of the intermediate-level maintenance support program should complement the technical support provided by MERCs to facilities within each region. An effective MAV will provide a unique benefit, tailored to each supported facility. However, white glove inspections that follow pre-defined checklists and check generic indicators only point out deficiencies and offer little value. An effective MAV is not an inspection, but rather a program to benefit all facilities by assisting in the sharing of expertise, information, and effective practices between all Air Force BMETs.

With the MAV focus shifting away from the inspection mindset and more toward complementing the current technical services, some changes are forthcoming. Each MAV will include gathering contract and training related information. This information will be maintained in an AFMLO database designed to monitor our capabilities as a career field. Additionally, the MERC representative and the supported facility representative, together, will determine which equipment will be supported by the MERC technical team on their next visit.

The MAV provides an opportunity for imaginative BMETs to share good ideas and effective practices with other facilities. The MERC representative should be watchful for any ideas which could benefit other facilities. Using the MAV as a format to exchange ideas and gather information will add value to the intermediate-level maintenance service provided by the MERCs. (AFMLO/FOM, Capt William Wood, 343-4024)

Quality Assurance

Safety Alert -- Ventilators, Intensive Care, MDC 17429, Nellcor Puritan-Bennett 7200 Series Ventilators

Reference ECRI *Health Devices Alerts* number 1995-A44, 3 November 1995, Accession No. A2903. An increased number of 990C and 990E error codes may occur at the end of the Power-On-Self-Test Cycle in these units when they are set in the Pressure Control Ventilation mode or set to a High Peak Flow when powered on. If either error code occurs, the above unit then enters the Safety Valve Open state and audibly and visually alarms. The manufacturer initiated a recall by letter dated 2 October 1995, informing customers that a software upgrade to correct the problem will be installed on their units at no charge. Users should verify receipt of 2 October 1995 letter from Nellcor Puritan-Bennett. A Nellcor Puritan-Bennett Customer Service Engineer will contact your facility to arrange for installation of the software upgrade for all affected units. The manufacturer states the ventilators may be used before the software is upgraded, but recommends that users exit the Pressure Control Ventilation mode and set the Peak Flow to 10 L/min before powering off the unit. For further information, U.S. customers should contact the Nellcor Puritan-Bennett Technical Support Department at 1-800-255-6774, extension #4, or customer service at 1-800-255-6773. Overseas customers should contact their local Nellcor Puritan-Bennett representative. (AFMLO/FOM, Capt William Wood, DSN 343-4024)

Safety Alert -- Ventilators, Intensive Care, MDC 17429, Siemens Medical Systems, Servo 300 Ventilators

Reference ECRI *Health Devices Alerts* number 1995-A50, 15 December 1995, Accession No. A2928. Action item references previous Accession Nos. A2820 dated 4 August 1995, and A2757 dated 28 April 1995. Some of these units were noted to exhibit functional irregularities when exposed to high levels of electromagnetic interference (EMI). Siemens alerted customers to the problem and planned a software corrective action as a remedy. Recently, the firm began performing software upgrades on all affected units. Siemens is also installing revised computer interface circuit boards during the upgrade, in response to other EMI complaints and to facilitate future graphics capabilities. Siemens initiated this field correction in the U.S. by an Urgent Device Safety Alert Update dated 17 October 1995. A Siemens representative will contact your facility to schedule the software upgrade and computer interface circuit board revision. Users should verify receipt of the 17 October 1995 Urgent Device Safety Alert Update from Siemens and ensure notification by a Siemens representative to schedule the upgrade. For further information, CONUS customers should contact Siemens Technical Support or Customer Service at 1-800-561-7385. Overseas customers should contact their local Siemens representative. (AFMLO/FOM, Capt William Wood, DSN 343-4024)

Medical Materiel Complaint Reporting for Biomedical Equipment

The Medical Materiel Complaint program exists to provide a mechanism for the user of medical materiel (both supplies and equipment) to report a harmful, defective, or unsatisfactory product to the contracting agency through

which the product was procured. In many cases, the "user" of biomedical equipment may be the biomedical equipment technician (BMET) who discovers a problem while performing a safety inspection, calibrating a piece of biomedical equipment, or connecting two pieces of equipment together. In some cases, the BMET may notice a trend of failures with a particular item which each individual user may only see one time. Therefore, it is important for you to be familiar with **AFMAN 23-110, Vol 5, Chapter 19.**

Documenting Medical Materiel Complaints on SF 380, "Reporting and Processing Medical Materiel Complaint/Quality Improvement Report" is required by the Safe Medical Devices Act. (See **AFMAN 23-110, Vol 5, Chapter 19, Attachment 1** for preparation and submission instructions). It is very important to complete the SF 380 thoroughly. While all information is significant, it is especially important to include the stock number, manufacturer's name, model number, serial numbers, date manufactured, quantity on hand, and quantity suspended. Please be very specific when you describe the complaint. Describe the problem in detail, and if you have already contacted the manufacturer concerning the problem, indicate to whom you spoke and include their telephone number.

Why is it important for you to document complaints so thoroughly? Your complaint is sent to the Defense Personnel Support Center's (DPSC) Quality Assurance Division. An individual in that office reviews your complaint and takes appropriate action based on the complaint. That individual may:

- (1) work with the Defense Medical Standardization Board (DMSB) to initiate a total recall of the item;
- (2) review the item contract and enforce appropriate provisions of the contract;
- (3) use the information to improve specifications for a future purchase of a similar item; or
- (4) notify the manufacturer and the Food and Drug Administration (FDA) of the problem.

Therefore, DPSC must be able to understand the problem you describe. The individual reviewing the complaint may have never encountered the particular equipment. Also, DPSC may not have a copy of the technical literature for the product, and may not be familiar with the particular model or brand of item you describe.

Many of the complaints generated by Air Force personnel document actual design problems with biomedical equipment, and result in modification recalls by manufacturers. These recalls are later printed in the FDA Enforcement Report.

Additionally, medical materiel complaints dealing with biomedical equipment are published in the AFMLL to ensure BMETs are aware of potential problems, identify trends, and possibly prevent the recurrence of problems.

Please take time to *carefully* prepare and submit Medical Materiel Complaints. The Medical Materiel Complaint program is a valuable quality assurance (QA) tool. (AFMLO/FOM, Capt William Wood, DSN 343-4024)

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, Capt William Wood, DSN 343-4024)

Medical Equipment Management

Use of Patient Identification Camera for Mammography Cassettes

A suggestion was recently reviewed which proposed using a Kodak X-Omatic Model 2 Patient Identification Camera for MIN-R 2 cassettes in lieu of purchasing a new dedicated MIN-R patient identification camera. The suggestion was

recommended for approval and optional implementation.

Using the Model 2 Camera for MIN-R 2 cassettes requires adjusting the font size of the printer used to make the patient identification film flash cards. The suggestor was able to get all patient information (facility name, patient name, patient I.D. number, date of exam, and technologists initials) on the film using a 12 point font and by adjusting the position of the card within the window.

Facilities who already own a Kodak Model 4 patient identification camera have automatic capability for both general radiography and mammography cassettes. Each facility should evaluate this suggestion for applicability to your particular needs based on current workload and department configuration. At minimum, this suggested modification can provide a temporary solution while in the process of procuring a dedicated or dual purpose camera.

If your facility adopts this suggestion, please complete an AF Form 1000-1, Suggestion Evaluation and Transmittal, citing the suggestion number (REE950078), and forward it to the originating base suggestion program office 64FTW/MO, Reese AFB, TX 79489. Information and guidance on the Air Force Suggestion Program can be found in AFI 38-401.

We commend MSgt Robert C. Bates and SSgt Michael C. Nilsen for this suggestion. (AFMLO/FOM, Mr. David Baker, DSN 343-4030)

Investment Equipment Threshold Change Update

Reference AFMLL 1-96, page CE-6, **Investment Equipment Threshold Change for Fiscal Year 96.**

If you encountered difficulties making the record changes described in the referenced article, the following instructions will allow you to make the required expendability code changes.

Identify all equipment master records which have an expendability code of "3" and a unit price less than \$100,000.

Review the records to ensure there are no due-ins against the master record. *IF THERE ARE DUE-INS AGAINST THE MASTER RECORD, DO NOT CHANGE THE EXPENDABILITY CODE UNTIL AFTER THE DUE-INS ARE RECEIVED AND ISSUED.*

Verify the record is not a component record of an end item of investment equipment whose unit price is greater than \$100,000. Equipment records for components of an end item should retain the same expendability code as the end item. For example, an x-ray system may cost \$400,000 and would have an expendability code of 3 for investment equipment. Any component of that x-ray system; i.e., the table, generator, bucky, tube stand, tomographic attachment, etc., would be maintained as expendability code 3 even though the unit cost of each component might be less than \$100,000.

If there are no due-ins and the record is not a component of investment equipment, process a "PCZ" transaction to lower the price of the item below \$50,000. Next, process an "EXZ" to change the expendability code from 3 to 2. Finally, process another "PCZ" to change the item back to its original price.

The next Medical Logistics System (MEDLOG) release by the Standard Systems Group (SSG) at Maxwell AFB AL will include the changes necessary to implement the investment threshold change to \$100,000. According to the SSG, this release is projected for Spring 1996.

Please contact us if you have questions concerning the threshold change or the medical investment

equipment program. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

Shared Procurement Equipment Items Currently Available

AFMLL 17-95, Attachment 1, pages 16 and 17, contains a list of all current Shared Procurement contracts and optional contracts available through 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 5-95, pages CE-5 and CE-6. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

"Piggyback" Contracts Currently Available

AFMLL 02/03-96, Attachment 1, pages 1 and 2, contains a list of all "piggyback" contracts currently available through Defense Personnel Support Center (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 attached list includes available quantities and "Order By" dates. To order, send your requisitions to DPSC (using the MILSTRIP process), Attn: Mr. J. Gallagher/DPSC-MQA, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

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