

**RESOLUTION 2020-103**

**PASSED: SEPTEMBER 14, 2020**

**AUTHORIZING THE WAIVER OF COMPETITIVE BIDDING AND AWARDING THE PURCHASE OF CARDIAC MONITORS TO ZOLL MEDICAL CORPORATION AND APPROVING THE PURCHASE OF ADDITIONAL ITEMS TO PLACE THE MONITORS IN SERVICE IN AN AMOUNT NOT TO EXCEED \$63,000.**

**WHEREAS**, the City of DeKalb is a home rule unit as defined in Article VII, Section 6(a) of the 1970 Illinois Constitution and has jurisdiction over matters pertaining to its government and affairs; and

**WHEREAS**, it is in the best interest of the City to purchase emergency medical equipment for the Fire Department; and

**NOW, THEREFORE, BE IT RESOLVED BY THE COUNCIL OF THE CITY OF DEKALB, ILLINOIS:**

**SECTION 1:** That the City Council of the City of DeKalb hereby authorizes the Mayor to enter into a purchase agreement with Zoll Medical Corporation on terms and conditions acceptable to him, for the purpose of purchasing two (2) cardiac monitors, chargers, batteries, and electrodes and approving the purchase of mounting brackets to place these monitors in service for a total purchase price not to exceed \$63,000, without requiring further authorization or approval of City Council, provided that any costs or expenses to be incurred within the present budget year are within the scope of the then approved budget.

**SECTION 2:** That the City Clerk and/or the Executive Assistant of the City of DeKalb, Illinois be authorized and directed to attest the Mayor's Signature and shall be effective thereupon.

**PASSED BY THE CITY COUNCIL** of the City of DeKalb, Illinois, at a Regular meeting thereof held on the 14<sup>th</sup> day of September 2020 and approved by me as Mayor on the same day. Passed by an 8-0 roll call vote. Aye: Morris, Finucane, Smith, Perkins, McAdams, Verbic, Faivre, Mayor Smith. Nay: None.

**ATTEST:**



**RUTH A. SCOTT**, Executive Assistant



**JERRY SMITH**, Mayor





**TO: Dekalb Fire Department**  
 700 Pine Street  
 Dekalb, IL 60115

Attn: **Chief Jeff McMaster**

email: [jeff.mcmaster@cityofdekalb.com](mailto:jeff.mcmaster@cityofdekalb.com)

**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

**QUOTATION 352169 V:1**

DATE: August 11, 2020

TERMS: Net 30 Days

FOB: Shipping Point

FREIGHT: Free Freight

ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
1	601-2221011-01	<p><b>X Series ® Manual Monitor/Defibrillator</b>            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.</p> <p><b>Accessories Included:</b></p> <ul style="list-style-type: none"> <li>• MFC cable</li> <li>• MFC CPR connector</li> <li>• A/C power adapter/ battery charger</li> <li>• A/C power cord</li> <li>• One (1) roll printer paper</li> <li>• 6.6 Ah Li-ion battery</li> <li>• Carry case</li> <li>• Declaration of Conformity</li> <li>• Operator's Manual</li> <li>• Quick Reference Guide</li> </ul> <p>• <b>One (1)-year EMS warranty</b></p> <p><b>Advanced Options:</b>  <b>Real CPR Help Expansion Pack</b>            CPR Dashboard quantitative depth and rate in real time, release indicator, interruption timer, perfusion performance indicator (PPI)            • See - Thru CPR artifact filtering</p> <p><b>ZOLL Noninvasive Pacing Technology:</b></p>	2	\$37,275.00	\$28,701.75	\$57,403.50 *

To the extent that ZOLL and Customer, or Customer's Representative have negotiated and executed overriding terms and conditions ("Overriding T's & C's"), those terms and conditions would apply to quotation. In all other cases, this quote is made subject to ZOLL's Standard Commercial Terms and Conditions ("ZOLL T's & C's") which for capital equipment, accessories and consumables can be found at <http://www.zoll.com/GTC> and for software products can be found at <http://www.zoll.com/SSPTC> and for hosted software products can be found at <http://www.zoll.com/SSHTC>. Except in the case of overriding T's and C's, any Purchase Order ("PO") issued in response to this quotation will be deemed to incorporate ZOLL T's & C's, and any other terms and conditions presented shall have no force or effect except to the extent agreed in writing by ZOLL.

Caroline Guibord  
 EMS Territory Manager  
 773-425-0710

1. DELIVERY WILL BE MADE 60-90 DAYS AFTER RECEIPT OF ACCEPTED PURCHASE ORDER.
2. PRICES QUOTED ARE VALID UNTIL SEPTEMBER 30, 2020.
3. APPLICABLE TAX WILL BE ADDED AT THE TIME OF INVOICING.
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](mailto: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](http://www.zollwebstore.com).



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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
		<b>Masimo Pulse Oximetry</b>  <b>SP02</b> <ul style="list-style-type: none"> <li>• Signal Extraction Technology (SET)</li> <li>• Rainbow SET</li> </ul> <b>NIBP Welch Allyn includes:</b> <ul style="list-style-type: none"> <li>• Smartcuff 10 foot Dual Lumen hose</li> <li>• SureBP Reusable Adult Medium Cuff</li> </ul> <b>End Tidal Carbon Dioxide monitoring (ETCO2)</b> <b>Orion Microstream Technology:</b> Order required Microstream tubing sets separately  <b>Interpretative 12- Lead ECG:</b> <ul style="list-style-type: none"> <li>• 12-Lead one step ECG cable- includes 4- Lead limb lead cable and removable precordial 6- Lead set</li> </ul>				
2	8000-0330	SpO2 Rainbow Reusable Patient Cable: Connects to LNCS Single Use and Reusable Sensors (4 ft)	2	\$295.00	\$227.15	\$454.30 *
3	8000-0294	SpO2 LNCS Adult Reusable Sensor (1 each)	2	\$295.00	\$227.15	\$454.30 *
4	8000-002005-01	Cable Sleeve, Propaq / X Series, ZOLL Blue	4	\$49.95	\$38.46	\$153.84 *

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5	8000-0580-01	Six hour rechargeable Smart battery	4	\$519.75	\$381.15	\$1,524.60	*
6	8900-0402	<b>CPR stat*padz</b> HVP Multi-Function CPR Electrodes - 1 pair	2	\$78.75	\$57.75	\$115.50	*
7	8300-000676	OneStep Cable, X Series	2	\$446.25	\$343.61	\$687.22	*
8	8009-0020	CPR-D Padz and CPR Stat Padz Connector for R Series	2	\$393.75	\$303.19	\$606.38	*
9	8900-000219-01	OneStep Pediatric CPR Electrode (1 pair)	2	\$91.88	\$70.75	\$141.50	*
10	7800-0312	<b>LifePak 12 Biphasic w/Pacing, 12 lead + 3 parameters or more Trade-In</b>	2		(\$3,000.00)	(\$6,000.00)	**
11	20100000102011010	<b>AED Plus with AED Cover.</b> Includes: LCD screen showing voice prompt messages, device advisory messages, elapsed time, shock count and chest compression bar. Supplied with Public Safety PASS Cover, Softcase, Operator's Guide and <b>(5) five year limited warranty.</b>	3	\$1,995.00	\$1,416.45	\$4,249.35	*

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12	8000-0807-01	Type 123 Lithium Batteries, quantity of ten (10) with storage sleeve	3	\$78.75	\$63.00	\$189.00	*
13	8900-0402	CPR stat-padz HVP Multi-Function CPR Electrodes - 1 pair	3	\$78.75	\$63.00	\$189.00	*
14	8900-0810-01	pedi-padz® II Pediatric Multi-Function Electrodes - Designed for use with the AED Plus. The AED recognizes when pedi-padz II are connected and automatically proceeds with a pediatric ECG and adjusts energy to pediatric levels. Twenty four (24) month shelf-life. One pair.	3	\$99.75	\$79.80	\$239.40	*
15	7800-9923	Physio LifePak 500BI Trade-In	3		(\$200.00)	(\$600.00)	**

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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
		<p align="center">**Trade in value is only guaranteed through September 30, 2020</p> <p align="center">**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.</p> <p align="center">*Reflects Discount Pricing.</p>				

					<b>TOTAL</b>	<b>\$59,807.89</b>
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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.





**FDA** 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](mailto: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



# Automated External Defibrillators (AEDs)

## For Purchasers and Clinical Engineers

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

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?](#)
- [Check Your AED: Is it FDA Approved?](#)
- [FDA-Approved AEDs](#)
- [Important Information for AED Manufacturers](#)
- [The FDA's Continued Efforts to Keep AEDs Reliable](#)

## 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?

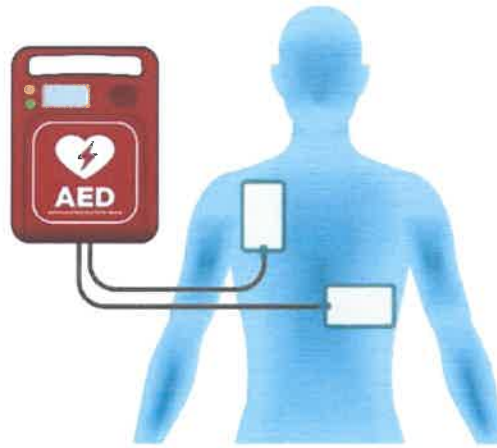
The FDA published a final order in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories. Manufacturers of all necessary AED accessories, such as batteries, pad electrodes, adapters and hardware keys for pediatric use, must file a premarket 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 (<https://www.fda.gov/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	AED Type	Approval Date	Premarket Database
Cardiac Science Corporation	Powerheart G3 AED ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001</a> )	Public Access	12/07/2018	P160033 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033</a> )
Cardiac Science Corporation	Powerheart G3 Plus AED ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001</a> )	Public Access	12/07/2018	P160033 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033</a> )
Cardiac Science Corporation	Powerheart G5 AED ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001</a> )	Public Access	12/07/2018	P160033 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033</a> )
Cardiac Science Corporation	Powerheart G3 PRO AED ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160034">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160034</a> )	Professional Use	12/06/2018	P160034 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160034">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160034</a> )
Defibtech, LLC	Lifeline/ReviveR DDU-100 ( <a href="https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032">https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032</a> )	Public Access	02/01/2018	P160032 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032</a> )
Defibtech, LLC	Lifeline/ReviveR AUTO DDU-120 ( <a href="https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032">https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032</a> )	Public Access	02/01/2018	P160032 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032</a> )
Defibtech, LLC	Lifeline/ReviveR VIEW DDU-2300 ( <a href="https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032">https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032</a> )	Public Access	02/01/2018	P160032 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032</a> )
Defibtech, LLC	Lifeline/ReviveR VIEW AUTO DDU-2200 ( <a href="https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032">https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032</a> )	Public Access	02/01/2018	P160032 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032</a> )
Defibtech,	Lifeline/ReviveR ECG DDU-2450 ( <a href="https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032">https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032</a> )	Public Access	02/01/2018	P160032 ( <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160032</a> )

LLC	devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Access			(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160032)
Defibtech, LLC	Lifeline/Reviver ECG+ DDU-2475 (https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Public Access	02/01/2018	P160032	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160032)
HeartSine Technologies, LLC	SAM 350P (Samaritan Public Access Automated External Defibrillator) (https://www.fda.gov/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	Public Access	01/12/2017	P160008	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160008)
HeartSine Technologies, LLC	SAM 360P (Samaritan Public Access Automated External Defibrillator) (https://www.fda.gov/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	Public Access	01/12/2017	P160008	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160008)
HeartSine Technologies, LLC	SAM 450P (Samaritan Public Access Automated External Defibrillator) (https://www.fda.gov/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	Public Access	01/12/2017	P160008	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160008)
Philips Medical Systems	HeartStart Home	Home Use	06/06/2019	P160029	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160029)
Philips Medical Systems	HeartStart OnSite	Public Access	06/06/2019	P160029	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160029)
Philips Medical Systems	HeartStart FR3	Public Access	*See note	*See note	
Philips Medical Systems	HeartStart FRx	Public Access	*See note	*See note	
Physio-Control, Inc.	LIFEPAK CR Plus Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/lifepak-crr-plus-defibrillator-lifepak-expressr-defibrillator-and-charge-pakr-battery-charger)	Public Access	12/21/2017	P160012	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160012)
Physio-Control, Inc.	LIFEPAK EXPRESS Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/lifepak-crr-plus-defibrillator-lifepak-expressr-defibrillator-and-charge-pakr-battery-charger)	Public Access	12/21/2017	P160012	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160012)
Physio-Control, Inc.	LIFEPAK CR2 Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/lifepakr-cr2-defibrillator-p170018)	Public Access	12/21/2018	P170018	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P170018)
Physio-Control, Inc.	LIFEPAK 15 Monitor/Defibrillator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S001)	Professional Use	07/02/2018	P160026	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160026)
Physio-Control, Inc.	LIFEPAK 20E Defibrillator/ Monitor (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S006)	Professional Use	07/02/2018	P160026	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160026)
Physio-Control, Inc.	LIFEPAK 1000 Defibrillator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S006)	Professional Use	07/02/2018	P160026	(https://www.accessdata.fda.gov/scripts/cdrh/cf 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)	Public Access	05/26/2017	P160015	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160015)
ZOLL Medical Corporation	X Series Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160022)
ZOLL Medical Corporation	R Series Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160022)
ZOLL Medical Corporation	AED Pro Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022	(https://www.accessdata.fda.gov/scripts/cdrh/cf id=P160022)
ZOLL Medical Corporation	AED 3 BLS Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022	(https://www.accessdata.fda.gov/scripts/cdrh/cf 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

## Important Information for AED Manufacturers

To ensure the quality and reliability of AEDs the FDA now requires manufacturers to obtain premarket approval (<https://www.fda.gov/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 (<https://www.fda.gov/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](https://www.pharmamedtechbi.com/~media/Images/Publications/Archive/The%20Gray%20Sheet/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.



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We appreciate your consideration of ZOLL® products for the DeKalb Fire Department. This letter serves as confirmation that ZOLL® Medical Corporation at 269 Mill Road in Chelmsford, Massachusetts, is the sole manufacturer and source of X Series® Defibrillators for the EMS Market. ZOLL® or Caroline Guibord, EMS Territory Manager, will not sell an X Series® Defibrillator to DeKalb Fire Department through any vendor or dealer.

The ZOLL® monitor line is the only source for the patented Rectilinear Biphasic Waveform. This waveform is proven clinically superior by the FDA for the synchronized cardioversion of Atrial Fibrillation and for High Impedance Ventricular Fibrillation. ZOLL® is also the only source of the RLB 40msec pulse duration pacing waveform. This pacing technology is patented technology as well and is not available from any other manufacturer.

Additionally, ZOLL is the sole provider of the Inovise 12 lead algorithm for ALS monitors in the EMS environment. This 12 lead algorithm provides the highest level of accuracy and specificity for determining ST elevations in the EMS environment. Additionally, the exclusive capabilities of the Inovise 12 lead and ZOLL X series to simultaneously capture all EKG leads provides for higher levels of accuracy, reduces the need for acquiring multiple EKG's, therefore increasing the speed and quality of care for the patients. These technologies are exclusive to the Inovise 12 lead algorithm, which can only be found in the ZOLL X series for the EMS Market and not available from any other manufacturer.

ZOLL® is also the sole source manufacturer of FDA approved Real CPR Help and See thru CPR technologies only available in the ZOLL® X Series® and other ZOLL® defibrillation equipment. The ZOLL® monitor line, including the ZOLL X series® is the only ALS Cardiac monitor with both Real CPR Help and See thru CPR technologies. See thru CPR is also the only technology of its kind on the market allowing the rescuer to filter through the CPR to see a verifiable rhythm without stopping CPR. These technologies must be capable of being used through defibrillation pads than must have an attached accelerometer to enable CPR feedback and artifact filtering functionality and are

disposable with each event. These technologies and the ZOLL® X Series® cardiac resuscitation monitor are not available from any other manufacturer.

In addition, the X series monitor is the only EMS monitor with the following capabilities:

- Device must be capable of acquiring a blood pressure measurement on inflation within 15 to 30 seconds
- Device must be capable of synchronizing the oscillation to the R-wave of the ECG during Non-invasive blood pressure monitoring
- Device must have impedance pneumography for monitoring respiratory rate via ECG Leads I or II
- Device must have a minimum IP55 rating for water and solid foreign objects
- Device shall not exceed 10.6 lbs. (4.82 kg) without battery and paper

Should you have any questions or require additional information please contact me at:  
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