THE BIOMEDICAL EQUIPMENT REFERENCE MANUAL

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Biomedical Equipment Inventory < attached >

References for this guide:

Administrative Policy and Procedures… (available on CHONET)

AD 2.2 Biomedical Equipment Repair
AD 3.4 Cellular Phone Ban in Critical Care Areas
AD 5.1 Patient Owned Electrical Equipment
AD 5.6 Equipment Involved in Patient Injury
CHILDREN'S HOSPITAL & RESEARCH CENTER AT OAKLAND

BIOMEDICAL ENGINEERING DEPARTMENT

Who we are:

Biomedical Engineering is a team of engineering professionals working in a clinical environment to resolve technology issues related to patient care.

Our aim is to reduce risks associated with medical technology, improve patient outcomes, provide support to the technology based clinical equipment used in the delivery of healthcare, and to enhance patient care in the most efficient manner possible. We accomplish this through the cost-effective acquisition, maintenance, and repair of all clinical technology and the proper management of the clinical technical resources.

It is the goal of the Biomedical Engineering Department to be THE technical liaison, reference, and resource for all clinical equipment that may be used in the facilities.

The Biomedical Engineering department oversees medical equipment repairs, maintenance and service, independent of ownership or service methodology. Powered (electrical, pneumatic, etc.) equipment that is involved in direct patient care is included in the medical equipment management program.

Biomed must approve devices before they are used in the clinical environment.

Departments must notify Biomed when medical devices enter or leave the hospital, regardless of ownership. This includes DEMO’s and LOANER’s.

Exception: Rental Equipment provided by an Approved* Vendor.

Examples of Services Offered:

✓ Regular Preventive Maintenance/Safety/Performance Testing & Calibrations.
✓ Biomedical equipment repairs
✓ Pre-purchase evaluations and consulting.
✓ Equipment Recommendations.
✓ Consultation on Purchasing (including service options such as manuals, other service media, training classes, and specialized equipment).
✓ Incoming Biomedical equipment inspections.
✓ Service Biomedical equipment (specialized test equipment, parts inventory).
✓ Medical equipment maintenance service contract support.
✓ User error tracking and reporting
✓ User (Inservice) training on biomedical equipment.
✓ Recalls and Alerts (manufacturer, FDA, ECRI, Sentinel Alerts, etc.)
✓ History File on every Biomedical device used, regardless of ownership.
✓ Obsolescence notifications and replacement recommendations
✓ Biomedical equipment risk assessment program
✓ Equipment incident consultations
EMERGENCY BIOMEDICAL EQUIPMENT

REPAIR REQUEST PROCEDURES:

For biomedical equipment **emergencies**, always first inform your supervisor.

Biomedical Engineering should be called ASAP (x3610). During normal hours of operation, a Biomedical Engineer should respond immediately.

✓ If necessary, see “After Hours Emergencies” procedures outlined below.

AFTER-HOURS BIOMEDICAL EQUIPMENT “EMERGENCIES”:

1. Inform your immediate Supervisor.
   ✓ In most cases they should be able to resolve the issue.

2. Inform the Nursing Supervisor of the situation.

3. If necessary, call (x3291) or page (7566) the Watch Engineer.

If the Watch Engineer is contacted, he should respond in person to determine if the problem can be handled without calling in Biomed on overtime (i.e. with assistance from staff or the Nursing Supervisor), over the phone with Biomed help, or if an after hours call-in (overtime) to Biomed is needed. The Watch Engineer is responsible to coordinate contact with a Biomedical Engineer.

❖ Once the immediate problems relating to the emergency are resolved, a work request should be entered into the “Eng & BioMed Work Request” program.

❖ It is critical that the Equipment Control # and specific information on the equipment failure is entered by the equipment user who first noticed the problem into the “Eng & BioMed Work Request” program for the Biomedical Engineers to effectively handle the problem. This work request program is found on networked hospital computers, via the Novell Application Launched Window.

If the problem is not an emergency, but needs prompt attention, please enter the Equipment Control # and other pertinent information into the “Eng & BioMed Work Request” program, *before* placing a phone call to the Biomed department.

✓ See “PRIORITY & ROUTINE BIOMEDICAL EQUIPMENT REPAIR REQUEST PROCEDURES”.
PRIORITY & ROUTINE BIOMEDICAL EQUIPMENT

REPAIR REQUEST PROCEDURES:

1) Remove defective biomedical equipment from service.

2) Submit a work request via any networked hospital PC, through the Novell Application Launched Window’s “Eng & BioMed Work Request” icon. If you need help entering a work order, there is a help file in the program, or you may call the Biomed department (x3610) or Engineering department (x3291).

   **Important:** Be sure to include as much information as possible in the fields provided, especially the **Equipment Control #** (silver colored barcode ID). Also include name of the person who originally identified the problem, their extension, and a detailed description of the problem (not just “broken”).

   Note: The Equipment Control # that you enter must exactly match what is on the barcode label, or you will get an error. The most common mistakes are inserting an extra space or dash; or not including a required space or dash.

3) A copy of your work request will print at your local network printer AND in Biomed/Engineering.

4) Please attach your copy of the Work Request to the defective device (or area). You may want to make/keep an additional copy of the Work Order for future reference, tracking, or follow up purposes.

5) **Before** having the defective equipment delivered to Biomed, make sure the device is properly cleaned and disinfected per Hospital policy.

6) Defective Biomedical devices should be delivered to Biomedical Engineering for service, with a Work Order attached. Biomed is located on the ground floor of the main hospital, near the loading dock. The sooner the device is delivered, the sooner it can be repaired and returned to active service!

   Note: If the unit is not portable, make sure to note it’s EXACT location in the “Area” field in the Work Order, with a copy of the Work Order attached.

7) Please make sure to include any accessories used when the problem occurred. If possible, do **NOT** change ANY settings on the device. Your help here greatly improves the Biomedical Engineering department’s ability to diagnose problems and provide efficient service for you, our customer.
POSSIBLE PATIENT HARM INCIDENTS
IN INVOLVING BIOMEDICAL EQUIPMENT

* SMDA = Safe Medical Device Act: If there is a probability that the device in
question has caused or contributed to the death of a patient, immediately notify
your supervisor and follow the SMDA policies and procedures.

If this is not an SMDA reportable incident, but conditions are (or were) present
for possible patient or staff harm involving equipment, then…

1) Immediately notify your Supervisor. Follow all specified procedures as
described in your Policies & Procedures manual.

2) If possible, use other equipment to finish the procedure. Do NOT change any
settings or move any accessories unless absolutely necessary. As long as it
does not pose a risk, leave the unit in question plugged in and turned on.

3) Isolate the equipment, enter a work request (as described earlier), and tag the
device with your copy of the Work Order. You may also want to tag it with
an additional ORANGE DEFECTIVE EQUIPMENT STICKER, found
outside the Biomedical Engineering shop on the incoming equipment shelf.

4) Call Biomed at x3610, or have the operator page Biomed. During off-hours,
call (x3291) or page (7566) the Watch Engineer.

5) Complete an incident report, using as much detail as possible. Remember, it
is CRITICAL that you make certain to include the device’s Biomedical
Equipment Control Number (silver colored tag). If there is no control
number, you must record the exact model and serial number. Without this
specific information, there may be no easy way of tracking the specific device
involved in the incident.

6) The Risk Manager will determine the course of investigation.
NEW, DEMO, LOANER, RENTAL, PATIENT, and/or other NON-HOSPITAL OWNED EQUIPMENT INSPECTION REQUIREMENTS:

All Biomedical Equipment, or other devices used in the patient care area, regardless of ownership, must be held to the same safety and performance standards. Clinical departments are required to notify Biomed when a patient care device enters or leaves the facility. Even non-medical equipment that is intended for use in the patient care area must meet stringent “hospital grade” standards.

1) Biomedical Engineering should check out all biomedical equipment coming into the facility prior to use. This includes new equipment purchases, demo, rental, loaner, patient or staff owned equipment.

2) Biomed will perform an incoming inspection procedure that will include a safety test. All of these devices must pass the Biomed-Engineering safety inspection before being used in the facility, which (if applicable) includes an electrical safety inspection per NFPA99, Title 22, etc.

3) After the device passes the incoming safety inspection, Biomed will assign an equipment control number (silver color barcode sticker) indicating the device has been evaluated, and is considered electrically safe.

4) The equipment shall be returned to the original requesting department. The requesting department is responsible for performing an operational check, and ensuring all inservice or operator-training requirements have been met before the device is used.

5) Departments should inform Biomed when such a device leaves the facility in order to accurately maintain the biomedical equipment inventory. Regular reviews of the equipment inventory shall be done in order to help departments maintain their non-hospital owned equipment inventory.

6) “Approved Vendor” Policy. Childrens Hospital Oakland Biomedical Engineering department has an “Approved Vendor” policy, which allows specified vendors to bring in their rental or leased biomedical equipment into the facility for use without having to be seen by Biomed first. An “approved vendor” has agreed to provide biomedical equipment that meets all applicable safety standards, and the hospital ensures the integrity of the program by regular on-site inspections of the preferred vendor’s operations. The approved vendor’s equipment will be readily identifiable by their own ID sticker, and rental equipment documentation should be maintained on-site by the requesting department, so that it may be referenced as needed. **MediqPRN, UHS, KCI and SRC are recognized as “Approved Vendors”** for rental or leased Medical Equipment. Note: Infusion Therapy devices still must be inspected by Biomed prior to use.
At least annually, and upon request, the Biomedical Engineering department can provide a detailed report showing your department’s active biomedical equipment inventory. A copy of this inventory should be kept where staff that uses the equipment may easily refer to it, as needed. Your help in maintaining an accurate inventory is very important. If you know of any biomedical equipment used in the monitoring, diagnoses, or therapy of patients that is not on this list, but resides in your department, please notify Biomed.

**IMPORTANT NOTE**: You may find out **ANY biomedical device’s current status** by simply accessing the “Eng & BioMed Work Request” Program and entering the device’s Equipment Control #. You can view a synopsis of recent history of the device (repairs and PM’s), any open work order, and when it is due for PM (or if it is past due for PM).

The Biomedical Equipment Inventory List should have the following information:

- **Control #** = Biomedical Equipment Control Number (silver colored barcode tag).
- **Cost Ctr** = a 3-letter code representing the Cost Center that is financially responsible for the device. (Note: Several “departments” could share the same cost center.)
- **Dept** = a 3-letter code typically representing the “user” department.
- **KnownAs** = Name by which the device may be more commonly “known as”.
- **Class(-ification)** = A generic device name for a group of similar items. Devices with the same classification may have the same Risk score, PM Procedures, Testing Intervals, etc.
- **Manufacturer** = The Original Manufacturer of device. May not be same as the company that currently provides the same device or service.
- **Model** = the Model Number or Model Name of the device
- **Serial** = the Serial Number of device
- **Last Rep.** = Last Repair, the most recent repair date (which also includes an Inspection).
- **Last Insp.** = Last Inspection, the date of the most recently completed Inspection
- **Next Insp.** = Next Inspection, when the device will come due again for Inspection.
- **Area** = the Room Number (see Engineering room numbering system) describing it’s location. (Note: “Area’s” outside the Main Hospital typically have a 3-letter prefix.)
- **Asset #** = CHO’s “Asset” or property ID number (green). Used only by accounting.