Алматы (7273)495-231
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Саранск (8342)22-96-24
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35
Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

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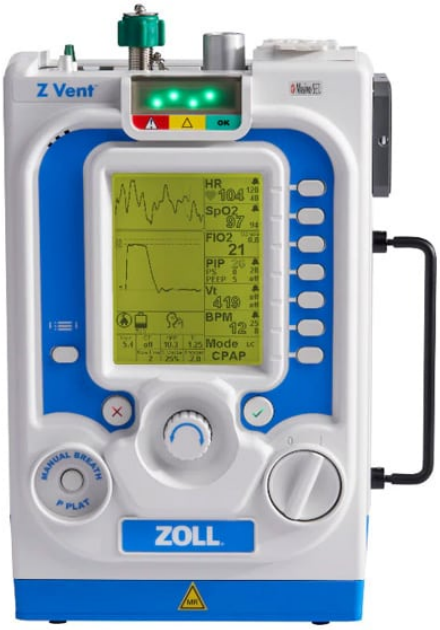
Технические характеристики на аппараты ИВЛ Z Vent Basic, Z Vent, Z Vent MR, EMV+, EMV+ MR, Eagle II, Eagle II MR, AEV компании ZOLL

Виды аксессуаров: аккумуляторы, блоки питания переменного/постоянного тока, сетевые шнуры с разъемом, удлинительные шнуры, наборы шнуров, мягкие чехлы, фильтры, съемные входные фильтры пенного компрессора, тепловлагообменники, адаптеры, дозирующие ингаляторы, удлинительные шнуры, кабели, цепи, контуры, тележки на колесиках без МРТ, опорные рычаги дыхательного контура для тележки на колесиках, монтажные кронштейны, сумки для переноски, чемоданы, комплекты обратного клапана, маски и др.



Product Overview

This chapter describes ZOLL ventilators and provides more detailed descriptions of the following:

- Ventilator models
- Operating modes support
- Manual Breath and Pressure Plateau support
- Main features
- Controls and indicators
- Display screen
- Fresh Gas/Emergency Air Intake and attachments
- Top Panel
- Pulse Oximeter compatibility
- Power sources
- Pneumatic design
- Oxygen Input
- Patient circuits

Ventilator Models

ZOLL currently offers the following ventilator models:

- Z Vent Basic
- Z Vent
- Z Vent MR
- EMV+
- EMV+ MR
- Eagle II
- Eagle II MR
- AEV

Operating Mode Support

The following table lists the operating mode supported by ZOLL ventilator models.

Note: A more detailed description of the operating modes supported by ZOLL ventilator models including a regional mode reference (outside of the United States) appears in Chapter 4.

Ventilator Model	Operating Mode Support					
	AC(V)	AC(P)	SIMV (V)	SIMV (P)	CPAP*	BL*
Z Vent Basic	X	X			X	X
Z Vent, Z Vent MR	X	X	X	X	X	X
EMV+ EMV+ MR	X	X	X	X	X	X
Eagle II Eagle II MR	X	X	X	X	X	X
AEV	X	X			X	X
X Mode supported by ventilator model * Spontaneously Breathing Patient Mode ** When Mask CPAP selected from Startup Menu						

Manual Breath and Pressure Plateau Feature

The following table lists the availability of Manual Breath and Pressure Plateau features on ZOLL ventilator models.

Ventilator Model	Manual Breath	Plateau Pressure
Z Vent Basic	X	
Z Vent, Z Vent MR	X	X
EMV+ EMV+ MR	X	X
Eagle II Eagle II MR	X	X
AEV	X	

Note: If the ventilator offers the plateau pressure feature, the button is labeled, “Manual Breath/ P Plat”. See Figure 2-2 in this chapter.

Ventilator Description

The sections that follow provide a description of the ZOLL ventilators.

Main Features

Figure 2-1 shows the ventilator's main features.

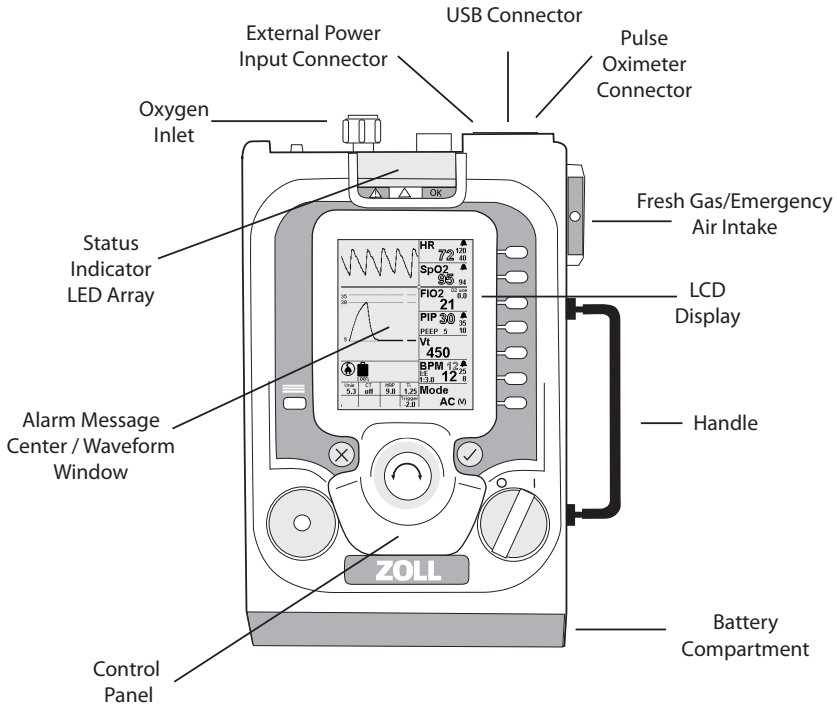


Figure 2-1 Main Features

Item	Location	Description
Oxygen Inlet	Top	Enables connection to an external high pressure oxygen source.
Status Indicator LED Array	Top	Lights to indicate ventilator status and a visible alarm indicator.
External Power Input Connector	Top	Enables connection to an external power source.
USB Connector	Top	Enables connection to a USB compatible device for servicing the ventilator.
Pulse Oximeter Connector	Top	Enables connection to a pulse oximeter sensor
LCD Display	Front	Displays settings, ventilation data, and alarm information.
Alarm Message Center	Front	Displays active alarms and alarm mitigation information.

Item	Location	Description
Control Panel	Front	Provides user access to the ventilator settings.
Battery Compartment	Bottom	Holds the ventilator's rechargeable Li-ion battery.
Fresh Gas/Emergency Air Intake	Side	Enables the ventilator internal compressor to use ambient air and acts as an anti-asphyxia valve.
Handle	Side	

Controls and Indicators

The ventilator controls and indicators (shown in Figure 2-2) facilitate ease of use and visibility in all operating environments.

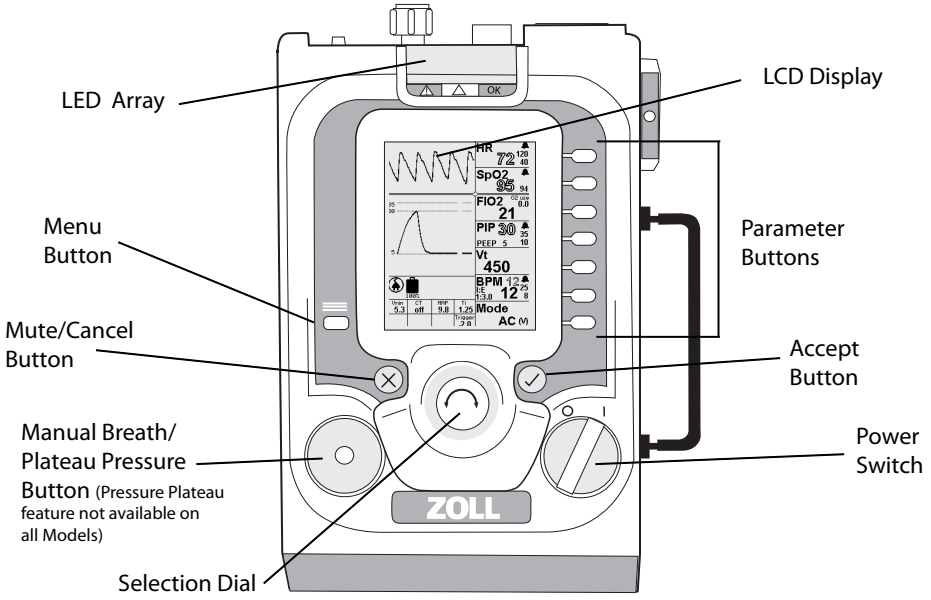


Figure 2-2 Controls and Indicators

Controls

The ventilator's controls consist of the following:

Control	Function
Power Switch	Enables the user to turn the ventilator ON and OFF.
Parameter Buttons	Enables the user to access primary parameters, secondary parameters and context menus associated with a primary parameter (if applicable), and then modify settings using the Selection Dial).
Menu Button	Enables the user to access the Menu.
Selection Dial	Enables the user to set values for a chosen (highlighted) Primary Parameter, Secondary Parameter, Context Menu item, and Menu item. Values accelerate with speed of turning.

Control	Function
Mute/Cancel Button	The Mute/Cancel button mutes the audible alarm allowing the user time to change parameters. It can also be used to cancel parameter entries.
Accept Button	The Accept button allows the user to accept parameter value settings, acknowledge popup messages, and accept menu choices.
Manual Breath Button/ Plateau Pressure	Enables the user to deliver a manual breath and measure Plateau Pressure. **Note:** Plateau Pressure is an optional ventilator control. If your ventilator supports the Plateau Pressure option, the button is labeled "Manual Breath / P Plat".

Indicators

The ventilator's indicators consist of the following:

Indicator	Description
LCD Display	Displays settings, patient data, and alarm information.
LED Array	Indicates operational status (Red, Yellow, or Green).

Display Screen

The ventilator's display screen has four functional areas as shown in Figure 2-3:

- Alarm Message Center/Waveform Window
- Parameter Windows
- Shared Icon Area
- Auxiliary Parameter Boxes.

These functional areas are discussed in the following sections.

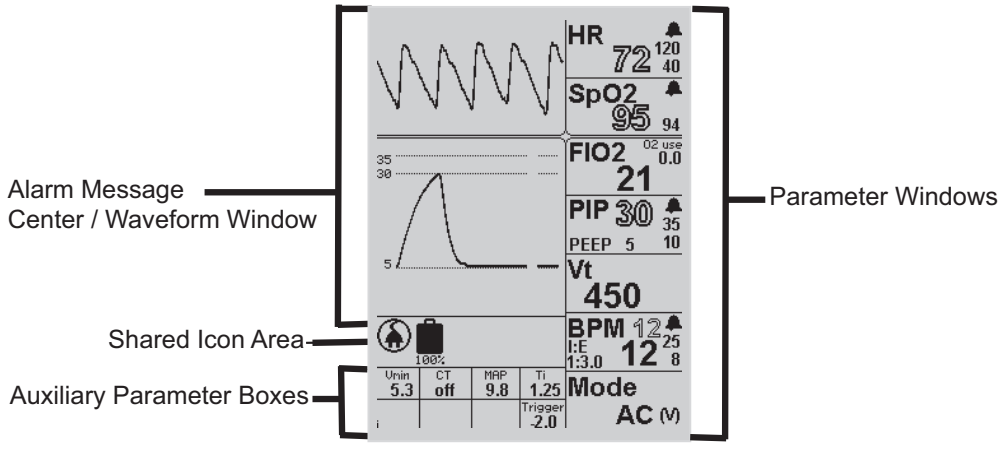


Figure 2-3 Display Screen Functional Areas

Message Area

The display screen's message area can display the following:

- **Airway Pressure and Pleth Waveform Plots** -- Under normal operation (as in the example above), the message area displays plots for airway pressure and, when the pulse oximeter is connected, the Pleth waveform. When a plot is necessary to facilitate a parameter adjustment, the message area displays both the plot and the parameter's context menu.
- **Menus** -- Displays the Menu after you press the Menu button on the ventilator's control panel, or displays a parameter's context menu (which appears after you ***press and hold*** the associated parameter button on the control panel).
- **Alarms** -- When an alarms occur, the message area displays Smart Help™ messages that identify the alarms and describe possible causes and actions that you can take in response.
- **Popup Windows** -- Display information that assists you when adjusting parameter values.

Parameter Windows

Each parameter window displays its primary parameter and associated secondary parameters, that can include, associated parameters and alarm limits.

Two types of values appear in a parameter window.

- Solid text is used for primary and secondary parameter values you can adjust.
- Outlined text is used for patient-dependent measured values.

Chapter 4, "Using the Ventilator" contains more information and instructions for adjusting parameter values.

Shared Icon Area

Directly below the message area, the device displays icons that indicate

- The ventilator's power source (operating on external power or its battery)
- The battery charging status
- An oxygen supply is attached
- Alarms are muted or audible

Auxiliary Parameter Boxes

Some parameters have values that the ventilator displays in the parameter boxes at the bottom of the display screen. You can adjust these values using the parameter's context menu.

Fresh Gas/Emergency Air Intake and Attachments

The Fresh Gas/Emergency Air Intake is located on the side of the ventilator as shown in Figure 2-4.

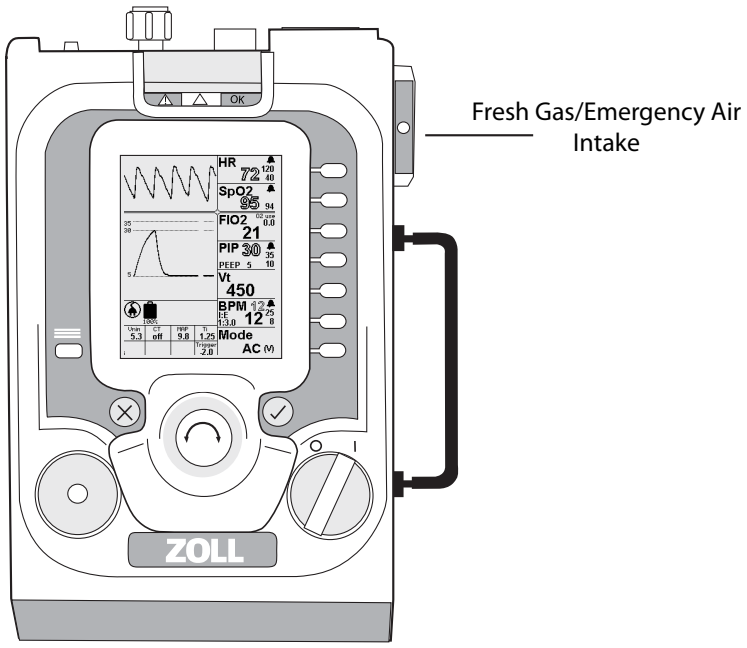


Figure 2-4 Fresh Gas/Emergency Air Intake

The Fresh Gas/Emergency Air Intake allows ambient air into the device's internal compressor. The intake also acts as an anti-asphyxia valve that enables the patient to breathe ambient air should the ventilator fail. The Fresh Gas/Emergency Air Intake contains a particulate filter and permits the user to connect either a bacteria/viral or a chemical/biological filter depending on ambient conditions.

An Oxygen Reservoir Kit is attached to the Fresh Gas/Emergency Air Intake to allow low flow oxygen use with the ventilator to provide supplemental oxygen to patients, an ISO 5362 compliant breathing bag is attached with to a manifold which is connected to a low flow oxygen source (either an oxygen flow meter or oxygen concentrator).

Oxygen is delivered through the Fresh Gas/Emergency Air Intake when the device's internal compressor cycles to deliver a breath.

Oxygen Reservoir Kit (Optional)

The Oxygen Reservoir Kit serves 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.

See Chapter 3 for more information about using low flow oxygen sources.

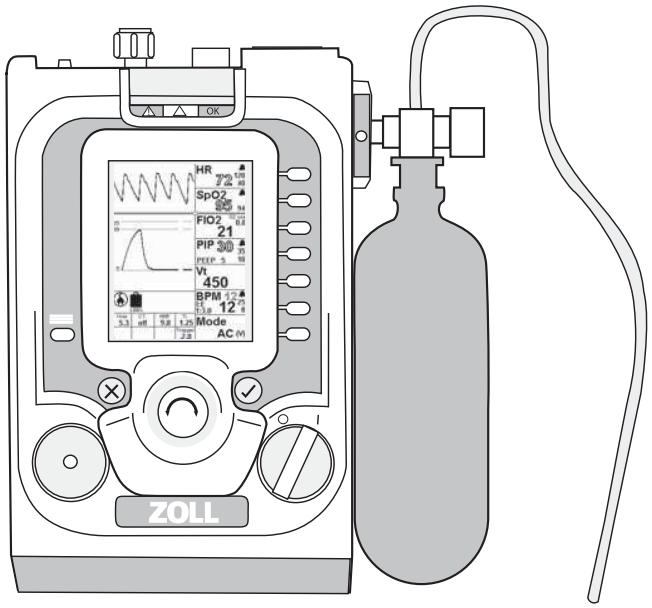


Figure 2-5 Ventilator with O_2 Reservoir Kit

Top Panel

The oxygen hose, patient circuit, external power, and pulse oximeter attach to the top panel of the ventilator. The USB port is only used when servicing the device.The ventilator top panel appears as shown in Figure 2-6.

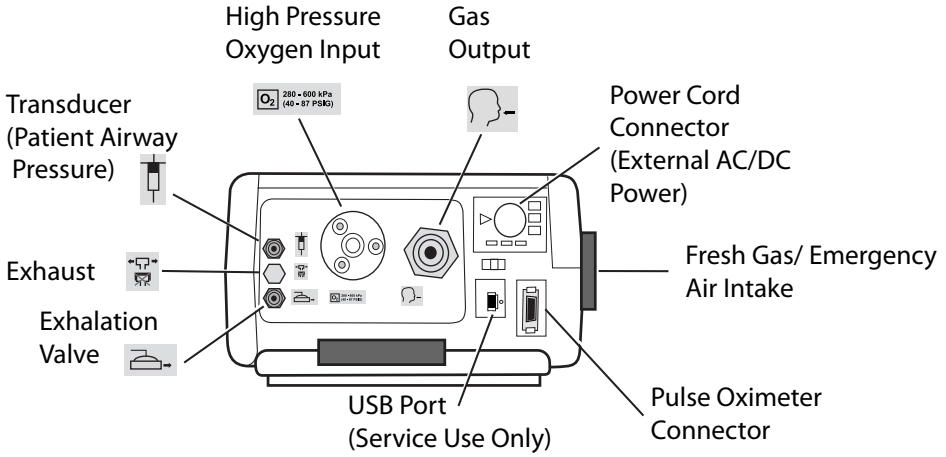


Figure 2-6 Top Panel

Pulse Oximeter Compatibility

The ventilator can accommodate an optional connection of external Masimo Pulse Oximeter. When the appropriate sensor is connected, the pulse oximeter provides continuous noninvasive monitoring of the oxyhemoglobin saturation (SpO_2) and pulse rate (measured by the SpO_2 sensor) for adult, pediatric and infant patients.

The Masimo LNCS series of probes are approved for use with the ventilator. The Accessory table in Appendix A lists the sensors which are available for use with the ventilator.

Power Sources

The ventilator can operate using external power or it can operate powered by its internal Li-ion battery.

The external AC/DC Power cable is a universal supply that can operate with an input of 100 to 240 VAC 50/60 Hz. The external supply can also power the device when provided with a 400 Hz input.

The external AC/DC Power cable that ZOLL provides with the ventilator delivers a DC input to the device of 24 V at 4.2 A. When this external power source is present, the ventilator automatically charges its internal battery while operating.

Only use the external power supply provided with the ventilator when connecting to AC power. The device is docked when connected to a power supply that is attached to a wall, bench, or fixed location. Use Power Supply Holder Kit to dock the ventilator.

Operating Using External DC Power

The ventilator can also operate using external DC power. When connected to a standard vehicle DC outlet using either the 12 or 28 VDC Power Cable that ZOLL offers, the ventilator automatically charges its internal battery while operating. The input DC supply is monitored and the ventilator issues alarms for the following conditions:

- Insufficient current
- High voltage
- Disconnect/ low voltage
- DC reversed

Note: The input connector of the ventilator accepts DC voltages between 11.8 to 30.3 VDC.

Caution When using the standard vehicle DC outlet, do not jump start the vehicle during operation of the ventilator.

Operating Using Battery Power

When an external power failure occurs, the ventilator automatically switches to its internal battery for operating power and activates the External Power Fault alarm; there is no interruption in operation. When external power returns, operating power automatically switches to the external power source and the following symbol displays on the ventilator screen as shown in Figure 2-7.

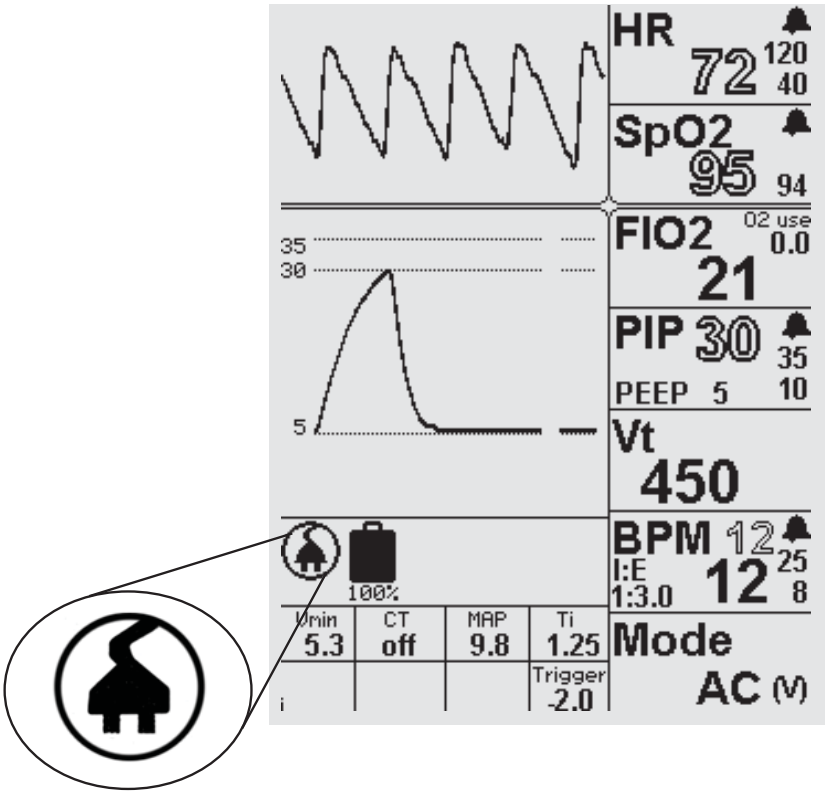


Figure 2-7 External Power GUI Symbol

In the event that the ventilator needs to be shutdown, turn the POWER switch to the OFF ("**O**") position. If this fails to work or puts the patient or user at possible risk, disconnect the device from the external power source.

Pneumatic Design

The ventilator includes an oxygen valve and a compressor to provide the appropriate gas mixture for the patient. The system includes transducers for pressure measurements including O_2 input supply and barometric pressure.

The Wye circuit is part of the ventilator's pneumatic system. The inspiratory side of the wye circuit provides gas to the patient. The expiratory side exhausts directly to atmosphere without returning to the ventilator. The ventilator pneumatically controls the exhalation valve (to maintain PEEP) and a transducer within the ventilator measures the airway pressure.

The ventilator breath transitions from expiratory to inspiratory phase is triggered by patient effort (negative pressure) or time. The breaths are time or flow cycled and can either be pressure or volume (flow) targeted.

Figure 2-8 depicts a diagram of the ventilator's pneumatic design.

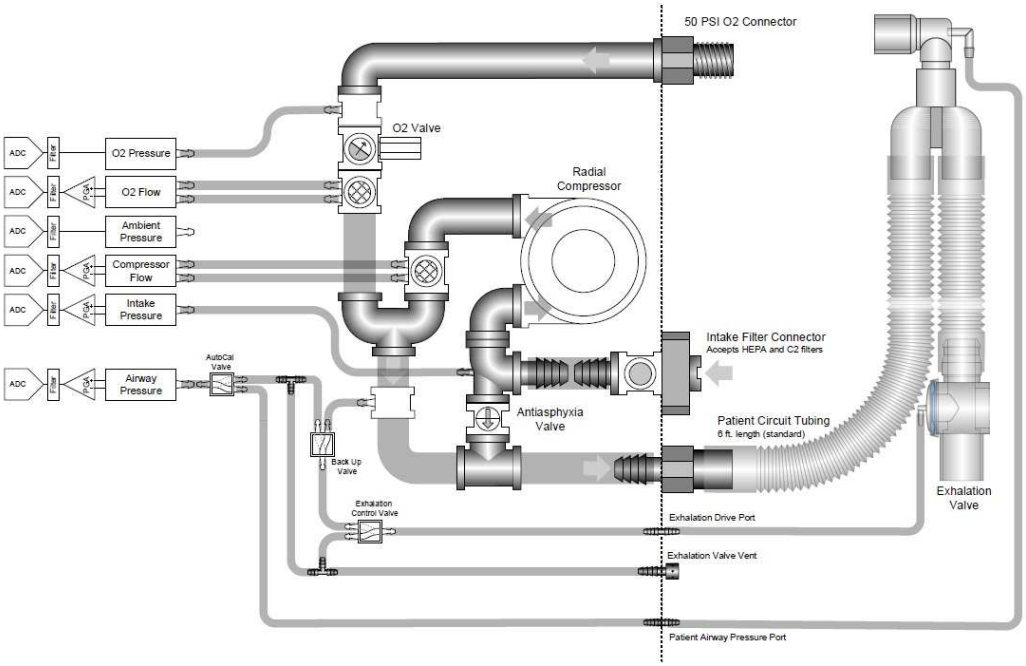


Figure 2-8 Pneumatic Design

Oxygen Input: High Pressure Gas Supply

An external high pressure gas source connects to the ventilator using the high pressure oxygen input port. The device attaches to a regulated medical grade (USP) O_2 system or O_2 cylinder supply of 40 to 87 psig (280 to 600 kPa). Maximum flow rate of the oxygen supply is 100 liters per minute. The Oxygen Input fitting (See Figure 2-9) has a male oxygen Diameter Index Safety System (DISS) thread.

Note: If external oxygen is connected, the oxygen pressure must be at least 41 psig (± 2 psig) (283 kPa (± 14 kPa)) at the time the ventilator performs its Self-Check after turning on the ventilator.

High Pressure Oxygen Supply Hose

A standard oxygen hose is available for connecting the ventilator to a high pressure oxygen source. (Also see Chapter 6 “Operating Environments”). Hoses are available from ZOLL, or a suitable alternative as described below can be used as indicated.

High Pressure Oxygen Hose for compliance with ISO standard (ISO STANDARD 5359)		
Ventilator Side Connections	**Hose Attributes**	**Supply Side Connections**
DISS	6 ft (maximum 20 ft) Green or White (as determined by local regulations) non-conductive	Quick Disconnect, DISS, etc.

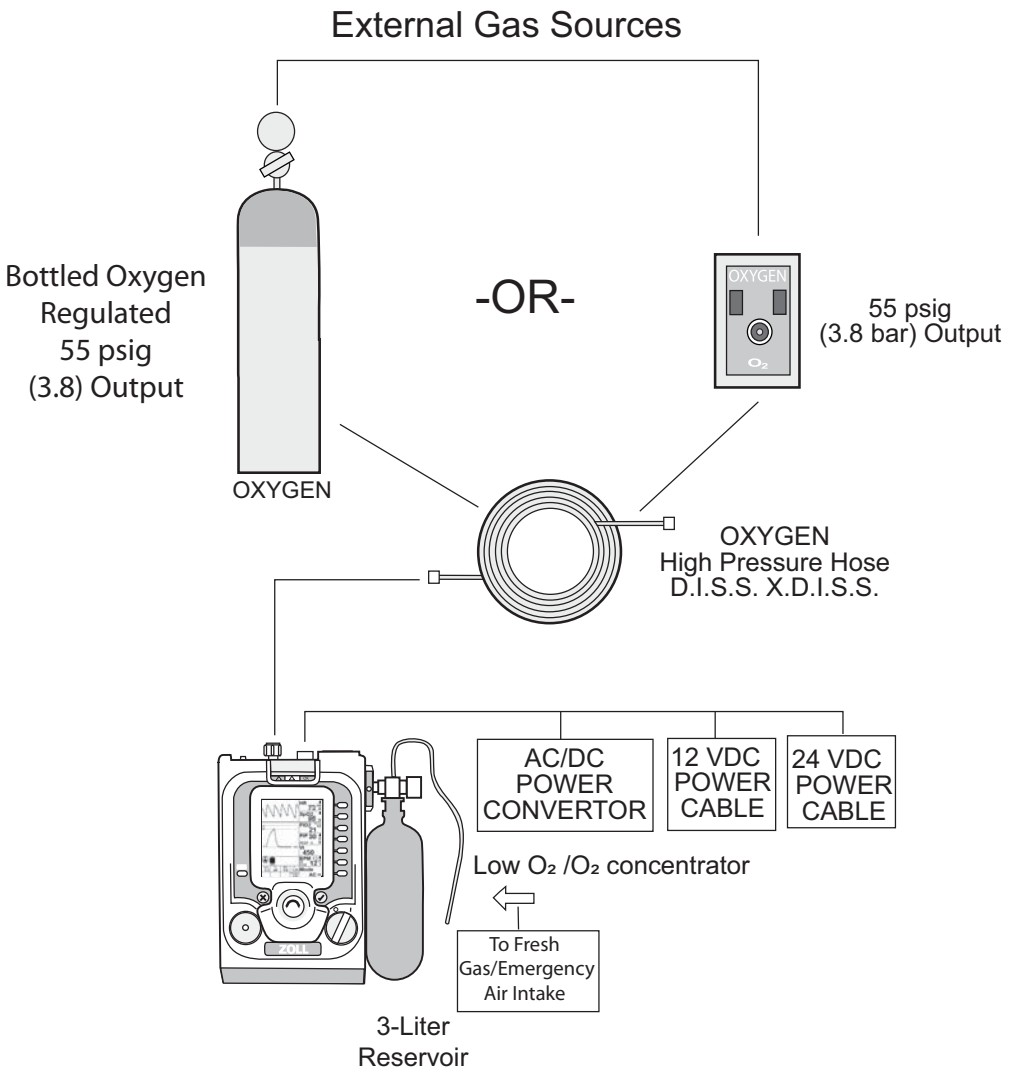


Figure 2-9 Ventilator Gas Sources

ZOLL

ZOLL Ventilator Operator's Guide

Models: EMV+, AEV, Eagle II

906-0731-01-01 Rev. A

ZOLL Ventilator Models

The ZOLL Ventilator is available as the AEV, EMV+, and Eagle II models. The ventilator offers a range of ventilatory modes to support EMS, military, air transport, and hospital transport needs.

The AEV ventilator is designed for managing ventilator support patients during ambulance transport. Its ventilation modes (AC, CPAP with PS, and BL) are specifically chosen to be consistent with pre-hospital care provider's operating procedures.

The EMV+ ventilator's rugged design makes it ideal for use in emergency vehicle and air transport of patients. It has a wide range of ventilation modes, such as AC, SIMV, CPAP, and BL.

The Eagle II ventilator adapts the design of for the EMV+ for use by emergency departments and intra-hospital transport. Its design also allows it to be mounted onto walls or onto specified boom arms and roll stands as well as gurneys.

The ZOLL MRI ventilators have been approved for use in MRI suites. The EMV+ and Eagle II ventilators have MRI-compatible variants available. The MRI-compatible ventilators can operate in 3.0 Tesla environments and can be placed approximately 6 1/2 ft. from the bore opening for easy and safe access to the patient. See Chapter 3 for more information regarding safe operation in the MRI Environment.

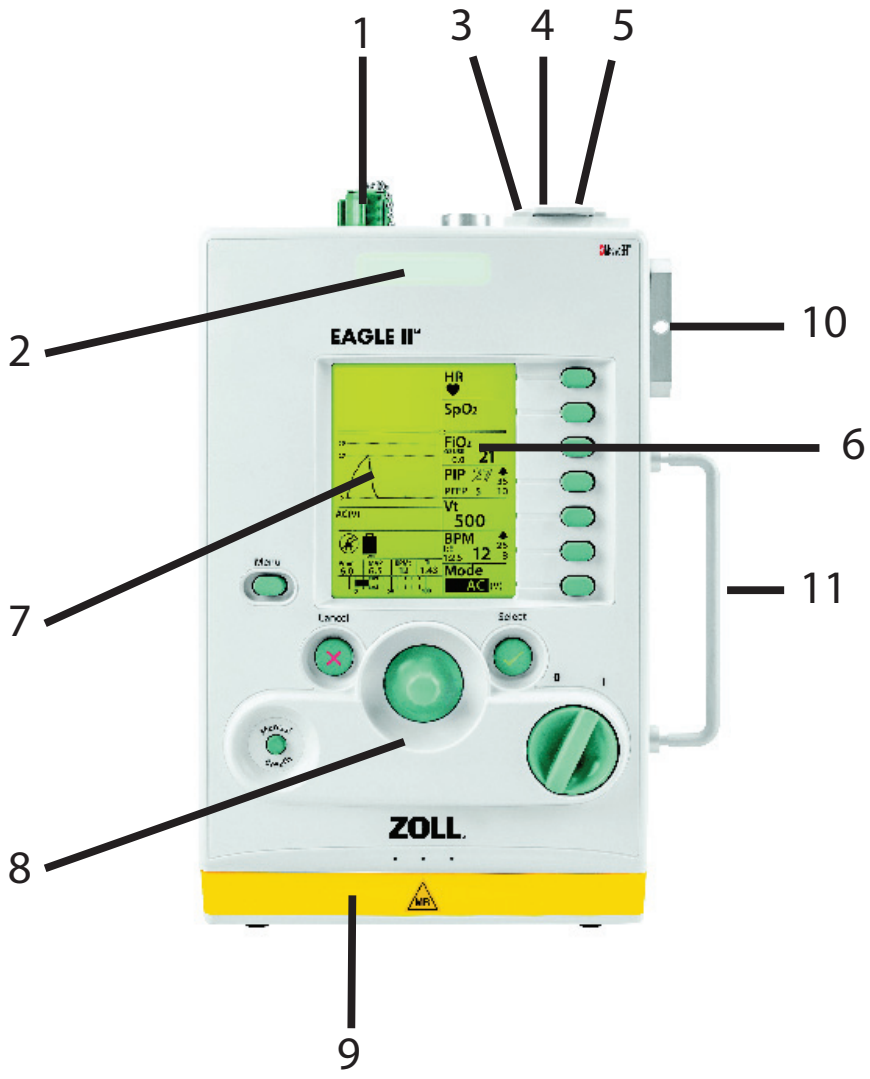
ZOLL Ventilator Features

The ZOLL Ventilator models have these common features:

- Rugged design
- Weight: ~10 lbs
- 10 hour battery life
- Rapid charger to achieve 90% battery capacity in 2 hours
- High performance internal compressor
- Smart Help messages
- Integral SpO_2 (Masimo)
- Airworthiness Release
- Daylight visible display
- Oxygen efficient
- Supports infant, pediatric, and adult patients
- Limited 1 year warranty

ZOLL Ventilator Device Description

The following illustration shows the ZOLL Ventilator's main features:



	Item	Description
		Top
1.	Oxygen Inlet	Connects the device to an external oxygen source
2.	Status Indicator LED Array	Lights up to indicate status of the device, connected to alarms
3.	External Power Input Connector	Connects the device to an external power source
4.	USB Connector	Connects the device to a USB drive or USB compatible device
5.	Pulse Oximeter Connector	Connects the device to a Pulse Oximeter sensor
		Front
6.	LCD Display	Displays the device's settings, patient data, and alarm information
7.	Alarm Message Center	Displays active alarms and mitigation information
8.	Control Panel	Access to the device settings
		Bottom
9.	Battery Compartment	Contains the device's rechargeable Li-ion battery
		Side
10.	Fresh Gas/Emergency Air Intake	Allows the device's internal compressor to take ambient air and acts as an anti-asphyxia valve
11.	Handle	

Appendix A Specifications

General

Parameter	Operating Range
Operating Modes	EMV+® and Eagle II™: AC,SIMV, CPAP with and without Pressure Support, BL Modes, and Leak Compensation for Active and Noninvasive ventilation. AEV®: AC, CPAP (with and without Pressure Support), BL Modes, and Leak Compensation for Noninvasive ventilation.)
Breath Target	Volume or Pressure
Flow Rate	0 to 100 LPM at 40 cm H_2O
Breath Rate	1 to 80 BPM ±1 BPM over the interval Setting Resolution: 1 BPM Measurement: 1 to 90 BPM ± 1 BPM over the interval
Inspiratory Time (Ti)	Setting: .1 to 3 ± 100ms for I:E from 1:1 to 1:99 .1 to 5 ± 100ms for I:E from 4.0:1 to 1:99 (Inverse I:E) Setting resolution: 0.05s
Tidal Volume	Setting: 50 to 2000 ml ATPD ± (5 ml +10% setting) Inverse I:E ratio is available on the EMV+ and Eagle II models) Setting Resolution: 10 ml (Measurement: 0 to 9999 ml ATPD ± (5 ml +10% setting) above 100 ml (5 ml below 100 ml)
FIO_2	21 to 100% ± (3% of full scale ± 10% of setting)
PEEP/EPAP	Setting: 0 to 30 cm H_2O ± (2 cm H_2O + 8% of reading) Setting Resolution: 10 ml Measurement: 0 to 30 cm H_2O ± (2 cm H_2O + 8% of reading)

Parameter	Operating Range
Peak Inspiratory Pressure (PIP)	Setting: 10 to 80 cm H_2O ± (2 cmH_2O + 8% of setting) Setting Resolution: 1 cm H_2O Measurement: 0 to 99 cm H_2O ± (2 cm H_2O + 8% of reading)
Pressure Support (PS)/ IPAP	0 to 60 cm H_2O ± (2 cm H_2O + 8% of setting).
Oxygen Input Pressure	Nominal: 55 psig Range: 40 to 87 psig
Mean Airway Pressure (MAP)	Reading: 0 to 99.9 cm H_2O ± (2 cm H_2O +8% of reading) Resolution: 1 cm H_2O
Airway Pressure High Limit	Setting: 20 to 100 cm H_2O Setting Resolution: 1 cm H_2O
Airway Pressure Low Limit	Setting: Off, 3 to 35 cm H_2O Setting Resolution: 1 cm H_2O
Breath Trigger	-6.0 to -0.5 cm H_2O ± (0.25 cm H_2O + 5% of setting below)
Airway Pressure Waveform	0 to 99 cm H_2O ± (2 cm H_2O + 8% of reading)
Minute Volume	0 to 99.9 lpm ± (0.1 lpm + 8% of reading)
LED Status/Alarm Indicator	Red, Yellow, and Green
Alarm Volume	82 dBA @ 1 meter
Noise Level	~60 dBA when measured at 1 meter (operating at default settings using the compressor only)
Operating Voltages	AC Supply: 100 to 240 VAC (50/60 and 400 Hz) -- use only the AC/DC power supply that ZOLL provides with the device. DC Supply: Nominal 12.5 to 28.0 VDC (accepts DC voltages between 11.8 to 30 VDC).
Operating Time Internal Battery	10 hours at default settings
Ventilator Temperature Ranges	Standard Operating Temperature: -10° to 40° C (14° to 104° F) Extended Operating Temperature: -13° to 49° C (9° to 120° F) Extreme Operating Temperature: -25° to 55° C (13° to 131° F)
Battery Temperature Ranges	Battery Charge: 0°C to 45°C (32°F to 113°F) Battery Discharge: up to 75°C
Size	8.0” Wide X 12.5” High X 4.5” Deep (20.3 cm Wide X 31.8 cm High X 11.4 cm Deep)
Weight	~9.7 lbs (4.4 kg)
Warranty	Limited, 1 year

Pulse Oximeter

Range

Saturation (% SpO_2)	1%-100%
Pulse Rate (bpm)	25-240
Perfusion	0.02%-20%

Accuracy

Saturation (% SpO_2)-During No Motion Conditions

Adults, Pediatrics	70%-100% ± 2 digits
	0%-69% unspecified
Neonates	70%-100% ± 3 digits
	0%-69% unspecified

Saturation (% SpO_2)-During Motion Conditions

Adults, Pediatrics	70%-100% ± 3 digits
	0%-69% unspecified
Neonates	70%-100% ± 3 digits
	0%-69% unspecified

Pulse Rate (bpm)-During No Motion Conditions

Adults, Pediatric, Neonates 25 to 240 ± 3 digits

Pulse Rate (bpm)-During Motion Conditions

Adults, Pediatric, Neonates 25 to 240 ± 5 digits

Resolution

Saturation (% SpO_2) 1%
Pulse Rate (bpm) 1

Low Perfusion Performance

>0.02% Pulse Amplitude Saturation (% SpO_2) ± 2 digits
and% Transmission >5% Pulse Rate ± 3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Device Classification

The following table describes the ZOLL Ventilator's device classification:

Category	Classification
Type of Protection against Electric Shock	The medical power supply (which contains the system's safety barrier) is labeled as Class I or Class II. Electrical shock protection is not dependent upon earthing since this power supply design includes double insulation.
Degree of Protection against Electric Shock Applied Parts	The ventilator circuit is Type BF applied part. The pulse oximeter is Type BF Defibrillation Proof Applied Part.
Degree of Protection against Harmful Ingress of Water	IPX4: Splash-proof equipment rating, include: • Padded case with rain flap • Bacterial/viral filter to protect the compressor
Method of Sterilization or Disinfection	O_2 Supply hoses and connections should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth. The unit's housing should also be cleaned as necessary with a damp, soapy cloth and throughly dried with a lint-free cloth. Do not clean with abrasives or chlorinated hydrocarbon cleansers. Ventilator circuits are only for single use. Follow all IFU instructions.
Degree of Safety of Application in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide	Equipment *not* suitable for use in presence of Flammable Anesthetic Mixture of Air or with Oxygen or Nitrous Oxide
Mode of Operation	Continuous Operation

The device meets the electromagnetic tests as specified by regulations. The following tables provide guidance as to the environments in which you can operate the device.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The ZOLL ventilators use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ZOLL ventilators are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEF 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

The ZOLL ventilators are intended for use in the electromagnetic environment specified below. The customer or user of the ventilator should ensure that they are used in such an environment

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Immunity Test	Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ZOLL ventilators requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.

Power frequency (50/60) magnetic field IEC 6100-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location at a typical commercial or hospital environment. For devices labeled for MR environments, follow the specific directions that ZOLL provides.
Note: U_T is the AC mains voltage prior to application of the test level			

Immunity Test	**Test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the ZOLL ventilator, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V	d = 1.17 $\sqrt{P}$
	10 Vrms 150 kHz to 80MHz outside ISM bands[a]	10 V	d = 1.12 $\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	d = 0.6 $\sqrt{P}$ 80 MHz to 800 MHz d = 1.15 $\sqrt{P}$ 800 MHz to 2.5 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occurring the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.

d. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ZOLL ventilators. The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the ventilators as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside ISM bands $d = 1.17\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.12\sqrt{P}$	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.15\sqrt{P}$
0.01	0.117	0.12	0.06	0.115
0.1	0.37	0.38	0.19	0.36
1	1.17	1.2	0.6	1.15
10	3.7	3.8	1.9	3.6
100	11.7	12	6	11.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

Note 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

ZOLL

Z Vent Ventilator Operator's Guide

9650-002360-01 Rev. C

Appendix A Specifications

General

Parameter	Operating Range
Operating Modes	AC,SIMV, CPAP with and without Pressure Support, BL Mode, and Leak Compensation for Invasive and Noninvasive ventilation
Breath Target	Volume or Pressure
Flow Rate	0 to 100 LPM at 40 cm H_2O
Breath Rate	1 to 80 BPM +/- 1 BPM over the interval Setting Resolution: 1 BPM Measurement: 1 to 90 BPM +/- 1 BPM over the interval
Inspiratory Time (Ti)	Setting: 0 to 3 +/- 0.1 sec for I:E from 1:1 to 1:99 0 to 5 +/- 0.1 sec for I:E from 4.0:1 to 1:99 (Inverse I:E) Setting resolution: 0.05 s
Tidal Volume	Setting: 50 to 2000 ml ATPD +/- (5 ml +10% setting) Inverse I:E ratio is available. Setting Resolution: 10 ml (Measurement: 0 to 9999 ml ATPD +/- (5 ml +10% setting) above 100 ml (5 ml below 100 ml)
FIO_2	21 to 100% +/- (3% of full scale +/- 10% of setting)
PEEP/EPAP	Setting: 0 to 30 cm H_2O+/- (2 cm H_2O + 8% of reading) Setting Resolution: 1 cm H_2O Measurement: 0 to 30 cm H_2O +/- (2 cm H_2O + 8% of reading)
Peak Inspiratory Pressure (PIP)	Setting: 10 to 80 cm H_2O +/- (2 cm H_2O + 8% of setting) Setting Resolution: 1 cm H_2O Measurement: 0 to 99 cm H_2O +/- (2 cm H_2O + 8% of reading)
Pressure Support (PS)/ IPAP	0 to 60 cm H_2O +/- (2 cm H_2O + 8% of setting).

Parameter	Operating Range
Oxygen Input Pressure	Nominal: 55 psig (380 kPa) Range: 40 to 87 psig (280 to 600 kPa)
Mean Airway Pressure (MAP)	Reading: 0 to 99.9 cm H_2O +/- (2 cm H_2O + 8% of reading) Resolution: 1 cm H_2O
Airway Pressure High Limit	Setting: 20 to 100 cm H_2O Setting Resolution: 1 cm H_2O
Airway Pressure Low Limit	Setting: Off, 3 to 35 cm H_2O Setting Resolution: 1 cm H_2O
Breath Trigger	-6.0 to -0.5 cm H_2O +/- (0.25 cm H_2O + 5% of setting below)
Airway Pressure Waveform	0 to 99 cm H_2O +/- (2 cm H_2O + 8% of reading)
Minute Volume	0 to 99.9 lpm +/- (0.1 lpm + 8% of reading)
LED Status/Alarm Indicator	Red, Yellow, and Green
Alarm Volume	82 dBA @ 1 meter
Noise Level	~60 dBA when measured at 1 meter (operating at default settings using the compressor only)
Operating Voltages	AC Supply: 100 to 240 VAC (50/60 and 400 Hz) -- use only the AC/DC power supply that ZOLL provides with the device. DC Supply: Nominal 12.5 to 28.0 VDC (accepts DC voltages between 11.8 to 30 VDC).
Operating Time Internal Battery	10 hours at default settings
Ventilator Temperature Ranges	Standard Operating Temperature: -10 °C to 40 °C (14 °F to 104 °F) Extended Operating Temperature: -13 °C to 49 °C (9 °F to 120 °F) Extreme Operating Temperature: -26 °C to 55 °C (13 °F to 131 °F)
Battery Temperature Ranges	Battery Charge: 0 °C to 45 °C (32 °F to 113 °F) Battery Discharge: up to 75 °C (167 °F)
Size	8.0” Wide X 12.5” High X 4.5” Deep (20.3 cm Wide X 31.8 cm High X 11.4 cm Deep)
Weight	~9.7 lbs (4.4 kg)
Warranty	Limited, 1 year
Altitude	-685.8 m (-2,250 ft) to 7620 m (25,000 ft) above sea level or 110 to 37.6 kPa
Operational Humidity	15% to 95% non-condensing
Transport and Storage	Temperature: EN1789 for ambulance 6.3.2.1 Storage Temperature test Humidity: 15 to 95 % RH (non-condensing)
Vibration	IEC 60068-2-6, IEC 60068-2-34, IEC 60068-2-36, IEC 60068-2-64
Shock	IEC 60068-2-27
Bump	IEC 60068-2-29
Shock/Vibration	MIL SRD 810G, Method 514.6, Procedure I:Jet Aircraft, Fixed Wing, and Rotary Wing

Pulse Oximeter

Parameter	Specification
Range	Saturation (% SpO2):1% to 100% Pulse Rate (bpm): 25 to 240 Perfusion: 0.02% to 20%
Accuracy	Saturation (% SpO_2) - During No Motion Conditions: Adults, Pediatrics: 70%-100% +/- 2 digits, 0%-69% unspecified Neonates: 70%-100% +/- 3 digits, 0%-69% unspecified Saturation (% SpO_2) - During Motion Conditions Adults, Pediatrics: 70%-100% +/- 3 digits, 0%-69% unspecified Neonates: 70%-100% +/- 3 digits, 0%-69% unspecified
Pulse Rate (bpm)	Pulse Rate (bpm) - During No Motion Conditions: Adults, Pediatric, Neonates: 5 to 240 +/- 3 digits Pulse Rate (bpm) - During Motion Conditions Adults, Pediatric, Neonates: 5 to 240 +/- 5 digits
Resolution	Saturation (% SpO_2): 1%, Pulse Rate (bpm): 1
Low Perfusion Performance	>0.02% Pulse Amplitude Saturation (% SpO_2) +/- 2 digits and% Transmission >5% Pulse Rate +/- 3 digits
Interfering Substances	Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Device Classification

The following table describes the ventilator's device classification:

Category	Classification
Type of Protection against Electric Shock	The medical power supply (which contains the system's safety barrier) is labeled as Class I or Class II. Electrical shock protection is not dependent upon earthing since this power supply design includes double insulation.
Degree of Protection against Electric Shock Applied Parts	The ventilator circuit is Type BF applied part. The pulse oximeter is Type BF Defibrillation Proof Applied Part.
Degree of Protection against Harmful Ingress of Water	IPX4: Splash-proof equipment rating, include: • Padded case with rain flap • Bacterial/viral filter to protect the compressor

Category	Classification
Method of Sterilization or Disinfection	O_2 Supply hoses and connections should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth. The device's housing should also be cleaned as necessary with a damp, soapy cloth and throughly dried with a lint-free cloth. Do not clean with abrasives or chlorinated hydrocarbon cleansers. Ventilator circuits are only for single use. Follow all IFU instructions.
Degree of Safety of Application in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide	Equipment *not* suitable for use in presence of Flammable Anesthetic Mixture of Air or with Oxygen or Nitrous Oxide
Mode of Operation	Continuous Operation

The device meets the electromagnetic tests as specified by regulations. The following tables provide guidance as to the environments in which you can operate the device.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The ventilator used RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEF 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

The ventilator is intended for use in the electromagnetic environment specified below. The customer or user of the ventilator should ensure that they are used in such an environment.

Immunity Test	Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	Test level	Compliance level	Electromagnetic environment-guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60) magnetic field IEC 6100-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location at a typical commercial or hospital environment. For devices labeled for MR environments, follow the specific directions that ZOLL provides.
Note: U_T is the AC mains voltage prior to application of the test level			

Immunity Test	Test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V	d = 1.17 $\sqrt{P}$
	10 Vrms 150 kHz to 80MHz outside ISM bands[a]	10 V	d = 1.12 $\sqrt{P}$

Immunity Test	Test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	d = 0.6 $\sqrt{P}$ 80 MHz to 800 MHz d = 1.15 $\sqrt{P}$ 800 MHz to 2.5 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occurring the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to
verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.

d. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ventilator (device). The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside ISM bands $d = 1.17\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.12\sqrt{P}$	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.15\sqrt{P}$
0.01	0.117	0.12	0.06	0.115
0.1	0.37	0.38	0.19	0.36
1	1.17	1.2	0.6	1.15
10	3.7	3.8	1.9	3.6
100	11.7	12	6	11.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

Note 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix A Specifications

General

Parameter	Operating Range
Operating Modes	AC,SIMV, CPAP with and without Pressure Support, BL Mode, and Leak Compensation for Invasive and Noninvasive ventilation
Breath Target	Volume or Pressure
Flow Rate	0 to 100 LPM at 40 cm H_2O (hPa)
Breath Rate	1 to 80 BPM ± 1 BPM over the interval Setting Resolution: 1 BPM Measurement: 1 to 90 BPM ± 1 BPM over the interval
Inspiratory Time (Ti)	Setting: 0 to 3 ± 0.1 sec for I:E from 1:1 to 1:99 0 to 5 ± 0.1 sec for I:E from 4.0:1 to 1:99 (Inverse I:E) Setting resolution: 0.05 s
Tidal Volume	Setting: 50 to 2000 ml ATPD ± (5 ml +10% setting) Inverse I:E ratio is available. Setting Resolution: 10 ml (Measurement: 0 to 9999 ml ATPD ± (5 ml +10% setting) above 100 ml (5 ml below 100 ml) (Measured effective Vt: 50 ml to 2000 ml)
FIO_2	21 to 100% ± (3% of full scale ± 10% of setting)
PEEP/EPAP	Setting: 0 to 30 cm H_2O± (2 cm H_2O (kPa) + 8% of reading) Setting Resolution: 1 cm H_2O (hPa) Measurement: 0 to 30 cm H_2O ± (2 cm H_2O (kPa) + 8% of reading)
Peak Inspiratory Pressure (PIP)	Setting: 10 to 80 cm H_2O ± (2 cm H_2O (kPa) + 8% of setting) Setting Resolution: 1 cm H_2O (hPa) Measurement: 0 to 99 cm H_2O ± (2 cm H_2O (kPa) + 8% of reading)
Pressure Support (PS)/ IPAP	0 to 60 cm H_2O ± (2 cm H_2O (kPa) + 8% of setting)
Oxygen Input Pressure	Nominal: 55 psig (380 kPa) Extreme Range: 40 to 87 psig (280 to 600 kPa) *

Parameter	Operating Range
Mean Airway Pressure (MAP)	Reading: 0 to 99.9 cm H_2O ± (2 cm H_2O (kPa) + 8% of reading) Resolution: 1 cm H_2O (hPa)
Airway Pressure High Limit	Setting: 20 to 100 cm H_2O (hPa) Setting Resolution: 1 cm H_2O (hPa)
Airway Pressure Low Limit	Setting: Off, 3 to 35 cm H_2O (hPa) Setting Resolution: 1 cm H_2O (1 hPa)
Breath Trigger	-6.0 to -0.5 cm H_2O ± (0.25 cm H_2O (kPa) + 5% of setting below)
Airway Pressure Waveform	0 to 99 cm H_2O ± (2 cm H_2O (kPa) + 8% of reading)
Minute Volume	0 to 99.9 lpm ± (0.1 lpm + 8% of reading)
LED Status/Alarm Indicator	Red, Yellow, and Green
Alarm Volume	80 dBA @ 1 meter
Noise Level	~60 dBA when measured at 1 meter (operating at default settings using the compressor only)
Operating Voltages	AC Supply: 100 to 240 VAC (50/60 and 400 Hz) -- use only the AC/DC power supply that ZOLL provides with the ventilator. DC Supply: Nominal 12.5 to 30.3 VDC (accepts DC voltages between 11.8 to 30.3 VDC).
Operating Time Internal Battery	10 hours at default settings
Ventilator Temperature Ranges	Standard Operating Temperature: -10 to 40 °C (14 to 104 °F) Extended Operating Temperature: -13 to 49 °C * (9 to 120 °F *) Extreme Operating Temperature: -26 to 55 °C * (13 to 131 °F *)
Battery Temperature Ranges	Battery Charge: 0 to 45 °C (32 to 113 °F) Battery Discharge: up to 75 °C (167 °F)
Size	8.0” Wide x 12.5” High x 4.5” Deep (20.3 cm Wide x 31.8 cm High x 11.4 cm Deep)
Weight	~9.7 lbs (4.4 kg)
Warranty	Limited, 1 year
Altitude	Standard Altitude: 110 to 70 kPa (-2.250 to 10000 ft) Extended Altitude: 70 to 57.2 kPa (10000 to 15000 ft) Extreme Altitude: 57.2 to 37.6 kPa (15000 to 25,000 ft)
Extreme Operational Humidity	15% to 95% non-condensing but not requiring a water vapor pressure greater than 50hpa *
Transport and Storage	Temperature: -40 to 70 °C (-40 to 158 °F) Humidity: 15 to 95 % RH (non-condensing) but not requiring a water vapor pressure greater than 50hpa
Vibration	IEC 60068-2-6, IEC 60068-2-34, IEC 60068-2-36, IEC 60068-2-64
Shock	IEC 60068-2-27
Bump	IEC 60068-2-29
Shock/Vibration (Military)	MIL SRD 810G, Method 514.6, Procedure I: Jet Aircraft, Fixed Wing, and Rotary Wing
Road Ambulance EN 1789	EN 1789:2007+A2:2014 Medical vehicles and their equipment. Road ambulances. (Sections applicable to medical device)
Commercial Aircraft RTCA/DO-160G	Environmental Conditions and Test Procedures for Airborne Equipment Vibration (Section 8): Fixed wing Category S and Helicopter Category U2, Zones 1&2 EMC (Section 21): Category M, Conducted and Radiated emissions
* No degradation of performance within extreme ranges.	

Pulse Oximeter

Parameter	Specification
Range	Saturation (% SpO2):1% to 100% Pulse Rate (bpm): 25 to 240 Perfusion: 0.02% to 20%
Accuracy	Saturation (% SpO_2) - During No Motion Conditions: Adults, Pediatrics: 70%-100% ± 2 digits, 0%-69% unspecified Neonates: 70%-100% ± 3 digits, 0%-69% unspecified Saturation (% SpO_2) - During Motion Conditions Adults, Pediatrics: 70%-100% ± 3 digits, 0%-69% unspecified Neonates: 70%-100% ± 3 digits, 0%-69% unspecified
Pulse Rate (bpm)	Pulse Rate (bpm) - During No Motion Conditions: Adults, Pediatric, Neonates: 5 to 240 ± 3 digits Pulse Rate (bpm) - During Motion Conditions Adults, Pediatric, Neonates: 5 to 240 ± 5 digits
Resolution	Saturation (% SpO_2): 1%, Pulse Rate (bpm): 1
Low Perfusion Performance	>0.02% Pulse Amplitude Saturation (% SpO_2) ± 2 digits and% Transmission >5% Pulse Rate ± 3 digits
Interfering Substances	Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Device Classification

The following table describes the ventilator's device classification:

Category	Classification
Type of Protection against Electric Shock	The medical power supply (which contains the system's safety barrier) is labeled as Class I.
Degree of Protection against Electric Shock Applied Parts	The ventilator circuit is Type BF applied part. The pulse oximeter is Type BF Defibrillation Proof Applied Part.
Degree of Protection against Harmful Ingress of Water	IP54: Dust protected and splash-proof equipment rating, include: • Padded case (recommended) • Bacterial/viral filter to protect the compressor
Method of Sterilization or Disinfection	O_2 Supply hoses and connections should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth. The device's housing should also be cleaned as necessary with a damp, soapy cloth and throughly dried with a lint-free cloth. Do not clean with abrasives or chlorinated hydrocarbon cleansers. Disposable ventilator circuits are only for single use. Follow all IFU instructions. Reusable circuits must be sterilized according to product labeling included with the accessory.
Degree of Safety of Application in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide	Equipment *not* suitable for use in presence of Flammable Anesthetic Mixture of Air or with Oxygen or Nitrous Oxide
Mode of Operation	Continuous Operation

Emissions and Immunity Compliance

ZOLL ventilators are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Be prepared to use a manual ventilation technique in the event of ventilator interference or failure.

Warning! **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**

The ventilator has an external sensor/transducer (the Pulse Oximeter sensor) that could affect product compliance.

Warning! **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**

Warning! **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of a ZOLL ventilator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

ZOLL ventilators should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ventilator. Ventilator alarms may be issued in the event the ventilator is affected by electromagnetic disturbance.

Compliance for each emissions and immunity standard or test specified:

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Emissions Test	Compliance	Electromagnetic Environment Guidance
ZOLL ventilators are intended for use in the electromagnetic environment specified below. The customer or user of the ventilator should ensure that they are used in such an environment		
RF emissions CISPR 11	Group 1	ZOLL ventilators use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	ZOLL ventilators are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEF 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The device is intended for use in the electromagnetic environment as specified below. Operations outside of this environment could result in interference with the display or the ability to provide therapy.

Immunity Test	Test level	Compliance level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % Ut, 0.5 cycles at 0, 45,90, 135,180,225, 270, and 315 degrees; 0 % Ut, 1 cycle and 70 % Ut, 25/30 cycles; single phase at 0 degrees	0 % Ut, 0.5 cycles at 0, 45,90, 135,180,225, 270, and 315 degrees; 0 % Ut, 1 cycle and 70 % Ut, 25/30 cycles; single phase at 0 degrees	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60) magnetic field IEC 6100-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location at a typical commercial or hospital environment. For ventilators labeled for MR environments, follow the specific directions that ZOLL provides.
Conducted RF IEC 61000-4-6	3 V, 0.15 MHz -80 MHz; 10 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz; 80 % AM at 5 Hz	3 V, 0.15 MHz - 80 MHz; 10 Vin ISM and amateur radio bands between 0.15 MHz and 80 MHz; 80 % AM at 5 Hz	
Radiated RF IEC 61000-4-3	20 V/m, 80 MHz - 2.7 GHz, 80 % AM at 5 Hz	20 V/m, 80 MHz - 2.7 GHz, 80 % AM at 5 Hz	

NOTE 1: U_T is the AC mains voltage prior to application of the test level

NOTE 2: ESD discharges and/or high field environments may cause the ventilator to alarm.

- In the event of an Internal Communication Failure (for example, Service Codes: 1471, 1472, 1474, and 1475) remove external power supply and cycle power to reset the ventilator.
- In the event of fault or failure with pulse oximeter (for example: Service Codes: 2301 and 3301), the alarms self-clear, in event the problem persist follow mitigation instructions.

No deviations from this collateral standard or allowances were used.

Basic Safety and Essential Performance

Instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life:

- Perform preventive maintenance on the ventilator on an annual basis.
- Follow service procedures as defined in the service manual to ensure EMC performance.
- Be prepared to use a manual ventilation technique if the use location is near (for example., less than 1.5 km from) AM, FM, or TV broadcast antennas.

Appendix B
Accessories

The following accessories are available for use with a ZOLL ventilator. To order any of these items, contact ZOLL or your local distributor.

Part Description
AC/DC Power Supply, 100-240 VAC, 100 W, 24 V, 4.2 A, IEC 320 Plug
AC Power line cord, 6 ft (United States Version)
Battery Pack, 6.6 Ah, 14.8 V, Lithium-Ion, 4S3P
AC/DC Power Supply and Line Cord with NEMA 5-15P termination
Extension Cord 8 ft US Hospital Grade Female Plug to Country-Specific Connector (Contact factory for complete part number for each country)
Cord set, 6 ft, IEC 60320-C5 Plug to Country-Specific Connector (Contact factory for complete part number for each country)
Padded Carry Case, Tan, for ventilator and accessories
Filter, Bacterial/Viral (B/V)
Filter, HME/B/V, Heat and Moisture Exchanger
Filter, Disk, B/V, Emergency Air Intake (replaceable part/service item)
Removable foam compressor inlet filter (replaceable part/service item)
Heat and Moisture Exchanger/Bacterial and Viral Filter (HMF), Adult, Dead-space ≤ 75 ml
Heat and Moisture Exchanger/Bacterial and Viral Filter (HMF), Adult, Dead-space ≤ 75 ml (Case of 25)
Heat and Moisture Exchanger/Bacterial and Viral Filter (HMF), Pediatric, Dead-space ≤ 25 ml

Part Description
Heat and Moisture Exchanger/Bacterial and Viral Filter (HMF), Pediatric (Case of 25)
Heat and Moisture Exchanger/Bacterial and Viral Filter (HMF), Infant
Heat and Moisture Exchanger/Bacterial and Viral Filter (HMF), Infant (Case of 25)
Adapter, Metered Dose Inhaler, Adult
Adapter, Metered Dose Inhaler, Adult (Case of 25)
Adapter, Metered Dose Inhaler, Pediatric/Infant
Adapter, Metered Dose Inhaler, Pediatric/Infant (Case of 25)
3 Liter O_2 Reservoir Kit
DC Power Cable, 28 VDC, Military Vehicle
DC Power Cable, 12 VDC. Ambulance
Cable, 3 ft, Masimo SET Oximeter, LNCS Type DC-1, Adult Digit Sensor to DB9 Male **Note:** All LNCS Masimo cables are approved for use with the ZOLL ventilators
Cable, 4 ft, Masimo LNCS Patient Cable Type LNC-4, DB9 Female to Male **Note:** All LNCS Masimo cables are approved for use with the ZOLL ventilators
Cable, 3 ft, Masimo Adult Ear Sensor, LNCS Type DC-1, Adult Sensor to DB9 Male **Note:** All LNCS Masimo cables are approved for use with the ZOLL ventilators
Cable, 6 ft, BS 546 (UK-SA) Plug Right Angle
Cable, 3 ft, Masimo SET Oximeter, LNCS Type Inf/Inf-3, Infant Sensor to DB9 Male
Cable, 3 ft, Pulse Oximeter, Reusable, Finger Sensor, Pediatric
Cable, 18”, Pulse Oximeter, Disposable, Finger Sensor, Adult
Cable, 18”, Pulse Oximeter, Disposable, Finger Sensor, Pediatric
Cable, 3 ft, Masimo SET Oximeter, LNCS Type DC-1, Adult Digit Sensor to DB9 Male, Single Patient **Note:** All LNCS Masimo cables are approved for use with the ZOLL ventilators
Cable, 3 ft, Masimo SET Oximeter, LNCS Type DC-1, Pediatric Digit Sensor to DB9 Male, Single Patient **Note:** All LNCS Masimo cables are approved for use with the ZOLL ventilators
Extension Cord Assembly, AS 3112 (Australian) Plug to US Hospital Grade Plug
Cable, 6 ft, Continental Europe CEE 7/7 to IEC-60320-C5 2.5 Amp Connector
Circuit, 6 ft, Vent, Single Limb, Pediatric/Adult (disposable)
Circuit, 6 ft, Vent, Single Limb, Pediatric/Adult (disposable) (Case of 15)
Circuit, 6 ft, Vent, Single Limb, Infant/Pediatric (disposable)
Circuit, 6 ft, Vent, Single Limb, Infant/Pediatric (disposable) (Case of 20)
Circuit, 12 ft, Vent, Single Limb, Pediatric/Adult (disposable)

Part Description
Circuit, 12 ft, Vent, Single Limb, Pediatric/Adult (disposable) (Case of 10)
Circuit, 12 ft, Vent, Single Limb, Infant/Pediatric (disposable)
Circuit, 12 ft, Vent, Single Limb, Infant/Pediatric (disposable) (Case of 10)
Circuit (reusable)
Circuit (reusable) (Case of 10)
High pressure Oxygen Hose, DISS x DISS, oxygen, 6’
Non-MRI Rolling Cart
MRI conditional Rolling Cart
IV support arm for Rolling Cart (aluminum, MRI safe)
Breathing Circuit support arm for Rolling Cart (ferrous, not for MRI use)
CCLAW (Critical Care Litter Attachment Widget) Mounting Bracket
Carry-all Case with Foam Inserts, without AC Receptacle
Carry-all Case with AC Receptacle
Case, Transit Carry
Case, Transit Carry, with AC Bulkhead Connector
Case, Transit Carry, with AC Bulkhead & USB Connectors
Case, Transit Carry, with Wheels & Pull-Out Handle
Case, Transit Carry, with Wheels & Pull-Out Handle, AC Bulkhead Connector
Check Valve Kit
Mask, CPAP, #6, Large Adult
Mask, CPAP, #6, Large Adult (Case of 20)
Mask, CPAP, #5, Adult
Mask, CPAP, #5, Adult (Case of 20)
Mask, CPAP, #4, Child
Mask, CPAP, #4, Child (Case of 20)
Mask, CPAP, #3, Small Child
Mask, CPAP, #3, Small Child (Case of 20)
Mask, CPAP, #3, Small Child (Case of 40)
Mask, CPAP, #2, Infant
Mask, CPAP, #2, Infant (Case of 20)
Mask, CPAP, #2, Infant (Case of 40)
Mask, CPAP, #1, Small Infant
Mask, CPAP, #4, Child with harness

Part Description
Mask, CPAP, #4, Child with Harness (Case of 20)
Mask, CPAP, #4, Child with Harness (Case of 50)
Mask, CPAP, #5, Adult with Harness
Mask, CPAP, #5, Adult with Harness (Case of 20)
Mask, CPAP, #5, Adult with Harness (Case of 50)
Mask, CPAP, #6, Large Adult with Harness
Mask, CPAP, #6, Large Adult with Harness (Case of 20)
Mask, CPAP, #6, Large Adult with Harness (Case of 50)
Harness, Mask, Universal
Harness, Mask, Universal (Case of 10)
Test Lung, plastic/silicone
Power Supply Holder Kit
AC Power line cord, (US Hospital Grade)