ADDING NEW MANUFACTURE/MODEL PAIRING TO CMMS

1. Site Applicability

All Sites in BC Biomedical Engineering.

2. Purpose

The accurate and consistent entry of new Models in the CMMS (TMS).

3. Definitions

Acronym or Word	Definition
Category and Subcategory	The Category field is a broad classification of assets designed for grouping and locating similar assets. Sub Category is a more specific field than Category. These fields are populated with the ECRI UMDNS definitions. This is a mandatory and controlled field.
CMMS	Computerized Maintenance Management System
ECRI UMDNS	ECRI is the standard database used for reference of naming Manufacturers and Sub-Categories in TMS. ECRI Institute publishes a Universal Medical Device Nomenclature System (UMDNS). This is a library of defined device type descriptions and assigned XX-XXX device codes. This library is used to populate the Category and Sub-Category fields. Note: In the absence of finding a suitable ECRI definition, the CMMS team will generate custom codes BE-XXX and associated Category and Sub-Category.
M3	The Manufacturer Model Module (TMS Contracts Module in "Customer" portion)
Manufacturer	The Manufacturer is the entity most legally responsible if a patient is harmed by the asset. As much as reasonably possible, this will match the current manufacturer in ECRI.
MDS2	Manufacturer Disclosure Statement for Medical Device Security
Model Name	The *Model Name* field can be used to include additional descriptive information as shown in the examples in this document. The team will use the manufacturer's model identifier from the front of the device to formulate the model name. The family or series of the model will be included in this identifier whenever possible (e.g. Siemens AXIOM series).
Model Number	The descriptor when paired with the *Manufacturer* creates a unique identifier for the asset (e.g. Covidien – 840). Each asset may only have

	one *Model Number* and one *Manufacturer*. Note: The *Model Number* descriptor may be numeric, alphabetic or alphanumeric, This field also triggers the hierarchical identification of the Model Name, Category, Sub Category and Risk Number (PM Priority) of the asset. This is a mandatory and controlled field.
SOP	Standard Operating Procedure
Workstation	Devices designed to acquire, process, and store data and/or images specific to a particular procedure (e.g., radiography, cardiology, ultrasound). The main component of a workstation is usually a high-capacity digital computer. Workstations typically obtain the data directly from the devices that perform the procedure (e.g., digital radiographic units, gamma cameras) or through digitized scans of printed or electronic images (e.g., films, image plates). They typically consist of a high-speed digital computer with a powerful microprocessor, optical/magnetic disks, and input and output devices; a workstation usually follows the instructions of specialized software for data and/or image processing. Workstations are frequently installed as a component of or interact with department and/or hospital information systems, including picture archiving and communication systems.
Information Systems, Data Management	Information systems designed to manage clinical and/or administrative data in a healthcare facility. These systems consist of hardware, including workstations (usually with digital computers) and peripheral devices (e.g., high-capability storage devices, printers) that are typically connected as a local area network (LAN), as well as software, including operating systems, a database management system, and application programs. Data management information systems can collect, store, analyze, retrieve, display, and/or print information related to the whole facility (i.e., hospitalwide) or to one or more clinical specialties or procedures. Dedicated systems intended for clinical applications (e.g., cardiology, oncology) and/or administrative procedures (e.g., finances, reimbursement, materials management) are available, including bar-coding systems. Data management information systems that exchange information with medical imaging equipment (such as digital radiology imagers) usually follow DICOM (Digital Imaging and Communications in Medicine), a standard in the field of medical informatics that ensures interoperability.

4. Scope

Included

- This standard operating procedure applies to any new asset being added to the CMMS, where the *Model Number* and *Model Names* do not already exist in the CMMS.
- This SOP applies to the creation of Manufacturers that do not already exist in the CMMS.
- This SOP applies to the unique situations where Models are entered but no appropriate Sub Category (or Category) has been created. PM Change Committee will review information after Category/Subcategory is created.
- This SOP also applies retrospectively to data cleaning/consistency efforts for the provincial CMMS team.

Excluded

- None

5. Guidelines and Protocols

5.1 Technologists Entering New Inventory

5.1.1 All devices in a system that meet the criteria based on SOP#: P-14-16-40003 "What Constitutes An Asset" will require labelling and entry into the database system.

Refer to SOP "What Constitutes an Asset" to determine what items will need to be inventoried in CMMS; some items will be excluded and will not require any further steps to capture.

Example: New EEG System – compared with "What Constitutes an Asset"

Device	Requires Tagging and Inventory	How to Inventory
Windows Dell PC	Yes	Refer to 7.3
Power Supply	Yes	Refer to 7.1
Monitor	Not Provincially required	Refer to 7.1
EEG 32 Headbox	Yes	Refer to 7.1
HD Camera mounted to cart	Yes	Refer to 7.1
Cart	Not Provincially required	Refer to 7.1
Keyboard	No	No further action
Leadwires for Patients	No	No further action

5.1.2 **Perform Asset Query search in TMS using "wildcard" searches** (% or * symbol) around Manufacturer, Model Name, or Model # (e.g. *GC000235*).

Check first:

a. *Model Name* field – recommended for the majority of searches. If no results then,
b. *Model Number* field

5.1.3 **Manufacturer and Model Exist**:

- Select Manufacturer and Model for new asset entry.
- The following fields will auto-populate:
  - Category
  - Sub category
  - Asset description
  - PM Priority
  - Template PM Schedule(s) – Next Due Date (NDD) will be updated based on the completion of first Incoming Inspection.

Question: Information incorrect for Sub Category, PM Priority and Scheduling?

Go to: **http://bcbiomed.org/** website, and Submit "**PM Change Request Ticket**"

5.1.4 **Manufacturer and Model DOES NOT exist**:

- Go to: **http://bcbiomed.org/ , Submit "New Model Request"**
  - Fill in all relevant information, including a suggested Sub Category
  - Attach the minimum of 2 JPG formatted pictures, each picture smaller then 2MB in size.
    - Rear Serial # Label (maximize label in the picture).
    - Model identifying information from the front of the device.
    - Computer based equipment - must include a framed picture from the "Help /About" menu of the primary software.
    - Tablets/phones will require a screen shot of the Application from the main screen. Examples of these pictures are in Appendix A.
    - Submit additional pictures of any other model identifiers of the device.

Note: It is encouraged to provide pictures of the full device (example: CT scanner), but not required.

5.1.5 **A model number identified using this guideline will take precedence over legacy methods**.

5.1.6 Notify your local Database Administrator when an Acquisition or Merger of medical device Manufacturers has occurred.

Notify your local Database Administrator if an Acquisition or Merger of a Manufacturer has occurred, the merger will be corrected in TMS once the merge has been confirmed in ECRI.

5.2 Provincial CMMS Team

5.2.1 Verify that Manufacturer/Model Pair does not exist in TMS using:

- M3 Module is querying Manufacturer and Model Name with wildcards.
- Asset Query in the *Model Name field with* wildcards
- Asset Query in the *Model Number* field with wildcards

5.2.2 NEW MANUFACTURER OR MERGER IN DATABASE

If the Manufacturer doesn't exist in the TMS, or a Merger has occurred, **ECRI Sourcebase** will be used as the standard reference updating in the CMMS.

Manufacturers will be added into the CMMS based on New Model request submissions. Mergers between companies will be applied when they are posted onto ECRI.

The following information is required for Manufacturer entry:

- Manufacturer Code – labelled as "Manufacturer"
- Manufacturer Description - hidden from user interface.

a) Examples of Manufacturer entries:

i) Large International Corporations

When possible, large corporations will be reduced to a single manufacturer.

Large corporations could have multiple permutations of the manufacturers' name (e.g. GE or GE CANADA INC). Efforts are made to reduce to a single manufacturer by using the ECRI Sourcebase reference. For example, the manufacturer "GE" was selected as "GE HEALTHCARE TECHNOLOGIES".

ii) Divisions of Parent Corporations

A division of a large company will be used when the Parent Corporation would not be used to identify the device in recalls, and thereby requiring it to be entered into the CMMS as a separate manufacturer.

Example - An ECRI Alert required BIOSENSE WEBSTER to be separate from its parent corporation JOHNSON & JOHNSON CORP. The end result in CMMS was "BIOSENSE WEBSTER INC A JOHNSON & JOHNSON CORP".

iii) Corporate Mergers

Corporate Mergers occur when the former Manufacturer Name will no longer be used for alerts and recalls, and a new Company takes over. This update only occurs when confirmed in the ECRI Sourcebase.

Example: CRITIKON INC A JOHNSON & JOHNSON CO has been purchased by GE.

> A search in ECRI Sourcebase produces: "Critikon Inc A Johnson & Johnson Co, See: GE HEALTHCARE TECHNOLOGIES [440964] - Waukesha, United States"
>
> CMMS update was to merge Critikon devices into GE HEALTHCARE TECHNOLOGIES

5.2.3 MODEL NUMBER AND NAME IDENTIFICATION

The CMMS team will use the following criteria to determine the model number and model name:

a) The manufacturer's identification label/serial number to identify "Model Number":

i) If the words "Model Number" or its equivalents "Model No.", "Model #" or "Model" is explicitly labeled

ii) If no clear indication for the *Model Number* then follow the hierarchical list from the manufacturer's identification label/serial number / will be used:

(1) "Type", "Nbr" (European), if not

(2) "REF", or equivalents "Reference #", "REF#", if not

(3) "Part Number", or equivalents "Part No." or "P/N", if not

(4) Identify Model Number from the front of the device

iii) The *Model Name* field will be used to include additional model identifying information as shown in the examples in Appendix A of this document.

b) For consistency in CMMS, the following decision were made by the BCBME CMMS team:

i) Model Name and Number will be in all Capital Letters

ii) Model Number - Special characters (i.e. &,*,#, etc.) removed, and will be spelt out

Example: (AMX4+ would become AMX4Plus)

iii) Model Name: all spaces and special characters (i.e. &,*,#, etc.) included.

iv) Model Name can include information from Website and "GUIDID" Database to add any additional identifiers to help find the Model in CMMS later.

5.2.4 NEW CATEGORY AND SUB CATEGORY IDENTIFICATION

Category and Sub Category used in a hierarchical relationship in CMMS, and standardizes a fleet of devices with:

- Risk Class (PM Priority)
- Default scheduling.

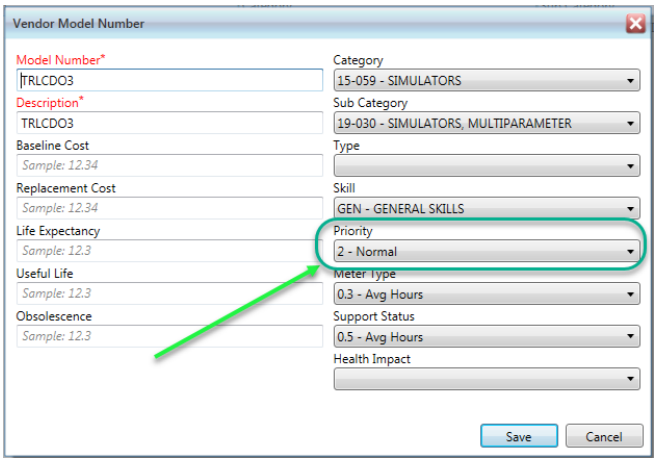
CMMS uses the Category and Sub Category Codes as a hierarchical relationship.

a) **A Sub-category can have only one Risk Number**. If a Model in a Sub Category is no longer in that Risk Number (PM Priority), then a new Sub-Category has to be created.

b) A Model number can only have one Sub Category.

c) ECRI UMDNS Codes are the standard reference for naming new Category and Sub Category.

d) The Risk Number of the Sub-Category must be included in the Vendor Model creation table



5.2.5 Creating a new Sub Category:

a) Minimize the number of Sub Categories created by choosing the most generic UMDNS term.

b) ECRI Capital Purchasing Module can be used to help identify UMDNS code if searching by Model/Vendor.

c) Recommended 3 hierarchical levels as much as possible (e.g. Infusion Pumps, Multi-therapy, Ambulatory)

d) Determining a Sub Catagory:

i) ECRI UMDNS – the definition should best match the device's clinical function. In general, a unique clinical function of the medical device should be represented by one and only one sub category (e.g. Ventilator, Adult, is different than Ventilator, CPAP).

ii) IF ECRI has changed UMDNS codes and terms, the CMMS team will update as required.

iii) At the discretion of the CMMS Team and the PM Change Committee, if no suitable ECRI definition is available, a unique Biomedical Engineering nomenclature and code will be generated with the format BE-XXX.

iv) Once the Sub Category has been determined, the Category is defined as the highest level of the UMDNS term. (E.g. Sub Category = BEDS, ELECTRIC, BIRTHING to Category = BEDS). If the Category does not already exist then it must be created before the Sub Category in the CMMS.

5.2.6 MDS2 Documentation

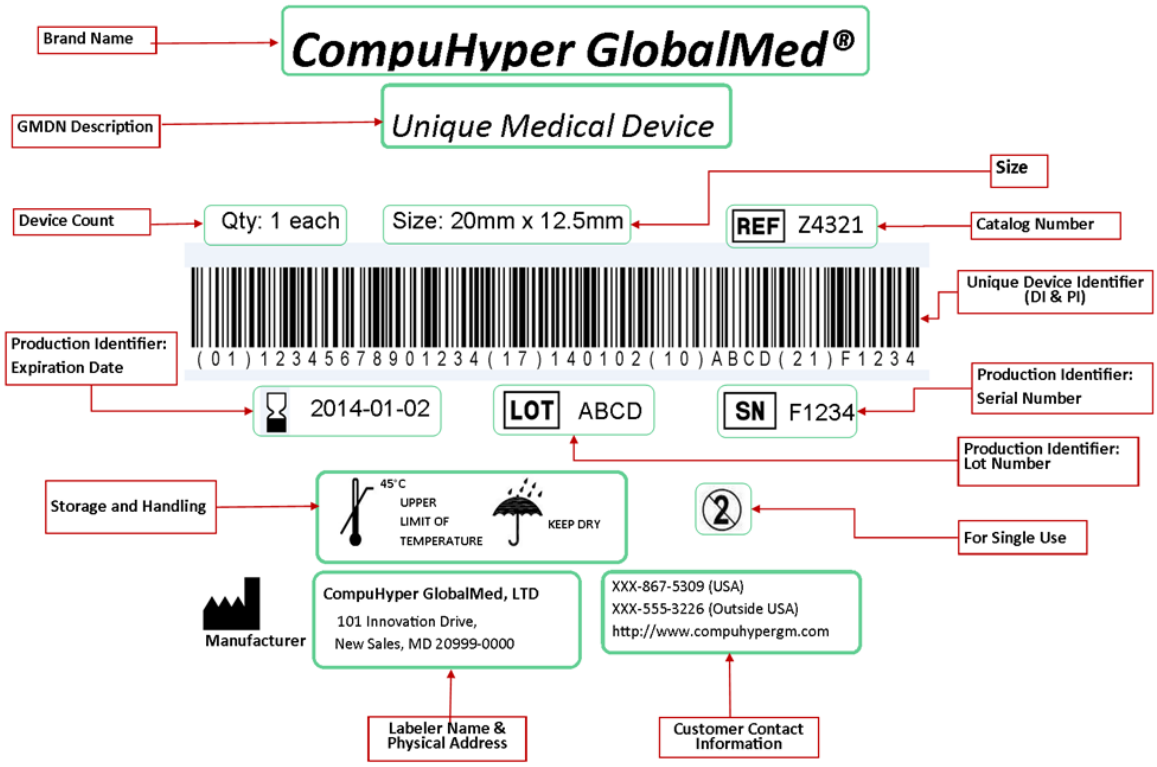
As a requirement for Cybersecurity documentation, all new Models with Wireless, Bluetooth, Cellular, Networkable capabilities and/or retains Patient data require an MDS2 form from the Vendor. The Provincial Supply Chain requires, in the capital purchasing contracts, that Vendor's supply MDS2 forms.

The information is captured in CMMS for all that model in the M3, once the new Model is created.

If the Vendor cannot supply an MDS2 document, a tech can request a blank template from the the Provincial CMMS team during the "New Model Request" Process, and forwarded to the Company for completion.

5.2.7 GUIDID CAPTURE

Device Serial number labels that include GUIDID Barcodes are entered into the M3 module.



a) Record number after prefix (01)

b) GUIDID link found on "ACCESS GUIDID" Database: http://accessgudid.nlm.nih.gov/

Example GUIDID Label above:

Recorded GUIDID for this device is: 12345678901234, and not record the (01)

6. Reference Documents

SOP P-14-16-40003 "What Constitutes an Asset"

Revision History

Revision No.	Date of Issue	Revised By	Comments
Version 1.0	April 18, 2013	LM Engineer	Issued as DRAFT
Version 1.1	April 25, 2013	LM Engineer	Review- DBAs
Version 1.2	April 26, 2013	LM Engineer	Active – Approved by LM Manager
Version 1.3	November 24, 2015	LM Engineer	DRAFT – Repurpose for BCBME
Version 1.4	December 18, 2015	BCBME CMMS Team	DRAFT Review
Version 1.5	June 30, 2016	BCBME CMMS Team	Issue for Province
Version 1.6	Oct 13, 2021	BCBME CMMS Team	Reformatted to new template, Included Cybersecurity Documentation, the model module information capture, the link to PM Procedure Group, and updates to Computer and Tablet Software Model Requests.
Version 1.7	Nov 24, 2021	Federated Directors	Minor edits and Approval of changes.

Appendix A - PROCEDURE WITH EXAMPLES FOR MEDICAL DEVICES:

1. MODEL NUMBER OF AN ASSET IDENTIFIED

1.1.1 The *Model Number* of the device is clearly identified as "Model Number" or its equivalents "Model No." or "Model #" or Model is explicitly labeled.

Look at the serial number / identification label on the device. If the word *Model Number* (or its equivalents) is listed, this should be used as the *Model Number*. See Fig 1.

Fig 1 – Model Number identified – The manufacturer also includes the *Model Name*, "Symbia Intevo Excel", on a separate label and was a 100% match to the front labelling.

The entered model name in this case would be "10764801 Symbia Intevo Excel"

1.1.2 *Model* identified

Look at the serial number / identification label on the device.

The word "Model" is listed and this should be used as the Model Number. For this example the *Model Number* will be **EspritVentilator (**space removed).

The *Model Name* of this device can be submitted as **Esprit Ventilator V1000** (include P/N found on label). See Fig 2.

Fig 2 - Model Number and Model Name identified

1.2 MODEL NUMBER NOT CLEARLY IDENTIFIED

1.2.1 "Model Number" not indicated on serial number / identification label.

If the model number is not identified on the serial number / identification label, then one of the following will be used in priority sequence for the *Model Number*:

- "Type", "Nbr" (European), if not
- "REF", or equivalents "Reference #", "REF#", if not (see example 3)
- "Part Number", or equivalents "Part No." or "P/N", if not
- Identify Model Number from the front of the device

After completing the *Model Number*, the Model Name can be entered. Model Name is a duplication of the Model Number, and can also include the name used in Manufacturer websites and GUIDID information. Websites are only to be used for *MODEL NAME* ONLY (FAMILY NAME), and cannot be used for Model Number.

Example 3 the *Model Number* will be 64MTPX (see Fig 3.1).

Due to absence of labelling on the front of the device the *Model Number* was created as 64MTPX.

However, using the manufacturer website, it was determined the series/family of devices was the Connex 6000 SERIES and was also added to the M*odel Name* (see Fig 3.2).

Fig 3.1 - Use "REF" as an Equivalent

Fig 3.2 - No Model Name label

1.3 COMPUTER, PHONE, AND TABLET BASED DEVICES

1.3.1 COMPUTER BASED ASSETS

Computer based devices are entered as ASSETS under their clinical software application and not the computer hardware.

Specific computer hardware, networking and relevant application information is entered under the IT Information tab of the Asset Record by the technologist after the Software is entered as a New Model.

When a new Model Request is submitted, the Technologist must include:

1. Picture of the Help/About Screen of the Clinical Application (see figure 4.1), and a picture of any or all of the below information:
2. Name of the Application at the Startup Screen (splash screen)
3. A label/sticker of the Clinical Software loaded on the Computer
4. Name of the Application from the package sent by manufacturer, or use the following hierarchical criteria:
    i. Type", "Nbr" (European), if not
    ii. "REF", or equivalents "Reference #", "REF#", if not iii. "Part Number", or equivalents "Part No." or "P/N", if not iv. Identify Model Number from the front of the device

The Build and Patch information will not be part of the *Model Number* or *Model Name* and should be entered under the IT Tab Information.

a) Example 4 - Computer based medical devices

- The *Model Number* for this example was entered as Neuroworks 7.1.0 and the sub-category is ELECTROENCEPHALOGRAPHS (see Fig 4.1).
- In this example, the *Model Number* was repeated as the *Model Name*.

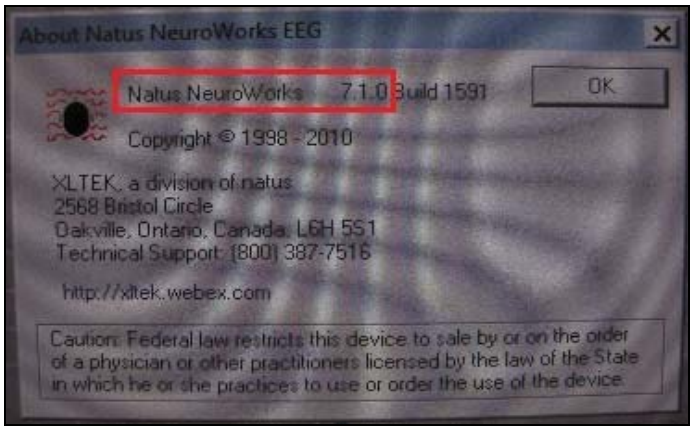


Fig 4.1 – Computer Based medical device with Help About menu picture used for the *Model Number*.

Pulmonary Function (EEG system) – sometimes they are tagged all as system and some cases individual; define accessories. Affects the Passwords as well. Method of tagging devices, Parent/Child Systems.

b) Example 5 - Computer based medical devices

- Following the priority sequence for Computer Based Devices from the Help – About screen the *Model Number* is entered as Endoworks 7.4 Note: The *Model Name* is entered as Endoworks 7.4 since there is no other information on the splash screen. The sub-category is INFORMATION SYSTEMS, PICTURE ARCHIVING/COMMUNICATION, ENDOSCOPY (see Fig 5.2).

Fig 5.1 Shows no relevant information

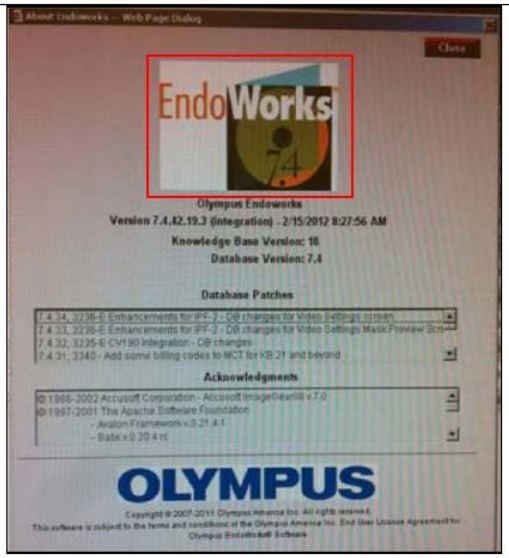


Fig 5.2 Shows Model Number as Version 7.4.42.19.3

1.3.2 TABLET/PHONE – they don't have Help/About – send a screen shot of application name on the Homescreen.

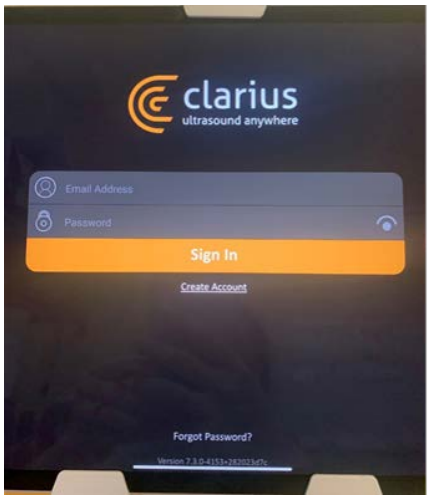


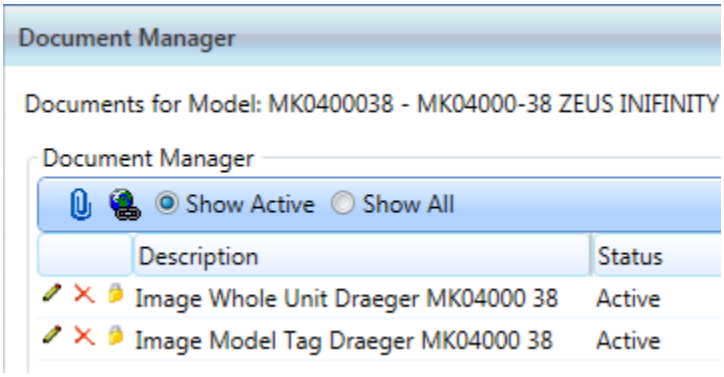
Fig 5.3 Application Name Homescreen. Model Number CLARIUSULTRASOUNDAPP

Appendix B – ATTACHING IMAGES

Images are to be cropped to contain only the relevant information at an easily readable size and be oriented correctly.
The naming standard format for images to a model are to follow the example below:

"Image"<description of image> Manufacturer Model Name.

For example:



Appendix C - FREQUENTLY ASKED QUESTIONS (FAQ)

1. **Why are all the space, dashes, slashes, etc (special characters) missing from the Model field?**

   - There are currently more than 142,000 devices in the CMMS. Characters are stripped from all Model Numbers to enable simplified searches.

2. **Why are the Type, REF, Cat. No., Part Number, Part No. or P/N used as the Model Number?**

   - Medical device manufacturers are not consistent with the Model Number labelling for their devices and are, in fact, not even consistent across the different product lines they produce. This process defines a standardized method for determining key asset information.

   - If you feel additional information is important, it can be placed in the Model Name field.

3. **What is Unique Device Identifier (UDI) I've heard about?** (GUIDID)

   - The FDA has legislated manufacturers to develop a UDI number that is specific to the Manufacturer and identifies the Model (and other things). This legislation came into effect Sept 2013 and will be fully implemented by Sept 2020. Health Canada recognizes these unique identifiers but does not mandate Manufacturers to comply. This only affects new medical devices to market and will not be applied retroactively to existing, or legacy medical devices.

   - It is anticipated that this will take the "guess work" and decision making out of the process as the key asset information will be better defined.

   - The DBM team is currently preparing for this change in workflow and will be amending this document as required.

4. **Can the Model Number be determined from a copy of the Purchase Order (PO) from the purchase of the device?**

   No, the PO cannot be used. Generally there are 2 concerns when using the information from the PO. The first being that the catalogue number transcribed from the PO may not be labeled on the medical device. Secondly the method by which the purchasing agent determines the information on a PO is unknown and may not correlate well with the BCBME process to keep data clean.