

# Memorandum

Date: 4 April 2013  
To: All PMBE Staff  
From: Michael Cusack, PBME Equipment Management Committee  
Subject: AED Risk Classification Change – High Risk to Life Support (WO 1754549)

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The risk classification for all models of automatic external defibrillators (device type DEFIB, AED ONLY) has been changed from High Risk to Life Support, effective immediately.

The Equipment Management Committee (EMC) is enacting the change based on a Standards FAQ published by the Joint Commission, where it specified that “defibrillation is a response to life-threatening cardiac arrhythmias,” and, therefore “the Joint Commission considers defibrillators life support equipment.” The FAQ answer specifically included AEDs in its discussion of appropriate maintenance strategies for defibrillators.

This updates the EMC’s initial assessment of AEDs as non-Life Support devices when that category was introduced by the Joint Commission in 2005, since the available information at that time suggested that the *pacing* functionality in some manual defibrillators qualified them as Life Support devices.

This risk class change applies to all AEDs models and manufacturers, and applies to BWH, DFCI, MGH, and NSMC.

<b>Manufacturer</b>	<b>Model</b>	<b>Notes</b>
CARDIAC SCIENCE INC (67592)	9200RD	one device, Retired
CARDIAC SCIENCE INC (67592)	9300E-101	one device, Missing
CARDIAC SCIENCE INC (67592)	POWERHEART AED G3	
PHILIPS MEDICAL SYSTEMS	HEARTSTART FRX	
PHILIPS MEDICAL SYSTEMS	HS-1	NSPG/Salem only
PHILIPS MEDICAL SYSTEMS	M3860A FR2+ HEARTSTART	
PHYSIO CONTROL CORP	LP 500	
SURVIVALINK CORP	9210 FIRSTSAVE	all Missing or Retired
SURVIVALINK CORP	9210D	one device, Retired
WELCH ALLYN/ PROTOCOL INC	AED 10	
WELCH ALLYN/ PROTOCOL INC	AED 20	all Retired
ZOLL MEDICAL CORP	AED 20	
ZOLL MEDICAL CORP	AED PLUS	
ZOLL MEDICAL CORP	AED PRO	

Please direct any questions to Michael Cusack.

Approval dates

PBME EMC:	12/3/2012
BWH MEMC:	n/a
MGH MEMC:	n/a

Additional information on is located at:

L:\DBEMAIN\Equipment\Equipment Management\PBME EMC\Topics\2012.05 AEDs - Risk Class and WDT

Topic 2012.05 / WO 1754549

Attachments:

- The Joint Commission – Standards FAQ Details (1 pg.)
- MGH Medical Equipment Management Committee: Management of Life-Support Equipment, February 16, 2005 (2 pgs.)
- AED Inventory by Manufacturer, Model, Institution, and Status (2 January 2013) (1 pg.)

## The Joint Commission – Standards FAQ Details

Environment of Care (CAMH / Hospitals)

Defibrillators – Life Support or Non-life Support Equipment

Current | June 15, 2009

### **Q. Are defibrillators considered life support equipment?**

A. The following definition appears in the glossary of the Comprehensive Accreditation Manual:

Life Support Equipment: Any device used for the purpose of sustaining life and whose failure to perform its primary function, when used according to manufacturer's instructions and clinical protocol, will lead to patient death in the absence of immediate intervention (examples include ventilators, heart-lung bypass machines).

Defibrillation is a response to life-threatening cardiac arrhythmias, ventricular fibrillation and ventricular tachycardia. Defibrillation consists of delivering a therapeutic dose of electricity to the affected heart with a defibrillator. The dose of electricity restores a normal heart rhythm, allowing the heart to continue to function in the patient. Therefore, the Joint Commission considers defibrillators life support equipment.

As it is required that organizations maintain an inventory of all medical equipment or selected medical equipment categorized by physical risk associated with use (including all life support equipment), defibrillators must be included in an organization's medical equipment inventory.

Maintenance activities then must be identified for equipment on the inventory. A maintenance strategy for defibrillators could include a range of activities from a visual inspection of the single-use AED (automatic external defibrillator) to the daily testing of a defibrillator in clinical use settings based on organization policy.

[http://www.jointcommission.org/mobile/standards\\_information/jcfaqdetails.aspx?StandardsFAQId=52&StandardsFAQChapterId=64](http://www.jointcommission.org/mobile/standards_information/jcfaqdetails.aspx?StandardsFAQId=52&StandardsFAQChapterId=64)  
accessed 2 January 2013

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**JCAHO Environment of Care Standard EC.6.20**

Medical Equipment is maintained, tested, and inspected.

Beginning 2004 JCAHO revised its accreditation process “Shared Visions – New Pathways.”

- Medical equipment and the requirements for documenting maintenance will now be divided into two categories: Life-support equipment and Non-life-support equipment.
- Revision of its overall scoring system using Elements of Performance for each standard.

**Element of Performance (EP) 3:** Type A (Yes/No for compliance)

The hospital documents inspection and maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (EC.6.10)

**Purpose:** To ensure that life-support equipment receives a high priority in the equipment maintenance program.

**Implementation Plan:**

1. Define and document a category of life-support equipment
  - a. Adopting the JCAHO suggested definition (review 9/30/04 and 10/21/04)
  - b. Update MEMP and confirm with MEMC at BWH (done Dec. 2004) and MGH

Definition of Life-Support Equipment (JCAHO suggested definition for life-support equipment, CAMH 2005):

*“Devices intended to sustain life and whose failure to perform its primary function, when used according to the manufacturer’s instructions and clinical protocol, is expected to result in imminent death in the absence of immediate intervention.”*

2. Identify all Life-Support Equipment and ensure inclusion in the equipment inventory
  - a. List approved by PBME EMC 10/21/04

<b>Life-Support Device</b>	<b>DTMG</b>
Anesthesia Machines	Biomedical Engineering
Anesthesia Ventilators	Biomedical Engineering
Bypass Machines (Heart-lung, Liver)	Biomedical Engineering
Defibrillators with Pacing	Biomedical Engineering
ECMO	Respiratory Care
Intra-aortic Balloon Pumps	Biomedical Engineering
Pacemakers, External	Biomedical Engineering
Ventilators	Respiratory Care
Ventricular Assist Devices (LVAD, Bi-VAD)	Biomedical Engineering

- b. Defibrillators without pacing, e.g. AED only defibrillators, were excluded.
- c. New Risk Class Created: Life Support
- d. Confirm Inventory

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3. Define strategies for the maintenance of this equipment
  - a. Goal = 100% compliance
  - b. Top Priority
  - c. SM Interval = 6 months unless a documented analysis indicates otherwise
  - d. Monitoring: Monthly compliance report
  - e. Collaborative effort to locate and access equipment (DTMG, Nursing, etc.), review reports, educate staff.
  - f. Identification of back-up (spare) equipment
  
4. Document compliance
  - a. What is required? EC.6.20 EP 3 is a Type A Element of Performance
  - b. Create new Report (Risk Class = Life Support)
  - c. Begin monitoring compliance January 2005
  - d. Compliance reviewed at monthly PBME EMC meetings
  
5. Document a corrective action plan and actions taken for any deficiencies

Reasons for non-compliance	Corrective Action Plan
Equipment inaccessible (i.e., in use)	DTMG Notifies unit leadership
Unable to locate Equipment	Change status to "Missing" if criteria per policy are met
Equipment out for repair or awaiting parts	Device will have an open work order; maintenance will be performed upon completion of repair
Resource Limitations	

*Plan reviewed by PBME EMC 1/20/2005.*

**Next Steps:**

- Confirm with MEMC
- Update the MEMP
- Educate staff – DTMG's and Users

AED Inventory by Manufacturer, Model, Institution, and Status (2 January 2013)

	BWH				DFCI		Awaiting receipt	MGH			NSPG	SALEM			SKRH	UNION	Total
	In stock	In use	Missing	Retired	In use	Retired		In use	Missing	Retired	In use	In use	Retired	In use	In use		
<u>CARDIAC SCIENCE INC (67592)</u>	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
9200RD											1						1
9300E-101									1								1
POWERHEART AED G3								2		3							5
<u>PHILIPS MEDICAL SYSTEMS</u>	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
HEARTSTART FRX							1	45	1	3	2	1				1	54
HS-1											15	4					19
M3860A FR2+ HEARTSTART								56		8		10	3				77
<u>PHYSIO CONTROL CORP</u>	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
LP 500								1					1	4	1		7
<u>SURVIVALINK CORP</u>	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
9210 FIRSTSAVE									1	5							6
9210D										1							1
<u>WELCH ALLYN/ PROTOCOL INC</u>	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
AED 10								1									1
AED 20										1			1				2
<u>ZOLL MEDICAL CORP</u>	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
AED 20								1									1
AED PLUS	1	94	2	4	14	9		1									125
AED PRO					1												1
Total	1	94	2	4	15	9	1	107	3	22	17	15	5	4	2		323