Implementing an AEM Program in HEMS Enterprise

EQ2 LLC

Website: https://www.eq2llc.com

Tel: 888-312-4367 (HEMS)

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INTRODUCTION

Regulatory Compliance

With respect to regulatory compliance, the rules became stricter during the last several years as concerns were raised by medical device manufacturers. Because of these changes preventive maintenance requirements centered around manufacturer's recommended procedures, and these procedures placed additional demands on both human and capital resources of the clinical engineering departments. Regrettably, these increases of departmental resources came at a time when hospital budgets have been reduced due to external pressures on the healthcare industry.

In the past, many HTM departments utilized risk-based PM to alleviate the burden of this workload. Further, most clinical engineers used this opportunity to perform tasks on equipment that they regarded as needing more attention while saving time on the devices they determined not to present a risk to patient safety. In fact, many of devices with a low risk score did not have a manufacturer's based preventive maintenance procedure to begin with or only required an operational check which the device's user performed prior to patient use. Using sophisticated algorithms, the CMMS (computerized maintenance management system) performed the device stratification for risk-based PM and the reasoning for PM exclusion was easy to demonstrate to regulatory inspectors or the environment of care committee.

Due to recent changes, screening devices based on risk alone is no longer permitted. Further, all patient care devices need to be inspected 100 percent of the time regardless of the devices risk score, and this created a pain point for many HTM departments. Most departments were unable to expand their human resources and an expansion will need to be demonstrated to your administrative team. Fortunately, another exception was created which would allow HTM departments to reduce some of their workload: AEM (Alternative Equipment Maintenance/Management).

Alternative Equipment Management/Maintenance (AEM)

Of course, implementing an AEM program is not as easy as it first appears, since it has many rules and restrictions. Indeed, the exceptions are one of the easier aspects of an AEM program. For instance, medical device lasers, imaging devices, and radiologic devices are all prohibited from being on an AEM program. Thus, these medical device categories must have the manufacturers PM performed on them always and a 100 percent completion rate. In

addition to the three taboo device types, HTM is not allowed to place medical devices that are new to them on an AEM program without a sufficient history (PM history or device years). Moreover, devices that are new to them are defined as equipment types that are new to the organization and not just another manufacturer's infusion pump. In determining sufficient history, HTM departments can set a policy as to a required amount of PM history or a set level of device years. For example, if you have 5 equivalent devices for 8 years, you have 40 device years for that device type. If your policy states device years of 35, this type is eligible for your AEM program. Likewise, you may specify a PM history of 6 PMs before a device is placed into an AEM program. Other factors include setting a specified limit on failure rate (< 2%) and/or having backup devices available for use (> 5). Furthermore, these devices must be maintained at 100 percent compliance always.

To implement an AEM program at your facility, the HTM leadership must develop a clearly written plan in their department policies, and these policies will be presented to regulatory agencies when requested. Equally, your AEM program must not reduce the risk to patient safety as you modify your PM procedures. For instance, you may increase the interval between inspections (every 2 years versus annually), but you will perform the manufacture's steps completely during the 2-year inspection interval. On the other hand, you may choose to modify a step to inspect a component and replace if necessary, as opposed to replacement only method on a PM task. Likewise, your history might determine that you want to perform a unique additional step to the manufacturer's PM procedure that will improve patient safety and reduce the failure rate. Again, implementing an AEM program requires additional work and planning along with a continual monitoring of the program: monthly, quarterly, etc.

With your AEM policies in place, you can begin to evaluate which equipment types you are going to place into your AEM program. Knowing the rules of AEM, you can easily eliminate the taboo devices from the inventory along with unfamiliar device types that are new to you or your organization. But what about high risk medical devices that are not on the taboo list and you have a documented history? According to the rules, you may place these device types onto an AEM program, but you must not lower patient safety and you must complete these PMs at a 100 percent rate all the time. Nevertheless, do you want to assume the risk of deviating from the manufacturer's procedure? In my opinion, high risk medical devices should also be taboo equipment and high-risk medical devices should not be placed on an AEM program. Even with these exclusions, there are many device types that can be placed into an AEM program and these devices are normally found in large quantities such as vital signs monitors.

Now we have a better understanding of which medical device types that we'll consider for our AEM program. Likewise, you must develop a process to review the eligibility of the devices that you place on the AEM program. For many HTM departments, the tool of choice will be their CMMS, so they can review the documented PM failures and failure rate of devices placed on the program. Also, they can begin to document a medical device history for those new equipment types that were added to the CMMS over the years. Of course, more robust CMMS systems, like EQ2's HEMS Enterprise, incorporate an AEM dashboard or tool that can automate the process for both determining device type eligibility and continued candidacy. In short, implementing an AEM program will require a continued assessment of the program to ensure that patient safety has not been jeopardized or equipment failure rate and downtime increased.

Which PM procedures are you going to use in your AEM program? We know that the manufacture's procedures are the gold standard, and they can easily be used as for your task steps with a modified PM frequency. For instance, changing your vehicles oil every 6000 miles as opposed to every 3000 miles. In either case, you perform the same PM tasks, but augment the frequency at which the PM tasks are performed. Other organizations supply PM procedures (ECRI and ASHE), but they won't authorize their procedures for AEM use. However, this does not prevent you from using these alternative procedures for your PM program, but you will need to document and prove that your use of these alternative procedures did not reduce patient safety. No doubt, there is a managerial effort required to implement a successful AEM program.

Data Standardization

Data standardization in your CMMS is vital for a well-managed regulatory compliance and AEM program. It's imperative that device types be standardized to ensure that the PM procedures, risk scores, and device recalls are successfully accomplished. For example, if two similar device types are named differently in the CMMS, you will miss one or the other during comparison for equipment replacement or moving devices into an AEM program. Furthermore, your CMMS may contain specialized reports or dashboards that rely on data fields to stratify your equipment inventory.

To maintain standardization, many departments limit the number of users that can add key data elements such as device type, equipment class or system, vendor, and model numbers. These fields drive many different reports in CMMS programs, and they are used for device recalls or for equipment replacement planning. Furthermore, all your data elements need to

be standardized for proper reporting on all metrics within the CMMS. For example, using proper coding on work orders to track PM failures or devices in use which will be used for your AEM and regulatory compliance monitoring. Thus, many HTM departments identify one individual or a small group or committee before entering new data elements into the CMMS, and this control ensures standardization and proper reporting.

EQ2's AEM Dashboard, part of the Dashboard products, will assist with AEM device eligibility and continuous monitoring.

Looking Ahead

In the end, we see that adhering to our regulatory compliance is essential for both patient safety and minimizing equipment failure rates. Using HEMS Enterprise, we can set the proper intervals and procedures and use the reports or dashboards to monitor our adherence to our department policies that meet the needs of our regulatory agencies: Federal, State, Medicare, JC, or DNV. Additionally, we can use HEMS to move equipment into an AEM program and use reports or dashboards to ensure both program eligibility and regulatory compliance is adhered too as well. Finally, a standardized CMMS (Computerized Maintenance Management System – HEMS) is essential for following your department policies and for proper reporting of your department's KPIs (Key Performance Indicators). Thus, we can gather timely information on these topics at AAMI Exchange and other professional meetings.

AEM IMPLEMENTATION IN HEMS

This section will highlight the modules in HEMS Enterprise that need to be configured for proper AEM implementation.

- Equipment type class and system fields
- PM procedure types
- Proper work order documentation

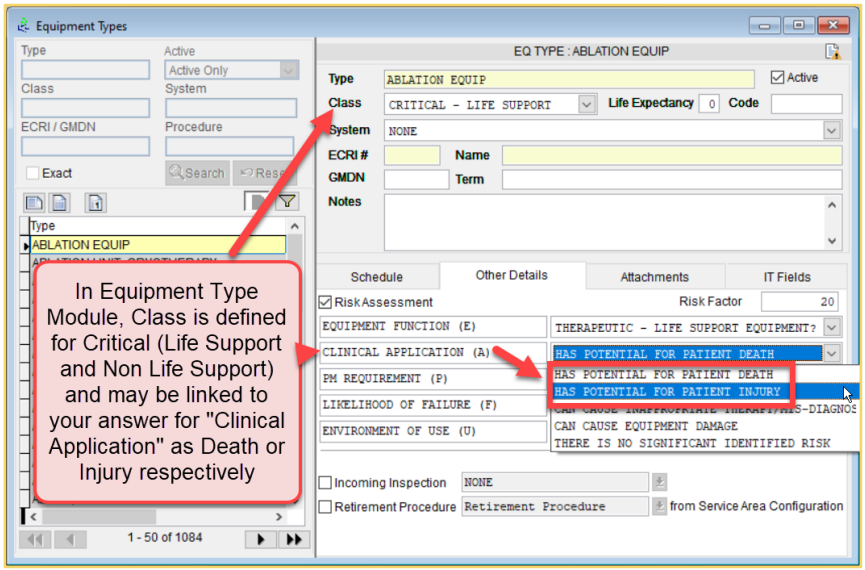
Additionally, your department policies should reflect all decisions in implementing your AEM program and EQ2 does not provide a recommended plan to any client. Chiefly, EQ2's programs provide the client with the framework to implement their department policies when identifying and placing assets on an AEM plan.

After your policies are created and your AEM Dashboard is configured with your policies information, then you can use this Dashboard to identify or recommend equipment that may be eligible for AEM. Of course, this is highly dependent on the accuracy of your equipment inventory in identifying taboo devices, high risk devices, adequate history, failure rates below target, and backup devices to name a few.

HEMS DETERMINANTS

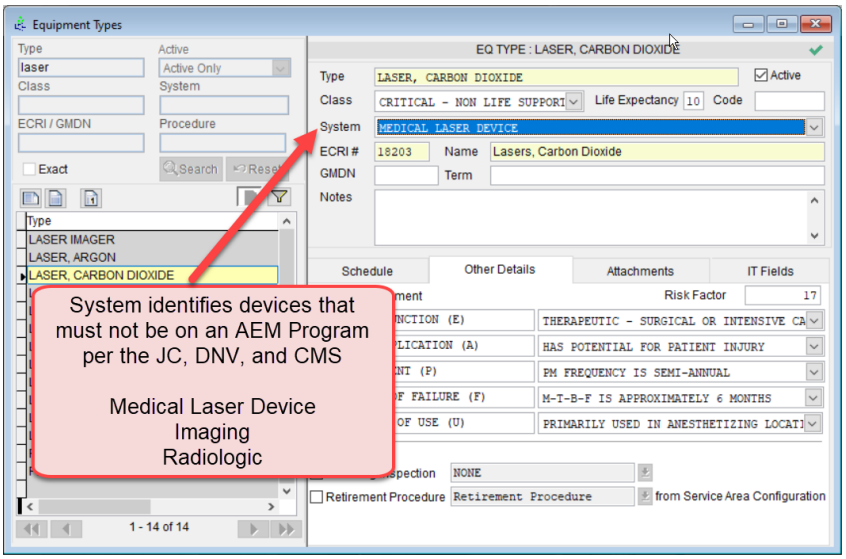
Equipment Class

- Critical – Life Support
- Critical – Non-Life Support
- Both are considered High Risk/Critical devices as defined by JC, DNV, CMS and are not recommended for an AEM program



Equipment System: Devices that should not be on AEM

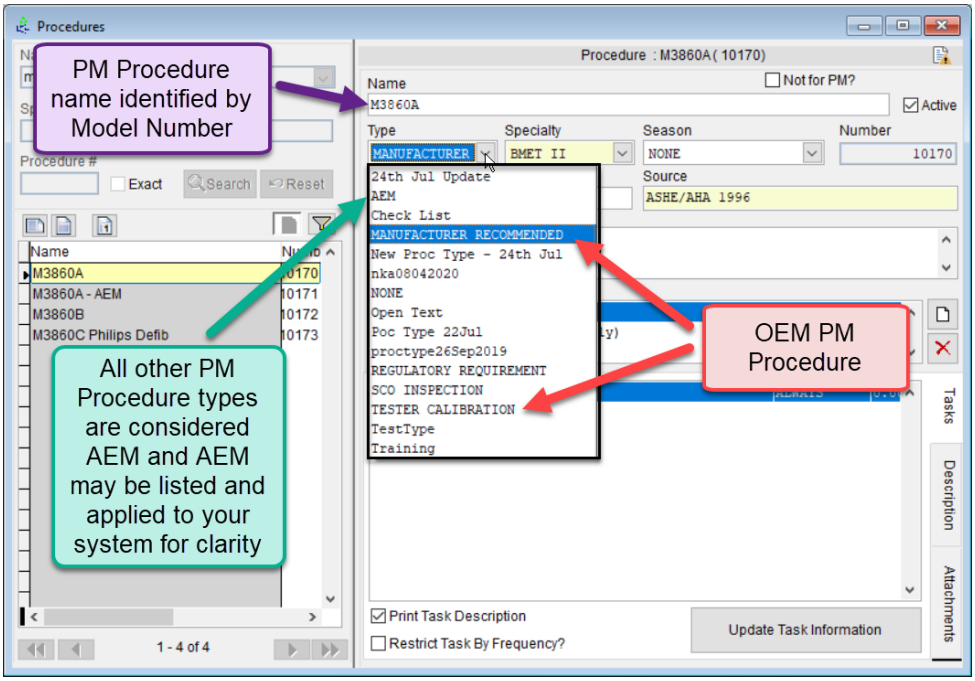
- Medical Laser Device
- Imaging Device
- Radiologic Device



PM Procedure Type

- Manufacturer Recommended
- Tester Calibration
- Both PM procedure types identify a device that is on an OEM program

All other PM procedure types in HEMS Enterprise are classified as being on an AEM program and it's not required to create this type in HEMS but may be useful for your staff and inspectors. Specifically, the equipment inventory dashboard indicates the PM type which is great for inspections.

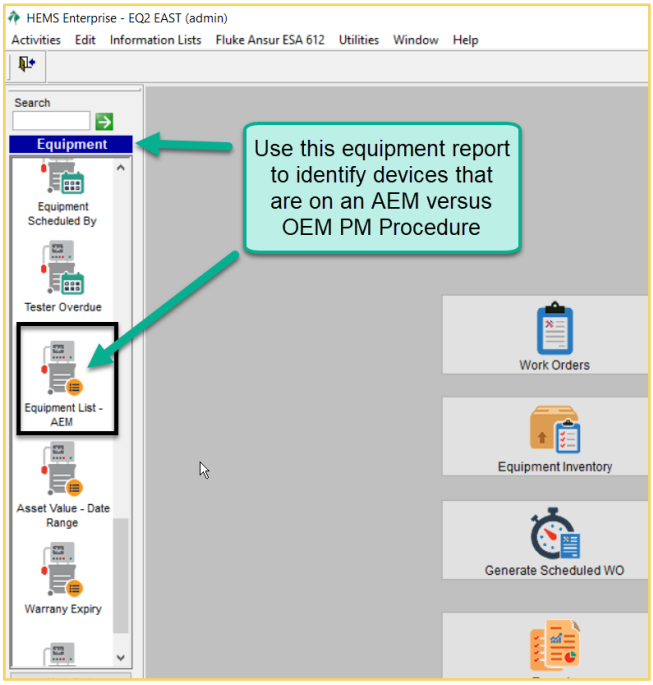


Since the premise of an AEM program is the alteration of the PM procedure whether in specific task description or task or PM frequency, *HEMS will use the PM procedure type as a key identifier for devices on AEM versus OEM*. In fact, the Equipment List – AEM report uses these criteria to identify your equipment inventory on AEM or OEM.

As a best practice, it is recommended to identify all OEM procedures with the model number or manufacturer and model number in the PM procedure name which further identifies an OEM PM procedure. For example, using the procedure names of M3860A or Philips M3860A will identify the procedure as OEM and make it clear as to which assets should be assigned this specific procedure.

Class, System, and PM procedure type must be set for each equipment type in your HEMS inventory for AEM/OEM automation and reporting.

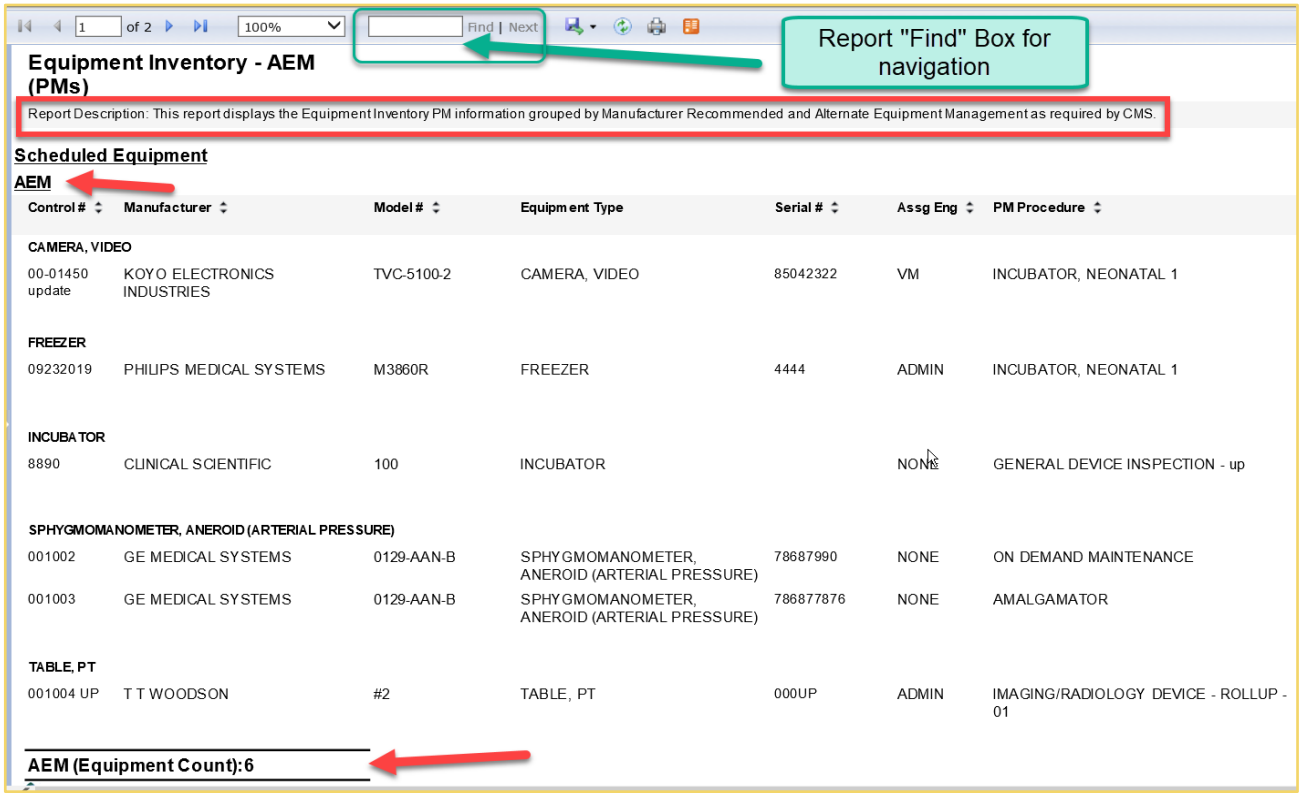
Reporting on AEM versus OEM Inventory in HEMS Enterprise



When an inspector requests a report that identifies assets that are on an AEM versus OEM procedure, you can quickly go to the equipment reports menu and select the "Equipment List-AEM" near the bottom of the list. After clicking the report icon, the report generates without the need to set any filters.

TIP: Using the report find box, you can type "manufacturer" and quickly jump to the assets on OEM.

Report Example

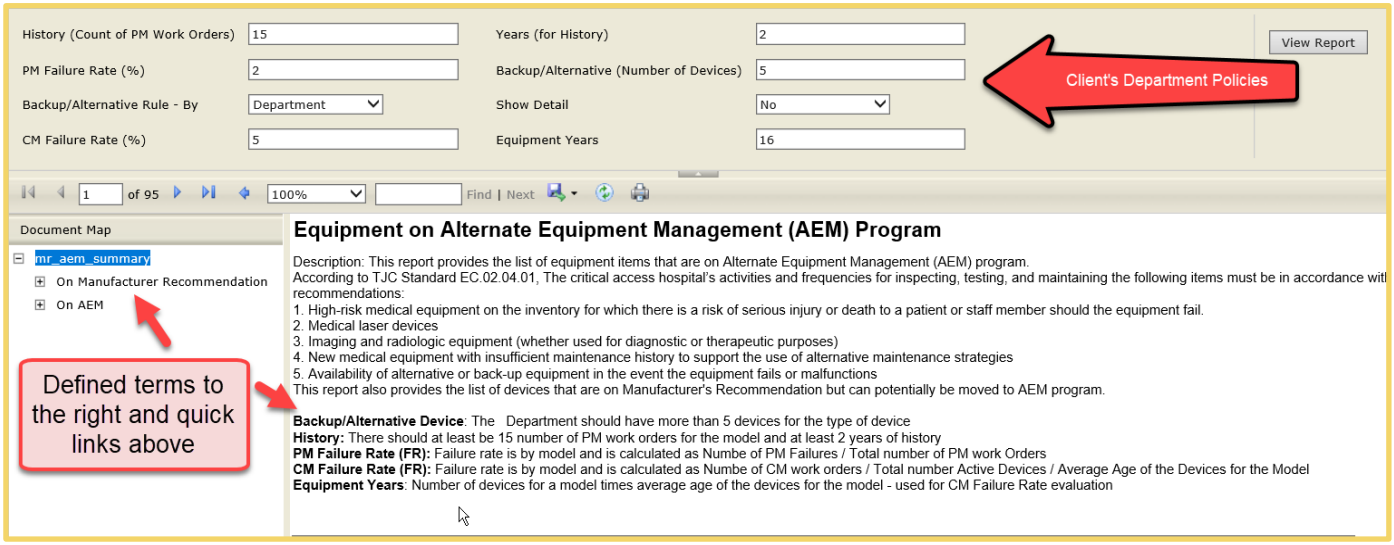


AEM DASHBOARD

Dashboard Configuration: Your AEM Policies

The client will present their metrics from their department policies and EQ2 will program the values into your AEM Dashboard. Using the values and your class, system, and PM procedure type values entered, the report can suggest devices that warrant being on an AEM program and identify devices that should not be on an AEM program.

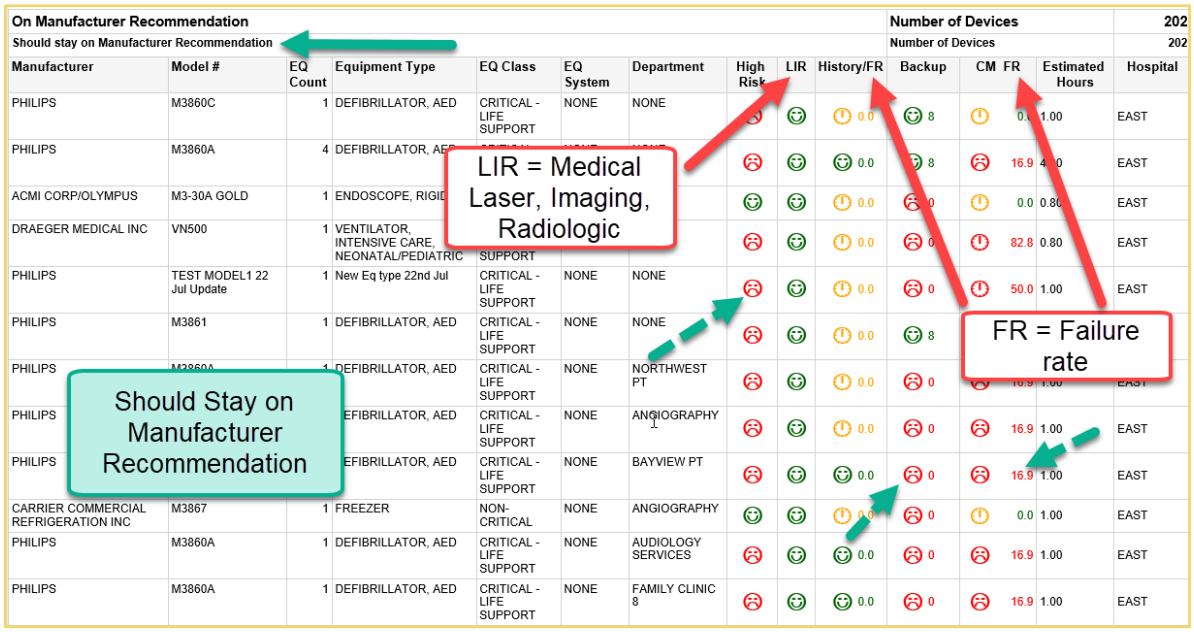
As time moves forward, previously eligible devices may no longer be eligible due to high failure rates or lack of backup devices. Therefore, this dashboard will assist the manager in both identifying eligible devices for AEM and assist with the continuous monitoring required by CMS, JC, and DNV.



With your department's policy metrics entered into the report, the AEM dashboard will be able to screen eligible candidates and be used to perform routine follow-up on AEM assets in your inventory. For convenience, the dashboard will use a red frown face where a device is not recommended for AEM and a green smiley face for eligible assets based on your inventory settings and AEM criteria. Further, yellow icons will indicate borderline assets. Finally, failure rate calculations will appear in the history field for both PM and CM failure rates.

Should Stay on Manufacturer Recommendation

This is the default first page and it indicates all the assets that should remain on the manufacturer's recommendation OEM program. Therefore, no filtering is required for this view and there is a sub-link, "Should Stay on Manufacturer Recommendation", to return to this view.

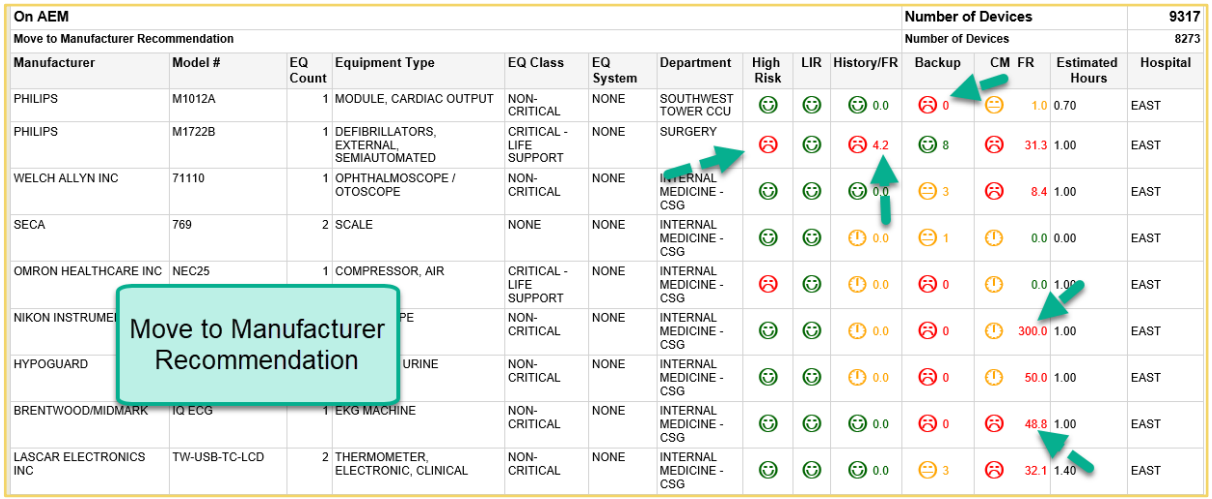


On Manufacturer Recommendation — Number of Devices: 202
Should stay on Manufacturer Recommendation — Number of Devices: 202

Manufacturer	Model #	EQ Count	Equipment Type	EQ Class	EQ System	Department	High Risk	LIR	History/FR	Backup	CM FR	Estimated Hours	Hospital
PHILIPS	M3860C	1	DEFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	NONE			0.0	8		1.00	EAST
PHILIPS	M3860A	4	DEFIBRILLATOR, AED						0.0	8	16.9	1.00	EAST
ACMI CORP/OLYMPUS	M3-30A GOLD	1	ENDOSCOPE, RIGID						0.0		0.0	0.80	EAST
DRAEGER MEDICAL INC	VN500	1	VENTILATOR, INTENSIVE CARE, NEONATAL/PEDIATRIC		SUPPORT				0.0	0	82.8	0.80	EAST
PHILIPS	TEST MODEL1 22 Jul Update	1	New Eq type 22nd Jul	CRITICAL - LIFE SUPPORT	NONE	NONE			0.0	0	50.0	1.00	EAST
PHILIPS	M3861	1	DEFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	NONE			0.0	8			
PHILIPS		1	DEFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	NORTHWEST PT			0.0	0			EAST
PHILIPS			EFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	ANGIOGRAPHY			0.0	0	16.9	1.00	EAST
PHILIPS			EFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	BAYVIEW PT			0.0	0	16.9	1.00	EAST
CARRIER COMMERCIAL REFRIGERATION INC	M3867	1	FREEZER	NON-CRITICAL	NONE	ANGIOGRAPHY			0.0	0	0.0	1.00	EAST
PHILIPS	M3860A	1	DEFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	AUDIOLOGY SERVICES			0.0	0	16.9	1.00	EAST
PHILIPS	M3860A	1	DEFIBRILLATOR, AED	CRITICAL - LIFE SUPPORT	NONE	FAMILY CLINIC 8			0.0	0	16.9	1.00	EAST

Should Move from AEM to Manufacturer Recommendation

This view is obtained by filtering using the "On AEM" link and "Move to Manufacturer Recommendation" sub-link by expanding the "+". If devices were previously on AEM, a parameter may have changed requiring the move back to OEM. [No backups or increased failure rate]



On AEM — Number of Devices: 9317
Move to Manufacturer Recommendation — Number of Devices: 8273

Manufacturer	Model #	EQ Count	Equipment Type	EQ Class	EQ System	Department	High Risk	LIR	History/FR	Backup	CM FR	Estimated Hours	Hospital
PHILIPS	M1012A	1	MODULE, CARDIAC OUTPUT	NON-CRITICAL	NONE	SOUTHWEST TOWER CCU			0.0	0	1.0	0.70	EAST
PHILIPS	M1722B	1	DEFIBRILLATORS, EXTERNAL, SEMIAUTOMATED	CRITICAL - LIFE SUPPORT	NONE	SURGERY			4.2	8	31.3	1.00	EAST
WELCH ALLYN INC	71110	1	OPHTHALMOSCOPE / OTOSCOPE	NON-CRITICAL	NONE	INTERNAL MEDICINE - CSG			0.0	3	8.4	1.00	EAST
SECA	769	2	SCALE	NONE	NONE	INTERNAL MEDICINE - CSG			0.0	1	0.0	0.00	EAST
OMRON HEALTHCARE INC	NEC25	1	COMPRESSOR, AIR	CRITICAL - LIFE SUPPORT	NONE	INTERNAL MEDICINE - CSG			0.0	0	0.0	1.00	EAST
NIKON INSTRUMEI			PE	NON-CRITICAL	NONE	INTERNAL MEDICINE - CSG			0.0	0	300.0	1.00	EAST
HYPOGUARD			URINE	NON-CRITICAL	NONE	INTERNAL MEDICINE - CSG			0.0	0	50.0	1.00	EAST
BRENTWOOD/MIDMARK	IQ ECG	1	EKG MACHINE	NON-CRITICAL	NONE	INTERNAL MEDICINE - CSG			0.0	0	48.8	1.00	EAST
LASCAR ELECTRONICS INC	TW-USB-TC-LCD	2	THERMOMETER, ELECTRONIC, CLINICAL	NON-CRITICAL	NONE	INTERNAL MEDICINE - CSG			0.0	3	32.1	1.40	EAST

Above, some high-risk devices are on AEM along with devices with a high failure rate (%Failure indicated), lack of CM (corrective maintenance) history or backup devices. Using the report, you can always monitor your devices for AEM eligibility.

Devices That Can Remain on AEM

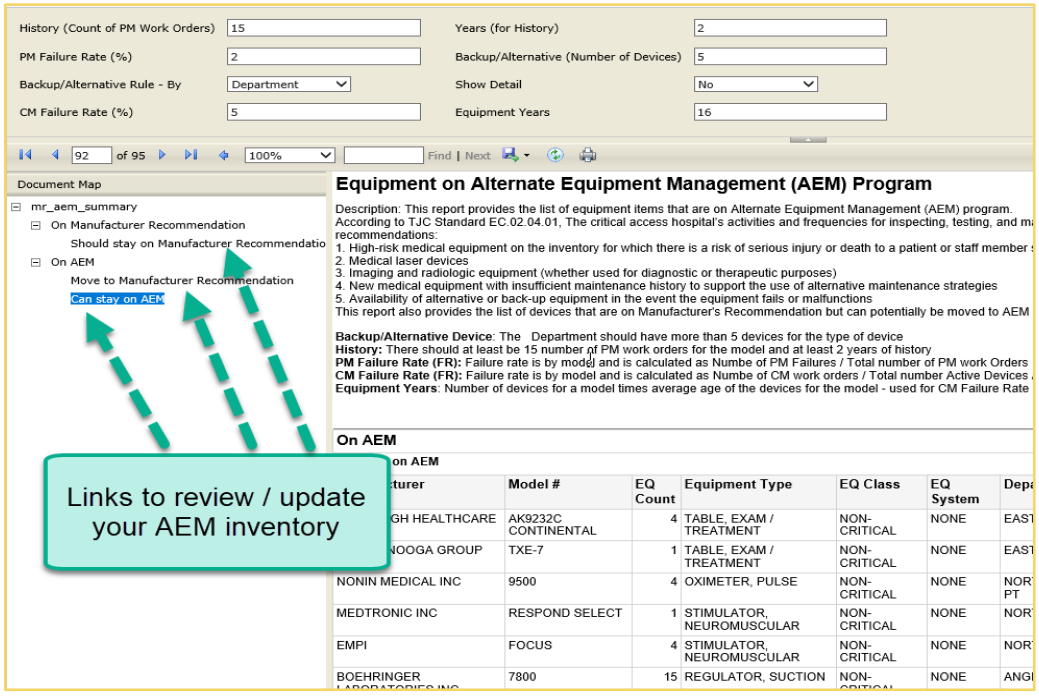
This view is obtained by filtering using the “On AEM” link and “Can Stay on AEM” sub-link by expanding the “+”.

On AEM										Number of Devices			9317
Can stay on AEM										Number of Devices			1044
Manufacturer	Model #	EQ Count	Equipment Type	EQ Class	EQ System	Department	High Risk	LIR	History/FR	Backup	CM FR	Estimated Hours	Hospital
HUNTLEIGH HEALTHCARE INC	AK9232C CONTINENTAL	4	TABLE, EXAM / TREATMENT	NON-CRITICAL	NONE	EAST PT			0.0	5	0.0	0.00	EAST
CHATTANOOGA GROUP	TXE-7	1	TABLE, EXAM / TREATMENT	NON-CRITICAL	NONE	EAST PT			0.0	5	0.0	0.00	EAST
NONIN MEDICAL INC	9500	4	OXIMETER, PULSE	NON-CRITICAL	NONE	NORTHWEST PT			0.0	12	3.6	4.00	EAST
MEDTRONIC INC	RESPOND SELECT	1	STIMULATOR, NEUROMUSCULAR	NON-CRITICAL	NONE	NORTH PT			0.0	5	0.0	0.80	EAST
EMPI	FOCUS	4	STIMULATOR, NEUROMUSCULAR	NON-CRITICAL	NONE	NORTH PT			0.0	5	0.0	2.40	EAST
BOEHRINGER LABORATORIES INC	7800	15	REGULATOR, SUCTION	NON-CRITICAL	NONE	ANGIOGRAPHY			0.0	14	1.8	0.00	EAST
HUNTLEIGH HEALTHCARE INC	D900	6	DOPPLER, BLOOD FLOW	NON-CRITICAL	NONE	ANGIOGRAPHY			0.0	9	4.6	6.00	EAST
DYNATECH NEVADA INC	177	4	TESTER, DMM	NON-CRITICAL	NONE	CLINICAL ENGINEERING			0.0	12	0.0	4.00	EAST
RAULAND-BORG CORP	NCBBK	12	NURSE CALL SYSTEM	NON-CRITICAL	NONE	CLINICAL ENGINEERING			0.0	18	1.1	12.00	EAST
MEDTRONIC		1	TESTER	NON-CRITICAL	TESTER	CLINICAL ENGINEERING			0.0	10	2.8	1.00	EAST
FLUKE BIOM		2	TESTER	NON-CRITICAL	TESTER	CLINICAL ENGINEERING			0.0	10	0.0	2.00	EAST
FLUKE BIOMEDICAL	35050AT	2	TESTER	NON-CRITICAL	TESTER	CLINICAL ENGINEERING			0.0	10	4.5	2.00	EAST
WAVETEK	SAM JR.	1	POWER METER	NON-CRITICAL	NONE	CLINICAL ENGINEERING			0.0	7	3.2	0.00	EAST
DYNATECH NEVADA INC	8060A	1	TESTER, DMM	NON-CRITICAL	NONE	CLINICAL ENGINEERING			0.0	12	0.0	1.00	EAST
EXTECH INSTRUMENTS CORP	407727	2	POWER METER	NON-CRITICAL	NONE	CLINICAL ENGINEERING			0.0	7	0.0	2.00	EAST

Can stay on AEM

Above, all devices are either a green smiley or yellow smiley/clock indicating an eligible asset for AEM. As always, a manager’s review and AEM selection should be considered the ultimate authority in the AEM program selection using the report as a screening tool.

AEM Dashboard Navigation



Final Thoughts

Using an AEM program may reduce your preventive maintenance workload allowing you to redirect the recovered labor hours for more thorough critical device PMs or for cybersecurity needs. In all cases, your AEM program must not reduce patient safety or equipment uptime and an AEM program requires complete documentation.

As shown, the AEM Dashboard provides a powerful tool to assist the manager when determining devices that are eligible for AEM and it provides the ability to continually monitor a device's eligibility for AEM. For more information on the AEM Dashboard, contact EQ2 Sales for pricing and the AEM Dashboard comes with the BI Dashboard (Business Intelligence).

Finally, for both the HEMS reports and/or AEM Dashboard to operate properly, your data must define the necessary attributes to your equipment types: Class (High versus Non-High Risk), System (Medical Laser, Imaging, and Radiologic devices), and PM procedure type (Manufacturer Recommended or Tester Calibration). Without the attributes, the dashboard will not be able to differentiate your equipment types/models. Of course, your PM procedure type will help with the AEM/OEM determination for the report and HEMS will use your actual device history, failure rates, and equipment counts from your inventory along with work order data. Most importantly, with your data properly setup in your system, HEMS and the AEM Dashboard will simplify your implementation and continued monitoring of your AEM program.