INCOMING INSPECTIONS

1. Purpose

To define the procedure to be followed when a medical device arrives in a Health Authority:

1.1.1 When the device first arrives (initial inspection) in the Health Authority, or

1.1.2 When the device returns to the Health Authority (e.g. after repair)

2. Definitions

Acronym or Word	Definition
BCBME	British Columbia Biomedical Engineering
CSA	Canadian Standards Association
CMMS	Computerized Maintenance Management System, which is the database that houses all medical device records, including repairs, inspections, purchase information, warranties, parts, etc.
Demonstration (of medical device)	Demonstration of a medical device involves no patient contact (i.e. sales presentation)
Evaluation (of medical device)	Evaluation of a medical device may involve patient contact (i.e. evaluating a new infusion pump in a clinical setting)
FMO	Facilities Maintenance & Operations
IEC	International Electrotechnical Commission
II	Incoming inspection ('acceptance testing') refers to the inspection procedure to be followed on all medical devices prior to being used in a clinical setting
IT	Information Technology
PC	Personal Computer
Performance Verification	Performance verification ('functional check', 'checkout procedure', 'post-repair procedure') compares the performance of the device to technical specifications established by the manufacturer in their maintenance or service manual. These are designed to test the operating status of a medical device and allow for any necessary adjustments or calibration to ensure the equipment's full functionality. Typically performed as part of an incoming inspection or following a repair before returning to clinical service. These inspections are not meant to extend the life of equipment.
PM	Preventive Maintenance, is a set of qualitative and quantitative tasks that aims to extend the life of the equipment and reduce failure rates, by detecting potential and hidden failures (i.e. by calibration, part replacement, lubrication, cleaning, etc) during scheduled inspections.

3. Scope

3.1 Included:

The procedure applies for both new and used medical devices.

- Note: clauses specific to a new device can be excluded if the device is not new.

All medical devices that will be supported by BCBME for their lifecycle, or by special request (e.g. Lab, FMO, etc.):

3.1.1 Purchased devices

3.1.2 Donated devices

3.1.3 Devices on loan from vendors

3.1.4 Devices on lease or rental (if applicable)

3.1.5 Devices on a contract of any sort (if applicable)

3.1.6 Devices in for evaluation

3.1.7 Devices transferred from another Health Authority

3.1.8 Physician owned devices that are the responsibility of BCBME (if applicable)

- Devices returning to the Health Authority after being sent out for service, loan, etc.

3.1.9 Research medical equipment if used on patients (Health Authority dependent – reference specific Health Authority SOP)

3.2 Excluded:

3.2.1 Medical devices in for demonstration or testing only

- Not for clinical, diagnostic, or treatment of patients
- Note: These devices are required to meet Health Canada and the BC Electrical Safety Regulation.

3.2.2 Assets not the responsibility of BCBME

3.2.3 Patient owned devices

4. Principles

- Medical devices and associated accessories, upon entering any Health Authority site, will be inspected before being used.
- Incoming Inspections are intended to ensure that:
  - All items in the purchase order have been received in acceptable condition o Outstanding terms and conditions relevant to BME in the purchase order are noted, and follow up is arranged
  - All medical devices entering the hospital are safe, meet specifications, and are operating as expected
  - All appropriate approvals have been obtained and all necessary standards/regulations have been met
  - Appropriate documentation is obtained and filed (electronic and paper), and that the devices are entered into the CMMS

5. Procedure

If the device fails any tests described in this procedure, notify a Supervisor regarding the problem and determine remedial action.

5.1 Prior to Inspection

Ensure you have:

5.1.1 A copy of the Purchase Order, or other documentation that may accompany the device

5.1.2 The manufacturer's documentation describing the functional test procedure or the job procedure for the device type.

5.1.3 All biomedical test equipment required to perform the Incoming Inspection and any specialized tools, jigs, or cables etc. necessary to complete the functional tests o If accessories, sets, tools or applied parts are unavailable for testing, either the vendor or end user is responsible for functional tests.

5.1.4 All appropriate sets, probes, and accessories needed to test the device as it will be used in the clinical setting

5.1.5 Taken precautions to protect yourself from device contamination

5.2 Purchase Order

5.2.1 Verify that all items on the purchase order have been received and are in acceptable condition. This includes, but is not limited to: accessories, components, operator manuals, service manuals, etc.

5.2.2 Review the purchase order and note any outstanding conditions or items (e.g. service training). Follow your Health Authority's procedures for obtaining any missing items (e.g. adding service training to education planners).

5.3 Physical Inspection

5.3.1 Contamination – Evidence of soil or blood, moisture damage, scrapes, cuts, tape residue

5.3.2 Housing enclosure – cracking, impact damage, discoloration, corrosion, button and screen condition, mounting and/or fasteners

5.3.3 Accessories – probes, external components, sets (if appropriate), etc.

5.3.4 Cabling – cuts, electrical requirements, abnormal jacketing condition, excessive twisting, connectors are clean, pins are straight, strain reliefs, electrodes/transducers

5.3.5 Markings, Labeling and Stickers – relevant, warnings as needed, legible

5.3.6 Mechanical Integrity – Cracked or obstructed wheels, moving parts behave normally, tipping hazard, mounting component integrity, swinging parts that may cause damage.

5.4 Power Cycle Test

5.4.1 For new models, excluding Permanently Installed Equipment, test 1 representative sample for its capability to handle a power outage.

- With the device running, power off the device by disconnecting the power cord. Wait for 10 seconds and then switch the device back on.

5.5 Electrical Safety

5.5.1 Ensure that all equipment has a CSA or equivalent electrical safety label attached. See Appendix A for a list of acceptable labels and approved certifying bodies.

- In absence of an acceptable electrical safety label, a Standards Council of Canada accredited Certification Body or Inspection Body can perform a Special Inspection to ensure compliance.

5.5.2 Perform electrical safety tests. See Appendix C for detailed instructions.

<u>Permanently Installed Equipment (PIE)</u>

5.5.3 The vendor must provide a report demonstrating that they have performed an inspection of the equipment following installation.

5.5.4 BME will review report and determine if vendor has performed all inspections outlined in this procedure, and if necessary, perform any inspection activities that vendor may not have performed.

5.5.5 File the report in the CMMS.

5.6 Other Safety Inspections

5.6.1 During incoming testing of devices that require Dose Area Product (DAP) acceptance measurements (e.g. radiation emitting devices, blood processing devices) either:

a) Record in the procedure "Notes/Comments", Time Charge notes, or WO Completion Comments all of the required DAP measurements

OR

b) Attach vendor work order with values, and in Completion Comments include "See Attached DAP Acceptance Measurements in Service Work Order"

5.6.2 Perform any other device applicable safety inspections as per manufacturer recommendations, such as:

- Mechanical (e.g. bed entrapment)
- Gas flow, gas pressure, etc.
- Laser (laser safety officer standards)
- Other relevant radiation tests (radiation safety standards)

5.7 Configurations

5.7.1 Position or mount any accessories where they are needed and verify they function without causing any hazard or damage

5.7.2 Verify the clock's time and confirm that the automatic daylight savings setting is turned on. If device has a clock, ensure that it is accurately set. If available, automatic daylight savings time is to be turned on

5.7.3 Ensure the clinical configuration defaults are set according to the needs of the clinical program.

5.7.4 If the device is networked, verify that if patient data is acquired it successfully transmits to the server

5.7.5 Conduct system testing to verify that the device interacts properly with anything it needs to in order to operate at full capacity, including communication testing if needed

5.8 Performance Verification

The following hierarchy should be followed for performance verification:

1) If vendor carries out on-site performance verification and provides suitable documentation, it is not necessary to re-perform the verification

a) Excludes performance verification that is required by regulation to be done in-house

2) Check manufacturer's manual and follow appropriate performance verification steps

3) Perform PM Job Procedure (from TMS or manufacturer's PM procedure)

a) Apply judgment to remove unnecessary preventative components

b) Verification of all device ranges and limits is not necessarily required

4) In the absence of all of the above, review with a Supervisor to confirm adequate performance verification tasks (i.e. may include self-test, power on test, another automated test, checking fundamental specifications etc.)

a) Vendor engagement may be warranted in cases where the device is unfamiliar or the service documentation is insufficient.

5) If performance verification of a certain specification is not possible due to lack of tools or accessories, use judgment to determine if the device can still safely be put into service. Notify the clinical area Supervisor about the gaps in performance testing.

5.9 Document

5.9.1 Enter all assets into the CMMS, as per CMMS Standard Operating Procedures (SOP). If any assets are new models in the CMMS, submit a New Model Request

5.9.2 Open and complete an Incoming Inspection (II) work order in the CMMS, following the Incoming Inspection Procedure. If the asset is an IT based device (PC, laptop, etc.)

- Follow the instructions in SOP003 "What Constitutes an Asset", Appendix D – Criteria for IT Based Medical Devices. This defines which assets are recorded in the CMMS, and how they are recorded o Complete all appropriate fields on the IT Information Tab of the asset

5.10 Privacy & Security

5.10.1 If the device stores patient data, ensure that appropriate security and privacy measures are taken

- Refer to your relevant Health Authority's SOP for securing personal information on clinical devices

5.10.2 Make appropriate notations in the CMMS o E.g. Antivirus Software Version

6. Reference Documents

- Cybersecurity Incoming Inspections SOP #P-14-16-40014

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