ZOLL®
an Asahi Kasei company

269 Mill Road
Chelmsford, MA 01824
978.421.9655 (main)
978.421.0015 (fax)
zoll.com

RESPONSE PREPARED FOR:

City of Seguin

Request for Bids - Bid No. AF-2026-34 - Intelligent Transport Ventilator
ZOLL ZVent Portable Ventilator
Proposal Due: March 10, 2026 at 3:00PM

269 Mill Road
Chelmsford, MA 01824
978.421.9655 (main)
978.421.0015 (fax)
zoll.com

March 10, 2026

City of Seguin
Steve Parker
210 E. Gonzales
Seguin TX 78155

Re: Request for Bids - Bid No. AF-2026-34 - Intelligent Transport Ventilator

Steve Parker:

ZOLL® Medical Corporation ("ZOLL") is pleased to respond to your Request for Bids - Bid No. AF-2026-34 - Intelligent Transport Ventilator.

ZOLL is focused on improving patient outcomes with "cutting-edge" resuscitation and acute critical care technology. Our family of products offers the most integrated system of clinical solutions for Fire and EMS services as well as complementary products and services to provide data integration and management. We understand the unique needs of first responders and for four decades have been committed to developing “leading-edge” resuscitation products with those needs in mind; to that end our proposal was developed by taking into consideration your needs, and we are pleased to offer our Z Vent® Portable Ventilator.

ZOLL® ventilators are designed with the user in mind. Removing the complexities of most portable ventilators, ZOLL ventilators provide on-screen prompts that enable clinicians to quickly and easily initiate efficient oxygenation and treatment to patients. ZOLL ventilators feature Smart Help™ technology to facilitate alarm resolution, as well as Masimo® pulse oximetry, for accurate SpO2 and pulse-rate readings.

Designed to be lightweight and energy-efficient, Z Vent is ideal for all types of transport: ground ambulances, critical care transports, and air transports. Weighing less than 10 pounds (4.5kg), with a battery runtime of 10 hours, Z Vent is the ideal portable ventilator supporting infants through adults. The ruggedized housing is built to military standards, withstanding the elements that EMS personnel may face on any given day. With an integrated energy-efficient compressor, Z Vent helps conserve oxygen during transports where every bit of oxygen counts. The Z Vent® ventilator is easy to use, portable, durable, and rugged.

We believe we have offered very compelling clinical reasons for the City of Seguin to include ZOLL in its award decision and we are confident that ZOLL’s clinically advanced technology would significantly improve clinical outcomes for the City of Seguin. We are confident that our proposal is comprehensive and responsive. We respectfully request that you consider the Z Vent® Portable Ventilator device on the unique merits and benefits of each. Product specifications and brochures have been included for your review and evaluation in Sections 11 & 12 of our proposal.

ZOLL
an Asahi Kasei company

The City of Seguin is a member of Public Safety Association Inc PSAI ("Savvik") 2024-06 GPO Contract. Savvik features competitive prices on ZOLL defibrillators and related accessories, these discounted prices are available to you only under the terms and conditions of the Public Safety Association Inc PSAI 2024-06 GPO Contract. If ZOLL is awarded this bid, the terms and conditions of the Savvik 2024-06 GPO Membership exclusively apply and shall be incorporated by reference, with no additional terms added, unless as mutually agreed upon by the Parties. However, should City of Seguin not be amenable to making purchases for the discounted prices provided in this bid submittal, the pricing provided in this submittal cannot be honored and ZOLL reserves the right to adjust the pricing accordingly and negotiate the final agreement terms and conditions. ZOLL is submitting a response to this Bid No AF-2026-34 with the reserved right to review and mutually agree upon written purchasing terms and conditions if ZOLL shall be awarded this Bid. ZOLL may agree to the majority of purchasing terms and conditions proposed in this Bid, however, mutual agreement is required. Additionally, ZOLL has included its exceptions to terms and conditions listed in Section 4 of our proposal.

Thank you for the opportunity to respond to this bid request. We stand ready to serve the needs of the City of Seguin and look forward to the possibility of a long and mutually rewarding partnership. If you need further information or have any questions concerning this submittal, please do not hesitate to call me at +1 (858) 229-1717 or e-mail me at bprice@zoll.com.

With Regards,

Brian Price

Brian Price
Vent Territory Manager
BP/IS

Signed by:
Neil Johnston
73F27B738B0A445...

Neil Johnston
Vice President/General Manager, Hospital
NJ/IS

Enclosures

269 Mill Road
Chelmsford, MA 01824
978.421.9655 (main)
978.421.0015 (fax)
zoll.com

Table of Contents

ZOLL
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SECTION 1

Quote NO. Q-135730 V:3 with Signature Page

Quote NO. Q -137030 V:1 with Signature Page

PRICING IN THIS SECTION IS CONFIDENTIAL

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
Federal ID# 04-2711626

Phone: (800) 348-9011
Fax: (978) 421-0015
Email: esales@zoll.com

Quote No: Q-135730 Version: 3

Seguin Fire Department
660 State Highway 46 S
Seguin, TX 78155

ZOLL Customer No: 477036

Garrick Herbert
(830) 401-2310
gherbert@seguintexas.gov

Quote No: Q-135730
Version: 3

Issued Date: March 10, 2026
Expiration Date: May 9, 2026

Terms: Net due in 30 days

FOB: Shipping Point

Freight: Prepay & Add

Prepared by: Brian Price
Vent Territory Manager
bprice@zoll.com
+1 8582291717

Item	Contract Reference	Part Number	Description	Qty	List Price	Adj. Price	Total Price
1	CH-19732	8660-001401-01	**Z Vent® Portable Ventilator** Includes: 1 each: Circuit, Vent, Single Limb, WYE, Adult/Pedi, 1 each: Circuit, Vent, Single Limb, WYE, Infant, 1 Assembly Oxygen Hose 6 inch Long, 2 each: Filter, Foam, Inlet, 1/2 inch dia X 108 inch Long, Individually Bagged, 2 each: Filter, Disk, Fresh Gas/Emergency Air Intake, Individually Bagged, 1 Power Cord, 6 inch 18AWG 3 SPT-2, NEMA 5- 15P, IEC60320-C5 (Check MFR), 1Power Supply, 100-240 VAC, 100W, 24V, 42A, IEC 320 & DT7L Plugs.	5	$22,388.00	$15,215.20	$76,076.00
2	CH-19732	820-0106-15	**Adult Disposable Circuit,Disposable Circuit, EMV+, AEV, Eagle II, 6 foot length, Single patient use, (case of 15)**	1	$308.00	$230.23	$230.23
3	CH-19732	465-0024-00	**Filter, Bacterial/Viral (BV) (Case of 50)**	1	$560.00	$462.40	$462.40

Subtotal: $76,768.63

Total: $76,768.63

Contract Reference	Description
CH-19732	Reflects Public Safety Association Inc PSAI 2024-06 contract Pricing. Notwithstanding anything to the contrary herein, the terms and conditions set forth in Public Safety Association Inc PSAI Buying Group Contract No. 2024-06 shall apply to the customer's purchase of the products set forth on this quote.

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
Federal ID# 04-2711626

Phone: (800) 348-9011
Fax: (978) 421-0015
Email: esales@zoll.com

Seguin Fire Department
Quote No: Q-135730 Version: 3

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 for capital equipment, accessories and consumables can be found at https://www.zoll.com/terms-and-conditions-of-sale, for software products can be found at https://www.zoll.com/software-legal, and for ExpertCare Service Plans can be found at https://www.zoll.com/ExpertCare-Service-Terms. 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.

1. Delivery will be made upon availability.
2. This Quote expires on May 9, 2026. Pricing is subject to change after this date.
3. Applicable tax, shipping & handling will be added at the time of invoicing.
4. All purchase orders are subject to credit approval before being accepted by ZOLL.
5. To place an order, please forward the purchase order with a copy of this quotation to esales@zoll.com or via fax to 978-421-0015.
6. All discounts from list price are contingent upon payment within the agreed upon terms.
7. Place your future accessory orders online by visiting the ZOLL web store.

Order Information (to be completed by the customer)

[ ] Tax Exempt Entity (Tax Exempt Certificate must be provided to ZOLL)

[ ] Taxable Entity (Applicable tax will be applied at time of invoice)

BILL TO ADDRESS	SHIP TO ADDRESS
Name/Department:	Name/Department:
Address:	Address:
City / State / Zip Code:	City / State / Zip Code:

Is a Purchase Order (PO) required for the purchase and/or payment of the products listed on this quotation?

[ ] Yes PO Number: _____ PO Amount: _____
(A copy of the Purchase Order must be included with this Quote when returned to ZOLL)

[ ] No (Please complete the below section when submitting this order)

For organizations that do not require a PO, ZOLL requires written execution of this order. The person signing below represents and warrants that she or he has the authority to bind the party for which he or she is signing to the terms and prices in this quotation.

Seguin Fire Department
Authorized Signature:

_____

Name: _____

Title: _____

Date: _____

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
Federal ID# 04-2711626

Phone: (800) 348-9011
Fax: (978) 421-0015
Email: esales@zoll.com

Quote No: Q-137030 Version: 1

Seguin Fire Department
660 Texas # 46
Seguin, TX 78155

ZOLL Customer No: 477036

Garrick Herbert
(830) 401-2310
gherbert@seguintexas.gov

Quote No: Q-137030
Version: 1

Issued Date: March 4, 2026
Expiration Date: May 9, 2026

Terms: Net due in 30 days

FOB: Shipping Point

Freight: Prepay & Add

Prepared by: Brian Price
Vent Territory Manager
bprice@zoll.com
+1 8582291717

Item	Contract Reference	Part Number	Description	Qty	List Price	Adj. Price	Total Price
1		8778-89004-PP-V	**Vent - Precision Service Plan - 4 Year At Time of Sale** Includes: Annual preventive maintenance (Includes battery replacement during 4-year PM), and Repairs: Parts and labor per ZOLL Limited Product Warranty. Shipping and use of a Service Loaner upon request during device service, no charge shipping. Service Plan is a continuation of ZOLL Limited Product Warranty.	5	$5,110.00	$4,599.00	$22,995.00

Subtotal: $22,995.00

Total: $22,995.00

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 for capital equipment, accessories and consumables can be found at https://www.zoll.com/terms-and-conditions-of-sale, for software products can be found at https://www.zoll.com/software-legal, and for ExpertCare Service Plans can be found at https://www.zoll.com/ExpertCare-Service-Terms. 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.

1. Delivery will be made upon availability.
2. This Quote expires on May 9, 2026. Pricing is subject to change after this date.
3. Applicable tax, shipping & handling will be added at the time of invoicing.
4. All purchase orders are subject to credit approval before being accepted by ZOLL.
5. To place an order, please forward the purchase order with a copy of this quotation to esales@zoll.com or via fax to 978-421-0015.
6. All discounts from list price are contingent upon payment within the agreed upon terms.
7. Place your future accessory orders online by visiting the ZOLL web store.

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
Federal ID# 04-2711626

Phone: (800) 348-9011
Fax: (978) 421-0015
Email: esales@zoll.com

Seguin Fire Department
Quote No: Q-137030 Version: 1

Order Information (to be completed by the customer)

[ ] Tax Exempt Entity (Tax Exempt Certificate must be provided to ZOLL)

[ ] Taxable Entity (Applicable tax will be applied at time of invoice)

BILL TO ADDRESS	SHIP TO ADDRESS
Name/Department:	Name/Department:
Address:	Address:
City / State / Zip Code:	City / State / Zip Code:

Is a Purchase Order (PO) required for the purchase and/or payment of the products listed on this quotation?

[ ] Yes PO Number: _____ PO Amount: _____
(A copy of the Purchase Order must be included with this Quote when returned to ZOLL)

[ ] No (Please complete the below section when submitting this order)

For organizations that do not require a PO, ZOLL requires written execution of this order. The person signing below represents and warrants that she or he has the authority to bind the party for which he or she is signing to the terms and prices in this quotation.

Seguin Fire Department
Authorized Signature:

_____

Name: _____

Title: _____

Date: _____

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SECTION 2

Price Sheet AF-2026-34

PRICE SHEET AF-2026-34

City of Seguin Fire Department
Transport Ventilators

Vendor Name: ZOLL Medical Corporation
Company: ZOLL Medical Corporation
Date: March 10, 2026

All pricing shall be firm and include delivery, setup, and all applicable costs unless otherwise noted.

Base Equipment

Item	Description	Unit Price	Qty	Total
1	Transport Ventilator – Base Unit	$15,215.20	5	$76,076.00

Total: Seventy-Six Thousand Seventy-Six Dollars and Zero Cents

Batteries

Item	Description	Unit Price	Qty	Total
2	Additional Battery Unit	$Free if purchased with Precision Service Plan		$

Breathing Circuits

Case of 15

Item	Description	Unit Price	Qty	Total
3	Replacement Breathing Circuits – Adult	$230.23	1	$230.23
4	Replacement Breathing Circuits – Pediatric	$230.23	1	$230.23

Total for each: Two Hundred Thirty Dollars and Twenty-Three Cents

Filters

Case of 50

Item	Description	Unit Price (per box/case)	Qty	Total
5	Bacterial/Viral Filters	$462.40	1	$462.40

Total: Four Hundred Sixty-Two Dollars and Forty Cents

Warranty Options

Item	Description	Unit Price	Term	Total
6	Extended Warranty	$4,599.00	4 yrs	$22,995.00

Total: Twenty-Two Thousand Nine Hundred Ninety-Five Dollars and Zero Cents

Maintenance (Optional)

Item	Description	Annual Cost	Term	Total
7	Annual Maintenance Agreement	$_____	____ yrs	$_____

Accessories / Consumables

List any additional accessories or consumables not listed above.

Item	Description	Unit Price	Qty	Total
8	_____	$_____	____	$_____
9	_____	$_____	____	$_____

GRAND TOTAL: $99,763.63

Ninety-Nine Thousand Seven Hundred Sixty-Three Dollars and Sixty-Three Cents

Vendor Certification

The undersigned certifies that pricing submitted is accurate and firm for the term of this solicitation.

Authorized Signature: Signed by: Neil Johnston 73F27B738B0A445...
Printed Name: Neil Johnston
Title: Vice President/General Manager, Hospital
Date: Mar 10, 2026

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an Asahi Kasei company

SECTION 3
Addendum Form

ADDENDUM FORM
Bid # AF-2026-34

Receipt is hereby acknowledged of the following Addenda to the Specifications:

ADDENDUM NO. 1 DATED February 23, 2026
ADDENDUM NO. 2 DATED March 3, 2026
ADDENDUM NO. 3 DATED _____
ADDENDUM NO. 4 DATED _____
ADDENDUM NO. 5 DATED _____
ADDENDUM NO. 6 DATED _____

- **The Undersigned affirms that it is duly authorized to submit this bid, that this bid has not been prepared in collusion with any other bidder, and that the content of this bid as to prices, terms, or conditions of said bid has not been communicated to any other bidder prior to the official opening of this bid.**
- **The Undersigned certifies that pursuant to Section 2270.002 of the Texas Government Code, Bidder does not boycott Israel and will not boycott Israel during the term of the contract resulting from this solicitation.**
- **The Undersigned certifies that pursuant to S.B 19, Bidder does not boycott energy companies and will not boycott energy companies during the term of the contract.**
- **The Undersigned certifies that pursuant to S.B. 13, Bidder does not have a practice, policy, guidance, or directive that discriminates against a firearm entity or firearm trade association; and will not discriminate during the term of the contract against a firearm entity or firearm trade association.**

ZOLL Medical Corporation
Company Name

Signed by: Neil Johnston 73F27B738B0A445...
Authorized Signature

269 Mill Road
Address

Neil Johnston
Printed Name

Chelmsford, MA 01824
City, State, Zip Code

Vice President/General Manager, Hospital
Title

800-348-9011
Phone No.

Mar 10, 2026
Date

Email Address: esales@zoll.com & bids@zoll.com

ZOLL®
an Asahi Kasei company

SECTION 4

Bidder's Exceptions Form

BIDDER'S EXCEPTION FORM
Bid # AF-2026-34

This form must be completed and signed by an authorized representative of the company. Failure to do so may cause total bid to be rejected. If no exceptions are to proposed, indicate by stating "No Exceptions to Specifications" and sign in the appropriate space.

STATEMENT OF BIDDER:

WE PROPOSE THE FOLLOWING EXCEPTIONS TO THE **INSURANCE REQUIREMENTS** SPECIFICATIONS:

SECTION	PAGE/ PARAGRAPH #	EXCEPTION
Insurance	Pg 19/Par. 1	Sec. B - Add: *CONTRACTOR shall have the right to review any modifications to these insurance requirements to confirm requested changes are commercially reasonable and commensurate with types and amounts typically carried by similar firms* at the end of the paragraph
Insurance	Pg.20/Par.1	Add'l policy endorsements: Add-*In the event of a regulatory proceeding or claim to which the City is a party* at the beginning of paragraph 1. This is due to confidentiality of ZOLL's insurance information.
Insurance	Pg. 20/Par. a.	Add'l Insd – ZOLL is only able to include the City as an additional insured under CGL with respect to ongoing operations of ZOLL under the agreement.
Insurance	Pg. 20/Par. a and b.	Delete a. and b. entirely – Due to the number of these types of requirements, ZOLL does not agree to endorse its insurance policies to provide notices to other parties. We are bound under the terms of the contract to maintain insurance. Allowing any cancellation or changes that would adversely affect the agreement would put ZOLL in breach of contract. Therefore, ZOLL would not allow any cancellation without replacement coverage.
Insurance	Pg. 20/Notices	Change to - *CONTRACTOR shall endeavor to notify CITY in the event of any change in coverage that would adversely affect this agreement and shall give such notices not less than thirty (30) days prior to the change, which notice must be followed by a replacement CERTIFICATE OF INSURANCE*
Insurance Affidavit	Pg. 23	The affidavit has not been signed by ZOLL's Broker(s). ZOLL Medical has a full-time Director of Risk Management on staff who is responsible for ZOLL's insurance program. As part of that role, all insurance clauses in contracts are reviewed in-house and are not sent to our Insurance Broker for review. ZOLL agrees to forward a valid certificate of Insurance within 10 days of notice award.

NOTE: If additional pages are needed, attach to the back of this page and note "See Page 2-Deviations" on this page.

Patrice J Comb

ZOLL Medical Corporation
Company Name

Patrice J. Comb, Director, Risk Management
Authorized Signature

See Pages 2 to 5 Deviations

BIDDER'S EXCEPTION FORM
Bid # AF-2026-34

This form must be completed and signed by an authorized representative of the company. Failure to do so may cause total bid to be rejected. If no exceptions are to proposed, indicate by stating "No Exceptions to Specifications" and sign in the appropriate space.

STATEMENT OF BIDDER:

WE PROPOSE THE FOLLOWING EXCEPTIONS TO THE SPECIFICATIONS:

SECTION	PAGE/ PARAGRAPH #	EXCEPTION
Specifications, Section 2.2 to 2kg.	Pg. 3/Par. 1	The Z Vent goes down to 5kg patients, not down
Specifications, Section 2.3	Pg. 4/Par. 6	Our flow rate is 0-100 liters per minute.
Specifications, Section 2.3	Pg. 4/Par. 10	Our inspiratory time is .1 to 5 seconds.
Specifications, Section 2.4	Pg. 4/Par. 1	We do not have a LCD color display.
Specifications, Section 2.4 over time).	Pg. 4/Par. 3	The Z Vent will display only 1 waveform (pressure
Specifications, Section 2.4 Volume.	Pg. 4/Par. 4	The Z Vent does not monitor Exhaled Tidal
Specifications, Section 2.6 have a 10 hour Li internal battery).	Pg. 4/Par. 2	Z Vent does not have hot-swapable battery (we
Specifications, Section 2.13 integration.	Pg. 4/Par. 3	Z Vent does not offer any ePCR compatibility or
Specifications, Section 3.2 technical issues during normal business hours.	Pg. 4/Par. 2	4-hour maximum response time for critical
Specifications, Section 4.1 Section 12 of our bid response packet.	Pg. 4/Par. 3	Please refer to ZOLL's standard warranty in
Specifications, Section 5	Pg. 19/Par. 1	Delivery shall be FOB Shipping Point per Savvik.
Specifications, Section 5 valid purchase order.	Pg. 19/Par. 2	Delivery timeline shall be 30-60 days from date of

Specifications, Section 7.2 Pg. 19/Par. 7 ZOLL proposes to change acceptance testing from 7 days to 10 days.

ADA Section Pg. 24/Par. 3 There are no subcontractors performing under this agreement.

General Conditions of Bidding, Section 3 Pg. 26/Par. B ZOLL would like to remove this Section 3(B) in its entirety.

General Conditions of Bidding, Section 14 Pg. 30/Par. A ZOLL proposes the following language: *The Contractor warrants to the City that all goods delivered will be in accordance with Contractor's standard Product Warranty. Any products returned shall be in accordance with Contractor's standard Return Policy.*

General Conditions of Bidding, Section 14 Pg. 30/Par. B ZOLL proposes to remove the language after the first sentence as we do not price match. City is already receiving Savvik prices on our goods. Propose to only keep: *The City will pay the price for goods specified by the Contractor's bid.*

General Conditions of Bidding, Section 14 Pg. 30/Par. C ZOLL proposes to remove this Section 14(C) in its entirety.

General Conditions of Bidding, Section 16 Pg. 32/Par. C Delivery shall be FOB Shipping Point per Savvik.

General Conditions of Bidding, Section 16 Pg. 32/Par. C ZOLL proposes the following language: ~~*The title and risk of loss of the goods will not pass to the City until receipt and acceptance takes place at the FOB point.*~~ *The City department receiving deliveries or issuing purchase orders under this contract will inspect and accept any and all deliveries made and may reject those items which are damaged or which do not conform to the specifications, provided any inspection is completed within ten (10) days or otherwise delivery shall be deemed to be accepted. The Contractor is responsible for the proper labeling, packing, and delivery to final destination, including replacement of rejected deliveries* ~~*at no additional cost*~~ *in accordance with Contractor's standard Product Warranty and Return Policy.*

General Conditions of Bidding, Section 16 Pg. 32/Par. E ZOLL proposes modifications to this section: *Vendor must keep the City advised as to the status of the delivery. When delivery delay can be foreseen, the Vendor shall endeavor to give prior notice to the City.*

General Conditions of Bidding, Section 16 Pg. 32/Par. F ZOLL proposes modification to this section as we do not agree to a cover clause: *Default in promised delivery, without acceptable reasons, or failure to meet specifications without remedy shall cause the City to purchase the goods elsewhere* ~~*and charge any increase in cost and handling to the defaulting vendor. This does not limit any other remedies to the City for damage entitled under the Uniform Commercial Code.*~~

General Conditions of Bidding, Section 17 Pg. 32/Par. A ZOLL proposes modifications to this section: *Delivered articles not in accordance with any applicable samples and specifications must be removed by the bidder at his expense.* ~~*All disputes concerning quality of supplies delivered under this proposal will be determined by the City's Purchasing Manager or his/her designated representative.*~~

General Conditions of Bidding, Section 17 Pg. 32/Par. B ZOLL proposes modifications to this section: *All articles enumerated in the proposal shall be subject to inspection or delivery by an officer designated for the purpose* ~~*and if found inferior to the quality called for, or not equal in value to the department's samples, or deficient in weight, measurements, workmanship or otherwise, this fact shall be reported to the Purchasing*~~

~~*Manager who shall have the right to reject the whole or any part of the same*~~. *Acceptance of deliveries shall be upon inspection of delivery within ten (10) days; or, if acceptance testing will be performed by City, within thirty (30) days of delivery, after which acceptance is deemed to have occurred if no notice is provided by the City to Contractor within the applicable time period. If acceptance testing is to be performed by City, the acceptance test plan shall be provided to the Contractor in advance. In no event shall acceptance exceed the time periods set forth above.*

General Conditions of Bidding, Section 18 Pg. 32/Par. A ZOLL proposes modifications to this section: *Payment of invoices by the City shall be made thirty (30) days after* ~~*receipt and acceptance of all equipment or performance of services covered by each purchase order or following the receipt*~~ *the date of an accurate invoice,* ~~*whichever is later,*~~ *in compliance with state statute . Bidder shall state his bid in accordance with the standard payment terms and conditions of the City of Seguin of Net 30 days. All bids must be stated in terms of dollars and cents, the bidder's lowest, best, and final price.*

General Conditions of Bidding, Section 19 Pg. 33/Par. 1 ZOLL proposes to make this section mutual: *No right or interest in the contract shall be assigned, nor delegation of any obligation made by* ~~*Vendor*~~ *either party without the written permission of the other party*~~*City*~~*. Any attempted assignment or delegation by* ~~*Vendor*~~ *either party shall be wholly void and totally ineffective for all purposes unless made in conformity with this paragraph.*

General Conditions of Bidding, Section 21 Pg. 33/Par. 1 ZOLL proposes to expand Force Majeure: *In the event that the performance by either party of any of its obligations under this contract is interrupted or delayed by events reasonably outside of their control such as acts of God, war, riot, material shortages, disruption in supply chain, epidemics, pandemics, or civil commotion, then the party is excused from such performance for the period of time reasonably necessary to remedy the effects of the events.*

General Conditions of Bidding, Section 22 Pg. 33/Par. 1 ZOLL proposes to remove the last sentence of this Section 22 as we do not agree to a cover clause.

General Conditions of Bidding, Section 23 Pg. 33/Par. A ZOLL proposes to make this Section 23(A) mutual: *Failure by either party to perform any material obligation*~~*of its provisions*~~ *will constitute a default and breach of contract, in which case, the other party may require corrective action within thirty (30)* ~~*10*~~ *days from the date the defaulting party receives written notice citing the nature of the breach. Failure of the defaulting party to take corrective action or to provide a satisfactory written reply excusing such failure within the prescribed Thirty (30)* ~~*10*~~ *days will authorize the other party to terminate this agreement by written notice.*

General Conditions of Bidding, Section 23 Pg. 33/Par. B ZOLL proposes to make this Section 23(B) mutual: ~~*The City*~~*Either party reserves the right to terminate this contract upon thirty (30) days written notice for any reason* ~~*deemed by the City Council to serve the public interest*~~*. Termination for convenience will not be made when termination is authorized under any other provisions of this contract. In the event of such termination the City will pay the Contractor those costs directly attributable to supplies obtained in compliance with the contract prior to termination. Provided, however, that no costs will be paid to the Contractor which are recoverable in the normal course of doing business. The City is not liable for loss of any profits anticipated to be made hereunder.*

General Conditions of Bidding, Section 27 Pg. 34/Par. 1 ZOLL's Legal provided edits to this Section 27: *THE VENDOR WILL INDEMNIFY, HOLD HARMLESS AND DEFEND THE CITY AND ITS EMPLOYEES, AGENTS, OFFICERS AND SERVANTS FROM ANY AND ALL THIRD PARTY LAWSUITS, CLAIMS, DEMANDS AND CAUSES OF ACTION* ~~*OF ANY KIND*~~*TO THE EXTENT ARISING DIRECTLY FROM A DEFECT IN THE APPLICABLE PRODUCTS PROVIDED UNDER THIS BID*~~*THE NEGLIGENT OR INTENTIONAL ACTS ERRORS OR OMISSIONS OF THE VENDOR, ITS*~~

~~*OFFICERS, EMPLOYEES OR AGENTS*~~ *AND PERSONAL INJURY OR DEATH CAUSED BY THE APPLICABLE PRODUCTS PROVIDED UNDER THIS BID. THIS WILL INCLUDE, BUT NOT BE LIMITED TO, THE AMOUNTS OF JUDGMENTS, PENALTIES, INTEREST, COURT COSTS, REASONABLE LEGAL FEES, AND ALL OTHER EXPENSES INCURRED BY THE CITY ARISING IN FAVOR OF ANY PARTY, INCLUDING THE AMOUNTS OF ANY DAMAGES OR AWARDS RESULTING FROM CLAIMS DEMANDS AND CAUSES OF ACTION FOR PERSONAL INJURIES, DEATH OR DAMAGES TO PROPERTY ALLEGED OR ACTUAL INFRINGEMENT OF PATENTS, COPYRIGHTS, AND TRADEMARKS AND WITHOUT LIMITATION BY ENUMERATION, ALL OTHER CLAIMS, DEMANDS, OR CAUSES OF ACTION OF EVERY CHARACTER OCCURRING, RESULTING, OR ARISING FROM ANY NEGLIGENT OR INTENTIONAL WRONGFUL ACT, ERROR OR OMISSION OF THE VENDOR OR ITS AGENTS OR EMPLOYEES. THIS OBLIGATION BY THE VENDOR WILL NOT BE LIMITED BY REASON OF THE SPECIFICATION OF ANY PARTICULAR INSURANCE COVERAGE REQUIRED UNDER THIS AGREEMENT. ANY INDEMNITY SHALL BE CONDITIONED UPON PROMPT WRITTEN NOTIFICATION BY THE CITY TO BIDDER OF THE CLAIM, COOPERATING WITH THE BIDDER IN DEFENSE OF THE CLAIM, AND GIVING BIDDER SOLE CONTROL OF THE DEFENSE, NEGOTIATION, AND SETTLEMENT OF ANY SUCH CLAIM. IN NO EVENT SHALL BIDDER BE LIABLE FOR CONSEQUENTIAL, SPECIAL, PUNITIVE, OR ANY OTHER INDIRECT DAMAGES OF ANY KIND.*

Bidder shall indemnify the City and its affiliates, officers, directors, agents and employees from third party claims resulting from infringement by the Products provided by Bidder to the City under this Agreement of any US patent issued as of the date of delivery of the applicable Product. THE FOREGOING IS IN LIEU OF ANY WARRANTIES OF NONINFRINGEMENT, WHICH ARE HEREBY DISCLAIMED. The foregoing obligation of Bidder does not apply with respect to Products or portions or components thereof (i) that are not supplied by Bidder; (ii) that are modified after shipment, if the alleged infringement relates to such modifications; (iii) that are combined with other products, processes or materials where the alleged infringement relates to such combination; (iv) where the City continues allegedly infringing activity after being notified thereof or after being informed of modifications that would have avoided the alleged infringement; (v) where The City's use of the Product is incident to an infringement not resulting solely from the Product; and (vi) where the City's use is not strictly in accordance with this Agreement and Bidder's product documentation. If the use or sale of a Product is enjoined by order or settlement, Bidder shall have the option to (i) procure for the City the right to continue using the Product; (ii) replace the Product with a non-infringing Product; (iii) modify the Product so it becomes non-infringing; or (iv) accept return of the infringing Product and grant the City a credit for a pro-rated amount of the purchase price. This constitutes the entire liability of Bidder for infringement by Products furnished hereunder. Any indemnity will be conditioned upon prompt written notification by City to Bidder of the claim, cooperating with Bidder in the defense of the claim, and giving Bidder sole control of the defense, negotiation, and settlement of any such claim. IN NO EVENT SHALL BIDDER BE LIABLE FOR CONSEQUENTIAL, SPECIAL, PUNITIVE, OR ANY OTHER INDIRECT DAMAGES OF ANY KIND.

General Conditions of Bidding, Section 28 Pg. 34/Par. 1 ZOLL proposes to remove this Section 28, Patents, in its entirety.

General Conditions of Bidding, Section 34 Pg. 36/Par. 1 ZOLL proposes to include "applicable" in this Section 33. *The Bidder shall comply with all applicable Federal, State and local laws and ordinances relating to Social Security, Unemployment Insurance, Income Tax Withholding, Workers' Compensation, pensions and similar matters.*

NOTE: If additional pages are needed, attach to the back of this page and note "See Page 2-Deviations" on this page.

ZOLL Medical Corporation

Company Name

Signed by: Neil Johnston 73F27B738B0A445...

Authorized Signature

ZOLL
an Asahi Kasei company

SECTION 5

Insurance Requirement Affidavit

CITY OF SEGUIN
INSURANCE REQUIREMENT AFFIDAVIT

To be Completed By Appropriate Insurance Agent

and submitted with bid proposal.

I, the undersigned Agent/Broker, certify that the insurance requirements contained in this bid document have been reviewed by me with the below identified Contractor. If the below identified Contractor is awarded this contract by the City of Seguin, I will be able to, within ten (10) days after being notified of such award, furnish a valid insurance certificate to the City meeting all of the requirements defined in this bid.

_____ _____

Agent (Signature) Agent (Print)

Name of Agency/Broker: _____

Address of Agent/Broker: _____

City/State/Zip: _____

Agent/Broker Telephone #: (_____) _____

CONTRACTOR'S NAME: _____
(Print or Type)

NOTE TO AGENT/BROKER

If this time requirement is not met, the City has the right to invalidate the bid award and award the contract to the next lowest bidder meeting specifications. Should an awarded bid be invalidated the Contractor may be liable for breach of contract. If you have any questions concerning these requirements, please contact the Purchasing Manager for the City of Seguin at (830) 401-2451

ZOLL Medical has a full-time Director of Risk Management on staff who is responsible for ZOLL's insurance program. As part of that role, all insurance clauses in contracts are reviewed in-house and are not sent to our Insurance Broker for review.

ZOLL agrees to forward a valid certificate of Insurance within 10 days of notice award.

ZOLL Medical Corporation
By: Patrice J Comb
Director of Risk Management

Patrice J Comb

CITY OF SEGUIN
INSURANCE REQUIREMENT AFFIDAVIT

To be Completed By Appropriate Insurance Agent

and submitted with bid proposal.

I, the undersigned Agent/Broker, certify that the insurance requirements contained in this bid document have been reviewed by me with the below identified Contractor. If the below identified Contractor is awarded this contract by the City of Seguin, I will be able to, within ten (10) days after being notified of such award, furnish a valid insurance certificate to the City meeting all of the requirements defined in this bid.

_____ _____
Agent (Signature) Agent (Print)

Name of Agency/Broker: _____

Address of Agent/Broker: _____

City/State/Zip: _____

Agent/Broker Telephone #: ( ) _____

CONTRACTOR'S NAME: _____
(Print or Type)

NOTE TO AGENT/BROKER

If this time requirement is not met, the City has the right to invalidate the bid award and award the contract to the next lowest bidder meeting specifications. Should an awarded bid be invalidated the Contractor may be liable for breach of contract. If you have any questions concerning these requirements, please contact the Purchasing Manager for the City of Seguin at (830) 401-2451

ZOLL Medical has a full-time Director of Risk Management on staff who is responsible for ZOLL's insurance program. As part of that role, all insurance clauses in contracts are reviewed in-house and are not sent to our Insurance Broker for review.

ZOLL agrees to forward a valid certificate of Insurance within 10 days of notice award.

ZOLL Medical Corporation
By: Patrice J Comb
Director of Risk Management

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SECTION 6

Form 1295

CERTIFICATE OF INTERESTED PARTIES

FORM 1295

Complete Nos. 1 - 4 and 6 if there are interested parties.
Complete Nos. 1, 2, 3, 5, and 6 if there are no interested parties.

OFFICE USE ONLY
CERTIFICATION OF FILING

Certificate Number:
2026-1430648

Date Filed:
03/09/2026

Date Acknowledged:

1 Name of business entity filing form, and the city, state and country of the business entity's place of business.
ZOLL Medical Corporation
Chelmsford, MA United States

2 Name of governmental entity or state agency that is a party to the contract for which the form is being filed.
City of Seguin

3 Provide the identification number used by the governmental entity or state agency to track or identify the contract, and provide a description of the services, goods, or other property to be provided under the contract.
Bid No. AF-2026-34
Ventilators and related equipment for Intelligent Transport Ventilator

4 Name of Interested Party	City, State, Country (place of business)	Nature of interest (check applicable)	
		Controlling	Intermediary

5 Check only if there is NO Interested Party. [X]

6 UNSWORN DECLARATION

My name is Neil Johnston, and my date of birth is Sept 4, 1980.

My address is 269 Mill Road, Chelmsford (city), MA (state), 01824 (zip code), USA (country).

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Middlesex County, State of MA, on the 10th day of March (month), 2026 (year).

Signed by: Neil Johnston 73F27B738B0A445...

Signature of authorized agent of contracting business entity
(Declarant)

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SECTION 7
Conflict of Interest Questionnaire

CONFLICT OF INTEREST QUESTIONNAIRE

FORM CIQ

For vendor doing business with local governmental entity

This questionnaire reflects changes made to the law by H.B. 23, 84th Leg., Regular Session.

This questionnaire is being filed in accordance with Chapter 176, Local Government Code, by a vendor who has a business relationship as defined by Section 176.001(1-a) with a local governmental entity and the vendor meets requirements under Section 176.006(a).

By law this questionnaire must be filed with the records administrator of the local governmental entity not later than the 7th business day after the date the vendor becomes aware of facts that require the statement to be filed. *See* Section 176.006(a-1), Local Government Code.

A vendor commits an offense if the vendor knowingly violates Section 176.006, Local Government Code. An offense under this section is a misdemeanor.

OFFICE USE ONLY

Date Received

1 **Name of vendor who has a business relationship with local governmental entity.**

N/A

2 ☐ **Check this box if you are filing an update to a previously filed questionnaire.** (The law requires that you file an updated completed questionnaire with the appropriate filing authority not later than the 7th business day after the date on which you became aware that the originally filed questionnaire was incomplete or inaccurate.)

3 **Name of local government officer about whom the information is being disclosed.**

N/A

Name of Officer

4 **Describe each employment or other business relationship with the local government officer, or a family member of the officer, as described by Section 176.003(a)(2)(A). Also describe any family relationship with the local government officer. Complete subparts A and B for each employment or business relationship described. Attach additional pages to this Form CIQ as necessary.**

N/A

A. Is the local government officer or a family member of the officer receiving or likely to receive taxable income, other than investment income, from the vendor?

☐ Yes ☐ No

B. Is the vendor receiving or likely to receive taxable income, other than investment income, from or at the direction of the local government officer or a family member of the officer AND the taxable income is not received from the local governmental entity?

☐ Yes ☐ No

5 **Describe each employment or business relationship that the vendor named in Section 1 maintains with a corporation or other business entity with respect to which the local government officer serves as an officer or director, or holds an ownership interest of one percent or more.**

N/A

6 ☐ Check this box if the vendor has given the local government officer or a family member of the officer one or more gifts as described in Section 176.003(a)(2)(B), excluding gifts described in Section 176.003(a-1).

7 Signed by: Mil Johnston 73F27B738B0A445...

Signature of vendor doing business with the governmental entity

Mar 10, 2026

Date

CONFLICT OF INTEREST QUESTIONNAIRE
For vendor doing business with local governmental entity

A complete copy of Chapter 176 of the Local Government Code may be found at http://www.statutes.legis.state.tx.us/Docs/LG/htm/LG.176.htm. For easy reference, below are some of the sections cited on this form.

Local Government Code § 176.001(1-a): "Business relationship" means a connection between two or more parties based on commercial activity of one of the parties. The term does not include a connection based on:

(A) a transaction that is subject to rate or fee regulation by a federal, state, or local governmental entity or an agency of a federal, state, or local governmental entity;

(B) a transaction conducted at a price and subject to terms available to the public; or

(C) a purchase or lease of goods or services from a person that is chartered by a state or federal agency and that is subject to regular examination by, and reporting to, that agency.

Local Government Code § 176.003(a)(2)(A) and (B):

(a) A local government officer shall file a conflicts disclosure statement with respect to a vendor if:

***

(2) the vendor:

(A) has an employment or other business relationship with the local government officer or a family member of the officer that results in the officer or family member receiving taxable income, other than investment income, that exceeds $2,500 during the 12-month period preceding the date that the officer becomes aware that

(i) a contract between the local governmental entity and vendor has been executed; or

(ii) the local governmental entity is considering entering into a contract with the vendor;

(B) has given to the local government officer or a family member of the officer one or more gifts that have an aggregate value of more than $100 in the 12-month period preceding the date the officer becomes aware that:

(i) a contract between the local governmental entity and vendor has been executed; or

(ii) the local governmental entity is considering entering into a contract with the vendor.

Local Government Code § 176.006(a) and (a-1)

(a) A vendor shall file a completed conflict of interest questionnaire if the vendor has a business relationship with a local governmental entity and:

(1) has an employment or other business relationship with a local government officer of that local governmental entity, or a family member of the officer, described by Section 176.003(a)(2)(A);

(2) has given a local government officer of that local governmental entity, or a family member of the officer, one or more gifts with the aggregate value specified by Section 176.003(a)(2)(B), excluding any gift described by Section 176.003(a-1); or

(3) has a family relationship with a local government officer of that local governmental entity.

(a-1) The completed conflict of interest questionnaire must be filed with the appropriate records administrator not later than the seventh business day after the later of:

(1) the date that the vendor:

(A) begins discussions or negotiations to enter into a contract with the local governmental entity; or

(B) submits to the local governmental entity an application, response to a request for proposals or bids, correspondence, or another writing related to a potential contract with the local governmental entity; or

(2) the date the vendor becomes aware:

(A) of an employment or other business relationship with a local government officer, or a family member of the officer, described by Subsection (a);

(B) that the vendor has given one or more gifts described by Subsection (a); or

(C) of a family relationship with a local government officer.

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SECTION 8
Required Documentation

EMC Test Report

Project Number: 5170484 **Proposal:** SUW 202404006246

Report Number: 5170484EMC01 **Revision Level:** 1

Client: ZOLL Medical Corporation

Equipment Under Test: 731 Series Ventilator

Model Number: EMV+ w\Class 1 Power Supply (3 Prong)

Applicable Standards: IEC 60601-1-2:2020 AMD+1

Report issued on: 26 April 2024

Test Result: Compliant

Clause 5 Review Not in Evaluation Scope

FOR THE SCOPE OF ACCREDITATION UNDER CERTIFICATE NUMBER: 3212.01
This report must not be used by the client to claim product certification, approval, or endorsement by A2LA, NIST, or any agency of the Federal Government.

Prepared by: _____
Shawn McGuinness, EMC Engineering Leader

Reviewed by: _____
Sean Vick, EMC Sr. Engineer

December 13, 2024

Zoll Medical Corporation
Jeffrey Churchill
Senior Manager, Regulatory Affairs
269 Mill Road
Chelmsford, Massachusetts 01824

Re: K233486
Trade/Device Name: 731 Series Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: December 11, 2024
Received: December 11, 2024

Dear Jeffrey Churchill:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director, Respiratory Devices Team
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233486

Device Name

731 Series Ventilator

Indications for Use *(Describe)*

Ventilation
Each model of the ZOLL 731 Series of Ventilators is indicated for use in the management of infant through adult patients weighing greater than or equal to 5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. ZOLL Ventilators are appropriate for use in hospitals, outside the hospital, during transport and in severe environments where they may be exposed to rain, dust, rough handling, and extremes in temperature and humidity. With an appropriate third-party filter in place, they may be operated in environments where chemical and/or biological toxins are present. When marked with an "MRI conditional" label, ZOLL ventilators are suitable for use in an MRI environment with appropriate precautions. ZOLL ventilators are intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation, and by first responders under the direction of skilled medical care providers.

Pulse Oximetry (SpO2)
The ZOLL Ventilator pulse oximeter with Masimo SET technology is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate. The pulse SpO2 oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

an Asahi Kasei company

269 Mill Road
Chelmsford, MA 01824
978.421.9655 *(main)*
978.421.0025 *(fax)*
zoll.com

510(K) SUMMARY

Sponsor Information:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824

Contact Person: Jeffrey Churchill
Associate Director, Regulatory Affairs
Phone: (339) 222-0524
Email: Jeffrey.Churchill@zoll.com

Date of Summary: December 13, 2024

Device Name and Classification:

510(k) Number: K233486
Trade/Proprietary Name: 731 Series Ventilator
Common Name: Transport Ventilator
Classification Name: Continuous Ventilator (21 CFR 868.5895)
Product Code: CBK, DQA

Predicate Device:

731 Series Ventilators (K162832, cleared 08/02/2017)
Regulation Number: 868.5895
Regulatory Class: Class II
Product Code: CBK, DQA

Device Description:

The ZOLL 731 Series Ventilators family consists of AEV, EMV+, Eagle II and Z Vent models which are small, durable, full-featured portable mechanical ventilators which provide ventilatory support for infants (≥ 5 kg), pediatric and adult patients. 731 Series ventilators are designed to operate in hospitals, prehospital, and field hospital settings. The ventilators can be operated from an AC or DC external power source, or from an integrated battery system, and support the following pressure and volume

ventilation modes: Assist/Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV) with or without Pressure Support (PS), Continuous Positive Airway Pressure (CPAP) with or without PS, with and without Noninvasive Positive Pressure ventilation (NPPV)/ Positive Pressure Ventilation (PPV).

The ventilator can use 6 ft or 12 ft patient circuits to support adult, pediatric, and infant patients. ZOLL provides the following circuit types:

- Pediatric/Adult, 6 ft and 12 ft, intended for use when delivering tidal volume from 200 ml to Adult.
- Infant/Pediatric, 6 ft and 12 ft, intended for use when delivering tidal volume from 50 ml to 300 ml.

The optional Oxygen Reservoir Kit can be used for the following purposes:

- Acts as a reservoir, collecting oxygen during the expiratory phase of ventilation.
- Provides an interface to the ventilator and the attachment of the low-flow oxygen supply hose.
- Provides an inlet in the event the low-flow oxygen supply fails, or the tidal volume is greater than the supplied oxygen.

Indications for Use:

Ventilation

Each model of the ZOLL 731 Series of ventilators is indicated for use in the management of infant through adult patients weighing greater than or equal to 5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. ZOLL ventilators are appropriate for use in hospitals, outside the hospital, during transport and in severe environments where they may be exposed to rain, dust, rough handling, and extremes in temperature and humidity. With an appropriate third-party filter in place, they may be operated in environments where chemical and/or biological toxins are present. When marked with an "MRI conditional" label, ZOLL ventilators are suitable for use in an MRI environment with appropriate precautions. ZOLL ventilators are intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation, and by first responders under the direction of skilled medical care providers.

Pulse Oximetry (SpO2)

The ZOLL ventilator pulse oximeter with Masimo SET technology is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate. The pulse SpO2 oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

Comparison of Technological Characteristics:

The 731 Series Ventilator has been in the field for over 10 years. After the recent deployment and use of the ventilators with COVID-19 patients, care providers have identified specific areas for potential

improvement. Evolution in the standard of care has changed the level of patient sedation and patient management needs has motivated a comprehensive review of the pneumatic alarm system. This review focused on the patient-ventilator interaction which impacts alarm detection and the ventilator response to the alarm condition. As part of the current submission, ZOLL plans to update the ventilator software to revision 5.25 to improve the alarm logic specifically to target better functionality with COVID-19 patients.

The principles of operation are identical between the predicate ZOLL 731 Series Ventilator (K162832) and the proposed device. The indications for use remain the same from the predicate to the proposed ZOLL 731 Series Ventilator. The technological difference between the predicate device (K162832) and the proposed device is the introduction of software revision 5.25, which updates the ventilator alarm logic. Changes to the alarm logic were originally released under the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency as software revision 5.24, followed by intended commercialized software revision 5.25.

Under software revision 5.25, substantial equivalence has been determined to the predicate device, cleared under K162832. The following have been evaluated for substantial equivalence:

- Alarm System
- Functions and Features
- Indications for Use
- Intended Use
- Labeling
- Pulse Oximeter Specifications
- Ventilator Specifications

Substantial Equivalence – Non-Clinical Evidence:

The following performance data were provided in support of substantial equivalence determination:

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submission for Software Contained Medical Devices,* issued June 14, 2023. Extensive testing in the form of the software verification and system level validation ensured that the 731 Series Ventilators performs as well as the indicated predicate devices and met all its functional requirements and performance specifications.

Safety Testing per International Standards

The device was determined to be compliant with the following internationally recognized test standards as seen below in **Table 1**:

Table 1: 731 Series Ventilator Compliance Standards

FDA Consensus #	Standard Designation	Year
NR	EN 794-3	1998/A2:2009
5-134	EN ISO 15223-1	2021
15-135	ISO 20417	2021
19-4	EN 60601-1	2006/A1:2013
19-8	EN 60601-1-2	2014
5-132	EN 60601-1-6	2020
5-76	IEC 60601-1-8	2012
19-15	IEC 60601-1-12	2015
13-79	EN 62304	2006/A1:2016
5-129	EN 62366-1	2015+A1:2020
2-258	EN ISO 10993-1	2018
2-245	ISO 10993-5	2009
2-174	ISO 10993-10	2010
1-139	EN ISO 80601-2-61	2017
NR	EN ISO 13485	2016
5-125	EN ISO 14971	2019
1-103	ISO 5367	2014
NR	Mil-Std-810G	1/2000 with change C3 (5/2003)
NR	Mil-Std-461F	12/2007
NR	RTCA/DO 160	2010
19-33	IEC 62133-2	2017
NR	EN 1789	2007+A2:2014
19-45	AIM 7351731	Rev. 3.00 2021-06-04

Usability Testing

No usability validation is included in this plan. The user interface remains unchanged. There is no change in instructions on how to set alarms limits. There are no changes to alarm system audio annunciation, LED response and LCD indication (use of alarm message center, icon area and alarm flashing parameters).

Electrical Safety and electromagnetic compatibility (EMC)

The 731 Series Ventilator has been tested to meet applicable testing standards listed in **Table 1**.

Substantial Equivalence –Clinical Evidence:

Clinical evidence was not necessary to show substantial equivalence.

Conclusion:

As part of the change control process, the subject device has undergone the appropriate verification and validation testing, all of which confirms that the device meets its design, performance, and safety specifications. The information presented herein provides reasonable assurance of safety and effectiveness while following the least burdensome approach as defined in FDA's Guidance – *The Least Burdensome Provisions: Concept and Principles* published February 9, 2019. Performance data demonstrates that the features and functions of the subject device are substantially equivalent to those of the predicate device.

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Chelmsford, MA 01824
978.421.9655 (main)
978.421.0025 (fax)
zoll.com

Product Bulletin

11Jul 2025

Important Information Regarding Software Version 5.25 for the 731 Ventilators

Dear Valued Customers,

We would like to inform you about an important update concerning software version 5.25 for the 731 ventilators.

In response to the COVID-19 pandemic, software version 5.25 was initially released in 2021 under the FDA Enforcement Guidance Policy. We are pleased to announce that software version 5.25 has been cleared by the US FDA and covers those changes previously released under the FDA Enforcement Guidance Policy as well as some cybersecurity updates.

What does this mean for you?

- Our service team will reach out to schedule the installation of the FDA-cleared SW version 5.25 during your next annual maintenance visit.
- The ZOLL Ventilator Operator's Guide Alarm Supplement, previously supplied with SW version 5.25 has been updated to remove the enforcement policy. Continue to use the ZOLL Ventilator Operator's Guide Alarm Supplement previously provided until your upgrade is complete.
- There is no impact on how the ventilator is used.

For the latest version of the ventilators operator's manual, please visit the ZOLL Medical website (https://www.zoll.com/Education-and-Resources).

If you have any questions, our customer service team is happy to assist you at any time.

Best regards

Andy Baetz
Senior Product Manager
ZOLL Medical

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 079546 0029 Rev. 01

Holder of Certificate: **ZOLL Medical Corporation**
269 Mill Road
Chelmsford MA 01824-4105
USA

Certification Mark:

TÜV SÜD
DIN EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, and Servicing and Distribution of Defibrillators, External Pacemakers, Multi-parameter Monitoring Systems, Adapters, Cables, Leads, Electrodes, Probes, Sensors, Portable Ventilators with Patient Breathing Circuits, Aspirators, Intrathoracic Pressure Regulation (IPR) Devices for the Areas of Cardiac Resuscitation, Critical Care and Vital Signs Monitoring**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 079546 0029 Rev. 01

Report No.: 72194520-CN

Valid from: 2024-06-02
Valid until: 2027-06-01

Date, 2024-04-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 079546 0029 Rev. 01

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

ZOLL Medical Corporation
269 Mill Road, Chelmsford MA 01824-4105, USA

Design and Development, Production, Quality Control, Customer Service

ZOLL Medical Corporation
271 Mill Road, Chelmsford MA 01824-4105, USA

Quality & Regulatory Affairs, Warehousing, Distribution, and Servicing

ZOLL Medical Corporation
31 High Street, Billerica MA 01862, USA

Inspection of Incoming Raw Materials and Warehousing
Distribution of Finished Goods Products

ZOLL Medical Corporation
11 Alpha Rd, Chelmsford MA 01824, USA

Warehousing of raw materials.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZOLL Ventilator for MRI
Quick Reference Guide

ZOLL

MRI Environment Use

Warnings!

- Ensure that the ventilator is labeled and cleared for MRI use. DO NOT use the ventilator if the MR label is not visible on it.

  The MR label appears on the ventilator as follows:

Z Vent:	Right side of front panel at bottom
EMV+:	Center of front panel at bottom
Eagle II:	Center of front panel at bottom and center of side panels at bottom

- Failure to follow instructions can result in MRI artifacts, possible injury to the patient or operator, or device malfunction.
- DO NOT use the pulse oximeter in an MRI environment.
- DO NOT use the ventilator power supply in an MRI environment.
- Place the ventilator behind the 130 Gauss field line.
- Only use an aluminum non-magnetic cylinder and oxygen hose to provide the oxygen supply.
- Follow safety procedures for the MRI environment and only use the device in an approved configuration.

Cautions

- Secure the ventilator to a suitable MRI-compatible stand (rolling cart).
- Use 12 ft. (3.65 m) ventilator circuits with the ventilator which can extend into the bore. Properly manage Tubing Compliance (CT) and PEEP.

9652-000511-01 Rev. B

ZOLL Ventilator for MRI
Quick Reference Guide

ZOLL

Ventilator Connections and Setup

Warning! For MRI use, see previous instructions for MRI environment

1. Make the following ventilator connections and ensure that all connections are secure:

   Patient circuit connections:

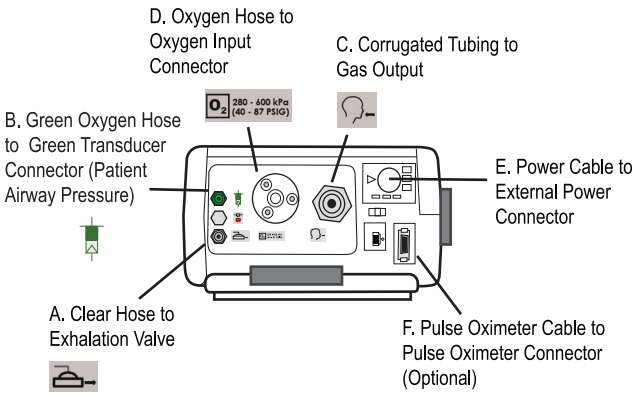
   - A. Exhalation port
   - B. Transducer port
   - C. Gas output port

   Remaining connections:

   - D. Oxygen via high-pressure hose (Compressed O_2: 55 psig [380 kPa]) O_2 280 - 600 kPa (40 - 87 PSIG)
   - E. Power cable

   Optional connections:

   - F. Pulse oximeter



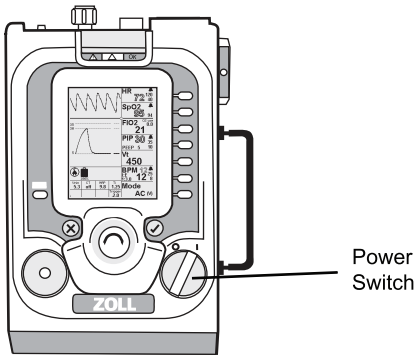
For complete details on operating the ventilator, refer to the ZOLL Ventilator Operator's Guide.

ZOLL Ventilator for MRI
Quick Reference Guide

ZOLL

Ventilator Connections and Setup

2. Verify the power source (battery and/or external power).
3. Start the ventilator by turning the Power Switch to “I” (ON).
4. Allow the ventilator to perform it’s inital Self Check.



5. Use default settings or configure ventilator parameters for the patient.
6. Perform Operational Test (Refer to the ZOLL Ventilator Operator’s Guide for details.)
7. Attach the patient to the patient circuit to begin ventilation.
8. Configure the alarms for the patient.

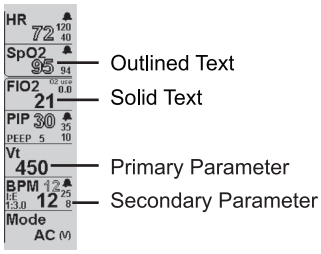
Warning! DO NOT leave the patient unattended.

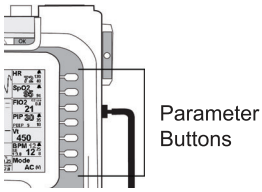
ZOLL Ventilator for MRI
Quick Reference Guide

ZOLL

Ventilator Settings

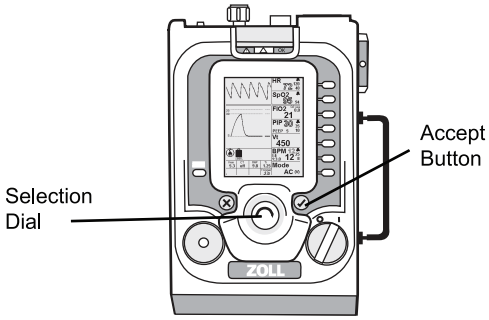
1. To change settings, press the applicable parameter button to highlight the setting:
   - Single press for primary parameters (only solid text parameters can be adjusted).
   - Double/multiple press for secondary parameters/alarm limits.
   - Press and hold for context menus.





2. Turn the Dial to the desired value.
3. Press the Accept button to confirm the selection.

Note: Popup messages (settings conflict, alarm disable, extreme ranges) may appear that require you to confirm, or change operating parameters.

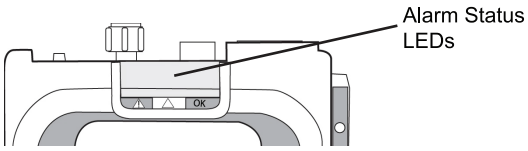


ZOLL Ventilator for MRI
Quick Reference Guide

ZOLL

Alarms

For complete details on all alarms and resolution details, refer to the ZOLL Ventilator Operator's Guide.

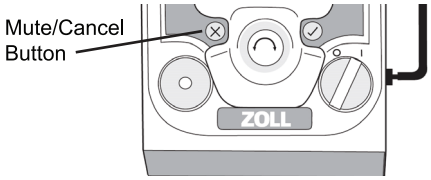


Green: Patient and ventilator are operating as intended.

Yellow (Low Priority): Patient and ventilator are functioning within set parameters; however, the operator must be aware of conditions during ventilator operation.

Red (Medium and High Priority): Patient and/or ventilator are not performing as intended and immediate attention is required.

To mute low and medium priority alarms, press the Mute/Cancel button .

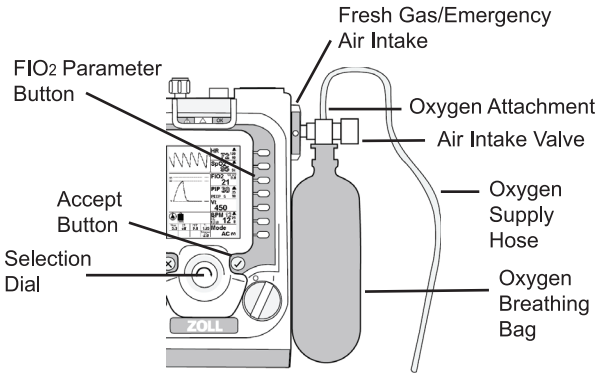


ZOLL Ventilator for MRI
Quick Reference Guide

Low Flow (O_2 Reservoir) Oxygen Source Use

Warning! Oxygen supply source components must be MRI compatible

1. Attach the O_2 supply hose to the Oxygen Reservoir Kit adapter and the gas source.
2. Configure the O_2 source:
   a. Concentrator use: start the O_2 concentrator, set to maximum flow, and adjust as required.
   b. Flow meter use: set to patient's approximate minute volume flow, and adjust as required.
3. Configure the ventilator, using the appropriate patient setting:
   a. Press and hold the FIO_2 parameter button; the FIO_2 menu displays.
   b. Use the dial to turn on setting.
   c. Press the Accept buttton to confirm the selection; the + icon displays in the O_2 parameter window.
4. Attach the patient circuit and pulse oximeter to the patient.
5. Monitor the patient and the pulse oximeter, and adjust O_2 flow to maintain the desired pulse oximeter level.



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SECTION 9
Service Agreement

ZOLL Medical Corporation
ExpertCare Service Plan Terms and Conditions

The customer ("Customer") listed on the purchase order (the "Order") has agreed to purchase the ExpertCare Service Plan described on the Order (the "Service Plan"). Depending upon the Service Plan being purchased by the Customer, Extended Warranty and/or Preventive Maintenance services may be included. Only the provisions in these Terms and Conditions that relate to the particular Service Plan being purchased by Customer will apply to the Customer. The Customer will be invoiced the price of the Service Plan upon ZOLL's receipt of a quote with an authorized signature from the Customer, the Order, or a credit card number.

Extended Warranty Terms and Conditions. The following provisions apply to purchases of Service Plans that include an Extended Warranty ("EW") plan.

1. The EW expands the term of ZOLL's standard warranty ("Factory Warranty") with the services and/or number of years selected by the Customer. EW coverage commences upon the expiration of the Factory Warranty, and is subject to the terms and conditions contained in the original Factory Warranty documentation. The EW does not apply to accessories.

2. The EW is not transferrable and cannot be cancelled. However, if the Customer replaces equipment covered by an EW with new ZOLL equipment ("New Equipment") then, upon Customer's request, the remaining time under the EW will be transferred to the New Equipment at the end of the New Equipment's Factory Warranty. All requests to transfer the remaining balance of an EW must be submitted in writing to the ZOLL Service Contracts department (ServiceContractsAdmin@zoll.com) within 60 days of the date of shipment of the New Equipment. Failure to submit the EW transfer request will result in the forfeiture of the remaining EW.

3. If the Customer has a claim under an EW, Customer must call the ZOLL Help Desk to arrange for a Return Authorization in advance of sending the unit for evaluation by the ZOLL Service Depot.

4. All repairs are performed at a ZOLL Service Depot. If a unit needs to be repaired, upon the Customer's request, a loaner will be provided free of charge pursuant to ZOLL's Loaner Policy.

5. If no claims are made under the EW during the EW period, the purchase price of the EW is not refundable.

Preventive Maintenance Terms and Conditions. The following provisions apply to purchases of Service Plans that include Preventive Maintenance ("PM").

1. PM Service Plans are not transferrable and cannot be cancelled. However, if the Customer replaces equipment with New Equipment then, upon Customer's request, the remaining time under the PM will be transferred to the New Equipment. All requests to transfer the remaining balance of PM must be submitted in writing to the ZOLL Service Contracts department (ServiceContractsAdmin@zoll.com) within 60 days of the date of shipment of new equipment. Failure to submit the PM transfer request will result in the forfeiture of the remaining PM and no monies will be refunded to the customer.

2. Any PM that remains unused as of the end of a one-year PM contract will be forfeited and no monies will be refunded to the Customer. Any PMs that remain unused as of the end of the initial year of a multi-year PM contract will automatically roll over into the next year of the PM contract. Any PMs that remain unused as of the end of the second and subsequent years of the PM contract will be forfeited, and no monies will be refunded to the Customer.

3. It is the Customer's responsibility to ensure (i) devices covered by the PM contract are available for Preventative Maintenance at the scheduled times; (ii) its devices are operated and stored in accordance with the user manuals for such equipment; and (iii) PM is performed annually to maintain superior performance.

4. If ZOLL determines during the course of performing PM that a repair is required, the device will not be certified. If the device is not covered under ZOLL warranty, the PM service is considered completed. ZOLL will request Customer authorization in order to repair the device. The Customer is responsible for all costs associated with repairing the device at ZOLL's then-prevailing rates. Customer has 10 days after receipt of a quotation to approve or decline a repair. If the repair is approved by the Customer and completed within 90 days of the completed PM, ZOLL will waive the minimum

service fee. In the event the Customer does not respond within such 10-day period or declines the repair, the device will be returned to Customer unrepaired, uncertified, and labeled as “Not for Clinical Use.”

Accidental Damage Coverage. The Service Plan purchased by Customer Includes one device outer housing replacement per year per device. Catastrophic damage beyond repair will not be covered. Cosmetic damage that does not affect the functionality of the device will not qualify for outer housing replacement.

BATTERY REPLACEMENT PROGRAM

1. Batteries must be maintained in accordance with ZOLL’s battery maintenance program and instructions.

2. In the event that the Customer’s battery and/or battery charger displays a fault during the term of the purchased Service Plan, ZOLL will, upon visual verification of the failure, replace the applicable battery with a new battery.

3. Battery failures must be evaluated and confirmed by ZOLL Technical Support or by a ZOLL on-site field service technician prior to replacement.

4. Only batteries identified as part of the Service Plan will be replaced.

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SECTION 10
ExpertCare Flyer

ExpertCare® Service

Dedication beyond delivery

Z Vent: Ventilation Simplified

Peace of mind — Trust your equipment to the people who know it best.

When your focus is on saving lives, you shouldn't need to worry about the maintenance and repair of your lifesaving devices. Our **ExpertCare Service** program gives you confidence that your equipment is ready every time it's needed.

Why ExpertCare?

- Industry-leading products and services
- We strive to exceed expectations
- Unparalleled service to keep your equipment in optimal working order
- Experts at troubleshooting
- Complimentary loaner program minimizes downtime during repairs and annual preventive maintenance
- ZOLL-certified parts
- 24/7 Technical support

We offer a variety of service contract options to cater to your needs and budget.

ExpertCare Service Plans: Z Vent® Ventilators

	PM	PRECISION	WORRY-FREE
Preventive Maintenance[1] ▪ Documentation for regulatory agencies ▪ Track PM schedule ▪ Certified performance test ▪ Replace filters ▪ Replace battery compartment cover as needed	■	■	■
Complimentary loaner equipment upon request	■	■	■
Shipping fees waived[2]	■	■	■
Minimum service fee waived[3]	■	■	■
24/7 technical support	■	■	■
Real-time video support via SightCall *During normal business hours*	■	■	■
General software updates *At time of PM*	■	■	■
Repairs: Parts and labor per ZOLL Limited Product Warranty		■	■
Lithium-ion and coin battery replacement[4]			■
Software updates outside of PM *Requires a calibration/calibration check and reset of calibration due date*			■
Accidental damage coverage[5]			■
On-site Support (Optional) 48- to 72-hour response[6]		■	■

[1] Battery replacement included at 4-year PM when PM, Precision, or Worry-Free Plans are purchased for 4 or 5 years.
[2] For PM plan, shipping is covered for PM device only.
[3] For PM Plan, fee waived if repair is required within 90 days of PM.
[4] One battery per year/device upon verified failure during PM performed by ZOLL Service team member.
[5] Includes one device outer housing replacement/year/device; EXCLUSIONS: catastrophic damage/damage beyond repair
[6] Dependent on geographical location; our service team will determine and communicate the fastest way to resolve your service issue.

Need more information?

Please contact your ZOLL representative

Call 800-348-9011 | Email ServiceContractsAdmin@zoll.com

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SECTION 11
Product Specifications

Z Vent®

ZOLL®

VENTILATION SIMPLIFIED™

Ready for the Streets

Full Patient Range
For patients from infant (> 5 kg BW) through adult

Light, Rugged, All-weather Device
Under 10 pounds (4.4 kg) yet rugged

Smart Help™ Feature
Guides operator through on-screen prompts, when responding to alarms

Intuitive Design
User-friendly, straight-forward interface

Unprecedented Battery Runtime
No additional battery backup needed with a 10-hour battery run-time. Battery recharges to 90% in 2 hours.

AWR Certified
Airworthiness Release certified for use aboard U.S. Air Force and U.S. Army aircraft – both fixed-wing and rotor – during all phases of flight

MRI Conditional*
Specially designed to meet the challenging requirements for patients who require magnetic resonance imaging (MRI)

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
978-421-9655
800-804-4356

For subsidiary addresses and fax numbers, as well as other global locations, please go to **www.zoll.com/contacts.**

Z Vent® Specifications

Clinical Specifications

Operating Modes: AC, SIMV*, CPAP and BL

Breath Target: Volume and pressure

Special Functions: Plateau Pressure*, Manual Breath, Apnea Back Up, Oxygen in Use, Inverse Ratio*

Flow Rate: 0 to 100 LPM @40 H_2O

Breath Rate: 0 to 80 BPM

Tidal Volume: 50 to 2000 ml ATPD +/- 10% of setting

Inspiratory Time: 0.1 to 5.0 seconds

I:E Ratio: 1:99 to 4:1

FiO_2: 21 to 100% +/- 3% of full scale +/- 10% of setting

PEEP: 0 to 30 cm H2O

Peak Inspiratory Pressure (PIP): 10 to 80 cm H_2O

Trigger Sensitivity: -6.0 cm to -0.5 cm H_2O

Oxygen Input Pressure: 55 psig (-25%; + 20%) (380 kPa)

Safety Specifications

Airway Pressure High Limit: 20 to 100 cm H_2O values

Airway Pressure Low Limit: Off, 3 to 35 cm H_2O

BPM High Alarm Limit: Off, 2 to 99

BPM Low Alarm Limit: 2 to 40

LED Status/Alarm Indicator: Red, yellow, and green LCD/LED adjustable

Environmental

Operating Voltages: 100 to 240 VAC (50/60 Hz and 400 Hz) or 12.5 to 28.0 VDC

Operating Time: Internal battery 10 hours

Temperature Ranges:

Operating: -26° to 55°C (-14 to 131°F) with battery charging, battery discharge and AC power operation

Battery Charging: 0° to 45°C (32° to 113°F)

Long-term Storage: -46° to 71°C (-50.8° to 159°F) Optimal storage conditions

Ambulance:
- DIN-EN 1789

Airworthiness
- RTCA/DO-160G

Altitude Compensation: -2,250 to 25,000 ft. (-685 to 7,620 meters)

Temperature and Humidity Testing: MIL STD 810F

Ingress Testing: MIL STD 810 F

Shock and Vibration Testing: MIL SRD 810G

Vibration Testing: IEC 60068-2-6, ICE 60068-2-34, IEC 60068-2-36, IEC 60068-2-64

Shock Testing: IEC 60068-2-27

Altitude Testing: MIL STD 810F

EMC Testing: MIL STD 461F

Ingress Protection: IP54 (Dust protected and splash-proof)

General

Size: 8.0" wide x 12.5" high x 4.5" deep (20.3 cm wide x 31.8 cm

Weight: 9.7 lbs (4.4 kg)

*optional

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SECTION 12
Product Brochure

VENTILATION SIMPLIFIED™

EASY TO USE

PORTABLE

DURABLE

Z VENT — VENTILATION SIMPLIFIED™

DESIGNED WITH YOUR BUDGET IN MIND

Z Vent is a valuable solution that can upgrade your airway management to BL mode for enhanced patient comfort and an economical one that can lower your costs from the use of disposable CPAP sets, even when you provide treatments only a few times per week.

ZOLL MEDICAL CORPORATION

269 Mill Road | Chelmsford, MA 01824 | 978-421-9655 | 800-804-4356 | zoll.com

Printed in U.S.A.
MCN EP 2103 0359

For subsidiary addresses and fax numbers, as well as other global locations, please go to zoll.com/contacts.

ZOLL®

Z Vent®

ZOLL®

VENTILATION SIMPLIFIED™

*MOVING CARE **FORWARD***

A PORTABLE VENTILATOR FOR EMS

Z Vent® is the ideal transport ventilator designed for pre-hospital and inter-hospital use. Z Vent offers unmatched durability and portability, delivering a full range of ventilation options in a device that's simple to use.

EASY TO USE – READY WHEN YOU ARE

Z Vent removes the complexity associated with many portable ventilators. Our Smart Help™ technology enables users to quickly resolve an alarm with simple on-screen prompts, a feature only available on ZOLL® ventilators, while a Touch, Turn, and Confirm interface makes changing settings quick and easy.

In non-invasive ventilation modes, Z Vent's Apnea Backup feature automatically ventilates patients when spontaneous breathing ceases, while Automatic Leak Compensation adjusts oxygen flow for an ill-fitting mask.

PORTABLE – GOES ANYWHERE YOU GO

Weighing just 9.7 pounds (4.4 kg), Z Vent is light and easy to carry. Its internal compressor consumes less than half of the oxygen of many transport ventilators.[1] And with a 10-hour battery, Z Vent ensures you can continue to provide care, even during long transports.

RUGGED – BEYOND MILITARY STANDARDS

Designed to surpass high military standards, Z Vent is resistant to dust, dirt, jetting water, and challenging weather elements. It has a temperature range of -28° C to 55° C (-18° F to 131° F) and is proven to withstand a drop from over 1 meter, which allows it to operate at conditions that many ventilators are not rated to endure.

MADE FOR FLIGHT

Z Vent is certified for use aboard commercial and U.S. military aircraft – both fixed-wing and rotor – during all phases of flight. With automatic altitude compensation, Z Vent is designed to operate from -2,000 to 25,000 feet (-610 to 7,620 m).

[1] www.ccforum.biomedcentral.com/articles/10.1186/cc4410. Accessed 29 Mar 2021.

A STANDARD FOR EMS

Z Vent has an ingress protection rating of IP54. Like everything else medics carry, ventilators must stand up to the tough physical demands of the EMS environment. With enhanced durability, Z Vent sets the standard for ruggedness.

Parameter	Z Vent Rating
Operation Temperature Range	-28° to 55° Celsius (-18° to 131° Fahrenheit)
Ingress Protection–Extreme Dust	Surpasses MIL Standard 810F (Test Method 510.4, Procedure 1)
Ingress Protection–Extreme Rain	Surpasses MIL Standard 810F (Test Method 506.4, Procedure 1)
Crash Testing	20g
Drop Testing (with carry case)	26 drops from 120 centimeters (48 inches) on all surfaces.

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SECTION 13
Product Warranty

ZOLL®

Warranty Matrix

ZOLL LIMITED PRODUCT WARRANTY

ZOLL Medical Corporation (ZOLL) warrants to the customer that the product(s) purchased from ZOLL or its authorized dealers shall be free from defects in material and workmanship under normal use and maintenance conditions for the period of time set forth in the attached schedule. This warranty begins on the date of shipment from ZOLL's facility. During the applicable warranty period, ZOLL shall, at no cost to customer, either repair or replace (at ZOLL's sole discretion) any part of the product found to be defective in material or workmanship. If ZOLL's inspection detects no defects in material or workmanship, ZOLL's regular service charges shall apply. This warranty is not transferrable.

The foregoing warranty shall not apply if the defect, failure or other nonconformance of the product is caused by or attributable to: (i) any maintenance, repair or modification of the product by any party other than ZOLL or its authorized representatives, unless such modification is made with the prior written approval of ZOLL; (ii) use of the product with any associated or complementary equipment, accessory or software not supplied or qualified by ZOLL; (iii) any accident, negligence, misuse or accidental damage of the product; or (iv) use of the product in contradiction with applicable operating instructions or outside of the product's intended purpose, environment or setting. The foregoing warranty shall not apply to any equipment on which any original serial numbers have been removed or destroyed. The following are not covered under the warranty: (1) items subject to normal wear and burnout during use, including but not limited to, lamps, fuses, batteries, patient cables and accessories (except to the limited extent set forth in this warranty), and (2) software included as part of the equipment (including software embodied in read-only memory, known as "firmware").

ZOLL, in its sole discretion, will determine whether warranty service on the product will be performed in the field or through ship-in repair. For field repair, this warranty service will be provided by ZOLL at the customer's facility or an authorized ZOLL facility during normal business hours. For ship-in repair, all products and/or assemblies requiring warranty service should be returned to a location designated by ZOLL, freight prepaid. Products repaired or replaced under this warranty retain the remainder of the warranty period of the repaired or replaced product.

Repair or replacement constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL for any breach of any warranty related to the equipment, accessories or electrodes supplied hereunder.

Products cannot be returned without approval from ZOLL. The serial number of the returned device and a description of the defect must be provided. ZOLL reserves the right to charge shipping fees on returned items if not covered by warranty.

THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL 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. ZOLL IS NOT LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF BUSINESS OR PROFITS) WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

GLOBAL LIMITED PRODUCT WARRANTIES

PRODUCT	EMS		HOSPITAL		MILITARY/FEDERAL GOVERNMENT		PUBLIC SAFETY / ALTERNATE CARE	
MONITORS/ DEFIBRILLATORS	US & Canada	International	US & Canada	International	US & Canada	International	US & Canada	International
Zenix®	1 year	N/A	5 years	N/A	N/A	N/A	5 years	N/A
X Series®	1 year	1 year	5 years	1 year	5 years	1 year^	5 years	N/A
R Series®	N/A	N/A	5 years	3 years	5 years	3 years	5 years	N/A
Propaq®	1 year	1 year	5 years	1 year	5 years	1 year^	N/A	N/A
ZOLL M2®	N/A	3 years	N/A	3 years	N/A	N/A	N/A	N/A
VENTILATORS								
Z Vent®	1 year	1 year	1 year	1 year	5 years	N/A	1 year	N/A
EMV+®	1 year	1 year	1 year	1 year	5 years	1 year	1 year	N/A
330 Multifunction Aspirator	1 year	1 year	N/A	N/A	5 years	1 year	N/A	N/A
bellavista®	N/A	N/A	1 year*	2 years	1 year*	2 years	1 year*	2 years
3100	N/A	N/A	1 year	1 year	1 year	2 years	N/A	N/A
LTV®	1 year**	1 year**	1 year**	1 year**	1 year**	2 years**	1 year**	1 year**
fabian®	N/A	N/A	2 years***	2 years	2 years***	2 years	N/A	N/A
MECHANICAL CPR								
AutoPulse®	1 year	1 year	1 year	1 year	1 year	1 year	1 year	N/A
AutoPulse® NXT	1 year	1 year	1 year	1 year	1 year	1 year	1 year	N/A
ResQPUMP®	1 year	1 year	N/A	N/A	1 year	1 year	N/A	N/A

PRODUCT	EMS		HOSPITAL		MILITARY / FEDERAL GOVERNMENT		PUBLIC SAFETY / ALTERNATE CARE	
AED'S & Trauma Kits	US & Canada	International	US & Canada	International	US & Canada	International	US & Canada	International
AED Plus®	5 years	5 years	5 years	5 years	5 years	5 years	5 years	5 years
AED Pro®	5 years	5 years	5 years	5 years	5 years	5 years	5 years	5 years
ZOLL AED 3®	6 years	6 years	6 years	6 years	6 years	6 years	6 years	6 years
Powerheart® G5	6 years	6 years	6 years	6 years	6 years	6 years	6 years	6 years
Mobilize™	N/A	N/A	N/A	N/A	N/A	N/A	1 year	N/A

ADD 2 YEARS ADDITIONAL WARRANTY FROM SHIP DATE WITH AED REGISTRATION
Registering ZOLL AED Plus, Powerheart, and ZOLL AED 3 devices provides two additional years of warranty (not applicable in Japan).

PRODUCT	EMS		HOSPITAL		MILITARY / FEDERAL GOVERNMENT		PUBLIC SAFETY / ALTERNATE CARE	
TEMPERATURE MANAGEMENT	US & Canada	International	US & Canada	International	US & Canada	International	US & Canada	International
Thermogard XP®	1 year	1 year	1 year	1 year	1 year	1 year	N/A	N/A
Thermogard HP®	1 year	1 year	1 year	1 year	1 year	1 year	N/A	N/A
SUPERSATURATED OXYGEN THERAPY	US & Canada	International	US & Canada	International	US & Canada	International	US & Canada	International
TherOx®	1 year	1 year	1 year	1 year	1 year	1 year	N/A	N/A

* 2 year Product Warranty in Canada
**Or 8,800 hours, whichever comes first
***Available in Canada only
^EU Military add one additional year for total of 2 years.

GLOBAL LIMITED PRODUCT WARRANTIES

BATTERIES			
MONITORS/ DEFIBRILLATORS	**Part Number**	**Description**	**Warranty**
Zenix®	8016-000111-01	SurePower 4 Battery	1 year
X Series®	8000-0580-01	Battery, Lithium-Ion, SurePower™ II	1 year
R Series® and ZOLL M2	8019-0535-01	SurePower™ Rechargeable Lithium-Ion Battery Pack	1 year
Propaq®	8000-0580-01	Battery, Lithium-Ion, SurePower™ II	1 year
VENTILATORS			
Z Vent®	703-0731-01-01	Battery Pack, 6.6 AH, 14.8V, Lithium-Ion, 12-Cell Conditioned	90 days
EMV+®	703-0731-01-01	Battery Pack, 6.6 AH, 14.8V, Lithium-Ion,12-Cell Conditioned	90 days
LTV®	19333-201	Power manager, SprintPack with cable protector	6 months
LTV®	19444-001	Battery, SprintPack	6 months
MECHANICAL CPR			
AutoPulse®	8700-0752-01	Lithium-Ion Battery	1 year
AutoPulse® NXT	8700-001012-01	AutoPulse NXT Lithium-Ion Battery	1 year
AEDs			
AED Plus®	8000-0807-01	Type 123 Lithium Batteries	N/A
AED Pro®	8000-0860-01 8019-0535-01	Non-Rechargeable Lithium Battery Pack SurePower™ Rechargeable Lithium-Ion Battery Pack 1 year	90 days 1 year
ZOLL AED 3®	8000-000696	Lithium Manganese Dioxide Battery Pack	90 days
Powerheart® G3 Pro	9145-301	Intellisense® Lithium Battery	90 days
Powerheart® G3 Plus	9146-302	Intellisense® Lithium Battery	90 days*
Powerheart® G3 Elite	9146-702	Intellisense® Lithium Battery	90 days*
Powerheart® G5	XBTAED001A	Intellisense® Lithium Battery	90 days*

* Intellisense® Lithium Battery Replacement Program
(Four years from date of installation. Conditions Apply - See Policy For Details)

GLOBAL LIMITED PRODUCT WARRANTIES

CHARGERS		
Part Number	Description	Warranty
8200-00010-01	SurePower™ Single Bay Charger	1 year
8050-0030-01	SurePower™ Charger Station	1 year
8300-0500-01	SurePower™ Charger Station w/Charger Adaptors	1 year
8700-0753-01	AutoPulse® Battery Charger, U.S., Multi-Chemistry	1 year
8700-001071-01	AutoPulse® NXT Charger, North America	1 year
8911-000290-01	Mobilize® Refill, Item PC, Tablet Charger	90 days

ACCESSORIES		
Product	Description	Warranty
X Series® R Series® Propaq®	SPO2 Cables and Sensors	9 months
X Series®	Masimo Rainbow® EMS RC-4 Patient Cable (8000-001392)	2 years
R Series®	Mainstream – CAPNO 5 CO2 Sensor and Cable (8000-0312) Sidestream – CAPNO 5 LoFlo CO2 Module (8000-0367)	Limited lifetime warranty *(Original purchaser only)*
Thermogard®	Catheters / Start-Up kits / Guidewires	6 months
Thermogard®	Surface products: / Surface Start-Up kits / Surface Pads	6 months
TherOx® SSO_2	Catheters and Cartridges	Warranty is valid through the shelf life date stated on the packaging.
ZOLL M2®	Accessories / Electrodes / Other Cables	90 days
bellvista® LTV® fabian® 3100	Accessories	90 days
All AEDs	Accessories	90 days