CareFusion

Vela™ Ventilator Diamond Series

Operator's Manual

CareFusion
22745 Savi Ranch Parkway
Yorba Linda, CA 92887
USA

800.231.2466 toll-free
714.283.2228 tel
714.283.8493 fax

EC REP **CareFusion** Germany 234 GmbH
Leibnizstrasse 7
97204 Hoechberg
Germany

+49 931 4972-0 tel
+49 931 4972-423 fax

carefusion.com

CE
0086

Literature number: L3264 Revision M

Revision History

Date	Revision	Changes
September 2009	A	Release
May 2010	B	Revised the Intended Use Notice
		Added the warning: "The Vela ventilator is approved for institutional use only and should not be used to transport patients outside of the institutional setting."
May 2010	C	Rebranded the manual to the CareFusion style
June 2010	D	Added phthalates information. Rebranded the manual to the VIASYS style.
June 2010	E	Rebranded the manual to the CareFusion style.
January 2011	F	Added notes to describe Volume Limit and invalid $EtCO_2$ timeout.
June 2011	G	In Table 1.2, changed the Inspiratory Pause tolerance. In the third paragraph of the section "FIO_2 Monitor Calibration," removed the reference to single-point calibration. In Table 3.2, changed the Flow Trig range.
May 2012	H	Corrected a problem that causes Table 203 and Table 205 to convert to PDF incorrectly.
April 2013	J	Updated the Audible Battery Status Alarm and Alarm Categories sections to be more specific with respect to operation. Updated the Patient Circuit Alarms section to include changes related to the release of 03.02.00 Vela software. Updated the Mains AC Fuses section to include information on the fuse part number 56000-20078. Made minor edits, formatting changes, updates, and corrections.
August 2013	K	Added a statement to the section "Patient Select Screen" to describe the default values that are set when the New Patient option is selected. Added the warning that the use of the low flow oxygen inlet may affect monitored tidal volumes. Updated the section "Cleaning of Accessories and Ventilator Parts" to replace Klenzyme with Revital-OX™
March 2014	L	In the warnings concerning the affect caused by the use of the low flow oxygen inlet, changed "monitored tidal volumes" to "tidal volumes." Removed the note about delivered tidal volumes not being affected. Revised the description of the Oxygen Sensor to explain the characteristics of galvanic cells. In the "FIO_2 Monitor Calibration" section, removed the statement about routine maintenance not normally being required. Changed FiO2 to FIO_2 throughout the document.
October 2014	M	Added a warning that states that an FiO_2 of greater than 30% is not to be used when using the low flow option. Added a warning that states that the low flow oxygen should be limited to a maximum of 10 SLPM.

	Added a warning that states that an oxygen monitor should be used while using the low flow option. In the section "Items Required for Ventilation Setup," removed the phrase that states that medical grade oxygen flow rate is not to exceed 80 L/min at 0.5 psig (.035 bar). In the description of the oxygen sensor, changed the specification to replace the sensor from the two-year service interval to the one-year service interval. Changed L/min to lpm where appropriate throughout the document. Removed Appendix C, Low Flow Oxygen Chart.

Warranty

The Vela™ ventilator systems are warranted to be free from defects in material and workmanship and to meet the published specifications for TWO (2) years or 8,000 hours, whichever occurs first, and the turbine is warranted to be free from defects in material and workmanship for FIVE (5) years or 40,000 hours, whichever occurs first.

The liability of CareFusion (referred to as the Company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the Company, for parts that become defective or fail to meet published specifications during the warranty period; the Company is not liable under this warranty unless (A) the Company is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to the Company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the Company for adjustment no later than four weeks following the last day of the warranty period; and (D) the Company's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of the Company for repair or alteration by the Buyer must be in writing to prevent voiding the warranty. In no event shall the Company be liable to the Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

The Company warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by the Company or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitation of Liabilities

This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment parts. This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by the Company or authorized for use in writing by the Company or if the equipment is not maintained in accordance with the prescribed schedule of maintenance.

The warranty stated above shall extend for a period of TWO (2) years from the date of shipment or 8,000 hours of use, whichever occurs first, or for the turbine, for a period of FIVE (5) years from date of shipment or 40,000 hours of use, whichever occurs first, with the following exceptions:

- Components for monitoring of physical variables such as temperature, pressure, or flow are warranted for ninety (90) days from date of receipt.
- Elastomeric components and other parts or components subject to deterioration, over which the Company has no control, are warranted for sixty (60) days from date of receipt.
- Internal batteries are warranted for ninety (90) days from the date of receipt.

The foregoing is in lieu of any warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of the Company.

Contents

Figures

Tables

Notices

EMC Notice

This equipment generates, uses, and can radiate radio frequency (RF) energy. If this equipment is not installed and used in accordance with the instructions in this manual, electromagnetic interference may result.

This equipment has been tested and found to comply with the limits of acceptance set forth in Standard EN 60601-1-2 for Medical Products. These limits provide reasonable protection against electromagnetic interference (EMC) when operated in the intended use environments described in this manual.

This ventilator is also designed and manufactured to comply with the safety requirements of Standard EN 60601-1, IEC 60601-2-12, CAN/CSA-C22.2 No. 601.1-M90, and UL 60601-1.

This ventilator can be affected by portable and mobile RF communications equipment.

This ventilator should not be stacked with other equipment.

The following cables were used in the evaluation of this ventilator:

- 15619 – Normally Open Patient Call Cable (Length – 1.7 meters)
- 15620 – Normally Closed Patient Call Cable (Length – 1.7 meters)
- 70600 – Cable, Communications (Length – 1 meter)
- 70693 – Cable, Communications (Length – 3 meters)
- Standard Centronix™ Printer Cable (Length – 2 meters)
- Standard SVGA Monitor Cable (Length – 2 meters)

Use of other cables may result in increased emissions or decreased immunity.

See Tables 201, 202, 203, and 205 starting on page 111 for further information regarding the VELA Ventilator and EMC.

MRI Notice

This equipment contains electromagnetic components whose operation can be affected by intense electromagnetic fields.

Do not operate the ventilator in a MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the ventilator.

Intended Use Notice

The Vela ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lb) who require the following general types of ventilation support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation

The ventilator is suitable for use in institutional and transport settings. It is not intended for use as an emergency medical transport ventilator or homecare applications.

Regulatory Notice

U.S. federal law restricts the sale of this device except by or on order of a physician.

The benefit of treatment with medical respiratory support devices outweighs the remote possibility of exposure to phthalates.

IEC Classification

Type of Equipment: Medical Equipment, Lung Ventilator

- The Vela ventilators are suitable for use in institutional and transport environments.
- Ordinary equipment, not protected against the ingress of liquids.
- Not protected/Not suitable for use in the presence of flammable anesthetic gases.
- Class I/Internally Powered, Type BF

Declaration of Conformity Notice

This device is manufactured by CareFusion

This medical equipment complies with the Medical Device Directive, 93/42/EEC, and the following Technical Standards, to which Conformity is declared:

CE
0086

EN 60601-1, EN 60601-2-12, and ISO 13485:2003
EU Notified Body: BSI (Reg. No. 0086)
Trade name: Vela

If you have a question regarding the Declaration of Conformity for this product, please contact CareFusion at the number given in Appendix A.

Manufactured by:
CareFusion
22745 Savi Ranch Parkway
Yorba Linda, California 92887-4668

Safety Information

Please review the following safety information prior to operating the ventilator. Attempting to operate the ventilator without fully understanding its features and functions may result in unsafe operating conditions.

Warnings and Cautions which are general to the use of the ventilator under all circumstances are included in this section. Some Warnings and Cautions are also inserted within the manual where they are most meaningful.

Notes are also located throughout the manual to provide additional information related to specific features.

If you have a question regarding the installation, set up, operation, or maintenance of the ventilator, contact Customer Care as shown in Appendix A, Contact & Ordering Information.

Terms

WARNINGS identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

CAUTIONS identify conditions or practices that could result in damage to the ventilator or other equipment.

NOTES identify supplemental information to help you better understand how the ventilator works.

Warnings

Warnings and Cautions appear throughout this manual where they are relevant. The Warnings and Cautions listed here apply generally any time you operate the ventilator.

- To avoid explosion, do not operate the ventilator in the presence of flammable anesthetics or in an atmosphere of explosive gases. Operating the ventilator in flammable or explosive atmospheres may result in fire or explosion. Keep the ventilator away from all sources of ignition when using oxygen.
- On high pressure oxygen cylinders, use only approved reducing or regulating valves marked for oxygen service. Such equipment must be operated strictly in accordance with the manufacturer's directions. A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure.
- To avoid personal injury and the risk of electric shock, as well as damage to the ventilator, do not operate the ventilator with its covers or panels removed. Refer all servicing to a CareFusion certified service technician.
- All electromechanical systems are subject to malfunction or failure from both internal and external causes. Although the ventilator has been designed to detect and notify you of various conditions by means of alarms, and to shut down in case of possible unsafe operating conditions, anyone operating the ventilator should be trained to respond with a well-rehearsed procedure to provide emergency ventilation in case the ventilator ceases to operate.

- The Vela ventilator is approved for institutional use only and should not be used to transport patients outside of the institutional setting.
- Care should be taken to ensure that the patient does not disconnect from the patient breathing circuit. Such disconnections could be hazardous to the patient.
- Use the internal F_IO_2 analyzer to monitor oxygen concentrations. This is required to ensure the desired fraction of inspired oxygen (F_IO_2) is being delivered to the patient. Consult a physician to determine the desired concentration of inspired oxygen to be delivered.
- Do not attach a one-way check valve to the outlet of the exhalation valve. Doing so may adversely affect the operation of the ventilator and may be harmful to the patient.
- Do not operate the ventilator without setting the alarms. All alarms must be set to ensure safe operation. Ensure that all critical alarms, such as the Low Pressure alarm, have been set.
- Operating an improperly functioning ventilator may be harmful to the patient or operator. If the ventilator does not start up properly, or fails to pass the User Verification Tests, remove it from service and contact your CareFusion certified service technician.
- Do not operate the ventilator unless you are trained to do so. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Operation by untrained personnel may result in unsafe operating conditions.
- Do not operate the ventilator unless qualified personnel are in attendance to promptly respond to alarms, inoperative conditions, or sudden malfunctions. Patients on life-support equipment should be visually monitored at all times. Qualified personnel should be prepared to provide an alternate form of ventilation, if needed.
- Lower air density at higher altitudes affects tidal volume delivery and exhaled tidal volume measurements.
- Delivered percentage oxygen may be higher than set at elevations above 5000 feet.
- Do not ignore the ventilator's audible alarms. Alarms indicate conditions that require your immediate attention.
- Do not try to service or repair an improperly functioning ventilator yourself. Contact your CareFusion certified service technician for all repairs and service.
- Do not use parts, accessories, or options that have not been authorized for use with the ventilator. Using unauthorized parts, accessories, or options may be harmful to the patient or damage the ventilator.
- Do not connect the ventilator to a patient without first pressure testing the patient breathing circuit. Failing to pressure test the patient breathing circuit may result in injury or inadequate therapy. If using a heated humidifier, be sure to include it in the circuit when pressure testing.
- Check the exhalation valve diaphragm after cleaning it, or once per month, to ensure that it is not worn or damaged. A worn or damaged exhalation valve diaphragm may result in improper patient ventilation. Replace the diaphragm as necessary.
- Check all audible and visual alarms daily to make sure they are operating properly. If an alarm fails to activate, contact your CareFusion certified service technician.

- Although the system continues to ventilate with a XDCR FAULT alert, the accuracy of the tidal volume, minute volume, and pressure measurements may be reduced. Remove the ventilator from service and contact your CareFusion certified service technician.
- Always ensure that the high pressure alarm limit is set below the Over Pressure Relief setting. Otherwise, a HIGH PRES alarm may not occur and the patient may be subjected to sustained high pressures.
- Although the system continues to ventilate when a NO CAL DATA alert is present, the accuracy of the volume and pressures may be reduced. The system may generate pressures and volumes that are inconsistent with the front panel settings. Remove the ventilator from service and contact your CareFusion certified service technician.
- Disconnect the patient prior to accessing the verification self-checks. The ventilator does not deliver gas during these procedures.
- The Vela is designed to ensure that the user and patient are not exposed to excessive leakage current per applicable standards (UL 60601-1 and IEC 60601-1). However, this cannot be guaranteed when external devices are attached to the ventilator. In order to reduce the risk of excessive enclosure leakage current from external equipment attached to the printer and video ports, isolation of the protective earth paths must be provided to ensure proper connection. This isolation should ensure that the cable shields are isolated at the peripheral end of the cable.
- Use of the *low flow oxygen inlet* may affect tidal volumes. The degree of the effect is dependent on the ventilator settings and gas flow to the inlet.
- An FiO_2 of greater than 30% may not be achievable when the low flow oxygen option is being used.
- When the low flow oxygen option is being used, the maximum flow from the source should not exceed 10 SLPM.
- When the low flow oxygen option is being used, an external, fully functional oxygen monitoring system should be used.

Cautions

The following cautions apply any time you work with the ventilator.

- A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. Upon loss of protective ground, all conductive parts, including knobs and controls, which may appear to be insulated, can render an electric shock. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the ventilator, and make sure the power cord is in good condition.
- Grounding reliability can only be achieved when the equipment is connected to an equivalent outlet marked "hospital only" or "hospital grade. "
- To avoid fire hazard, use only the fuse specified in the ventilator's parts list and is identical in type, voltage rating, and current rating to the existing fuse. Fuses should only be changed by CareFusion certified service technicians.

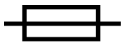
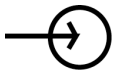
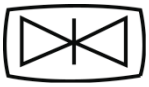
- To minimize the potential for electrostatic shock, do not use anti-static or electrically conductive hoses and tubing with the ventilator.
- Run the User Verification Tests prior to clinical application, at least once a month (or as specified by your department guidelines), and any time you suspect the ventilator is not operating properly.
- Do not store the ventilator in hot areas for prolonged periods of time. Temperatures above 27°C (80°F) can shorten battery life. Failing to charge the ventilator while in storage may also shorten battery life.
- When the integrity of the external power earth conductor arrangement is in doubt, operate the ventilator from its internal batteries
- The maximum voltage that can be applied to the Patient Assist Call modular connector is 25 volts RMS or 31 V DC.

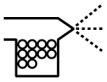
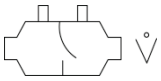
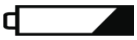
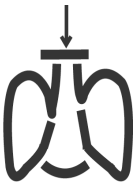
  The following cautions apply when cleaning the ventilator or when sterilizing ventilator accessories.
- Do not clean or dry the ventilator with a high pressure air gun. Applying high pressure air to the ventilator may damage the internal components of the pneumatic circuit and render the ventilator inoperable.
- Do not over clean the ventilator. Repeated use of a cleaning agent can cause residue build-up on critical components. Excessive residue build up can affect ventilator performance.
- Do not sterilize the ventilator. Standard sterilization techniques may damage the ventilator.
- Do not use cleaning agents that contain phenols, ammonium chloride, chloride compounds, or more than 2% glutaraldehyde. These agents may damage the ventilator's plastic components and front panel overlay.
- When cleaning the ventilator:
  - Do not use harsh abrasives.
  - Do not immerse the ventilator in liquid sterilizing agents or liquids of any kind.
  - Do not spray cleaning solution into the exhalation valve or directly onto the front panel.
  - Do not allow cleaning solution to pool on the front panel.
- The flow sensor assembly is a delicate precision assembly. Exercise care when removing, replacing, or cleaning the assembly.
- Do not insert cleaning instruments (such as a cloth, brush, or pipe cleaner) into the flow sensor.
- Do not use a high pressure gas nozzle to dry the flow sensor. High pressure gas may damage the flow sensor.
- Dry the exhalation flow sensor tubes using a low flow gas source (less than 10 LPM) to ensure the differential pressure ports are free of moisture and debris.
- To avoid possible damage to elastomeric components, the peak temperature for accessories should not exceed 131°F (55°C) for gas (ETO) and 275°F (135°C) 15-minute cycle time for steam autoclave.

- Be sure to check with the manufacturer of all chemicals and sterilizing equipment to ensure safe handling procedures are followed.
- It is not necessary to remove the four screws to remove the fan inlet filter. To do so causes mounting hardware to become loose within the ventilator, which may result in electrical damage.

Equipment Symbols

The following symbols may be referenced on the ventilator or in accompanying documentation.

Symbol	Source/Compliance	Meaning
	Symbol #03-02 IEC 60878	Indicates ATTENTION, consult ACCOMPANYING DOCUMENTS
	Symbol #5016 IEC 60417	This symbol indicates a FUSE.
	Symbol #5034 IEC 60417 Symbol #01-36 IEC 60878	This symbol indicates INPUT.
	Symbol #5035 IEC 60417 Symbol #01-37 IEC 60878	This symbol indicates OUTPUT
	Symbol #5019 IEC 60417 Symbol #01-20 IEC 60878	This symbol indicates protective EARTH (ground).
	Symbol #5021 IEC 60417 Symbol # 01-24 IEC 60878	This symbol indicates the EQUIPOTENTIAL connection used to connect various parts of the equipment or of a system to the same potential, not necessarily being the earth (ground) potential (e.g., for local bonding).
	Symbol # 5333 IEC 60417 Symbol #02-03 IEC 60878	This symbol indicates TYPE BF equipment, which indicates equipment that provides a particular degree of protection against electric shock, particularly with regards to allowable leakage current and reliability of the protective earth connection.
	Symbol #5032 IEC 60417 Symbol #01-14 IEC 30878	This symbol indicates the equipment is suitable for alternating current.
	Symbol# 5049 IEC 60417	This Symbol indicates the ON condition for a part of the equipment. When pressed, the ventilator operates from the MAINS voltage (if connected) or internal or external batteries if the battery charge is within operating specifications.
	Symbol #5007 IEC 60417 Symbol #01-01 IEC 60878	Indicates ON (Power)
	Symbol #5008 IEC 60417 Symbol #01-02 IEC 60878	Indicates OFF (Power)
 ACCEPT	Symbol #0651 ISO 7000	Horizontal return with line feed. Indicates ACCEPT entered values for a specific field.
 CANCEL	Graphical Symbol in general use internationally for "DO NOT"	This symbol indicates CANCEL. Do not accept entered values. The ventilator continues to operate at previous settings.
	Symbol #5467 IEC 60417	Pressing the button with this symbol FREEZES the current display.

Symbol	Source/Compliance	Meaning
	Symbol #5569 IEC 60417	This symbol indicates a CONTROL LOCK.
	CareFusion symbol	This symbol represents a NEBULIZER.
	Symbol #5319 IEC 60417	This symbol indicates ALARM SILENCE
	Symbol #5307 IEC 60417	This symbol indicates ALARM RESET
	CareFusion symbol	Increase OXYGEN
	CareFusion symbol	Indicates VARIABLE ORIFICE FLOW SENSOR
	Symbol #5031 IEC 60417	This symbol indicates DIRECT CURRENT (DC)
	Symbol #5546 IEC 60417	This symbol indicates the INTERNAL BATTERY STATUS display
	CareFusion symbol	This symbol indicates INSPIRATORY HOLD
	CareFusion symbol	This symbol indicates EXPIRATORY HOLD
	CareFusion symbol	This symbol indicates MANUAL BREATH
	Symbol # EN 15986:2011	This symbol indicates the product contains di (2-ethylhexyl) phthalate.

Vela™ Ventilator Diamond Series

Chapter 1 Introduction

The Vela ventilator system is an easy to use, self-contained, servo-controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for pediatric through adult patients. Its revolutionary user interface provides maximum flexibility with simple operator interaction. It has a flat panel color LCD with real time graphics display and digital monitoring capabilities, a touch screen for easy interaction, membrane buttons and a dial for changing settings. A precision gas delivery turbine with servo controlled active inhalation and exhalation improves performance over previous generations of ventilators.

The Vela may be configured as a conventional ventilator or non-invasive positive pressure ventilator (NPPV). It has been designed to function using most commonly available accessories; there are no proprietary circuits required for your Vela. It is easy to clean and its design does not allow liquids to pool on its surfaces, reducing the likelihood of fluid leakage into the body of the ventilator.

The three models of the Vela come with a wide range of features for the critical care environment. Optional features can be added at the time of purchase or at a later date.

Features

Packaged in a compact, lightweight unit, the Vela Ventilator provides extensive features:

- Compressor free technology, allowing uninterrupted ventilation.
- A broad range of operating modes including Assist/Control, SIMV, and CPAP.
- Volume Control, PRVC, APRV Bi-Phasic, Pressure Control, and Pressure Support Ventilation.
- Apnea Backup ventilation in SIMV and CPAP/PSV.
- Revolutionary user interface for easy operation and extensive monitoring capabilities.
- All models have integrated graphics. Comprehensive model includes Loops and Trends.
- Communication package including a remote nurse call connection, fiber-optic connection, printer connection and video output port.
- The Vela has both high pressure oxygen inlet with blender and low flow oxygen inlet with accumulator.
- The Vela delivers and displays tidal volumes as BTPS (**B**ody **T**emperature **P**ressure **S**aturated) corrected.
- Self-testing at power-up and background testing during normal operation.
- Internal battery with up to six-hour life.
- Easily understandable User's Guide for quick reference.

For ordering information of option upgrade packages, see Appendix A or contact your CareFusion products representative.

Vela Model Matrix

Table 1.1 Vela Model Matrix

OPTION	Vela	Vela +	Vela Comprehensive
% O_2	X	X	X
100% O_2	X	X	X
FIO_2 monitor	X	X	X
Nebulizer	X	X	X
Inspiratory Hold	X	X	X
Expiratory Hold	X	X	X
Assist/Control	X	X	X
SIMV	X	X	X
CPAP	X	X	X
Pressure Control	X	X	X
Pressure Support	X	X	X
Basic Waveform Graphics	X	X	X
PRVC/Vsync		X	X
NPPV		X	X
Leak Compensation		X	X
Loops			X
Trends			X
MIP/NIF			X
$ETCO_2$	Option	Option	Option*
Square Waveform			X
APRV/BiPhasic			X
Assured Volume			X
* Software is activated; hardware to be purchased.			

Performance Specifications and Tolerances

Table 1.2 Ventilator Parameters and Alarms Ranges/Tolerances

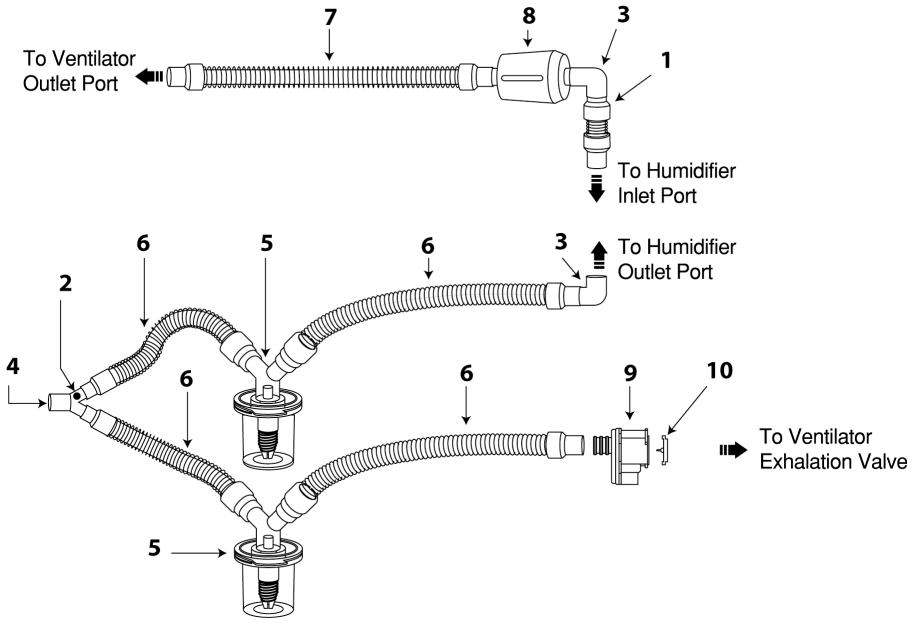
PARAMETERS	RANGES	TOLERANCES
Controls		
Tidal Volume Tidal Volume in PRVC (Plus & Comp Only)	50 to 2000 ml 50 to 2000 ml	Greater of: ± 10 ml or 10% Greater of: ± 20 ml or 10%
Breath Rate	2 to 80 bpm	Lesser of: ± 1 breath or 10% of breath period
Peak Flow *Maximum Flow*	10 to 140 lpm 180 lpm	Greater of: ± 2 lpm or 10%
PEEP/CPAP	0 to 35 cmH_2O	Greater of: ± 2 cmH_2O or 10%
Pressure Support	OFF, 1-60 cmH_2O	Greater of: ± 2 cmH_2O or 8%
Oxygen Percent	21 to 100%	± 3 % from 21 to 50% ± 5 % from 51 to 100%
Bias Flow	10 to 20 lpm	± 1 lpm
Sigh 1.5 X V_t (Set)	ON/OFF, 1 Sigh every 100 breaths or 7 minutes, whichever occurs first	± 1 breath period
Manual Breath	X 1	NA
Inspiratory Hold	6 second max.	± 0.05 sec
100% O_2 3min.	ON/OFF, 3 minute max.	+ 0 %; - 5 %
Over Pressure Relief	20 to 130 cmH_2O	± 10 cmH_2O
Inspiratory Pause	OFF, 0.1 – 2.0 sec	± 0.05 seconds
Square Waveform (Comp only)	ON/OFF	N/A
Expiratory Hold	6 second max.	Greater of: ± 2 cmH_2O or 10%
MIP/NIF (Comp only)	30 second max.	Greater of: ± 2 cmH_2O or 5%
CO_2 Enable	ON/OFF	NA
Inspiratory Pressure	1 to 100 cmH_2O	Greater of: ± 2 cmH_2O or 8%
Inspiratory Time	0.3 to 10.0 sec.	± 0.05 seconds
Trigger Sensitivity	1 to 20 L/min	± 0.5 L/min at a setting of 1 L/min; ± 1 L/min at a setting of 2-20 L/min
APRV Biphasic *Time High* (Comp only)	0.3 to 30 sec.	± 0.05 seconds
APRV Biphasic *Time Low* (Comp only)	0.3 to 30 sec.	± 0.05 seconds

PARAMETERS	RANGES	TOLERANCES
APRV Biphasic *Pressure High* (Comp only)	0 to 60 cmH_20	Greater of: ± 2 cmH_20 or 10%
APRV Biphasic *Pressure Low* (Comp only)	0 to 45 cmH_20	Greater of: ± 2 cmH_20 or 10%
NPPV Pressure Control (Plus & Comp Only)	1 to 40 cmH_20	Greater of: ± 2 cmH_20 or 8%
NPPV Pressure Support (Plus & Comp Only)	OFF, 1 to 40 cmH_20	Greater of: ± 2 cmH_20 or 8%
Assured Volume (Comp only)	OFF, 50 to 2,000 ml	Greater of: ± 10 ml or 10%
Volume Limit	50 to 2,500 ml	Greater of: ± 10 ml or 10%
Alarms		
High Pressure Alarm Limit	5 to 120 cmH_2O	Setting of 5 to 20 cmH_2O: ± 2 cmH_2O Setting of 21 to 120 cmH_2O: ± 4 cmH_2O
Low Pressure Alarm Limit	OFF, 2 to 60 cmH_2O	Setting of 2 to 20 cmH_2O : ± 2 cmH_2O Setting of 21 to 60 cmH_2O: ± 4 cmH_2O
Low Minute Volume Alarm	OFF-0.1 to 99.9 L	Greater of: ± 10% or 20 ml
High Breath Rate	OFF, 3 to 150 bpm	Greater of: ±1 bpm or 5% of breath period
Apnea Interval	10 to 60 sec.	± 0.5 sec
Backup Breath Rate	Greater of: 12 bpm or set breath rate	Greater of: ± 1 breath of 10% of Breath period
Low Regulated O_2 Pressure	35 psig (2.41 bar)	± 2 psig (0.14 bar)
High Regulated O_2 Pressure	65 psig (6.00 bar)	± 2 psig (0.14 bar)
Alarm Silence	60 sec. max.	± 1 second
Alarm Volume	65 to 85 dBA at 1 meter	± 8 dBA
Low $ETCO_2$	OFF/1 to 150 mmHg / 0.1 to 20.0 kPa	The Low $EtCO_2$ alarm must be set at least 5 mmHg (0.7 kPa) below the High $EtCO_2$ alarm setting.
High $ETCO_2$	OFF/5 to 150 mmHg / 0.7 to 20.0 kPa	The High $EtCO_2$ alarm must be set at least 5 mmHg (0.7 kPa) above the Low $EtCO_2$ alarm setting.

PARAMETERS	RANGES	TOLERANCES
Monitors		
Total Breath Rate (*f*)	0 to 250 bpm	Greater of: ± 1 bpm or 5% of breath period
Spontaneous Breath Rate (*f*)	0 to 250 bpm	Greater of: ± 1 bpm or 5% of breath period
I:E Ratio (I:E)	1.99 to 99:1	Greater of: ± 50 ms or 5%
Exhaled Minute Volume (V_e)	0 to 99.9 L	Greater of: ± 10% or the measured breath rate x 10 ml
Spontaneous Exhaled Minute Volume Spon (V_e)	0 to 99.9 L	Greater of: ± 10% or the measured breath rate x 10 ml
Mandatory Exhaled Minute Volume (Mand V_e)	0 to 99.9 L	Greater of: ± 10% or the measured breath rate x 10 ml
Peak Inspiratory Pressure (P_{peak})	0 to 140 cmH_2O	Greater of: ± 2 cmH_2O or 5%
Mean Airway Pressure (P_{mean})	0 to 99 cmH_2O	Greater of: ± 2 cmH_2O or 10%
Inspiratory Time (Ti)	0.01 to 99.99 sec.	± 0.05 seconds
Expiratory Time (Te)	0.01to 99.99 sec.	± 0.05 seconds
Positive End Expiratory Pressure (PEEP)	0 to 99 cmH_2O	Greater of: ± 2 cmH_2O or 10%
Mandatory Exhaled Tidal Volume (Mand V_t)	0 to 4,000 ml	Greater of: ± 10% or 10ml
Spontaneous Exhaled Tidal Volume (Spon V_t)	0 to 4,000 ml	Greater of: ± 10% or 10ml
Inspired Tidal Volume (V_{ti})	0 to 4,000 ml	Greater of: ± 10% or 10ml
Oxygen regulated pressure	0 to 100 psig (0 to 6.89 bar)	Greater of: ± 10% or 3 psig (0.21 bar)
Percent Oxygen	18 % to 100 %	± 2 %
f/Vt	0 to 500 b^2/min/L	Derived from accuracies for spontaneous breath rate and spontaneous tidal volume.
$ETCO_2$	0 to 150 mmHg / 0.7 – 19.9 kPa	± 2 mmHg for 5 to 40 mmHg / 0.7 to 5.3 kPa ± 5% of reading for 41 to 70 mmHg/ 5.3 to 9.3 kPa ± 8% of reading for 71 to 100 mmHg / 9.3 to 13.2 kPa ± 10% of reading for 101 to 150 mmHg /9.3 to 19.9 kPa

Note:

Specifications apply to Vela models that support the mode or feature described.



Item No.	Description	Quantity	Adult, # 11570	Ped, # 11571
1	22mm I.D. Cuff Adapter	1	00423	00423
2	Tapered Plug, 7.5mm Male	1	04124	04124
3	90 Degree Elbow Adapter	2	04709	04709
4	Wye Connector	1	20225	20225
5	Water Trap, Natural, Autoclavable	2	09413	09413
6	Circuit Tubing, 30" (76.2 cm) Smooth Bore	4	09531	33546
7	Circuit Tubing, 18" (45.7 cm) Smooth Bore	1	09532	33545
8	Main Flow Bacteria Filter, 0.3 microns	1	09534	09534
9	Exhalation Valve Body	1	20005	20005
10	Exhalation Valve Diaphragm	1	16240	16240

Figure 1.1 Patient Circuit Assembly

Table 1.3 Breathing Circuit Characteristics

Breathing Circuit Characteristics

	Adult	**Pediatric**
Inspiratory Resistance, cmH_2O L/min	0.27 at 60 L/min	0.29 at 30 L/min
Expiratory Resistance, cmH_2O /L/min	0.06 at 60 L/min	0.06 at 30 L/min
Compliance, ml/ cmH_2O	1.81	1.35
Internal Volume, ml	1,843	1,374

Note:

All testing and calculations were based on BTPD (Body Temperature Pressure Dry) conditions. The operator is advised, that when adding accessories or components to the patient circuit, to ensure that the inspiratory and expiratory resistance of the resulting breathing system does not exceed 0.6 kPa (6 cmH2O) @ 60 L/min for adults and 30 L/min for pediatric patients.

Cleaning, Sterilizing or Disinfecting the Patient Breathing Circuit

If you are using a CareFusion Products reusable patient-breathing circuit, use the instructions below. When using another reusable patient-breathing circuit, refer to the original equipment manufacturer's cleaning instructions. If you are using Single Patient Use (disposable) circuits, follow your infection control policy to determine the usable cycle or life.

Removing the Patient Circuit for Cleaning

1. Disconnect the circuit from the ventilator and exhalation valve housing.
2. Disconnect the circuit tubing from all inline components such as a heated humidifier or bacteria filters.

Caution!

Do not submerge bacteria filters in liquids of any kind. Instead, use a steam autoclave to sterilize the filters. To avoid possible damage to elastomeric components, the peak temperature for CareFusion products accessories should not exceed 275°F (135°C) for steam autoclaving.

Disinfecting the CareFusion Patient Circuit

1. Clean the circuit with a soft bristle brush using Ultra Ivory ® or an equivalent detergent. Pay particular attention to crevices and hard to clean areas. Dry the circuit with a soft cloth. After cleaning the patient-breathing circuit, make sure all excess cleaning solution is completely removed to prevent residue buildup.
2. To disinfect the circuit, immerse it in boiling water for 15 minutes.
3. Before reinstalling the patient-breathing circuit, inspect it for excessive wear. If you find signs of damage, obtain a new patient-breathing circuit.

Cleaning and Sterilizing Recommendations for the Patient Circuit

1. Clean the circuit with an enzymatic cleaner such as KlenZyme™ (part # 33775) in a warm bath that is over 95°F (35°C) and under 150°F (65.5°C) for 10 minutes.
2. Gently rinse the circuit for one to two minutes.
3. Dry the circuit with a gentle air flow to remove water from all passages.
4. Sterilize the circuit using any of the following methods:

- Autoclave at 20 psig, 275°F (135°C), moist heat for seven minutes or 0 PSIG (gravity) 135°C moist heat for 15 minutes at 135°C.
- Wash the circuit in a Glutaraldehyde, such as Cidex™ (2%), for 30 minutes, or according to the manufacturer's specifications.

5. Gently rinse the circuit completely and allow it to dry.
6. Clean the circuit with a soft bristle brush using Ultra Ivory® or an equivalent detergent according to the manufacturer's recommendations. Pay particular attention to crevices or hard to clean areas.
7. Dry the circuit with a soft cloth.
8. Immerse the circuit in boiling water for 15 minutes to disinfect it.

Caution!

The main flow Bacteria Filter, P/N 09534, is compatible with steam autoclave ONLY.

The following schematic shows the flow-delivery system of the ventilator.

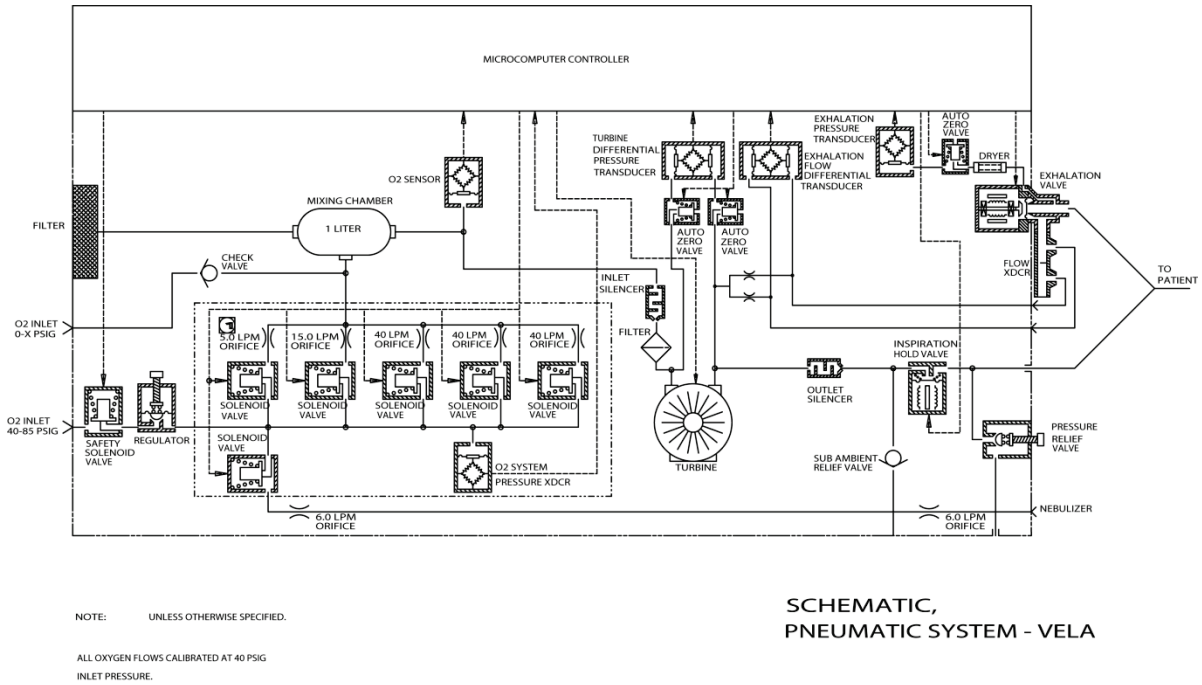


Figure 1.2 Flow Delivery System Schematic

Vela™ Ventilator Diamond Series

Chapter 2 Unpacking and Setup

Ventilator Assembly and Physical Setup

Unpacking the Ventilator

The Vela is designed for simplicity of operation and set-up. It requires minimal assembly. You should receive the following items with your ventilator. If you do not receive these items or something is missing or damaged, please contact CareFusion customer service as shown in Appendix A.

Table 2.1 Items shipped with the Standard model Vela Ventilator

Part Number	Description	Quantity
16240	Exhalation Valve Diaphragm	2
Various	15' (3m) high pressure oxygen hose (Country specific)	1
20005	Exhalation Valve Body	2
16496	Variable Orifice Flow Sensor	2
Various	Users Guide (See Appendix A for specific language)	1
Various	Operator's Manual (See Appendix A for specific language)	1
L2864	Op Manual on CD	1

Items Required for Ventilator Setup

You need the following to set up your Vela ventilator:

- **Power Source.** The ventilator operates from a standard 100, 110, 220, or 240 VAC power source, the internal battery or qualified DC Inverter. The factory equipped internal battery is capable of providing power during short-term patient transports or AC power interruptions.
- **Pressurized Oxygen.** The oxygen source must provide clean, dry, medical grade oxygen at a line pressure of 40 to 85 psig (2.8 to 6.0 bar).
- **Low Flow Oxygen.** The low flow oxygen source must provide clean, medical grade oxygen.

Warning!

Use of the low flow oxygen inlet may affect tidal volumes. The degree of the effect is dependent on the ventilator settings and gas flow to the inlet.

Warning!

An FiO_2 of greater than 30% may not be achievable when the low flow oxygen option is being used.

Warning!

When the low flow oxygen option is being used, the maximum flow from the source should not exceed 10 SLPM.

Warning!

When the low flow oxygen option is being used, an external, fully functional oxygen monitoring system should be used.

Pressurized Oxygen Supply

Pressure Range:	40 to 85 psig (2.8 to 6.0 bar) (Supply Oxygen)
Temperature:	10 to 40 °C (50 to 104 °F)
Humidity: (minimum)	Dew Point of gas should be 1.7° C (3° F) below the ambient temperature
Minimum Flow:	80 L/min at 20 psig (1.4 bar)
Inlet Fitting:	CGA DISS-type body, No. 1240

Assembling the Ventilator

If you ordered one of the stands for the Vela, use the assembly instructions included in the packaging. The ventilator body is easily attached to the base by means of two thumbscrews as shown in the following figure.

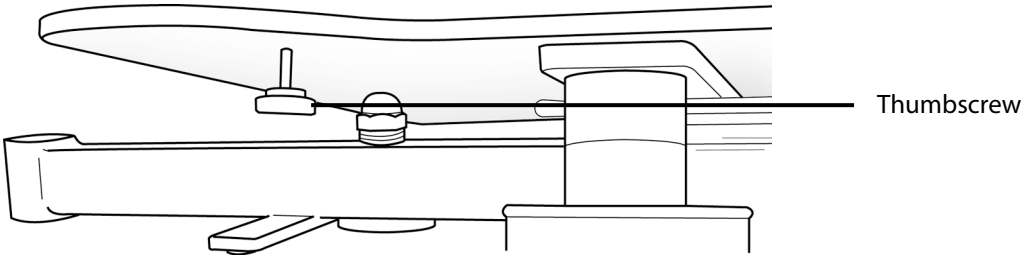


Figure 2.1 Ventilator Base Showing Thumbscrew

Setting Up the Front of the Ventilator

Attaching the Exhalation Diaphragm and Valve Body

Carefully seat the rim of the diaphragm on the exhalation valve and gently press around the rim to insure it is seated evenly as shown in the following figure.

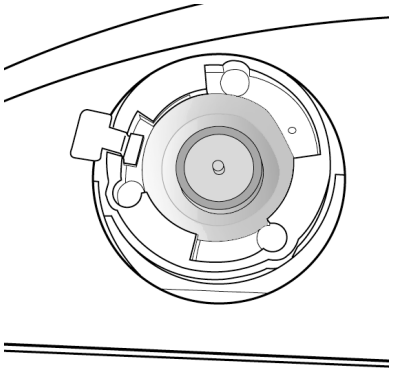


Figure 2.2 Exhalation Diaphragm in place

Line up the fins of the Exhalation Valve Body with the openings in the exhalation valve housing.

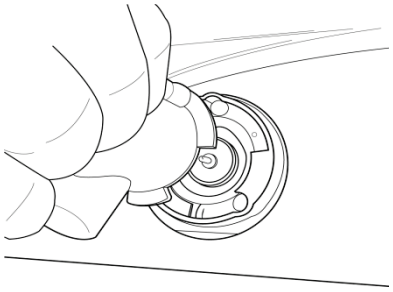


Figure 2. 3 Aligning the valve body

Press gently in and rotate clockwise until you hear a click.

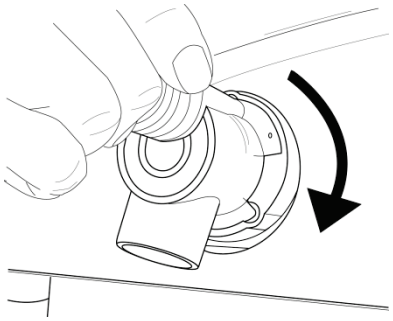


Figure 2.4 Engaging the valve body

The locking tab for the exhalation valve body should be firmly in place and the valve body should not swivel.

Attaching the Variable Orifice Flow Sensor

The flow sensor is attached to the valve body as shown in the following figure. Gently push the flow sensor into the valve body port until it seats. Do not force it farther in. This might damage the sensor or the valve body.

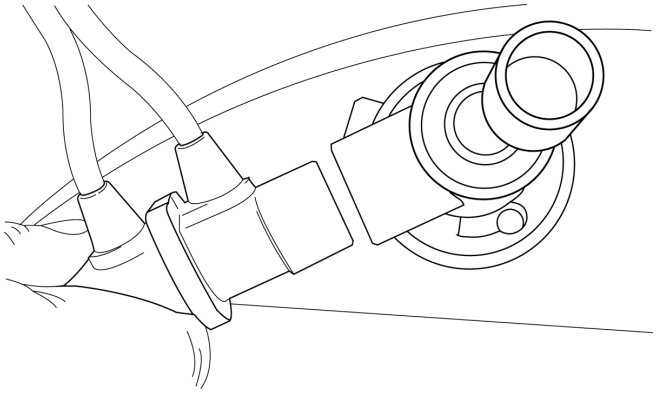
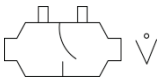


Figure 2.5 Attaching the Flow Sensor

The Variable Orifice sensor connects to the receptacle on the front of the ventilator marked with the icon shown here.



This is a locking connector. To connect, first pull back the plastic locking shroud then push firmly into the ventilator receptacle. Slide the locking shroud back into place when connection is made.

To disconnect, first retract the plastic shroud then firmly pull the connector away from the ventilator. Do not pull up or down as this can damage the connector.

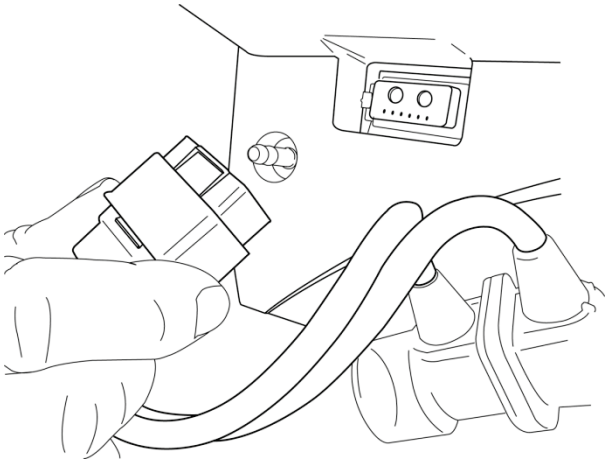


Figure 2.6 Connecting the Variable Orifice Flow Sensor

Caution!

Fully retract the plastic connector shroud before attaching these connectors. Failure to do this can result in damage to the connector.

Attaching the Patient Circuit

The patient circuit connections are shown in figure 2.7. The inspiratory limb of the patient circuit connects directly to the gas output of the ventilator. An active humidification system or passive Heat and Moisture Exchanger (HME) if prescribed, should be placed in-line in the patient circuit per the manufacturer's instructions.

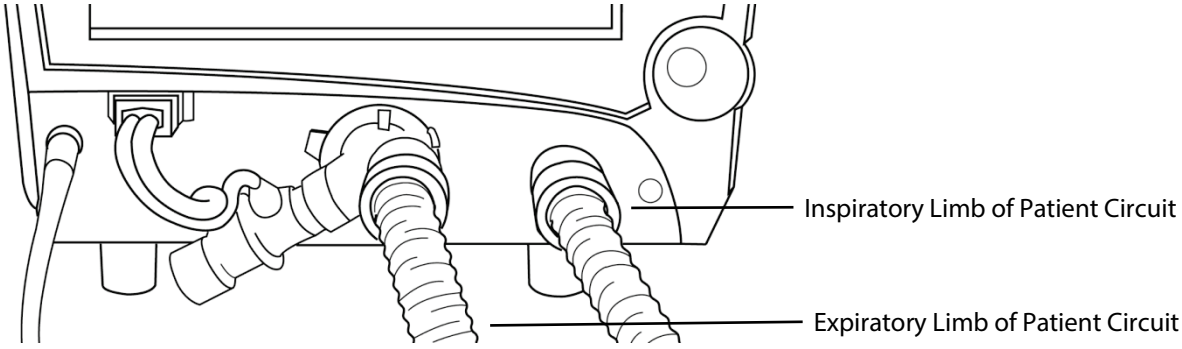


Figure 2.7 Patient Circuit Connections

Attaching a Nebulizer

You can use an in-line nebulizer with the Vela ventilator (see Chapter 3, Operation). To use a nebulizer, you must have a high-pressure oxygen source attached to the ventilator. Attach the nebulizer tubing as shown in the following figure.

The fitting is marked with the icon shown here.

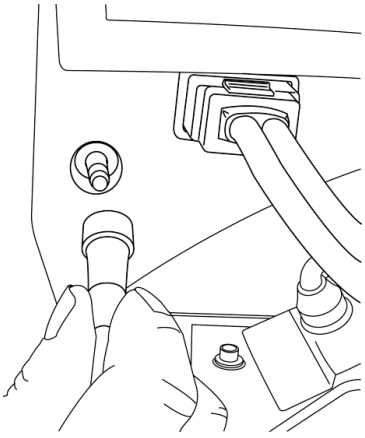


Figure 2.8 Attaching nebulizer tubing

Caution!

Powering the nebulizer from an external flow meter is not recommended.

Caution!

Using a nebulizer may impact the volumes delivered to the patient.

Synchronized Nebulizer

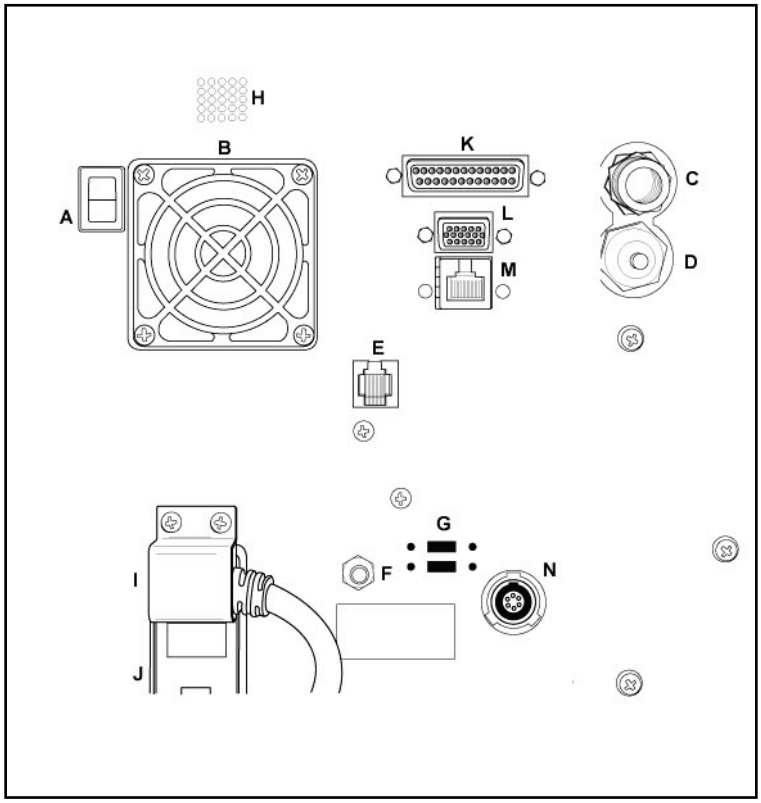
The standard in-line nebulizer is powered by 100% oxygen for delivery of prescribed medications in the ventilator circuit. When nebulization is active, the nebulizer flow is synchronized with the inspiratory phase of each breath and can be adjusted in increments of one minute for a maximum of 60 minutes. You may end the nebulization period early by pushing the Nebulizer button again.

Note:

See "Chapter 3, Operation" (section G) for important details concerning operation and safety when using the nebulizer feature.

Connections and Layout of the Rear of the Ventilator

The oxygen connections, the remote nurse call connection and communication connections are located on the rear panel of the ventilator. The power cable and the power ON/OFF switch are also on the rear panel.



A – Power switch	B – Fan and fan filter
C – High-pressure oxygen fitting	D – Low-pressure oxygen fitting
E – Nurse call system connection	F – Ground terminal
G – Future options	H – Alarm speaker
I – Power cord	J – Fuses
K – Parallel printer port	L – Video output port
M – MIB port	N – CO_2 connector

Figure 2.9 Rear Panel Components

Warning!

The Vela is designed to ensure that the user and patient are not exposed to excessive leakage current per applicable standards (UL 60601-1 and IEC 60601-1). However, this cannot be guaranteed when external devices are attached to the ventilator.

To prevent the risk of excessive enclosure leakage current from external equipment attached to the printer or video ports, the protective earth paths must be isolated to ensure proper connection.

This isolation should ensure that the cable shields are isolated at the peripheral end of the cable.

Oxygen Sensor

The oxygen sensor is a disposable galvanic cell located at the bottom, rear of the ventilator behind the air inlet filter. The electrical output of galvanic cells changes as they are consumed; therefore, an F_IO_2 Monitor Calibration should be performed before using the ventilator on every patient. The oxygen sensor needs to be replaced at the routine one-year service interval or according to the shelf life stated on the sensor.

Note:

If the oxygen sensor becomes depleted before preventive maintenance is performed, you may turn the F_IO_2 monitor off. This silences the oxygen F_IO_2 alarms. The oxygen blender continues to work unaffected and the F_IO_2 parameter setting can still be set to deliver the desired F_IO_2. The F_IO_2 monitor can be turned off in the Extended Functions screen as described in Chapter 2. If the F_IO_2 monitor is disabled, it is highly suggested that an external oxygen analyzer then be used to verify blender and F_IO_2 accuracy.

Caution!

Service should only be carried out by a trained and certified CareFusion service technician.

Connecting Oxygen Sources

Vela can accept high or low pressure O2 sources as shown below.

Attaching a high pressure O_2 Hose

Attach the high-pressure oxygen hose to the threaded DISS connector on the upper right of the rear panel.

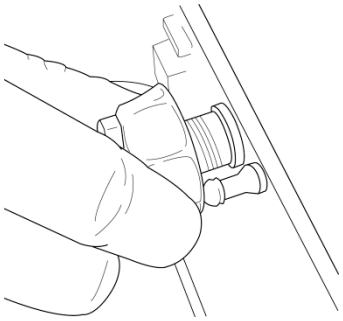


Figure 2.10 Connecting the high pressure O_2 hose

Attaching the low pressure Oxygen tubing

Attach the low pressure oxygen tubing to the tapered connector beneath the high pressure oxygen connector. For titration of your patient's F_IO_2 using the low pressure oxygen connector see Appendix C.

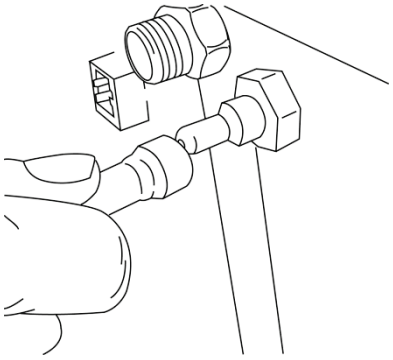


Figure 2.11 Low pressure oxygen tubing connection

Note:

Do not use low pressure and high pressure O_2 connectors at the same time.

Note:

When low pressure oxygen is supplied, the F_IO_2 control must be set to 21% to prevent alarms associated with oxygen supply pressure and delivered oxygen concentration. The low pressure oxygen connection adds supplemental oxygen to the patient's breathing gas (see Appendix C).

Nurse Call Connection

The Vela can be connected to a remote nurse call system via the modular connector on the rear panel shown in figure 2.9. The jack is configured to interface with normally closed signals (NC, open on alarm) with the use of cable part # 15620, or normally open signals (NO close on alarm) with the use of cable part # 15619.

Printer Connector

The Vela has a standard 25-pin (receptacle) Centronics parallel printer port for interfacing to an HP Deskjet 940C, 5650, or any other compatible printer.

SVGA Connector

There is an SVGA output connector on the rear panel of the Vela to enable real time display of the screen from a separate external display device such as an LCD projector or remote monitor.

Warning!

The Vela is designed to ensure that the user and patient are not exposed to excessive leakage current per applicable standards (UL2601 and IEC60601-1). However, this cannot be guaranteed when external devices are attached to the ventilator.

To prevent the risk of excessive enclosure leakage current from external equipment attached to the printer or video ports, the protective earth paths must be isolated to ensure proper connection.

This isolation should ensure that the cable shields are isolated at the peripheral end of the cable.

Power up

To power up the ventilator, connect the power cord to a suitable AC power supply and turn on the power switch located on the rear panel of the ventilator as shown here. Protection is provided to the power switch by a moveable protective cover. Accidental interruption of power is immediately notified via the audible alarm. If the ventilator is turned off for any reason or mains power is interrupted the audible alarm sounds.

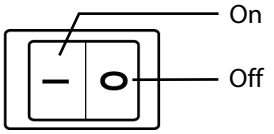


Figure 2.12 Power Switch Positions

The power up / reboot time for this instrument is a maximum of 12 seconds.

Warning!

A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. If the protective ground is lost, all conductive parts, including knobs and controls which may *appear* to be insulated, can render an electric shock. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the ventilator, and make sure the power cord is in good condition.

Warning!

If the integrity of the external power earth conductor arrangement is in doubt, unplug the ventilator from the mains AC and operate it from its internal battery

Extended Functions

The Extended Functions Screen in the Patient Screen Select dialog allows access to stored data and customization of the front panel.

To access Extended Functions, touch the Screen Indicator in the top center section of the touch screen (see figure 2.13)

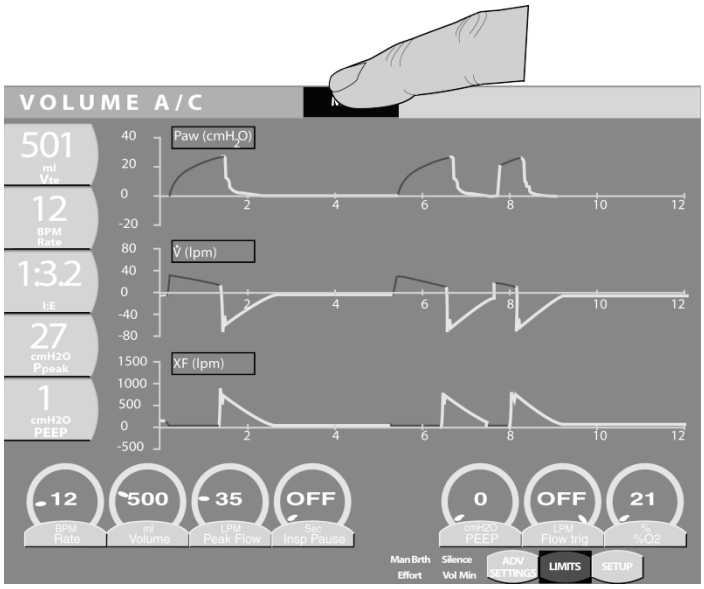


Figure 2.13 Touch the Screens Indicator on the Main Screen

The Screen Select menu appears. Press Extended Functions.

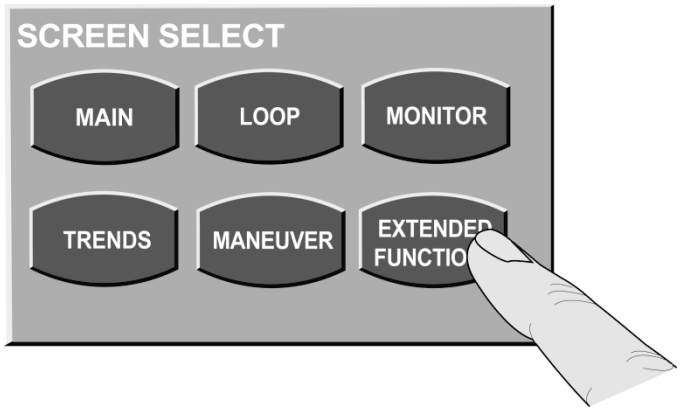


Figure 2.14 Screen Select screen

The Extended Functions Menu appears.

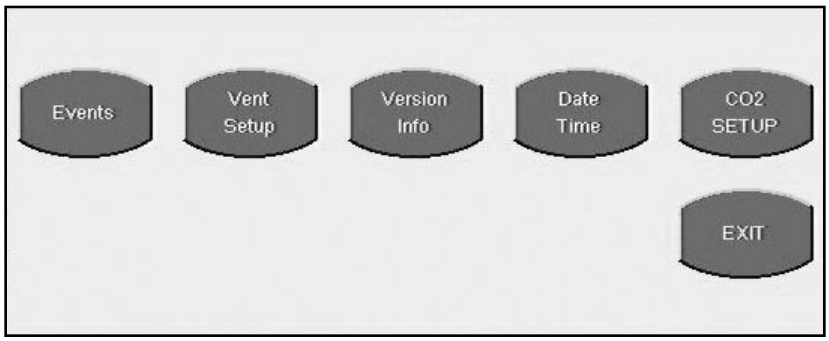


Figure 2.15 Extended Functions Menu

The extended Functions menu is available from several different screens within the Vela Software screens. Some of the functions accessible from this screen are for use by a trained Technician when servicing the Vela*. For a complete explanation of these functions, see your Vela Service Manual.

Table 2.2 Extended Functions

Events	Stores Data events for Service evaluation & troubleshooting *
Transducer Test	Allows Service testing of transducer function. **
Version Info	Displays the software version information and the turbine and ventilator serial number.
Date/Time	Displays total hours of ventilator and turbine operation and the date/time configuration.
Vent setup	Allows setting of these functions:
Low Min Vol	Enable or disable an "OFF" setting for the Low Minute Volume Alarm.
Locks	Enable or disable the front panel lock switch.
FIO_2 *Monitor*	Turns the FIO_2 monitor on or off. Disabling results in the inability to perform FIO_2 calibration and the inability to monitor the FIO_2.
Altitude units of measure	Toggles between feet and meters for the altitude setting.
Altitude setting	Allows setting of altitude for accurate volume measurement.
Language buttons	Select the desired language for the front panel.
Ext. Communications	Allows setting of communications choice via MIB Output (VOXP, GSP)
Baud	Allows setting of Baud rate
Format	Allows user to change communcation format
End of Msg.	Allows user to change end of massage
Neb Time	Allows setting of time (1-60 minutes) nebulizer is active.
Alarm Loudness	Allows setting of alarm loudness
Dim Screen	Allows setting the screen to Dim or Bright
Video Normal/Inverse	Reverses the color configuration of the graphic interface
CO_2 Setup	Allows access to $ETCO_2$ setup to enable $ETCO_2$ monitoring

** On power down, or in the case of a power loss resulting in a shutdown of the device, all event data, including alarm conditions, is maintained in the event log*

*** Denotes function for use by trained Service technician.*

Operational Verification Testing

Prior to using the Vela ventilator on a new patient the following checks should be carried out to ensure optimum performance. **Verification testing should always be performed "off patient"**.

Warning!

Disconnect patient from the ventilator before performing verification testing.

Note:

All personnel performing preventive maintenance and product repair *must be trained* and certified by CareFusion.

Note:

If any portion of the following performance check fails, and you are unable to correct the problem, contact your CareFusion certified service technician.

User Verification tests

1. After disconnecting the patient, turn the ventilator OFF (i.e., STANDBY).
2. Press and hold the **Accept** button.
3. While holding the **Accept** button, turn the ventilator ON. Continue to hold the button until the ventilator completes the Power On Self Tests (POST).
4. Release the **Accept** button when the UVT Remove Patient message appears in the screen. The Audible Alarm sounds. Press the Alarm Silence button to clear the alarm.

Figure 2.16 UVT Startup Screen

5. Press the **Patient Removed** touch screen icon. The UVT test selection screen displays (see figure 2.18).

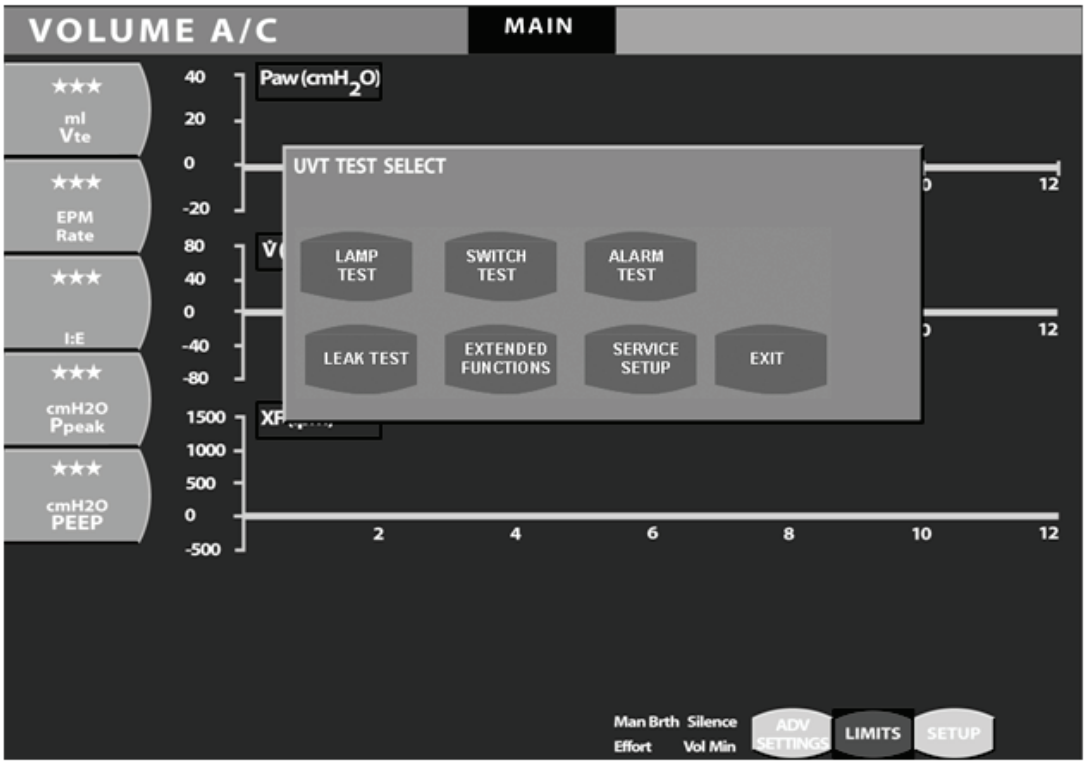


Figure 2.17 The UVT Screen with the Main screen in Service mode

6. Press the appropriate touch screen icon to begin each test.

Lamp Test

Run this test to check the front lamps to make sure they are functioning properly.

7. Press the **Lamp Test** touch screen icon to start the test. The ventilator illuminates all front panel LEDs except the Power LED and the DC LED.
8. Press the **Lamp Test** touch screen icon again to turn the LEDs off and exit the test. You cannot start another test until you exit this test.

Switch Test

Run this test to check the front panel membrane switches to make sure they are working properly.

9. Press the **SWITCH TEST** icon.

10. Press each membrane switch control in turn. Watch for the name of the control to appear in the message bar at the bottom left of the touch screen as follows:

Figure 2.18 Switch control messages

11. Press the **SWITCH TEST** icon again to exit the test. You cannot start another test until you exit this test.

Alarm Test

Run this test to check the audible alarm.

12. Press the **Alarm Test** touch screen icon to start the test. The audible alarm sounds.
13. Press the **Alarm Test** touch screen icon again to silence the audible alarm and exit the test. You cannot start another test until you exit this test.

Leak Test

Note:

This test should be performed with **all circuit accessories installed** (e.g., humidifier, water traps, and so on.) Make sure all connections are secure and all openings occluded before beginning the test.

Run this test to make sure the patient breathing circuit is not leaking.

1. Attach a one-liter test lung at the patient breathing circuit wye.
2. Press the **Leak Test** touch screen icon to run the test. The test begins by increasing the pressure in the patient breathing circuit to 60 cmH2O. The ventilator then displays the following messages in sequence:

   Leak test requested
   Leak test in progress

   The ventilator holds and measures the circuit pressure again. If the pressure loss is within acceptable limits, the test passes and the ventilator displays the following message:

   xx.x Passed

   where xx.x is the ending measurement.

   Otherwise, the test fails and the ventilator displays the following message:

   xx.x Failed

   If the test fails, check all connections to make sure there are no leaks and repeat the test.

   If the test fails again, call CareFusion technical support as shown in Appendix A.

F_IO_2 Monitor Calibration

The F_IO_2 Monitor Calibration screen is accessible **only** from the Extended Functions Screen and **OFF Patient during the UVT**. Press the Extended Functions touch-screen icon to access the F_IO_2 Mon Calibration button.

When the F_IO_2 Mon Calibration button is touched, the calibration menu appears. You have a choice of doing an ambient air calibration or a 100% oxygen calibration. Calibration should be completed when the ventilator is off the patient. Calibration takes approximately 4 minutes. The calibration is fully automatic once you touch the appropriate button.

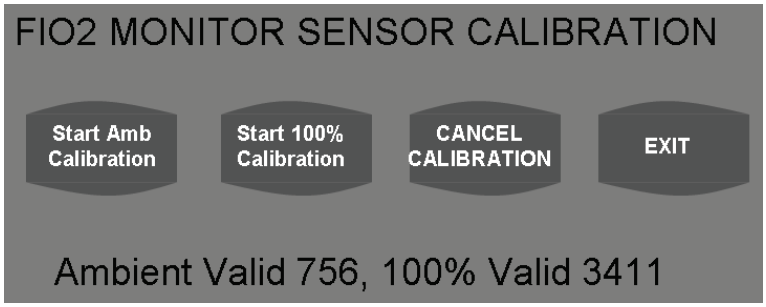


Figure 2.19 F_IO_2 Calibration Screen

The F_IO_2 monitor comes calibrated from the factory. If the monitored oxygen concentration falls outside the acceptable error range of the sensor, a CHK O2 CAL alert appears in the alarm indicator bar. A full calibration (both ambient and 100% O_2) should be performed. A full calibration provides an accuracy of plus or minus 3%.

To exit the F_IO_2 Calibration screen, touch the EXIT touch screen icon.

To exit the Extended Functions screen, touch the EXIT Touch screen icon to return to the Main screen.

Note:

If the F_IO_2 Monitor is turned OFF, as described in Table 2.2, Extended Functions, it is not possible to calibrate the F_IO_2 Monitor. The F_IO_2 Monitor must be turned ON to be calibrated.

Exit

To exit the UVTs press the **EXIT** touch screen icon. The touch screen freezes while the Vela performs the POST test and then begins normal operation.

Manual Verification Tests

1. Before attaching the Vela to a new patient, perform the following Operational Verification checks.
2. Attach a test lung to the circuit. (Siemens 190 Adult test lung highly suggested or equivalent)
3. Turn on the Vela, choose New Patient and Accept. This returns all settings to the defaults.
4. Change the Flow Rate setting to 60 LPM.
5. Change the PEEP setting to 5 cmH2O.
6. To check monitor performance, allow the ventilator to operate for two minutes. View the monitored parameters. The values should appear as follows:

Table 2.3 Parameter values

Parameter	Value
Minute volume (Ve)	6 L± 1.2 L
Tidal Volume (Mand VT)	500 ml ±100 ml (±10% VT delivered and ±10% VTmonitored)
I:E Ratio	1:6.1 ± 10%
Breath Rate	12 bpm ± 2 bpm
Ppeak	Should equal manometer display ± 5 cmH2O (freeze & measure pressure waveform)
PEEP	5 cmH2O ± 2 cmH2O
Inspiratory Time (Ti)	0.68 seconds ± 0.05 seconds

Check the alarms as follows:

7. Power Fail Check
8. Remove the power cord from the wall. The ventilator should do the following:
    a. Switch to battery power.
    b. Sound the audible alarm.
    c. Turn the AC Power Source indicator OFF.
    d. Display the BATTERY ON message in the alarm window.
    e. LED for internal battery lights.
9. Press the Alarm Reset button to clear the alarm.
10. Plug the AC power cord back into the wall socket.
11. High Pressure Limit Check

12. Lower the High Pressure Alarm setting to 5 cmH2O below the Peak Inspiratory Pressure (PIP). When the ventilator cycles to inspiration and the high pressure limit is violated, the high pressure alarm should occur. When this happens the ventilator should:

    a. Immediately cycle into the expiratory phase.

    b. Sound the audible alarm.

    c. Display the HIGH PRES message in the alarm window.

13. Return the High Pressure Alarm setting to 5 cmH2O above PIP, and press the Alarm Reset button to clear the alarm.
14. Pressure Relief Valve
15. The pressure relief valve (pop-off) sets the maximum pressure allowed in the system. This provides a safety back-up for the High Pressure alarm. This is a variable mechanical relief valve located on the front panel of the ventilator, lower right-hand corner as the user is facing the ventilator. The valve does not terminate inspiration, but releases excessive circuit pressure. The maximum pressure must be set above the High Pressure alarm setting.
16. The valve is set by rotating it to any value from 0 to 130 cmH2O. To set the Pressure Relief Valve, do the following:
17. Attached a test lung to the patient breathing circuit.
18. Set the Pressure Relief Valve to the maximum (130 cmH2O).
19. Set the mode to Pressure A/C.
20. Set the High Pressure Alarm to 80 cmH2O
21. Set the Inspiratory Pressure to achieve at least 80 cmH2O as displayed on the monitor.
22. Monitor the Ppeak.
23. Adjust the Pressure Relief Valve until the pressure shown on the monitor reaches the desired pressure, usually 5 – 15 cmH2O above the desired inspiratory pressure.
24. Lower the High Pressure alarm to a value between the Inspiratory Pressure setting and the Pressure Relief setting or as dictated by protocol.

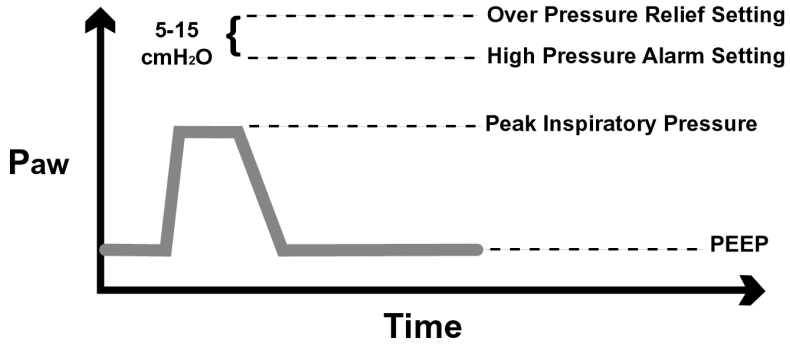


Figure 2.20 Pressure Relief Valve Setting

Service Set Up

When the service set up button is depressed, ventilator information appears. This screen gives the technician the opportunity to verify Ventilator serial number and model. For password protected enhancements, password is entered and accepted by pressing password accept key.

Vela Ventilator Performance Checklist

This checklist is for use during the Vela Operational Verification Procedure.

Serial Number_____ Hours_____ Date_____

Verification Step	**Check & Initial**
1. Inspect the ventilator and components for appearance and cleanliness. Confirm the Exhalation valve, diaphragm, air intake filter, test circuit and test lungs are correctly installed. Wipe the ventilator clean if needed using a cloth moistened with an approved cleaning solution.	☐ _____
2. Enter the User Verification Test (UVT). Touch the Patient Removed button.	☐ _____
A. LAMP TEST Confirm the proper functioning of the front panel lamps and LEDs.	☐ _____
B. SWITCH TEST Confirm the proper functioning of the membrane switches.	☐ _____
C. ALARM TEST Test the alarm volume. Adjust as required.	☐ _____
D. LEAK TEST Check the patient breathing circuit on the ventilator and conduct a leak test. Make sure all needed components are firmly attached in the circuit.	☐ _____
3. Complete the O_2 calibration.	☐ _____
4. Exit the UVT and begin conducting a brief performance test.	☐ _____

Accept **New Patient** to enable default settings and close Patient Setup screen.

Verification Step	Check & Initial
5. After at least two minutes of operation compare the displayed readings to the following:	☐ _____

Parameter	Value
Minute Volume	6 L ±1.2 L
Tidal Volume	500 mL ±100 mL (±10% Vt delivered and ±10% Vt monitored)
I:E Ratio	1:6.1 ± 10%
Breath Rate	12 bpm ±2 bpm
Ppeak	Should equal monitor display ±5 cmH2O
PEEP	5 cmH2O ±2 cmH20
Inspiratory Time	0.68 sec ±0.05 sec

6. Set Pressure Relief Valve ☐ _____
7. Check alarms
   - A. Power Fail Check ☐ _____
   - B. High Pressure Limit Check ☐ _____

Procedure Complete

Signature: _____ Date: _____

Chapter 3 Operation

Membrane Buttons and LEDs

The Vela membrane panel differs between the International model and the USA model, see figures 3.1 or 3.2 for the panel supplied on your Vela.

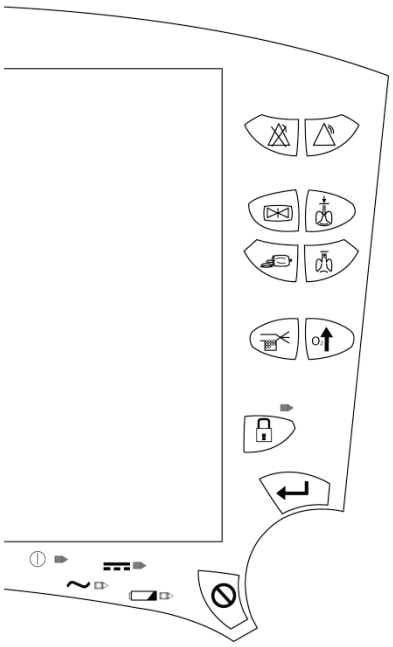


Figure 3.1 Vela Membrane panel (International)

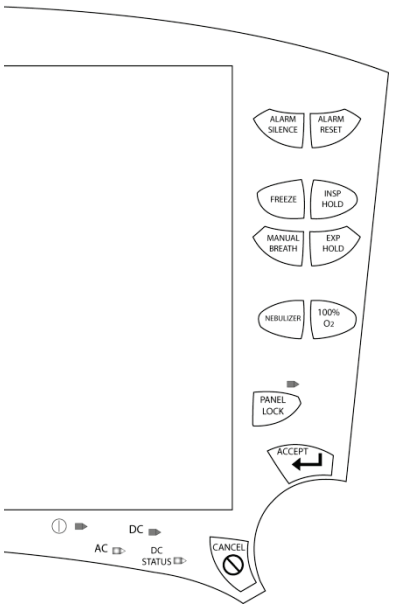


Figure 3.2 Vela Membrane Panel (USA)

Membrane Button Functions

Alarm Silence

Pressing this button disables the audible portion of an alarm for 60 seconds (± 1 second) or until the Alarm Silence button is pressed again. This button is not functional for a VENT INOP alarm.

Alarm Reset

Cancels the visual indicator for alarms that are no longer active.

Freeze

The FREEZE button freezes the current screen and suspends real-time update of data until pressed again. When the screen is frozen you can scroll through displayed waveforms, trends, or loops using the Data Dial to move the cursor on screen.

Figure 3.3 shows a flow/volume loop in "freeze" mode. As the dotted line cursor traces the "frozen" loop curve, flags display the values along the curve of the loop.

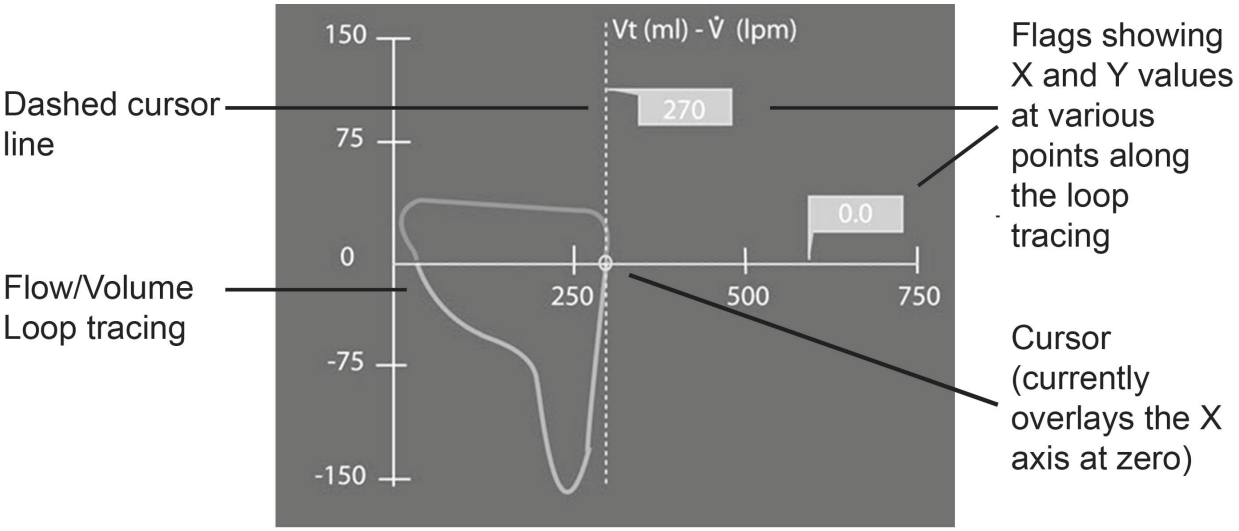


Figure 3.3 Flow/Volume Loop in Freeze Mode

Inspiratory Hold

When the INSP HOLD button is pressed and held, once the preset volume of a volume breath has been delivered, the patient is not allowed to exhale for a maximum of 6 seconds.

Expiratory Hold

When the EXP HOLD button is pressed and held, at the start of the next breath interval the ventilator does not allow the patient to inspire or exhale for a maximum of 6 seconds.

 Manual Breath

Pressing this button during the expiration phase of a breath delivers a single mandatory breath at current ventilator settings. No breath is delivered if the button is pressed during inspiration.

Note:

To quickly resume ventilation after suctioning or other procedures, press the manual breath button.

 Synchronized Nebulizer

When an in-line nebulizer is attached and the Nebulizer button is pressed, the ventilator supplies nebulized gas to the patient at 6 L/min (see the Nebulizer section of Chapter 2 Unpacking & Setup for attachment instructions).

When nebulization is active, the nebulizer flow is synchronized with the inspiratory phase of each breath and can be adjusted in increments of 1 minute for a maximum of 60 minutes. You may end the nebulization period early by pushing the Nebulizer button again.

Caution!

Using the nebulizer may impact patient volumes. During volume control breaths, approximately 50ml is added to the Tidal Volume for every 0.5 seconds of inspiratory time. If this added volume is undesirable for your patient, adjust the set Tidal Volume appropriately.

This added volume also slightly increases the Peak Pressure. Properly set High Pressure alarms help protect the patient from injury. Backpressure from a nebulizer can reduce nebulizer flow. This backpressure varies depending on the manufacturer and/or brand of nebulizer used. The user should be aware of this and take steps to account for the effect of backpressure. Neither volume nor peak pressure is affected for Pressure Control or Pressure Support breaths.

Caution!

Use of an external flow meter to power the nebulizer is not recommended.

Warning!

Using the nebulizer may impact your patient's volumes.

100% O2

When this button is pressed, the ventilator increases the oxygen concentration delivered to the patient to 100% for 3 minutes. If the 100 %O2 button is pressed again within the three-minute period, the maneuver is cancelled and the ventilator returns to the prior settings for F_IO_2.

Panel Lock

The PANEL LOCK button disables all front panel controls except MANUAL BREATH, 100 %O2, ALARM RESET, ALARM SILENCE, and the PANEL LOCK button.

Accept

Accepts data entered into a field on the touch screen.

Cancel

Cancels data entered into a field on the touch screen. The ventilator continues to ventilate at current settings.

Message Bar

Message	Definition
3 Second I Time	Maximum I time reached
Alarm test – in progress	Test Status
Circ pressure XDCR test – in progress / requested	Test Status
Confirm Apnea Settings	Alerts user to confirm apnea settings
Exhl Diff pressure XDCR test – in progress / requested	Test Status
Failed	Test Status
Filter test – in progress / requested	Test Status
FLOW TERMINATION	Terminated by set flow cycle
INSPIRATORY TIME TERMINATION	Breath terminated by set inspiratory time
100% O2	100%
ACCEPT	Accept
CANCEL	Cancel
EXP HOLD	Expiratory hold maneuver
FREEZE	Freeze Screen
INSP HOLD	Inspiratory hold maneuver
LOCK	Screen lock
MAN BREATH	Manual breath
NEBULIZER	Nebulizer active
RESET	Alarm – visual reset
SILENCE	Alarm Silence
Lamp test – in progress / OFF / ON	Test Status
Leak test – in progress / requested	Test Status
Newest	Occurs in event log screen, indicates most recent event
NEW SENSOR	Message to notify the clinician that a new sensor has been detected by the ventilator check
Passed	Test Status
Printer Busy / Error / Offline / Out of Paper / Ready / Printing	Printer function information
Settings Limited – Recheck Settings	Prompts uses to check settings
Turb Diff pressure XDCR test – in progress / requested	Test Status
Volume Limit Termination	Breath terminated by tidal volume limit

Printing Screen Information

The Vela has a standard 25-pin (receptacle) Centronics parallel printer port for interfacing to an HP Deskjet 940C, 5650, or any other compatible printer.

Note:

For a list of printers which are approved for use with the Vela, call Customer Service at the numbers shown in Appendix A

To print an image of the currently displayed screen, press the PRINT key in the lower right corner of the touch screen. The screen freezes momentarily as the information is output and then updates as the image prints. See figure 2.9, item K for connection.

Patient Setup

Patient Select Screen

The first screen to appear after you power up the ventilator is the Patient Select screen. You can choose to resume ventilation of the current patient (RESUME CURRENT) or select NEW PATIENT to reconfigure ventilator settings.

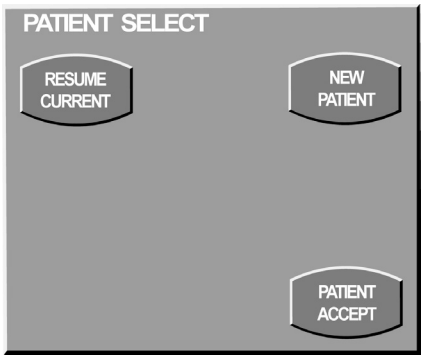


Figure 3.4 Patient Select Screen

The Patient Select Screen defaults to Resume Current. If you accept this choice, the ventilator continues ventilation at the most recent patient settings.

The New Patient choice clears saved loops and trends and resets all settings to default values. Touch the New Patient button to select this choice. The default values are the normal operational conditions for the ventilator.

Touch Patient Accept to accept your selection. If you selected New Patient, ventilation commences with the default settings and the setup screen displays. Patient default message will appear in alarm message box to prompt user to confirm settings. Alarm reset clears message.

Note:

The Ventilation setup screen can also be accessed at any time by pressing the Setup button on the bottom right corner of the touch screen.

Ventilation Setup Screen

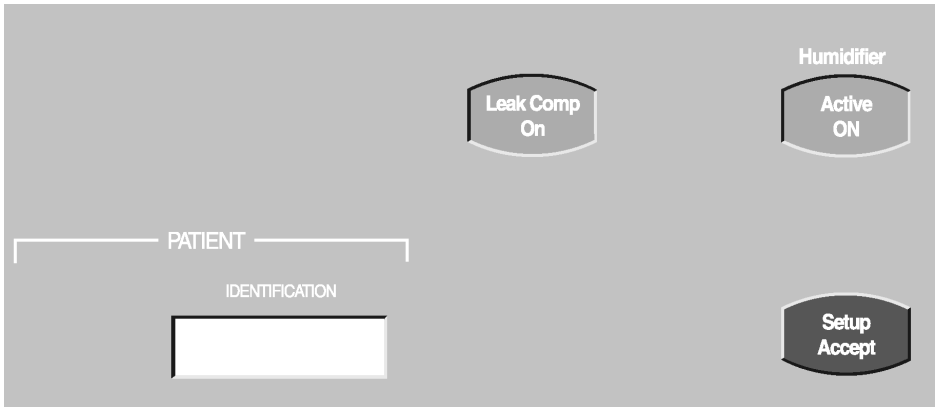


Figure 3.5 Setup

Humidifier

HUMIDIFIER ACTIVE (Active humidification enable/disable), ON/OFF

You can set the type of humidification being used as active (ON) or passive (OFF). Active humidification assumes 37 ºC; Passive assumes 25 ºC. The relative humidification values compensate the exhaled volumes.

Range: Active ON/OFF

The ventilator delivers and displays tidal volumes as BTPS (**B**ody **T**emperature **P**ressure **S**aturated) corrected.

Patient Identification

Patient ID. In this screen, you may input an alphanumeric patient identification number. To create a patient ID, touch the Touch Screen directly over the Patient IDENTIFICATION field.

A secondary screen appears showing the characters available for patient identification. Rotate the data dial to scroll through the characters. Press the ACCEPT membrane button to accept each character and build your Patient ID code. When the Patient ID code is complete, touch the Touch Screen directly over the Patient IDENTIFICATION field.

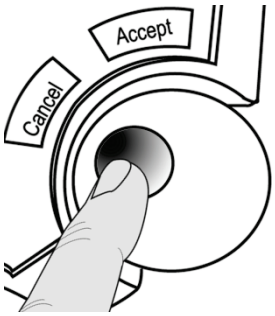


Figure 3.6 Data Dial

Note:

All the primary breath controls, at the bottom of the touch screen, are enabled during setup. The Advanced Settings dialog box and the Alarm Limits dialog box are also enabled during setup.

Touch the SETUP ACCEPT button to accept the settings as displayed and the ventilator begins ventilation using the changes made while in the Setup Screen.

NPPV Leak Compensation

You may select Leak Compensation ON or OFF for invasive ventilation modes. It is intended to allow the ventilator to compensate for leaks around tracheal tubes. It will compensate for minor leakages, typically less than 5 liters per minute.

The NPPV Leak Compensation function ensures that any gas flow leakage around a mask (non-vented) or tracheal tube up to 40 liters per minute, in addition to the set bias flow, is automatically determined and compensated for. The determination of leakage amount is made during exhalation after all patient exhalation has occurred. Subsequently, leak comp adjusts bias flow to maintain PEEP and establish a new baseline for patient triggering.

Leak compensation does not add a calculated volume to the monitored exhaled volume. Exhaled volume monitoring will continue to indicate the patient's exhaled volume flowing through the exhaled flow sensor.

Note:

Exhaled volume measurement will indicate the patient's exhaled volume minus volume lost to leakage during exhalation.

- The default for invasive ventilation is OFF
- The default for non-invasive ventilation is ON.
- When any of the NPPV modes are selected the leak compensation function is automatically enabled, and when any NPPV mode is exited the leak compensation function returns to its previous or default setting.
- Whenever Leak Compensation is ON, a highlighted status message displays “Lk Comp” at the bottom of the touch screen.

Setting the Ventilation Breath Type and Mode

To access the mode selection options, touch the Mode indicator at the top left of the touch screen.

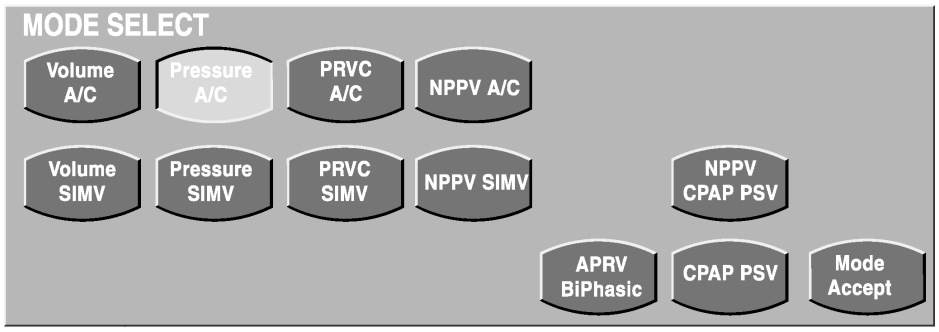


Figure 3.7 Mode Select Screen

The choices displayed in the Mode Select screen are a combination of breath type and ventilation delivery mode.

The following breath type and ventilation modes are available. When a mode is accepted, its name is displayed at the top left of the touch screen.

Table 3.1 Displayed Modes

Displayed Mode	Description
Volume A/C	Volume breath with Assist ventilation (default).
Pressure A/C	Pressure breath with Assist ventilation
Volume SIMV	Volume breath with Synchronized Intermittent Mandatory Ventilation (SIMV)
Pressure SIMV	Pressure Breath with Synchronized Intermittent Mandatory Ventilation (SIMV)
CPAP / PSV	Continuous Positive Airway Pressure (Demand Breath) with Pressure Support Ventilation
APRV / Biphasic	Spontaneous demand breath at two alternating baseline pressure levels or controlled ventilation cycled by time
PRVC A/C	Pressure Regulated Volume Controlled breath with Assist Ventilation
PRVC SIMV	Pressure Regulated Volume Controlled breath with Synchronized Intermittent Mandatory Ventilation (SIMV) and an adjustable level of pressure support for spontaneous breaths.
NPPV A/C	Non-invasive Positive Pressure with Assist Ventilation
NPPV / SIMV	Non-invasive Positive Pressure with Synchronized Intermittent Mandatory Ventilation (SIMV)
NPPV / CPAP PSV	Non-invasive Positive Pressure and Continuous Positive Airway Pressure (Demand Breath) with Pressure Support Ventilation

Note:

Modes listed above are all found in the Vela Comprehensive model. Other Vela models may have a subset of the above modes.

Apnea Backup Ventilation

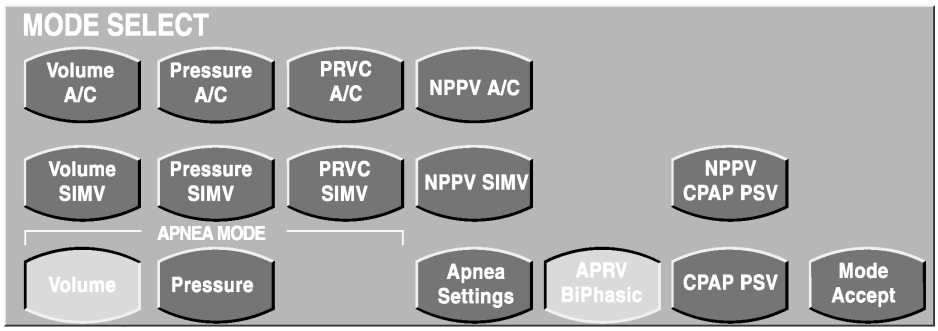


Figure 3.8 Apnea choices in CPAP/PSV mode

The APNEA MODE choices appear when either the APRV/BiPhasic, CPAP/PSV, or NPPV/CPAP PSV mode is selected. Apnea backup is active in all SIMV and CPAP modes. In SIMV, the apnea backup breaths are delivered at the current ventilator breath settings (Volume or Pressure). Apnea backup defaults to a breath rate of 12 unless a higher rate is set. The ventilator ceases apnea backup and resumes ventilation at the current settings once the patient initiates two breaths in a row or the Alarm Reset button is pushed.

Note:

When APRV/BiPhasic, CPAP/PSV, or NPPV/CPAP PSV is selected, you MUST do the following:

1. Select the breath type for APNEA backup mode.

2. Set the primary controls visible at the bottom of the touch screen, for the selected apnea breath type before pressing the MODE ACCEPT button. The controls for the apnea breath type are not visible once the MODE ACCEPT button has been pressed. Only those controls that are active and required for CPAP/PSV remain. You can access the Apnea Backup controls anytime by touching the Mode Indicator at the top left of the screen to open the Mode menu.

The following section contains a brief description of the breath types and ventilation mode combinations available for adult and pediatric patients.

Breath Types

There are two basic breath types:

- **Mandatory** breaths (delivered according to set ventilator parameters)
- **Demand** breaths (triggered by the patient)

All breaths are defined by four variables[1]:

- **Trigger** (initiates the breath),
- **Control** (controls the delivery),
- **Limit** (terminates the breath), and
- **Cycle** (how often is the breath delivered).

Mandatory Breaths

Mandatory breaths can be triggered by the machine, the patient, or the operator. There are 2 mandatory breath types delivered by the Vela.

Volume breaths which are:

- Controlled by flow (inspiratory);
- Limited by pre-set volume or maximum inspiratory pressure.
- Cycled by volume, flow, and time.

Note:
The Volume Controlled breath is the default breath type.

Pressure breaths, which are:

- Controlled by pressure (inspiratory + PEEP);
- Limited by pressure (inspiratory + PEEP + margin);
- Cycled by time or flow.

Demand Breaths

All demand breaths are patient-triggered, controlled by pressure, and patient or time cycled. Demand breaths can be either pressure supported (PSV) or spontaneous.

---

[1] Proceedings of the Consensus Conference on the Essentials of Mechanical Ventilators, by Branson and Chatburn, 1992

A PSV (Pressure Support Ventilation) breath is a demand breath where the pressure level during inspiration is a preset PSV level plus PEEP. PSV breaths are:

- Controlled by pressure (preset PSV level + PEEP);
- Limited by pressure (preset PSV level + PEEP + margin)
- Cycled by time (PSV Tmax) or flow (PSV Cycle).

Pressure Support is active when CPAP/PSV mode is selected

A Spontaneous breath is a demand breath where the pressure level during inspiration is preset at the PEEP level.

Ventilation Modes and Breath Types

Non-Invasive Ventilation

Vela is capable of performing non-invasive positive pressure ventilation (NPPV) with a standard dual-limb or double lumen "F" circuit. Adjust sensitivity to accommodate patient effort without auto-cycling. Activating leak compensation or increasing the level of Bias Flow may help overcome leaks and optimize the sensitivity setting. Set the alarms to avoid unnecessary alerts while maintaining adequate monitoring. If appropriate, you can turn the Low Minute Volume alarm OFF in the Extended Functions Screen (see Chapter 4, Monitors & Displays). NPPV Modes include NPPV/AC, NPPV/SIMV, and NPPV/CPAP/PS.

When any of the NPPV modes are selected the leak compensation function is automatically enabled, and when any NPPV mode is exited the leak compensation function returns to its previous or default setting.

To provide Non-Invasive Positive Pressure Ventilation (NPPV) a face mask or nasal mask is employed to connect the patient to the Vela. The Vela will produce positive pressure breaths to either deliver a mandatory breath or assist the patient's inspiration in one of several NPPV modes (see below).

Since the connection to the patient via a mask may introduce leaks, a leak compensation mechanism is employed to maintain the preset pressures even with introduced leakage up to 40 liters-per-minute in addition to the bias flow.

Note:

The mask itself may introduce additional rebreathed volume when compared to a tracheal or tracheostomy tube. The user must consider that additional rebreathed volume may be introduced.

The volume of the oro and/or nasopharyngeal airway of the patient should be considered. Even though this volume is the same as a spontaneously breathing patient, it is an additional rebreathed volume when compared to a tracheal tube connection.

Normally a small amount of leakage will occur around the mask as the patient moves or the mask is repositioned. This small mask leakage, in many cases, can carry with it some of the exhaled carbon dioxide from the mask, thus reducing added dead space.

Only masks, specifically labeled and intended for non-invasive ventilation, should be employed on the Vela. Masks should not have valves or leak vents.

Mask Leakage compensation is effective up to 40 liters-per-minute plus the bias flow.

It is important that a reasonably good mask seal, with the patient's face, should be achieved. Excessive leakage will adversely affect exhaled volume measurement accuracy.

NPPV A/C

NPPV Assist Control (A/C) is delivered as a Pressure Control breath. Any patient trigger will receive a Pressure Control breath and the breathing pattern is normally time cycled (see Pressure A/C mode for more information).

NPPV SIMV

NPPV SIMV is a Pressure Control SIMV mode. The SIMV time synchronized mandatory breaths are Pressure Control breaths and the spontaneous breaths are either CPAP type breaths or, at the user's discretion, can be Pressure Support Breaths (see Pressure Support mode for more information).

NPPV CPAP / PSV

NPPV CPAP/PSV consists of CPAP breathing at the user preset baseline pressure with the option of using Pressure Support as an adjunctive adjustable pressure (See Pressure Support and CPAP).

Assist Control Ventilation (A/C)

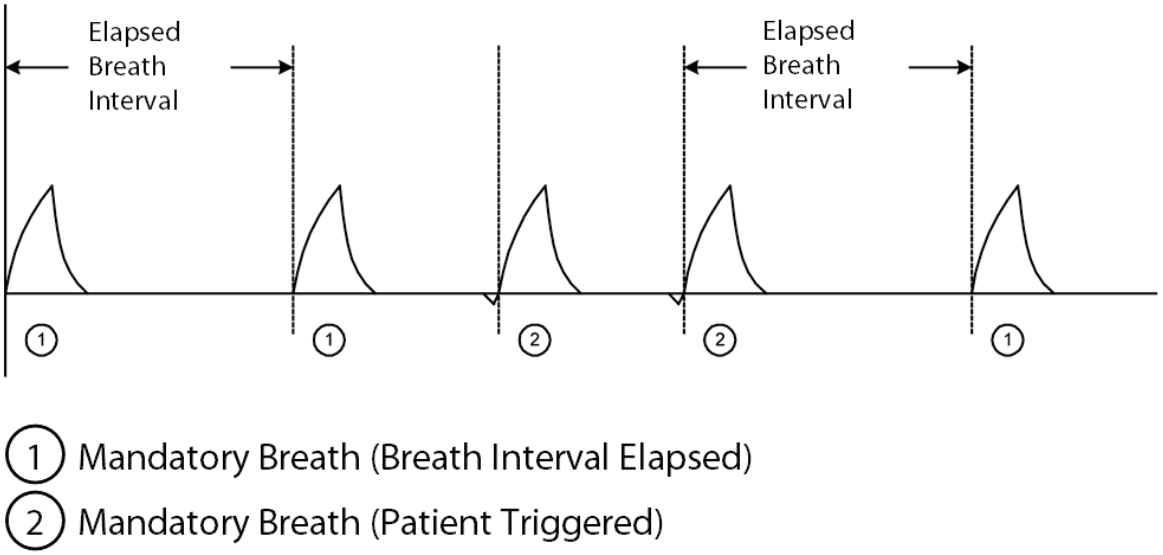


Figure 3.9 Assist Control Ventilation Waveform

This is the default mode for all patient types. In Assist Control ventilation mode, all breaths initiated and delivered are mandatory breaths. The initiation of a breath is triggered by one of the following:

- patient effort activates the inspiratory trigger mechanism,
- the breath interval, as set by the RATE control, times out,
- the operator presses the MANUAL BREATH button.

Initiation of a breath by any means resets the breath interval timing mechanism. It is possible for the patient to initiate every breath if he/she is breathing faster than the preset breath rate. If the patient is *not* actively breathing, the ventilator automatically delivers breaths at the preset interval (set breath rate). Demand breaths are not possible in Assist/Control mode.

Synchronized Intermittent Mandatory Ventilation (SIMV)

In SIMV mode, the ventilator can deliver both mandatory and demand breath types. Mandatory breaths are delivered when the SIMV "time window" is open and one of the following occurs:

- a patient effort is detected;
- the breath interval has elapsed with no patient effort detected;
- the MANUAL BREATH button has been pressed.

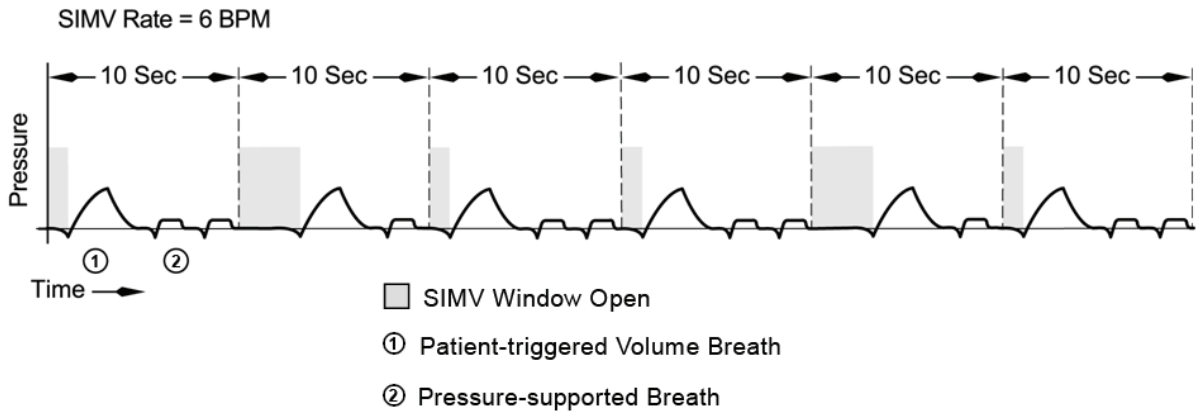


Figure 3.10 SIMV Waveform

The breath interval is established by the preset breath rate. It resets as soon the interval time has elapsed, or when the MANUAL BREATH button is pressed.

Apnea Backup Ventilation is active in SIMV mode. During apnea backup ventilation, the ventilator delivers a mandatory breath if no breaths are detected during the apnea "time out" period. In SIMV the breath is delivered at the current ventilator settings with a minimum default rate of 12 breaths per minute. The "timeout" period is determined by the Apnea Interval set in the Alarms screen. A high priority audible and visual alarm occurs when apnea backup ventilation is initiated. The ventilator leaves apnea backup and resumes ventilation at the current settings once the patient initiates two breaths in a row or the Alarm Reset button is pushed.

Continuous Positive Airway Pressure (CPAP) / Pressure Support Ventilation (PSV)

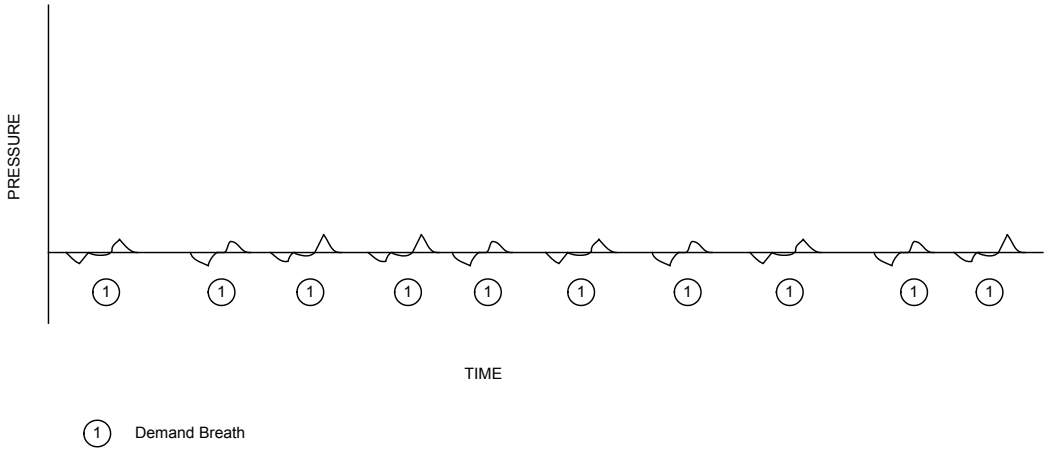


Figure 3.11 CPAP Waveform

In CPAP/PSV mode, all breaths are patient-initiated demand breaths unless the mandatory MANUAL BREATH button is pressed. When the Manual Breath key is pressed, a single breath is delivered at the currently selected Apnea Backup control settings.

Pressure Support is active in CPAP mode (see Demand Breaths in this Chapter).

Apnea Backup ventilation is active in CPAP/PSV mode. During Apnea Backup, the ventilator automatically initiates a breath when no breaths have been delivered during the preset apnea "time out" interval. The apnea "time out" interval is the Apnea Interval alarm setting.

At the onset of apnea backup ventilation, the ventilator delivers a mandatory breath. The ventilator continues to deliver breaths at the breath settings selected in the APNEA MODE screen during setup, until the patient initiates two consecutive breaths or the Alarm Reset button is pushed.

During setup, a choice of Volume or Pressure breaths is offered for apnea backup delivery. If no selection is made, the ventilator delivers apnea backup breaths at the default breath type and control settings. If the rate is set below 12 breaths per minute, apnea backup defaults to 12.

Note:

When CPAP/PSV is selected, you MUST do the following:

1. Select the breath type for APNEA backup mode.

2. Set the primary controls visible at the bottom of the touch screen, for the selected apnea breath type before pressing the MODE ACCEPT button. The controls for the apnea breath type are not visible once the MODE ACCEPT button has been pressed. Only those controls that are active and required for CPAP/PSV are displayed. You can access the Apnea Backup controls anytime by touching the Mode Indicator at the top left of the screen to open the Mode menu.

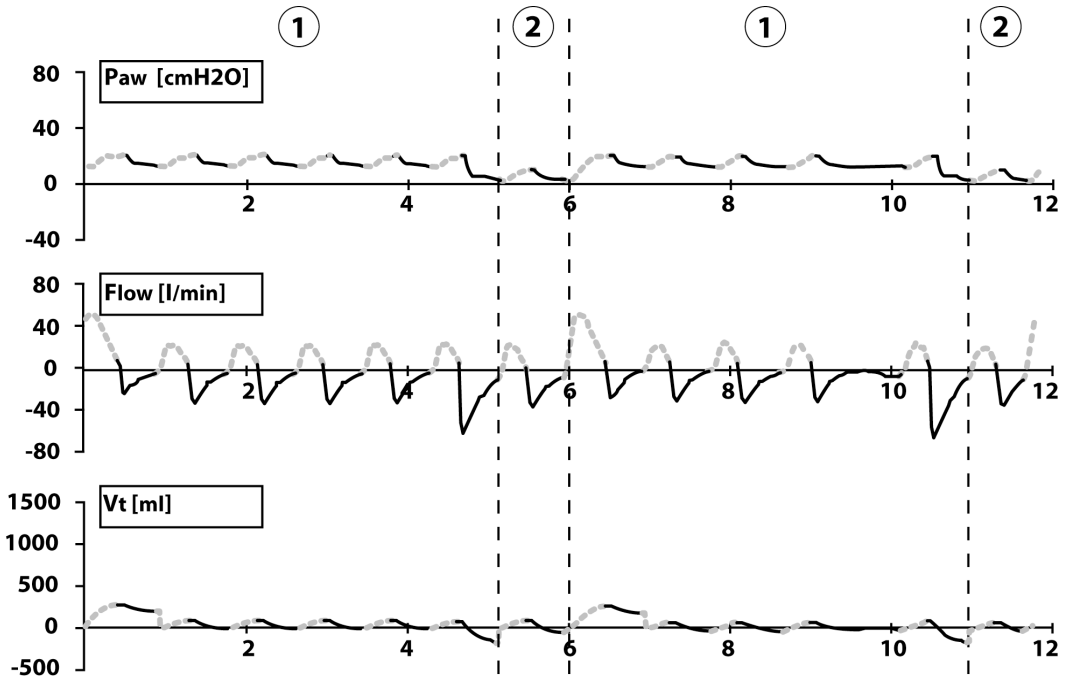
Airway Pressure Release Ventilation (APRV / BIPHASIC)

APRV / BiPhasic is a time cycled pressure mode. The ventilator cycles between two different baseline pressures based on time, which can be synchronized with patient effort. Controlled ventilation can be maintained by time cycling the transitions between baseline pressures. Pressure support can be added to improve comfort for the spontaneously breathing patient.

In this mode, the patient is allowed to breathe spontaneously at either of the two preset baseline pressure levels. These are set using the Pres High and Pres Low controls. The maximum duration at each pressure during time cycling is set with the Time High and Time Low controls.

The operator can also adjust the length of the respective trigger (Sync) windows with the Time High and Time Low Sync controls, which are advanced settings of Time High and Time Low. The Sync windows are adjustable from 0 to 50%, in 5% increments of set Time High and Time Low.

The ventilator synchronizes the change from Pressure Low to Pressure High with the detection of inspiratory flow or the first inspiratory effort detected within the T Low Sync window. Transition from Pressure High to Pressure Low occurs with the first end of inspiration detected after the T High Sync window opens.



(1) = Time high, Pressure High (2) = Time Low, Pressure Low

Figure 3.12 APRV / BiPhasic Mode

Primary controls active in APRV / BiPhasic mode are Time High, Pressure High, Time Low, Pressure Low, Pressure Support, Flow Trigger and %O2. Advanced settings available in APRV / BiPhasic mode are T High PSV, T High Sync, T Low Sync, Pressure, Pressure Support Cycle, Pressure Support Tmax and Bias Flow.

Note:

Time High and Time Low are **maximum** time settings for a time-cycled transition. Actual times may vary depending on the patient's spontaneous breathing pattern and the Sync window setting.

Setting the Sync to 0% cycles the transition between pressure levels on time only and will not provide synchronization with patient efforts.

The MANUAL BREATH button is not active in APRV / BiPhasic.

Adjustable PSV in APRV / BiPhasic

APRV / BiPhasic features adjustable PSV. The PSV is delivered above the current phase baseline pressure. PSV breaths are available during Time High also, by activating T High PSV (an advanced setting of Time High). If T High PSV is activated, during Time High, the ventilator will deliver the same PSV level for both Pressure Low and Pressure High.

Apnea Ventilation in APRV / BiPhasic

Apnea ventilation is available in APRV / BiPhasic. If the patient does not initiate a spontaneous effort, or the ventilator does not time cycle between pressure levels before the apnea interval has elapsed, the ventilator will alarm for apnea and begin apnea ventilation at the apnea ventilation settings. A spontaneous effort from the patient or a transition in baseline pressure will reset the apnea alarm and timer and return the ventilator to APRV / BiPhasic ventilation.

Airway Pressure Release Ventilation Time Sync (APRV / BIPHASIC)

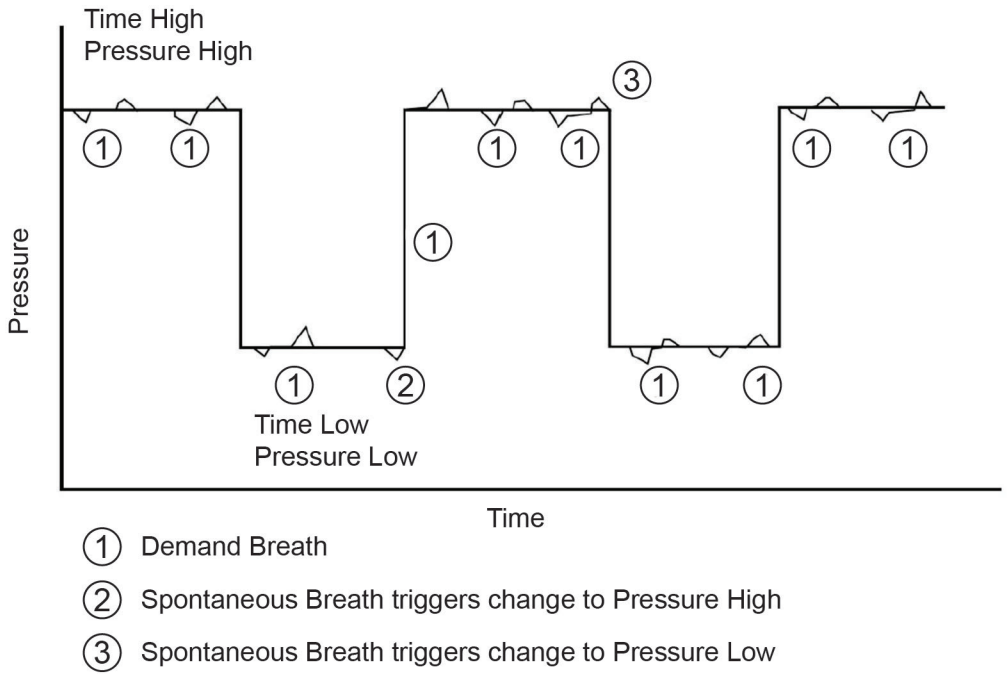


Figure 3.13 APRV / BIPHASIC Time Sync

Pressure Regulated Volume Control (PRVC)

Pressure Regulated Volume Control (PRVC) breaths are pressure breaths where the pressure level is automatically modulated to achieve a preset volume. PRVC breaths are:

- Controlled by pressure (inspiratory + PEEP) and volume;
- Limited by pressure (inspiratory + PEEP + margin);
- Cycled by time.

PRVC breath operation is as follows:

- When PRVC is selected, a decelerating flow, volume controlled test breath, to the set tidal volume with a 40-millisecond pause is delivered to the patient. The demand system is active during this test breath.
- The ventilator sets the target pressure at the end inspiratory pressure of the test breath for the first pressure control breath.
- The next breath and all subsequent breaths are delivered as pressure control breaths.
- The inspiratory pressure is based on the dynamic compliance of the previous breath and the set tidal volume.

- The maximum step change between two consecutive breaths is 3 centimeters of water pressure.
- The maximum tidal volume delivered in a single breath is determined by the volume limit setting.

The test breath sequence is initiated when any of the following occur:

- Entering the Mode (PRVC)
- Changing the set tidal volume while in PRVC
- Reaching the Volume Limit setting
- Delivered tidal volume > 1.5 times the set volume
- Activation of any of the following alarms
  - High Peak Pressure Alarm
  - Low Peak Pressure Alarm
  - Patient Circuit Disconnect Alarm

Caution!

The Low Pressure alarm must be set at PEEP or above to ensure timely delivery of the test breath.

Note:

Alarm limits and Volume Limit should be set in PRVC to prevent inadvertent pressure and volume changes.

Modes Associated with the PRVC Breath Type

PRVC Assist Control (A/C) Mode

All breaths are mandatory breaths. A breath can be triggered by detection of a patient effort, the breath interval timing out or the MANUAL BREATH key being activated.

Initiation of a breath resets the breath interval. A patient may initiate all breaths. When there is no patient effort, breaths are delivered at the set breath rate.

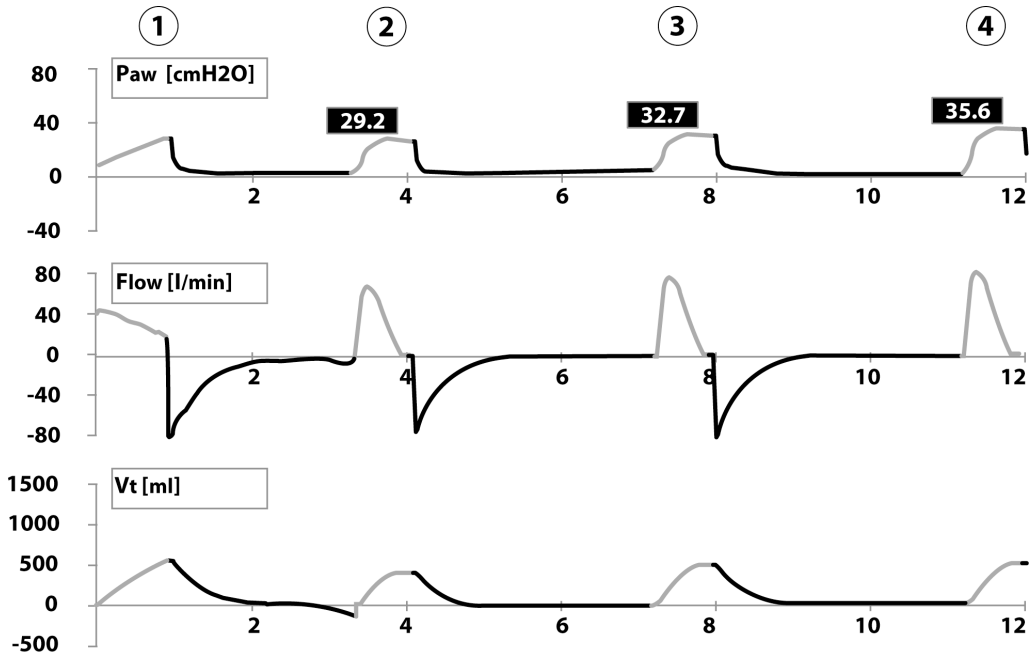


Figure 3.14 PRVC A/C

(PRVC A/C with test breath (1) and step changes (2-4) to achieve target volume)

Primary controls active in PRVC A/C mode are Rate, Volume, Inspiratory Time, PEEP, Flow Trigger and %O2.

PRVC SIMV Mode

In SIMV mode, the ventilator can deliver both mandatory and demand breath types. Mandatory breaths are delivered when the SIMV "time window" is open and one of the following occurs: a patient effort is detected, the breath interval has elapsed with no patient effort detected or the MANUAL BREATH key is activated.

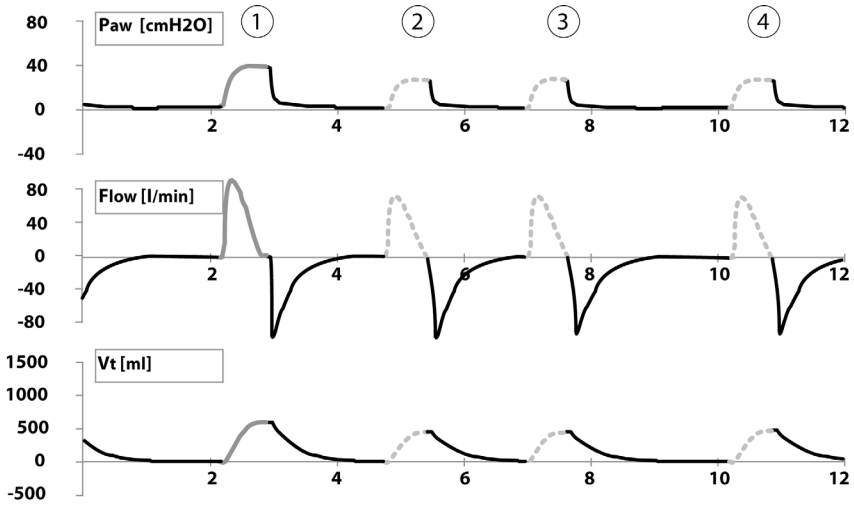


Figure 3.15 PRVC SIMV with mandatory (1) and assisted (2-4) breaths

Primary controls active in PRVC SIMV mode are Rate, Volume, Inspiratory Time, Pressure Support, PEEP, Flow Trigger and %O2.

Advanced settings available in PRVC SIMV mode are Volume Limit, Pressure Support Flow Cycle, Pressure Support Tmax, and Bias Flow.

Primary Breath Controls

The primary breath controls are operator set controls, which directly affect the way a breath is delivered to your patient. They are displayed along the bottom of the touch screen. *Only the controls that are active in the currently selected mode of ventilation are displayed.*

Table 3.2 Primary Breath Controls

Displayed Control	Description	Range
bpm **Rate**	Breath rate shown in Breaths per Minute	2 to 80 bpm
ml **Vt**	Tidal Volume in milliliters	50 to 2,000 ml
cmH_2O **Insp Pres**	Inspiratory Pressure in centimeters of water pressure	1 to 100 cmH_2O
lpm **Peak Flow**	Peak Inspiratory Flow in Liters per Minute	10 to 140 lpm
sec **Insp Time**	Inspiratory Time in Seconds	0.30 to 10 sec
sec **Insp Pause**	Sets an inspiratory pause which is in effect for each Volume breath delivered	OFF, 0.1 to 2.0 sec
cmH_2O **PSV**	Pressure Support in centimeters of water pressure	Off, 1 to 60 cmH_2O
cmH_2O **PEEP**	Positive end expiratory pressure in centimeters of water pressure	0 to 35 cmH_2O
L/min **Flow Trig**	Sets inspiratory flow trigger point in liters per minute	1 to 20 L/min
% **$\%O_2$**	Controls the percentage of oxygen in the delivered gas.	21% to 100%

To Activate a Primary Control

To activate a primary breath control, touch the touch screen directly over the control. The control highlights (changes color) indicating that it is active. To modify the settings for the highlighted control, turn the data dial below the touch screen. Turning in a clockwise direction increases the selected value, turning counterclockwise decreases it.

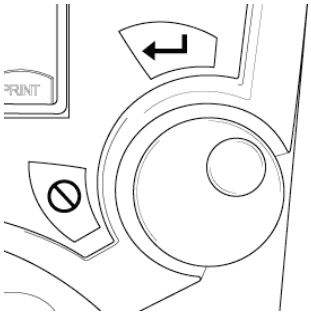


Figure 3.16 The Data Dial.

To accept the displayed value, either touch the touch screen directly over the highlighted control or press the ACCEPT membrane button by the data dial. The control color changes back to normal and the ventilator begins operating with the new setting. If you press the CANCEL button or do not actively accept the new setting within 15 seconds, ventilation continues at the previous settings.

Note:

Not all controls are active in every mode and the effect of some may differ depending on the mode of ventilation selected.

Descriptions of Primary Breath Controls

Breath Rate (Rate)

The breath rate control sets the breath interval. Its function is dependent upon the selected mode of ventilation and it has different effects on the breath cycle, depending on which mode is selected.

Range: 2 to 80 bpm

Default: 12 bpm

Tidal Volume (Volume)

A volume breath delivers a predetermined volume of gas to the patient. Tidal Volume, together with the Insp Flow, and Waveform settings determine how the flow is delivered.

Range: 0.05 to 2.0 L

Default: 0.50 L

Sigh: 1.5 x Volume

Inspiratory Pressure (Insp Pres)

During a mandatory pressure breath, the ventilator controls the Inspiratory Pressure in the circuit. For Pressure, the pressure achieved is a combination of the preset Insp. Pres. level plus PEEP.

Range: 1 to 100 cmH2O

Maximum Flow: 180 L/min

Default: 15 cmH2O

Inspiratory Time (I-Time)

The I-Time control sets the inspiratory time cycle variable for all mandatory breaths.

Range: 0.3 to 10.0 seconds

Default: 1.0 second

Peak Flow

In a volume mode, the Peak Flow setting controls the flow at which the breath is delivered during the inspiratory phase of a mandatory breath.

Range: 10 to 140 lpm

Default: 35 lpm

Inspiratory Pause (Insp Pause)

Sets the inspiratory pause time for volume controlled breaths.

Range: Off, 0.1 to 2.0 sec

Default: Off

PSV (Pressure Support)

The PSV control sets the pressure in the circuit during a pressure supported breath.

Range: Off, 1 to 60 cmH_2O

Maximum Flow: 180 L/min

Default: Off

Positive End Expiratory Pressure (PEEP)

PEEP is the pressure that is maintained in the patient circuit at the end of exhalation.

Range: 0 to 35 cmH_2O

Default: 3 cmH_2O

Inspiratory Flow Trigger (Flow Trig)

The inspiratory trigger mechanism is activated when the Net Flow becomes greater than the Inspiratory Flow Trigger setting. Net Flow is defined as [Delivered Flow – Exhaled Flow].

Range: 1 to 20 lpm

Defaults: 2 lpm

$\%O_2$

The % O2 control sets the percentage of oxygen in the delivered gas.

Range: 21 to 100%

Default: 21%

Pressure High (Pres High)

This control is only available in APRV / BIPHASIC Mode. It controls the baseline pressure achieved during Time High.

Range: 0 to 60 cmH2O

Default: 15 cmH2O

Time High

Available in APRV / BIPHASIC mode only, this control sets the maximum time for which the Pressure High setting is maintained.

Range: 0.3 to 30 seconds

Default: 4 seconds

Time Low

In APRV / BIPHASIC mode, this control sets the maximum time for which the Pressure Low setting is maintained.

Range: 0.3 to 30 seconds

Default: 2 second

Pressure Low

In APRV / BIPHASIC Mode, this control sets the baseline pressure achieved during Time Low.

Range: 0 to 45 cmH2O

Default: 6 cmH2O

Advanced Settings

When the mode and the primary breath controls have been set, you can further refine delivery of the breath by accessing the Advanced Settings from within the currently set mode. Advanced settings allow you to make specific refinements to each primary breath control setting.

Accessing the Advanced Settings

To access the advanced settings, touch the ADV SETTINGS button located at the bottom right of the touch screen with the Limits, Setup and Print buttons (see Figure 3.17). The Advanced Settings window appears. When you select a primary control by touching and highlighting the control, the available advanced settings for that selected control appears in the advanced settings window.

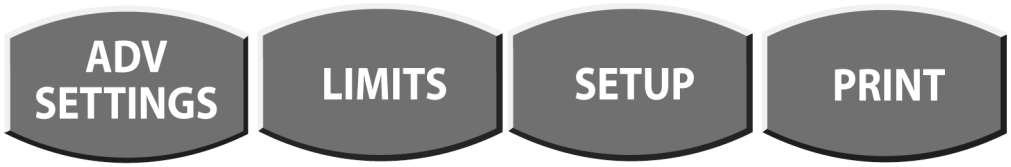


Figure 3.17 Accessing the advanced settings screen

Figure 3.18 Advanced settings indicator

NOTE:

Primary Controls, which feature an advance setting, will display a yellow triangle to the right of the control name.

NOTE:

Not every primary control will have an associated advanced setting.

Table 3.3 Controls and Advanced Settings Associated with Breath Type & Mode

BREATH TYPE & MODE	**VOL A/C**	**VOL SIMV**	**PRES A/C**	**PRES SIMV**	**PRVC A/C**	**PRVC SIMV**	**CPAP / PSV**	**APRV / BIPHASIC**	**NPPV A/C**	**NPPV / SIMV**	**NPPV / CPAP / PS**
PRIMARY CONTROLS											
RATE bpm	√	√	√	√	√	√			√	√	
VOLUME ml	√	√			√	√					
INSP PRES cmH_2O			√	√							
NPPV INSP PRES cmH_2O									√	√	
PEAK FLOW lpm	√	√									
INSP TIME sec			√	√	√	√			√	√	
INSP PAUSE sec	√ (NOT IN VSYNC)	√ (NOT IN VSYNC)									
PSV cmH_2O		√		√		√	√	√			
NPPV PSV cmH_2O										√	√
PEEP cmH_2O	√	√	√	√	√	√	√	√	√	√	√
FLOW TRIG L/min	√	√	√	√	√	√	√	√	√	√	√
% OXYGEN %O2	√	√	√	√	√	√	√	√	√	√	√
PRES HIGH cmH_2O								√			
TIME HIGH sec								√			
TIME LOW sec								√			
PRES LOW cmH_2O								√			
APNEA (PRESSURE & VOLUME) SETTINGS							√	√			√
ADVANCED SETTINGS AVAILABLE WITHIN EACH MODE	Vsync (Vol limit, Flow Cycle), Sigh, Waveform Bias flow	Vsync, Sigh, Waveform, PSV cycle, PSV Tmax, Bias flow, Vol limit*, Flow Cycle*	Assured Vol, PC Flow cycle, Bias flow	Assured Vol, PC Flow cycle, PSV cycle, PSV Tmax, Bias flow	Bias flow, Vol Limit, PC Flow cycle	Vol limit, PC Flow cycle, PSV cycle, PSV Tmax, Bias flow	PSV cycle, PSV Tmax, Bias flow	PSV cycle, PSV Tmax, Bias flow, T High Sync, T High PSV, T Low Sync	PC Flow cycle, Bias flow	PC Flow cycle, PSV cycle, PSV Tmax, Bias flow	PSV cycle, PSV Tmax, Bias flow

Advanced Settings Characteristics and Ranges

Assured Volume (Comprehensive)

The Assured Volume control, when activated, sets the minimum tidal volume, delivered from the ventilator, in a pressure controlled breath. This control is always used with the time cycling criterion in pressure control ventilation.

Once you set the Assured Volume, the ventilator calculates the inspiratory flow required to deliver the Assured Volume in the set inspiratory time. When a Pressure Control breath is delivered and Peak Flow decelerates to this calculated inspiratory flow, and if the Assured Volume has not been met, the ventilator will automatically transition to a continuous flow inspiration to assure that the preset Assured Volume has been delivered. Once the inspiratory time has elapsed and the Assured Volume has been delivered the ventilator will cycle into exhalation. When the Assured Volume is met or exceeded during delivery of the pressure control breath, the ventilator will complete the breath as a normal Pressure Control breath.

Minimum tidal volume delivered from the ventilator when the Assured Volume control is active in a pressure control breath.

Range: OFF, 0.05 to 2.0 L

Defaults: OFF

Volume Limit

The Volume Limit setting sets the volume limit for a pressure breath and is active for PRVC/Vsync breaths only. When the volume delivered to the patient meets or exceeds the preset Vol Limit, the inspiratory phase of the breath is terminated. When the volume limit threshold has been reached, the ventilator message bar displays the words “Volume Limit Termination”.

Range: 0.05 to 2.50 L

Default: 2.50 L

Note:

Excessive inspiratory flow rates or highly compliant ventilator circuits may allow delivery of a tidal volume that exceeds the volume limit setting. This is due to the ventilator circuit recoiling and providing additional tidal volume to the patient. Delivered tidal volumes should be closely monitored to ensure Volume Limit accuracy.

Vsync

Vsync may be selected in **Volume Assist Control and Volume SIMV modes**. When selected is generates a decelerating flow, volume **test breath** to the set tidal volume. A 40 millisecond post-inspiratory pause is generated during this test breath. The ventilator **sets the target pressure**, for the next breath, utilizing this post-inspiratory pause pressure, for the **Pressure Control breath**. The next breath and all **subsequent breaths** are delivered as **Pressure Control** breaths. Inspiratory pressure is adjusted automatically by the ventilator to **maintain the target volume** based on the dynamic compliance of the previous breath. The maximum step change between two consecutive breaths is 3 centimeters of water pressure. The **maximum** tidal volume delivered in a single breath is determined by the **Volume Limit setting**.

Vsync breaths are:

- Controlled by pressure (inspiratory + PEEP) and volume
- Limited by pressure (inspiratory + PEEP + margin)
- Cycled by time or flow. Inspiratory time in Vsync is determined indirectly by setting the peak inspiratory flow. The set inspiratory time is displayed in the message bar.

Vsync breath operation is as follows:

This test breath sequence is initiated when any of the following occur:

- Entering the Mode (Vsync)
- Changing the set tidal volume while in Vsync
- Reaching the Volume Limit setting
- Delivered tidal volume > 1.5 times the set volume
- Activation of any of the following alarms
  - High Peak Pressure
  - Low Peak
  - Patient Circuit Disconnect

Waveform

On the Comprehensive model, during the delivery of a volume breath, flow can be delivered in one of two user selectable waveforms: Decelerating or Square. The default waveform for all models is Decelerating Wave.

Decelerating Wave (Decel)

The ventilator delivers gas starting at the peak flow setting and decreasing until the flow reaches 50% of the set peak flow.

Square Wave (Square) (Comprehensive only)

The ventilator delivers gas at the set peak flow for the duration of the inspiration.

Sigh

The ventilator delivers sigh volume breaths when this setting is ON. A sigh volume breath is delivered every 100th breath or every 7 minutes whichever, comes first in place of the next normal volume breath.

Range: Off, On (every 100 breaths or 7 minutes)

Sigh Volume: 1.5 times set tidal volume

Sigh Breath Interval (sec): Set Normal Breath Interval x 2 (Assist mode) or set Normal Breath Interval (SIMV mode)

Default: Off

Sigh breaths are only available for Volume breaths in Assist and SIMV modes.

Bias Flow

Range: 10 to 20 lpm

Defaults: 10.0 lpm

PC Flow Cycle

Sets the percentage of peak inspiratory flow at which the inspiratory phase of a PC breath is terminated.

Range: 5 to 70%

Default: Off

PC Flow Cycle is active for Pressure Control breath only.

PSV Cycle

Sets the percentage of peak inspiratory flow at which the inspiratory phase of a PSV breath is terminated.

Range: 5 to 70%

Default: 25%

PSV Cycle is active for PSV breaths only.

PSV Tmax

Controls the maximum inspiratory time of a pressure-supported breath.

Range: 0.3 to 3.0 seconds

Default: 3.0 seconds

% T High Sync

% T High Sync sets the trigger (sync) window to transition from Pressure high to Pressure low. This transition occurs at the first end of the inspiration detected after the Sync window opens.

Range: 0 – 50 %

Default: 0%

T High PSV

T High PSV allows pressure support to be active in Time High. Pressure Support in Time High is delivered at the same PSV level as Pressure Low.

Range: 0 = OFF, 1 = ON

Default: 0 = OFF

% T Low Sync

% T Low Sync sets the trigger (sync) window to transition from Pressure low to Pressure high. This transition occurs with the detection of inspiratory flow or the first inspiratory effort detected after the Sync window opens.

Range: 0 – 50%

Default: 0%

Vela™ Ventilator Diamond Series

Chapter 4 Monitors and Displays

Graphic Displays

The Main Screen: Waveforms

Three waveforms can be selected and simultaneously displayed on the MAIN screen as shown in figure 4.1. A red tracing indicates the inspiratory portion of a mandatory breath. A yellow tracing indicates the inspiratory portion of an assisted or spontaneous breath. A blue tracing represents the expiratory phase of a breath.

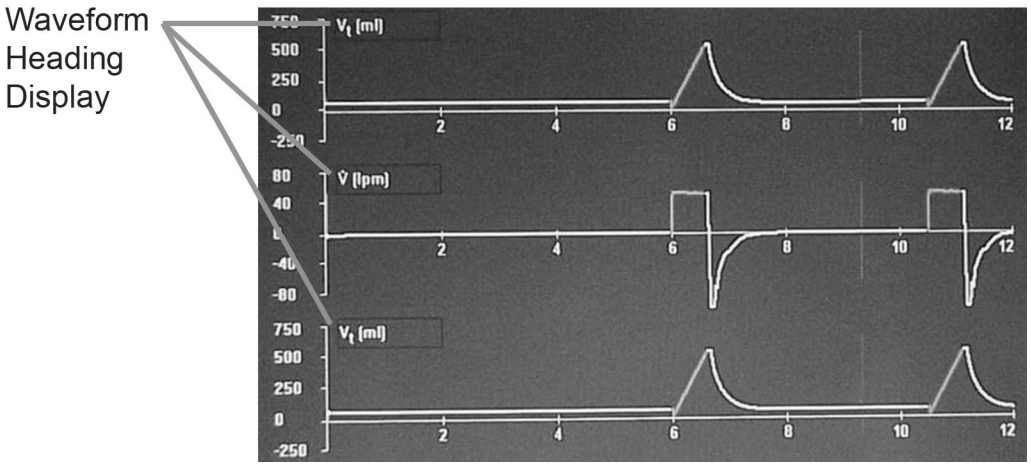


Figure 4.1 Waveform Graphs Displayed on the Main Screen

When you touch and highlight the waveform heading display on the touch screen a scrollable menu appears showing the choice of waveforms.

To scroll through the choices, turn the data dial below the touch screen. To make your selection, press the Accept membrane button next to the data dial.

Each waveform is continuously updated unless the Print touch screen button or the FREEZE membrane key is pressed. Touching Print freezes the display momentarily while data is transferred to a connected parallel printer. Once the data is captured for printing, the active screen update resumes.

The FREEZE membrane button suspends the screen update until pressed a second time.

Table 4.1 Waveform Choices

Heading Display	Waveform Shown	Range	
P_{aw} (cmH_2O)	Airway Pressure	Minimum Maximum	–5 to +10 cmH_2O –60 to + 120 cmH_2O
V (lpm)	Flow	Minimum: Maximum:	–6 to +6 lpm –300 to +300 lpm
V_t (ml)	Airway Tidal Volume	Minimum Maximum	–20 to + 60 ml –700 to + 2100 ml
P_{CO_2}*	CO_2 value through the respiratory cycle	Minimum Maximum	–10 to +30 mmHg –60 to +180 mmHg

* Option (only when installed and enabled)

Axis Ranges

The scale (vertical axis) and sweep speed (horizontal axis) of the displayed graphs are also modifiable using the touch screen. To change the displayed range, touch either axis of the displayed graph to highlight it. The highlighted axis can then be modified using the data dial below the touch screen To accept the change, touch the highlighted axis again or press Accept.

The Loops Screen (Comprehensive model only)

To access the loops screen:

Touch the screen indicator in the top center window that indicates the current screen configuration.

The Screen Select box displays.

Select LOOP from the menu that appears.

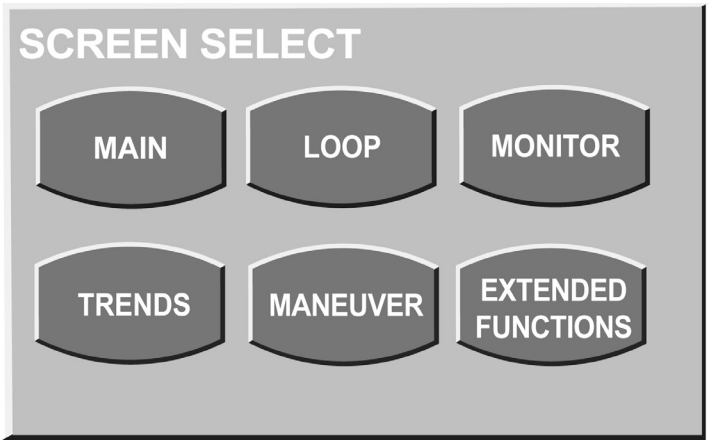


Figure 4.2 Screen Selection

The ventilator is able to display up to 2 loops in real time, selected from the following.

Flow / Volume Loop

When selected, the ventilator displays a Flow / Volume loop within the following ranges.

Flow Ranges:

Minimum: –6 to +6 lpm

Maximum: –300 to +300 lpm

Volume Ranges:

Minimum: 0 to 60 ml

Maximum: 0 to 2000 ml

Pressure / Volume Loop

Pressure Ranges:

Minimum: –5 to +10 cmH2O

Maximum: –60 to +120 cmH2O

Volume Ranges:

Minimum: 0 to 60 ml

Maximum: 0 to 2000 ml

Using the Freeze Button to Compare Loops

On the Comprehensive model, you can freeze the Loops screen and select a reference loop for comparison. Once real-time data refresh resumes (by pressing the Freeze button again), the selected loop remains in the background behind the real time graphic. To create a reference loop refer to figure 4.3, 4.4 and 4.5 and do the following.

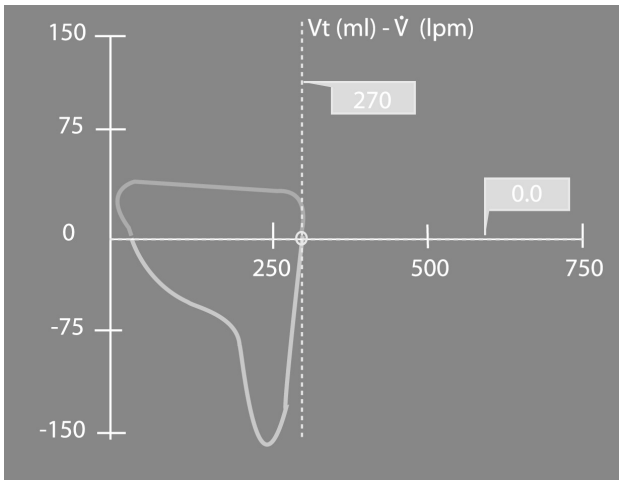


Figure 4.3 Flow/Volume Loop Frozen

Touch the Save Loop button displayed in the bar on the right, beneath the frozen graphic display. See figure 4.4 below.

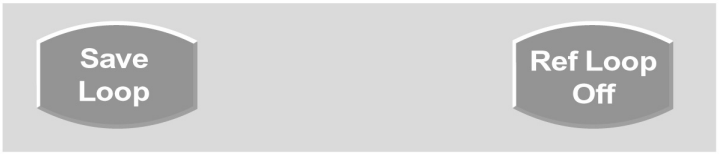


Figure 4.4 Loop Comparison Buttons

This puts the selected loop into memory and places a time reference into a field in the bar on the left beneath the graphics display as shown in figure 4.5. A total of four (4) loops can be saved at one time.

Figure 4.5 Saved Loops Display

Touch the screen directly over the reference loop you wish to use as a comparison. The reference highlights (changes color). See figure 4.5.

Touch the Ref Loop button on the right side of the bar until it toggles to On.

When you touch the Freeze button again, the reference loop remains in the background and the screen refreshes loops in real time over it. To turn off this feature, freeze the screen again and toggle the Ref Loop button to Off by touching it.

Digital Displays

The Monitor Screen

To access the monitor screen:

1. Touch the screen indicator in the top center of the Main Screen display.
2. The Screen Select box displays, see figure 4.6.
3. Select MONITOR from the selection box that appears.

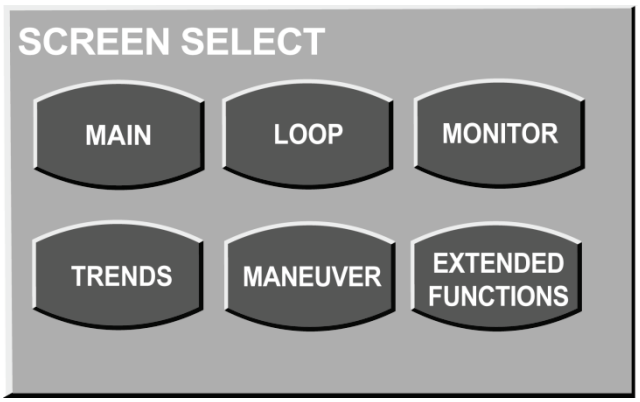


Figure 4.6 Screen Select Box

The monitor screen displays a total of 15 different monitored values simultaneously. Each value can be independently selected from a menu of possible choices (see table 4.2).

4. Use the touch screen to select and highlight the value to be displayed.
5. Turn the data dial beneath the touch screen to scroll through the menu choices.
6. To accept your selection, press the accept button adjacent to the data dial.

Figure 4.7 The Monitor Screen

Table 4.2 Monitored Values Menu Choices

Display	Value
Vte (ml)	Expired tidal volume
Vti (ml)	Inspired tidal volume
Spon Vt (ml)	Spontaneous tidal volume
Mand Vt (ml)	Mandatory tidal volume
Ve (L)	Minute Volume
Spon Ve (L)	Spontaneous minute volume
Rate (bpm)	Breath Rate
Spon Rate (bpm)	Spontaneous breath rate
Ti (sec)	Inspiratory time
Te (sec)	Expiratory Time
I:E	Inspiratory/Expiratory ratio
Ppeak (cmH2O)	Peak inspiratory pressure
Pmean (cmH2O)	Mean inspiratory pressure
PEEP (cmH2O)	Positive end expiratory pressure
O_2 Regulated (psig)	Oxygen regulated inlet pressure
F_IO_2 (%)	Percentage of oxygen
f/vt	Rapid Shallow Breathing Index
$ETCO_2$	End Tidal CO_2 (only when installed and enabled)

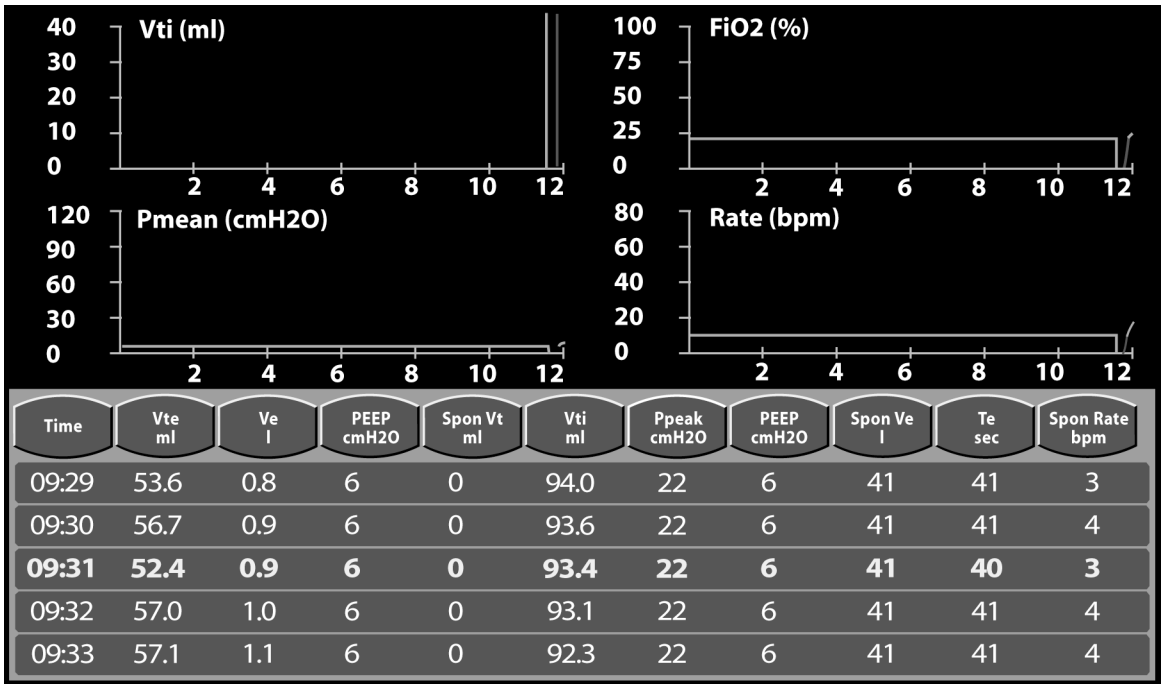
Main Screen Monitors

Five parameters are continuously displayed on the Main screen to the left of the waveform displays. These are configurable in the same way as the displays on the Monitors screen.

1. Use the touch screen to select and highlight the value to be displayed.
2. Turn the data dial beneath the touch screen to scroll through the menu choices.
3. To accept your selection, press the accept button adjacent to the data dial.

The Trends Screen (Comprehensive model only)

The monitored parameters described in the previous section are trended as one minute averaged values over a running 24-hour period. To access the Trends screen, press the screen indicator in the top center portion of the touch screen display. The screen menu appears. Press the TREND button on the screen menu to open the trends screen.



Time	Vte ml	Ve l	PEEP cmH2O	Spon Vt ml	Vti ml	Ppeak cmH2O	PEEP cmH2O	Spon Ve l	Te sec	Spon Rate bpm
09:29	53.6	0.8	6	0	94.0	22	6	41	41	3
09:30	56.7	0.9	6	0	93.6	22	6	41	41	4
09:31	**52.4**	**0.9**	**6**	**0**	**93.4**	**22**	**6**	**41**	**40**	**3**
09:32	57.0	1.0	6	0	93.1	22	6	41	41	4
09:33	57.1	1.1	6	0	92.3	22	6	41	41	4

Figure 4.8 The Trends Screen

Four histograms and a spreadsheet are displayed on the touch screen. Each histogram and column on the spreadsheet can be configured from the 16 monitored parameters. Touch the title bar of any histogram or the heading of any column to open a scrollable menu. Move through the list by turning the data dial. Highlight the item to be displayed and press the highlighted display or the ACCEPT button above the data dial to accept the new item for display.

Histograms can be scaled. Touch either axis and with the axis highlighted, use the data dial to adjust the scale. Touch the axis again or press the accept button to accept the change.

To look at histogram or spreadsheet trends over time, press the FREEZE button and use the data dial to move the cursor through the time line. The time line is shown in yellow text on the spreadsheet.

The Trends screen updates every 10 minutes. While the screen is frozen, no updates occur until the screen is unfrozen. Trend data is stored every minute by the ventilator.

The Maneuvers Screen

The following maneuvers are available with the Vela.

- MIP/NIF (Maneuver Screen) (Comprehensive model only)
- AUTOPEEP (Expiratory Hold)
- Static Compliance (Inspiratory Hold)
- Circuit Resistance (Inspiratory Hold)

MIP/NIF

MIP/NIF (Maximum Inspiratory Pressure or Negative Inspiratory Force) is accessed through the Screen Select Box.

1. Touch the screen indicator in the top center of the Main Screen display.
2. The Screen Select box displays, see figure 4.7.
3. Select MANEUVER from the selection box that appears.

The MIP/NIF button can be used to measure the patient's inspiratory effort. Press and hold this touch screen button and then encourage the patient to inhale as deeply as possible. This closes both the expiratory and inspiratory valves until the button is released or 30 seconds pass, whichever occurs first. The Message Bar in the lower left hand corner of the touch screen displays the starting pressure (Pstart, the airway pressure (Paw) and the Maximum Inspiratory Pressure (MIP), also known as Negative Inspiratory Force (NIF).

Pstart --------- Paw -------- MIP --------- cmH2O.

When the button is released, or 30 seconds pass, the ventilator resumes ventilation and the highest MIP value is displayed. This message remains until another message is displayed. It can be cleared by pressing the Accept Button.

AUTOPEEP

AUTOPEEP is performed with the Expiratory Hold button. Press and hold this button to start the maneuver. At the end of the next expiratory time period, the inspiratory valve is closed for a maximum of 6 seconds. Successful completion of the AutoPEEP maneuver requires a passive patient. The message bar displays the following data:

Paw nn Pex mm AUTOPEEP xx cmH_2O

Where nn is the baseline airway pressure at the beginning of the maneuver, mm is the ending exhalation pressure and xx is the measured AutoPEEP.

Static Compliance

Static compliance is performed with the Inspiratory Hold button. Press and hold this button to start the maneuver. At the end of the next inspiratory period, the expiratory valve is closed for a maximum of 6 seconds. Successful completion of the static compliance maneuver requires a passive patient. The message bar first displays the current airway pressure as Paw xxx cmH2O. At the end of inspiration the message changes to display the plateau pressure as Pplat xxx cmH2O. When the button is released, or six seconds pass, the alveolar distending pressure and the static compliance is displayed as:

Palvd xxx cmH_2O Cst xxx ml/cmH_2O

Circuit Resistance

Circuit Resistance measurement is performed with the Inspiratory Hold button. Press and hold this button to start the maneuver. At the end of the next inspiratory period, the expiratory valve is closed for a maximum of six seconds. Successful completion of this measurement requires a passive patient. The message bar first displays the current circuit resistance as **Paw xxx cmH_2O**. At the end of inspiration, the message changes to display the plateau pressure as **Pplat xxx cmH_2O**. When the button is released, or six seconds pass, the alveolar distending pressure and the static compliance is displayed, followed by the circuit resistance displayed as **Circuit Resistance xxx cmH_2O/L/sec**.

Vela™ Ventilator Diamond Series

Chapter 5 Alarms and Indicators

The alarm system generates a visual and an audible alarm when a condition is detected that meets the criteria of a user-selected alarm setting.

Note:

For optimal awareness of an alarm state, the ideal operator position is one meter in front of the Vela screen at an angle subtended by 30 degrees from the screen midpoint horizontal and normal to the screen plane.

Status Indicators

The ventilator displays the following status indicators.

Mains/Battery Indicators

These are visual status indicators on the bottom of the ventilator front panel for the mains power and the internal battery. Figure 5.1 shows the Battery Status display.

The sequence in which the power sources are used by the ventilator is:

- Mains AC
- Internal Battery

Power On Indicator

The green **On** indicator lights up whenever the power switch is on (I) and power is being supplied from any of the available power sources (AC or internal battery).

AC Power Indicator

The green **AC** indicator is on whenever AC power is applied to the ventilator. It displays whether the power switch is on (I) or off (O).

DC Power Indicator

The green **DC** indicator is lit whenever the internal battery is providing the primary source of power for the ventilator.

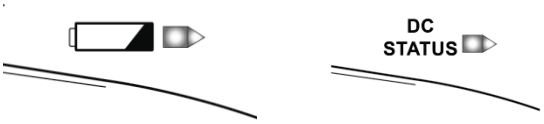
DC (Battery) Status Indicator

The DC (Battery) **Status** indicator (Figure 5.1) illuminates in a different color depending on the charge state of the battery charge system.

Note:

The DC (Battery) Status indicator illuminates only when the ventilator is connected to the AC power source. If the ventilator is plugged into AC power and no battery status light is illuminated, the battery should be checked and/or replaced. Replacement of the internal battery must be done by a CareFusion trained technician.

- Green (full charge),
- Yellow (less than 50%)
- Red (less than 20%)



International Overlay U.S. Overlay

Figure 5.1 DC Status Indicator

Audible Battery Status Alarms

When the battery charge falls below 50%, an intermittent tone alarm sounds. This alarm can be silenced for 60 seconds by pressing the Alarm Silence button on the control panel. The alarm can be cleared by pressing the Alarm Reset button twice.

When the battery charge falls below 20%, an intermittent tone sounds. This audible alarm can be silenced for 60 seconds by pressing the Silence button. After 60 seconds, the audible alarm restarts if an alternate power source has not been found.

Loss of AC Power / Patient Transport

While AC power is not applied to the ventilator (when it is running on battery power during patient transport or because of an AC power failure), audible and visible (ON BATTERY POWER), medium-priority alarms occur. Pressing Reset silences the audible alarm, but the visible alarm remains in the alarm status indicator at the upper, right side of the touch screen as an Alert until AC power is restored. Pressing Reset cancels the visible Alert ON BATTERY POWER only when AC power is restored.

Note:

Alarm settings are retained independent of power loss.

Alarm Categories

Vela ventilator alarms are grouped into three categories:

- High priority (warning), requires immediate action.
- Medium priority (caution),
- Low priority (advisory).

The priority determines the audible indication associated with the alarm, the priority symbol displayed in the alarm window, and the background color of the alarm message bar.

Alarm Displays

There is a visual display for all categories of alarm whenever the alarm condition is active. A message appears in the bar at the upper right of the touch screen.

For a high priority alarm, the status bar is RED and flashes at a rate of 2 Hz (fast). A medium priority alarm displays a yellow status bar and flashes at ½ Hz (slow). A low priority alarm (or advisory) displays a yellow colored status bar and does not flash. The alarm indicator is solid green with no message when no alarms are current.

For flashing alarms, the message flashes until the cause of the alarm is no longer present. Both high and medium priority alarms that have been resolved appear as a solid yellow non-flashing bar until the alarm Reset button is pressed. See table 5.1 for alarm messages.

Multiple alarms can display together. If only one alarm is current, it appears alone in the alarm indicator. If 2 or more alarms are present, an arrow appears on the right of the alarm indicator and a drop down box is enabled. You can activate the drop down box by touching the arrow, and deactivate it by touching the arrow again. The box is able to display up to nine total alarm messages.

If multiple alarms are current, the alarm messages are prioritized with the highest priority at the top and the lowest priority at the bottom. If more than nine alarms are current, only the nine highest priority alarms are displayed.

Audible Alarms

A continuous or intermittent tone sounds during high and medium priority alarms. There is no audible component for low priority alarms.

Alarm Controls

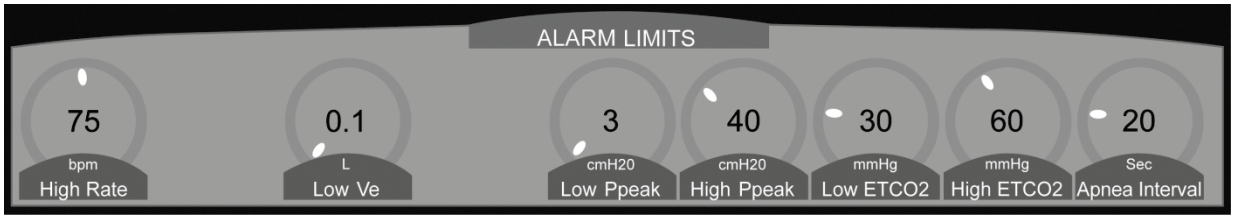
Note:

Operator-made changes to the alarm limits do not change the factory default settings. Operator set limits only stay in effect until a new patient is selected, at which time the factory default settings are reinstated.

Setting Alarm Limits

To set the limits for each alarm, touch the red Alarm LIMITS button on the bottom of the touch screen.

The Alarm Limits screen appears (see Figure 5.2). To set the limits for an alarm, select it by touching the touch screen immediately over the alarm control. The control highlights (changes color) on the screen. With the control selected, rotate the data dial below the front panel until the control reaches the setting you require. To accept the new setting, either touch the screen over the control again or press the ACCEPT button.



* Low and High EtCO2 are optional.

Figure 5.2 Alarm Limits Screen

Caution!

When setting Alarm LIMITS, consideration must be made to avoid selecting limits that are too extreme which could potentially result in harm to the patient.

Alarm Silence

You can disable the audible alarm for 60 seconds by pressing the Alarm Silence button. Pressing the alarm silence button again before the 60 second period is complete restarts the alarm. This feature is functional for all alarms, with the exception of the "Vent Inop" alarm, which cannot be silenced.

Alarm Reset

The alarm reset button clears visual indicators for alarms that are no longer active.

Alarm Types

Machine Alarms

Low Battery

This is a medium priority audible/visual alarm at 50% of battery charge. It changes to a high priority audible/visual alarm when the battery charge drops below 20%. **LOW BATTERY** is displayed in the alarm message window.

Ventilator Inoperative

This is high priority audible/visual alarm. **VENT INOP** is displayed if the ventilator fails due to a non-recoverable condition, such as loss of power. The safety valve opens and the patient is allowed to breathe room air.

Note:

PEEP is not maintained during a VENT INOP alarm condition.

Fan Failure

This is a low priority audible/visual alarm. **FAN FAILURE** is displayed whenever the fan stops rotating.

Transducer Fault (XDCR FAULT)

This is a medium priority audible and visual alarm. XDCR FAULT occurs when a transducer's zero point has drifted out of range. If the alarm does not clear by pressing the reset button twice, replace the exhalation valve body and reseat the diaphragm. If this condition continues, remove the ventilator from service and contact your CareFusion certified service technician.

Default Settings (DEFAULTS)

This is a medium priority audible and visual alarm. The ventilator is shipped from the factory with built-in default settings for all operational parameters. Once the user sets a front panel control, the corresponding default value for that control is overridden by the new setting. The new setting is then stored in the ventilator so that it can be retained even when the ventilator is turned OFF. When the ventilator is turned ON, the retained settings are automatically restored. If something happens that prevents the ventilator from retrieving these retained settings, the ventilator restores the original factory default settings, allowing the ventilator to continue to operate safely. This alarm notifies you that the ventilator is operating at the default settings. The alarm is cleared by pressing the reset button twice and setting the controls to the desired settings. If this alarm occurs frequently, contact your CareFusion certified service technician.

Pressure Alarms

Low Peak Pressure

This is a high priority audible/visual alarm. LOW PIP is displayed whenever the peak inspiratory pressure for a given breath is less than the preset threshold for Low PPEAK.

Range: Off, 2 to 60 cmH2O

Default: 3 cm H2O

Limitations: Not active for spontaneous breaths.

High Peak Pressure

This is a high priority audible/visual alarm. **HIGH PIP** is displayed whenever the preset High PPEAK threshold is exceeded. Inspiration is terminated and circuit pressure is allowed to return to the current set baseline pressure + 5 cmH_2O. Circuit pressure must return to baseline + 5 cmH_2O before the next breath can be delivered.

- Normal High P_{PEAK} Alarm

  Alarms if the inspiratory pressure in the patient circuit exceeds the set High P_{PEAK} alarm threshold during the inspiratory phase of a breath, except during sigh breath cycles.

  Range: 5 to 120 cmH2O

  Defaults: 40 cmH2O

  Not active for Sigh Breaths

- Sigh High P_{PEAK} Alarm

  Alarms if the inspiratory pressure in the patient circuit exceeds the Sigh High P_{PEAK} alarm threshold during a sigh breath cycle.

  Range: 1.5 x (Normal High PPEAK), up to a maximum of 120 cmH_2O

  Active only for Sigh Breaths.

High PEEP

This is a high priority audible/visual alarm. **HIGH PEEP** is displayed if the baseline pressure (PEEP) does not return to the set PEEP + 15 cmH_2O during exhalation. The alarm automatically clears once the pressure returns to within 15 cmH_2O.

Note:

Maximum Circuit Pressure Limit:
The ventilator has an independent adjustable mechanical pressure relief valve, which limits the maximum pressure at the wye from 20 to 130 cmH_2O. See Operational Verification Testing / Manual Verification Tests for specific instructions on setting the pressure relief valve.

Volume Alarms

Low Exhaled Minute Volume (Low V_e)

This is a high priority audible/visual alarm. **LOW MINUTE VOLUME** is displayed whenever the monitored exhaled minute volume is less than the Low Exhaled Minute Volume threshold setting.

Range: Off, 0.1 to 99.9 L

Default: 0.1

Rate/Time Alarms

Apnea Interval (Apnea)

This is a high priority audible/visual alarm. **APNEA** is displayed if the ventilator does not detect a breath initiation (by any means) within the preset period of time.

Range: 10 to 60 seconds

Default: 20 seconds

High Rate

This is a medium priority audible/visual alarm. **HIGH RATE** is displayed if the monitored total breath rate exceeds the alarm setting.

Range: 3 to 150 bpm, Off

Default: 75

O_2 Alarms

CHK O_2 CAL

This is a high priority audible and visual alarm. CHK O2 CAL is displayed if the monitored Delivered O2% is outside the range of the set F_IO_2. If the O2 setting is 21-60, the alarm activates with 6% deviation; 61-80% set O2, the alarm activates with a 7% deviation and with set values of 81-100%, the alarm activates with an 8% deviation.

F_IO_2 Set	Percent Deviation to Activate CHK O_2 CAL Alarm
.21 to .60	6%
.61 to .80	7%
.81. to 1.0	8%

O_2 RANGE ERROR

This is a high priority audible and visual alarm that is activated when the:

- CHK O2 CAL is activated
- CHK O2 CAL alarm has not been corrected
- Monitored delivered O_2 is outside the range of the set F_IO_2 by an additional 4%

F_IO_2 Set	Percent Deviation to Activate O2 RANGE ERROR alarm
.21 to .60	10% for longer than 20 seconds
.61 to .80	11% for longer than 20 seconds
.81 to 1.0	12% for longer than 20 seconds

O_2 INLET LOW

This is a high-priority, audible/visible alarm that activates when the high-pressure oxygen supply to the ventilator drops below 35 psig (2.41 bar) and the $\%O_2$ control is set to greater than 21%. The patient continues to be ventilated with room air (21% O_2) only.

Patient Circuit Alarms

All patient circuit alarms are high priority audible and visual alarms. Patient circuit alarms occur when the breathing circuit tubing is disconnected or occluded. For users of VELA software version 02.02.16 and lower, the visual alarm for a circuit occlusion and circuit disconnect is CIRCUIT FAULT. For users of 03.02.00 and above, for a circuit occlusion the visual alarm is CIRCUIT OCCLUSION, and for a circuit disconnect the visual alarm is CIRCUIT DISCONNECT.

Note:

A CIRCUIT DISCONNECT or CIRCUIT FAULT alarm can appear when a mask is not fitted well to the patient's face during non-invasive ventilation. Improving the mask fit will eliminate this alarm.

Table 5.1 Alarm Conditions

Message	Alarm Condition	Range	Priority
LOW BATTERY	Battery charge has fallen below 50% (medium priority alarm) or 20% (high priority alarm)	NA	Medium/High
ON BATTERY POWER	During Patient Transport / Loss of AC Power	NA	Medium/Low
SAFETY VALVE	Safety valve is open	NA	High
VENT INOP	Ventilator failure due to non-recoverable condition. The safety valve opens and the patient is allowed to breathe room air. PEEP is not maintained	NA	High
O_2 Inlet Low	Oxygen supply to the ventilator drops below 35.0 psig (2.41 bar) and the $\%O_2$ is set to > 21%. Patient continues to be ventilated with room air only	NA	High
LOW PIP	The peak inspiratory pressure for a breath is less than the set LOW P_{PEAK}. Not active for spontaneous breaths.	Off, 2 to 60 cmH_2O Default 3 cmH_2O	High
HIGH PIP	Peak inspiratory pressure is greater than the set HIGH P_{PEAK}. Inspiration is terminated and the circuit pressure allowed to return to baseline pressure ± 5 cmH_2O before the next breath is delivered.	Normal Breath Range: 5 to 120 cmH_2O default 40 cmH_2O Sigh Breath Range: 1.5 x set normal HIGH P_{PEAK} Only active for sigh breaths	High
HIGH PEEP	Baseline pressure (Positive End Expiratory Pressure) does not return to PEEP + 15 cmH_2O during exhalation. Automatically clears when pressure returns to within 15 cmH_2O of PEEP.	Automatic	High
LOW MINUTE VOLUME	Monitored exhaled minute volume (V_e) is less than the set LOW V_e alarm threshold.	OFF (0), 0.1 to 99.9 L Default 0.1	High

Message	Alarm Condition	Range	Priority
APNEA	Active in CPAP and SIMV modes. The ventilator does not detect a breath within the preset APNEA time interval.	10 to 60 sec Default 20 sec	High
HIGH RATE	The monitored total breath rate exceeds the set alarm RATE.	OFF, 3 to 150 bpm Default 75 bpm	Medium
CHK O_2 CAL	Delivered oxygen percentage differs from the set FIO_2 by 6 - 8%.	NA	High
O_2 RANGE ERROR	Delivered oxygen percentage differs from the set FIO_2 by 10 – 12% for longer than 20 seconds.	The alarm is disabled for 180 seconds when the 100 %O_2 button is pressed	High
CIRCUIT OCCLUSION*	This occurs when the patient circuit is occluded	NA	High
CIRCUIT DISCONNECT*	This occurs when the patient circuit is open because of a gross disconnection of the patient tubing from the patient, humidifier or ventilator.	NA	High
CIRCUIT FAULT**	This occurs when the patient circuit is occluded or open because of a gross disconnection of the patient tubing from the patient, humidifier or ventilator.	NA	High
CO_2 Communication Error*	The sensor is not properly plugged in or a Non–CAREFUSION Sensor is in use.	NA	Medium
CO_2 Out of Range*	The CO_2 measured by the sensor exceeds 150 mmHg (20.0 kPa).	$EtCO_2$ < 150 mmHg (20.0 kPa)	Medium
Invalid $EtCO_2$*	No breaths are being detected by the CAPNOSTAT® 5.	NA	Medium
Low $EtCO_2$*	The measured $EtCO_2$ is lower than the set Low EtCO2 alarm limit.	OFF, 1 – 150 mmHg / 0.1 – 20.0 kPa	Low
High $EtCO_2$*	The measured $EtCO_2$ is higher than the set High $EtCO_2$ alarm limit.	OFF, 5 – 150 mmHg / 0.7 – 20 kPa	Low

*software 03.02.00 and above

**software 02.02.16 and below

Chapter 6 Capnography

Warnings

- During the Calibration Check routine, the Altitude Setting (accessible at the Utility Screen), must be set appropriately to ensure that the calibration is performed using the ambient barometric pressure.
- Only capnography cables supplied by CareFusion are compatible with the VELA ventilator.
- Periodically check the CO_2 sensor for excessive moisture or secretion buildup.
- A system leak, such as that caused by un-cuffed endotracheal tubes, may affect flow-related readings. These include flow, pressure, CO_2 production, and other respiratory mechanics parameters.
- Nitrous oxide, excessive levels of oxygen, and halogenated hydrocarbons can influence the CO_2 measurements.
- Do not use CO_2 measurements as the sole basis for changing ventilation parameters without reference to the clinical condition and independent monitors such as blood gas. CO_2 measurements may be inaccurate in the presence of a breathing-circuit leak, secretions, or sensor malfunction.
- Do not position the CO_2 sensor or cable in any manner that may cause entanglement, strangulation, or accidental self-extubation. Use clips as appropriate to secure the sensor cable to the breathing circuit.

Cautions

- The CAPNOSTAT® 5 contains no user-serviceable parts.
- Do not use damaged sensors or cables.
- Do not sterilize or immerse sensors, except as directed in the *VELA Operator's Manual*.
- Do not apply excessive tension to any sensor cable.
- We recommend that the CO_2 sensor be removed from the circuit whenever an aerosolized medication is delivered. This is due to the increased viscosity of the medications, which may contaminate the sensor windows, causing the sensor to fail prematurely or to display incorrect data.

Theory of Operation

The CAPNOSTAT® 5 measures CO_2 by using the infrared absorption technique, which has endured and evolved in the clinical setting for over the past two decades and remains the most popular and versatile technique today. The principle is based on the fact that CO_2 molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR beam is passed through a gas sample containing CO_2, the electronic signal from the photo detector (which measures the remaining light energy) can be obtained. This signal is then compared to the energy of the IR source and calibrated to accurately reflect CO_2 concentration in the sample.

Unpacking and Setup

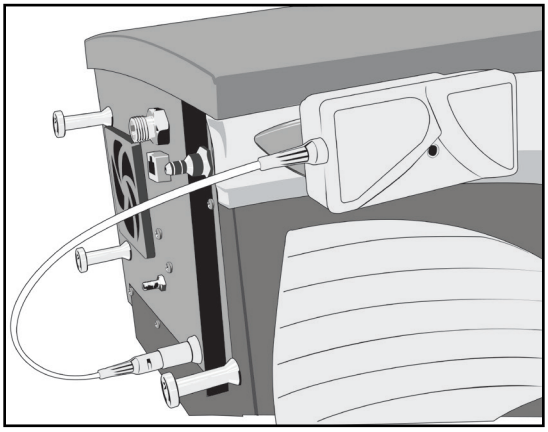
Unpacking

The CareFusion capnography system may be shipped with the following items. If something is missing or damaged, please call CareFusion Respiratory Systems Customer Service for replacement.

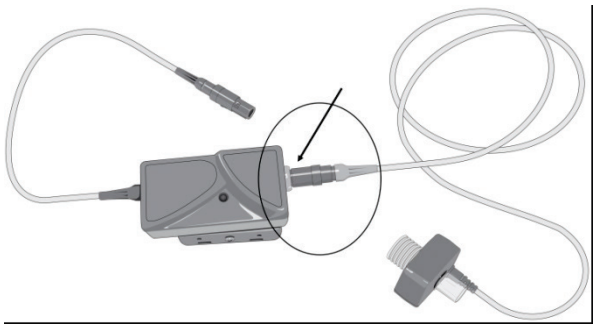
Description	Quantity
VELA Capnography power box	1
CAPNOSTAT® 5 / cable assembly	1
Adult / Pediatric non-disposable airway adaptor	1
Single-patient use adult / pediatric airway adapters	Box of 10
5% CO_2 calibration gas (±0.03%, bal N_2)	Box of 1
Calibration gas pressure regulator	Box of 1

Setup

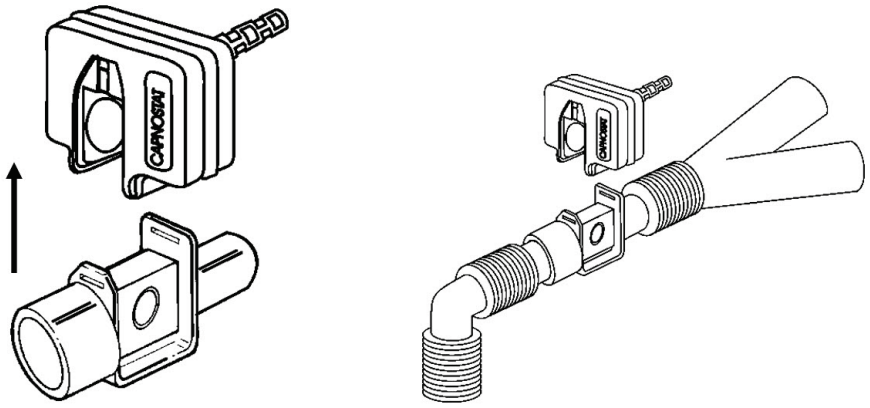
1. Connect the CO_2 power box to the side rail of the ventilator and the CO_2 connector from the power box to the back of the Vela.



2. Attach the CO_2 sensor cable to the connection on the front of the CO_2 power box.



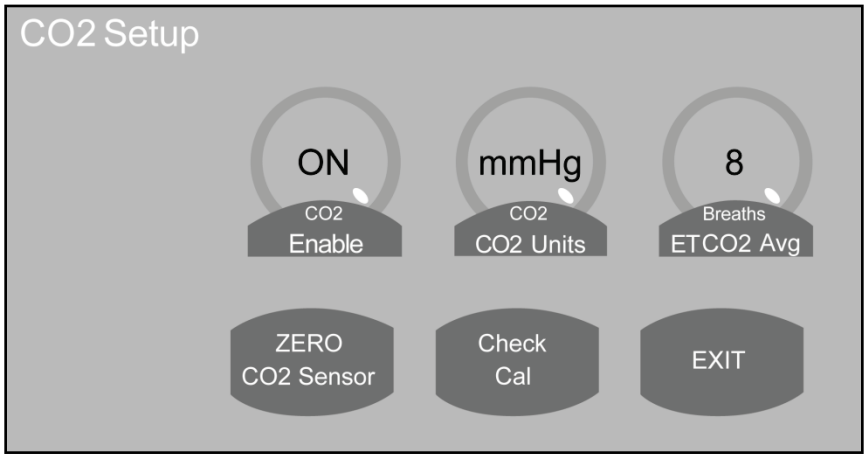
3. Access the CO_2 Setup screen by touching the screen indicator in the top center of the touch screen. Touch Extended Functions, and then CO_2 setup.
4. Enable CO_2 Monitoring by touching the Enable screen icon. Turn the data dial to ON. Press the ACCEPT button.
5. Remove the appropriate airway adaptor from its packaging and make sure it is undamaged and ready to use.
6. Insert the airway adaptor into the CO_2 sensor. The adaptor will "click" into place when properly inserted.
7. Once the airway adaptor is placed in the sensor, a "sensor zero" procedure must be performed. Follow the instruction in the section titled "Zeroing the CAPNOSTAT® 5". The zero procedure must also be performed when switching between disposable and reusable airway adaptors.
8. Once the sensor is successfully zeroed, place the airway adaptor and sensor into the ventilator circuit between the wye and endotracheal tube (and any adaptors).



Settings and Monitors

Setup and Utilities

These controls are accessed by touching the screen indicator at the top, center of the touchscreen. Touch Extended Functions, and then CO_2 setup.



1. CO2 Enable

When CO2 monitoring is enabled, all CO2 monitoring and alarm functions are also enabled. When CO2 Monitoring is disabled all CO2 monitoring and alarm functions are disabled.

Range: On or Off

Default: Disable

2. CO2 Units

Selects the units in which the EtCO2 and PCO2 scalar are displayed

Range: kPa or mmHg

Default: mmHg

3. EtCO2 Averaging

EtCO2 is measured for each breath. The user shall be able to select number of breaths over which the displayed EtCO2 is averaged.

Range: 1 or 8 breath(s)

Default: 8 breaths

4. Zero CO2 Sensor

This control initiates the sensor zero procedure. This procedure need only be done when changing between different airway adaptor types (disposable or reusable) and as part of the Calibration Check. See section “Zeroing the CAPNOSTAT® 5”.

5. Calibration Check

This control provides access to a calibration check procedure. This procedure need only be done during yearly preventative maintenance. See section "Checking the accuracy of the CAPNOSTAT® 5."

Note:

The Zero CO_2 Sensor and Check Calibration controls are available only when CO2 is enabled, and a sensor has been connected and has completed initialization – this initialization may take up to five seconds.

Monitored Values

End Tidal CO2 (EtCO2)

EtCO2 is the patients peak expired CO2 as measured and reported by the CO2 sensor in the airway. EtCO2 is measured for each breath. The display is either a breath by breath measurement or averaged.

Range: 0 – 150 mmHg (0 to 20.0 kPa)

Resolution: 1 mmHg (0.1 kPa) or two significant digits (whichever is greater).

Accuracy:

± 2 mmHg for 0 to 40 mmHg

± 5% of reading for 41 to 70 mmHg

± 8% of reading for 71 to 100 mmHg

± 10% of reading for 101 to 150 mmHg

Note:

The minimum differential between inspired and expired CO2 must be 5 mmHg (0.7kPa) or greater.

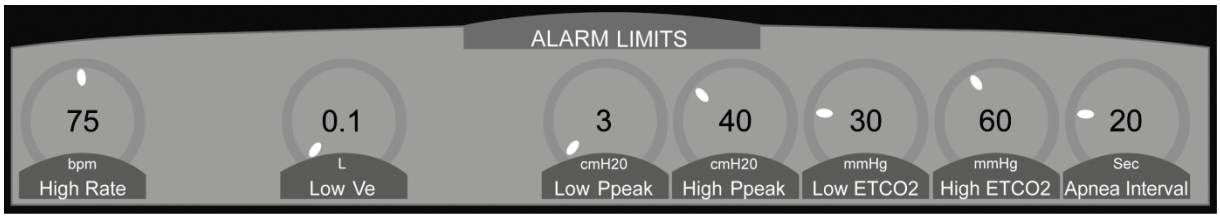
Waveform

PCO2 wave (capnogram)

This displays the CO2 value through the respiratory cycle as measured and reported by the CO2 sensor at the wye.

Maximum range: 0 to 150 mmHg (0 to 20 kPa)

Alarms



1. High $EtCO_2$

Creates a low priority alarm if the monitored $EtCO_2$ exceeds this setting.

Range: 5 to 150 mmHg (0.7 to 20 kPa) or Off
Resolution: 1 mmHg (0.1 kPa)
Default: 60 mmHg (8 kPa)

Note:

The High $EtCO_2$ alarm must be set at least 5 mmHg (0.7 kPa) above the Low $EtCO_2$ alarm setting.

2. Low EtCO2

Creates a low priority alarm if the monitored $EtCO_2$ exceeds this setting.

Range: 1 to 150 mmHg (0.1 to 20 kPa) or Off
Resolution: 1 mmHg (0.1 kPa)
Default: 30 mmHg (4 kPa)

Note:

The Low $EtCO_2$ alarm must be set at least 5 mmHg (0.7 kPa) below the High $EtCO_2$ alarm setting.

Note:

The invalid $EtCO_2$ timeout is the maximum time allowed from the detection of one breath to the next breath. At start up or following a zero, three breaths need to be detected before this timer is activated. It is important to note that the Capnostat is not an apnea monitor. The software cannot discriminate between patient apnea and a sensor that is disconnected.

Operation

Zeroing the CAPNOSTAT® 5

The CAPNOSTAT® 5 should be zeroed when it is connected to the VELA and monitoring is started. A zero is also required to adjust the sensor to the optical characteristics when changing airway adapter types (single patient use or reusable).

Warning!

Failure to correctly zero the CAPNOSTAT® 5 may result in incorrect data being displayed.

Warning!

The airway adapter and CO_2 sensor must not be attached to the patient circuit during the zero procedure.

Note:

The Capnostat ® must be at operating temperature to be zeroed. If required, the VELA will wait up to 120 seconds for the sensor to warm-up.

Note:

While the Zero routine is in process, all CO_2 alarms are turned off. The alarms will resume when the procedure is complete.

1. Attach the end of the CO_2 sensor cable to the back of the VELA as previously described.
2. Attach the CO_2 sensor to the appropriate airway adaptor.
3. Access the CO_2 Setup screen by touching the screen indicator in the top center of the touch screen. Touch Extended Functions, and then CO_2 setup
4. Ensure that CO_2 Monitoring is ON.
5. Press Zero CO_2
6. If the sensor is ready to zero, a message "Zeroing CO_2 Sensor…" will be displayed.

Note:

If the message "CO_2 Sensor not ready…" is displayed, the sensor is not ready to be zeroed. The sensor will not be ready to zero if it is not up to its operating temperature, it detects breaths or if there is a sensor malfunction. When the sensor becomes ready to zero, "Zeroing CO_2 Sensor…" will be displayed.

7. When the sensor is zeroed, "CO_2 Sensor Zero Pass" will be displayed. The CO_2 sensor is now ready for use.

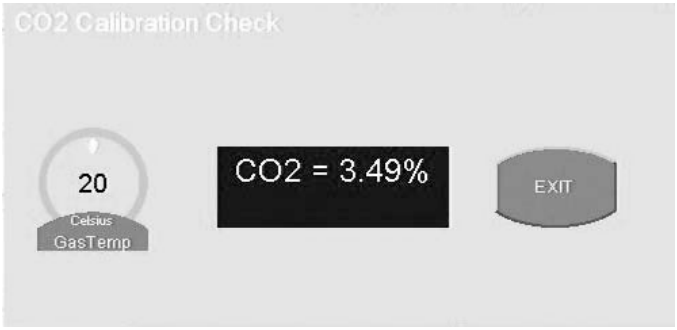
Note:

If the CO_2 sensor does not return a Zero pass or fail response, the message 'Zero CO_2 TIMEOUT will be displayed (note that in this event the actual operation of zeroing the sensor may subsequently continue to completion: if this should occur prior to activation of the 'Exit' control, then the message will be replaced by Zero CO_2 PASS or Zero CO_2 FAIL as appropriate.

Checking the accuracy of the CAPNOSTAT® 5

The accuracy of the CAPNOSTAT® 5 sensor should compared against a calibration gas every twelve (12) months.

1. Attach end of the CO_2 sensor cable to the Vela as previously described.
2. Attach the CO_2 sensor to the appropriate airway adaptor.
3. Access the CO_2 Setup screen by touching the screen indicator in the top center of the touch screen. Touch Extended Functions, and then CO_2 setup
4. Follow the procedure for zeroing the CAPNOSTAT® 5.
5. Press Check Cal.
6. Set the gas Temperature setting to that of the calibration gas (typically room temperature).



7. Attach a regulated flowing gas mixture of 5% CO_2 (± 0.03%) balance nitrogen (N2) to the airway adapter. Set the flow rate of the calibration gas to 2 – 5 liters per minute.
8. Allow 10 seconds for the reading to stabilize. The expected reading is 5% ± 0.26%

Note:

While the Calibration Check routine is in process, all CO_2 alarms are suspended. The alarms will resume when the procedure is complete.

Cleaning

Sensor

Cleaning the outside of the sensor and cable:

- Use a cloth dampened with 70% isopropyl alcohol, 10% bleach solution, disinfectant spray cleaner such as Steris Coverage® SprayHB, ammonia or mild soap.
- Wipe surfaces with a clean-water dampened cloth before use. Ensure sensor is clean and dry before use.

Airway Adaptors

Cleaning reusable adaptors:

- Clean by rinsing adaptor in warm soapy water followed by soaking in a liquid disinfectant such as 70% isopropyl alcohol, 10% bleach solution, 2.4% gluteraldehyde solution such as Cidex®, Steris System1® or ammonia. Rise with sterile water and dry before use.
- May also be disinfected using one of the following methods:
  - Steam autoclave – adult adaptors only
  - Immerse and soak in 2.4% gluteraldehyde solution such as Cidex® for 10 hours.
  - Immerse and soak in 0.26% paracetic acid solution such as Perasafe® for 10 minutes.
  - Cidex® OPA – follow manufacturer's instructions for use.

Before reusing the adaptor, ensure the windows are dry, free of residue and that the adaptors have not been damaged during the cleaning/disinfecting process.

Disposable adaptors:

Treat all single patient use adaptors in accordance with institutional protocol for single patient use items.

Troubleshooting

CO_2 Communication Error	Medium priority alarm. Ensure the sensor is properly plugged in. Reinsert the sensor in necessary. If the error persists, call technical support.
CO_2 Sensor Faulty	Medium priority alarm. Ensure the sensor is properly plugged in. Reinsert the sensor in necessary. If the error persists, call technical support.
CO_2 Sensor Over Temp	Medium priority alarm. Ensure the sensor is not exposed to extreme temperatures (heat lamps, etc.). If the error persists, call technical support.
CO_2 Zero Required	Medium priority alarm. Check airway adapter and clean if needed. If error persists, perform an adapter zero procedure.
CO_2 Out of Range	Creates a medium priority alarm when the CO_2 measured by the sensor exceeds 150 mmHg (20.0 kPa). If error persists, perform a zero procedure.
Check CO_2 Airway Adaptor	Medium priority alarm. Check airway adapter and clean if needed. If error persists, perform an adapter zero procedure.
Invalid CO_2	Medium priority alarm. No breaths are being detected by the CAPNOSTAT® 5. Ensure spontaneous or mechanical breaths are being delivered to the patient. Confirm that the airway adapter is placed in the airway between any connector(s) and the circuit wye and that the sensor is firmly attached to the adaptor.

Specifications

Sensors	
Sensor Type	Mainstream, non-dispersive infrared single-beam optics, dual wavelengths. No moving parts
Sensor Physical Characteristics	Weight: 25 g (78 g with standard cable and connectors) Size: 33 mm x 43 mm x 23 mm. Cable length: 3 m
Sensor Compatibility	The CareFusion Capnostat® 5 is interchangeable between CareFusion equipment only.
CO_2 Measurement	
CO_2 Measurement range	0 – 150 mmHg (0 to 20 kPa)
CO_2 Measurement Accuracy	± 2 mmHg for 0 to 40 mmHg ± 5% of reading for 41 to 70 mmHg ± 8% of reading for 71 to 100 mmHg ± 10% of reading for 101 to 150 mmHg
CO_2 Resolution	1 mmHg
CO_2 Stability	< 0.8 mmHg over four hours
Airway Adaptors	
Adult/Pediatric Single Patient Use	For use with endotracheal tube greater than 4mm ID Dead space: 5 mL Weight: 7.7 g Color: Clear
Adult/Pediatric Reusable	For use with endotracheal tube greater than 4mm ID Dead space: 5 mL Weight: 12 g Color: Black

All adaptors and cables for capnography are Latex free.

Vela™ Ventilator Diamond Series

Chapter 7 Maintenance and Cleaning

Cleaning and Sterilization

The Vela is designed for easy maintenance. All exposed parts of the ventilator are corrosion resistant. To prevent pooling of liquids, there are no flat surfaces on the ventilator body. Depending on the desired method, either cleaning or cleaning and sterilization should be performed.

Caution!

DO NOT submerge the ventilator or pour cleaning liquids over, into or onto the ventilator.

Cleaning

Cleaning of External Surfaces

All external surfaces of the ventilator can be wiped clean with a soft cloth using Isopropyl Alcohol

Cleaning of Accessories and Ventilator Parts

Accessories

The following accessories can be cleaned using Revital-OX™ 2X Concentrate Enzymatic Detergent made by STERIS Corporation:

- The exhalation valve body
- The exhalation flow sensor.
- The exhalation diaphragm

Cleaning Method for the Exhalation Valve Assembly

1. Remove the exhalation valve assembly for cleaning.
2. Press and hold the release latch on the lower left of the exhalation valve housing.
3. Grasp the exhalation valve body, rotate it counter-clockwise until the alignment slots line up, and then gently pull it free from the housing.
4. Grasp the exhalation valve diaphragm by the center and remove it from the exhalation valve body.
5. Using a clean soft cloth and Isopropyl Alcohol, wipe all exposed surfaces around the exhalation valve housing. Do not allow cleaning fluid to spill into the opening in the exhalation valve housing.

To manually clean the exhalation valve body, flow sensor and diaphragm:

1. Rinse accessory under cool, running tap water to remove gross soil.

2. Prepare Revital-OX™ 2X Concentrate Enzymatic Detergent according to manufacturer's recommendations at ¼ oz/gal using tap water.
3. Immerse accessory in the prepared detergent for a minimum of 2 minutes. Agitate accessory to remove air bubbles.
4. Remove accessory from the cleaning solution and thoroughly rinse in a bath (minimum of gallon) of sterile UPS (United States Pharmacopeia) water for a minimum of one minute. Agitate periodically to ensure thorough rinsing.
5. Dry accessories with a clean, lint free cloth. Visually inspect for visible soil.

Sterilization

The following accessory parts can be sterilized:

- The exhalation valve body
- The exhalation flow sensor
- The exhalation diaphragm

Method of Sterilization:

The preferred method of sterilization is

1. Steam Sterilization (autoclave), minimum 132° C (270° F) maximum temperature 134 ºC (273 ºF). It is recommended that the accessories listed above be replaced after 30 cleaning and sterilization cycles.
2. After cleaning the surfaces, make sure all excess cleaning solution is completely removed to prevent residue buildup.
3. Sterilize the exhalation valve body, flow sensor and diaphragm using steam autoclaving within the guidelines stated above.
4. Using a low flow gas source (less than 10 L/min) ensure the differential pressure tubes are free of moisture and debris.
5. To avoid possible damage to elastomeric components, the peak temperature for CareFusion accessories should not exceed 275 °F (135 °C) for steam autoclave.
6. Steam autoclave at 0 gravity cycle time is 15 minutes. At HiVac (27 psi) cycle time is 7 minutes and drying time is 10 minutes.
7. Ultrasonic cleaning is not recommended. Liquid sterilizing agents containing more than 2% glutaraldehyde are also not recommended. If such agents must be used, be sure to thoroughly rinse and dry the assembly to prevent residue buildup. Residue buildup in the differential pressure ports can cause inaccurate pressure and volume readings.
8. Prior to replacing the exhalation valve diaphragm, inspect it for excessive wear. If signs of damage are found, obtain a new diaphragm.
9. Insert the diaphragm. Hold it by the center and set it into the exhalation valve-housing receptacle. Gently tap around the perimeter until the diaphragm is firmly seated.

10. Line up the tabs of the exhalation valve body with the alignment slots on the exhalation valve housing. Gently push the exhalation valve body into place and rotate it clockwise until the release latch pops out. The exhalation valve body 'clicks' into place.
11. Gently pull on the exhalation valve body to make sure it is securely attached to the ventilator.

Other Accessories

For all other accessories purchased for use with your VELA ventilator, but not supplied by CareFusion, follow the manufacturer's recommendations for cleaning or sterilization.

Recommended Periodic Maintenance

CareFusion is committed to product support. If you have any questions concerning your ventilator's operation or maintenance contact your product support representative as shown in Appendix A, Contact Information.

Every 500 hours, the air intake filter should be checked and cleaned if necessary. A reminder message is displayed on the front panel at 500 hour increments. To clear this message, press the Accept Key. To clean the filter, remove it from its recess and immerse in warm soapy water. Rinse thoroughly and dry thoroughly before replacing in the ventilator.

Preventive maintenance should be performed on your Vela ventilator every year. Call the applicable number given in Appendix A to arrange for a qualified service technician to perform this.

Warning!

Electric shock hazard - Do not remove any of the ventilator covers or panels. Refer *all* servicing to an authorized CareFusion service technician.

The yearly maintenance includes the following.

Replacement of:

- The Rear Air Inlet Filter
- The Oxygen Inlet Filter
- The Turbine Muffler Filter Cores and O-rings
- The Fan Filter

At this time the following maintenance is performed:

- Removal and replacement of the above items
- Calibration check
- Verification testing to confirm the ventilator is functioning within optimum parameters.

Note:

Battery performance checks should be performed as outlined in the Vela Service Manual. In addition to the battery-test procedures, CareFusion recommends that the internal batteries be replaced every 10,000 hours, or every two years.

Note:

VELA maintenance should only be performed by a trained and authorized service technician. CareFusion will make available to qualified technicians, service manuals, which include such items as circuit diagrams, component parts lists, calibration instructions and other information to assist in repair of those parts of the ventilator designated by the manufacturer as repairable items.

Operational Verification Tests

Perform the Operational Verification Tests (described in Chapter 2) at the following times:

- Before connecting the ventilator to a new patient
- As specified by your department guidelines
- Any time you suspect the ventilator is not operating properly

Warning!

If a mechanical or electrical problem is recognized while running the Verification Tests, or while operating the ventilator, the ventilator must be removed from use and referred to qualified personnel for servicing.

Using an inoperative ventilator may result in patient injury.

Battery Care

The Vela has an internal, Nickel Metal Hydride battery pack that provides power backup for short periods in the event that the mains power supply is lost. The standard internal battery pack provides about six (6) hours of operation under moderate settings when fully charged and in good operating condition. The condition of the battery and condition of the charge may not always be optimal. Therefore, it is prudent to expect 4 to 4.5 hours of reliable battery backup.

Note:

CareFusion recommends that when the ventilator is used in a transport situation, the expected transport time should not be greater than 50% of the usable battery life. This provides a safety margin in the event of schedule delays or premature consumption of the battery power. Should the expected transport time be delayed beyond this, a dedicated transport system should be considered. As with any patient transport, suitable manual ventilation backup should be available.

Whenever the ventilator is connected to an appropriate AC voltage source, the batteries receive a trickle charge. Do not allow your battery to become completely discharged as this

may damage the ventilator. To ensure that the batteries remain charged and to prolong their life, we recommend that you keep the ventilator plugged in to the AC power supply when not in use. The Battery Status Indicators on the front panel enable you to monitor the available charge remaining in your battery. (See Chapter, 5 Alarms and Indicators, for details of the "Low Battery" alarm).

Precedence of Use

The sequence in which the power sources are used by the ventilator is:

1. AC
2. Internal Battery

Caution!

Do not store the ventilator in hot areas for prolonged periods of time. Temperatures above 80°F (27°C) can shorten battery life.

Failing to charge the ventilator while in storage may also shorten battery life. High rates, pressurized flow can also reduce total battery backup time.

Caution!

When the integrity of the external power earth conductor arrangement is in doubt, operate the ventilator from its internal battery.

Battery Status Indicators

Battery status indicators showing the state of charge of the internal batteries appear on the front panel of the ventilator.

The DC Status indicator shown in Figure 5.1 for the internal battery illuminates in a different color depending on the available charge remaining in the battery.

Note:

If the ventilator is plugged in to the mains power supply and no battery status light is lit, the battery should be checked and/or replaced. Replacement of the Internal battery must be done by a CareFusion trained technician.

- Green (full charge),
- Yellow (Less than 50%)
- Red (less than 20%)

Caution!

A battery that is fully drained (i.e. void of any charge) may cause damage to the ventilator and should be replaced.

Audible Battery Status Alarms

When the battery charge falls below 50%, an intermittent tone alarm sounds. This alarm can be silenced temporarily for 60 seconds by pressing the Alarm Silence button on the control panel. The alarm can be cleared by pressing the Alarm Reset button twice.

When the battery charge falls below 20%, an intermittent tone sounds. This audible alarm can be silenced for 60 seconds by pressing the Silence button. After 60 seconds, the audible alarm restarts if an alternate power source has not been found.

Failure to charge

If the internal batteries do not show significant re-charge after being connected to an AC power source for 8 hours, contact CareFusion as shown in Appendix A to arrange for replacement. Total time to re-charge depends upon the extent of battery depletion and ventilator usage while charging is taking place.

Fuses

The Vela has the following replaceable fuses associated with internal power sources.

Warning!

Do not remove or replace fuses or perform any maintenance tasks on the ventilator while your patient is connected. **Always perform these tasks "off patient".**

Battery Fuses

The internal battery fuses are 5A, 250V 5 x 20mm slow blow type. The internal battery fuse should only be replaced by a trained, authorized CareFusion technician.

Caution!

To avoid fire hazard, use only the fuse specified in the ventilator's parts list or one that is identical in type, voltage rating, and current rating to the existing fuse. Internal fuses should only be changed by a trained authorized technician.

Mains AC Fuses

The AC power fuses are housed within the power entry module located on the back panel. Check that the correct voltage for your mains supply is showing through the window in the power entry module. Use the values in the following table to determine the appropriate replacement fuses.

Table 7.1 Mains fuses

Nominal Line Voltage	Fuse	Amperage	Type	CareFusion Part No.
115 VAC	250V 5 x 20 mm	3.15 A	Fast Blow	71612
230 VAC	250V 5 x 20 mm	1.6 A	Slow Blow	56000-20078

Changing the AC Fuses:

Warning!

Ensure that the mains power cord is unplugged from the main AC outlet before attempting to remove or replaces fuses.

To replace the mains (AC) electrical fuses, refer to figures 7.1 to 7.3 and do the following:

Remove the power cord protective cover.
Unplug the A/C power cord.

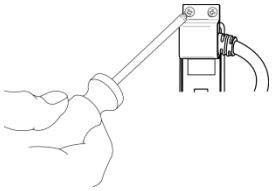


Figure 7.1 Remove the power cord guard

The AC power module is a universal module for A/C voltages from 100-240 volts. Using a flat bladed screwdriver, lift open the cover. Using the same screwdriver, loosen and pull out the red fuse holder as shown in figure 6.2.

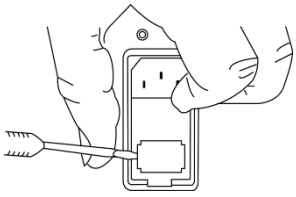


Figure 7.2 Pry out the fuse holder

Remove the fuses from both sides of the fuse holder and replace them with the appropriate fuses (refer to Table 7.1) available from CareFusion customer support.

Warning!

It is important that the fuses are replaced with the same type and value as those removed. Failure to do so can result in ventilator malfunction.

For use with 100 to 120 volts, make sure the 4 metal tabs are facing up as shown in figure 6.3 and carefully push the fuse holder in to the A/C power module until it seats. Close the cover and check that “115V” is visible in the red window.

For use with 220220 to 240 volts, make sure the 4 metal tabs are facing down and carefully push the fuse holder in to the A/C power module unit until it seats. Close the cover and check that “230V” is visible in the red window.

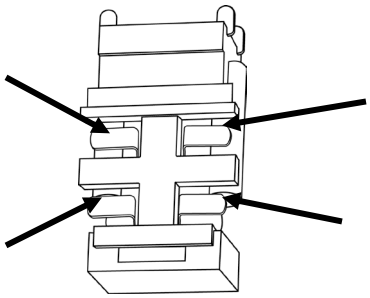


Figure 7.3 Fuse holder with metal tabs upward

Appendix A Contact and Ordering Information

How to Call for Service

To get help with any of the preventive maintenance routines, or to request service for your ventilator, contact CareFusion at the following numbers:

Technical and Clinical Support

Hours: 6:30 AM to 4:30 PM (Pacific Time) Monday through Friday

Phone: (800) 231-2466 (From within the U.S. only) or (714) 283-2228

Fax: (714) 283- 8471

After-hours service:

Phone: (800)231-2466 (From within the U.S. only)

Fax: (714) 283-8473 or (714) 283-8419

To obtain Vela Ventilator parts contact customer service at:

Hours: 7:00 Am to 4:30 PM (Pacific Time) Monday through Friday

Phone: (800) 328-4139 (from within the U.S. only) or (714) 283-2228

Fax: (714) 283-8473 or (714) 283-8419

Online service for warranty replacements parts can be found at:

http://www.carefusion.com/customer-support/us-support/support-ventilation.aspx

CareFusion Customer Care Help line

Hours: 24 hours, seven days a week

Phone: From within the U.S. only: (800) 934-2473 or (800) 231-2466 or (800) 520-4368

Fax: (714) 283-8473 or (714) 283-8419

Email: support.vent.us@carefusion.com

Parts that can be ordered from CareFusion are listed in the following table.

Part No.	Description
00423	22mm I.D. Cuff Adapter
04124	Tapered Plug, 7.5mm Male
04709	90 Degree Elbow Adapter
20225	Wye Connector
09413	Water Trap, Natural, Autoclavable
09531	Circuit Tubing, 30" (76.2 cm) Smooth Bore
16240	Exhalation Valve Diaphragm
10472	15' (3 m) high pressure oxygen hose
20005	Exhalation Valve Body
16496	Variable Orifice Flow Sensor
16578	Reusable CO_2 sensor and cable
16605	Single-Patient Use Pediatric/Adult Airway Adapters (10 per box)
16607	Reusable Pediatric/Adult Airway Adapters
79043	5% CO_2 Calibration Gas (±0.03%, bal N2) (4 per box)
79044	Calibration Gas Pressure Regulator
L1536	Users Guide English
L3264	Operator's Manual English
L2854-102	Operator's Manual German
L2854-103	Operator's Manual French
L2854-104	Operator's Manual Italian
L2854-105	Operator's Manual Spanish
L2854-107	Operator's Manual Japanese
L2854-118	Operator's Manual Russian
L2887	Operator's Manual on CD.

Appendix B Specifications

Oxygen Supply

High Pressure Connector

Pressure Range: 40 to 85 psig (2.76 to 5.86 bar) (Supply Oxygen)

Temperature: 10 to 40 °C (50 to 104 °F)

Humidity: Dew Point of gas should be 1.7 °C (3 °F) below the ambient temperature (minimum)

Minimum Flow: 80 SLPM at 20 psig (1.38 bar)

Inlet Fitting: CGA DISS-type body, No. 1240

Low Pressure Connector

Pressure Range: 0 to 0.5 psig (0.0345) (Supply Oxygen)

Maximum Flow: 80 SLPM

Inlet Fitting: ¼ inch (5.14 mm) tapered

Electrical Supply

AC Power Supply

The ventilator operates within specification when connected to the following AC power supplies:

Voltage Range: (100 to 240 V AC)

Frequency Range: 50 to 60 Hz

DC Power Supply

The ventilator can also operate from a 48 VDC power source (internal battery).

Internal Battery:

The ventilator operates within specification for approximately 6 hours with a fresh, fully charged battery under moderate load. Maximum charge time for a full charge is 8 to 12 hours.

Data Output

Warning!

The Vela is designed to ensure that the user and patient are not exposed to excessive leakage current per applicable standards (UL 60601-1 and IEC 60601-1). However, this cannot be guaranteed when external devices are attached to the ventilator.

To prevent the risk of excessive enclosure leakage current from external equipment attached to the printer or video ports, the protective earth paths must be isolated to ensure proper connection.

This isolation should ensure that the cable shields are isolated at the peripheral end of the cable.

Remote Nurse Call

The ventilator has a modular jack configured to interface with external systems that are either wired for normally closed (NC, open on alarm) with the use of cable part # 15620, or normally open (NO close on alarm) signals with the use of cable part # 15619.

Fiber-optic Output

The ventilator provides a fiber-optic output connector, which allows for interfacing to an external patient monitor.

Printer

The ventilator has a standard 25-pin female Centronics parallel printer port on the rear panel which interfaces to an HP 940C printer.

Video Output

The ventilator provides a video output connector, which allows for interfacing to an externally located 256-color, 800 x 600, SVGA monitor.

Atmospheric & Environmental Specifications

Temperature and Humidity

Storage

Temperature: –20 to 60 °C (–4 to 140 °F)

Humidity: 10 to 95% RH non-condensing

Operating

Temperature: 5 to 40 °C (41 to 104 °F)

Humidity: 15 to 95% RH non-condensing

Barometric Pressure

Range: 760 to 545 mmHg

Physical Dimensions

Overall Size

13″ W x 14.5″ D x 12″ H (33.0 cm x 36.8 cm x 30.5 cm)

Weight

38 lb (17.3 kg)

Table 7.2 EMC Tables

60601-1-2 IEC:2001 (E) Table 201

Guidance and manufacturer's declaration – electromagnetic emissions		
The VELA Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the VELA Ventilator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The VELA Ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The VELA Ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Class A	
Voltage Fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

Table 202

Guidance and manufacturer's declaration - electromagnetic immunity			
The VELA Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the VELA Ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 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	± 6 kV for power supply lines ± 1 kV for input/output lines	± 6 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 differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95% dip in U_T) for 5 seconds	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. **Compliance is dependent on the operator following recommended charging and maintenance of the installed battery backup.**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 203

Guidance and manufacturer's declaration - electromagnetic immunity			
The VELA Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the VELA Ventilator should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz In ISM bands[a]	3 V 10 V	Portable and mobile RF communications equipment should be used no closer to any part of the VELA Ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.16\sqrt{P}$ $d = 1.20\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 occur in 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 medicinal) 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 is 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 FR transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VELA Ventilator is used exceeds the applicable RF compliance level above, the VELA Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VELA Ventilator.

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

Table 205

Recommended separation distance between portable and mobile RF communications equipment and the VELA Ventilator

The VELA Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VELA Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VELA Ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM bands $d = 1.16\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.20\sqrt{P}$	80 MHz to 800 MHz $d = 4\sqrt{P}$	80 MHz to 800 MHz $d = 7.66\sqrt{P}$
0,01	0.12	0.12	0.12	0.23
0,1	0.37	0.38	0.38	0.73
1	1.16	1.20	1.20	2.30
10	3.67	3.79	3.79	7.27
100	11.60	12.00	12.00	23.00

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 of the higher frequency range 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 is 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 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 C Glossary

Breath Interval	Elapsed time from the start of one breath to the start of the next.
Preset	An operator set ventilator parameter.
Trigger	Value at which the ventilator initiates delivery of a breath as a result of measured patient effort.
BTPS	Body Temperature at Ambient Pressure, Saturated.
ATPD	Ambient Temperature, Ambient Pressure, Dry.
Demand Flow	The flow generated by the ventilator to meet the patient's flow demand in order to maintain PEEP at the pre-set level.
AC	Alternating Current (mains electricity).
Bias Flow	A continuous flow through the patient breathing circuit.
bpm	Breaths per minute.
Breath Period	The length of time between machine-initiated breaths. Depends on the Breath Rate setting.
Breath Rate	The number of breaths delivered in a minute.
BTPD	Body Temperature at Ambient Pressure, Dry
Button	A push button switch used to toggle a function on or off.
cmH_2O	Centimeters of water pressure.
Controls	Any button, switch, or knob that allows you to modify the ventilator's behavior.
Event	An anomalous condition that occurs during ventilator operation.
Flow	The rate at which gas is delivered. Measured in liters per minute (lpm).
Indicators	A visual element showing operational status.
L	Liters. A unit of volume.
LED	Light Emitting Diode
lpm	Liters per minute. A unit of flow.
Mode	An operating state of the ventilator that determines the allowable breath types.
Monitored Parameter	A measured value displayed in the monitor window.
O_2	Oxygen
Patient Breathing Circuit	The tubing that provides the ventilatory interface between the patient and ventilator.
Paw	Airway Pressure. Measured in cmH_2O at the exhalation valve.
PEEP	Positive End Expiratory Pressure.

P_{peak}	Peak Inspiratory Pressure. Shows the highest circuit pressure to occur during inspiration as measured at the exhalation valve. The display is updated at the end of inspiration. P_{peak} is not updated for spontaneous breaths.
P_{plat}	Plateau Pressure. Measured during an Inspiratory Hold maneuver. Used to calculate Static Compliance. (Cst).
psig	Pounds per square inch gauge. 1 psig = .07bar
Sigh Breath	A Volume Controlled machine breath having a tidal volume equal to one-and-a-half times (150% of) the current tidal volume setting.
User Verification Tests (UVT)	A group of tests to check ventilator performance prior to connecting the ventilator to a patient.
WOB	Patient Work of Breathing i.e. a measure of Patient Effort.
$EtCO_2$	End Tidal CO_2 is the patient's peak expired CO_2 as measured and reported by the CO_2 sensor in the airway.
f/Vt	Rapid Shallow Breathing Index is the spontaneous breath rate per tidal volume.

Index

G

H

I

L

M

N

O

P

R

S

T

U

V

W

Vela™ Ventilator Diamond Series