System Medical Advisory November 21, 2017
Automated External Defibrillation (AED):
Revised Specifications

Automated external defibrillators (AEDs) are classified by the U.S. Food and Drug Administration (FDA) as restricted devices and require labeling stating these devices are restricted "to use by or on the order of a physician." Medical devices such as AEDs generally require a physician serving as the medical director or medical oversight for the person or organization purchasing and/or operating the devices in order to achieve compliance with FDA rules regarding the sale and use of these restricted devices.
Recently, Philips' (a major U.S. manufacturer of AEDs) North American Emergency Care & Resuscitation business operations reached agreement with the US Department of Justice and the Food and Drug Administration related to compliance with manufacturing quality requirements. This agreement resulted in suspension of AED manufacturing at specific facilities and limits distribution of specific AEDs (and accessories) within the U.S. This is not a recall of Philips AEDs.

The impact of this change along with recent Philips FR3 AED performance concerns experienced by the Austin Fire Department and FRx concerns experienced by a small number of City of Austin Public Access Defibrillation programs caused the OMD to reevaluate the AED approval process. Please note that all AEDs currently in use under the Medical Direction and/or Medical Oversight of the OMD remain approved for use though the Philips FR3 and FRx models are no longer approved for future purchase. We continue to advise organizations to plan for replacement of older model AEDs such as the Philips FR1 and FR2 AEDs since these devices are rapidly approaching the end of their useful life and are nearing (or have reached) the end of their support from the manufacturer.

Our reevaluation has resulted in the OMD no longer approving specific AED models. Instead, the OMD is now providing very specific design, feature and configuration requirements for AEDs and/or AED Systems. These specifications provide EMS System agencies with additional options for meeting the specific design requirements. Please review the requirements prior to purchasing AEDs in order to maintain AED purchase/use authorization from the OMD. These requirements are effective immediately. The revised AED specifications are attached and; also available on the OMD web page. Should you have any questions regarding these AED specifications, please contact the OMD.

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Automated External Defibrillation (AED)
Selection & Purchasing Requirements (11.20.2017)

Automated external defibrillators (AEDs) are classified by the U.S. Food and Drug Administration (FDA) as restricted devices and require labeling stating these devices are restricted "to use by or on the order of a physician." Devices such as AEDs generally require a physician serving as the medical director or medical oversight for the person purchasing and/or operating the devices in order to achieve compliance with FDA rules regarding the sale and use of these restricted devices.

This document outlines current specifications and requirements for the purchase and use of AEDs under the direction or oversight of the Medical Director for the Austin-Travis County EMS System and Medical Director for Public Access Defibrillation (PAD) Programs within the City of Austin and Travis County.

Public Safety - Specifications for AEDs Utilized by First-Line Response Apparatus

First-line response apparatus are defined as those public safety units (e.g., ambulance, fire apparatus, motorcycle, special response unit, park ranger, etc.) that are dispatched as part of an initial 9-1-1 response for suspected cardiac arrest patients (excludes special event response). For this reason, these AED specifications are greater than those for other response units not typically assigned to cardiac arrest responses.

The City of Austin Medical Director may at any time withdraw his/her authorization for purchase or use of a specific AED model when the device has demonstrated performance which in the opinion of the Medical Director may harm or adversely affect cardiac arrest patients or System providers. Approved AED models meet all of the following specifications:

The specific AED model is:

1. FDA approved at the time of selection and purchase.
2. Not currently the subject of a manufacturer or FDA voluntary or mandatory recall.
3. Not currently restricted from purchase by the current Medical Director due to safety or performance concerns.
4. Capable of treating both adult patients and pediatric patients using appropriate energy doses (neonatal dosing is not required).
5. Capable of performing self-tests and providing audible & visual notification when operator attention is needed as well as notification when the device is ready for use.
6. Capable of storing AED event data.
7. Capable of user retrieval of data for user defined post event review and analysis
8. Capable of storing and allowing user initiated transfer of the following data -
    a. All user input and user/device actions including date/time stamp for each
    b. Continuous ECG while powered on
    c. Device feedback including rate and depth prompting

    d. Device errors and identified non-ideal conditions (e.g. artifact, interference)
9. Intended for use, per the manufacturer, for the public safety first response environment
10. Capable of providing both audible and visual prompting cues for device operation.
11. Capable of automatic rhythm analysis at specified time intervals
    a. If automatic shock delivery is available this setting must be user configurable to be turned off.
12. Capable of monitoring and providing immediate (within approximately 10 seconds) audible and/or visual feedback for compression depth and rate consistent with current CPR guidelines.
    a. Feedback for compression rate must include both rates above and below the guideline recommended rate range.
    b. Feedback for compression depth must include depth below the guideline recommended minimum depth.
13. Immediate rate and depth feedback must be provided by either:
    a. the AED alone, or
    b. a combination of the AED and a separate FDA approved feedback device.
14. Capable of user configuration for
    a. shock energy, intervals and sequencing settings,
    b. CPR first vs. Shock first,
    c. CPR interval,
    d. return to CPR prompt following shock delivery,
    e. ECG display on/off (if capability exists),
    f. date/time,
    g. device prompt complexity (if multiple levels are available), and
    h. breathing prompt interval (if this prompt is available).

    NOTE: If the AED is NOT capable of configuration as noted above, an AED manufacturer's default configuration must be approved by the OMD to satisfy this user configuration specification.

15. Designed for use with defibrillation pads capable of both sternum-apex and anterior-posterior placement.
16. Configured per the OMD

Additional requirements for AED selection and purchase include:

17. Software required for user configuration of the AED (if applicable) must be included and provided to both the purchasing agency and the OMD.
18. Peripheral hardware (e.g., cable, infrared reader) required for user configuration of the AED (if applicable) must be specifically identified to the purchasing agency and OMD during the selection process.
19. Software required for user transfer of AED data must be included and provided to both the purchasing agency and the OMD.
20. Peripheral hardware (e.g., cable, infrared reader, digital data storage device) required for user transfer of stored data must be specifically identified to the purchasing agency and OMD during the selection process.
21. Software required for post event review of AED data must be included and provided to both the purchasing agency and the OMD.

Additional Suggested and Approved Specifications for AEDs Utilized by First-Line Response Apparatus

22. Configuration settings include volume levels and prompt detail selections.
23. Compression feedback includes immediate feedback for depth exceeding the guideline recommendations.
24. Compression feedback includes immediate feedback for release/recoil consistent with current guidelines for CPR.

Public Safety - Specifications for AEDs Utilized by Other Non-First-Line Response Apparatus

AEDs for these types of response apparatus are slightly reduced because these units are less likely to be the first arriving unit at the side of a cardiac arrest patient. Additionally, these units will likely respond along with a first-line response apparatus such as a fire apparatus or EMS ambulance.

Public Safety response apparatus not defined as first-line are apparatus typically include:

- Chief Officer (e.g., battalion chief and above, EMS commander and above) provided the apparatus AED is not intended to serve as a backup device for a first-line apparatus
- Public Safety administrative vehicles
- Public Safety special event units (not assigned to 9-1-1 responses away from the special event or to potential cardiac arrest patients)

The City of Austin Medical Director may at any time withdraw his/her authorization for purchase or use of a specific AED model when the device has demonstrated performance which in the opinion of the Medical Director may harm or adversely affect cardiac arrest patients or System providers. Approved AED models meet all of the following specifications:

AEDs for these units/apparatus meet all of the above requirements <u>EXCEPT</u>:

- Requirements 12 – 18

AEDs Currently Restricted for Purchase by Public Safety Agencies

The following AED models are <u>not</u> currently authorized for purchase by first response agencies due to reliability and/or availability issues. Existing AEDs of these models may continue to be used provided no performance issues impacting patient or provider safety are identified by the OMD.

- Philips FR3 AED
- Philips FRx AED

Specifications for AEDs Utilized in Public Access Defibrillation Programs

Public access defibrillation (PAD) program AEDs are intended for use primarily by bystanders prior to arrival of public safety responders. To promote public use of AEDs and to promote simplicity of AED use, these AED specifications are intended to be minimal and relatively inexpensive. PAD programs wishing to operate under the medical oversight of the OMD must submit a completed PAD program agreement and receive approval.

The City of Austin Medical Director may at any time withdraw his/her authorization for purchase or use of a specific AED model when the device has demonstrated performance which in the opinion of the Medical Director may harm or adversely affect cardiac arrest patients or AED users. Approved AED models meet all of the following specifications:

The specific AED model is:

1. FDA approved at the time of selection and purchase.
2. Not currently the subject of a manufacturer or FDA voluntary or mandatory recall.
3. Not currently restricted from purchase by the current Medical Director due to safety or performance concerns.
4. Capable of treating both adult patients and pediatric patients using appropriate energy doses.
5. Capable of providing both audible and visual prompting cues for device operation.
6. Capable of automatic rhythm analysis at specified time intervals; If automatic shock delivery is available, this setting must be user configurable to be turned off.
7. Capable of performing self-tests and providing audible & visual notification when operator attention is needed as well as notification when the device is ready for use.
8. Capable of storing AED event data.
9. Capable of storing and allowing user initiated transfer of the following data -
    a. All user input and user/device actions including date/time stamp for each
    b. Continuous ECG while powered on
    c. Device feedback (if applicable)
    d. Device errors and identified non-ideal conditions (e.g. artifact, interference)

Additional requirements for AED selection and purchase include:

10. Software required for user transfer of AED data must be included and provided to both the purchasing organization and the OMD.
11. Peripheral hardware (e.g., cable, infrared reader, digital data storage device) required for user transfer of stored data must be specifically identified to the purchasing organization and OMD during the selection process.
12. Software required for post event review of AED data must be included and provided to both the purchasing organization and the OMD.

AEDs Currently Restricted for Purchase by PAD Programs

The following AED models are <u>not</u> currently authorized for purchase by PAD programs operating under the medical oversight of the OMD. Existing AEDs of these models may continue to be used provided no performance issues impacting patient or provider safety are identified by the OMD.

- Philips FRx AED