PHYSICIANS BIOMEDICAL
EQUIPMENT SERVICE
SALES • INSPECTIONS • SERVICE

BIOMEDICAL EQUIPMENT PROGRAM MANUAL

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Report Summary

Report Prepared For:
SAMPLE ASC
123 45TH STREET ANYWHERE FL, 33333

Report Date:
08/04/2017

Every attempt was made at the time of inspection to ensure that each device is operating safely, and according to manufacturer recommendations. However, please note- "the operator" is responsible for ensuring the safety of this device each and every time before that it is used on a patient. PBES nor its employees are responsible for patient injury due to a malfunction of this equipment, nor due to an "operator error", nor an "error or omission" of PBES.

PBES

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EQUIPMENT MANAGEMENT PROGRAM

PHYSICIANS BIOMEDICAL EQUIPMENT SERVICE

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Physician's Biomedical Equipment Services
Biomedical Equipment Management Program:

PBES-Policy # 3.0

Reviewed: 01/01/2017
Revised: 01/01/2017

OVERVIEW OF EQUIPMENT MANAGEMENT PROGRAM:

There is an Equipment Management Program designed to assess and control the clinical and physical risks of fixed and portable equipment used for the diagnosis, treatment, monitoring, and care of patients as well as other fixed and portable electrically powered equipment.

PBES-PL.3.1.

Written criteria, which include characteristics of equipment function, clinical application, maintenance requirements, and equipment incident history, are used to identify equipment to be included in the program.

PBES-P.L.3.2.

A current, accurate, unique inventory is kept of all equipment included in the Equipment Management Program. This inventory will be maintained, in such a way, so that all changes to the inventory within twelve months of the date of change of status will be documented.

PBES-P.L.3.3.

The Equipment Management Program will be maintained, in such a manner so, that the operational integrity of all medical equipment, included in the program, will be assured. Manufacturers Original Specifications, as well as, Federal Laws, Standards, and Recommendations will be adhered to in the operational performance testing of all equipment in the program. Federal, State and Local Laws, Standards, or Recommendations will be adhered to relating to the Electrical Safety Performance Testing of the equipment in the program. (e.g.-Safe Medical Device Act of 1992, NFPA Code99-2015, AAMI-ESM2015, TJC, HRS, ANSI, AAAHC, AAAAPSF, NIST.

PBES-P.L.3.4.

The Equipment Management Program is used to identify and document equipment problems, and failures that *have or may have* an effect on the *quality of care* of the patient, and/or the safety of the patient. This data will be trended.

Successful Completion of the inspection process will result in a Current Electrical Safety, and Calibration Inspection Label being affixed to the equipment. If, however, the equipment fails inspection a Defective Label will be affixed to the equipment, and the designated Risk Manager of the facility will be notified. Either the equipment will be repaired and re-inspected, or replaced.

POLICIES & PROCEDURES

PHYSICIANS BIOMEDICAL EQUIPMENT SERVICE

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Physician's Biomedical Equipment Services
Electrical Safety Inspection Policy

PBES-Policy # 10.0

Reviewed: 01/01/2017
Revised: 01/01/2017

The following tests will be performed on *all* equipment in the Performance of an Electrical Safety Inspection. These tests comply with The Joint Commission (TJC), Agency for Health Care Administration (AHCA), the National Fire Protection Agency (NFPA), OSHA, HRS and the Association for the Advancement of Medical Instrumentation (AAMI).

PBES-PL.10.1.
The Line voltage the equipment is plugged into, at the time of inspection, will be tested in the following manner.

- Line 1 to Line 2 will be measured.
- Line 1 to Ground will be measured.
- Line 2 to Ground will be measured.

The proper polarity of the outlet will be tested at the site where the equipment is used.
Testing in compliance with the NFPA Code 99-2015 Standards

Electrical Grounding Rules:

10.2.2.1 Grounding of Appliances.

10.2.2.1.1 All cord-connected electrically powered appliances that are not double insulated and are used in the patient care vicinity shall be provided with a three-wire power cord and a three-pin grounding-type plug.

10.2.2.1.2 Double-insulated appliances shall be permitted to have two conductor cords and shall be rated as Class II devices.

Electrical Leakage Current:

10.2.5 **Leakage Current—Fixed Equipment.** The leakage current flowing through the ground conductor of the power supply connection to ground of permanently wired appliances installed in general or critical care areas shall not exceed **10.0 mA** (ac or dc) with all grounds lifted.

10.2.6 **Touch Current—Portable Equipment.** The touch current for cord connected equipment shall not exceed **500 µA** with normal polarity and the ground wire disconnected (if a ground wire is provided).

10.3 Testing Requirements — Fixed and Portable.

10.3.1 Physical Integrity. The physical integrity of the power cord assembly composed of the power cord, attachment plug, and cord-strain relief shall be confirmed by visual inspection.

10.3.2 Resistance.

10.3.2.1 For appliances that are used in the patient care vicinity, the resistance between the appliance chassis, or any exposed conductive surface of the appliance, and the ground pin of the attachment plug shall be less than **0.500 ohm** under the following conditions:

(1) The cord shall be flexed at its connection to the attachment plug or connector.

(2) The cord shall be flexed at its connection to the strain relief on the chassis.

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10.3.3 Leakage Current Tests.

10.3.3.1 General.

10.3.3.1.1 The requirements in 10.3.3.2 through 10.3.3.4 shall apply to all tests.

10.3.3.1.2 Tests shall be performed with the power switch ON and OFF. The electrical leakage current in equipment (Power in the ON or OFF position) for cord connected equipment shall not exceed **500 µA** with normal polarity and the ground wire disconnected.

10.3.6 Lead or Lead wire Leakage Current Tests and Limits — Portable Equipment, such as EKG Machines and Patient Monitors.

10.3.6.1 The leakage current between all patient leads connected together and ground shall be measured with the power plug connected normally and the device on.
10.3.6.3 The leakage current shall not exceed **100 µA** for ground wire closed and **500 µA** ac for ground wire open.

Medical Grade AC Power Taps:

10.3.7 Multiple Outlet Connection. Two or more power receptacles supplied by a flexible cord shall be permitted to be used to supply power to plug-connected components of a movable equipment assembly that is rack-, table-, pedestal-, or cart mounted, provided that all of the following conditions are met:

(1) The receptacles are permanently attached to the equipment assembly.

(2) The sum of the ampacity of all appliances connected to the outlets does not exceed 75 percent of the ampacity of the flexible cord supplying the outlets.

(3) The ampacity of the flexible cord is in accordance with *NFPA 70*, *National Electrical Code*.

(4) The electrical and mechanical integrity of the assembly is regularly verified and documented.

(5) The ground wire and leakage current requirements listed above are adhered to.

10.4.0 Facility GFCI or GFI Outlet requirements and AC Outlet testing: (Optional testing available through a separate PBES contract).

Where GFCI protection is used in an operating room, one of the following shall apply:

(1) Each receptacle shall be an individual GFCI device.

(2) Each receptacle shall be individually protected by a single GFCI device. ELECTRICAL SYSTEMS 99-2015.

The testing interval will be determined by regulatory agency which is testing the facility, but in no case will be more than one year.

The testing will be in accordance to NFPA 99 policy which states, Ground-Fault Circuit Interrupter (GFCI). Class A ground-fault circuit interrupters trip when the current to ground is 6 mA or higher and do not trip when the current to ground is less than 4 mA.

Physician's Biomedical Equipment Services
Non-Patient Care Equipment Inspection Policy
PBES-Policy # 4.0

Reviewed: 01/01/2017
Revised: 01/01/2017

The following tests will be performed on *all non-patient care* equipment. These tests comply with The Joint Commission (TJC), Agency for Health Care Administration (AHCA), the National Fire Protection Agency (NFPA), OSHA, HRS, and the Association for the Advancement of Medical Instrumentation (AAMI).

Please note: the current Standards puts the impetus on the Staff to insure the integrity of appliances and equipment used in the healthcare facility but not specifically on a patient. All patient care equipment will be tested per **PBES Policy 10.0.**

PBES-4.0.1 - Non-Patient Electrical Appliances and Equipment.

- Visual Inspection of device and its accompanying power cord by proper facility appointed staff member.
- All Non-Patient care equipment used in the patient environment must have a three prong grounded power cable otherwise, the equipment must be double insulated.

PBES-4.0.2 - Testing Interval.

- Initial incoming inspection by proper facility appointed staff member.
- Followed by a periodic examination of device, and its accompanying power cord.

Non–patient care equipment:

Electrical equipment that is not used in a patient care environment may be subject to restrictions and testing requirements, as outlined below. As long as these restrictions are adhered to, *NFPA 99* no longer requires testing other than visual inspection by clinicians.

Non-medical equipment requirements

Household or office appliances not commonly equipped with grounded power cords are permitted outside of the patient care vicinity. Double-insulated appliances are permitted in the patient care vicinity [*NFPA 99*-10.4.2.3].

Testing Non–patient care-related electrical equipment, including facility- or patient-owned appliances that are used in the patient care vicinity and will, in normal use, contact patients, should be visually inspected by the patient's care staff or other personnel [*NFPA 99* 10.4.2.1].

Fixed medical equipment requirements

Ground Testing permanently wired equipment in the patient care vicinity should be tested before installation while the equipment is temporarily insulated from ground [*NFPA 99* 10.3.4.1], by a licensed electrician.

In general care and critical care areas, the leakage current flowing through the ground conductor of the Power Supply connection should not exceed 10 mA (ac or dc) [*NFPA 99* 10.3.4.2].

EQUIPMENT INVENTORY

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Physican's Biomedical Equipment Services

August - 2017

SAMPLE ASC

123 45TH STREET ANYWHERE FL, 33333

MANUFACTURER	EQUIPMENT NAME	CONTROL #	SERIAL #	MODEL #	PM INTERVAL	STATUS
BURDICK, INC.	EKG MACHINE	11296		850	12	ACTIVE

EQUIPMENT TEST RESULTS

Electrical Safety Inspection (ESI) & Physical Condition Checks (PCC) Procedures were performed on the following equipment. Where noted PM Maintenance and Calibration Certification Inspection Procedures were performed on the specified equipment. Meeting Manufacturer's as well as AAMI recommended standards. Unless otherwise noted in the PM notes, the equipment was found to be operating safely and properly at the time of inspection.

Every attempt was made at the time of inspection to ensure that each device is operating safely, and according to manufacturer recommendations. However, please note- "the operator" is responsible for ensuring the safety of this device each and every time before it is used on a patient. PBES nor its employees are responsible for patient injury due to a malfunction of this equipment, nor due to an "operator error", nor an "error or omission" of PBES.

Physican's Biomedical Equipment Services

Telphone: (321) 953-5880

PM/Electrical Safety Report: General Biomedical Equipment PM ID #: **60330**

Owner:	SAMPLE ASC
Location:	1265 36TH STREET VERO BEACH FL, 32960
Department:	PACU

Control #:	11296	Status:	ACTIVE
Manufacturer:	BURDICK, INC.	Model #:	850
Equipment Name	EKG MACHINE	Serial #:	
Last Inspection Date:	Friday, August 4, 2017	PM Interval (Months):	12
Re-Inspection Due Date:	Friday, August 31, 2018		

PM Notes: INSTALLED NEW BATTERY & CLIPS
Performed PM Maintenance, and Calibration Certification Inspection Procedures. Meets Manufacturer's as well as AAMI recommended Standards. This equipment was found to be operating safely, and properly at the time of inspection.

Electical Safety Inspection Reults:

Inspection Date:	8/4/2017	
Ground Wire Resistance	.260	Ω
Leakage Current: EQ-OFF-N:	47.800	µ amps
Leakage Current: EQ-ON-N:	52.32	µ amps
ECG Leadwire Leakage:	1.6	µ amps
ECG Isolation Leakage:	5.6	µ amps

Work Performed By: PBES TECH