New Model Evaluation Form

INSTRUCTIONS

Complete this form in its entirety when a new model of equipment enters an MGB facility for the first time, before any asset records are created in TMS and before any devices are commissioned into use. Submit the completed form to the CMMS administrators for entry into TMS by creating a data management work order and attaching a copy of the form. All evaluation forms must be approved by a manager, assistant director, or director, and no one can approve their own evaluations. New manufacturers and new device categories must be approved by an assistant director or director. Upload all supporting documents to the appropriate SFA based on institution.

Evaluator's name, title, and institution:
Requestor's name, title, and institution (if different from evaluator): ☐ same as evaluator
Date created:
DM WO number:

GENERAL INFORMATION

1. Enter the manufacturer description exactly as it appears in TMS:
   OR
   If the manufacturer is not in TMS, enter the manufacturer name here and complete Appendix A (New TMS Vendor Form):

2. Enter the full model name/description according to the manufacturer:

3. Enter the model number (if different):

4. Enter the recommended device category exactly as it appears in TMS:
   OR
   If you cannot find an applicable category, enter a proposed new category here and complete Appendix B (New TMS Device Category):

5. Describe the basic function(s) of the device:

6. Enter the manufacturer's standard warranty period in months, and general terms and conditions (including limitations); write "lifetime" for lifetime warranty or "none" for no warranty:

7. At which institution did the model first appear? Choose from list

   If you selected "other", provide details:

DOCUMENTS

8. Complete the table below to confirm which documents were obtained electronically. Provide details for any manuals not obtained (e.g. "mfr will not provide", "no service manual exists", etc.). Create separate .pdf files for maintenance procedures. **If no maintenance is required a separate .pdf file, in the form of an excerpt from the manual(s) or letter or email from the manufacturer, must be included to confirm that this is the case.** Upload all files to the appropriate folder (see no. 9 below) based on institution:

Document	Obtained	Rev. no./date	Details
Operator manual	☐		
Service manual	☐		
Maintenance procedure(s)	☐		
MDS2 form	☐		

9. Select which one applies:

☐ **BWH** \\Cifs2\biomed$\Technical References by Device\<**DEVICE CATEGORY>\<Manufacturer Model>**
☐ **MGH** L:\DBEMAIN\Document Dropbox**<DM WO number, manufacturer, model>**

MAINTENANCE

10. Complete the table on the next page to document all preventive maintenance activities prescribed by the manufacturer, including battery maintenance. Enter all information for each maintenance *interval* on one line (i.e. one line for semi-annual, one line for annual, etc.). Note whether the manufacturer specifies who should perform the activities (e.g. equipment operator, any technical personnel, manufacturer personnel only, etc.) and whether the activities are "required" or "recommended."

    Do not omit any maintenance activities, even those which are clearly the responsibility of the equipment operator, and do not add any activities which are not listed in the manufacturer's documentation. For maintenance involving batteries, specify whether the batteries are to be tested, conditioned, or replaced, and include the part number(s).

    If no preventive or battery maintenance activities are listed, type "no maintenance required" in the first row:

PREVENTIVE MAINTENANCE ACTIVITIES

Interval (wks/mos/yrs)	Description	Responsible party (if specified)	Tools/parts/training required (include part numbers)	"Required" or "Recommended"	APPROVER Add to TMS
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐
					Y ☐ N ☐

ATTRIBUTES AND FEATURES

11. Is the model capable of processing Protected Health Information (PHI, i.e. health information which is *individually* identifiable to a particular patient)? Check all which apply:
    - ☐ store (see 11.1 below)
    - ☐ display
    - ☐ transmit
    - ☐ the model is not capable of storing, nor displaying, nor transmitting PHI

    11.1 If the model can store PHI, check all applicable media types; otherwise leave blank:
    - ☐ internal hard drive
    - ☐ external hard drive
    - ☐ removable SD card
    - ☐ other (specify):

12. Does the model display time? Check all available configuration options (for Daylight Saving Time):
    - ☐ network time server
    - ☐ network broadcast/push
    - ☐ manual update
    - ☐ the model does not display time/include a clock

NETWORKING & CONNECTIVITY

13. Does the model contain wired or wireless connectivity capabilities? Check all which apply:
    - ☐ Ethernet/LAN
    - ☐ WiFi (list all modes, e.g. 802.11b/g/n)
    - ☐ Bluetooth
    - ☐ cellular
    - ☐ other
    - ☐ the model has no connectivity capabilities

    13.1 If yes to any of the above, provide details about connectivity-based functions of the model:

14. Does the model incorporate a computer-based or mobile operating system (e.g. Windows, Linux, iOS, etc.)?
    - ☐ yes
    - ☐ no

    14.1 If yes, provide details about hardware configuration(s), OS version(s), anti-virus software, patch validation, etc.:

EVALUATOR'S COMMENTS

15. Enter any comments, suggestions, recommendations (including AEM), or observations:

APPROVAL (manager, assistant director, or director only)

Name:
Title and institution:
Initials:
Date:

Appendix A – New TMS Vendor Form

Requested by:
Date:

1. What type of organization is the manufacturer? Check which one best applies:
   ☐ commercial enterprise/company
   ☐ individual (e.g. researcher, sole proprietorship) or laboratory
   ☐ other (provide details):

2. Enter the full name of the organization, including extensions like “Inc.”, “Ltd.”, etc. For individuals, enter the first name, last name, credentials (e.g. “MD” or “PhD”), institution, and department name. For labs, enter the full name of the lab; do not use abbreviations or acronyms:

3. Enter the mailing address. For individuals and labs within MGB include building, floor, and room number:

4. Enter the shipping address (if different from above):

5. Enter any MGB or institutional account number(s), if known:

6. Enter any individual contacts and information, including job title:

APPROVAL (assistant director or director only)

Name:
Title and institution:
Initials:
Date:
MGB vendor ID number:

Appendix B – New TMS Device Category Form

Requested by:
Date:

1. Enter the proposed category name:

2. Enter a description of the essential attributes and functionality of this type of device:

3. Enter a justification for creating the new category, focusing on the characteristics which distinguish it from all existing categories:

4. Select the severity level associated with failure of the equipment (refer to institutional MEMP): Choose an item

5. Calculate the Fennigkoh-Smith score:

   (E) Equipment Function: Choose an item

   (A) Clinical Application: Choose an item
   NOTE: There should be a *direct* connection between the application of the device and the severity of injury. For example, diagnostic devices generally cannot directly cause patient injury, but they can directly lead to an inappropriate therapy or misdiagnosis

   (S) Scheduled Maintenance Frequency: Choose an item.
   NOTE: Select an average value based on a sampling of relevant models

   (F) Likelihood of Equipment Failure: Choose an item.
   NOTE: select the closest value based on available historical data for similar categories and models; if no data is available select option "3" (approximately one year)

   (U) Environment of Use Classification: Choose an item.
   NOTE: select the most critical environment based on known use cases

   TOTAL = E + A + [(S + F + U) / 3] =

APPROVAL (assistant director or director only)

Name:
Title and institution:
Initials:
Date:
Risk Classification: Choose an item