BIOMEDICAL EQUIPMENT

USERS REFERENCE

MANUAL

UCSF Benioff Children's Hospital Oakland

747 52nd Street, Oakland CA 94609

Biomedical Engineering Department

424 Broadway, Oakland CA 94609

510-428-3610

Table of Contents

Reference for this Guide:

EC.13.2 Medical Equipment Management Plan

Administration and Environment of Care Policy and Procedures

EC.2.1	Biomed Equipment Repair
EC.23.3	Wireless Communications Devices: Restricted
EC.5.2	Electrical Equipment, Patient Owned
EC.5.5	Equipment Involved in Patient Injury
GA.5.7	Event Reporting System

1. The BIOMEDICAL ENGINEERING DEPARTMENT - Who we are, What we do:

Biomedical Engineering (Biomed) is a team of technical and engineering professionals working in a clinical environment to resolve clinical equipment technology issues related to patient care.

Our goal 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 all biomedical equipment repairs, maintenance and service, independent of ownership or service methodology. Biomedical Equipment includes any device used for therapy, treatment or diagnosis, as well as devices that are used within the direct patient care area.

The Biomedical Engineering department must approve all medical devices before they are used in the clinical environment. If in doubt, look for a CHO Equipment Control # (metallic-silver barcode tag).

Departments **must** notify Biomed when medical devices enter or leave the hospital through their department, regardless of ownership. This includes demonstration and loaner equipment.

Exception: Rental Equipment provided by an "Approved Rental Vendor" - see the Rental Vendor Policy section in the manual.

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 (In-service) training on biomedical equipment.
- ✓ Recalls and Alerts (manufacturer, FDA, ECRI, Sentinel Alerts, etc.)
- ✓ Service History File on every Biomedical device used, regardless of ownership.
- ✓ Obsolescence notifications and replacement recommendations
- ✓ Biomedical equipment risk assessment program
- ✓ Equipment incident investigations/consultations

Examples of Biomedical Equipment: Defibrillators, patient vital signs monitors, IV Infusion/Syringe/PCA pumps, Angiographic Injectors, Lab equipment (centrifuges/analyzers/microscopes/microtomes), Lasers, X-Ray, Sterilizers/Washers, Surgical tables, Surgical Lights, Infant Incubators, Infant warming beds, ECG, C-Arms, Microscopes, Cryosurgery, Ultrasound, Sphygmomanometers, Pulse Oximeters, Anesthetic Gas Analyzers, Anesthesia machines, Ventilators, Hypo/Hyperthermia units, Electro-surgical units, Muscle/Nerve stimulators, Non- Invasive Blood Pressure (NIBP) machines, patient thermometers, Otoscope/Ophthalmoscopes...

2. "HOW DO I KNOW IF A MEDICAL DEVICE IS SAFE TO USE?"

1. **Operators should always perform a safety inspection of each medical device before use.**

   This entails visually looking over the device for obvious signs of damage (exposed wire, cracked housing, etc.) before plugging the unit in, turning it on, and/or connecting it to the patient.

   If there is a problem, or you are concerned for any reason, remove the device, submit a Work Request (Start Menu), attach work order, and have it delivered to Biomedical Engineering.

2. **When first powered on, most electronic medical devices go through a startup "self-check" procedure.**

   If the device passes the operator safety inspection and self-check startup, you may safely use the device. Always be sure to submit a Work Request if you suspect a problem of any kind.

3. **Operators of medical devices can verify that the device they are about to use is included in the organization's medical equipment database by finding the CHO Equipment Control Number.**
   To verify if a device is in the hospital's medical equipment database, find the Equipment Control# on the silver CHO tag affixed to the device. Equipment Control numbers always have at least 3 letters (A-Z), with the first 3-4 characters designating the owning department, such as ICN1813 below.

Green Asset Tags (used by Materials) use numbers, such as 5-12345MC and are not used by Biomed.

   If a clinical device, or any electric/electronic device used in the direct patient care area does not have a CHO Equipment Control # or is not included in the "Approved Rental Equipment Vendor" list, remove the device from service, submit a Work Request (Start Menu), print & attach work order, and have the unit delivered to Biomedical Engineering for processing.

   Patient owned electrical devices (radio, TV, laptop PC, etc.) must be approved by Biomed before it can be used in the patient care area. Battery operated devices may be approved, so long as they are not plugged into an electrical outlet in the room. See Administrative EC 5.2 Electrical Equipment, Patient Owned. Decorations that must be plugged in and do not pass an electrical safety check are not allowed.

   Cell phones & Walkie-Talkies/Hand-Held Two-Way Radios can interfere with electronic medical equipment. For the Safety of our Patients, please be cognizant when using these types of devices near life-support equipment, and kindly remind others of this important safety concern. See EC.23.3 Wireless Communications Devices: Restricted.

4. **New Inspection "PM Due Labels (stickers)" are attached to all Equipment upon completion of preventative maintenance and indicates the next equipment PM Due date (if applicable) the color may change based on available stock.**

5. **If an inspector from an Authority Having Jurisdiction (AHJ) wishes to see more detailed information than is provided on the Work Request screen, please contact BioMed or Engineering.**

   Biomed (and Engineering) can generate detailed service history reports and the maintenance procedures for specific devices, as needed. AHJ's include JCAHO, DHS, CAP, FDA, etc.

   Department Manager can request an updated Biomedical Equipment Inventory report. Call Biomedical Engineering at x3610 and request Equipment Service History from Biomed Leadership. Basic information concerning time frame (1yr or 2yrs) and PM history, repair history or both will be required.

3. PRIORITY AND ROUTINE BIOMEDICAL EQUIPMENT REPAIRS

REPAIR REQUEST PROCEDURES: BIO, ENG & HOS work requests.

1. Remove defective medical equipment from service.

2. Submit a work request via any networked hospital PC, through the Windows Start Menu Application launched **"BIO, ENG & HOS work request"** icon. If you need help entering a workorder, there is a help file in the program, or you may call the Biomedical engineering department (x3610) or Facilities Engineering department (x3291) and request assistance.

3. You can also submit a workorder by scanning the Control # label QR code with an internet capable mobile device such as a cell phone or a tablet. This mobile app screen is opened to submit a work order for the control # scanned. You can also review the Next PM due date, Last PM & last repair on this page.

Important:

Include as much accurate information as possible in the fields provided. To ensure the proper device is repaired/assessed, the Equipment Control# that you enter must **exactly** match what is on the barcode/QR label, or you will get an error message. The most common mistakes are inserting an extra space or dash for Biomed equipment, or not including a required space or dash for (Facilities) Engineering equipment. For accuracy, include name of the person who originally identified the problem, their extension, and a detailed description of the problem **(not** just the word *"broken"*). If the device does not have a control# then use the room label (area ID) where the device will be located.

4. A copy of the work request will be displayed in Biomed/Engineering and can be printed at your local network printer (if selected).

5. 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.

6. Before having the defective equipment delivered to Biomed, make sure the device is properly **cleaned** and **Disinfected/Decontaminated,** per Hospital policy.

7. Defective Biomedical devices delivered to Biomedical Engineering for service, need to have a Work Order attached. Biomed is located about 10mins away at 4242 Broadway, here in Oakland. The sooner the device makes its way to Biomedical Engineering, the sooner it can be repaired and returned to service.

   Note: If the unit is not portable, and onsite service is requested, please make sure to note it's EXACT location in the "Area" field in the Work Order request. In those instances, Biomed will come to the location specified to service the device.

8. 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 turn-around repair time.

4. EMERGENCY BIOMEDICAL EQUIPMENT REPAIR REQUEST PROCEDURES

For biomedical equipment *emergencies,* always inform your supervisor to appraise them of the event

Biomedical Engineering should be called ASAP (x3610). During Biomedical Engineering's normal hours of operation (M-F, 6:30 am - 3:00 pm), a Biomedical Engineer should be onsite at the Main Hospital. Biomed may also be present during evening hours, M-F up until 11pm.

AFTER-HOURS BIOMEDICAL *EMERGENCY CONTACT PROCEDURE*

Inform your immediate Supervisor to first see if they can resolve the issue. Each department should have their own backup system or backup procedures that can be implemented for equipment emergencies. If they cannot, then follow the steps below.

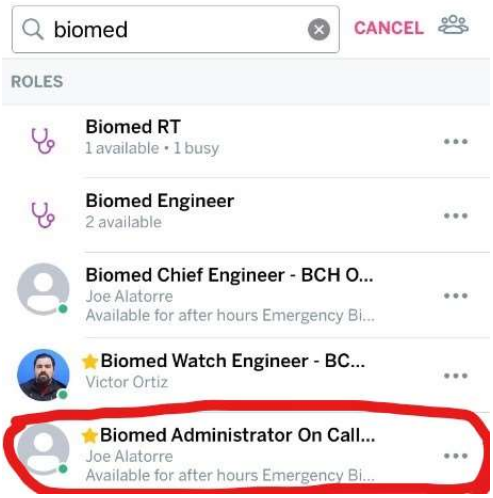
Please refer to the Biomed Policy B105 After Hours Support of Medical Devices found in the departmental section of PowerDMS:

a) First determine if there is a clinically acceptable backup device, system or procedure that may be implemented until the next Biomedical Engineering workday (see Biomed Dept. hours of operation).

b) Evaluate the problem with clinical staff's help/guidance, to see if the problem can be handled.
(i.e. with assistance from staff or the Nursing Supervisor).

c) If still not resolved, you can contact the **Biomedical Administrator On-Call** (Biomed AOC) through the Voalte App. Biomed Leadership is available 24-7 and they will respond to provide support.

Please see example on the right.



d) If the Biomed AOC cannot be reached, the Facilities Watch Engineer can be contacted x(3291) with the equipment information and the Facilities Watch Engineer can coordinate contact with Biomedical Leadership. Biomed Leadership or a Technician will then respond to the call to provide support.

e) If no one in the above procedures is able to reach a POC for Biomed, and service is **critically required** for High-Risk devices, the OEM (original equipment manufacturer) may be called in for emergency service after the requesting department has secured proper Director level authorization.

As soon as possible (after the immediate problems relating to the emergency are resolved), a Work Request should be entered into the system by the user who first noticed the problem.

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 **"BIO, ENG & HOS work request"** CMMS link for the Biomedical Engineers to effectively handle the problem. This Work Request app is found on networked hospital computers, via the Start Menu in Windows.

If the problem is not an emergency, but requires prompt attention, please enter the Equipment Control# and other pertinent information into the **"BIO, ENG & HOS work request"** application, **before** placing a phone call to the Biomed department.

5. POSSIBLE PATIENT HARM INCIDENTS INVOLVING BIOMEDICAL EQUIPMENT

Safe Medical Device Act

(SMDA)

If there is Patient harm or injury involving a medical device; when possible, immediately remove from service and 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, you may leave the unit in question plugged in and turned on. This could help determine what went wrong.

Call Biomed at x3610 and report the incident immediately. Biomed can provide much more help and perform more thorough investigation if informed immediately. If no answer in Biomed (e.g. during off-hours) call the Watch Engineer at ext3291 and follow **After-Hours Biomedical Emergency Contact Procedure**. Make sure you inform the POC that the device is involved in an incident with possible patient harm.

As soon as practical, isolate the equipment and enter a work request using Request code, **"BIOMED EQUIP HAZARD/INCIDENT"**, entering as much detail as possible. Please be sure to attach your copy of the Work Request to the device. You **MUST** include the Equipment Control# in the Work Request. If no Control number is visible, you must enter the make, model and serial # in the notes field of the Work Request.

If there is a probability that the device in question has caused or contributed to the death or serious injury of a patient, immediately notify your supervisor and follow the hospital's policy **EC.5.5 "Equipment Involved in Patient Injury.** If this is not an SMDA reportable incident, but conditions are (or were) present for possible patient or staff harm involving equipment, then enter an incident report using the **"EVENT REPORTING"**, Icon found in the Start Menu of any networked BCHO computer. This is not a substitute for submitting a Biomed work request. Both must be completed.

Details are very important. It is critical that you include the device's Equipment Control Number (silver colored BCHO tag) on the incident "Event report" as well, so that the Work Order and incident Event report number can be matched up. If there is no Equipment Control number available, then you must record the exact make, model and serial number in that document as well. Without this specific information, there may be no easy way of tracking the specific device involved in the incident.

6. INSPECTION REQUIREMENTS FOR NON-HOSPITAL OWNED EQUIPMENT (NEW, DEMONSTRATION, LOANER, RENTAL, PATIENT, OTHER)

All Medical 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 new patient care medical device enters or leaves the facility directly to/from the department. Even non-medical equipment that is intended for use in the direct patient care area must meet stringent "hospital grade" standards. All equipment should be routed through Biomedical Engineering before being used in the department.

1. Biomedical Engineering should inspect all biomedical equipment entering the facility prior to use. Biomed works closely with Materials Management and Shipping and Receiving to ensure no medical equipment bypasses Biomedical Engineering. 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 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, and other applicable regulatory authorities.

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

4. The equipment shall be delivered/returned to the original purchasing/requesting department. The requesting department/user is responsible for ownership of any IFU's or Operating Manuals and performing an operational check (per MFR's Operating Manual) and ensuring all in-services and operator-training requirements have been met before the device is used.

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

7. RENTAL EQUIPMENT and PROCEDURES (CT.101 Equipment Rental)

1. CPD Requests for Rentals should only be submitted after CPD staff has performed rounding for needed equipment including verification of the online RTLS system for unused equipment still located in hospital hallways. All departmental rental requests will be initiated by CPD staff members through a work order placed in MPRO3 utilizing the Biomed request code **"CPD Request for Rental".** This request should include the type of equipment being requested, number of each device requested, requesting department, patient room and urgency.

2. Clinical Technologies/Biomedical Engineering staff will vet each request and ensure all reasonable attempts have been made to utilize the current hospital stock of medical equipment. If rental equipment is needed, then an authorized Clin. Tech/biomed staff member will issue equipment from the internal stock of rental medical equipment. These devices are not subject to the incoming inspection policy as they are maintained internally by the Biomedical Engineering staff. If the equipment is not available internally then a Clin. Tech/Biomed staff member will source the device from a third-party vendor. Those devices will need to go through the incoming inspection process prior to use.

3. All rentals sourced from outside of the hospital will be subject to policies and procedures outlined in Environment of Care Policy **EC.4.1 Demo, Loaner, Rental & Leased Biomedical Equipment.**

4. For urgent afterhours assistance, a CPD representative should follow the afterhours procedures outlined in the BBQ: CPD Medical Device Request Guide.

An ***Approved Rental Equipment Vendor*** has agreed to provide biomedical equipment that meets all applicable safety standards, and the hospital ensures the integrity of the program by regular and unscheduled on-site inspections of the preferred vendor's operations and inspection of testing procedures and records.

All Rental equipment documentation will be maintained on-site, so that it may be referenced as needed by BCHO, or Authorities Having Jurisdiction (JCAHO, OHS, CAP, etc.).

8. BIOMEDICAL EQUIPMENT INVENTORY REPORT - LEGEND

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 immediately or submit a work order request.

IMPORTANT NOTE: You may find out a biomedical device's current status by simply accessing the **"BIO, ENG & HOS work request"** icon and entering the device's Equipment Control#. You can also scan a control# QR code to access this page on a mobile device. On this work order entry page 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 the Next PM (or if it is past due for PM). If you do not see a biomedical device listed in the Work Request program, please contact Biomed at x3610 before using for patient care, or in the patient care vicinity.

The Biomedical Equipment Inventory List should have the following information:

Field Name/ Abbreviation	Explanation
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 or current dept location (if not the same as the cost center).
Known As	Name by which the device may be more commonly "known as."
Class	An abbreviation for classification. A device name for a group of similar model 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 vendor/company that currently provides the same device or service.
Model	The model number or model name of the device.
Serial	The serial number of the device.
Last Rep	Last repair, the most recent repair date which may also include an Inspection.
Last Insp	Last inspection, the date of the most recently completed Inspection (PM or Preventive Maintenance).
NextInsp	Next Inspection, when the device will come due again for Inspection (PM or Preventive Maintenance).
Area	The Room Number (see Engineering room numbering system) describing its location. Note: Area's outside the Main Hospital may have a two or three-letter alpha-numeric prefix.
Asset#	The hospital's asset or property ID number (may be green). Used only by accounting.

9. Emergency Backup Medical Equipment

Each department must identify which medical devices in their inventory require a backup on site. The dept should create a list for the staff to reference what backup devices are on site and the location of the backup(s) stored. For those devices that a backup is not needed on site, a source of acquiring a backup device should be known.

When a backup device may be needed, and there is no available device in your department consider borrowing from another department in your facility. While an exact model may not be available, another model might suffice to provide the needed treatment / diagnostics.

If there is no available backup device in your facility, other options might be available at other UCSF facilities:

BCHO Oakland Campus (Main Hospital)	(510) 428-3000	747 52nd St. Oakland 94609
BCHO Walnut Creek Campus (Shadelands)	(925) 979-3400	2401 Shadelands Dr. Walnut Creek 94598
UCSF Medical Center Parnassus Campus	(415) 476-1000	505 Parnassus Ave, San Francisco 94143
UCSF Medical Center Mission Bay Campus	(415) 353-2221	1500 Owens St, San Francisco 94258
UCSF Medical Center, Mount Zion Campus	(415) 567-6600	1600 Divisadero St. San Francisco 94115