

Medical Equipment Management Policy

Even the best designed and maintained equipment can be dangerous in the hands of untrained operators, so it is vitally important to provide users with thorough training on the equipment's capabilities and limitations. **This training and education process begins with the decision to purchase equipment. A pre-purchase evaluation that involves nursing, medical, technical, engineering, and administrative personnel helps to ensure a choice of safe, effective, and serviceable equipment. See Pre-purchase evaluation form included next.**

The process of pre-purchase evaluation should be the end result of a sound, thorough technology assessment process by an integrated technology acquisition committee. This process will be the basis of the eventual medical equipment management program that will be evaluated by the JCAHO.

The technology acquisition committee should be responsible for determining what new technologies fit the mission of the hospital, how that technology compares with alternative technologies, what stage of the product life cycle the technology is in, and what effect the technology would have on patient care, payment, demand for services, and physician interest.

Prior to the acquisition of a medical device the integrated committee should pay attention to the following characteristics:

1. Safety
2. Homogeneity and Performance
3. Efficacy
4. Reliability
5. Serviceability
6. Interchangeability
7. Repeatability
8. Cost

Enclosed in this part of the EMMP manual are several guides, forms and charts that could provide additional insight information that the hospital can use in the process of creating its own technology assessment process and the integrated technology acquisition committee.

CIRACET will conduct every new acquisition evaluation if included in the contract. Otherwise, the Hospital should request a quotation or proposal. CIRACET will conduct the assessment if proposal is approved.



New Equipment Pre-Purchase Evaluation Form

This form is to be completed by the manufacturer and returned to the Plant Facilities Director with manuals and attachments as indicated below. This form must be completed by an employee of the manufacturer with sufficient technical information or knowledge to provide answers to the items below. If the manufacturer is uncertain about specific portions, it is suggested he send available materials promptly so further communication, if needed, will not be delayed. Refer questions to the Plant Facilities Director or _____.

1. TO: _____ DATE: _____
ITEM: _____ PROJECT: _____

2. LISTINGS:

Is the unit listed with U.L.? Yes No If yes, please specify UL Listing # _____
Is it listed with other certifying agencies? If so, please give specific standards/listing number. _____

3. LINE-OPERATED EQUIPMENT, INCLUDING BATTERY CHARGERS:

Line voltage limits for stable operation: _____ Frequency Limits: _____
From _____ To _____ VAC From _____ To _____ Hz
Phase: _____ Normal Operating Current: _____ Amp. Surge Current: _____ Amp
How will safety and/or operation be affected if the voltage goes outside the range of 100-130 volts:

4. BATTERY-OPERATED EQUIPMENT:

Type of Batteries or Packs: _____ Number per Unit: _____ Recharge Time: (where applicable) _____
Discharge Time: _____ Can unit be line-operated when batteries are fully discharged? Yes No
(under specified load) Will batteries charge while unit is line operated? Yes No

5. POWER CORD:

Required minimum is an 18 gauge, 3 conductor industrial or hospital grade cord at least 10' long with a Hubbell lock or Hospital grade U ground type plug.
Does your power cord meet these requirements Yes No
If not, specify differences and indicate cost of modification in Section 13.

6. POWER SWITCH AND OVERCURRENT INTERRUPTERS:

Type of power: _____ Single pole _____ Double pole
Switch (i.e., toggle, slide, etc.)
Is power switch clearly labeled? Yes No
Is power switch in line of sight from Operator position? Yes No
Type of over current Protection: _____ Ampacity: _____

Must protect all line (hot conductors) to all parts of unit. Must be easily accessible. If fuse, the size must e marked beside the holder and a clearly marked space provided. If over current protection does not conform to these specifications, see Section 13.

7. MECHANICAL DESIGN FOR PHYSICAL PROTECTION:

Unprotected openings on exposed horizontal surfaces not allowed.
Other openings must be guarded against spillage.
Small appliances used in patient's bed must be immersible in conductive fluid without macroshock hazard.. *If design does not conform to these specifications, see Section 13.*

8. ENVIRONMENTAL AND INTERFACE CHARACTERISTICS:

Temperature For Operation: From _____ To _____ F From _____ To _____ % R Humidity Limits For Storage: From _____ To _____ F From _____ To _____ %R
Maximum allowable storage time: _____
Sensitive to RF interference? Yes No
Known to generate RF interference? Yes No
Sensitive to power line transient? Yes No
Known to generate power line transient? Yes No



Known to require other utilities Yes No
 Are exposed to metal surfaces underground? Yes No
 If answer is "yes" to any of these questions, give details on separate page.
 Specific sterilizing procedures to be used? _____ Type of labeling for O2 & Flammable location: _____
 Quality of radiation emission: _____ Type of shielding: _____

9. PROVIDE THE FOLLOWING MANUALS AND TECHNICAL INFORMATION:

- | | |
|--------------------------------------|----------------------------|
| Operator's Manual | Block Diagrams |
| Wiring Diagrams | Preventive Maint. Prog. |
| Schematic Circuit Diag. | Operational tests |
| Parts List | Performance Specifications |
| Statement of known potential hazards | Service Manual |

10. WARRANTY/GUARANTY

Warranty will start after delivery and initial installation (if applicable).
 If modifications are made to conform to our specifications, will warranty be violated? Yes No

11. SERVICE AND TRAINING INFORMATION

Estimated response time for service calls from time of notice: _____ hours
 Is local service available? Yes No
 Give location and working hours of nearest service facility _____
 A replacement unit is available in _____ hours.
 Are training programs for service personnel available? Yes No
 Are training programs for users available? Yes No
 Give location, schedule, cost and instructor's qualifications for both types of training programs on a separate sheet.

12. LEAKAGE/RISK CURRENTS

ACCEPTABLE UNITS

Measurement Site	Device for patients with Intra Cardiac Leads	General Patient Devices	Non- Patient Devices	Indicate Worst leakage current
Patient's leads or Attachments to grnd	10 microamperes	50 microamperes	Not applicable	
With 120V Applied to patient Leads	20 microamperes	Not applicable	Not applicable	
Worst case to Ground	100 microamperes	500 microamperes	500 microamperes	

13. MODIFICATIONS/COMMENTS:

Please list description and cost quotation for any modifications, accessories, or other items necessary to fulfill the requirements states. *Cost of upgrading unit will weigh heavily on our decision to purchase.*

1. _____
2. _____
3. _____
4. _____

14. This form is to be completed and signed by the manufacturer's product manager or his equivalent.

Name _____ Title _____
 Address _____ Date _____
 Signature _____ Telephone _____

1. Acceptance Specifications for Patient-care and Non Patient-care Equipment

Acceptance by the Hospital of this equipment is contingent upon successful completion of an incoming inspection which will be conducted by the Engineering Department within fifteen (15) days from receipt by the Hospital of this equipment and will include, but is not limited to, equipment specification/performance and mechanical and electrical safety tests. (Also including possible repair history and/or device recalls) A three-conductor (grounded) power cord, no less than 18 AWG, with an approved hospital grade plug cap, is required. For portable or mobile equipment, the power cord is to be permanently attached. Grounding resistance is to be less than 0.5 ohms to any exposed conductive surface.

Patient Care

Leakage current is to be no more than 300 microamperes between any exposed conductive surface and ground, and no more than 50 microamperes (10 microamperes if the equipment is specified as being patient-isolated) between any patient lead and ground or any other patient lead, with the equipment on or off, grounded or ungrounded, and correct or reversed polarity.

Non Patient-Care

Leakage current is to be no more than 500 microamperes between any exposed conductive surface and ground with the equipment on or off, grounded or ungrounded, and correct or reversed wiring polarity.

Two copies of operator and service instruction manual are to be provided to the Hospital by vendor, the latter to include electrical and mechanical schematics, and parts and current price lists. Inclusion of technical service training should be considered and included as part of the original acquisition contract.

2. Acceptance Testing

The Hospital should inform CIRACET of any new biomedical equipment purchased. New equipment needs to be inspected, maintenance requirements determined and included in the inventory before putting it into service. An electrical safety and performance test will be performed. The results will be documented in a Preventive Maintenance Form; if the product passes the PM it will be accepted for use.



3. Equipment Retirement

The hospital must inform CIRACET whenever a biomedical device is retired, transferred, or sold. Equipment will be inactivated to avoid wasting time searching for unavailable equipment. The biomedical engineering staff will complete all corresponding documents as well as enter the corresponding details in the computerized management information system, CAMS.

At times, whenever deemed necessary the biomedical technician staff or CIRACET's biomedical engineers will present all sustaining literature necessary to retire certain devices that are considered to be obsolete whenever they malfunction when there are no replacement parts available, or repair is too expensive when compare to original cost. The final decision to retire equipment should come from the Plant Facilities and Engineering Director.