New Device Type or Model Evaluation Process

Instructions

This document outlines the process of evaluating a new device type or model for entry into the database. The process applies for clinical and IRB devices. Not all sections are intended to apply to all cases, so please fill it out as "not apply" when question not applicable.

The operator and service manuals are required to do the evaluation.

During the new model evaluation process there is information **general** to the model and information **specific** to the device. Both are necessary to gather during this assessment. The form separates the information to identify general model information versus device specific information.

Note: The fields in yellow are fields that are entered in the Biomed CMMS.

1. Basic information

1.1. What is the full name of the device manufacturer? If the device is "home-grown" prototype, provide as much information as you know about its development and use the institution name as the manufacturer e.g. "MGH"

1.2. What is the full name and number of the device model? Be as comprehensive as possible and include all that may apply. Add photo of model if consider necessary to clarify.

1.3. What existing device category do you recommend for this model? If no existing device category/subcategory seems applicable, describe what new category/subcategory would you recommend.

1.4. Is the new device part of a system of multiple hardware components that should have their own control numbers? If so, describe the system that the specific device evaluated belongs to. e.g. endoscopy towers

- Each serialized, individually powered device should have its own control number.
- Removable batteries which are serialized and have their own maintenance requirements are candidates for control numbers.

1.5. If multiple categories might apply, or you're not sure, list them all. For instance, a device can be at the same time a smoke evacuator and electrosurgical unit.

1.6. Identify if this is a new category for the database. New categories added to the database require an additional DBA reviewal process.

1.7. Describe what is the ECRI/Industry device category name. ECRI uses a Universal Medical Device Nomenclature System (UMDNS) which is the international standard for medical device identification. Use this link to find the category. https://www.ecri.org/components/Sourcebase/Pages/Search.aspx#Devices

1.8. Is the device FDA approved? Non-FDA approved devices are only allowed to use under research. Please select not apply if the device is exempt.

1.9. Is the device used Off-label? Off label use is only allowed to use under research.

2. Initial discovery

This section pertains to the first asset of the model to be purchased and implemented (or the first group of assets, if more than one was bought initially).

2.1. At which institution did this new device originate? In other words, which institution first purchased this first device that is under evaluation?

2.2. How did we discover (or how were we notified of) this new model? Select the source (Biomed initiated, Customer initiated, Surveillance rounds, IRB protocol, other) and answer the corresponding follow-up questions in the "Describe" free text field:

- What project number was this part of (if applicable)?
- Is this a fleet-wide replacement? If so, is the entire fleet being replaced at once, or in phases?
- Is this intended to be a new standard model?
- Is it replacing any existing model(s) of equipment? If so, which one(s)?
- If Customer requested an incoming inspection of the device(s). What is the customer's name and unit/practice? For follow-up correspondence.
- If found on rounds (follow-up correspondence to unit informing them to call us in the future). Where was the device found? and Was the device already in use?
- Other source, then provide details.

3. Initial purchase and implementation

This section pertains to the first asset of the model to be purchased and implemented (or the first group of assets, if more than one was bought initially).

3.1. What is the the initial application/planned use of the device, device type?

- Regular clinical use Evaluation/trial (for potential future clinical use)
- IRB (intended use or off-label use)
- Asset management/non-medical device
- Other (provide details)

3.2. If IRB protocol, what is the protocol number?

3.3. How many years is the standard warranty? Based on manufacturer standard time, terms and conditions.

3.4. Is the device under an extended warranty? Will the extended warranty apply to any additional devices purchased? If so, include a copy with this submission.

3.5. Is the device(s) owned by the hospital? If not, select what is the ownership status?

3.6. Which accessories were purchased with the device? (E.g. ultrasound transducers)

4. Documentation

4.1. Include the location of the electronic copies of each of the following documents with your submission; if you are unable to obtain any, provide details as to why:

1. Operators manual (Mandatory)
2. Service manual (Mandatory)
3. Specifications/data sheet
4. List any other documents included with this submission

4.2. Will any new stock parts or PeopleSoft numbers be created for this model? List required supplies and accessories of the device.

Note: All documents, as well as the completed New Equipment Model Evaluation form, will be stored on the PBMEREF drive under Technical References by Device Type. When the documents are ready to be moved, please store them in the Document Dropbox on DBMEMAIN. Please use the correct file naming conventions with manufacturer and model included (e.g., GE Marquette Electronics Dash 4000 Service Manual SW Vers 7.pdf)

5. Maintenance

5.1. List all scheduled/preventive maintenance intervals included in the service manual and give a brief description of each.

1. PM frequency
2. Inventory frequency. Per MGH standard frequency
3. Manufacturer battery replacement frequency
4. Operators maintenance frequency What user-based processes, if any, will be required to support this device? Document communications to the end-users.

If no maintenance is required in the service and operations manual, list any explanation provided by the manufacturer.

5.2. Are there any specific competencies required to support the device?

- Are there any restrictions included in the service manual related to maintenance? For example, does the manufacturer require training or certification for anyone who will work on the device? Does the manufacturer prohibit anyone but their own personnel from working on the device?
- Review what technical training, if any, was/will be provided to Biomed staff as part of the initial rollout.
- If the new device is a high-risk device and none of our technicians are trained. Review if can be trained or the device must be put on a service contract?
- If device needs to have a service contract work with Team Leader to obtain one.
- Review if competencies have been documented?

5.3. Are there any special tools/ parts maintenance requirements listed by the manufacturer, such as: proprietary test equipment, tools, or software; parts that need replacement during maintenance; or, PM kits? Provide details.

5.4. Is there a rationale for placing the device on an AEM?
Document the reasoning for performing PM procedures other than the manufacturer's recommendations, including data to support such decisions. Differences include maintenance activities and frequencies, or similar models already on AEM. Some devices will not be allowed to be included in an AEM (lasers, ultrasounds, new to market) and therefore require us to follow manufacturer's recommendations. Supporting information is required for all devices on an AEM program. Also note any future considerations for an AEM program that may help to reduce unnecessary maintenance activities. Consult the AEM Analysis Guidance document and complete the AEM Analysis form, both located on PBMEREF.

5.5. Is a loaner device needed? If so, determine the number of loaner devices to add to the loaner pool. If required, create the device-specific Loaner Device Exchange Procedure. Refer to Loaner Device Policy.

5.6. Are there any clinical systems maintenance? For instance, wireless-certificates frequency, server log-review frequency, server file storage clean-up frequency. Describe what maintenance activities and the frequency.

5.7. For Service Support type? In house, vendor support? Was a service contract included with the purchase (or purchased at the same time)? If so, include a copy with this submission. Will the contract apply to any additional devices purchased?

5.8. Will any new processes or additional biomed activities (other than routine inspection and maintenance by our technicians) be required to support this device? If so, provide details. For instance, water quality test for Dialysis.

5.9. Will any other departments/teams be involved with the ongoing support of the equipment? For instance, Sterile Processing Department for reprocessing the device.

5.10. Select the recommended Label Instructions for the device according to MEMP. Be aware that the label selection is independent of the risk classification.

6. General equipment attributes

6.1. Does the model store, display, or transmit Protected Health Information (PHI)?

6.2. Does the specific device actively store, display, or transmit Protected Health Information (PHI)?

6.3. What PHI storage media has the model?

6.4. What PHI storage media attributes has the specific device is actively using?

6.5. Does the model contain Clinical Alarms?

6.6. Does the device contain firmware or an operating system? List the revision numbers to be associated with this model; they will be added to TMS. If this is a computer-based device, skip this question and go to Section 8.

6.7. Does the device display and/or record the time? If so, how are Daylight Saving Time updates handled? Is the recommended procedure:

- Auto adjust for DST
- Via a network time protocol connection NTP
- Manually adjustment only
- No clock

- Other (provide details, e.g. location-dependent):

7. Category-specific attributes

7.1. Infusion pumps: List the names of all drug libraries to be associated with this model; they will be added to TMS.
7.2. Physiologic monitors: List the names of all defaults settings profiles to be associated with this model; they will be added to TMS.
7.3. Patient and infant scales: Review if the device can display weights in kilograms by default.
7.4. Describe if there are other device category specific attributes.

8. Networked devices

This section applies specifically to any devices that are PC, laptop, tablet, or mobile device-based.

8.1. Is it PC, laptop, or mobile? Select the computer hardware design
8.2. What is the manufacturer and model of the computer-based hardware (e.g. Microsoft Surface tablet, Apple iPhone7)?
8.3. Is the device integrated to a system? Will this device communicate with/connect to Epic, QPath or other systems?
8.4. What is the operating system?
8.5. Does the model have wireless capabilities?
8.6. Is the specific device using the wireless capabilities? If so, do assessment with Partners Wireless Manager and describe.
8.7. Does the model have network capabilities?
8.8. Is the device using the network capabilities? If so, describe which network (e.g. GE VLAN 22), another wired network.
8.9. Is the device using DHCP?
8.10. What is the device MAC Address?
8.11. What is the device IP address?

9. Risk assessment

Give your recommendation for risk class and score using the following two methods:

- A quantitative score and classification using the Fennigkoh-Smith formula.

  When scoring the devices, choose the most conservative level, considering the worst-case scenario so that the score would be higher and would err on the side of caution.

  Equipment Function - E: This variable considers the intended use of the device, with greater risk associated with devices that act directly on patient (e.g. give some therapy) than those that act indirectly (e.g. diagnose or analyze). As one would expect, then, therapeutic devices that provide life support (e.g. anesthesia machines) would be given a greater score than devices that are used as a diagnostic tool (e.g. physiological monitor).

Clinical Application - A: This variable considers the consequence to the patient if the device were to fail.

Schedule Maintenance - S: This variable considers the manufacturer's recommendation for scheduled maintenance.

Likelihood of failure - F: This factor takes into consideration design, components, and service history (if available) of the device. This is where your " clinical engineer training and instinct" come into play to make your best-guess estimate. If possible, you can perform an FMEA to help you determine the likelihood of failure.

Environmental Use Classification - U: This variable considers the location that the device will be used. The more acute the area, the greater the potential risk. In many cases, the medical device may be used in multiple locations, in which case, choose the highest acuity area.

- A qualitative assessment and classification using the new JC-prescribed severity levels in the MGH MEMP.

Severity Levels and Definitions	**Definition**
Severity	
1: Negligible Low Risk	Failure could reasonably be expected to have no adverse effect (health, financial, operational)
2: Marginal Normal Risk	Failure could reasonably be expected to result in reversible adverse effect (health, financial, operational)
3: Critical High Risk	Failure could reasonably be expected to result in permanent adverse effect (health, financial, operational)
4: Catastrophic High Risk (old Life Support)	Failure could result in loss of life, total financial loss, and/or cessation of all

NOTES: Ultimately the DBA should decide the risk classification, The DBA should use each new model opportunity to review the risk class for a given device; will look at all the models of equipment under that device type and arrive at a "consensus" risk class for the device type; ideally it will be obvious from looking at the active equipment in the inventory; if not, EMC will decide. We will also use this to establish or re-establish F-S scores for device types, put them in TMS, and maintain them over time.

10. Reviews and approvals

Requester name: Name of the person who filed the form.

Please follow New device/ model evaluation process for reviews and approval

- DBA approval
- Assistant director/Director review
- TLs post approval review