Issue Analysis Form

Date: May 12, 2020

Item: Work Session – Zoll Monitors

Lead Department(s): Fire/EMS & School Finance

Contact Person(s): Jason Koren, Daniel Thompson, Betsy Drewry

Description and Current Status

During the April 29, 2020 Budget Work Session, a Board Member made a request to receive more information on the new Zoll Monitors / Defibrillators included in the FY2021 Budget through the Capital Improvement Plan.

Five (5) monitors were included in the CIP and there is a need to replace 8 active Zoll X-Series monitors and 1 spare (total of 9). Grant applications have been filed for the purchase of 4 monitors with the Cameron Foundation (2) and the John Randolph Foundation (2). Those grants, if awarded, will likely be 50/50 awards and will require a local match.

Attached is:
USDA /FDA notification of non-approval of the X-Series Monitor effective 2/3/2021
Presentation on Zoll Monitors
Updated Price Quote for 5 monitors (no warranty) - $143,825.80
Updated Price Quote for 5 monitors (with warranty) - $176,115.80

Government Path

Does this require IDA action?	☐ Yes	☒ No
Does this require BZA action?	☐ Yes	☒ No
Does This require Planning Commission Action?	☐ Yes	☒ No
Does this require Board of Supervisors action?	☐ Yes	☒ No
Does this require a public hearing?	☐ Yes	☒ No
If so, before what date? 7 days prior to public hearing	☐ Yes	☐ No

Fiscal Impact Statement

The Proposed FY2021 budget includes the purchase of 5 monitors at a cost of $157,276. The FY2021 General Fund transfer to the debt reserve of $1,262,500 covers borrowing to replace the monitors.

County Impact

Replacement of the X-Series monitors by February 3, 2021 will bring County into

compliance with USDA / FDA regulations.

Notes

U.S. FOOD & DRUG ADMINISTRATION

September 26, 2019

Dear AED Owner, Healthcare Value Analysis Professional, Clinical Engineer, Physician Prescriber, or Physician Supervisor:

To help ensure the quality and reliability of automated external defibrillator (AED) systems, the FDA has established more stringent regulatory requirements for AEDs and their accessories by requiring these devices to be FDA-approved. If your AED is not FDA-approved, the accessories necessary for your AED may no longer be supported by the manufacturer, and thus no longer available after **February 3, 2021**.

To ensure the availability of life-saving treatment with the AEDs in your facilities, we encourage you to ensure that your AED is FDA-approved and if it is not, begin making plans to transition to an FDA-approved AED. To assist you, these are the steps the FDA recommends that you take.

1. **Check the list of FDA-approved AEDs on the Automated External Defibrillators (AEDs) webpage on FDA.gov to see if your AED is FDA-approved.**
2. **If your AED is not listed, you should plan to transition to an FDA-approved AED system. Contact the manufacturer of your current AED to discuss your transition plans.**
3. **Ensure that you have compatible AED accessories to meet your needs until you transition to an FDA-approved AED. This is particularly important because AED accessories may require frequent replacement.**

AEDs can be highly effective in saving the lives of people suffering cardiac arrest when used in the first few minutes following collapse from cardiac arrest. **Given the importance of these devices in emergency situations, the FDA recommends you continue to keep your AED available for use until you obtain an FDA-approved AED.**

For a medical device to be FDA-approved, the manufacturer must obtain premarket approval. Approval is based on a determination that there is sufficient valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness. In 2015, the FDA published a final order describing concerns about adverse event reports and product recalls for AED systems, and concluded that AED systems and necessary AED accessories require more FDA oversight. The final order established the requirement for premarket approval for all AEDs and necessary accessories. (https://www.federalregister.gov/documents/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems).

The FDA will continue to update the list of FDA-approved AEDs on the Automated External Defibrillators (AEDs) page on FDA.gov.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV 800-638-2041 or 301-796-7100.

Sincerely,
/s/
William Maisel, MD, MPH
Director
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Automated External Defibrillators (AEDs)

For Purchasers and Clinical Engineers

- Letter on AEDs and Accessories (/media/131108/download) (PDF)

For Patients and Consumers

- FDA-Approved Devices That Help Keep the Heart Beating (/consumers/consumer-updates/fda-approved-devices-help-keep-heart-beating)
- How AEDs in Public Places Can Restart Hearts (/consumers/consumer-updates/how-aeds-public-places-can-restart-hearts)

Automated external defibrillators (AEDs) are portable, life-saving devices designed to treat people experiencing sudden cardiac arrest, a medical condition in which the heart stops beating suddenly and unexpectedly.

The combination of CPR and early defibrillation is effective in saving lives when used in the first few minutes following collapse from sudden cardiac arrest.

On this page

What Are AEDs?

AEDs are portable, life-saving devices designed to treat people experiencing sudden cardiac arrest, a medical condition in which the heart suddenly and unexpectedly stops beating. The AED system includes accessories, such as a battery and pad electrodes, that

are necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock. There are two main types of AEDs: public access and professional use.

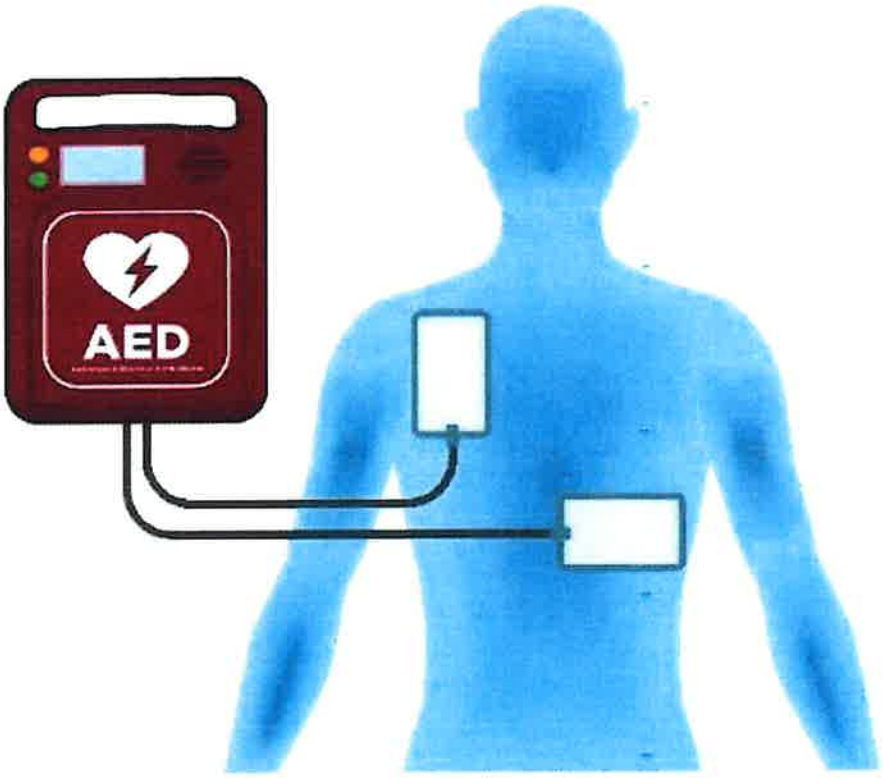
- **Public access AEDs** can be found in airports, community centers, schools, government buildings, hospitals, and other public locations. They are intended to be used by laypeople who have received minimal training.
- **Professional use AEDs** are used by first responders, such as emergency medical technicians (EMTs) and paramedics, who receive additional AED training.

AEDs can be semi-automated or fully automated.

- **Semi-automated defibrillators** analyze the heart's rhythm, and if an abnormal heart rhythm is detected that requires a shock, then the device prompts the user to press a button to deliver a defibrillation shock.
- **Fully automated defibrillators** analyze the heart's rhythm and deliver a defibrillation shock if commanded by the device software without user intervention.

Check Your AED: Is it FDA Approved?

The FDA published a final order in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories. Manufacturers of all necessary AED accessories, such as batteries, pad electrodes, adapters and hardware keys for pediatric use,



must file a premarket approval application (PMA) by February 3, 2020. If a PMA is not filed by February 3, 2020, the manufacturer must cease marketing their accessories by February 3, 2021.

There are now FDA-approved AEDs available, and we encourage you to ensure your AED is FDA-approved; if it is not, we encourage you to begin making plans to transition to an FDA-approved AED.

If you or your organization own(s) an AED system, the FDA recommends you:

- Check the table below to see if your AED is FDA-approved. Contact the manufacturer of your AED if you are not sure if your AED is FDA-approved.
- Contact the manufacturer of your AED if your AED is not FDA-approved and you have not received a letter about your AED.
- Be aware that if your AED is not FDA-approved, compatible necessary AED accessories may no longer be available to support your AED after February 3, 2021.
- Contact the manufacturer of your AED or AED accessories for information specific to your product.
- Given the importance of these devices in emergency situations, the FDA recommends you continue to keep your AED available for use until you receive an FDA- approved AED.
- Report problems with AEDs to the FDA by submitting a voluntary report online at MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

FDA-Approved AEDs

The table below lists all AEDs that have received premarket approval from the FDA. If your AED is listed below, no matter your purchase date, the AED is considered FDA-approved. The FDA will update this table when new AEDs are approved. For descriptions of these devices, their indications for use, and related information, follow the Premarket Database links.

Important: If your AED is not listed in this table, please contact the manufacturer of your AED for more information about your device.

Manufacturer	Device Name	Approval Date	Premarket Database
Cardiac Science Corporation	Powerheart G3 AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001)	12/07/2018	P160033 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033)
Cardiac Science Corporation	Powerheart G3 Plus AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001)	12/07/2018	P160033 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033)
Cardiac Science Corporation	Powerheart G5 AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001)	12/07/2018	P160033 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033)
Cardiac Science Corporation	Powerheart G3 PRO AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P160034)	12/06/2018	P160034 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160034)
Defibtech, LLC	Lifeline/ReviveR DDU-100 (/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032)
Defibtech, LLC	Lifeline/ReviveR AUTO DDU-120 (/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032)
Defibtech, LLC	Lifeline/ReviveR VIEW DDU-2300 (/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032)
Defibtech, LLC	Lifeline/ReviveR VIEW AUTO DDU-2200 (/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032)
Defibtech, LLC	Lifeline/ReviveR ECG DDU-2450 (/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032)

Manufacturer	Device Name	Approval Date	Premarket Database
Defibtech, LLC	Lifeline/ReviveR ECG+ DDU-2475 (/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032)
HeartSine Technologies, LLC	SAM 350P (Samaritan Public Access Automated External Defibrillator) (/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	01/12/2017	P160008 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160008)
HeartSine Technologies, LLC	SAM 360P (Samaritan Public Access Automated External Defibrillator) (/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	01/12/2017	P160008 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160008)
HeartSine Technologies, LLC	SAM 450P (Samaritan Public Access Automated External Defibrillator) (/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	01/12/2017	P160008 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160008)
Philips Medical Systems	HeartStart Home	06/06/2019	P160029 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160029)
Philips Medical Systems	HeartStart OnSite	06/06/2019	P160029 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160029)
Philips Medical Systems	HeartStart FR3	*See note	*See note
Philips Medical Systems	HeartStart FRx	*See note	*See note

Manufacturer	Device Name	Approval Date	Premarket Database
Physio-Control, Inc.	LIFEPAK CR Plus Defibrillator (/medical-devices/recently-approved-devices/lifepak-crr-plus-defibrillator-lifepak-expressr-defibrillator-and-charge-pakr-battery-charger)	12/21/2017	P160012 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160012)
Physio-Control, Inc.	LIFEPAK EXPRESS Defibrillator (/medical-devices/recently-approved-devices/lifepak-crr-plus-defibrillator-lifepak-expressr-defibrillator-and-charge-pakr-battery-charger)	12/21/2017	P160012 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160012)
Physio-Control, Inc.	LIFEPAK CR2 Defibrillator (/medical-devices/recently-approved-devices/lifepakr-cr2-defibrillator-p170018)	12/21/2018	P170018 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170018)
Physio-Control, Inc.	LIFEPAK 15 Monitor/Defibrillator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S001)	07/02/2018	P160026 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026)
Physio-Control, Inc.	LIFEPAK 20E Defibrillator/ Monitor (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S006)	07/02/2018	P160026 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026)
Physio-Control, Inc.	LIFEPAK 1000 Defibrillator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S006)	07/02/2018	P160026 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026)
ZOLL Medical Corporation	AED Plus and Fully Automatic AED Plus (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160015)	05/26/2017	P160015 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160015)
ZOLL Medical Corporation	X Series Defibrillator (/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160022)
ZOLL Medical Corporation	R Series Defibrillator (/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160022)

Manufacturer	Device Name	Approval Date	Premarket Database
ZOLL Medical Corporation	AED Pro Defibrillator (/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160022)
ZOLL Medical Corporation	AED 3 BLS Defibrillator (/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160022)
ZOLL Medical Corporation	Propaq MD Defibrillator (/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-propaqr-md-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160022)

*PMA is approvable subject to an FDA inspection that finds the manufacturing facilities, methods, and controls in compliance with the applicable requirements of the Quality System regulation (21 CFR Part 820)

Important Information for AED Manufacturers

To ensure the quality and reliability of AEDs the FDA now requires manufacturers to obtain premarket approval (/medical-devices/premarket-submissions/premarket-approval-pma)for all AEDs.

Manufacturers of currently legally marketed necessary AED accessories, such as batteries, pad electrodes, adapters and hardware keys for pediatric use, must file a premarket approval application (PMA) by February 3, 2020.

FDA does not intend to enforce compliance with the February 3, 2020, deadline for necessary AED accessories for one year in order to allow health care facilities time to transition to FDA-approved AEDs. Therefore, if a PMA is not filed by February 3, 2020, the manufacturer must cease marketing their accessories by February 3, 2021. This marketing deadline includes necessary AED accessories that are labeled for AEDs that are not FDA-approved.

FDA expects that necessary AED accessories will be labeled for use with an FDA-approved AED device (on the list above). Manufacturers submitting a PMA for necessary AED accessories should be aware that they can continue to market those accessories while the PMA is pending until the FDA issues a decision (approval, not approvable, or

denial decision). After a PMA decision is made, only FDA-approved accessories can continue to be marketed.

The FDA's premarket approval of new and existing AEDs is based on a determination that the application contains sufficient valid scientific evidence to reasonably assure the device is safe and effective for its intended use. This regulatory pathway requires manufacturers to receive FDA approval before initiating design, manufacturing, or labeling changes to the device, and imposes certain other annual reporting requirements.

Once the AEDs are on the market, the FDA proactively monitors the safety and reliability of AEDs by reviewing the AED manufacturers' manufacturing and design changes, performance reports, and medical device reports (MDRs). When a company initiates a correction or removal action, the FDA posts information about the action in the Medical Device Recall Database. For information on AED systems or necessary AED accessories that have been recalled, you can search the database using the device's product code. Once classified, the FDA monitors the recall to ensure that the recall strategy has been effective.

The FDA's Continued Efforts to Keep AEDs Reliable

The FDA recognizes the importance of AEDs as life-saving devices. Problems associated with many AEDs include design and manufacturing issues, such as inadequate control of components purchased from suppliers or inadequate validation of manufacturing processes. When this occurs, an AED device can malfunction and may contribute to patient harm or prevent the rescue of the patient.

Given this, the FDA has taken several actions to assure that current and future AED devices and accessories are safe and reliable. These actions include:

- **By February 3, 2021:** Manufacturers of necessary AED accessories (such as batteries, pad electrodes, adaptors and hardware keys for pediatric use) for AED systems that are not FDA-approved may market their AED accessories until February 3, 2021.
- **By February 3, 2020:** Manufacturers of necessary accessories (such as batteries, pad electrodes, adapters) for AED systems that are FDA-approved are required to file a premarket approval application.
- **April 2019:** The FDA sent letters to all AED manufacturers, who did not submit a premarket approval (PMA) application for their AEDs as required by the final order (https://www.federalregister.gov/documents/2015/02/03/2015-02049

/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems), reminding them they can no longer market their AED; the letters also informed the manufactures that necessary AED accessories may not be marketed after February 3, 2020, if a PMA is not filed. Manufacturers were asked to provide a plan for these AEDs and necessary AED accessories, including a timeline for servicing and phase-out activities, a plan for communicating with their customers, and an estimate of the volume of AEDs and accessories that remain in the field.

- **November 1, 2017:** The FDA and Philips Medical Systems LLC entered a consent decree (/news-events/press-announcements/fda-reaches-agreement-automatic-external-defibrillator-manufacturer-over-quality-control-issues)of permanent injunction prohibiting Philips Medical Systems, Philips Healthcare, and those individually named from manufacturing, processing, packing, holding, or distributing AEDs from two facilities until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- **February 2015:** The FDA published a final order (https://www.federalregister.gov/documents/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems) in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories.
- **December 2013:** The FDA issued a Safety Communication (http://wayback.archive-it.org/7993/20170722215732/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm376938.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) alerting all users of the Philips HeartStart FRx, HS1 Home and HS1 OnSite AEDs manufactured between 2005 and 2012 that these devices may fail to deliver a shock in the event of an emergency.
- **March 2013:** The FDA published a proposed order (https://www.regulations.gov/document?D=FDA-2013-N-0234-0001)to allow for notice and comment regarding the FDA's recommendation to require premarket approval (PMA) applications for AEDs and necessary AED accessories.
- **January 2011:** The FDA convened a public meeting (https://www.regulations.gov/document?D=FDA-2013-N-0234-0001)of the Circulatory System Device Panel of the Medical Devices Advisory Committee where the FDA presented its comprehensive assessment of AEDs. The panel of independent experts considered the FDA's assessment of AEDs and its recommendation that more stringent FDA oversight be applied to reduce future

AED problems. The panel agreed with the FDA's recommendation to require PMA applications for AEDs.

- **November 2010:** The FDA released the External Defibrillator Improvement Initiative Paper (https://www.pharmamedtechbi.com/~/media/Images/Publications/Archive/The Gray Sheet/36/47/01101122002/112210_aed_paper.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to foster the development of better-performing external defibrillators and to address the current industry practices for designing and manufacturing devices and identifying, reporting, and taking action to address device complaints they receive.

Zoll X-Series Replacements

Current Monitor Breakdown

- X series
  - Medic 5,6,7,8 (Staffed 24/7)
  - Medic 82 (Staffed M-F from 9-5)

- E Series
  - Medic 3 (Unstaffed Medic)
  - EMS1 (Staffed Shift Captain Vehicle)
  - Responders 1,5,6 and EMS8 (Unstaffed Quick Response SUVs)
  - Engine 8 (Staffed M-F from 9-5)
  - Engine 7 (Cross-staffed 24/7)
  - One spare in stock

FDA End of Life Order

- As of Feb 3, 2021 the FDA will require that all E-series monitors be taken out of service.
- This information was received in October 2019, immediately a request was placed with the CIP committee to replace 5 of the aging E-series monitors.
- Zoll is offering a $3,000 dollar credit to trade in the old monitors, much like an aged cell phone trade in they may be able to use them in other countries, or for parts.

CIP Request

- The CIP request was placed to replace 5 units. This request was based on the fact that the county anticipated applying for two separate grants for 2 monitors each.
- The 5 replacements would allow guaranteed replacement of the final transport unit in the county, the shift supervisor vehicle, and the 3 Responder vehicles in the county.
- The remaining 4 that would be sought after by grants would replace the 2 engines, the last EMS responder unit, and if possibly add a monitor to one of the other staffed engines in the county.

Prioritization of Vehicles

- Vehicles, as far as replacement of monitors are concerned, would be prioritized in the following order:
  - Staffed Transport (Ambulances)
  - Staffed non-transport EMS (EMS1)
  - Non-staffed transport EMS (Ambulances)
  - Non-staffed first response/staffed engines. (Responders/Engines)

Background on the Zoll Monitor

- Zoll monitors are usable by any EMS personnel from the level of Basic to Paramedic, though certain skills are only performable by an ALS provider (Intermediate or Paramedic)
  - Regardless of skill level, a patient's vitals are able to be assessed, a 12 lead EKG can be performed, and during a cardiac arrest the monitor will allow for pads to be applied and will notify the provider of when a shock is needed.
  - ALS providers have the ability to manually interpret EKGs, to pace slow heart rates, and to shock fast heart rates in order to "reset" them.
  - There is no skill that an Intermediate cannot perform with the monitor that a Paramedic is able to.

Differences in the two monitors

- The X series allows for many expanded abilities, including but not limited to:
  - Wireless connection to the already existent Cradlepoint wifi systems in each of our ambulances. The function of WIFI is utilized by the transferring of data at 1 of 2 times, either relaying an EKG taken in the field to a hospital, allowing the hospital to prepare for the incoming heart attack where seconds truly count, or the uploading of call data such as EKGs, vitals, medications, and procedures into our reporting software allowing for accurate time stamps.
  - X series allows us to work in adult, pediatric, & neonatal modes while the E series is only certified for adult modes.
  - Zoll states "The X Series has only reached about 40-50% capacity on the processor and continue to add new features with simple software updates that are free and done via the USB port on the X Series."

Statistics

- **The yearly incidence of EMS-assessed Out-of-Hospital Cardiac Arrest (OHCA) in the U.S. is 326,200.**
- **70% of all out of hospital cardiac arrests occur at home.**
- **From Jan 1, 2018 to Jun 30, 2019 Prince George County was dispatched for 102 Cardiac Arrests.**

Conclusion

- Currently the Cameron Foundation and JRF have submitted applications for 2 monitors each. We expect that if awarded they would be for a 50/50 where funds for 1 of the 2 would have to be secured prior to award.
- At the expense of roughly $32,000 each these monitors are not cheap, but it cannot be stressed enough that outside of the provider on board, they are the MOST critical piece of equipment we have.
- On 99% of the county's transports a Zoll X-Series monitor is utilized, there is no other piece of equipment that is utilized at that rate within PGFEMS.

NO WARRANTY

ZOLL Medical Corporation
Worldwide HeadQuarters
269 Mill Rd
Chelmsford, Massachusetts 01824-4105
(978) 421-9655 Main
(800) 348-9011
(978) 421-0015 Customer Support
FEDERAL ID#: 04-2711626

TO: **Prince George Fire/EMS**
6602 Courts Drive
P.O. Box 68
Prince George, VA 23875

Attn: **Jason Koren**

email: jkoren@princegeorgecountyva.gov

Tel: 804-712-5886

QUOTATION **342585 V:2**

DATE: May 04, 2020

TERMS: Net 30 Days

FOB: Destination **

FREIGHT: Free Freight

ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
1	601-2221011-01	**X Series ® Manual Monitor/Defibrillator** with 4 trace tri-mode display monitor/ defibrillator/ printer, comes with Real CPR Help®, advisory algorithm, advanced communications package (Wi-Fi, Bluetooth, USB cellular modem capable) USB data transfer capable and large 6.5"(16.5cm) diagonal screen, full 12 ECG lead view with both dynamic and static 12-lead mode display. **Accessories Included:** • MFC cable • MFC CPR connector • A/C power adapter/ battery charger • A/C power cord • One (1) roll printer paper • 6.6 Ah Li-ion battery • Carry case • Declaration of Conformity • Operator's Manual • Quick Reference Guide **• One (1)-year EMS warranty** **Advanced Options:** **Real CPR Help Expansion Pack** CPR Dashboard quantitive depth and rate in real time, release indicator, interruption timer, perfusion performance indicator (PPI) • See - Thru CPR artifact filtering **ZOLL Noninvasive Pacing Technology:**	5	$37,275.00	$30,565.50	$152,827.50 *

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Suzanne Ramler
EMS Territory Manager
804-615-1195

1. DELIVERY WILL BE MADE 60-90 DAYS AFTER RECEIPT OF ACCEPTED PURCHASE ORDER.
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4. ALL PURCHASE ORDERS ARE SUBJECT TO CREDIT APPROVAL BEFORE ACCEPTABLE BY ZOLL.
5. FAX PURCHASE ORDER AND QUOTATION TO ZOLL CUSTOMER SUPPORT AT 978-421-0015 OR EMAIL TO ESALES@ZOLL.COM.
6. ALL DISCOUNTS OFF LIST PRICE ARE CONTINGENT UPON PAYMENT WITHIN AGREED UPON TERMS.
7. PLACE YOUR ACCESSORY ORDERS ONLINE BY VISITING www.zollwebstore.com.

NO WARRANTY

ZOLL Medical Corporation
Worldwide HeadQuarters
269 Mill Rd
Chelmsford, Massachusetts 01824-4105
(978) 421-9655 Main
(800) 348-9011
(978) 421-0015 Customer Support
FEDERAL ID#: 04-2711626

TO: **Prince George Fire/EMS**
6602 Courts Drive
P.O. Box 68
Prince George, VA 23875

Attn: **Jason Koren**

email: jkoren@princegeorgecountyva.gov

Tel: 804-712-5886

QUOTATION **342585 V:2**

DATE: May 04, 2020

TERMS: Net 30 Days

FOB: Destination **

FREIGHT: Free Freight

ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE	
		Masimo Pulse Oximetry **SP02** • Signal Extraction Technology (SET) • Rainbow SET **NIBP Welch Allyn includes:** • Smartcuff 10 foot Dual Lumen hose • SureBP Reusable Adult Medium Cuff **End Tidal Carbon Dioxide monitoring (ETCO2)** **Oridion Microstream Technology:** Order required Microstream tubing sets separately **Interpretative 12- Lead ECG:** • 12-Lead one step ECG cable- includes 4- Lead limb lead cable and removable precordial 6- Lead set					
2	8000-0330	SpO2 Rainbow Reusable Patient Cable: Connects to LNCS Single Use and Reusable Sensors (4 ft)	5	$295.00	$241.90	$1,209.50	*
3	8000-0294	SpO2 LNCS Adult Reusable Sensor (1 each)	5	$295.00	$241.90	$1,209.50	*
4	8000-0580-01	Six hour rechargeable Smart battery	5	$519.75	$405.90	$2,029.50	*

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QUOTATION **342585 V:2**

DATE: May 04, 2020

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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
5	8200-000100-01	Single Bay Charger for the SurePower and SurePower II batteries.	2	$992.25	$774.90	$1,549.80 *
6	5001-9928	**ZOLL E Series w/Pacing, 12 lead + 3 parameters or more Trade-In**	5		($3,000.00)	($15,000.00) **

****Trade-In Value valid if all equipment purchased is in good operational and cosmetic condition, and includes all standard accessories. Customer assumes responsibility for shipping trade-in equipment to ZOLL Chelmsford within 60 days of receipt of new equipment. Customer agrees to pay cash value for trade-in equipment not shipped to ZOLL on a timely basis.**

***Reflects National Association of State Procurement Officials (NASPO) Contract Pricing. Master Contract #SW300.**

TOTAL **$143,825.80**

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Attn: **Jason Koren**

email: jkoren@princegeorgecountyva.gov

Tel: 804-712-5886

QUOTATION **342585 V:3**

DATE: May 04, 2020

TERMS: Net 30 Days

FOB: Destination **

FREIGHT: Free Freight

ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
1	601-2221011-01	**X Series ® Manual Monitor/Defibrillator** with 4 trace tri-mode display monitor/ defibrillator/ printer, comes with Real CPR Help®, advisory algorithm, advanced communications package (Wi-Fi, Bluetooth, USB cellular modem capable) USB data transfer capable and large 6.5"(16.5cm) diagonal screen, full 12 ECG lead view with both dynamic and static 12-lead mode display. **Accessories Included:** • MFC cable • MFC CPR connector • A/C power adapter/ battery charger • A/C power cord • One (1) roll printer paper • 6.6 Ah Li-ion battery • Carry case • Declaration of Conformity • Operator's Manual • Quick Reference Guide • **One (1)-year EMS warranty** **Advanced Options:** **Real CPR Help Expansion Pack** CPR Dashboard quantitive depth and rate in real time, release indicator, interruption timer, perfusion performance indicator (PPI) • See - Thru CPR artifact filtering **ZOLL Noninvasive Pacing Technology:**	5	$37,275.00	$30,565.50	$152,827.50 *

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DATE: May 04, 2020

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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE	
		Masimo Pulse Oximetry **SP02** • Signal Extraction Technology (SET) • Rainbow SET **NIBP Welch Allyn includes:** • Smartcuff 10 foot Dual Lumen hose • SureBP Reusable Adult Medium Cuff **End Tidal Carbon Dioxide monitoring (ETCO2)** **Oridion Microstream Technology:** Order required Microstream tubing sets separately **Interpretative 12- Lead ECG:** • 12-Lead one step ECG cable- includes 4- Lead limb lead cable and removable precordial 6- Lead set				
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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
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6	8778-89055-PP	Precision Service Plan, 5 Years, On- Site, Point of Sale	5	$7,175.00	$6,458.00	$32,290.00
7	5001-9928	**ZOLL E Series w/Pacing, 12 lead + 3 parameters or more Trade-In** ****Trade-In Value valid if all equipment purchased is in good operational and cosmetic condition, and includes all standard accessories. Customer assumes responsibility for shipping trade-in equipment to ZOLL Chelmsford within 60 days of receipt of new equipment. Customer agrees to pay cash value for trade-in equipment not shipped to ZOLL on a timely basis.** ***Reflects National Association of State Procurement Officials (NASPO) Contract Pricing. Master Contract #SW300.**	5		($3,000.00)	($15,000.00) **

TOTAL **$176,115.80**

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