

RESOLUTION NO. 18-60

A RESOLUTION AUTHORIZING ACCEPTANCE OF A PROPOSAL FROM ZOLL MEDICAL CORPORATION, CHELMSFORD, MASSACHUSETTS, FOR THE PURCHASE OF ONE (1) ZOLL "X SERIES MANUAL MONITOR/DEFIBRILLATOR" FOR THE TOTAL PURCHASE AMOUNT OF \$31,861.10.

WHEREAS, proposals were solicited for the purchase of one cardiac monitor, with 12-lead capability, battery chargers, and other related equipment; the proposal from Zoll Medical Corporation is recommended.

NOW, THEREFORE, BE IT RESOLVED BY THE COUNCIL OF THE CITY OF GLADSTONE, MISSOURI, AS FOLLOWS:

THAT, the City Manager of the City of Gladstone, Missouri, be and is hereby authorized to accept the proposal from Zoll Medical Corporation for the purchase amount of \$31,861.10.

One (1) Zoll "X Series Manual Monitor/Defibrillator - TOTAL COST: \$31,861.10


FURTHER, funds for such purpose are authorized from the General Fund.

INTRODUCED, READ, PASSED, AND ADOPTED BY THE COUNCIL OF THE CITY OF GLADSTONE, MISSOURI THIS 8th DAY OF OCTOBER 2018.



Mayor Bill Garnos

ATTEST:



Ruth Bocchino, City Clerk



Request for Council Action

RES # R-18-60

BILL # City Clerk Only

ORD # City Clerk Only

Date: 10/3/2018

Department: Public Safety

Meeting Date Requested: 10/8/2018

Public Hearing: Yes Date: [Click here to enter a date.](#)

Subject: Purchase of Zoll Cardiac Monitor - \$31,861.10

Background: The last three cardiac monitors have been “Zoll X-Series Manual Monitor/Defibrillator” and it is recommended to continue with Zoll cardiac monitors due to superior performance, reliability, and to maintain consistency of equipment for the Gladstone ambulance service.

Budget Discussion: Funds are budgeted in the amount of \$ 32,000.00 from the General Fund. Ongoing costs are estimated to be \$ 0 annually. Previous years’ funding was \$33,000.00

Public/Board/Staff Input:

Provide Original Contracts, Leases, Agreements, etc. to: City Clerk and Vendor

Mike Hasty
Department Director/Administrator

City Attorney

SW
City Manager



*Department of Public Safety
Administration
Memorandum MJH 18-35*

DATE: October 3, 2018

TO: Scott C. Wingerson, City Manager

FROM: Chief Michael J. Hasty, Director of Public Safety

CC: Dominic Accurso, Director of Finance
Division Chief Sean Daugherty, Fire/EMS Division Commander
Captain Jeffrey R. Self, Police Field Services Division Commander
Captain Robert Hays, Support Services Division Commander
Ruth Bocchino, City Clerk

RE: CARDIAC MONITOR PURCHASE

The 2019 General Fund Budget authorized \$32,000.00 for the purchase of a new cardiac monitor for our ambulance service. In 2015, testing and review of cardiac monitors from various manufacturers and vendors were conducted by paramedics in the Fire/EMS Division of the Public Safety Department. After this evaluation, a recommendation was made to acquire cardiac monitors manufactured by Zoll Medical Corporation due to superior capability and performance.

The last three cardiac monitors purchased by the city were manufactured by Zoll Medical Corporation and they have proven to be a very effective tool for paramedics in field. Division Chief Daugherty reviewed the specifications and costs of a Zoll "X-Series" and Physio Control "Lifepak 15" cardiac monitors. He recommends the city move forward with the acquisition of the cardiac monitor manufactured by Zoll Medical Corporation to maintain consistency of equipment. There are no other manufacturers of cardiac monitors that meet the specifications of equipment required for our ambulance service. The manufacturer of the Phillips "MRx" cardiac monitor/defibrillator was required to suspend the manufacture and distribution of external defibrillators pursuant to a consent decree with the U.S. Department of Justice, representing the U.S. Food and Drug Administration earlier this year.

I concur with the recommendation made by Division Chief Daugherty and have requested a resolution be placed on the Regular City Council Meeting Agenda for Monday, October 8, 2018 authorizing you to purchase one Zoll "X-Series" cardiac monitor directly from the manufacturer in the amount of \$31,861.10. Attached you will find supporting information on the research for this purchase collected by Division Chief Daugherty. Please advise if you need further information.



*Department of Public Safety
Fire/EMS
Memorandum – 19-10SCD*

DATE: 09/28/2018
TO: Director Michael J. Hasty
FROM: Division Chief Sean Daugherty
RE: Purchase of Cardiac Monitor

Sir,

The FY19 budget included the purchase of a new cardiac monitor as a capital expenditure for the Fire/EMS Division in Public Safety. In the last three fiscal years, we have acquired a cardiac monitor through capital expenditure and each time we have gone with Zoll. The preference is to stay with Zoll as they are easy to work with and all crew members are familiar with the product. Zoll has the following features and their service has been premier.

- Zoll monitor has the feature of live 12-lead monitoring for quicker analysis
- Cardiac monitor is small and lightweight
- These monitors have the capability to transmit electrocardiograms (EKG's) to the emergency departments (ED's) prior to crews arrival in critical situations.

The Zoll monitor bid is **\$31,861.10**.

We have had the Zoll monitor in our system now for three years and it has been exceptional. The Physio Life Pack 12 monitors that we have currently on the remaining trucks are becoming obsolete to the point Physio is no longer making parts for them.

It is my recommendation that we purchase the Zoll monitor and continue the continuity of replacing the outdated monitors. I would request that we stay with Zoll and its monitor since they are on three out of four of our apparatus.

Respectfully,


Division Chief Sean Daugherty/



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: Gladstone Ambulance

6569 North Prospect Avenue
 Gladstone, MO 64119

Attn: **Captain Tracey Cheney**

email: TraceyC@gladstone.mo.us

Tel: 816-454-8310

QUOTATION 265973 V:1

DATE: February 05, 2018

TERMS: Net 30 Days

FOB: Destination **

FREIGHT: Free Freight

ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
1	601-2221011-01	<p>X Series Manual Monitor/Defibrillator \$14,995 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>Accessories Included:</p> <ul style="list-style-type: none"> • 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 <p>• One (1)-year EMS warranty</p> <p>Advanced Options: Real CPR Help Expansion Pack \$ 895 CPR Dashboard quantitative depth and rate in real time, release indicator, interruption timer, perfusion performance indicator (PPI) • See - Thru CPR artifact filtering</p> <p>ZOLL NonInvasive Pacing Technology: \$2,550</p>	1	\$37,275.00	\$30,565.50	\$30,565.50 *

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 this quotation. In all other cases, this quote is made subject to ZOLL's Standard Commercial Terms and Conditions ("ZOLL T's & C's") which accompany this quote. 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 shall have no force or effect except to the extent agreed in writing by ZOLL.

Lori Rohling
 EMS Territory Manager
 773-474-0916

1. DELIVERY WILL BE MADE 60-90 DAYS AFTER RECEIPT OF ACCEPTED PURCHASE ORDER.
2. PRICES QUOTED ARE VALID FOR 60 DAYS.
3. APPLICABLE TAX ADDITIONAL.
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.



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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
		Maximo Pulse Oximetry SP02 \$1,795 • Signal Extraction Technology (SET) • Rainbow SET NIBP Welch Allyn Includes: \$3,495 • Smartcuff 10 foot Dual Lumen hose • SureBP Reusable Adult Medium Cuff End Tidal Carbon Dioxide monitoring (ETCO2) Oridion Microstream Technology: \$4,895 Order required Microstream tubing sets separately Interpretative 12-Lead ECG: \$8,450 • 12-Lead one step ECG cable- Includes 4- Lead limb lead cable and removable precordial 6- Lead set				
2	8 0 0 0 - 0 3 3 0	SpO2 Rainbow Reusable Patient Cable; Connects to LNCS Single Use and Reusable Sensors (4 ft)	1	\$295.00	\$241.90	\$241.90
3	8 0 0 0 - 0 2 9 4	SpO2 LNCS Adult Reusable Sensor (1 each)	1	\$295.00	\$241.90	\$241.90
4	8 0 0 0 - 0 5 8 0 - 0 1	Six hour rechargeable Smart battery	2	\$495.00	\$405.90	\$811.80

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ITEM	MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC PRICE	TOTAL PRICE
*Reflects National Association of State Procurement Officials (NASPO) Contract Pricing. Master Contract #SW300.						
TOTAL						\$31,861.10

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Lori Rohling
EMS Territory Manager
773-474-0916

ZOLL QUOTATION GENERAL TERMS & CONDITIONS

1. ACCEPTANCE. This Quotation constitutes an offer by ZOLL Medical Corporation to sell to the Customer the equipment (including a license to use certain software) listed in this Quotation and described in the specifications either attached to or referred to in this Quotation (hereinafter referred to as Equipment). Any acceptance of such offer is expressly limited to the terms of this Quotation, including these General Terms and Conditions. Acceptance shall be so limited to this Quotation notwithstanding (i) any conflicting written or oral representations made by ZOLL Medical Corporation or any agent or employee of ZOLL Medical Corporation or (ii) receipt or acknowledgment by ZOLL Medical Corporation of any purchase order, specification, or other document issued by the Customer. Any such document shall be wholly inapplicable to any sale made pursuant to this Quotation, and shall not be binding in any way on ZOLL Medical Corporation.

Acceptance of this Quotation by the Customer shall create an agreement between ZOLL Medical Corporation and the Customer (hereinafter referred to as the "Contract") the terms and conditions of which are expressly limited to the provisions of this Quotation including these Terms and Conditions. No waiver or modification of any of the provisions of this Quotation or the Contract shall be binding on ZOLL Medical Corporation unless such waiver, change or modification (i) is made in writing (ii) expressly states that it is a waiver, change or modification of this Quotation or the Contract and (iii) is signed by an authorized representative of ZOLL Medical Corporation.

2. DELIVERY AND RISK OF LOSS. Unless otherwise stated, all deliveries shall be F.O.B. ZOLL Medical Corporation's facility. Risk of loss or damage to the Equipment shall pass to the Customer upon delivery of the Equipment to the carrier.

3. TERMS OF PAYMENT. Unless otherwise stated in its Quotation payment by Customer is due thirty (30) days after the ship date appearing on ZOLL Medical Corporation invoice. Any amounts payable hereunder which remain unpaid after the date shall be subject to a late charge equal to 1.5% per month from the due date until such amount is paid.

4. CREDIT APPROVAL. All shipments and deliveries shall at all times be subject to the approval of credit by ZOLL Medical Corporation. ZOLL Medical Corporation may at any time decline to make any shipment or delivery except upon receipt of payment or security or upon terms regarding credit or security satisfactory to ZOLL Medical Corporation.

5. TAXES & FEES. The pricing quoted in its Quotation do not include sales use, excise, or other similar taxes or any duties or customs charges, or any order processing fees. The Customer shall pay in addition for the prices quoted the amount of any present or future sales, excise or other similar tax or customs duty or charge applicable to the sale or use of the Equipment sold hereunder (except any tax based on the net income of ZOLL Medical Corporation), and any order processing fees that ZOLL may apply from time to time. In lieu thereof the Customer may provide ZOLL Medical Corporation with a tax exemption certificate acceptable to the taxing authorities.

6. WARRANTY. (a) ZOLL Medical Corporation warrants to the Customer that from the earlier of the date of installation or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, the Equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period noted on the reverse side. Accessories and electrodes shall be warranted for ninety (90) days from the date of shipment. During such period ZOLL Medical Corporation will at no charge to the Customer either repair or replace (at ZOLL Medical Corporation's sole option) any part of the Equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any Equipment defect failure of the Equipment to perform any specified function, or any other nonconformance of the Equipment caused by or attributable to (i) any modification of the Equipment by the Customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the Equipment with any associated or complementary equipment accessory or software not specified by ZOLL Medical Corporation, or (iii) any misuse or abuse of the Equipment; (iv) exposure of the Equipment to conditions beyond the environmental, power or operating constraints specified by ZOLL Medical Corporation, or (v) installation or wiring of the Equipment other than in accordance with ZOLL Medical Corporation's instructions. (c) Warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, cables and accessories. (d) The foregoing warranty does not apply to software included as part of the Equipment (including software embodied in read-only memory known as "firmware"). (e) The foregoing warranty constitutes the exclusive remedy of the Customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the Equipment supplied hereunder. THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL MEDICAL CORPORATION EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7. SOFTWARE LICENSE. (a) All software (the "Software" which term shall include firmware) included as part of the Equipment is licensed to Customer pursuant to a nonexclusive limited license on the terms hereinafter set forth. (b) Customer may not copy, distribute, modify, translate or adapt the Software, and may not disassemble or reverse compile the Software, or seek in any manner to discover, disclose or use any proprietary algorithms, techniques or other confidential information contained therein. (c) All rights in the Software remain the property of ZOLL Medical Corporation, and Customer shall have no right or interest therein except as expressly provided herein. (d) Customer's right to use the Software may be terminated by ZOLL Medical Corporation in the event of any failure to comply with terms of this quotation. (e) Customer may transfer the license conferred hereby only in connection with a transfer of the Equipment and may not retain any copies of the Software following such transfer. (f) ZOLL Medical Corporation warrants that the read-only memory or other media on which the Software is recorded will be free from defects in materials and workmanship for the period and on terms set forth in section 6. (g) Customer understands that the Software is a complex and sophisticated software product and no assurance can be given that operation of the Software will be uninterrupted or error-free, or that the Software will meet Customer's requirements. Except as set forth in section 7(f), ZOLL MEDICAL CORPORATION MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE SOFTWARE AND IN PARTICULAR DISCLAIMS ANY IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS OF A PARTICULAR PURPOSE WITH RESPECT THERETO. Customer's exclusive remedy for any breach of warranty or defect relating to the Software shall be the repair or replacement of any defective read-only memory or other media so that it correctly reproduces the Software. This license applies only to ZOLL Medical Corporation Software.

8. DELAYS IN DELIVERY. ZOLL Medical Corporation shall not be liable for any delay in the delivery of any part of the Equipment if such delay is due to any cause beyond the control of the ZOLL Medical Corporation including, but not limited to acts of God, fires, epidemics, floods, riots, wars, sabotage, labor disputes, governmental actions, inability to obtain materials, components, manufacturing facilities or transportation or any other cause beyond the control of ZOLL Medical Corporation. In addition ZOLL Medical Corporation shall not be liable for any delay in delivery caused by failure of the Customer to provide any necessary information in a timely manner. In the event of any such delay, the date of shipment or performance hereunder shall be extended to the period equal to the time lost by reason of such delay. In the event of such delay ZOLL Medical Corporation may allocate available Equipment among its Customers on any reasonable and equitable basis. The delivery dates set forth in this Quotation are approximate only and ZOLL Medical Corporation shall not be liable for or shall the Contract be breached by, any delivery by ZOLL Medical Corporation within a reasonable time after such dates.

9. LIMITATIONS OF LIABILITY. IN NO EVENT SHALL ZOLL MEDICAL CORPORATION BE LIABLE FOR INDIRECT SPECIAL OR CONSEQUENTIAL DAMAGES RESULTING FROM ZOLL MEDICAL CORPORATION'S PERFORMANCE OR FAILURE TO PERFORM PURSUANT TO THIS QUOTATION OR THE CONTRACT OR THE FURNISHING, PERFORMANCE, OR USE OF ANY EQUIPMENT OR SOFTWARE SOLD HERETO, WHETHER DUE TO A BREACH OF CONTRACT, BREACH OF WARRANTY, THE NEGLIGENCE OF ZOLL MEDICAL CORPORATION OR OTHERWISE.

10. PATENT INDEMNITY. ZOLL Medical Corporation shall at its own expense defend any suit that may be instituted against the Customer for alleged infringement of any United States patents or copyrights related to the parts of the Equipment or the Software manufactured by ZOLL Medical Corporation, provided that (i) such alleged infringement consists only in the use of such Equipment or the Software by itself and not as a part of or in combination with any other devices or parts, (ii) the Customer gives ZOLL Medical Corporation immediate notice in writing of any such suit and permits ZOLL Medical Corporation through counsel of its choice, to answer the charge of infringement and defend such suit, and (iii) the Customer gives ZOLL Medical Corporation all requested information, assistance and authority at ZOLL Medical Corporation's expense, to enable ZOLL Medical Corporation to defend such suit.

In the case of a final award of damages for infringement in any such suit, ZOLL Medical Corporation will pay such award, but it shall not be responsible for any settlement made without its written consent.

Section 10 states ZOLL Medical Corporation's total responsibility and liability, and the Customer's sole remedy for any actual or alleged infringement of any patent by the Equipment or the Software or any part thereof provided hereunder. In no event shall ZOLL Medical Corporation be liable for any indirect, special, or consequential damages resulting from any such infringement.

11. CLAIMS FOR SHORTAGE. Each shipment of Equipment shall be promptly examined by the Customer upon receipt thereof. The Customer shall inform ZOLL Medical Corporation of any shortage in any shipment within ten (10) days of receipt of Equipment. If no such shortage is reported within ten (10) day period, the shipment shall be conclusively deemed to have been complete.

12. RETURNS AND CANCELLATION. (a) The Customer shall obtain authorization from ZOLL Medical Corporation prior to returning any of the Equipment. (b) The Customer receives authorization from ZOLL Medical Corporation to return a product for credit, the Customer shall be subject to a restocking charge of twenty percent (20%) of the original list purchase price, but not less than \$50.00 per product. (c) Any such change in delivery caused by the Customer that causes a delivery date greater than six (6) months from the Customer's original order date shall constitute a new order for the affected Equipment in determining the appropriate list price.

13. APPLICABLE LAW. This Quotation and the Contract shall be governed by the substantive laws of the Commonwealth of Massachusetts without regard to any choice of law provisions thereof.

14. COMPLIANCE WITH LAWS. (a) ZOLL Medical Corporation represents that all goods and services delivered pursuant to the Contract will be produced and supplied in compliance with all applicable state and federal laws and regulations, including the requirements of the Fair Labor Standards Act of 1938, as amended. (b) The Customer shall be responsible for compliance with any federal, state and local laws and regulations applicable to the installation or use of the Equipment furnished hereunder, and will obtain any permits required for such installation and use.

15. NON-WAIVER OF DEFAULT. In the event of any default by the Customer, ZOLL Medical Corporation may decline to make further shipments or render any further warranty or other services without in any way affecting its right under such order. If despite any default by Customer, ZOLL Medical Corporation elects to continue to make shipments its action shall not constitute a waiver of any default by the Customer or in any way affect ZOLL Medical Corporation's legal remedies regarding any such default. No claim or right arising out of a breach of the Agreement by the Customer can be discharged in whole or in part by waiver or renunciation of the claim or right unless the waiver or renunciation is supported by consideration and is in writing signed by ZOLL Medical Corporation.

16. ASSIGNMENT. This Quotation, and the Contract, may not be assigned by the Customer without the prior written consent of ZOLL Medical Corporation, and any assignment without such consent shall be null and void.

17. TITLE TO PRODUCTS. Title to right of possession of the products sold hereunder shall remain with ZOLL Medical Corporation until ZOLL Medical Corporation delivers the Equipment to the carrier and agrees to do all acts necessary to perfect and maintain such right and title in ZOLL Medical Corporation. Failure of the Customer to pay the purchase price for any product when due shall give ZOLL Medical Corporation the right, without liability to repossess the Equipment, with or without notice, and to avail itself of any remedy provided by law.

18. EQUAL EMPLOYMENT OPPORTUNITY / AFFIRMATIVE ACTION.

VETERAN'S EMPLOYMENT - If this order is subject to Executive Order 11710 and the rules, regulations, or orders of the Secretary of Labor issued thereunder the contract clause as set forth at 41 CFR 60-250.4 is hereby included as part of this order.

EMPLOYMENT OF HANDICAPPED - If this order is subject to Section 503 of the Rehabilitation Act of 1973, as amended and the rules, regulations or orders of the Secretary of Labor as issued thereunder, the contract clause at 41 CFR 60-741.7 is hereby included as part of this order.

EQUAL OPPORTUNITY EMPLOYMENT - If this order is subject to the provisions of Executive Order 11246, as amended, and the rules, regulations or orders of the Secretary of Labor issued thereunder, the contract clause set forth at 41 CFR 60-1.4 (a) and 60-1.4 (b) are hereby included as a part of this order and Seller agrees to comply with the reporting requirements set forth at 41 CFR 60-1.7 and the affirmative action compliance program requirements set forth at 41 CFR 60-1.40.

19. VALIDITY OF QUOTATION. This Quotation shall be valid and subject to acceptance by the Customer, in accordance with the terms of Section 1 hereof for the period set forth on the face hereof. After such period, the acceptance of this Quotation shall not be binding upon ZOLL Medical Corporation and shall not create a contract, unless such acceptance is acknowledged and accepted by ZOLL Medical Corporation by a writing signed by an authorized representative of ZOLL Medical Corporation.

20. GENERAL. Any Contract resulting from this Quotation shall be governed by and interpreted in accordance with the laws of the Commonwealth of Massachusetts. This constitutes the entire agreement between Buyer and Supplier with respect to the purchase and sale of the Products described in the face hereof, and only representations or statements contained herein shall be binding upon Supplier as a warranty or otherwise. Acceptance or acquiescence in the course of performance rendered pursuant hereto shall not be relevant to determining the meaning of this writing even though the accepting or acquiescing party has knowledge of the nature of the performance and opportunity for objection. No addition to or modification of any of the terms and conditions specified herein shall be binding upon Supplier unless made in writing and signed by a duly authorized representative of Supplier. The terms and conditions specified shall prevail notwithstanding any variance from the terms and conditions of any order or other form submitted by Buyer for the Products set forth on the face of this Agreement. To the extent that this writing may be treated as an acceptance of Buyer's prior offer, such acceptance is expressly made conditional on assent by Buyer to the terms hereof, and, without limitation, acceptance of the goods by Buyer to the terms hereof, and, without limitation, acceptance of the goods by Buyer shall constitute such assent. All cancellations and reschedules require a minimum of thirty (30) days notice.

City Of Gladstone, Missouri
Quote On Purchases

To: Director Hasty Date: 10/01/2018
From: Division Chief Sean Daugherty
Subject: Capital Purchase Purchase of: Cardiac Monitor
Reason For Purchase: Replace older monitor that parts aren't available for.

I have received (telephone), (in person), (written) quotations from:

- | | Quote |
|---|-------------------------|
| 1.) Firm: <u>Zoll Medical Corporation (Zoll X-Series)</u> | <u>\$31,861.10</u> |
| Person's Name: <u>Lori Rohling</u> | |
| Address: <u>269 Mill Road Clemsford, Massachussets 01824-4105</u> | |
| Telephone # <u>978-421-9655</u> | Date: <u>09/28/2018</u> |
|) | |
| 2.) Firm: <u>AEDSTODAY (Life Pak 15)</u> | <u>\$33,295.00</u> |
| Person's Name: <u>Customer Service</u> | |
| Address: <u>8091 Shaffer Parkway Littleton, CO 80127</u> | |
| Telephone # <u>888-225-7049</u> | Date: <u>10/01/2018</u> |

I recommend that the items be purchased from Zoll as they have been the sole source provider for the last three monitors that we have purchased and we already have the batteries and charging system in place for their monitor. There is only two available cardiac monitor suppliers available at the current time as Phillips had a recall on their monitors and the FDA has suspended them from manufacturing at this time (see attached). The staff is very comfortable in the use of the Zoll Monitor and it has been used with much success.

Signed: Sean Daugherty Date: 10/21/2018



Status of the Philips Monitor/Defibrillator Hold (Consent Decree) by the FDA

Thu, Jan 18, 2018 | By A.J. Heightman, MPA, EMT P

Philips recently reached agreement on a consent decree with the U.S. Department of Justice, representing the Food and Drug Administration (FDA), related to compliance with current good manufacturing practice requirements arising from past inspections focusing primarily on Philips' Emergency Care and Resuscitation (ECR) facilities in Andover, MA and Bothell, WA, in and before 2015.

The decree also provides for increased scrutiny, for a period of time, of the compliance of the other patient care businesses at Philips facilities with the Quality System Regulation.

Under the decree, Philips is required to suspend the manufacture and distribution of external defibrillators manufactured at these facilities, subject to certain exceptions, until FDA certifies through inspection the facilities' compliance with the Quality System Regulation.

Philips will continue the manufacture and distribution of certain automated external defibrillator (AED) models, service of AED and MRx devices, and provide consumables and the relevant accessories, to ensure uninterrupted

availability of these highly reliable life-saving devices in the U.S. Additionally, to meet the needs of global customers, Philips will also continue to export defibrillators including the FRx and FR3 AEDs once certain requirements have been met.

I reached out to Philips and asked them to discuss what the injunction means for Philips monitor/defibrillator customers.

Carla Kriwet, Chief Business Leader Connected Care & Health Informatics at Royal Philips has said that Philips is committed to delivering high quality, innovative products and solutions, is prepared to fulfill the terms of the decree, and hopes to resume the suspended defibrillator production in the course of 2018.

Philips officials also told me defibrillators currently in use by customers are recommended by Philips to remain in use, and should not be taken out of service because there is no reason to believe they pose a risk to patients.

The full consent decree is currently posted on Philips' website, along with information for users of Philips external defibrillators, describing how these products are impacted by the consent decree. Customers with questions not answered on Philips' website, can also contact Philips at + 1 800 263 3342 or via this link: <https://www.usa.philips.com/healthcare/about/news/public-website-consent-decree>

Matt Penzone, Sr. Field Marketing Manager for Emergency Care & Resuscitation at Philips North America then graciously answered the following questions about the consent decree and what it means for the EMS Industry

What is a consent decree?

The consent decree is a court order issued by a federal judge with terms agreed to in advance by the Philips and the US Government. This consent decree concerns quality systems compliance following FDA inspections of the Andover, MA and Bothell, WA Emergency Care & Resuscitation (ECR) manufacturing facilities in and before 2015. Philips takes this matter extremely seriously and we're committed to fulfilling the terms of the decree, building on the actions we have taken since 2015 to address these issues.

What does it mean for Philips?

At this time, under the terms of the Consent Decree and subject to limitations and conditions, Philips is permitted to continue to manufacture and ship HeartStart Home and HeartStart OnSite automated external defibrillators in order to meet public health needs. Under certain conditions, Philips may also manufacture and ship HeartStart FR3 devices.

It's important to note that we will continue to provide necessary consumables and accessories for defibrillator products without restriction and may continue to service existing devices, including the HeartStart MRx. We will also continue participation in clinical trials and sustain our ongoing R&D efforts into new Resuscitation solutions.

Are the Philips devices subject to this action safe to use?

Yes, it is important to understand that Philips defibrillators can remain in use by customers, enjoy strong reliability records and should not be taken out of service, as Philips has no reason to believe they pose a risk to patients.

Has there been any increase in the number of complaints with your devices within the affected businesses, whether for performance or safety?

No. There has been no increase in complaints for devices within the affected businesses for performance or safety. We intend to remain the world's leading supplier of defibrillators and make continued investments so that Philips products demonstrate the strong reliability our customers are accustomed to.

Does this impact the availability of other Philips products?

No, the primary impact of the consent decree on product availability relates to Philips' AED products. Because the HeartStart MRx ended production in earlier in 2017, the consent decree chiefly affects our AED products. Other consumer health products and medical devices manufactured by other Philips businesses at the Andover, MA and Bothell, WA sites, like Lumify Ultrasound, are not affected by the decree.

So what's next for Philips?

We're engaged in some exciting new projects to evolve and complement our existing offerings that we feel will help emergency responders play an even larger role in this evolving healthcare environment. Philips is fully committed to our AED and ALS defibrillator portfolio and to the EMS market, so we're eager to help advance Mobile-Integrated Health efforts and adoption of new, powerful technology like Lumify Point-of-Care Ultrasound.

Speaking of ultrasound, how is that going to help EMS?

Ultrasound is a powerful diagnostic tool but historically, the size, complexity and price have limited adoption outside the hospital. Now for the first time, Lumify is making high-quality, ultra-mobile Ultrasound a reality. It's versatile enough to be used in a variety scenarios and can helps care providers make diagnosis that impact treatment and transportation decisions. Just like with 12-Lead ECG acquisition & interpretation, a learning curve will exist but the huge benefits to patients will see Ultrasound become a standard of care in the near future.

By



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Editor-in-chief of *JEMS*, A.J. Heightman is a former EMS director and EMS operations director who has researched and specialized in MCI management training for 30 years.

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