

TV50

Ventilator

Operator's Manual



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Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

WARNING: It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

NOTE: This equipment must be operated by skilled/trained clinical professionals.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

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Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

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- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

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Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established. These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Responsibilities of Operators

The proper function of the ventilator can only be guaranteed if it is operated and serviced in accordance with the information provided in this manual and by an authorized Mindray service representative. Non-compliance with this information voids all guarantee claims.

The ventilator must be operated by qualified and trained personnel only. All operators must fully observe this operator's manual and relevant additional documentation. They must also comply with the WARNINGS, CAUTIONS, and NOTES detailed in this manual.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your ventilator.

Conventions

- ***Italic*** text is used in this manual to quote the referenced chapters or sections.
- [] is used to enclose screen texts.
- → is used to indicate operational procedures.

Password

A password is required to access different menus within the ventilator.

- System menu: 1234

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1.0

Safety

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1.1 Safety Information

WARNING — Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or property damage.

CAUTION — Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, product fault, damage or property loss.

NOTE — Highlights important precautions and provides descriptions or explanations for better use of this product.

1.1.1 Warnings

WARNING: The ventilator must be operated and used by authorized and well-trained medical personnel only. Unauthorized or untrained personnel shall never be allowed to perform any operations. The ventilator must be operated strictly following the Operator's Manual.

WARNING: The equipment, cables and accessories must be inspected before use to guarantee their proper and safe operation.

WARNING: To avoid the risk of electric shock, this equipment must be connected to a properly installed power outlet with protective earth terminal only. Do not use the power outlet if it is not connected to a protective earth terminal. Use the lithium ion batteries temporarily to supply power to the equipment.

WARNING: Use external power source before the batteries are depleted.

WARNING: Do not use the equipment in the presence of flammable or explosive materials to prevent fire or explosion. When O₂ is used, keep the ventilator away from any fire sources.

WARNING: Do not place the ventilator adjacent to any barrier, which may prevent cold air from flowing, resulting in equipment overheat.

WARNING: Do not open the case of the equipment, as you may suffer an electric shock. All servicing and upgrading operations of the equipment must be carried out by the service personnel trained and authorized by the manufacturer only.

WARNING: Set alarm volume and alarm limits based on the patient's actual condition. Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep an eye on the patient's actual clinical situations.

WARNING: The physiological parameters and alarm messages displayed on the screen of the equipment are for clinicians' reference only and cannot directly act as a basis for clinical treatment.

WARNING: Observe local applicable laws and regulations or hospital regulations on waste treatment to dispose of packaging materials. And keep the packaging material out of children's reach.

WARNING: All staff should be aware that disassembling or cleaning some parts of the ventilator can cause risk of infection.

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- WARNING:** The service mode can only be accessed when the equipment is disconnected from the patient.
- WARNING:** Positive pressure ventilation may be accompanied by some side effects such as barotrauma, hypoventilation, hyperventilation, etc.
- WARNING:** Using the ventilator in the vicinity of high frequency electrosurgery equipment, defibrillators or short-wave therapy equipment may impair normal functioning of the ventilator and endanger the patient.
- WARNING:** Do not use antistatic or conductive masks or patient tubings when high frequency surgical equipment is in use as this may cause burns.
- WARNING:** To avoid the risk of fire in the presence of sufficient oxygen, do not use the ventilator in a hyperbaric chamber.
- WARNING:** If the internal monitoring system in the equipment fails, an alternative plan must be in place to ensure adequate level of monitoring. The operator of the ventilator must be responsible for the patient's proper ventilation and safety under all circumstances.
- WARNING:** As required by the relevant laws and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If the ventilator is not configured with such monitoring function or this function is turned off, please use a monitor which complies with the requirements of ISO 80601-2-55 for oxygen concentration monitoring.
- WARNING:** All analog or digital devices connected to this system must be certified to the specified standards (such as IEC 60950-1 for data processing equipment and IEC 60601-1 for medical electrical equipment). All configurations shall comply with the valid version of IEC 60601-1. The personnel connecting the optional equipment to the I/O signal port shall be responsible for medical system configuration and system compliance with IEC 60601-1 as well.
- WARNING:** Do not touch the patient when connecting the peripheral equipment via the I/O signal ports, to prevent patient leakage current from exceeding the requirements specified by the standard.
- WARNING:** This equipment is not suitable for use in an MRI environment.
- WARNING:** When the ventilator's gas supply input system fails or has faults, please contact the manufacturer immediately for service by specified personnel.
- WARNING:** The ventilator should not be used with helium or mixtures with helium.
- WARNING:** Remove the support arm before moving the ventilator to prevent the ventilator from tipping.
- WARNING:** The oxygen and air gas mixer of the ventilator contains no grease and thus no de-grease process is needed. Do not use lubricants that contain oil or grease, and rubber hose assemblies should not be contaminated with grease. Oil- or grease-containing lubricants may burn up or explode when exposed to a high O₂ concentration.

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- WARNING:** The maximum pressure of hose is 1.4 MPa@21°C and please check whether its gas supply pressure meets hose requirements before usage.
- WARNING:** Hose connectors adopt standardized gas terminal connector with gas nature. Different types of gas and gas with different pressures shall not be exchanged with each other.
- WARNING:** Hose may be aging quickly by long-term exposure to acidity, alkalinity or ultraviolet rays.
- WARNING:** Do not cascade two or more hose assemblies together.
- WARNING:** The ventilator arm could bear 1kg maximally and do not hang over 1kg goods.
- WARNING:** After the ventilator is installed or the main control board is changed, reset the altitude. After the altitude setting is modified, please perform flow calibration (factory).
- WARNING:** When disconnecting fast connectors, please operate by two hands to prevent potential injury caused by sudden pressure release.
- WARNING:** Do not block the gas intake port or emergency intake port, thereby interfering with patient ventilation.
- WARNING:** To prevent interrupted operation of the ventilator due to electromagnetic interference, avoid using the ventilator adjacent to or stacking with other devices. If adjacent or stacked use is necessary, verify the ventilator's normal operation in the configuration to be used.
- WARNING:** Ensure that the ventilator is securely fixed to the trolley or placed on a safe and steady surface to prevent personal injury and equipment damage.
- WARNING:** Move the ventilator carefully around or through obstacles (such as thresholds) to prevent it from tipping or causing damage.
- WARNING:** Keep the brake down when the ventilator is moved into place to prevent unexpected movement of and damage to the equipment.
- WARNING:** Avoid the use of polluted air. When the equipment enables air supply for ventilation, harmful substances may enter the patient tubing if the air has been contaminated.
- WARNING:** When a [Technical Error **] alarm is triggered, remove the equipment, record the error code and contact the Customer Service Department immediately to prevent damage to the patient caused by equipment faults.
- WARNING:** Do not splash liquid onto the ventilator to prevent ventilator faults.
- WARNING:** Blower fan could cause gas to be heated. To reduce the temperature of gas inside the patient tubing and prevent patient injury accordingly, ensure that the length of patient tubing from the humidifier to the tubing connector is greater than 1.2 meters.

- WARNING:** The internal battery is to be used temporarily if the integrity of the protective earth conductor or the protective grounding system in the installation is in doubt.
- WARNING:** Nebulizers or humidifiers may increase the resistance of breathing system filters. For this reason, the operator shall keep an eye on the filter for increased resistance and blockage.
- WARNING:** Nebulization may impact the ventilation accuracy of the ventilator.
- WARNING:** For non-invasive ventilation, the patient's actual expiratory tidal volume is different from that monitored by the ventilator due to leakage around the facial mask.
- WARNING:** Check whether the alarm limits have been appropriately set before starting ventilation.
- WARNING:** Always connect the equipment to an easily accessible power socket if external power supply is used, so that the power plug can be disconnected conveniently and quickly in the event of a fault.
- WARNING:** No modification of this equipment is allowed.
- WARNING:** Stop using the ventilator immediately and contact the Customer Service Department when the buzzer sounds an alarm.
- WARNING:** Route the flow sensor cable to avoid the risk of patient entanglement or unintended extubation.
- WARNING:** System leakage, such as leakage caused by an uncuffed endotracheal tube, may influence airflow readings, including airflow parameters, pressure, CO₂ production, and other respiratory mechanics parameters.
- WARNING:** When the ventilator is connected to a patient, do not remove or replace the fuse, or perform any other maintenance tasks. Such operations must be performed when the patient is not using the ventilator.
- WARNING:** Ensure that the AC power cord is disconnected before removing or replacing the fuse.
- WARNING:** Hazard can exist if different alarm presets are used for the same or similar equipment in any single area. Please read the manual to confirm alarm presets for the ventilator before use.
- WARNING:** When the blower fails, the ventilator cannot supply gas to the patient.
- WARNING:** A fan failure could result in oxygen enrichment inside the ventilator and a subsequent fire hazard.
- WARNING:** If necessary, contact the manufacturer for the circuit diagram, list of parts and calibration instructions of products or other information related to equipment maintenance.

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- WARNING:** When the equipment is connected to other electrical equipment with specific functions, if it cannot be determined from the specifications of each equipment whether the combination is dangerous (for example, electric shock caused by the accumulation of leakage current), contact the manufacturer or experts in this field in the hospital to ensure that the necessary safety of all equipment in the combination is not compromised.
- WARNING:** Place the power cord and accessories carefully to avoid patient apnea, cable entanglement, or electrical interference.
- WARNING:** The copyright of the software of this device is solely owned by the company. No organization or individual shall commit any infringement, such as tampering, copying or exchanging, by any means or form without permission.
- WARNING:** Exercise caution when moving or resting the ventilator on a slope greater than 10°. Before moving, be sure to take out the objects on the basket and IV pole.
- WARNING:** When the ambient temperature is 50°C and the inspiratory pressure of the ventilator is at least 60 cmH₂O, the maximum temperature on the surface of breathing mask may exceed 51°C but not exceed 53°C.
- WARNING:** An additional multiple socket-outlet or extension cord should not be connected to the device.
- WARNING:** To prevent the high-voltage electric shock, the ventilator must be disconnected from the AC power supplier and batteries must be removed before the ventilator is disassembled.
- WARNING:** All the service parts for replacement, accessories and consumables are originals produced by Mindray or recognized by Mindray.
- WARNING:** Do not use the ventilator and sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns to the patient.
- WARNING:** Refer to the humidifier accompanying operator's manual to install and use the humidifier.
- WARNING:** Do not perform the CO₂ zeroing in direct sunlight.
- WARNING:** When the ventilator is used in rescue vehicles, fixed wing aircraft or helicopter, it must always be appropriately secured during transport.
- WARNING:** Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.
- WARNING:** Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.

WARNING: The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.

1.1.2 Cautions

CAUTION: The ventilator must be inspected and serviced regularly by trained service personnel.

CAUTION: Always prepare a respirator as a backup to ensure patient safety.

CAUTION: Always have a dedicated person attend and monitor the operations on the equipment once the ventilator is connected to the patient.

CAUTION: During the operation of the ventilator, do not disassemble the expiration valve unless in standby status.

CAUTION: Use only the accessories specified in this manual to ensure patient safety.

CAUTION: Dispose of the equipment and its accessories that approach the end of service life in compliance with applicable local laws and regulations or hospital regulations.

CAUTION: Electromagnetic field may affect the equipment performance. Therefore, other devices used in the vicinity of the equipment must meet corresponding EMC requirements. Mobile phone, X-ray or MRI devices are possible sources of interference as they may emit higher levels of electromagnetic radiation.

CAUTION: This system is capable of operating properly at the interference levels indicated in this manual. Higher levels of interference may trigger alarms and even stop mechanical ventilation. Please keep the equipment away from high-intensity electric fields which may cause the system to issue false alarms.

CAUTION: Ensure that the voltage and frequency of the power supply fall into the specified ranges on the equipment's label or in this manual before connecting the equipment to a power supply.

CAUTION: Always install or transfer the equipment carefully to prevent the it from fall, collision, violent vibration or other damage from external mechanical force.

CAUTION: Check whether the reusable patient tubing is damaged or leaky before use. If so, do not use it.

CAUTION: Please disconnect the power plug of the ventilator to electrically isolate the ventilator circuits from all electrodes of the input power.

CAUTION: To minimize the risk of fire, do not use gas supply hose assemblies that are worn or contaminated with combustible materials (such as grease or oil).

CAUTION: Clinicians are responsible for ensuring that all ventilator settings are appropriate.

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- CAUTION:** Ensure that the ventilator is set up for appropriate patient type with the proper patient tubing to prevent possible patient injury. Ensure that the System Check is performed before each patient.
- CAUTION:** Perform pressure zeroing before use of the ventilator, or when the measured values have deviations.
- CAUTION:** Ensure that the ventilator's ventilation parameters have been properly set before starting ventilation to prevent injury to the patient.
- CAUTION:** When ventilating with a mask, avoid high airway pressures. High airway pressure may lead to gastric distension.
- CAUTION:** In non-invasive ventilation, $P_{peak} > 33$ cmH₂O may increase the risk of gastric insufflation. When ventilating at such a pressure, please consider using an invasive ventilation mode.
- CAUTION:** Use only the hoses that have been approved to serve medical purposes and for connection with oxygen supplies and the ventilator to reduce the risk of fire.
- CAUTION:** Ensure the ventilation at the rear side of the ventilator to reduce the risk of fire.
- CAUTION:** Switch off the oxygen supply when the ventilator is not in a ventilating mode to reduce the risk of fire.
- CAUTION:** Avoid storing the ventilator in an environment that is higher than 50°C in temperature for a long time. Such an environment may damage the internal batteries or shorten their service lives.
- CAUTION:** Use the original packaging materials to ship the ventilator.
- CAUTION:** Use only the specified fuses or the fuses of the same type, rated voltage, and rated current with the current fuses to prevent the risk of fire. Contact the Customer Service Department when it is necessary to replace the fuse.
- CAUTION:** The ventilator is applicable to the patient environment.
- CAUTION:** Additional multi-hole sockets or extension cords shall not be connected to the system.
- CAUTION:** Before moving the ventilator, ensure that the casters and brakes can work properly, and the main unit is locked on the trolley.
- CAUTION:** If the ventilator is used in a toxic or infectious environment, the patient should inhale 100% medical grade oxygen so that toxic substances or viruses cannot enter the breathing gas. The patient must be transported immediately to a breathable environment to prevent inhalation of toxic or infectious gases when spontaneous breathing is resumed.
- CAUTION:** To ensure that the backup battery is available when the ventilator is operating in the emergency transfer scenario, keep the battery in place when the ventilator is operating.
- CAUTION:** Always keep the battery fully charged for safety reasons. Even when using external power supply, sudden power failure may cause data loss.

- CAUTION:** Check the oxygen cylinder pressure before use to prevent insufficient oxygen supply during use.
- CAUTION:** When using the device in a very high temperature environment, avoid inflow of air. Set the oxygen concentration to 100%. If the patient inhales overheated gas, lung injury will occur. The patient must be transported immediately to a breathable environment to prevent lung injury due to inhalation of overheated gases.
- CAUTION:** Do not use the equipment beyond the specified environment and gas supply (or power supply) range. The operation of the equipment may not meet the specifications.
- CAUTION:** The ventilator should be installed on the portable gas cylinder bracket for the outdoor emergency transfer scenario. For ambulance use, it can be fixed by the dock. For indoor use, accessories can be selected according to requirements.
- CAUTION:** The ventilator is electrically driven and electronically controlled, and it is driven by the blower motor to form a stable air-oxygen mixture. For details, see *A.1 Pneumatic Circuit Principle*. The supplied tidal volume or minute volume and O₂ concentration are affected by the pressure at the patient connector.
- CAUTION:** Some settings are protected by passwords. Password changes must be performed by authorized personnel. If you need to obtain a password to access these functions, please contact relevant personnel.
- CAUTION:** Dry the equipment immediately after rain or water splashing.
- CAUTION:** External exhaust outlets of ventilator shall not be located to place which has any electrical component.
- CAUTION:** Soiling caused by dust may compromise the functional integrity of the device. Do not use the ventilator without a dust filter.
- CAUTION:** Use in rescue vehicles, fixed wing aircraft, or helicopter may increase the risk of auto triggering. Adjust flow trigger if needed.

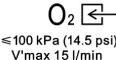
1.1.3 Notes

- NOTE:** Put the ventilator and its components in a location that facilitates observation, operation and maintenance.
- NOTE:** Keep this manual close to the equipment so that it can be obtained conveniently when needed.
- NOTE:** The software of the equipment was developed in compliance with the IEC 62304, with potential risks from program errors minimized.
- NOTE:** This manual describes the product for the purpose of fully covering its functions and configuration options, and the product you have purchased may not support part of these functions or configuration options.

- NOTE:** When the oxygen supply is insufficient, the ventilator automatically switches to the blower to supply the patient with ambient air.
- NOTE:** In normal use, the operator should stand in front of the equipment.
- NOTE:** The ventilator returns to normal in 10 seconds after defibrillation.
- NOTE:** According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Besides, the residual risks are disclosed in the corresponding chapter of this manual as warnings or cautions.
- NOTE:** The time between two uses from the minimum or maximum storage temperature to ready for normal operation of the ventilator is approximately 1 hour.

1.2 Device Symbols

1.2.1 Symbols on the Ventilator/Package/Labeling

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Caution		Warning
	Fuse		Protective earth (ground)
	Battery LED		AC/DC power supply
	USB connector		Network connector
 ≤100 kPa (14.5 psi) V _{max} 15 l/min	Low-pressure O ₂ supply connector	 280-650 kPa (41-94 psi) V _{max} 200 l/min	High-pressure O ₂ supply connector
	Locking/unlocking		No pushing
	Inspiration connector		AUDIO PAUSED key
	Date of manufacture		Manufacturer

	Keep dry		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation
	This way up		Fragile, handle with care
	Recyclable		Stacking limit by number
	Ventilator gas inlet		Ventilator gas outlet
	Serial number		Unique Device Identifier
	Defibrillation-proof type BF applied part		Rechargeable battery
	Class II equipment		Standby key
	Medical Device		Refer to instruction manual/booklet
	Flow sensor		Polarity of d.c. power connector
	Expiratory valve		
	Authorized representative in the European community		

IP22

IP22: protected against ingress of foreign objects no less than 12.5 mm and against access to hazardous parts with a finger; protected against harmful effects of vertically falling water drops with the device tilted at any angle up to 15°.

IP33

IP33: protected against ingress of foreign objects no less than 2.5 mm, and against access to hazardous parts with a tool; protect against harmful effects of spraying water.

IP34

IP34: protected against ingress of foreign objects no less than 2.5 mm, and against access to hazardous parts with a tool; protect against harmful effects of splashing water.



The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it.

* For system products, this label may be attached to the main unit only.



This product is provided with a CE marking in accordance with the regulations stated in Regulation (EU) 2017/745 or the Council Directive 93/42/EEC concerning Medical Devices. The number adjacent to the CE marking (0123) is the number of the EU-notified body certified for meeting the requirements of the Regulation.

1.2.2 Interface Symbols

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	AUDIO PAUSED		Alarm limits off
	Recent alarms		Number of alarms
	Alarm settings		Screenshot
	USB connected		USB disconnected
	Invasive ventilation		Non-invasive ventilation
	Network connected		Network disconnected
	WLAN connected		WLAN disconnected
	5G connected		5G disconnected

	Adjust screen brightness/volume to day mode		Adjust screen brightness/volume to night mode
	Adult		Pediatric
	Infant		Bluetooth
	Battery display (disconnected with external power supply)		Battery display (connected with external power supply)
	Outdoor mode icon		No battery

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

GEOMETRIC SHAPE	MEANING	SAFETY COLOR	CONTRAST COLOR	GRAPHICAL SYMBOL COLOR
	Prohibition	Red	White	Black
	Mandatory action	Blue	White	White
	Warning	Yellow	Black	Black

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2.0

The Basics

Introduction	2-2
Product Appearance	2-3

2.1 Introduction

2.1.1 Intended Use

2.1.1.1 Intended Purpose

The ventilator is intended for providing ventilation assistance and breathing support for patients.

2.1.1.2 Intended Users

The ventilator must only be operated and used by authorized medical personnel well trained in the use of this product. It must be operated strictly following the Operator's Manual.

2.1.1.3 Intended Patient Population

The ventilator can be used in adult, pediatric and infant patients.

2.1.1.4 Intended Medical Conditions

For prolonged periods of ventilation and respiratory support for patients with apnea or respiratory failure, patients are fully dependent on or partly dependent on such equipment. This product is intended to be used in intensive care situations within a professional healthcare facility, or during transport within a professional healthcare facility and emergency medical services environment such as in ambulances or aircraft, etc.

2.1.1.5 Contraindications

There are no absolute contraindications for this product. For some special diseases, however, some necessary treatments shall be taken for ventilator mechanical ventilation, or special ventilation modes shall be adopted to prevent possible patient injury.

2.1.2 Product Description

The ventilator consists of a main unit (including the pneumatic circuit, the electronic system, the mechanical structure, the display and the CO₂ module), a trolley and a support arm.

The ventilator is applicable to the patient environment. Connect the patient to the ventilator via the patient tubing. Applied parts of the ventilator include CO₂ module accessories, patient tubings and masks.

2.2 Product Appearance

2.2.1 Front View

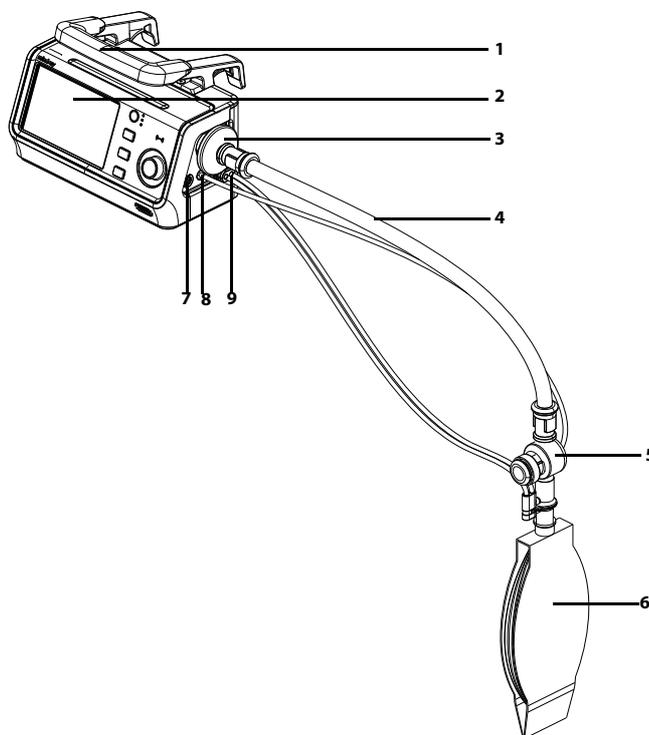


Figure 2-1 Front View

NO.	COMPONENT	DESCRIPTION
1	Handle	Used to carry the ventilator.
2	Display	/
3	Inspiratory filter	/
4	Patient tubing	/
5	Expiration valve	/
6	Test lung	For System Check or Flow Calibration.
7	Mainstream CO2 module connector	/
8	Expiratory valve port	/
9	Flow sensor port	/

Table 2-1 Components List

2.2.2 Rear View

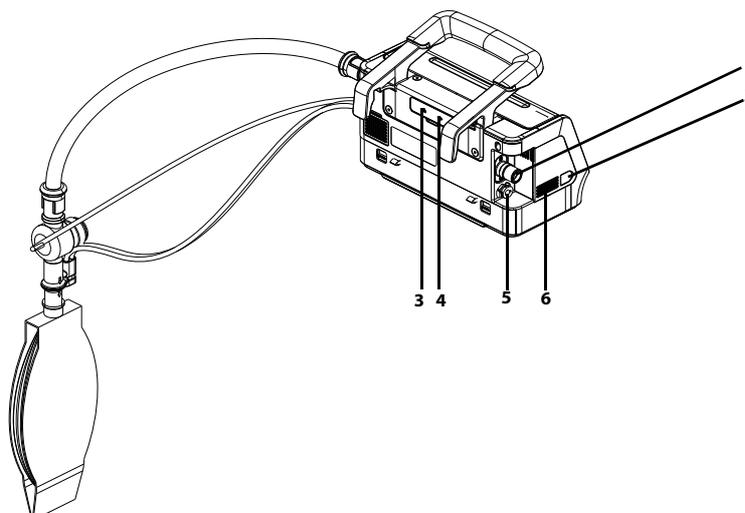


Figure 2-2 Rear View

NO.	COMPONENT	DESCRIPTION
1	High-pressure O2 supply inlet	Connects to high-pressure O2 supply.
2	DC power connector	/
3	Network connector^a	RJ45 connector, supporting wired network 10 M/100 M, and complied with technical standard IEEE 802.3. It can connect to a PC to perform software upgrading and synchronize time with external device through SNTP protocol. It complies with Mindray internal protocol, HL7 protocol and SNTP protocol. The intended information flow is between the PC and the ventilator. The connector must be used by the specified service personnel.

Table 2-2 Components List

NO.	COMPONENT	DESCRIPTION
4	USB connector	Type A connector, complied with USB 3.0 standard. It can upgrade the software for ventilator; export captured screen, configuration information and historical data (such as patient data, alarm log, and calibration table); transfer configuration data between machines of the same type; provide power to the electronic nebulizer and connect to the mouse or U disk; connect to the calibration devices (such as VT Plus or PF300). The intended information flow is between the ventilator and the U disk. The connector must be used by the specified service personnel.
5	Low-pressure O2 supply inlet	Connects to low-pressure O2 supply.
6	HEPA filter inlet	/

Table 2-2 Components List

- a. *In addition to the wired network, the ventilator also configures with wireless network. Wireless network and mobile cellular network:*
- Mobile cellular network:**
It can connect with central monitoring system and communicate with the central monitoring system.
Supported 4G operating frequency: LTE FDD: B1/B3/B7/B8/B20/B28A, LTE TDD: B38/B40/B41, WCDMA: B1/B8, and GSM: B3/B8.
Supported 5G operating frequency: 5G NR: n1/n2/n3/n5/n7/n8/n12/n20/n28/n38/n40/n41/n48/n66/n71/n77/n78/n79, LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B9/B12/B13/B14/B17/B18/B19/B20/B25/B26/B28/B29/B30/B32/B66/B71, LTE-TDD: B34/B38/39/B40/B41/B42/B48.
It complies with Mindray internal protocol.
The intended information flow is from the ventilator to the central monitoring system.
The mobile cellular network must be used by the specified service personnel.
- Wireless network:**
It can connect to the external medical and information device; comply with the technical standard IEEE 802.11 a/b/g/n/ac and synchronize time with external device through SNTP protocol.
It complies with Mindray internal protocol, HL7 protocol and SNTP protocol.
The intended information flow is between the ventilator and the external information device.
The wireless network must be used by the specified service personnel.

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Installations and Connections

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WARNING: Do not use antistatic or conductive masks or patient tubings when high frequency surgical equipment is in use as this may cause burns.

WARNING: To ensure optimum performance of the ventilator, re-do System Check each time when accessories or components like patient tubing, humidifier, and filter are replaced.

WARNING: Adding accessories or other parts or components to the breathing system of the ventilator may increase the system's inspiratory and expiratory resistance.

3.1 Connecting the Power Supply

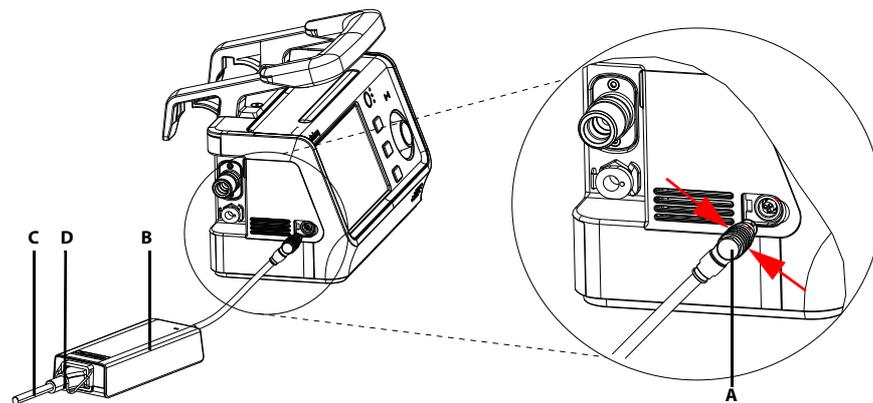


Figure 3-1 Connecting the Power Supply

- A.** DC power input connector
- B.** AC adapter
- C.** AC power cord of adapter
- D.** Anti-unplugging hook of power plug

- 1.** Align the red dot on the DC power input connector to the red dot beside the power interface of the main unit. When you hear a "snap" sound, the connector is installed in place.
- 2.** Plug one end of the AC power cord into the AC adapter, buckle the power cord with an anti-unplugging hook, and plug the other end into the AC power socket.

When unplugging the DC power input connector from the main unit, pinch the two sides of the red dot of the connector and then unplug it.

WARNING: Do not use the AC adapter outdoors.

3.2 Connecting the Gas Supply

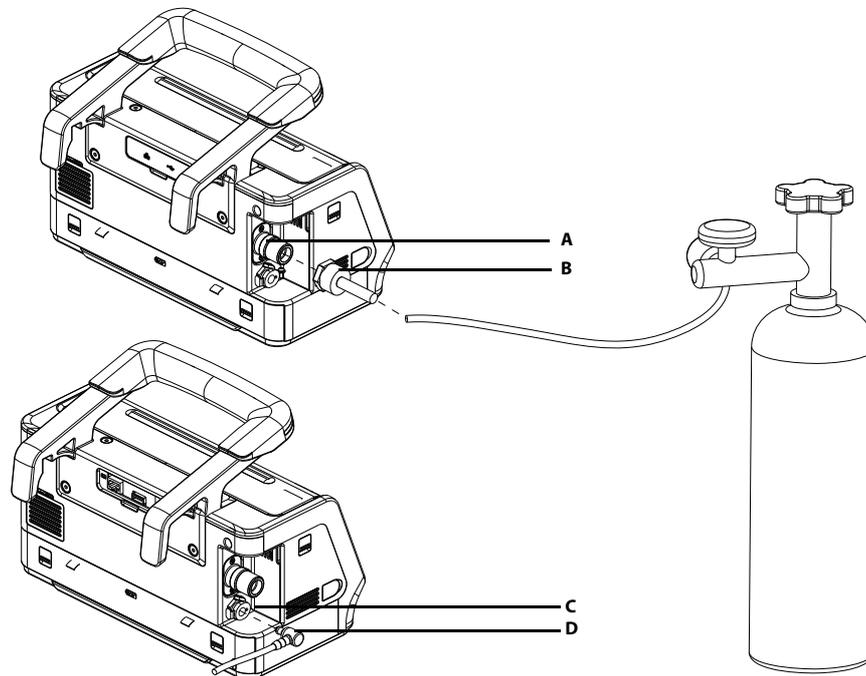


Figure 3-2 Connecting the Gas Supply

- A.** High-pressure O₂ supply connector
- B.** High-pressure O₂ supply hose and fitting
- C.** Low-pressure O₂ supply connector
- D.** Low-pressure O₂ supply hose

This ventilator provides two types of gas supply connection: high-pressure O₂ and low-pressure O₂.

When the ventilator is connected to high-pressure O₂ supply, the gas supply pressure is 280 to 650 kPa in normal working condition. If gas supply pressure is less than 280 kPa, it will compromise the performance of the ventilator and even stop ventilation. If gas supply pressure is within 600 to 1000KPa, it will compromise the performance of the ventilator but will not cause any hazard due to high-pressure gas. Connect the high-pressure O₂ supply as follows.

- 1.** Check if the sealing ring at the gas supply connection is in good condition before connecting the gas supply hose. If the sealing ring is damaged, do not use the hose. Replace the sealing ring to prevent leakage.
- 2.** Align the connector with and insert it into the inlet of high-pressure O₂ supply of the ventilator.

3. Ensure that the gas supply hose is properly connected to the gas supply inlet and tighten the hose nut by hand.

When the ventilator is connected to low-pressure O₂ supply, the flow of low-pressure O₂ supply cannot exceed 15 L/min. To reduce the risk of fire, do not use a low-pressure O₂ supply that delivers a flow greater than 15 L/min.

To connect the low-pressure O₂ supply, align the low-pressure O₂ supply hose with and insert it into the low-pressure O₂ supply connector. When a click is heard, it indicates that the gas supply hose is inserted in place. Depress the metal dome on the low-pressure O₂ supply connector to remove the gas supply hose.

WARNING: Inspect the O₂ supply connector carefully and ensure that there is no leakage. If gas leakage is significant, O₂ concentration in the ambient environment will exceed normal O₂ concentration in atmosphere, resulting in potentially dangerous O₂ enriched environment.

WARNING: Place the O₂ supply hose carefully, avoiding exposure to the environment in which possible damage to the supply hose is easily caused by cut or heating.

WARNING: To reduce the risk of fire, do not use a low-pressure O₂ supply that delivers a flow greater than 15 L/min.

WARNING: To prevent oxygen accumulation in and around the ventilator, ensure that the low-pressure O₂ supply is disconnected when the ventilator is not in working condition.

CAUTION: When the ventilator is sourced from an oxygen concentrator, never operate the concentrator with a humidifier. Any humidifier system supplied with the concentrator must be drained or removed before using the ventilator.

CAUTION: The setting of oxygen concentration is invalid when using the low-pressure O₂ supply. To prevent possible patient injury, use the low-pressure O₂ supply only when it can provide sufficient oxygen.

CAUTION: Before starting ventilation, ensure the appropriate oxygen source, either high-pressure oxygen (HPO) or low-pressure oxygen (LPO), was selected during configuration, referring to 5.3.10 Setting O₂ Supply Type.

CAUTION: To prevent possible patient injury, ensure an emergency backup O₂ supply (such as a gas cylinder) is available in case the low-pressure O₂ supply fails.

CAUTION: The low-pressure O₂ supply hose assembly shall comply with the requirements of ISO 5359.

3.3 Installing the Pump Holder

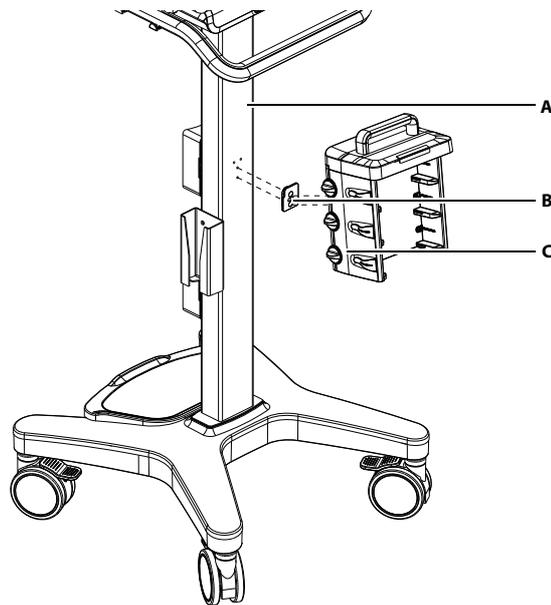


Figure 3-3 Installing the Pump Holder

- A.** Trolley
- B.** Pump holder
- C.** Infusion pump or syringe pump

Align the pump holder to the installing hole and tighten the locking nut. After the installation, the infusion pump or syringe pump can be hung. Do not hang more than 3 pumps.

Note: This ventilator cannot support simultaneous installation of the infusion/syringe pump and humidifier.

3.4 Installing the Patient Tubing

- WARNING:** To minimize the risk of bacterial contamination or physical damage, remove and install the bacterial filter with care.
- WARNING:** To prevent patient or ventilator contamination, always use a bacteria filter between the ventilator and the patient inspiratory limb.
- WARNING:** To prevent condensation, keep the flow sensor tubing upward when installing and using the flow sensor.
- CAUTION:** The use of an expiratory filter may lead to a significant increase in expiratory resistance. Excessive expiratory resistance may compromise ventilation and increase patient's work of breathing and intrinsic PEEP.
- CAUTION:** The patient tubing shall comply with the requirements of ISO 5367.
- CAUTION:** The bacteria filters shall comply with the requirements of ISO 23328- 1 and ISO 23328- 2.
- CAUTION:** The Heat & Moisture Exchange (HME) shall comply with the requirements of ISO 9360- 1 and ISO 9360- 2.

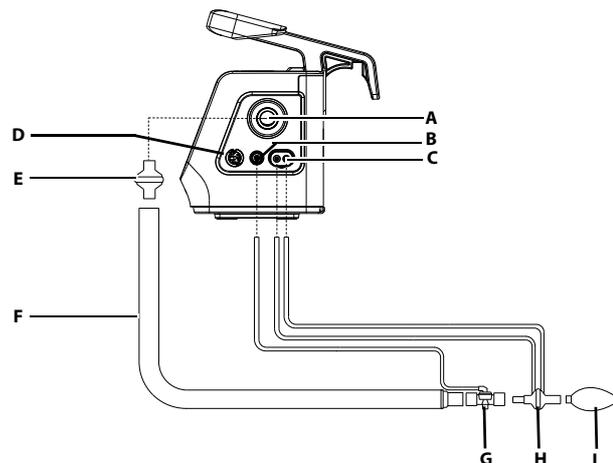


Figure 3-4 Installing the Patient Tubing

- | | |
|--|----------------------------|
| A. Inspiratory port | F. Patient tubing |
| B. Expiratory valve port | G. Expiratory valve |
| C. Flow sensor port | H. Flow sensor |
| D. Mainstream CO ₂ module port | I. Test lung |
| E. Bacteria filter | |

1. Install the bacteria filter onto the inspiratory port of the ventilator.
2. Connect one end of the patient tubing to the bacterial filter of the inspiratory port of the ventilator and the other end to the expiratory valve.
3. Connect the expiratory valve tubing to the expiratory valve port of the ventilator and connect the other end of the expiratory valve to the flow sensor.
4. Connect one end of the flow sensor sampling line to the flow sensor port and the other end to the test lung.

3.5 Installing the Electronic Nebulizer

NOTE: Install the specified nebulizer. The nebulizer assembly and its installation steps described in this section are only for reference. Refer to the nebulizer accompanying directions for use to install and use the nebulizer.

NOTE: To prevent the expiration valve from sticking due to nebulized medications, use only medications approved for nebulization, and regularly check and clean or replace the expiration valve membrane. For the disposable expiration valve, regularly check and replace the expiration valve as required.

NOTE: Do not use a Heat & Moisture Exchange (HME) in the patient tubing during nebulization.

NOTE: Nebulization of drugs may cause increased resistance or occlusion of the expiratory filter. Check the filter frequently and replace if expiratory resistance increases.

NOTE: Connect the nebulizer to the inspiratory limb. Connecting the nebulizer between the patient connector and the endotracheal tube increases dead space ventilation.

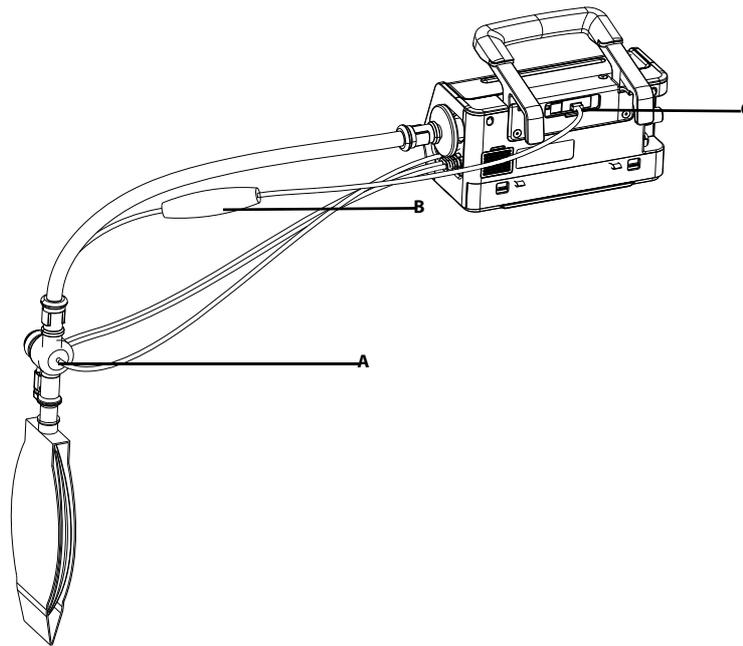


Figure 3-5 Installing the Electronic Nebulizer

- A.** Nebulizer
- B.** USB controller
- C.** USB connector

- 1.** Insert the USB connector of USB controller into the USB connector below the display.
- 2.** Connect the nebulizer with the patient tubing. Refer to the nebulizer accompanying operator's manual for the details.

During nebulization, aerosolized medicament is inhaled by the patient for the purpose of therapy.

WARNING: Keep the electronic nebulizer upright while attaching to the patient tubing. This orientation prevents patient secretions and condensates from contaminating the aerosol generator of the nebulizer and ensure proper nebulization.

WARNING: Refer to the nebulizer accompanying directions for use to install and use the nebulizer.

WARNING: Remove the mainstream CO₂ module adapter from patient tubing before initiating nebulization. CO₂ cannot be measured in the aerosol drug environment.

WARNING: Aerosolized medication may occlude the expiration valve and flow sensor. Please have them checked and cleaned after nebulization.

WARNING: During use of the electronic nebulizer, pay attention to the connection of the nebulizer to prevent interruption of nebulization.

WARNING: To prevent the exhalation valve from sticking due to nebulized drugs, use only drugs that are approved for nebulization, and inspect and clean or replace the exhalation valve membrane regularly.

CAUTION: Remove the nebulizer after completing nebulization, otherwise ventilation may be affected.

CAUTION: The remaining nebulized drug will affect the surrounding air.

3.6 Installing the Cylinder Assembly

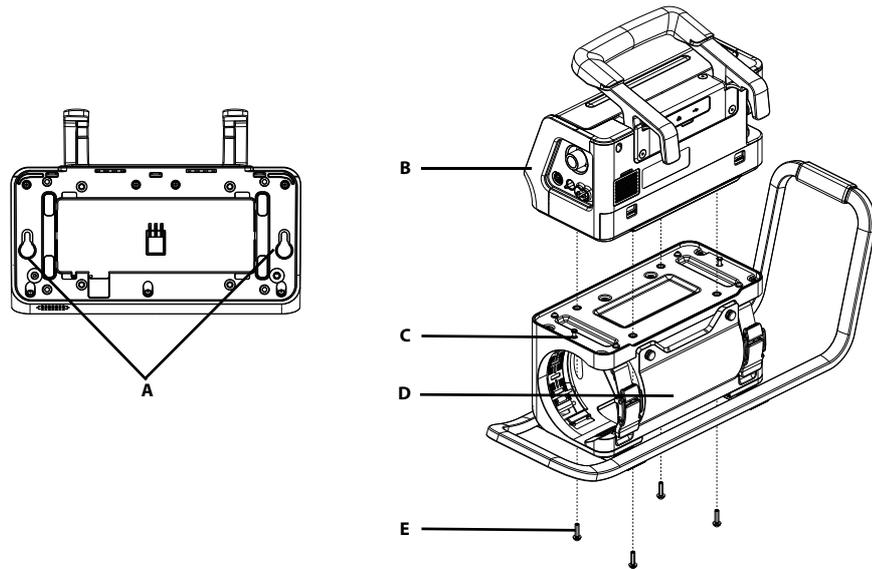


Figure 3-6 Install the Cylinder Assembly

- A.** Anti-fall opening at the bottom of the main unit
- B.** Main unit
- C.** Anti-fall column
- D.** Cylinder assembly
- E.** Screw

- 1.** Install the smaller end of the anti-fall opening at the bottom of the main unit by aligning with the anti-fall column and slide the hole to the larger end.
- 2.** Use four screws to lock the main unit and the cylinder bracket from the bottom of the cylinder assembly.

To remove the main unit from the gas cylinder assembly, loosen the four screws, slightly lift the main unit to separate it from the gas cylinder bracket, slide out the anti-fall opening and then extract it upward.

3.7 Replacing the Portable Gas Cylinder

CAUTION: Ensure that the oxygen cylinder is equipped with a pressure relief valve.

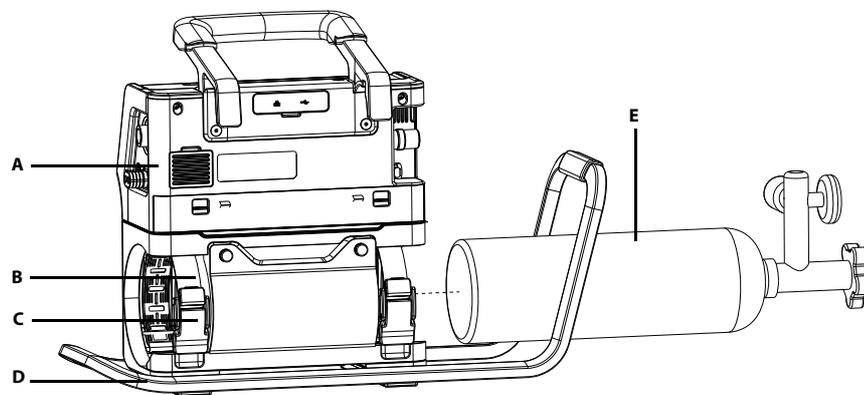


Figure 3-7 Replacing the Portable Gas Cylinder

- A.** Main unit
- B.** Cylinder fixing buckle
- C.** Fastening wrench
- D.** Portable gas cylinder bracket
- E.** Gas cylinder

- 1.** Disconnect the main unit from the pipe of the gas cylinder.
- 2.** Lift the fastening wrench and loosen the cylinder fixing buckle, and then take the cylinder out.
- 3.** Put the new cylinder into the cylinder assembly from the arch of the elbow, tighten the fixing buckle of the cylinder, and pull down the fastening wrench to tighten the cylinder.

The portable gas cylinder bracket is used to fix and carry the oxygen cylinder, and the bracket can be connected with the main unit of the ventilator to realize the integration of the main unit of the ventilator and the oxygen cylinder, and provide ventilation support with higher oxygen concentration for patients in time.

WARNING: When installing and replacing the oxygen cylinder, tighten the rotary switches on the oxygen cylinder and pressure relief valve by hand. Do not use tools to avoid damage to screw threads and sealing materials, which may cause leakage.

The accessory carrying bag can be hung onto the portable gas cylinder bracket. The accessory carrying bag can be used to carry and store the ventilator-related accessories, including the patient tubing, flow sensor, tube protective case, and test lung. Before replacing the gas cylinder, you need to lift the bag to take it out, and then loosen the cylinder fixing buckle.

NOTE: The accessory carrying bag is not waterproof. Avoid contact of ventilator accessories with liquid when storing.

NOTE: Do not use a washing machine to wash or dry the accessory carrying bag.

Use the accessory carrying bag as follows:

1. Align the two magnetic snap fasteners on the back of the accessory carrying bag with the buttons on the back of the cylinder assembly. The accessory carrying bag can be automatically interlocked from any direction. A click indicates that the bag is connected to the machine.
2. According to the silkscreen on the accessory carrying bag, pull the handle upwards vertically close to the inside of the gas cylinder assembly to quickly remove the accessory carrying bag.

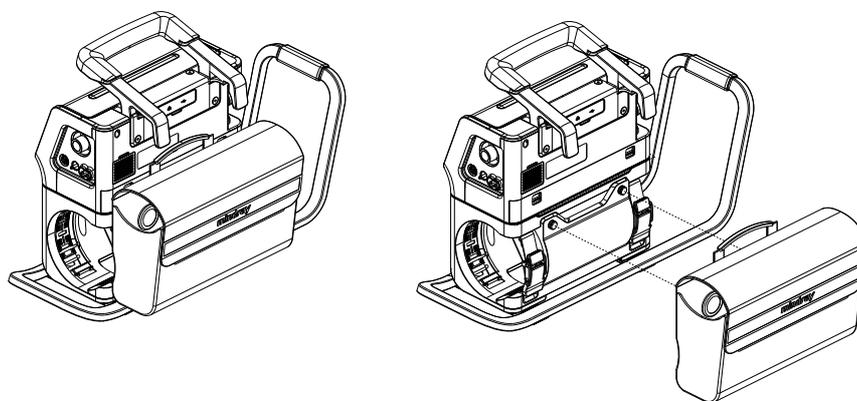


Figure 3-8 Using the Accessory Bag

3.8 Installing the Dock

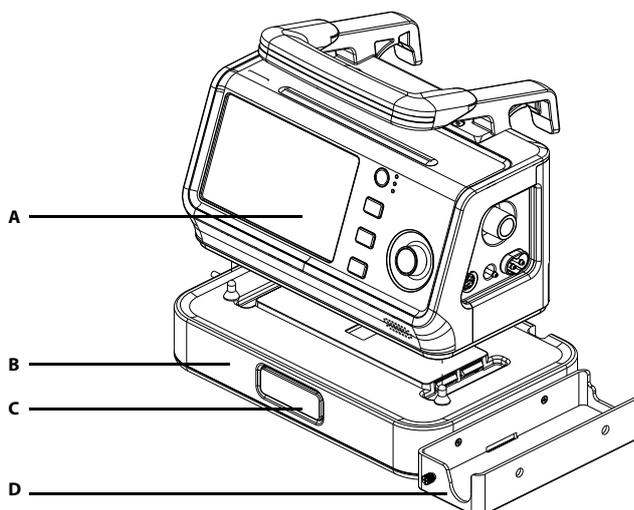


Figure 3-9 Installing the Dock

- A. Main unit
- B. Dock
- C. Unlock button
- D. AC adapter holder

1. Align the main unit with the slot on the dock and place it on the dock.
2. Connect the AC adapter.

To remove the main unit from the dock, press the unlock button on the dock with one hand, and lift the main unit with the other hand simultaneously.

When the ventilator is bumped or shaken (such as on an ambulance), secure the ventilator with a dock to prevent excessive movement or accidental fall of the equipment during transfer.

3.9 Attaching to the Rail System

This device can be attached to rail systems or stretcher bars with diameters not exceeding 38 mm by a rail holder. During installation, ensure that there is a distance of at least 60 mm between the rail and the wall. Attach the device to a position that suitable for the patient.

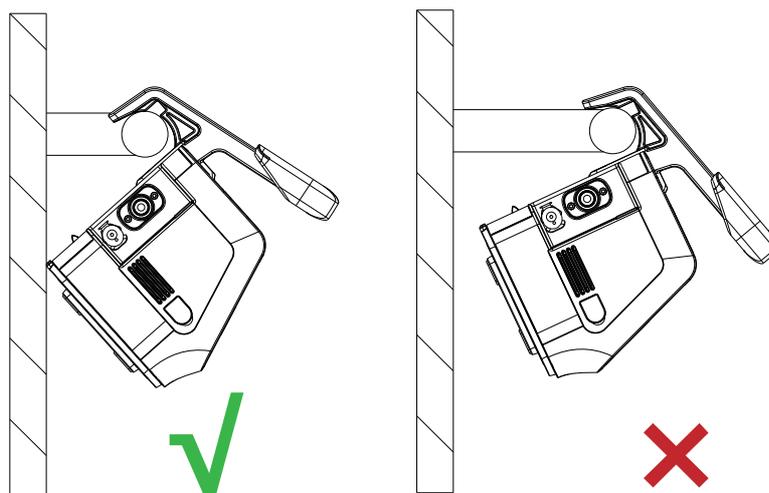


Figure 3-10 Attaching to the Rail System

WARNING: When transporting the ventilator with the rail holder, follow the wall clearance requirements and use other methods (such as Dock or fixing bracket) to secure or protect the device to prevent accidental loosening and falling.

User Interface

Display Controls.....	4-2
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4.1 Display Controls

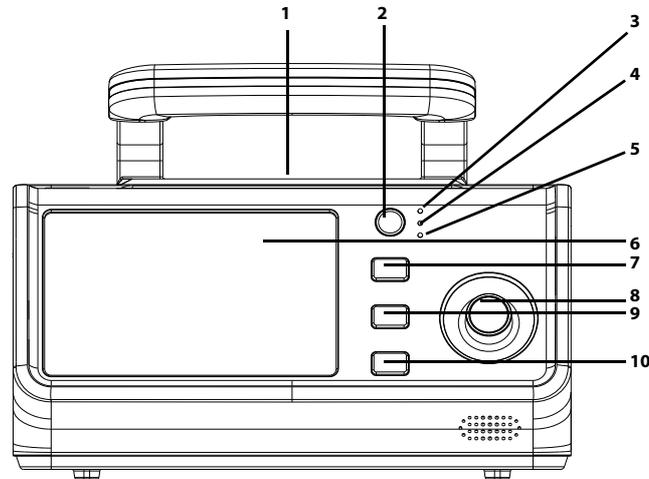


Figure 4-1 Display Controls

The control unit is composed of a small number of operating components. Main operating components are:

- 1. Alarm indicator**
The alarm indicator indicates different levels of alarms with different colors and flashing frequencies when an alarm is triggered.
- 2. Power switch (with indicator)**
You can press the key to power on/off the system. The indicator is on when the ventilator is powered on and off when the ventilator is powered off.
- 3. External power indicator**
 - Lit: when the ventilator is connected to an external power supply.
 - Not lit: when the ventilator is not connected to an external power supply.
- 4. Ambient light sensor**
When screen brightness is set to auto, the system automatically adjusts screen brightness according to the ambient light intensity.
- 5. Battery indicator**
 - Lit: indicates that the battery is being charged or is already fully charged, and the ventilator is operating on external power supply.
 - Flashing: indicates that the ventilator is being powered by the batteries.
 - Not lit: indicates that the ventilator is not connected to an external power supply, or that the ventilator does not have a battery installed, or that there is a fault with the battery.
- 6. Display (touch screen)**
The display shows the software interface of the ventilator system. You can select and change settings by touching the screen.

- 7. Outdoor mode/Power-off battery level display**
When the ventilator is powered on, this button displays the icon . Press this key to enter/exit the outdoor mode. When the ventilator is shut down, this button displays the remaining battery level icon .
- 8. Control knob**
Press the control knob to select menu items or confirm settings. Rotate the knob clockwise or anticlockwise to scroll through menu items or change settings.
- 9. Lock screen button**
Press the lock screen button to lock or unlock the screen.
- 10. AUDIO PAUSED key**
Press to initiate the AUDIO PAUSED for 120 seconds, so that audible alarm tones of the active alarms are switched off. The system automatically exits the AUDIO PAUSED state after 120 seconds and resumes the prompt tone of alarms. If a new alarm is triggered when the AUDIO PAUSED state is on, the system automatically exits the AUDIO PAUSED state and sounds the prompt tone of the new alarm. You can press the key again in the AUDIO PAUSED state to cancel the AUDIO PAUSED state.

The ventilator display shows ventilation parameters and pressure/flow/volume waveforms, etc. The following is a general layout of the main screen.

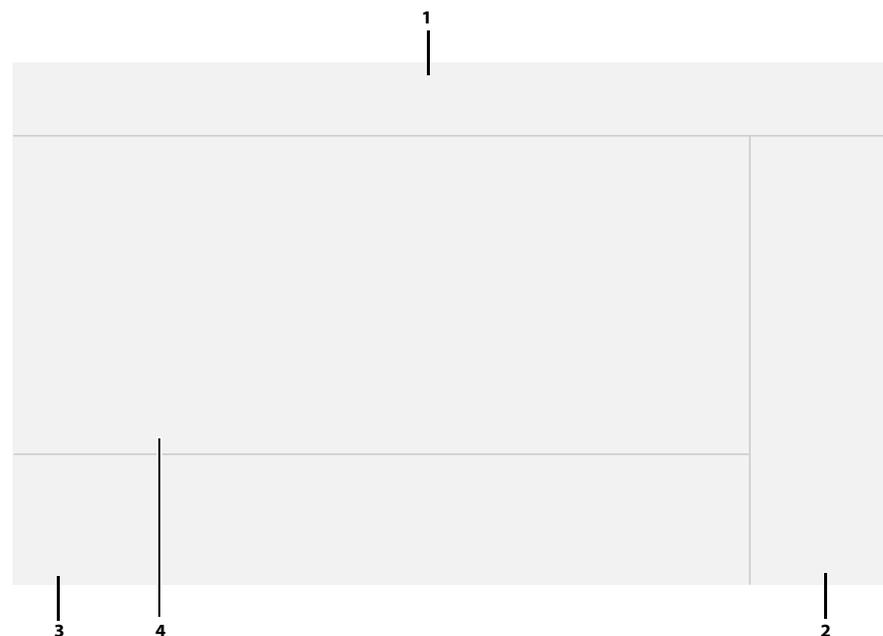


Figure 4-2 Main Screen

NO.	MAIN SCREEN	DESCRIPTION
1	Icon field	<p>It displays the following information:</p> <ul style="list-style-type: none"> • Ventilation mode icon: shows the current ventilation mode. Setting the ventilation mode is allowed. • Ventilation type icon: displays the icon  when the ventilation type is non-invasive; displays the icon  when the ventilation type is invasive. • Patient type icon. • Alarm message icon: includes physiological alarms, technical alarms and prompt messages, as well as the number of current alarms and prompt messages. Select the field to display a list of all active alarms. • When the AUDIO PAUSED hard key is selected, the Audio Pause icon  and the 120-second countdown are displayed. • Network status icon: displays the icon  when the [Network Type] is [WLAN] or [Hotspot]; displays the icon  when the [Network Type] is [LAN]; displays the icon  when the [Network Type] is [5G]. • USB status icon: The icon  is highlighted when the system is connected to an identifiable USB device. By selecting this icon you can export screen, data and transfer settings in the opened interface. • Bluetooth icon. • System time icon. • Power status icon. • Oxygen consumption monitoring icon: displays the speed of oxygen consumption (L/min) or the remaining oxygen supply time of the gas cylinder. In service menu, when the switch [Display oxygen cylinder remaining time] is on, the system displays the remaining time of the oxygen supply; when it is off, the system displays the oxygen consumption speed.
2	Softkey field	<p>Displays system check, patient information, alarm setup, screenshot, O2 ↑ Suction, Manual, menu and standby softkeys.</p>

Table 4-1 Main Screen

3	Ventilation mode and parameter setup field	Displays the keys for setting up ventilation modes and parameters.
4	Waveform/Spirometry/Values/Big Numeric screen field	Displays ventilator-related waveforms, spirometry, monitored values, or big numerics.

Table 4-1 Main Screen

4.2 Waveforms Screen

After ventilation is started, the ventilator enters the waveform screen by default, as shown in the following figure.

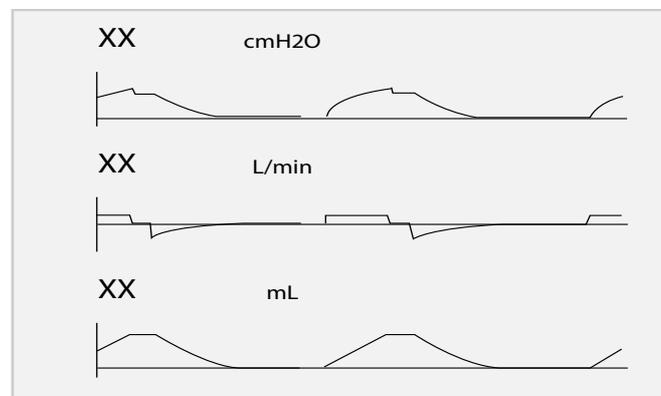


Figure 4-3 Waveforms Screen

4.3 Big Numeric Screen

Select [Menu] → [Screen] → [Choose Screen] → [Big Numeric Screen] to open the screen as shown below.

In addition to selecting the menu button, you can also directly slide the screen to switch between screens.



Figure 4-4 Big Numeric Screen

4.4 Measured Values Screen

Select [Menu] → [Screen] → [Choose Screen] → [Values Screen] to open the interface as shown below.

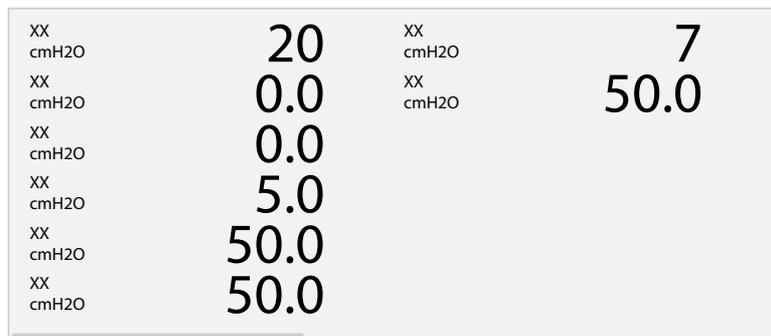


Figure 4-5 Measured Values Screen

4.5 Spirometry Screen

Select **[Menu]** → **[Screen]** → **[Choose Screen]** → **[Spirometry Screen]** to access the screen as shown below.

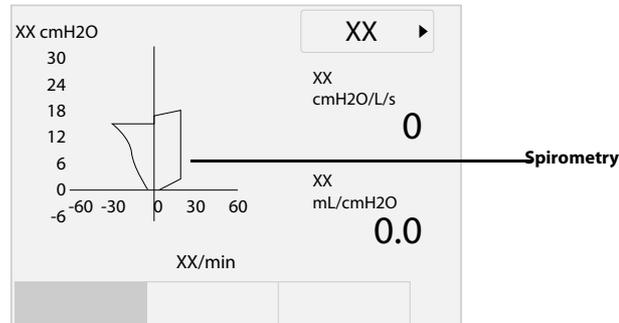


Figure 4-6 Spirometry Screen

Spirometry loops reflect patient lungs function and ventilation condition as well, such as the patient's lungs compliance, over-inflation, breathing system leakage and airway blockage.

The system provides lung function loops, including **[Paw-Volume]** loop, **[Flow-Volume]** loop and **[Flow-Paw]** loop, the data for which is collected from the waveform data on pressure, flow and volume.

Only one spirometry loop is displayed at a time. To select the desired loop:

1. Select **[Menu]** → **[Screen]** → **[Choose Screen]** → **[Spirometry Screen]** on the main screen.
2. Set the desired loop to be displayed.

The ventilator provides the function of reference loop. When **[Save Ref.]** is selected, the current respiratory cycle loop is saved as a reference loop, and the time it was saved is displayed. By selecting **[Display Ref.]** and then selecting a time point, the reference loop saved at that time can be viewed. By selecting **[Display Ref.]** and then selecting **[OFF]**, the reference loop being displayed can be hidden.

The ventilator saves up to 5 reference loops. If 5 reference loops have already been saved, the system will automatically clear the oldest reference loop and save the loop of the current respiratory cycle as reference loop if **[Save Ref.]** is selected again.

Select the **[Review Ref.]** key to display the review reference loop menu.

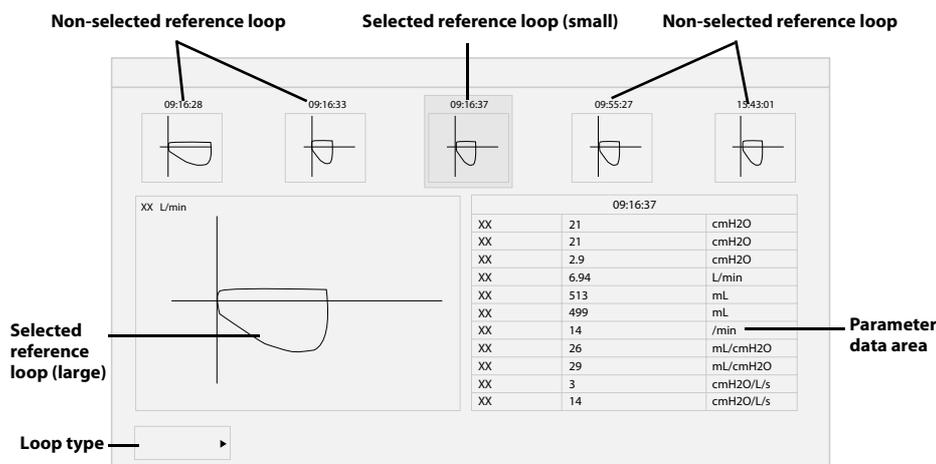


Figure 4-7 Reference Loop Review

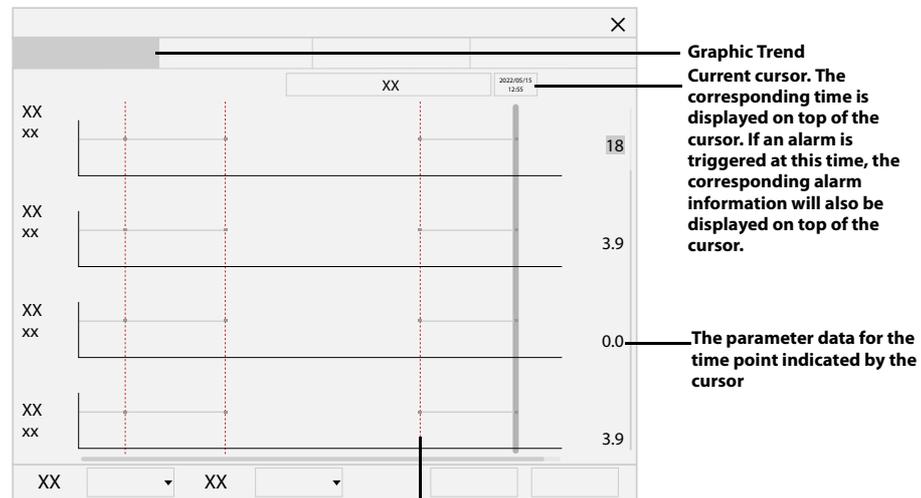
- **Small loop windows:** These small graphic windows show the reference loops. The reference loops (up to 5) are displayed from oldest (left) to newest (right). The information of selected reference loop is displayed in cyan highlight.
- **Large loop window:** This graphic window shows an enlarged view of the selected reference loop.
- **Loop type:** By selecting loop type, you can choose the type of loop to review.
- **Parameter data area:** This area displays monitored parameter data related to the saved reference loops.

4.6 History

Select the **[Menu]** → **[History]** key on the screen and the following interface will pop up. You can view the tabular trend, graphic trend, setting trend and event logbook in the interface.

4.6.1 Graphic Trend

Graphic trend records the trend of parameter values. It is reflected through a curve. Every point on the curve corresponds to the value of physiological parameter at a specific time point. Graphic trend also records parameter alarm events. Graphic trend data displays at one-minute intervals by default unless the zoom is selected.



Event marker. A colored dotted line indicates that some parameter alarm event happens at the time point. A parameter alarm event is marked with a dotted line in the color matching the alarm level. If multiple events happen, the line is in the color matching the highest alarm level.

Figure 4-8 Graphic Trend

4.6.1.1 About Graphic Trend

- In a graphic trend, the horizontal coordinates show the time and date.
- In a graphic trend, the vertical coordinates show the parameter data.
- In a graphic trend, the most recent trend data is displayed on the rightmost side.
- The system does not save the graphic trend data for the Standby mode.
- The system can display a rolling 120 hours of continuous trend data.
- Graphic Trends highlights the parameter data in the corresponding alarm color if an alarm condition existed for the parameter at the time of trend record storage.
- Select  to move the cursor to the previous event from its current position.
- Select  to move the cursor to the next event from its current position.

4.6.1.2 Zooming

In the Graphic interface, you can set **[Zoom]** to **[5 min]**, **[10 min]**, **[15 min]**, **[30 min]**, **[1 h]** and **[2 h]**.

4.6.1.3 Displaying Group

In the Graphic interface, you can set **[Group]** to **[Pressure]**, **[Volume]**, **[Time]**, **[Gas]**, **[Other]** and **[All]**.

4.6.2 Tabular Trend

In the Tabular Trend interface, you can view the monitoring parameter data and events of a patient. If no resolution is set, the trend will be displayed based on the data at an interval of one minute by default.

The screenshot shows a window titled 'Tabular Trend' with a close button (X) in the top right corner. The window contains a table with the following data:

	2022/02/28 04:38	2022/02/28 04:39	2022/02/28 04:40	2022/02/28 04:41	2022/02/28 04:42
XX	21	21	21	21	21
XX	20	20	20	20	20
XX	7.0	7.0	7.0	7.0	7.0
XX	2.9	2.9	2.9	2.9	2.9
XX	17	17	17	17	17
XX	12	12	12	12	12
XX	0	0	0	0	0
XX	12	12	12	12	12
XX	1:1.9	1:1.9	1:1.9	1:1.9	1:1.9
XX	1.70	1.70	1.70	1.70	1.70
XX	---	---	---	---	---
XX	0	0	0	0	0
XX	---	---	---	---	---

Labels on the right side of the table indicate: 'Tabular Trend' at the top, 'Cursor' pointing to the 04:42 column, and 'Parameter' pointing to the 1.70 value in the 10th row. At the bottom of the window, there are two dropdown menus, each containing 'XX' and a right-pointing arrow.

Figure 4-9 Tabular Trend

4.6.2.1 About Tabular Trend

- Tabular Trend displays the time and date on the horizontal axis.
- Tabular Trend displays the parameter data on the vertical axis.
- Tabular Trend displays the most recent trend data on the rightmost side.
- Tabular Trend is not stored when the machine is in standby status.
- The system can display a rolling 120 hours of continuous trend data.
- Tabular Trend highlights the parameter data in the corresponding alarm color if an alarm condition existed for the parameter at the time of trend record storage.
- Select  to move the cursor to the previous event from its current position.
- Select  to move the cursor to the next event from its current position.

4.6.2.2 Interval

In the Tabular Trend window, you can set **[Interval]** to **[1 min]**, **[5 min]**, **[10 min]**, **[15 min]**, **[30 min]**, **[1 h]**, and **[2 h]**.

4.6.2.3 Displaying Group

In the Table interface, you can set **[Group]** to **[Pressure]**, **[Volume]**, **[Time]**, **[Gas]**, **[Other]** and **[All]**.

4.6.3 Setting Trends

Setting Trends is used to record the ventilation mode settings and parameter settings.

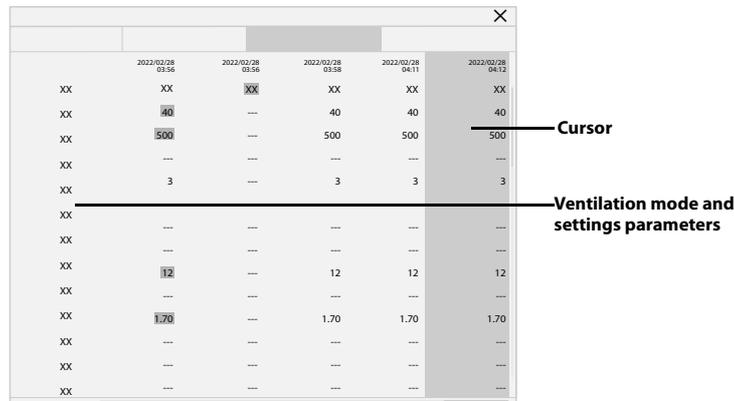


Figure 4-10 Setting Trends

4.6.3.1 About Setting Trends

- Settings Trends displays the time and date on the horizontal axis.
- Settings Trends displays the ventilation mode and setting parameter on the vertical axis.
- Settings Trends displays the most recent trend data on the rightmost side.

4.6.4 Event Logbook

Event Logbook records such events as power-on/off, ventilation mode setup, ventilation parameter setup, technical alarm, physiological alarm, standby status, starting ventilation, new patient, tools, default settings management, calibration, system check, alarm audio paused and O2 therapy event.

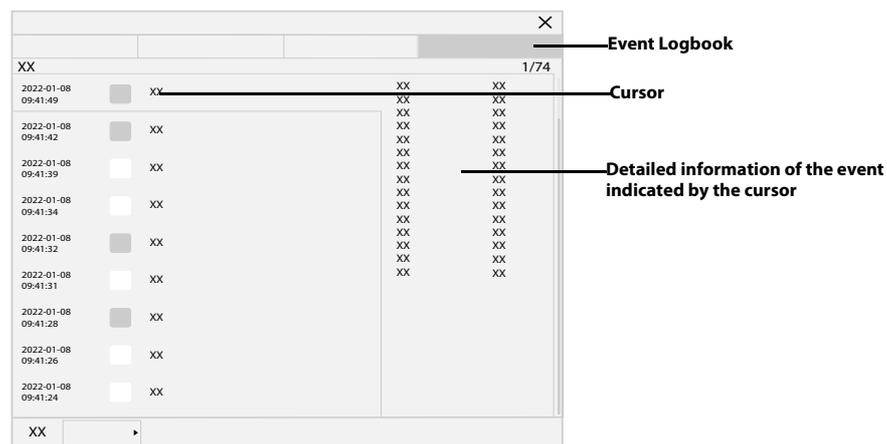


Figure 4-11 Event Logbook

4.6.4.1 About Event Logbook

- Event Logbook displays the most recent record at the top.

- The system can store up to 10,000 records of Event Logbook.

NOTE: **The system can store up to 10,000 records of Event Logbook. After the number of events exceeds 10,000, the earliest event will be overwritten by the latest event.**

4.6.4.2 Filtering

In the Event Logbook window, you can set [Filter] to [High Alarms], [Med Alarms], [Low Alarms], [All Alarms], [Operation Information], and [All Events].

4.7 Screen Capture

Select the icon  and the system will automatically take a screenshot of the current interface and save the screenshot as an image file. The system can store up to 50 screen captures.

4.8 Locking Screen

Press the  /  hard key on the main screen to enter locked status, and the prompt message [Screen locked. Press the Lock button to unlock screen.] will be displayed. During the period of screen locked, only  , [O2 ↑ Suction], and  /  keys are enabled. Touch screen, control knob, and other keys are disabled. Press this key again to unlock the screen.

System Settings

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5.1 Exporting to USB

The ventilator's exportation function provides the ability to export some data or settings to USB device.

5.1.1 Exporting Screen

Screen exportation involves exporting a saved screen capture for the ventilator. The exported file is saved in "jpg" format. This ventilator could save up to 50 screen captures.

To export screen capture,

1. Insert the USB device into the USB connector of the ventilator. The  key is highlighted on the main screen.
2. By selecting the  key, the system will open the [Data Transfer] interface.
3. On the opened interface, select the [Export Screenshot] tab first and then click the [Export Screenshot] key. The system will run a check to verify that there is enough storage space available on the USB device. If there is sufficient space, the system will start to export the screen.
4. After exporting is completed, select [Remove USB Device] to remove the USB device.

5.1.2 Exporting Data

Exporting data means to export data from the ventilator, such as patient demographics, current setting parameters, current alarm limits, trend data and so on.

To export data,

1. Insert the USB device into the USB connector of the ventilator. The  key is highlighted on the main screen.
2. By selecting the  key, the system will open the [Data Transfer] interface.
3. On the opened interface, select the [Export Data] tab and then select the [User Export] key. The system will run a check to verify that there is enough storage space available on the USB device. If there is sufficient space, the system will export data including patient information, current parameter settings, current alarm limits, history data, etc. The format of the exported data is "html".
4. If you need to export calibration data, event logbook and self-check logbook in addition to the above data, select the [Factory Export] tab and enter password. The system will run a check to verify that there is sufficient storage space available on the USB device. If there is sufficient space, the system will start to export data. The exported data is encrypted in the format of "blg".
5. After exporting is completed, select [Remove USB Device] to remove the USB device.

NOTE: If you need to check the exported data in format of "blg", please contact the Customer Service Department.

5.1.3 Transferring Settings

You can export or import settings while the ventilator is in Standby status.

To export settings,

1. Make sure that the machine is in Standby status.
2. Insert the USB device into the USB connector of the ventilator. The key is highlighted on the main screen .
3. By selecting the  key, the system will open the **[Data Transfer]** interface.
4. Select **[Transfer Settings]** → Enter system password → **[Export Settings]** in the opened interface. The system will run a check to verify that there is sufficient storage space available on the USB device. If there is sufficient space, the system will save the current settings and machine defaults to the USB device.
5. After exporting is completed, select **[Remove USB Device]** to remove the USB device.

To import settings,

1. Make sure that the machine is in Standby status.
2. Insert the USB device into the USB connector of the ventilator. The key is highlighted on the main screen .
3. By selecting the  key, the system will open the USB settings interface.
4. Select **[Transfer Settings]** → Enter system password → **[Import Settings]** in the opened interface. The system will upload the ventilator settings saved in the USB device.
5. After exporting is completed, select **[Remove USB Device]** to remove the USB device.

5.2 Transferring Data

The ventilator can transfer data in the following ways.

- **Transfer data through the wireless or wired network:**

1. Select the **[Bed Number Setting]** interface of the bedside ventilator and this ventilator, enter the same department, room No. and bed No. to pair the bedside ventilator with this ventilator.
2. Select **[Ok]**, and the message **[Do you want to synchronize the ventilation parameters of the bedside ventilator?]** is displayed on the screen.
3. Select **[Detail]** to view the parameter details of the bedside ventilator.
4. Select **[Ok]** to synchronize the patient information and ventilation parameters of the bedside ventilator with this ventilator.

5.3 Basic Settings

5.3.1 Setting TV/IBW

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[TV/IBW]**: set to an appropriate ratio. The system will calculate the default tidal volume (TV) in the ventilation mode depending on **[TV/IBW]**.

5.3.2 Setting IBW/Height

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[IBW/Height]** and toggle between **[IBW]** and **[Height]**. When the ventilator is in the standby mode, set the ideal body weight or height. The system calculates default values of TV, f, and fapnea in the ventilation mode automatically based on the set IBW or height and gender.

5.3.3 Setting Tinsp/I:E

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[Tinsp/I:E]** and toggle between **[Tinsp]** and **[I:E]**. Based on **[Tinsp/I:E]**, adopt the corresponding Tinsp or I:E ventilation parameter settings for the V-A/C, P-A/C, PRVC, CPRV and DuoLevel (when the time parameter for DuoLevel is **[f]**) ventilation modes.

5.3.4 Setting Flow/Tpause(%)

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[Flow/Tpause(%)]** and toggle between **[Flow]** and **[Tpause(%)]**. Use corresponding ventilation settings in the V-A/C, V-SIMV or CPRV ventilation mode, according to **[Flow/Tpause(%)]**.

5.3.5 Setting DuoLevel

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[DuoLevel Setup]: [Thigh]** or **[f]**.
 - In case of DuoLevel ventilation mode, the settable time control parameters are **[Thigh]** and **[Tlow]** if **[DuoLevel Setup]** is set to **[Thigh]**.
 - In case of DuoLevel ventilation mode, the settable time control parameters are **[f]** and **[Tinsp]** if **[DuoLevel Setup]** is set to **[f]** and **[Tinsp/I:E]** is set to **[Tinsp]**.
 - In case of DuoLevel ventilation mode, the settable time control parameters are **[f]** and **[I:E]** if **[DuoLevel Setup]** is set to **[f]** and **[Tinsp/I:E]** is set to **[I:E]**.

5.3.6 Setting Invasive Apnea Mode

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[Invasive Apnea Mode]: [Volume Control]** or **[Pressure Control]**. In case of invasive ventilation in V-SIMV, P-SIMV, PRVC-SIMV, CPAP/PSV, PSV, VS, Duolevel and APRV mode, the settable apnea ventilation control parameter is **[TVapnea]** if **[Invasive Apnea Mode]** is set to **[Volume Control]**, and is **[ΔPapnea]** if **[Invasive Apnea Mode]** is set to **[Pressure Control]**.

5.3.7 Setting Leakage Compensation

1. Select **[Menu]** → **[Setup]** → **[Ventilation]**.
2. Set **[Leakage Compensation]: (ON) or (OFF)**. When the switch is ON, the ventilator provides leakage compensation.

5.3.8 Setting O₂% Increment During O₂↑ Period

1. Select [Menu] → [Setup] → [Ventilation].
2. Set [Increase O₂% during O₂↑]: set oxygen enrichment in accordance with different patient types. After initiation of oxygen enrichment, the system will compare “current oxygen concentration + oxygen enrichment” with “100vol.%” and start ventilation according to the lower of the two values.

5.3.9 Setting Oxygen Sensor Monitoring

The ultrasonic oxygen sensor is characterized with long service life and good stability.

1. Select [Menu] → [Setup] → [O₂ Sensor].
2. Set the [Monitoring]:  (ON) or  (OFF). When the switch is ON, oxygen concentration of patient's inhaled gas can be monitored. You can switched off if oxygen concentration monitoring function accompanying the ventilator is not needed. In this case, the [O₂ Monitoring Off] prompt message is displayed on the screen. After Oxygen Sensor Monitoring off, the ventilator will disable relevant alarm messages and prompt messages.

CAUTION: Switching off oxygen concentration monitoring is allowable. To prevent potential patient injury, it is suggested not to switch off oxygen concentration monitoring continuously.

NOTE: The system total response time for oxygen concentration monitoring is no more than 18s.

NOTE: It takes approximately 3 minutes from powering on the ventilator to reaching the oxygen concentration monitoring performance specified in section B.7 Ventilator Accuracy of this manual.

5.3.10 Setting O₂ Supply Type

1. Select [Menu] → [Setup] → [Gas Supply].
2. Set the [O₂ Supply Type] to [HPO] or [LPO].

5.4 Screen Settings

5.4.1 Choosing Screen

1. Select [Menu] → [Screen] → [Choose Screen].
2. Set the screen to [Waveforms Screen], [Big Numeric Screen], [Values Screen] or [Spirometry Screen].

5.4.2 Adjusting Screen Brightness

1. Select [Menu] → [Screen] → [Brightness/Volume].
2. Select  or  and switch to corresponding screen brightness default.
3. If the above screen brightness is not satisfactory, set [Brightness] directly.  shows darker, and  shows brighter. If the ventilator is powered by batteries, you can select a less bright screen to save battery capacity.

NOTE: Select [Brightness/Volume] → [Auto]. When [Auto] is set to  (ON), the ventilator will automatically adjust the screen brightness according to the ambient light intensity.

NOTE: When the screen brightness is increased or outdoor mode is turned on, the consumption speed of the battery power will be increased and the power supply time of the battery will be shortened.

5.4.3 Adjusting Key Volume

1. Select [Menu] → [Screen] → [Brightness/Volume].
2. Select  or  and switch to corresponding key volume default.
3. If the above key volume is not satisfactory, set [Volume] directly.  means a lower volume,  means a higher volume., and  means the volume is turned off.

5.4.4 Setting Screen Layout

1. Select [Menu] → [Screen] → [Screen Setup].
2. Select corresponding icons to set the displayed number of waveforms and the wave drawing method.
3. If you need to adjust the specific waveform and measured values at each position, please set [Layout Setup Switch] as  (ON). Then select the waveform or measured value in the main screen and set the required waveform or measured value name in the interface that is displayed. If you need to close this function, please set [Layout Setup Switch] to  (OFF).
4. Select [Defaults] when necessary to restore the settings to default.

5.4.5 Setting Color

1. Select [Menu] → [Screen] → [Color].
2. Set the parameter display colors. The colors of waveform, parameter, spirometry loop, and parameter alarm limit are linked. If you set waveform or parameter color, the color of the relevant parameter or waveform also changes. The color of related parameter alarm limit will be a darker shade of the set color.

The following table lists the waveforms, related parameters and alarm limits.

WAVEFORMS	PARAMETER	RELATED SPIROMETRY LOOP	RELATED ALARM LIMITS
Paw	Ppeak, Pmean, Pplat, PEEP	PV loop, F-P loop	Paw
Flow	MVi, MVe, MVleak, MVspn, TVe, TVi, TVe spn, ftotal, fmand, fspn, TVe/IBW, I:E, Tinsp	F-V loop	MVe, TV, ftotal
Volume	/	/	/
/	FiO ₂	/	FiO ₂
CO ₂	EtCO ₂	/	EtCO ₂

Table 5-1 Setting Color

5.4.6 Setting Outdoor Mode

The outdoor mode is a configuration mode used when transferring patients outdoors. When the ventilator is in the outdoor mode, the background color of the new interface is the reverse color of the original interface and cannot be changed.

Press the Outdoor Mode hard key below the main screen to enter the outdoor mode. When the ventilator is turned on, this button displays ; when the ventilator is shut down, this button displays the remaining power icon .

5.5 System Settings

5.5.1 Setting Time and Date

1. Select **[Menu]** → **[System]** → Enter system password → **[Setup]** → **[Date & Time Setup]**.
2. Set **[Date]**, **[Time]**, **[Time Zone]** and **[DayLight Savings]**.
3. Set **[Date Format]** to **[YYYY-MM-DD]**, **[MM-DD-YYYY]** or **[DD-MM-YYYY]**.
4. Set **[24 h]**: (ON) or (OFF).

5.5.2 Setting Language

1. Select **[Menu]** → **[System]** → Enter system password → **[Setup]** → **[Language/Unit]**.
2. Set **[Language]** as required.
3. Restart the ventilator to activate the selected language.

5.5.3 Setting Unit

1. Select **[Menu]** → **[System]** → Enter system password → **[Setup]** → **[Language/Unit]**.
2. Set relevant units as required:
 - Set **[Pressure Unit]**: **[cmH2O]**, **[hPa]** or **[mbar]**.
 - Set **[CO2 Unit]**: **[mmHg]**, **[kPa]** or **[vol.%]**.
 - Set **[Height Unit]**: **[cm]** or **[inch]**.
 - Set **[Weight Unit]**: **[Kg]** or **[lb]**.
 - Set **[WOB Unit]**: **[J/min]** or **[J/L]**.
 - Set **[Gas Supply Pressure]**: **[kPa]**, **[psi]** or **[bar]**.
 - Set **[Minimum Alarm Volume]** to an appropriate value.

5.5.4 Changing Password

1. Select **[Menu]** → **[System]** → Enter system password → **[Setup]** → **[Change Password]**.
2. Enter the current password.
3. Enter the new password.
4. Confirm the password, that is, enter a new password again.

5.5.5 Setting Ventilator Location

1. Select **[Menu]** → **[System]** → Enter system password → **[Ventilator Location]**. The system displays the Device ID on the opened interface.
2. Set the **[Ventilator Name]**, **[Facility]** or **[Department]**.
3. Set the **[Room No]** or **[Bed No]**.
 - Select the **[Fixed]**, the **[Room No]** and **[Bed No]** will be locked and can not be changed in the **[Patient Settings]** menu. For details about the **[Patient Settings]** menu, refer to **6.3.1 Setting Patient Information on the Ventilator**.
 - Select the **[Unfixed]**, the **[Room No]** and **[Bed No]** will be unlocked and can be changed in the **[Patient Settings]** menu. For details about the **[Patient Settings]** menu, refer to **6.3.1 Setting Patient Information on the Ventilator**.
 - Select the **[Unfixed]**, you can set **[Auto Obtaining Bed No]** to (ON) or (OFF). When the wired network is connected and the switch is turned on, the ventilator automatically obtains the room No. and bed No. of the patient.

5.5.6 Patient Management

1. Select **[Menu]** → **[System]** → Enter system password → **[Patient Management]**.
2. Select the **[Field]**. On the opened interface, set the field which needs to be set in the **[Patient Settings]** menu. For details about the **[Patient Settings]** menu, refer to **6.3.1 Setting Patient Information on the Ventilator**.
3. Select the **[ADT Query]**. On the opened interface, set the **[Find Patient]** to **[All Patients]** or **[Current Department Patients]**. In addition, set the field which needs to be set in the **[Find Patient]** menu. For details about the **[Find Patient]** menu, refer to **6.3.2 Getting Patient Information from the ADT Server**.
4. Select the **[Discharge Patient]**. On the opened interface, set the **[Clear the Room and the Bed number when discharge]** to (ON) or (OFF). When the switch is turned on, if **[Room No]** and **[Bed No]** are **[Unfixed]**, the ventilator will clear the room No. and bed No. When the switch is turned off, the room No. and bed No. of the patient are retained by the ventilator when the patient is discharged.

5.5.7 Default Settings

The ventilator provides the following types of settings:

- Factory default settings, namely, values of factory preset setting items.
- User Defaults. You can change the ventilator's default settings based on the current settings during ventilation and save the changed settings as user default settings.
- Recent settings. In actual application, operators may change some settings. The ventilator stores these settings in real time. The stored settings are recent settings. After the ventilator is started, the latest settings are automatically loaded.
- Current settings, namely current settings of the ventilator.

5.5.7.1 Saving Current Settings

You can change the ventilator's default settings based on the settings during ventilation and save the changed settings as default settings.

1. Select **[Menu]** → **[System]** → Enter system password → **[Defaults]**.

2. Select **[Use Current Settings]** to save the current settings as default settings.

5.5.7.2 Restoring Factory Default Settings

You can restore factory default settings manually as required, while unit is in standby status.

1. Select **[Menu]** → **[System]** → Enter system password → **[Defaults]**.
2. Select **[Restore factory defaults]** to restore the factory default settings.

5.5.7.3 Default Setting Application

When the ventilator is used on a new patient after being turned on, the system loads the corresponding default settings based on the selected patient type.

NOTE: Records information automatically saved by the system including monitored trend, event log (including alarm log), setting trend, patient settings and equipment settings (including alarm settings). When there are changes in these data, the system stores the changed data in the flash memory chips of the main board automatically. When the ventilator restarts, the data are restored automatically.

5.5.8 Setting Network

CAUTION: Wireless network design, deployment, debugging and maintenance should be executed by Mindray service personnel or authorized technicians.

CAUTION: Always deploy the wireless network according to local wireless regulations.

CAUTION: Using 5G frequency band is recommended whenever possible. There are more interference sources in 2.4G frequency band.

CAUTION: Private APs and wireless routers are not allowed. These devices may cause radio interference and result in ventilator and CMS data loss.

CAUTION: To ensure network security and stability, data communication must be performed within a closed network or within a virtually isolated hospital network. The hospital is responsible for ensuring the security of the virtually isolated network.

CAUTION: WPA2-PSK and WPA2-Enterprise verification and encryption should be used if possible. Otherwise, the equipment may not be able to work or patient information may be leaked. WPA2-Enterprise and a long password are recommended.

CAUTION: Keep network authentication information, for example password, from being accessed by unauthorized users.

CAUTION: Do not connect non-medical devices to the ventilator network.

CAUTION: If wireless network signal is poor, there may be a risk of CMS data loss.

CAUTION: Maximum number of ventilators connected to a single AP is 16 for this ventilator. Too many ventilators connected to the same AP may result in network disconnection.

CAUTION: RF interference may result in wireless network disconnection.

CAUTION: Disconnecting from the network may result in CMS data loss and function failure. Check the patient in case of network disconnection and reconnect the network as soon as possible.

CAUTION: Ensure that the ventilator IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.

5.5.8.1 Setting Network Type

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]**.
2. Set **[Network Type]** to **[LAN]**, **[WLAN]**, **[Hotspot]**, **[5G]**.

5.5.8.2 Setting LAN/WLAN

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]** → **[Network Setup]**.
2. Select **[LAN Setup]** or **[WLAN Setup]** to set related items in the interface that appears.

5.5.8.3 Setting Central Station

The ventilator can be connected to the central monitoring system (CMS) through network connection to achieve the transmission of ventilation mode, ventilation control parameters, ventilation monitoring parameters, tools and alarm information from the ventilator to the CMS. The alarm delay from the ventilator to the CMS does not exceed 3 seconds. You can view the patient's ventilation data and alarms in the CMS. For details, refer to the CMS operator's manual.

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]** → **[Network Setup]**.
2. Select **[Central Station Setup]** to set related items in the interface that appears.
 - Set **[Network disconnection alarm]** to (ON) or (OFF). When this function is enabled, the ventilator will give an alarm when the ventilator is disconnected from the CMS, e-Gateway or the monitor.
 - Set **[Select CMS]** to (ON) or (OFF). When this function is enabled, the central monitoring system can be selected for the ventilator.
 - Select **[Add Central Station]** to set the relevant items of the central station to be added in the interface that appears.

5.5.8.4 Setting Device Discover

Set the multicast parameters so that the ventilator and monitor, and the ventilator and central monitoring system can discover each other. Only the internal devices in the same multicast group can discover each other.

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]**.

2. Select **[Device Discover]** to set related items and check the network connection status in the interface that appears.

5.5.8.5 Setting Information Security

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]**.
2. Select **[Information Security]** to set **[Encryption Connection Type]** in the interface that appears.
 - **[Only Private Encryption]**: Mindray private encryption is used to encrypt the transmission data. Devices connected to the SSL (Secure Socket Layer) encryption are not supported.
 - **[SSL Encryption Priority]**: Devices that support SSL encryption are preferentially connected in SSL encryption mode, and devices that do not support SSL encryption are connected in private encryption mode.

5.5.8.6 Setting ADT

The ADT application gateway is usually deployed in the eGateway. You can receive patient information from the ADT server of the hospital through the ADT application gateway.

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]**.
2. Select **[ADT]** to set related items in the interface that appears.

5.5.8.7 Setting SNTP

SNTP is used to synchronize the time of ventilator with the server.

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]**.
2. Select **[SNTP]** to set related items in the interface that appears. After the settings are done, you can select **[Test]** to test the connection status.

5.5.8.8 Setting HL7

You can transmit the real-time data, waveforms, and alarms of the ventilator to the hospital server through the HL7 protocol.

1. Select **[Menu]** → **[System]** → Enter system password → **[Interface]**.
2. Select **[HL7]** to set related items in the interface that appears. After the settings are done, you can select **[Test]** to test the connection status.

5.5.9 Viewing System Information

5.5.9.1 Version Information

Select **[Menu]** → **[System]** → Enter system password → **[System Info.]** → **[Software Version]** to check the system software version.

5.5.9.2 Configuration Information

Select **[Menu]** → **[System]** → Enter system password → **[System Info.]** → **[Config Info.]** to view the configuration information of the ventilator such as ventilation mode.

5.5.9.3 Maintenance Information

Select **[Menu]** → **[System]** → Enter system password → **[System Info.]** → **[Maintain]** to view the system total running time, system startup time, O₂ sensor last calibration time, flow sensor last calibration time, time left for the next backup air supply maintenance, and time of last maintenance.

5.5.10 Viewing Open Source Information

Select **[Menu]** → **[Screen]** → **[More]** to check the related open license and open source information.

5.5.11 Entering Storage Mode

Select **[Menu]** → **[System]** → **[Storage Mode]**, and follow the screen prompts to enter the storage mode.

5.6 Setting Tool Shortcut Key

1. Select **[Menu]** → **[Screen]** → **[Shortcut Key Setup]**.
2. Select the required shortcut key in the menu that displays. The system will add shortcut keys one at a time in the order of selection.

5.7 Factory Service Settings

Only the company's authorized maintenance staff can access the **[Service]** tab. For further assistance, please contact the company's Customer Service Department.

5.8 Calculating Oxygen Consumption

This ventilator is capable of monitoring the oxygen consumption rate. Input the current pressure and volume of the cylinder and start ventilation to monitor the oxygen cylinder for the remaining oxygen supply time. Before transporting the patient, it is necessary to check the current oxygen consumption data in the icon field of the main screen and estimate the transport duration and the current oxygen capacity to ensure sufficient oxygen supply to patients.

WARNING: To avoid the risk of insufficient oxygen supply during patient transport or surgical operation, please check the cylinder pressure and calculate the oxygen supply time before starting the system, and prepare a backup oxygen supply as needed.

WARNING: The estimation time of the oxygen consumption monitoring function may be shortened in case of gas leakage at the patient side of the ventilator. If leakage occurs to the patient tubing or cylinder pressure relief valve, the oxygen consumption will be inaccurate. Please estimate the oxygen consumption according to the actual clinical conditions of the patient.

The oxygen consumption is calculated as follows:

- Oxygen cylinder supply

Oxygen volume = Cylinder volume × Cylinder pressure.

E.g., for a cylinder volume of 2 L and cylinder pressure of 145 bar, the oxygen volume will be 290 L.

- Remaining gas supply time

Remaining gas supply time (min) = Oxygen volume (L) ÷ Oxygen consumption speed (L/min).

E.g., under the typical working mode, suppose that the cylinder volume is 2 L and the oxygen consumption speed is 5 L/min, then the remaining gas supply time will be 58 min.

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Start Ventilation

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6.1 Turning on the System

1. Insert the power cord into the power receptacle. Ensure the external power indicator light is lit.
2. Press the  hard key.
3. The alarm indicator light flashes yellow and red once in turn, and then the system conducts a self check of the speaker and buzzer once respectively.
4. A start-up screen and start-up check progress bar appear. Then the System Check screen is displayed.

NOTE: When the ventilator is started, the system detects whether audible alarm tones and alarm lamp function normally. If yes, the alarm lamp flashes yellow and red successively, and the speaker and the buzzer give check tones. If not, do not use the equipment and contact the Customer Service Department immediately.

6.2 System Check

CAUTION: If the ventilator fails any tests, remove it from clinical use. Do not use the ventilator until necessary repairs are completed and all tests have passed.

CAUTION: Before running System Check, disconnect the patient from the equipment and ensure that a backup ventilation mode is available for patient ventilation.

To enter the System Check screen,

- After the system is started, the system automatically enters the standby screen. Select the [**System Check**] key in the standby status to enter the System Check screen.
- In the non-standby status, select the [**Standby**] key and enter the standby status after confirmation. Then, select the [**System Check**] key in the standby status to enter the System Check screen.

The system check screen displays the last system check time and total system check result. Select the  key to query the last system check information of the ventilator system, including system check items and System Check results.

Connect the gas supply, proximal flow sensor and block the patient tubing as illustrated. Then select [**Continue**] to start system check item by item.

System check items include:

- Blower Test: test the speed of blower.
- O₂ Flow Sensor Test: test the flow sensor in O₂ limb.
- Insp. Flow Sensor Test
- Pressure Sensor Test: test the pressure at the inspiratory ports and expiratory pressure sensor.

- Exp. Valve Test
- Safety Valve Test
- Leakage (mL/min)
- O₂ Sensor Test

System Check result can be:

- Pass: indicates that check of this item is completed and is passed;
- Fail: indicates that check of this item is completed but is failed;
- Cancel: indicates that check of this item is cancelled;
- No Gas Supply: indicates that the O₂ supply is not connected.
- Monitoring Off: indicates that sensor monitoring function may not be switched on when O₂ sensor test is being carried out.
- No Sensor: indicates that the flow sensor is not connected.
- Sensor Reversed: indicates that the flow sensor is connected reversed.
- Sensor Failure: indicates that the oxygen sensor may not be working.

Total selftest results are listed as follows after all selftest items have been completed:

- Pass: all selftest items successfully pass the selftest.
- Partially Pass: some selftest items fail, but the mechanical ventilation is allowed.
- Fail. Ventilation Disabled: some important selftest items fail, but the mechanical ventilation is not allowed.
- High Leakage, Ventilation Disabled: Exp. Flow Sensor Test, Pressure Sensor Test, Exp. Valve Test, or Safety Valve Test fails, the mechanical ventilation is not allowed.
- Cancel: some selftest items cancelled and other selftest items have been successfully passed.

During System Check, the system prompts **[Running]** on the right side of the current check item. At the time, by selecting the **[Skip]** key, the system will immediately stop checking the item and simultaneously enter the next self check item. By select the **[Stop]** key, the system will stop the check of the current item and the checks of remaining items immediately, and display **[Cancel]** as the check result.

If the ventilator is equipped with the ultrasonic oxygen sensor, when the oxygen sensor selftest fails, the **[O2 Calibration]** key is displayed. Press this key to open the oxygen concentration calibration menu, and then calibrate oxygen concentration. When the proximal flow sensor test fails, the **[Flow Calibration]** key is displayed. Press this key to open the flow calibration menu, and then calibrate flow.

When checks of all items are completed, if you select **[Retry]**, the system starts a new round of checking. If you select **[Standby]**, the system exits the check and enters Standby status.

6.3 Managing Patient Information

NOTE: Set the patient information as needed. The ventilation of the device will not be affected if you do not set the patient information.

6.3.1 Setting Patient Information on the Ventilator

Open the patient setting menu in standby or ventilation mode and select the patient information:

- Select the patient type icon and set **[Gender]**, **[Height]/[IBW]** and **[Ventilation Type]** in the open **[Patient Settings]** menu. If you want to change the patient information for a new patient, select **[New Patient]** key in the **[Patient Settings]** menu, and then set **[Gender]**, **[Height]/[IBW]** and **[Ventilation Type]**.
- Upon alteration of **[Gender]**, **[Height]** or **[IBW]**, the settings of **[TV]**, **[TVapnea]**, **[f]** and **[fapnea]** will change accordingly, as well as TV high alarm limit, TV low alarm limit, MV high alarm limit and MV low alarm limit.
- Select **[More]** and set **[Bed No]**, **[Last Name]**, **[First Name]**, **[DOB]**, **[Paced]** or **[Custom Field]** in the opened interface, etc. The settings shown here can be affected by **5.5.6 Patient Management**.

During ventilation, the **[New Patient]** menu cannot be accessed.

NOTE: When connecting the ventilator to a new patient, pay attention to setting the correct patient type.

6.3.2 Getting Patient Information from the ADT Server

The ventilator can connect with the Admit-Discharge-Transfer (ADT) server through the eGateway, and the ventilator can load the patient information from ADT server.

To load patient information from the ADT server, perform the following procedure:

1. Connect the network cables.
2. Select **[Menu]** → **[System]** → Enter system password → **[Interface Setting]**.
3. Select **[LAN Setup]** tab, set **[IP Config.]**, **[IP Address]**, **[Subnet Mask]** and **[Gateway]** in the opened interface. In addition, the opened interface displays the MAC address of the ventilator.
4. Select **[eGateway]** tab and set the **[eGateway]** to  (ON) in the opened interface. Then set the **[IP Address]** of eGateway and ADT. Normally, there is no need to set the **[Port]**, but you can change it as required.
5. Ensure the network status is **[Connected]** in the **[eGateway]** tab.
6. Select the patient type field on the main screen and open the patient setting menu.
7. Select **[Find Patient]**, input **[Facility]**, **[Department]**, **[Room No]**, **[Bed No]**, **[First Name]**, **[Last Name]**, **[Patient ID]** or **[Visit Number]** in the opened interface. The settings shown here can be affected by **5.5.6 Patient Management**.
8. Select **[Query]**. Then list pops up, including all the patients that meet the query criteria.

9. Select a patient from the patient list, and then select **[Import]**. The imported data includes patient ID, visit number, first name, last name, bed number, room number, department, and facility.

NOTE: The IP address of the ventilator, eGateway and ADT must be on the same subnet.

NOTE: When the [eGateway] is set to  (ON), the ventilator can send the ventilation mode, ventilation type, monitored parameters, controlled parameters, waveforms and alarm limits data to the eGateway.

6.4 Ventilation Type

The ventilator provides two ventilation types: invasive and non-invasive.

WARNING: Check the alarm limit settings after switching over from NIV to Invasive.

6.4.1 Invasive Ventilation

Invasive ventilation means to ventilate the patient through manual airway (ET tube or Trach tube). In invasive ventilation, the enabled ventilation modes include:

- Adult patients: V-A/C, P-A/C, V-SIMV, P-SIMV, CPAP/PSV, PRVC, PRVC-SIMV, DuoLevel, APRV, VS, AMV, and CPRV ventilation modes.
- Pediatric patients: V-A/C, P-A/C, V-SIMV, P-SIMV, CPAP/PSV, PRVC, PRVC-SIMV, DuoLevel, APRV, VS, and AMV ventilation modes.
- Infant patients: V-A/C, P-A/C, V-SIMV, P-SIMV, CPAP/PSV, PRVC, PRVC-SIMV, DuoLevel, APRV, and VS ventilation modes.

6.4.2 Non-Invasive Ventilation (NIV)

NIV means to ventilate the patient by using a nasal mask or facial mask instead of ET tube or Trach tube. In NIV, the enabled ventilation modes include:

- Adult, pediatric and infant patients: CPAP/PSV, P-A/C, P-SIMV, DuoLevel, APRV and PSV-S/T ventilation modes.

CAUTION: Do not use NIV on patients with no or irregular spontaneous breaths. NIV is intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.

CAUTION: Do not attempt to use NIV on intubated patients.

6.4.3 Setting Ventilation Type

To set ventilation type, select the patient type icon  or set the **[Ventilation Type]** to **[NIV]** or **[Invasive]** in the standby mode.

6.5 Ventilation Mode

NOTE: At the expiratory phase, the ventilator will not automatically generate negative pressure. However, it may cause negative pressure because patients inhale air.

- NOTE:** The user can set high pressure alarm limit. If the pressure reaches the high pressure alarm limit in the inspiratory phase, the [Paw Too High] high-level alarm is triggered. The ventilator opens the expiration valve and switches to expiratory phase until the airway pressure reaches the preset PEEP value. If the airway pressure exceeds high pressure alarm limit +5 cmH₂O (adjustable pressure limit), the ventilator opens the safety valve to release pressure, so that the airway pressure falls to less than 3 cmH₂O for continuous 0.5 s. Make sure to set high pressure alarm limit properly to ensure patient safety.
- NOTE:** As false triggering of the ventilator can easily be caused by negative pressure produced during closed suction, it is recommended that the pressure-controlled ventilation mode (P-A/C mode or P-SIMV mode), in which ventilation trigger can be turned off, be used first. The operator should complete ventilation parameter settings in accordance with the patient's condition.
- NOTE:** In the inspiratory phase, waveforms turning red indicates that the patient has spontaneous inspiration or the pressure support ventilation is triggered in V-SIMV, P-SIMV, PRVC-SIMV, CPAP/PSV, Duolevel, APRV, VS, AMV, or PSV-S/T mode. When the patient triggers spontaneous breathing, a red triangle appears below the waveform to indicate spontaneous inspiratory triggering.

6.5.1 Ventilation Mode and Parameter Setup

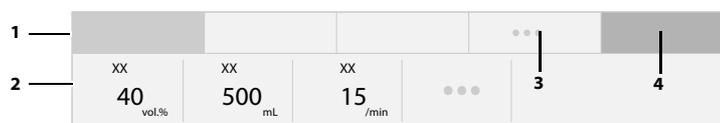


Figure 6-1 Ventilation Mode and Parameter Setup

1. Ventilation mode field

Displays the keys for setting up ventilation modes.

2. Parameter setup quick key field

Displays ventilation parameter settings corresponding to the ventilation mode. Select  to display more parameter settings. Select  to display all parameter settings corresponding to the mode, including sigh function parameters. Ventilation parameters vary subject to the ventilation mode.

3. Ventilation mode custom key

Select ventilation mode custom key  to open ventilation mode setting menu. In the opened menu, set the ventilation mode to be displayed in Area 1. The system will add the ventilation modes one at a time in the order of selection.

4. CPRV ventilation mode area (settable)

Select the Ventilation mode custom key  to open ventilation mode setting menu. In the accessed menu, set [CPRV] to  (ON), and then the CPRV ventilation mode will be shown on the area 4. Set [CPRV] to  (OFF), then the CPRV ventilation mode will not be shown on the area 4.

To set ventilation mode,

1. In the ventilation mode area, select the required ventilation mode key, and the ventilation parameters can be set in this ventilation mode will be displayed in the opened menu.
2. Select the key for the ventilation parameter to be set.
3. Press the control knob, and then turn it to set the selected parameter to the appropriate value.
4. Press the control knob again to confirm the setting.
5. Set other parameters in the same way.
6. Select the [Ok] key after completing the parameter settings.

To set quick key ventilation parameters,

1. In the parameter setup quick key field, select the ventilation parameter to be set.
2. Press the control knob, and turn it to set the selected parameter to the appropriate value.
3. Press the control knob to confirm the setting.
4. Set other parameters in the same way.

In the V-A/C, V-SIMV or CPRV ventilation mode, you can set the flow pattern.

1. In the ventilation mode setup filed, select the V-A/C, V-SIMV or CPRV ventilation mode.
2. Select the [Additional] or [More] tab in the opened window.
3. Select [Ok] when the setup is completed.

6.5.2 V-A/C

V-A/C is volume-assist/control ventilation mode. In V-A/C mode, a certain tidal volume is delivered to the patient within a certain period of gas delivery time. During the expiratory phase, V-A/C mode supports synchronization trigger. Namely, when the ventilator detects patient inspiratory effort, it delivers next mechanical ventilation in advance.

The following figure shows typical waveforms in V-A/C mode.

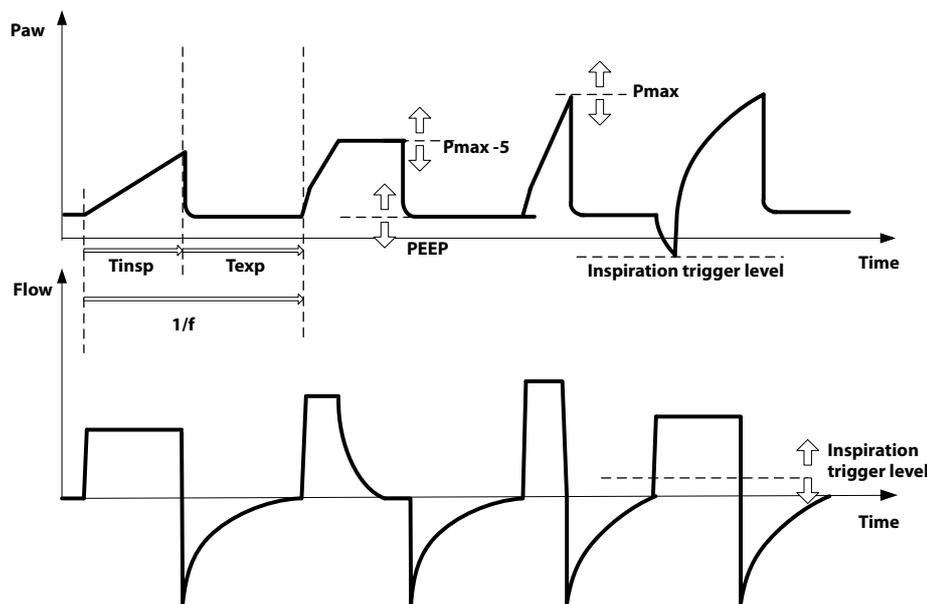


Figure 6-2 V-A/C

In V-A/C mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[TV]:	Tidal volume
[Tinsp] or [I:E]:	Inspiration time or ratio of inspiratory time to expiratory time
[f]:	Breathing frequency
[PEEP]:	Positive end-expiratory pressure
[Assist]:	Switching trigger ON/OFF
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Tpause(%)] or [Flow]:	Percent of inspiratory pause time or flow delivered to the patient in the inspiratory phase
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-1 V-A/C

6.5.3 P-A/C

P-A/C is pressure-assist/control ventilation mode. In P-A/C, the patient’s airway pressure rises to the preset pressure level within the time of pressure rising during the inspiration phase, and is held at this level till inspiration time is completed. Then the system switches to expiration. When the airway pressure is held at the preset pressure level, delivered gas flow has decelerating shape, and varies with the resistance and compliance of the patient’s lungs. During the inspiratory phase, when the volume of gas delivered exceeds the tidal volume high alarm limit, the system switches to the expiratory phase immediately. During the expiratory phase, synchronization trigger is supported. Namely, when the ventilator detects patient inspiratory effort, it delivers next mechanical ventilation breath immediately.

The following figure shows typical waveforms in P-A/C mode.

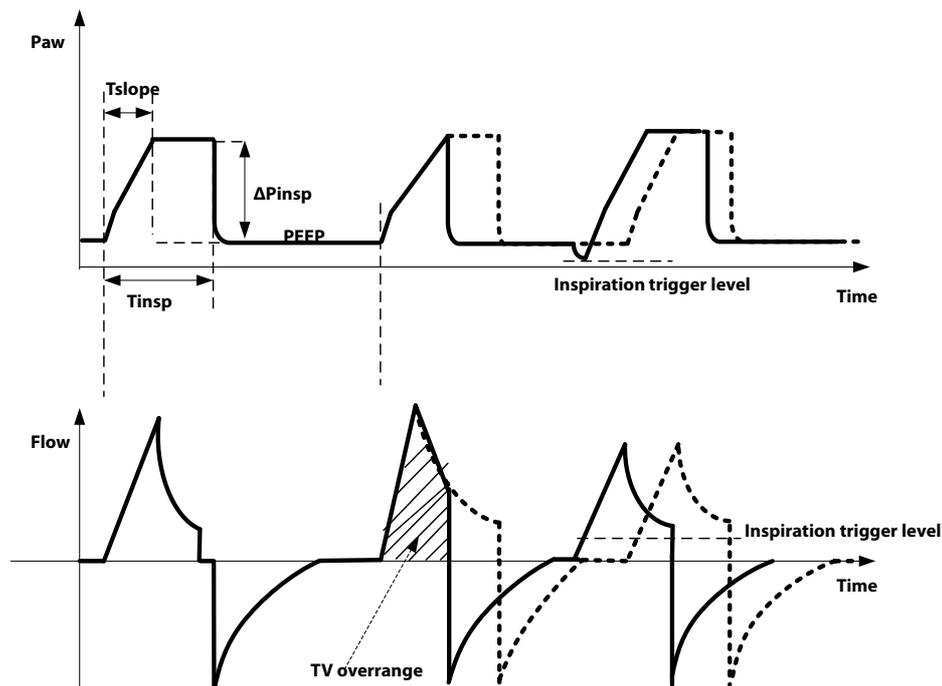


Figure 6-3 P-A/C

In P-A/C mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[ΔPinsp]:	Inspiratory pressure
[Tinsp] or [I:E]:	Inspiration time or inspiratory/expiratory time ratio
[f]:	Breathing frequency
[PEEP]:	Positive end-expiratory pressure
[Assist]:	Switching trigger ON/OFF
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Tslope]:	Time of pressure rising
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-2 P-A/C

6.5.4 V-SIMV

V-SIMV is volume-synchronized intermittent mandatory ventilation mode. It provides the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation frequency. Mandatory ventilation mode is volume mode (V-A/C mode). If patient triggers within the trigger window, ventilator delivers mandatory volume control breath once. Mandatory volume control breath is also delivered once if it is not triggered at the end of trigger window. Spontaneous breathing or pressure support breathing is supported outside the trigger window. The duration of trigger window is 5s for adults and 1.5s for pediatrics and infants. If the expiratory time is less than the duration of trigger window, the trigger window covers the expiratory time. The following figure shows typical waveforms in V-SIMV+PSV mode.

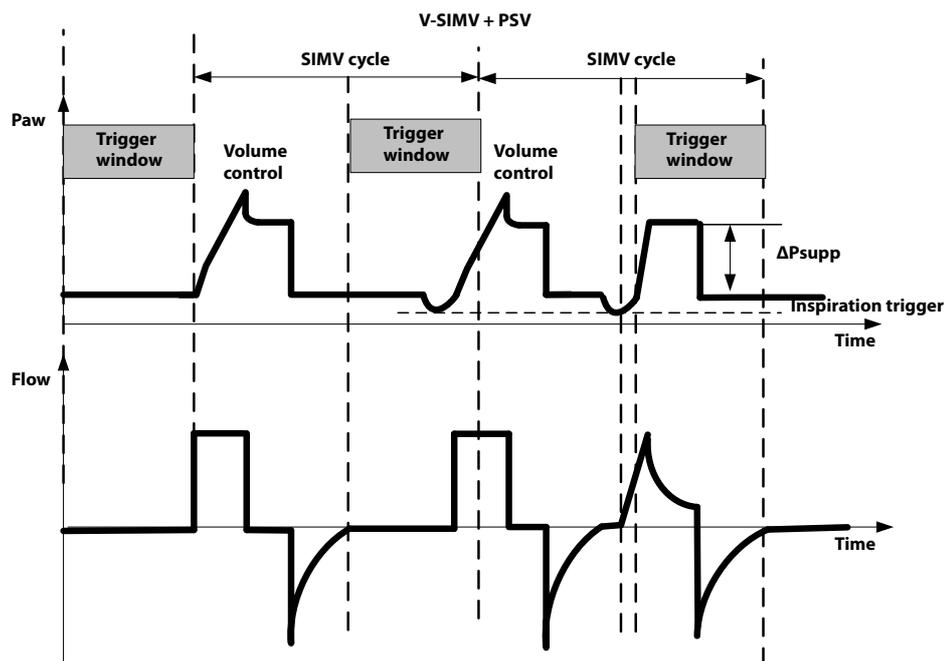


Figure 6-4 V-SIMV

In V-SIMV mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[TV]:	Tidal volume
[Tinsp]:	Inspiration time
[fsimv]:	Mandatory breathing frequency
[Tpause(%)] or [Flow]:	Percent of inspiratory pause time or flow delivered to the patient during inspiration
[ΔP_{supp}]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising

Table 6-3 V-SIMV

[Apnea Vent]:	Switch for apnea ventilation
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-3 V-SIMV

6.5.5 P-SIMV

P-SIMV is pressure-synchronized intermittent mandatory ventilation mode. It provides the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation frequency. Mandatory ventilation mode is pressure mode (P-A/C mode). If patient triggers within the trigger window, ventilator delivers mandatory pressure control breath once. Mandatory pressure control breath is also delivered once if it is not triggered at the end of trigger window. Spontaneous breathing or pressure support breathing is supported outside the trigger window. The duration of trigger window is 5s for adults and 1.5s for pediatrics and infants. If the expiratory time is less than the duration of trigger window, the trigger window covers the expiratory time. The following figure shows typical waveforms in P-SIMV+PSV mode.

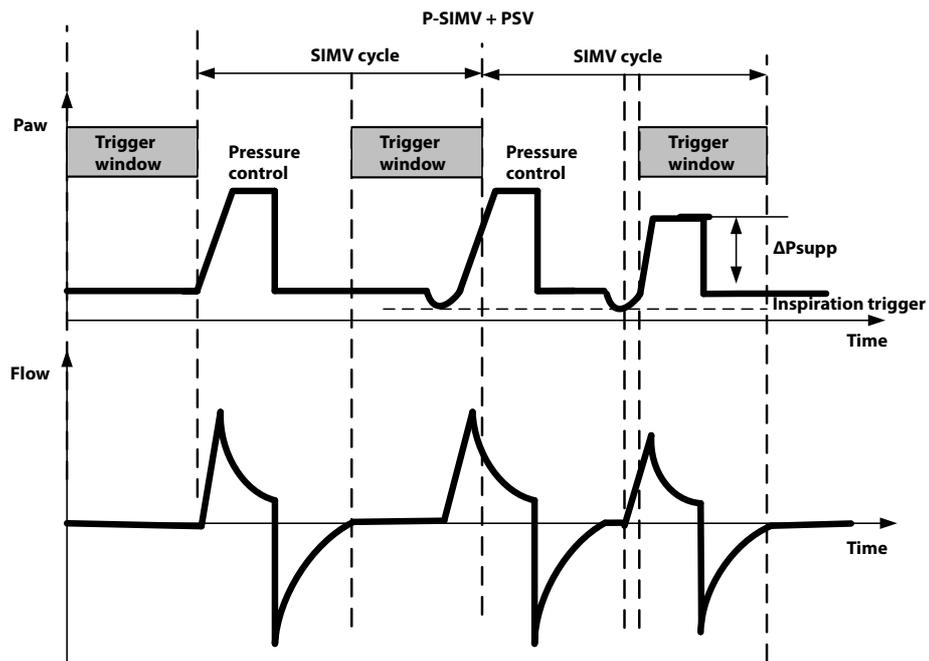


Figure 6-5 P-SIMV

In P-SIMV mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[ΔPinsp]:	Inspiratory pressure
[Tinsp]:	Inspiration time

Table 6-4 P-SIMV

[fsimv]:	Mandatory breathing frequency
[Tslope]:	Time of pressure rising
[PEEP]:	Positive end-expiratory pressure
[Exp%]:	Expiration trigger level
[ΔPsupp]:	Pressure support level
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Apnea Vent]:	Switch for apnea ventilation
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-4 P-SIMV

6.5.6 CPAP/PSV

PSV is pressure support ventilation mode. The system delivers a PSV when it detects that patient inspiratory effort reaches the preset inspiration trigger level. Time of pressure rising and pressure support level are set by the user. At the beginning of inspiratory phase, the patient’s airway pressure rises to the preset pressure level within the preset time of pressure rising, and is held at this pressure level till patient inspiratory flow is detected to reach the expiration trigger level. In PSV, when the airway pressure is held at the preset pressure level, delivered gas flow decelerates, and varies with the resistance and compliance of the patient’s lungs.

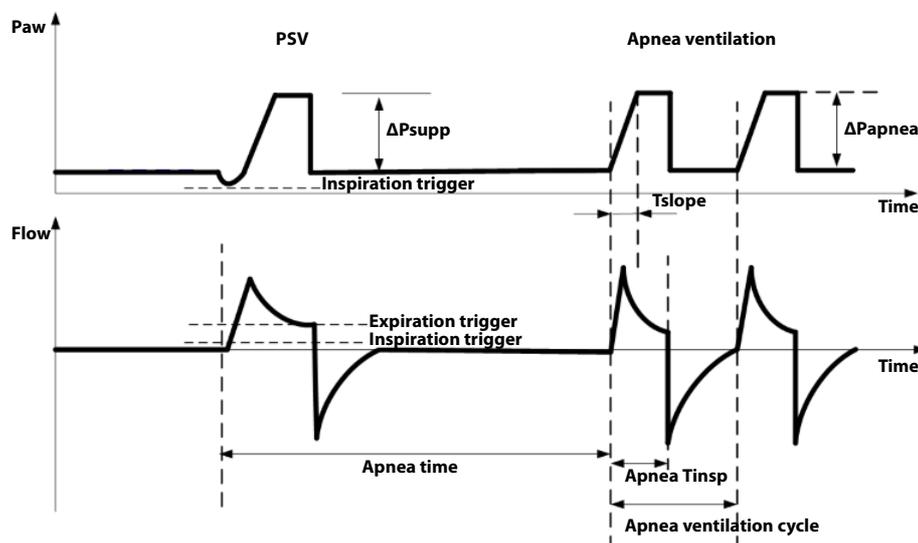


Figure 6-6 PSV

CPAP is continuous positive airway pressure ventilation mode. The airway pressure is held at the user-set positive pressure level throughout the ventilation cycle. The patient breathes spontaneously and determines his own breathing frequency, tidal volume, and breath time. The system starts apnea ventilation when it detects that the period of time in which patient does not perform continuous spontaneous breathing exceeds the preset apnea time.

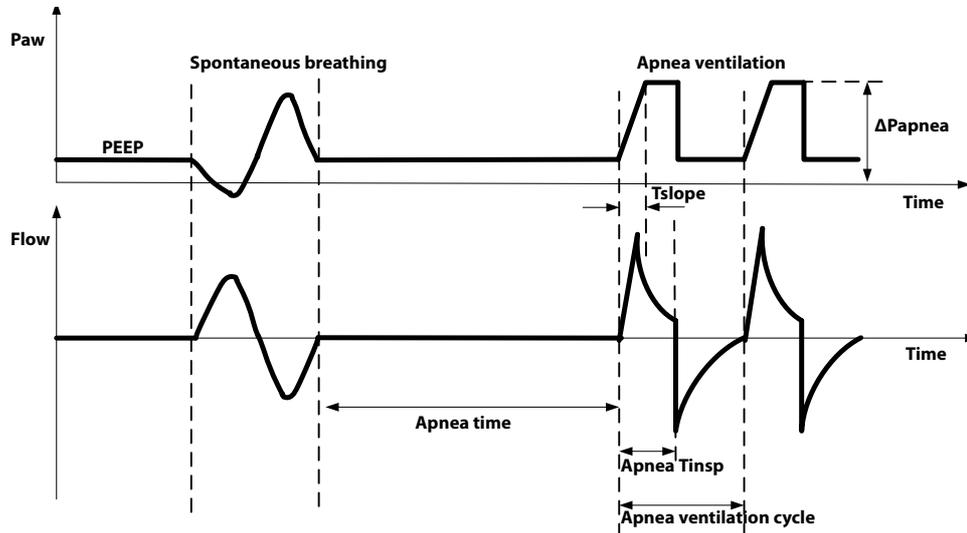


Figure 6-7 CPAP

In CPAP/PSV mode, you need to set the following basic ventilation parameters in Invasive ventilation:

[O2%]:	Oxygen concentration
[ΔPsupp]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-5 CPAP/PSV in Invasive Ventilation

In CPAP/PSV mode, you need to set the following basic ventilation parameters in Non-Invasive ventilation (NIV):

[O2%]:	Oxygen concentration
[ΔPsupp]:	Pressure support level

Table 6-6 CPAP/PSV in Non-invasive Ventilation

[PEEP]:	Positive end-expiratory pressure
[Ti max]:	Maximum time of inspiration
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-6 CPAP/PSV in Non-invasive Ventilation

6.5.7 PSV-S/T

PSV-S/T mode is called pressure support ventilation-spontaneous/timed ventilation mode, which means that the system will start pressure support ventilation (PSV) upon detection of patient's inspiration effort that reaches the preset inspiratory trigger level. Time of pressure rising and pressure support level are set by the user. At the beginning of the inspiratory phase, the patient's airway pressure increases to the preset pressure level within the preset time, and is held at this pressure level until the patient's inspiratory flow is detected to have reach the expiratory trigger level.

In the PSV-S/T ventilation mode, when the system detects that the patient doesn't trigger within the preset maximum breathing cycle (60s/breathing frequency), the system will start the Mandatory ventilation. The period of Mandatory ventilation is subject to [f] and [Tinsp]. When the system detects that the patient triggers within the preset maximum breathing cycle (60s/breathing frequency), the system will start the pressure-supported ventilation.

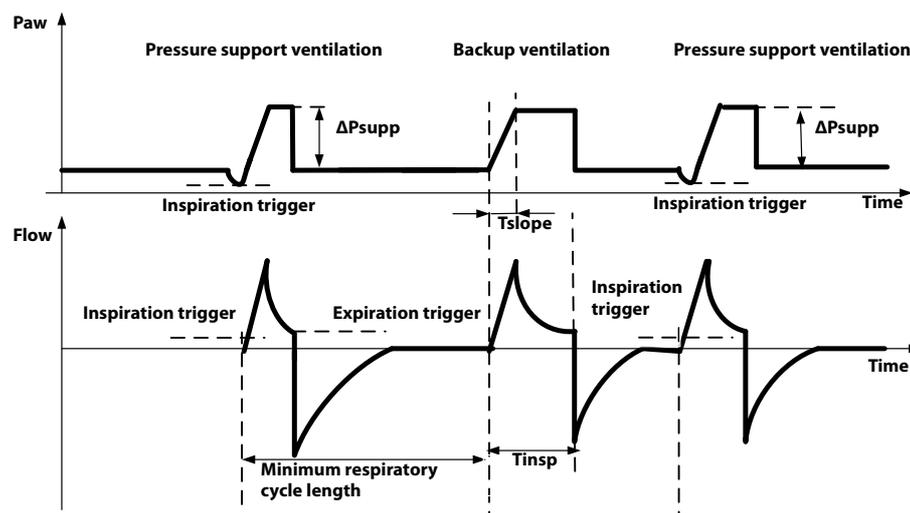


Figure 6-8 PSV-S/T

In PSV-S/T mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[Δ Psupp]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[f]:	Frequency of mandatory ventilation
[Tinsp]:	Inspiration time of mandatory ventilation
[Ti max]:	Maximum time of inspiratory phase (only applied to pressure-supported ventilation period)
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-7 PSV-S/T

6.5.8 PRVC

PRVC is pressure regulated volume control ventilation mode. It implements delivering set tidal volume by the way of pressure control ventilation. In PRVC, a relatively low pressure level is held as much as possible during the inspiratory phase, and the gas volume delivered is guaranteed to be equal to the preset tidal volume. Ppeak will vary according to the tidal volume setting and the resistance and compliance of the patient's lungs. Pressure adjustment increase of the ventilator cannot exceed 10 cmH₂O for the first 3 cycles, and cannot exceed 3 cmH₂O for each of the following cycles. The maximum pressure cannot exceed the pressure alarm high limit-5 cmH₂O.

The first PRVC delivered is experimental ventilation mode. And the gas delivery pressure of the first cycle is 10 cmH₂O+PEEP for the purpose of calculating compliance and resistance of the system and patient's lungs, and calculating pressure level based on the patient's condition. This pressure level will then be used as a regulating object for tidal volume control in the following ventilation cycles.

The following figure shows typical waveforms in PRVC mode.

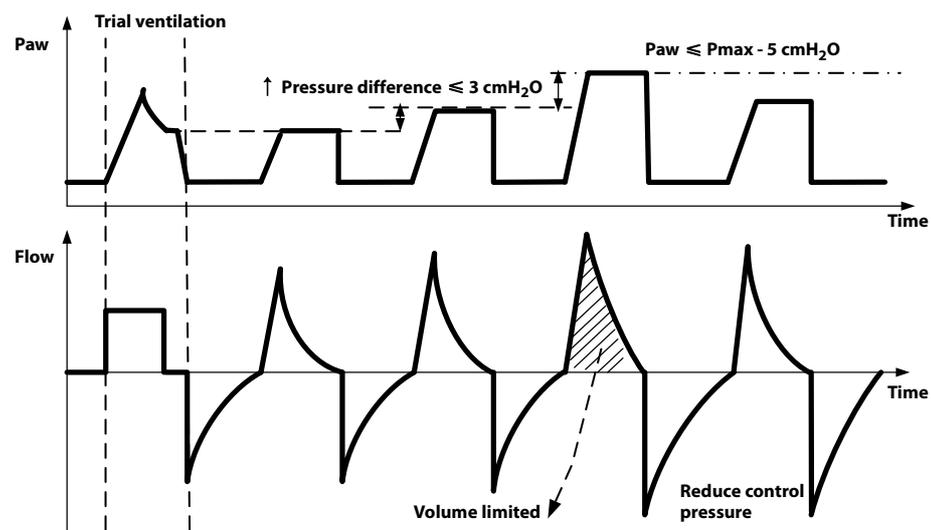


Figure 6-9 PRVC

In PRVC mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[TV]:	Tidal volume
[T _{insp}] or [I:E]:	Inspiration time or ratio of inspiratory time to expiratory time
[f]:	Breathing frequency
[PEEP]:	Positive end-expiratory pressure
[Assist]:	Switching trigger ON/OFF
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Tslope]:	Time of pressure rising
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-8 PRVC

6.5.9 PRVC-SIMV

PRVC-SIMV is pressure regulated volume control -synchronized intermittent mandatory ventilation mode. It provides the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation frequency. The provided mechanical ventilation mode is volume mode (PRVC mode). If patient triggers within the trigger window, ventilator delivers mandatory volume control breath once. Mandatory PRVC breath is also delivered once if it is not triggered at the end of trigger window. Spontaneous breathing or **pressure support breathing is supported outside the trigger window**. The duration of trigger window is 5s for adults and 1.5s for pediatrics and infants. If the expiratory time is less than the duration of trigger window, the trigger window covers the expiratory time. The following figure shows typical waveforms in PRVC -SIMV+PSV mode.

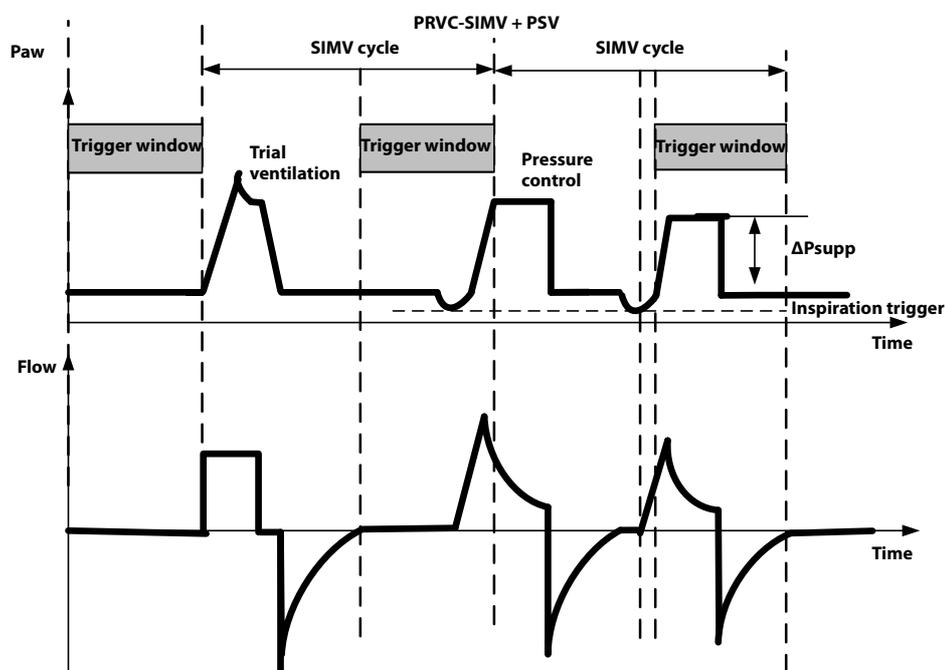


Figure 6-10 PRVC-SIMV

In PRVC-SIMV mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[TV]:	Tidal volume
[Tinsp]:	Inspiration time
[fsimv]:	Mandatory breathing frequency
[ΔPsupp]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[Apnea Vent]:	Switch for apnea ventilation
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-9 PRVC-SIMV

6.5.10 DuoLevel

DuoLevel is dual level positive airway pressure ventilation mode. In DuoLevel mode, the ventilator delivers positive airway pressure at two pressure levels alternatively during mechanical ventilation or spontaneous breathing. The patient can breathe spontaneously at either pressure level. During the low pressure phase, **pressure support can be set**. Trigger window is available during both high and low pressure phases, during which triggered transition to the other pressure level occurs. The trigger window during the low pressure phase is the later 5 seconds of low pressure time (Tlow), while the trigger window during the high pressure phase is the later 1/4 of high pressure time (Thigh). Within the trigger window of low pressure phase, inspiratory trigger transforms to high pressure gas delivery. Within the trigger window of high pressure phase, expiratory trigger transforms to low pressure gas delivery. The duration of trigger window is 5s for adults and 1.5s for pediatrics and infants. If the expiratory time is less than the duration of trigger window, the trigger window covers the expiratory time. The following figure shows typical waveforms in DuoLevel mode.

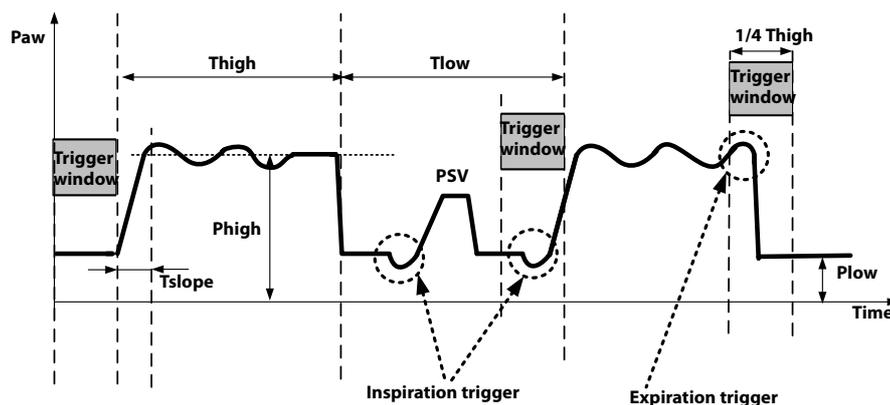


Figure 6-11 DuoLevel

In DuoLevel mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[Phigh]:	High pressure
[Thigh] or [f]:	Time of high pressure or breathing frequency
[Plow]:	Low pressure
[Tlow], [Tinsp] or [I:E]:	Time of low pressure, inspiration time or ratio of inspiratory time to expiratory time or inspiratory/ expiratory ratio
[ΔPsupp]:	Pressure support level
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-10 DuoLevel

6.5.11 APRV

APRV is airway pressure release ventilation mode. It can be seen as periodical, short period airway pressure release in CPAP mode.

The following figure shows typical waveforms in APRV mode.

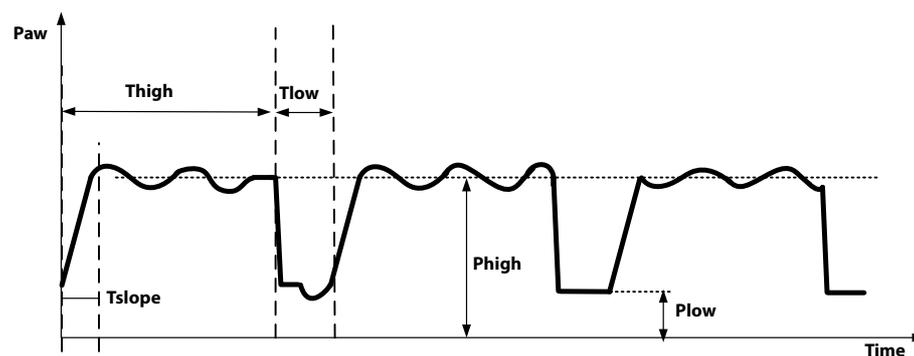


Figure 6-12 APRV

In APRV mode, you need to set the following ventilation parameters:

[O2%]:	Oxygen concentration
[Phigh]:	High pressure
[Thigh]:	Time of high pressure
[Plow]:	Low pressure
[Tlow]:	Time of low pressure
[Tslope]:	Time of pressure rising
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[F-Trig] or [P-Trig]:	Inspiration trigger level

Table 6-11 APRV

6.5.12

VS

VS refers to volume support ventilation, which means that the system will initiate volume support ventilation upon detection of the patient's inspiration effort reaching the preset inspiratory trigger level. This mode adjusts the pressure support levels depending on the patient's lung resistance, and compliance and inspiration efforts, to ensure provision of preset target tidal volume for the patient. In this mode, the duration of inspiratory and expiratory phases are controlled by the patients themselves. The system starts apnea ventilation when it detects that the period of time in which patient does not perform continuous effective inspiratory trigger exceeds the preset apnea time.

VS primary ventilation is the experimental ventilation mode, the gas delivery pressure of the first cycle is $10 \text{ cmH}_2\text{O} + \text{PEEP}$ for the purpose of calculating compliance and resistance of the system and patient's lungs, and calculating pressure support level based on the patient's condition. This pressure support level will then be used to regulate tidal volume control in the following ventilation cycles. Pressure increase of the ventilator cannot exceed $10 \text{ cmH}_2\text{O}$ for the first 3 cycles, and $3 \text{ cmH}_2\text{O}$ for each of the following cycles. The maximum pressure cannot exceed the pressure alarm high limit - $5 \text{ cmH}_2\text{O}$.

The following figure shows typical waveforms in VS mode.

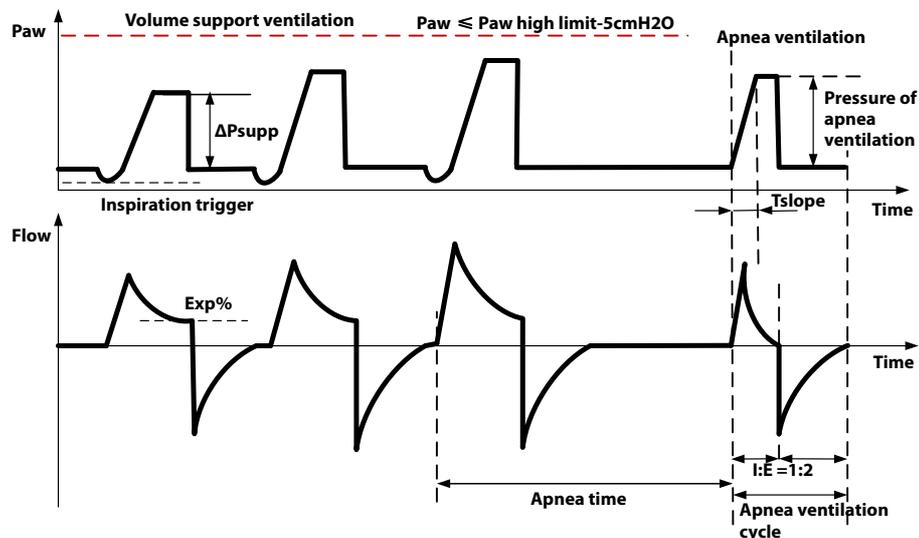


Figure 6-13 VS

In VS mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[TV]:	Tidal volume
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[TVapnea] or [ΔPapnea]:	Tidal volume or inspiration pressure in apnea ventilation cycle
[fapnea]:	Frequency of apnea ventilation
[Apnea Tinsp]:	Inspiration time of apnea ventilation
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-12 VS

6.5.13 AMV

AMV refers to adaptive minute ventilation, which is a ventilation mode that adjusts the patient’s ventilation parameters based on minimum work of breathing (WOB). The user only needs to enter the patient’s ideal body weight (IBW) and target minute ventilation volume percentage, the ventilator will calculate the tidal volume and breathing frequency with the minimum WOB using the Otis equation. It will also adjust the I:E ratio depending on the measured lung time constant. AMV is only suitable for adult and pediatric ventilation.

and pediatric ventilation.

Otis equation:

$$f = \frac{\sqrt{1 + 2a \cdot RC_{exp} \cdot \frac{MV - f \cdot V_d}{V_d}} - 1}{a \cdot RC_{exp}}$$

where, f is the breathing frequency under minimum WOB, MV is target minute volume, V_d is volume of patient's physiological dead space, RC_{exp} refers to time constant of lung, a is coefficient of waveform, For sine-wave, $a=2\pi^2/60$.

Target minute volume is calculated by the following formula:

Target minute volume MV= Minute volume % $\times f_{default} \times TV/IBW \times IBW/1000$

Where, TV/IBW refers to ideal body weight tidal volume. IBW is ideal body weight. $f_{default}$ is a group of defaults related to IBW, which values are listed as below:

IBW (kg)	$f_{default}$ (/min)
[3, 9)	35
[9, 13)	30
[13, 17)	25
[17, 23)	20
[23, 29)	15
[29, 36)	14
[36, 200)	12

Table 6-13 Relation Between IBW and $f_{default}$

The first three cycles of AMV is PCV experimental ventilation to calculate patient's lung resistance and compliance. Initial ventilation parameters are:

Adult experimental ventilation cycle setting parameters

IBW (kg)	P _{insp} (cmH ₂ O)	T _{insp} (s)	f(/min)
10-29	15	1	15
30-39	15	1	14
40-59	15	1	12
60-89	15	1	10
90-99	18	1.5	10
≥ 100	20	1.5	10

Table 6-14 Setting Parameters (Adults)

Pediatric experimental ventilation cycle setting parameters

IBW (kg)	P _{insp} (cmH ₂ O)	T _{insp} (s)	f(/min)
3-5	15	0.4	30
6-8	15	0.6	25
9-11	15	0.6	20
12-14	15	0.7	20

Table 6-15 Setting Parameters (Pediatrics)

15-20	15	0.8	20
21-23	15	0.9	15
24-29	15	1	15
30-35	15	1	14

Table 6-15 Setting Parameters (Pediatrics)

After three experimental ventilation, enter the automatic adjustment stage. Based on the principle of minimum WOB, ensure that the actual minute volume is as close as possible to the preset minute volume value. Mandatory ventilation is administered if the patient has no spontaneous breathing. Support ventilation is administered if the patient restores spontaneous breathing.

The following figure shows typical waveforms in AMV mode.

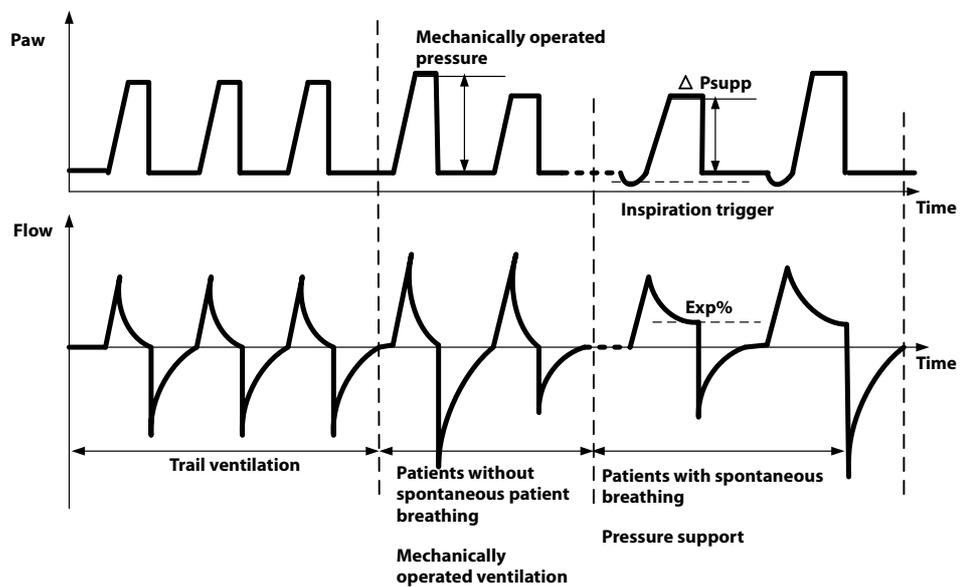


Figure 6-14 AMV

In AMV mode, you need to set the following basic ventilation parameters:

[O2%]:	Oxygen concentration
[MV%]:	Percentage of minute volume
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration trigger level
[Exp%]:	Expiration trigger level
[Tslope]:	Time of pressure rising
[IntelliCycle]:	Turn on or off the IntelliCycle function

Table 6-16 AMV

6.5.14 CPRV

NOTE: CPRV is applicable to adults only, and not applicable to pediatric and infant patients.

CPRV refers to cardiopulmonary resuscitation ventilation, which is a ventilation mode applied during the process of cardiopulmonary resuscitation (CPR), and can be activated quickly during CPR to provide the patient with mechanical ventilation in a timely fashion while avoiding harm to the patient caused by frequent trigger and over-ventilation during CPR.

CPRV mode is based on V-A/C mode, with the inspiratory trigger being turned off, the fraction of inspired oxygen concentration (FiO₂) default value at 100%, I:E ratio default value at 1:2, and PEEP default value at 0 cmH₂O. The user can initiate ventilation immediately after completion of patient type and IBW settings, and the ventilator will deliver volume-controlled ventilation at the preset tidal volume and frequency. Also, the user can set the tidal volume and breathing frequency.

The following figure shows typical waveforms in CPRV mode.

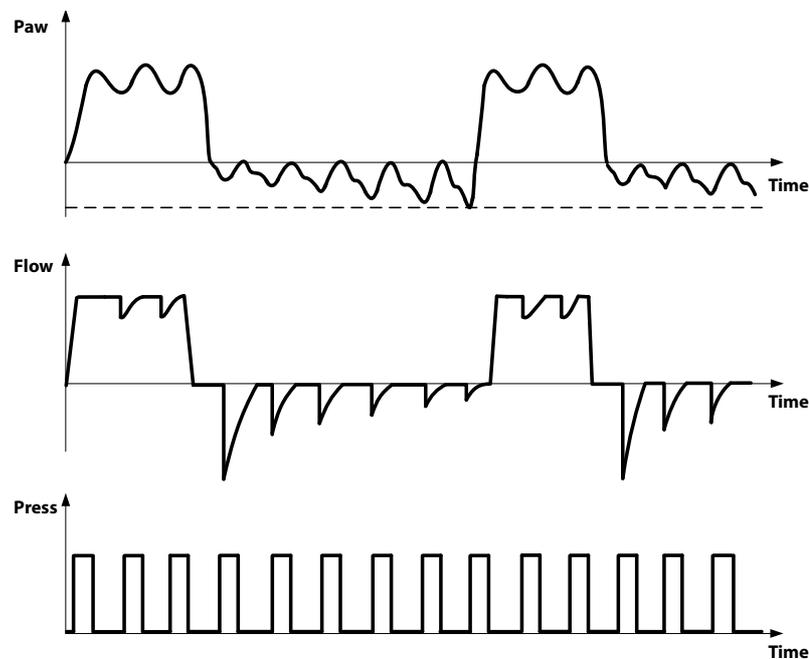


Figure 6-15 CPRV

In CPRV mode, you need to set the following basic ventilation parameters:

[TV]:	Tidal volume
[f]:	Breathing frequency
[O2%]:	Oxygen concentration
[Tinsp] or [I:E]:	Inspiration time or ratio of inspiratory time to expiratory time
[PEEP]:	Positive end-expiratory pressure

Table 6-17 CPRV

[Tpause(%)] or [Flow]:	Percentage of inspiratory pause time or flow delivered to the patient in the inspiratory phase
[Compression Prompt]:	Pressing prompt switch
[Comp. f]:	Pressing frequency
[EtCO ₂ reference line]:	The referential line of high and low alarm limit of expiratory EtCO ₂

Table 6-17 CPRV

6.5.15 Apnea Ventilation

Apnea ventilation mode is a backup ventilation mode initiated when the ventilator detects patient apnea in CPAP/PSV, VS, V-SIMV, P-SIMV, PRVC-SIMV, DuoLevel and APRV modes. Apnea ventilation can exit only under the following circumstances: patient's spontaneous breathing has been detected continuously twice, ventilation mode is switched over, or apnea ventilation is switched off (in SIMV modes).

This ventilator provides two types of apnea ventilation mode: volume-controlled apnea ventilation and pressure-controlled apnea ventilation. Both volume-controlled apnea ventilation and pressure-controlled apnea ventilation are supported in case of invasive ventilation. Only pressure-controlled apnea ventilation is supported in case of non-invasive ventilation.

Volume-controlled apnea ventilation means that tidal volume, breathing frequency, and inspiration time in the apnea ventilation cycle can be set in the mode supporting apnea ventilation. After entering apnea ventilation, the ventilator executes V-A/C mode ventilation with the set tidal volume, breathing frequency, and inspiration time in the apnea ventilation cycle (other parameters settings values are unchanged).

Pressure-controlled apnea ventilation means that inspiration pressure, breathing frequency, and inspiration time in the apnea ventilation cycle can be set in the mode supporting apnea ventilation. After entering apnea ventilation, the ventilator executes P-A/C ventilation with the set inspiration pressure, breathing frequency, and inspiration time in the apnea ventilation cycle (other parameter's setting values are unchanged).

CAUTION: You are suggested to initiate apnea ventilation in SIMV mode.

6.5.16 O₂ Therapy

O₂ therapy is a method to increase O₂ concentration in the airway at normal pressure through simple tube connections. O₂ therapy is a medical measure which can increase O₂ concentration in the alveolar gas and facilitate O₂ diffusion so as to increase PaO₂ and SpO₂ saturation and relieve or correct hypoxia by increasing O₂ concentration in the inspired gas. O₂ therapy is a way for hypoxia prevention or treatment, providing O₂ concentration higher than that in the air.

WARNING: O₂ therapy can only be used on patients with spontaneous breathing.

WARNING: During O₂ therapy, only the O₂ concentration FiO₂ and O₂ flow are monitored.

WARNING: During O₂ therapy, all physiological alarms are shielded except O₂ concentration physiological alarms.

WARNING: Airway pressure and expiration-dependent ventilation parameters, such as flow, minute volume, or apnea, are not monitored.

WARNING: Use SpO₂ monitoring for patients who are dependent only on an increased defined O₂ concentration. Otherwise, a deterioration in the patient's condition cannot be recognized.

WARNING: Only use oxygen masks or nasal catheters for O₂ Therapy. Do not use masks for non-invasive ventilation (NIV). The patient may be at risk if unsuitable masks are used.

WARNING: Insufficient source pressure may cause inaccurate control of oxygen concentration.

6.5.16.1 Preparing for O₂ Therapy

WARNING: Do not use antistatic or conductive masks, hoses or patient tubing. The use of such materials increases the risk of an electric shock for the patient and the risk of fire breaking out in oxygen-enriched atmospheres.

- Using Nasal Cannula for O₂ Therapy

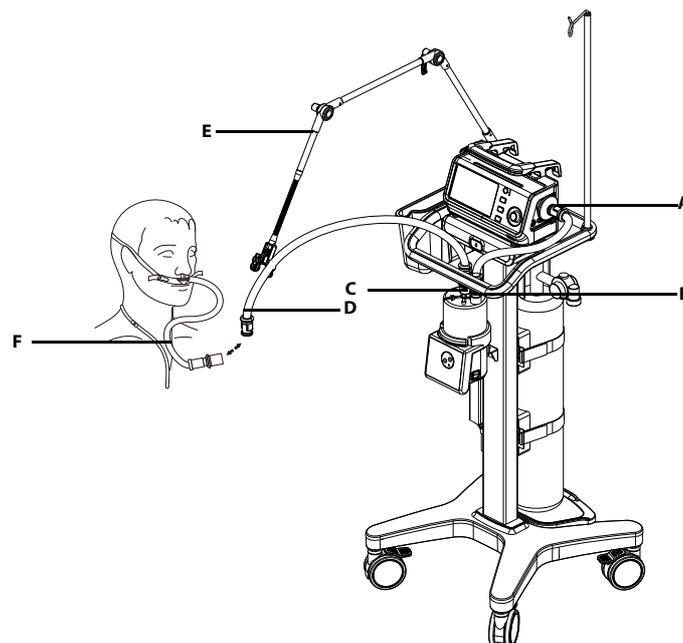


Figure 6-16 Using Nasal Cannula for O₂ Therapy

- A.** Inspiratory filter
- B.** Humidifier inlet
- C.** Humidifier outlet
- D.** Patient tubing with heating function
- E.** Support arm
- F.** Nasal cannula

1. Mount the filter onto the inspiratory port.
2. Connect the inspiratory filter to the humidifier inlet via the tube.
3. Connect the humidifier outlet to the nasal cannula via the tube with heating function.
4. The expiratory port is not connected with a tube.
5. Place the tubes onto the support arm hook.

6.5.16.2 Switching on O₂ Therapy

WARNING: The device must only be used under the supervision of qualified medical staff, so that help is immediately available if malfunctions occur or the patient has insufficient spontaneous breathing.

WARNING: This ventilator is a high flow device and should only be connected to a pipeline installation that allows for the indicated required flow at the terminal outlets, in order to avoid exceeding the pipeline flow capabilities and to minimize the risk that the ventilator interferes with adjacent equipment operation.

1. Select [O₂ Therapy] key in the ventilation mode area. The screen shows the ventilation parameters that can be set in the ventilation mode.
2. Set [Flow] and [O₂%] to appropriate values as required.
3. Select [Ok] after setting values.

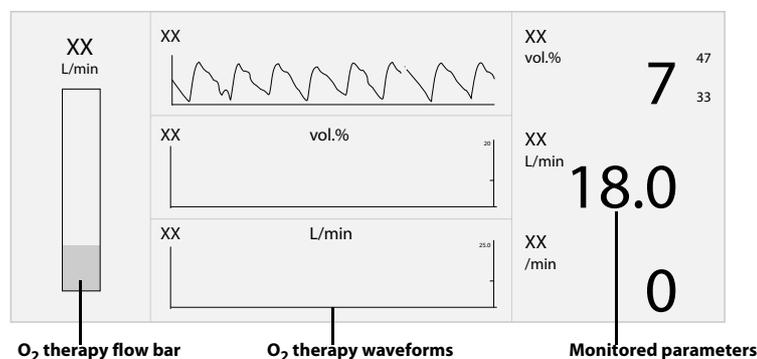


Figure 6-17 O₂ Therapy Screen

6.5.16.3 O₂ Therapy Timing/Timer

Select the O₂ Therapy Timing/Timer area in the top left corner.

Timing can be stopped or started by pressing the  or  keys. The time displayed on the timer can be reset to zero by selecting the  key.

The timer can be started by inputting the required time in minutes in **[O2 Duration]**. When the time expires, the system will emit a noise, but the oxygen supply will not be suspended.

6.5.16.4 Switching off O₂ Therapy

During O₂ therapy, select the **[Standby]** key to enter Standby status after confirmation or select other ventilation modes, so as to switch off the O₂ therapy function.

6.6 Other Ventilation Settings

6.6.1 Sigh

Sigh function can prevent pulmonary collapse, by aiding the collapsed pulmonary alveoli to reopen.

Pressure sigh function can be activated in V-A/C, P-A/C, PRCV, V-SIMV, P-SIMV, PRVC-SIMV and AMV modes. After activation of pressure sigh function, PEEP (positive end-expiratory pressure) will increase the preset **[Δint.PEEP]** intermittently. **[Interval]** refers to the time interval between two sigh stages. **[Cycles Sigh]** refers to the cycles of sigh during each sigh stage.

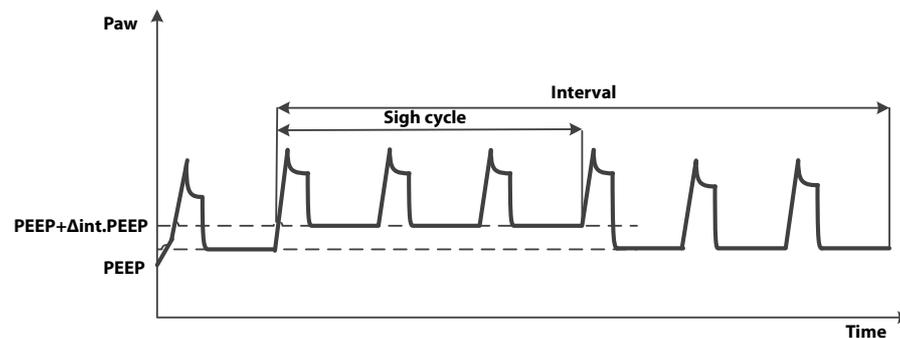


Figure 6-18 Sigh

Set the following sigh function parameters as required:

[Sigh]:	Switch for turning on sigh function
[Interval]:	Time interval between two of sigh stages
[Cycles Sigh]:	Sigh cycles
[Δint.PEEP]:	PEEP increase in sigh cycle

Table 6-19 Sigh

6.6.2 Leak Compensation

The leakage from the breathing circuit and mask may cause that the gas volume delivered to the patient's lung is lower than the setting value. The leakage also may cause the false inspiratory trigger or difficult switching between inspiratory and expiratory.

The ventilator provides leakage compensation function. The ventilator updates the amount of leakage at the end of each breathing cycle according to the difference between the inspired tidal volume and expired tidal volume, and the amount of leakage can be used for the calculation of real-time leakage flow in next breathing cycle.

During the expiration stage, the base flow will be regulated to compensate the leakage and maintain the PEEP valve. In order to prevent the false inspiratory trigger, flow trigger working mechanism is based on the compensated flow. Maximum leakage compensation flow is 65 L/min for adult patients, 45 L/min for pediatric patients and 15 L/min for infant patients respectively.

In volume control ventilation mode, the delivered gas volume is the sum of the setting TV and the amount of leakage. The leakage compensation in invasive ventilation: the upper limit of the leakage compensation is 80% of the setting TV.

In pressure control ventilation mode, the ventilator regulates the flow to compensate the leakage in order to maintain the inspiratory pressure. But the upper limit of the compensation is restricted by the TV high limit. The ventilator will not increase the flow and display the **[Volume Limited]** alarm message when the flow exceeds the TV high limit (If you want to reach the maximum leakage compensation, you can set the TV high limit to off).

Leakage compensation

The ventilator determines the difference between the delivered flow on the inspiration side and the measured flow on the expiration side.

This difference provides a measure of the amount of leakage and is displayed by the ventilator as the leakage minute volume MVleak.

The ventilator can compensate for this leakage in volume controlled ventilation.

Example: Tidal volume setting TV = 600 mL, 10 % leakage in tube.

Without Leakage compensation

The ventilator delivers 600 mL. This is indicated as the inspiratory tidal volume TV_i. 60 mL escape as leakage during inspiration, and 540 mL reach the lung.

540 mL are expired, and 40 mL again escape as leakage. A tidal volume of 500 mL is measured on the expiration side and indicated as TV_e.

With a ventilation rate of 10 strokes per minute, a minute volume of 6.0 L/min is delivered on the inspiration side and a minute volume of 5.0 L/min is measured on the expiration side. The lung is ventilated with an MV of 5.4 L/min.

Without leakage compensation, the set TV determines the volume delivered by the ventilator.

With Leakage compensation

With leakage compensation, the ventilator delivers 660 mL on the basis of the measured leakage minute volume, instead of the 600 mL set.

600 mL enter the lung and the displayed inspiratory tidal volume TV is 600 mL.

The volume of 500 mL measured on the expiration side is displayed without compensation, even when leakage compensation is activated.

The minute volume measured on the expiration side is 5.0 L/min and is also uncompensated.

If this were not so, the alarm for a low minute volume could be inhibited by the expiratory leakage compensation. The ventilator must always emit an alarm if the minute volume is too low.

With leakage compensation, the set TV determines the volume to be delivered to the patient.

This example has been simplified:

In fact, the calculated leakage correction takes into account the pressures in the hose system. A higher percentage volume is lost on the inspiration side than on the expiration side because the pressure during inspiration is higher.

The displayed leakage minute volume MVLeak is based on the mean pressure Pmean.

The leakage minute volume MVLeak also takes the inspiratory leaks into account. The sum of the minute volume MV + the leakage minute volume MVLeak is consequently greater than the inspiratory minute volume delivered to the patient.

Unlimited volume compensation is inappropriate.

The ventilator compensates for losses of up to 100 % of the set tidal volume TV.

Due to technical tolerances, a small leakage minute volume may be displayed even if the hose system is leakproof.

6.6.3 IntelliCycle

IntelliCycle synchrony enhancement technology improves the patient-ventilator synchrony during the whole ventilation cycle like an inspiratory trigger, the rise of inspiratory pressure, and expiratory trigger phase. This technology combines the characteristics of the patient's respiratory system to adjust parameters of inspiratory trigger, expiratory trigger and Tslope, reducing the frequently adjustment of ventilator settings during ventilation, alleviating the workload of medical staff and improving the patient-ventilator synchrony.

The synchrony of inspiratory trigger refers to the ventilator, which is under the ventilation mode with **[F-Trig]/[P-Trig]**, the allowance of inspiratory trigger and the startup of IntelliCycle, can trigger inspiration according to real-time monitoring patient inspiratory effort by waveform analysis, which can reduce the triggering delay, the work of triggering, ineffective triggering and auto-triggering.

The adjustment of inspiratory pressure rising refers to the ventilator, which is under the ventilation mode with **[Tslope]** and the startup of IntelliCycle, can set **[Tslope]** to the optimal value on the basis of the pressure waveforms of patient to adapt to the flow needs of patient, which can accelerate the rise of pressure, or reduce the overshoot of pressure effectively to reduce the patient's work of breathing (WOBpat).

The synchrony of expiratory trigger refers to the ventilator, which is under the ventilation mode with **[Exp%]** and the startup of IntelliCycle, can adjust the threshold of **[Exp%]** to the optimal value based on the patient's flow and pressure waveforms so as to improve the synchrony of expiratory trigger and reduce the time of premature or delayed termination.

NOTE: **The function of IntelliCycle is only suitable for adult and pediatric patients except infant ones.**

6.7 Alarm Settings

Select the [Alarm] key on the main screen to set the ventilation alarm limit and module alarm limit in the opened menu. In addition, you can also set alarm volume and view the most recent alarms. Please see **9.0 Alarms** for details.

6.8 Starting Ventilation

WARNING: Before using the ventilator on the patient, check that the oxygen concentration in the delivered gas is consistent with the setting value.

WARNING: Adopt manual ventilation immediately if the ventilator malfunctions and cannot continue ventilating the patient.

Select [Start Ventilation] key in Standby status, and the system begins to ventilate the patient according to your settings.

6.9 Ventilation Parameters

WARNING: As required by the relevant rules and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function or this function is switched off, use a monitor which complies with ISO 80601-2-55 for oxygen concentration monitoring.

NOTE: All the parameter values are calculated based on the real-time flow and pressure waveform data. For real-time flow and pressure data, low pass filter is adopted at original sampling rate of 1kHz and cutoff frequency of 20Hz.

NOTE: Tidal volume, minute volume displayed on the ventilator and related calculation parameters are in the BTPS condition.

NOTE: The maximum working pressure is ensured by the high pressure alarm limit and safety valve.

SETTING PARAMETER	DESCRIPTION
TV	The gas volume the patient inspires or expires each time during resting breathing.
Flow	Flow delivered to the patient during the inspiratory phase
O2%	The volume percentage of oxygen in the mixed gas delivered to the patient.
I:E	The ratio between the inspiratory and expiratory time.
PEEP	Positive end-expiratory pressure.
Phigh	Phigh is the high pressure level at which the patient can spontaneously breathe and is an absolute value.

Table 6-20 Ventilation Parameters

ΔP_{insp}	It is a relative value of the pressure, relative to PEEP.
Plow	Plow is the low pressure level at which the patient can breathe spontaneously.
ΔP_{supp}	Pressure support level in pressure control mode. It is a relative value relative to PEEP or Plow.
Tslope	Controls pressure rise slope in pressure mode.
Tpause(%)	Percent of gas delivery pause time in inspiratory time within the inspiratory phase.
MV%	Used for calculating the patient's target minute volume Target minute volume is equal to ideal minute volume * MV%.
f	The number of mechanically controlled breaths delivered to the patient in one minute.
fsimv	Mandatory breathing frequency set in SIMV mode.
Thigh	Thigh is the time that the ventilator will hold the high pressure level.
Tlow	Tlow is the time that the ventilator will hold the low pressure level.
Tinsp	Inspiration Time in one breathing cycle.
Ti max	The maximum time in the inspiratory phase
F-Trig/P-Trig	Pressure trigger and flow trigger included. When the trigger level is detected, the ventilator starts to enter the inspiratory phase. When F-Trig is active, at the late stage of expiration the ventilator delivers a base flow from the inspiratory limb to the expiratory limb. The base flow is essential for flow trigger. In non-invasive ventilation, the ventilator adjusts base flow from 0 L/min to maximum flow automatically to maintain PEEP and establish baseline for patient triggering. Maximum flow is 65 L/min for adult patients, 45 L/min for pediatric patients and 15 L/min for neonate patients respectively. In invasive ventilation, the ventilator adjusts base flow from 3 L/min to maximum flow automatically to maintain PEEP and establish baseline for patient triggering. Maximum flow is 20 L/min.
Exp%	Inspiratory termination level. The ventilator is switched to the expiratory phase when the inspiratory flow drops to peak flow*Exp%.
Assist	Used to turn on or off assist trigger. When assist trigger is on, the patient is allowed to trigger mechanical ventilation at the end of expiration.
Apnea Vent	Turn on or turn off apnea ventilation function.

Table 6-20 Ventilation Parameters

ΔPapnea	It is inspiration pressure in apnea ventilation when pressure mode is selected for apnea ventilation. It is a relative value relative to PEEP or P _{low} .
fapnea	Breathing frequency set in apnea ventilation mode.
TVapnea	It is delivered tidal volume in apnea ventilation when volume mode is selected for apnea ventilation.
Apnea T_{insp}	Inspiration time set in apnea ventilation mode.
Sigh	Turn on or turn off sigh function.
Interval	It is the setting value of time interval between two groups of sigh ventilation.
Cycles Sigh	It is the setting value of number of cycles of every group of sigh ventilation.
Δint.PEEP	It is intermittent PEEP augmentation, added during the sigh cycle.
Size	Choose between adult, pediatric and infant.
IBW	Used for calculating the patient's ideal minute volume.
Compression Prompt	Compression prompt switch.
Comp. f	The number of compression in one minute.
IntelliCycle	Turn on or off the IntelliCycle function
MONITORED PARAMETER	DESCRIPTION
P_{peak}	The maximum pressure value in one breathing cycle.
P_{plat}	The airway pressure during inspiratory pause.
P_{mean}	The mean pressure value in one breathing cycle.
PEEP	Positive end-expiratory pressure.
TV_i	The inspired tidal volume in one cycle.
TV_e	The expired tidal volume in one cycle.
TV_e spn	The spontaneous expired tidal volume in one cycle.
TV_e/IBW	Delivered tidal volume per ideal body weight.
MV_e	The accumulated expired tidal volume in one minute.
MV_i	The inspiratory tidal volume accumulated in one minute.
MV_{spn}	The accumulated spontaneous expired tidal volume in one minute.
MV_{leak}	The accumulated leakage (inspiratory volume minus expiratory volume) in one minute.
Leak%	The percentage of gas leakage volume in total volume of the ventilator.
I:E	Ratio of inspiration time to expiration time in one cycle
T_{insp}	Duration of the inspiratory phase
f_{total}	The accumulated number of breaths in one minute.

Table 6-20 Ventilation Parameters

fmand	The accumulated number of mandatory breaths in one minute.
fspn	The accumulated number of spontaneous breaths in one minute.
Ri	Inspiratory resistance the gas encounters when it flows inside the respiratory tract during respiration.
Re	Expiratory resistance the gas encounters when it flows inside the respiratory tract during respiration.
Cstat	Static compliance of respiratory system - easiness of patient's lungs being filled during mechanical ventilation.
Cdyn	Dynamic compliance of respiratory system - easiness of patient's lungs being filled during mechanical ventilation. It is calculated during the inspiratory phase.
RSBI	Rapid shallow breathing index - quotient between fspn and T _{Ve} spn (measured in liters).
WOB	Work of breathing – work required to deliver a certain volume of gas to the patient's lungs within one cycle.
RCexp	Patient's expiratory time constant – resistance multiplied with compliance.
P0.1	The occlusion pressure drop in the first 100 ms when the patient starts spontaneous breathing.
PEEPi	Intrinsic positive end-expiratory pressure (The PEEPi value displayed does not include PEEP).
PEEPtot	Total PEEP.
FiO2	The percentage of oxygen in the patient's inspired gas.
EtCO2	The concentration of CO ₂ measured at the end of expiration.

Table 6-20 Ventilation Parameters

6.10 Entering Standby Status

Press the **[Standby]** key to enter the Standby screen after confirmation.

WARNING: To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the Standby status. You must confirm that no patient is attached before entering Standby status.

WARNING: To prevent possible patient injury or damage to breathing circuit from overheated gas, turn off the humidifier before entering the Standby status.

6.11 Turning the System off

Press the  hard key in Standby status to turn the system off.

In non-standby status, if you press the  hard key, the system will prompt [**Please enter Standby mode to shut down the system.**]. Select [**Ok**], and the system will remain in non-standby status. Then select the [**Standby**] key to enter the standby interface after confirmation. Then select the  hard key in Standby to turn the system off.

CO₂ Monitoring

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7.1 Introduction

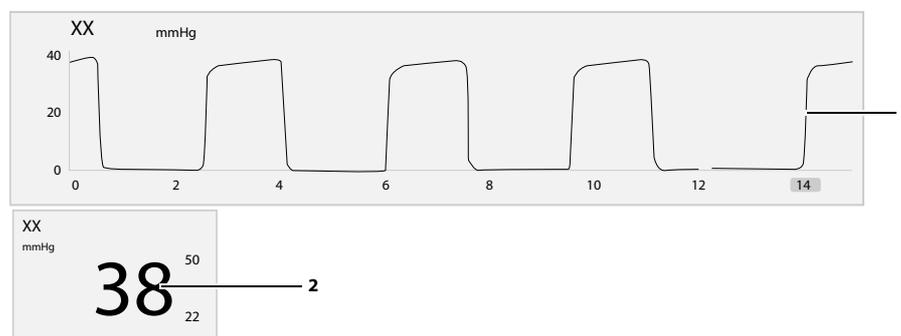
CO₂ monitoring is a continuous, non-invasive technique for determining the concentration of CO₂ in the patient's airway by measuring the absorption of infrared (IR) light of specific wavelengths. The CO₂ has its own absorption characteristic and the amount of light passing the gas probe depends on the concentration of the measured CO₂. When a specific band of IR light is passed through respiratory gas samples, some of IR light will be absorbed by the CO₂ molecules. The amount of IR light transmitted after it has been passed through the respiratory gas sample is measured with a photodetector. From the amount of IR light measured, the concentration of CO₂ is calculated.

The respiration rated range of CO₂ module is 0 to 150 /min, and the data sample rate 100 Hz. And the EtCO₂ concentration reading is using the peak of the expired CO₂ waveform.

The method used to determine the respiration rated range: Utilize a valve to permit switching between the two sampling gases at different frequencies (simulating the range of specified breath rates). Record the EtCO₂ value presented for each frequency. By drawing the coordinate diagram which indicates the corresponding relationship between end-tidal value and breathing frequency, the range of breathing frequency of EtCO₂ measurement accuracy complying with the specification can be obtained.

The CO₂ module configured for the ventilator provides automatic barometric pressure compensation.

The measurement provides:



1. CO₂ waveform.
2. End-tidal CO₂ (EtCO₂) concentration: the CO₂ concentration measured at the end of the expiration phase.

WARNING: Please ensure the cardiopulmonary condition is stable to get the most accurate CO₂ measurement.

NOTE: CO₂ cannot be measured in the aerosol drug environment. The sampling and monitoring of the CO₂ module are disabled when nebulizer function is initiated.

NOTE: As required by the international rules and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If your ventilator is not configured with such monitoring function, use a monitor which complies with related international standards for oxygen concentration monitoring.

7.2 Preparing for Measurement

1. Connect the sensor to the CO₂ module.
2. By default, the mainstream CO₂ module is set to the measurement mode. When the CO₂ module is inserted, the prompt message [CO₂ Sensor Warmup] will be displayed on the screen.
3. After warm-up is finished, connect the sensor to the airway adapter.
4. Perform a zero calibration, referring to **7.5 Zeroing the Sensor**.
5. After the zero calibration is finished, connect the airway as shown below.

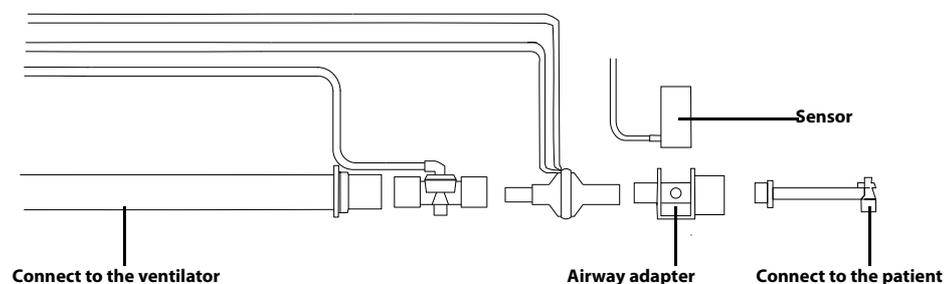


Figure 7-1 Preparing for Measurement

6. Ensure that there are no leakages in the airway, and then perform CO₂ measurements.

WARNING: Always ensure the integrity of the patient breathing circuit by verifying a proper CO₂ waveform on the ventilator display after insertion of the airway adapter.

WARNING: If the CO₂ waveform appears abnormally, inspect the CO₂ airway adapter. Replace it if needed.

WARNING: Do not use the CO₂ sensor if it appears to have been damaged or if it fails to operate normally. Contact the Customer Service Department.

WARNING: To reduce the risk of explosion, do not place the CO₂ sensor in a combustible or explosive environment.

WARNING: Inspect the CO₂ airway adapter periodically for excess moisture and secretion accumulation.

WARNING: Avoid extended direct contact of the CO₂ sensor with the human body.

- CAUTION:** To prevent premature failure of the CO₂ sensor, the CO₂ monitoring function is switched off from the moment of in which nebulization is activated until one minute after nebulization is completed. The medication may contaminate the airway adapter window due to its viscosity. It is suggested to remove the CO₂ sensor and airway adapter from the pneumatic circuit.
- NOTE:** Always position the sensor above the adapter in an upright position to avoid collection of fluids on the windows of the adapter. Large concentrations of fluids at this point will obstruct gas analysis.
- NOTE:** It takes approximately 2.5 minutes from powering on the CO₂ measurement to reaching the mainstream CO₂ monitoring performance specified in section *B.10 CO₂ Module Specifications* of this manual.
- NOTE:** The mainstream CO₂ measurement can be used, with specified accessories, on intubated and non-intubated, adult, pediatric and infant patients.
- NOTE:** Be sure to set the barometric pressure properly before using the mainstream CO₂ module. Improper settings will result in erroneous CO₂ reading.
- NOTE:** To avoid dead space, place the sensor and the airway adapter as close to the patient as possible.

7.3 Making CO₂ Settings

7.3.1 Establishing CO₂ Settings

When [**Monitoring**] is set to  (ON), the CO₂ module enters the operating mode. The ventilator displays CO₂ parameters and waveform, and provides physiological alarms and technical alarms related to the CO₂ module. When [**Monitoring**] is set to  (OFF), the CO₂ module enters standby mode. The ventilator does not display CO₂ parameters and waveform, or provide physiological alarms related to the CO₂ module.

The standby mode of CO₂ module is relevant to the Standby status of ventilator:

- If the ventilator enters Standby status, the CO₂ module also enters standby mode.
- If the ventilator exits Standby status, the CO₂ module is restored to the CO₂ operating mode before standby mode.
- CO₂ module entering or exiting standby mode has no effect upon the ventilator.

To manually enter or exit standby mode, select the [**Menu**] key → [**Setup**] → [**CO₂**] and set the [**Monitoring**] to  (OFF) or  (ON).

In standby mode, the working components of the CO₂ module, such as infrared light source, are automatically turned off to extend the service life of the module.

7.3.2 Setting Max Hold

The value of EtCO₂ in the CO₂ parameter area will be refreshed in real time. You can set the method to calculate EtCO₂.

1. Select the [**Menu**] key → [**Sensor**] → [**CO₂**].
2. Set [**Max Hold**] to [**10 s**] or [**20 s**]. The highest CO₂ concentration within the selected time interval is EtCO₂.

7.3.3 Setting Null for 30s from Zeroing

1. Select the [**Menu**] key → [**Setup**] → [**CO₂**].
2. Set [**Null for 30s from Zeroing**] to [**ON**] or [**OFF**]. When the feature is enabled, related parameters of CO₂ module will be invalid within 30s of starting zeroing CO₂ module. When the feature is disabled, related parameters of CO₂ module will be normal within 30s of starting zeroing CO₂ module.

7.3.4 Setting Unit

1. Select [**Menu**] → [**System**] → Enter system password → [**Setup**].
2. Set [**CO₂ Unit**]: mmHg, kPa or vol.%.

7.3.5 Setting Waveform

To set the waveform, please refer to **5.4.4 Setting Screen Layout**.

7.4 Measurement Limitations

Measurement accuracy may be compromised due to:

- Leakage or internal leakage of the sample gas
- Mechanical shock
- Cyclic pressure which is greater than 10 kPa (100 cmH₂O)
- Other interference source (if available)

7.5 Zeroing the Sensor

Zeroing the sensor aims to eliminate the effect of baseline drift on the readings during the measurement, so as to ensure measurement accuracy.

In the following situations, zeroing of the sensor is required:

1. The adapter is replaced.
2. The sensor is re-connected to the module.
3. When the sensor is not set in the optimal measurement mode and the ventilator displays the prompt message [**CO₂ Zero Required**]. In this case, check the airway adapter for blockage. If a blockage is detected, clear or replace the adapter.

To zero the sensor, do as follows:

1. Connect the sensor to the CO₂ module.
2. Select the [**Menu**] key → [**Setup**] → [**CO₂ Module**] and then set [**Monitoring**] to  (ON).
3. After warm-up is finished, connect the sensor to a clean, dry airway adapter. The adapter should be vented to the air and isolated from CO₂ sources, including ventilator, the patient's breathing and your own breathing.

4. Select the [**Menu**] key → [**Calibration**] → [**CO₂ In Maintenance**] and then select the [**Start**] key corresponding to CO₂ zeroing on the right side of the screen. The screen displays [**CO₂ Zero Running**].
5. A typical zeroing takes about 15 to 20 seconds. This message disappears after zeroing is completed.

WARNING: Before zeroing the sensor during the measurement, disconnect the sensor from the breathing system first.

WARNING: Failure to zero the mainstream CO₂ correctly may result in data display error. During the zeroing, the airway adapter and the CO₂ sensor should not be connected to the patient tubing.

WARNING: Do not rely on gas readings during zeroing.

7.6 Calibrating the Sensor

For a mainstream CO₂ module, calibration is not required. The system sends altitude to the mainstream CO₂ module for calibration compensation. Contact the company's Customer Service Department if calibration is necessary.

Additional Tools for Ventilation

Manual Breath/Inspiration Hold	8-2
O ₂ ↑ (Oxygen Enrichment)	8-2
Suction	8-3

8.1 Manual Breath/Inspiration Hold

The manual breath function and inspiratory hold function can be enabled by pressing or holding the **[Manual]** key in the softkey area of the main screen.

In the expiration stage, if you press and release the **[Manual]** key in a short time, the ventilator system will deliver a breath to the patient based on the current ventilation mode.

NOTE: Pressing the **[Manual Breath]** key during inspiratory phase cannot start a manual breath.

NOTE: Manual breath function is disabled in CPAP mode. When apnea ventilation occurs, the manual breath function is supported.

NOTE: Manual breath is disabled in standby status, oxygen therapy or CPRV mode.

In any phase of respiration, push and hold the the **[Manual]** key. If the ventilator is in the expiration phase, it will perform the inspiratory hold at the end of the next cycle; if the ventilator is in the inspiratory phase, it will perform the inspiratory hold at the end of the cycle. When the inspiration hold function is enabled, the message **[Insp. Hold Active]** will be displayed on the screen. Release the **[Manual]** key. The ventilator terminates the inspiration hold function. Inspiration Hold is active for a maximum of 30 seconds (for adult and pediatric patients) or 5 seconds (for infant patients). If the **[Manual]** key is pushed and exceeds the maximum time, the ventilator will terminate the inspiration hold function automatically.

During Inspiration Hold, the ventilator calculates Cstat and Pplat automatically and displays the calculation results in the prompt message box.

NOTE: There is at least one expiratory phase between two inspiration holds.

NOTE: The system will not respond to inspiration hold key operation in standby, oxygen therapy or CPRV modes.

NOTE: The expiration hold function is disabled in CPAP mode. When apnea ventilation occurs, the expiration hold function is supported.

8.2 O₂↑ (Oxygen Enrichment)

O₂↑ is also called as O₂ enrichment. It means to deliver oxygen with concentration higher than normal level within the specified time period. The oxygenation magnitude can be set by selecting **[Menu]** → **[Setup]** → **[Ventilation]**. The default oxygen enrichment magnitude is 60% for adult and pediatric patients, and 10% for infant patients.

Press the **[O₂ ↑ Suction]** key and the ventilator starts oxygen enrichment. At that time, the indicator light for **[O₂ ↑ Suction]** key will be illuminated, and the remaining oxygen enrichment time will be displayed. Oxygen enrichment is active for maximum two minutes. During oxygen enrichment, the currently set oxygen concentration is displayed in the **[O₂%]** parameter setup quick key field.

When the 2-minute period of oxygen enrichment is up or the [O₂ ↑ Suction] key is pressed again, the ventilator terminates oxygen enrichment.

NOTE: The system cannot start O₂↑ (oxygen enrichment) in the standby, oxygen therapy, or CPRV modes.

NOTE: When O₂ supply type is low-pressure, pressing the [O₂ ↑ Suction] key will not activate oxygen enrichment, rather display the prompt message [Fail to Start with Low Pressure O₂ Supply].

NOTE: When [O₂ Supply Failure] alarm is triggered, click [O₂ ↑ Suction] key, O₂↑ is disabled and prompts [O₂ Supply Failure. O₂ ↑ disabled.].

NOTE: If O₂↑ process triggers [O₂ Supply Failure] alarm, O₂↑ stops.

NOTE: Removing the patient tubing during oxygen enrichment will start suction function. Refer to 8.3 Suction.

8.3 Suction

The ventilator detects the procedure of disconnecting or reconnecting the patient tubing when the ICU staff conducts the suction maneuver for patients. The ventilator starts oxygen enrichment before and after the suction, and disables the otherwise relevant alarm messages during the suction.

1. Press the [O₂ ↑ Suction] key. The system delivers oxygen enrichment to the patient and monitors within the 120-second period of oxygen enrichment if the patient tubing are disconnected. Disconnect the patient tubing in this period.
2. After disconnecting the patient tubing, the system prompts [**The Patient is Disconnected! Reconnect Patient after Suction Completed!**], system stops ventilating the patient. In this case, you can apply manual suction to the patient.
3. Reconnect the patient tubing after the suction. When patient connection is detected, the system delivers oxygen enrichment to the patient for 120s.

During the oxygen enrichment periods, pressing the [Stop Suction] key can terminate the procedure.

NOTE: The system cannot start O₂↑ suction in the Standby modes, O₂ therapy or CPRV modes.

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Alarms

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9.1 Introduction

Alarms, triggered by a vital sign that appears abnormal or by technical problems of the ventilator, are indicated to the user by visual and audible alarm indications.

NOTE: When the ventilator is started, the system detects whether audible alarm tones and alarm lamp function normally. If yes, the alarm lamp flashes yellow and red successively, and the speaker and the buzzer give check tones. If not, do not use the equipment and contact us immediately.

NOTE: When multiple alarms of different priorities occur simultaneously, the ventilator selects the alarm of the highest priority and gives visual and audible alarm indications accordingly.

NOTE: If more than one alarms are triggered at the same level, alarm messages will be shown by the sequence of alarms triggered.

NOTE: The ventilator restore the latest configuration if restarts after the power failure.

WARNING: A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

WARNING: When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.

9.2 Alarm Categories

By nature, the ventilator's alarms fall into three categories: physiological alarms, technical alarms and prompt messages.

1. Physiological alarms

Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition. Physiological alarm messages are displayed in the alarm message field.

2. Technical alarms

Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to proper operation or mechanical problems. Technical alarm messages are displayed in the alarm message field.

3. Prompt messages

As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the ventilator will show some messages telling the system status. Messages of this kind are included into the prompt message category and are usually displayed in the prompt message field.

9.3 Alarm Priority Levels

By severity, the ventilator's alarms fall into three categories: high priority alarms, medium priority alarms and low priority alarms.

The priorities for all alarms are preset before the ventilator leaves the factory and are not user adjustable.

9.4 Alarm Signals

When an alarm occurs, the ventilator will indicate it to the user through visual or audible alarm signals.

- Alarm Lamp
- Audible alarm
- Alarm Messages
- Flashing numeric

Among them, the alarm lamp, audible alarm tones and alarm messages distinguish the priority of the alarm in different ways.

9.4.1 Alarm Lamp

If a technical alarm or physiological alarm occurs, the alarm lamp will flash. The flashing color and frequency match the alarm priority as follows:

- High priority alarms: the lamp quickly flashes red.
- Medium priority alarms: the lamp slowly flashes yellow.
- Low priority alarms: the lamp turns cyan without flashing.

9.4.2 Audible Alarm

The ventilator uses different alarm tone patterns to match the alarm priority:

- High priority alarms: broadcasts the high priority alarm tone.
- Medium priority alarms: broadcasts the medium priority alarm tone.
- Low priority alarms: broadcasts the low priority alarm tone.

A-weighted sound pressure level of audible alarm signals:

- Position of the operator: 1-meter in front of and 1.5-meter above the ventilator.
- A-weighted sound pressure level: not less than 45dB and not greater than 85 dB. The high priority alarm volume is not less than 60 dB at the default alarm volume level.

9.4.3 Alarm Messages

When an alarm occurs, an alarm message will appear in the ventilator's alarm message filed. The alarm message uses a different background color to match the alarm priority:

- High priority alarms: red
- Medium priority alarms: yellow
- Low priority alarms: cyan

The exclamatory marks (!) before the alarm message match the alarm priority as follows:

- High priority alarms: !!!
- Medium priority alarms: !!
- Low priority alarms: !

When an exclusive high-priority alarm occurs, the original ventilator alarm and prompt information are moved backwards. The exclusive high-priority alarm information will cover the original ventilation mode and patient category icon display area. See the figure below:



Figure 9-1 Exclusive High-priority Alarm

The exclusive high-priority alarms include [**Device Failure**], [**Tube Disconnected?**], [**Apnea**], [**System DOWN. Connect Ext. Power.**], and [**Paw Too High**]. If one of these alarms occurs, please refer to **D.0 Alarm Messages** to take corresponding actions.

9.4.4 Flashing Alarm Numeric

If an alarm triggered by an alarm limit violation occurs, the numeric of the measured parameter in alarm will flash at a specified frequency.

9.4.5 Alarm Status Symbol

Apart from the aforementioned alarm indicators, the ventilator still uses the following symbols telling the alarm status:

- : indicates that the alarm audio is paused and the alarm system is in **AUDIO PAUSED** mode.
- : indicates multiple alarm messages when this icon is displayed before alarm messages to show the number of alarms. The alarm message uses a different background color to match the alarm priority. Red background means that the highest priority of the multiple alarm messages is high while yellow background means that the highest priority of the multiple alarm messages is medium. You can view active alarms by selecting the alarm message field.
- : indicates that there is inactivated alarm(s) for which the alarm trigger condition has disappeared. Press this icon to view the most recent inactivated alarms (up to 9 alarm messages are displayed) in the opened interface. You can also clear the most recent alarms with the **[Reset]** key.
- : indicates that the alarm of a parameter is closed and the alarm signal is in the ALARM OFF mode.

9.5 Setting Alarm Volume

To set Alarm Volume:

1. Select **[Alarm]** key → **[Audio]**.
2. Set **[Alarm Volume]**:  indicates the lower volume,  indicates the higher volume. Alarm volume is limited by the lowest volume and cannot be lower than the lowest one. If there are no current alarms, the system will play the low priority alarm tone once at your set alarm volume when you adjust the volume.

To set minimum alarm volume:

1. Select **[Menu]** → **[System]** → Enter system password → **[Setup]**.
2. Set **[Minimum Alarm Volume]** to an appropriate value.

WARNING: Do not rely exclusively on the audible alarm system when using the ventilator. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.

9.6 Setting Alarm Management

1. Select **[Alarm]** key → **[Setup]** → **[Alarm Management]**.
2. Set it to  (ON) or  (OFF). When the switch is  (ON), the root cause of alarm triggering and disappearing will be analyzed and managed so as to avoid unnecessary alarm and nuisance alarms. Alarms are clearer to reduce alarm fatigue.

9.7 Setting Alarm Limits

CAUTION: In the case that high pressure alarm limit of 60 cmH₂O is not required under clinical conditions, setting the high pressure alarm limit to 60 cmH₂O or less is recommended so as to extend the service life of the spare air supply and the battery.

NOTE: An alarm is triggered when the parameter value is higher than the high limit or lower than the low limit.

NOTE: When using the ventilator, always keep an eye on whether the alarm limits of a specific parameter are set to the appropriate values.

Select [**Alarms**] → [**Vent Limits**] or [**Module Limits**], or select the flashing active monitored values to set ventilation or module-related alarm limits.

9.7.1 Auto Alarm Limits

Select [**Alarms**] → [**Vent Limits**] → [**Auto Limits**], the ventilator will update the parameter alarm limits based on the monitored value. The relationship is shown in the table below.

ALARM LIMIT	ADJUST FORMULA
Paw high limit	Average peak pressure+10cmH ₂ O or 35cmH ₂ O, whichever is greater
Low airway pressure limit	PEEP + 4 cmH ₂ O
MV high limit	1.5×MVe monitored value
MV low limit	0.6×MVe monitored value
TV high limit	1.5×TVe average value
TV low limit	0.5×TVe average value
ftotal high limit	1.4×Total frequency monitoring value, not more than 160/min
ftotal low limit	0.6×ftotal monitored value
Apnea time	15 s

Table 9-1 Auto Alarm Limits of Ventilator

The value used for average uses the monitoring value of the last eight ventilation cycles or the monitoring value in one minute, whichever is smaller.

If the calculated alarm limit is more than the high threshold of setting range or less than the low threshold, the corresponding threshold is used as the auto alarm limit.

9.8 AUDIO PAUSED

9.8.1 Setting AUDIO PAUSED

After the  hard key is pressed, the ventilator enters the AUDIO PAUSED state. The audio paused time is 120 seconds, and the current alarm sound can be turned off. When the 120 s countdown time is up, the AUDIO PAUSED status terminates and audible alarm tones start again.

WARNING: Pay close attention to the patient and ventilator to ensure no alarm messages are ignored during the period of AUDIO PAUSED. Possible patient or equipment hazard may be produced if the alarm condition continues while no action is taken.

NOTE: Under AUDIO PAUSED status, all the alarm indicators work normally except audible alarm tones.

9.8.2 Terminating AUDIO PAUSED

Under the alarm **AUDIO PAUSED** status, press the  key will terminate the **AUDIO PAUSED** status and restore audible alarm tones. The **AUDIO PAUSED** icon and 120-second countdown will disappear from the screen simultaneously.

9.9 Current Alarm

When there are currently active alarms, if the number is displayed before alarm messages, it indicates there are multiple active alarm messages. By selecting the alarm message field, you can view active alarm messages, alarm occurrence time and alarm priority in the opened alarm window. For certain alarms, select the triangle button on the right side to view relevant help information.

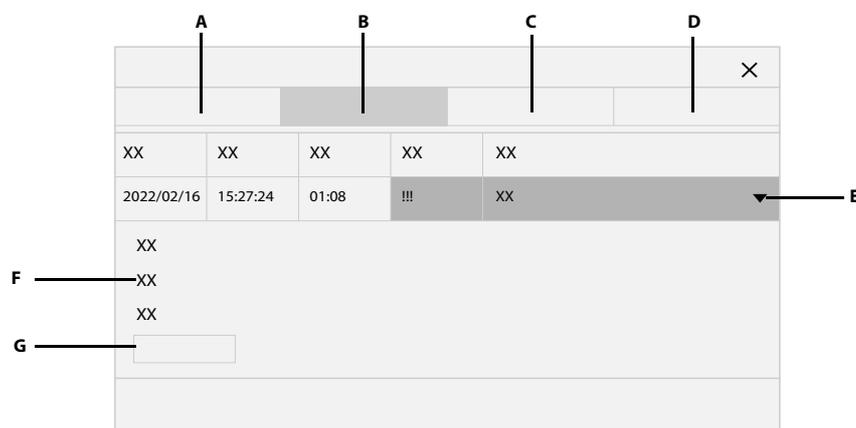


Figure 9-2 Help Information

- A. Alarm limits setup for ventilation parameters
- B. Current alarms
- C. Recent alarms
- D. Setup for alarm volume and alarm management
- E. Help information soft key

Press this soft key to display Help Information in the window that appears. Press this soft key again to close the Help Information window.

- F. Help information
- G. Associated information

Select the key to open the corresponding settings menu.

9.10 Recent Alarm

The  icon will appear if there is inactivated alarm (alarms) for which the alarm trigger condition has disappeared. By pressing the  icon, you can view the recent inactivated alarms in the opened window. You can also clear the recent inactivated alarms by pressing the [**Reset**] key.

9.11 ALARM OFF

When the alarm limit is set as [**OFF**] or alarm is disabled, the system will display an ALARM OFF icon  showing the parameter alarm limits, and corresponding physiological alarms will be closed. Namely, the alarm message, alarm lamp, audible alarm tones, and flashing alarm numeric for this physiological alarm will be all switched off.

WARNING: Switching off alarms can endanger the patient. Handle with care.

9.12 Alarm Tests

9.12.1 Loss of Power

1. Connect the ventilator to AC power and press the power button.
2. After the system starts up, disconnect the external power supply when the battery is fully charged.
3. Connect a test lung to the ventilator and start normal ventilation.
4. Ventilation time is approximately 5 hours for a ventilator configured with one battery, and approximately 10 hours for a ventilator configured with two batteries. When the battery power is depleted, the [**System DOWN. Connect Ext. Power.**] alarm is activated.
5. Reconnect the external power supply.
6. Verify that the alarm resets and the ventilator is again powered by external power supply.

9.12.2 Paw Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set Paw high alarm limit to current Peak+5 cmH₂O.
3. Squeeze the test lung hard during inspiration.
4. Verify that the [**Paw Too High**] alarm is activated, the ventilator cycles into expiration, and airway pressure falls to PEEP level.

9.12.3 Paw Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set Paw low alarm limit to current Peak+5 cmH₂O.
3. Check whether the [**Paw Too Low**] alarm is activated.

9.12.4 TVe Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the TV low alarm limit to be greater than the current TVe. Verify that the [**TVe Too Low**] alarm is activated.

9.12.5 TVe Too High

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the TV high alarm limit to be less than the current TVe. Verify that the [**TVe Too High**] alarm is activated.

9.12.6 MVe Too Low

1. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
2. Set the MV low alarm limit to be greater than the current MV. Verify that the [**MVe Too Low**] alarm is activated.

9.12.7 O₂ Supply Failure

1. Connect the ventilator to high-pressure O₂ supply, and set the O₂ supply type to high-pressure O₂ supply in the ventilator.
1. Close the high-pressure O₂ supply and verify whether the [**O₂ Supply Failure**] alarm has been activated.

9.12.8 PEEP Too Low

1. Remove the expiration valve membrane and install the expiration valve.
2. After the ventilator system starts up normally, connect a test lung to the ventilator and start ventilation.
3. Set PEEP to 30 cmH₂O. Verify that the [**PEEP Too Low**] alarm is activated.

9.12.9 Airway Obstructed

1. After the ventilator system starts up normally, connect a test lung to the ventilator and set the ventilator to pressure mode to start ventilation.
2. Disconnect the patient tubing from the test lung and plug the patient tubing with the leak test plug.
3. Verify that the [**Airway Obstructed?**] alarm is activated after several breathing cycles.
4. Connect patient tubing with the test lung and verify this alarm is reset automatically.

9.12.10 FiO₂ Too High

1. Connect the ventilator to low-pressure O₂ supply. Set the O₂ supply type to LPO.
2. Connect a test lung to the ventilator and start ventilation.
3. Set the FiO₂ high alarm limit to be less than the current O₂ concentration monitored value after ventilation is stable.
4. Verify that the [**FiO₂ Too High**] alarm is activated. Please resume the setting of the backup air supply after the test.

9.12.11 FiO₂ Too Low

1. Connect the ventilator to high-pressure O₂ supply. Set the O₂ supply type to HPO.
2. Connect a test lung to the ventilator and start ventilation.
3. Switch off the high-pressure O₂ supply after ventilation is stable.
4. Verify that the [**FiO₂ Too Low**] alarm is activated.

9.12.12 EtCO₂ Too High

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO₂ test module and set the CO₂ test module to operating mode.
3. After CO₂ warm-up is completed and the CO₂ module enters operating mode, deliver 3 % to 7 % of CO₂ standard gas to the airway adapter of mainstream CO₂ module. Set the EtCO₂ high alarm limit to be less than the standard gas concentration.
4. Verify that the [**EtCO₂ Too High**] alarm is activated.

9.12.13 EtCO₂ Too Low

1. Connect the CO₂ test module and set the CO₂ test module to operating mode.
2. Connect a test lung to the ventilator and start ventilation.
3. After CO₂ warm-up is completed and the CO₂ module enters operating mode, deliver 3 % to 7 % of CO₂ standard gas to the airway adapter of mainstream CO₂ module. Set the EtCO₂ low alarm limit to be greater than the standard gas concentration.
4. Verify that the [**EtCO₂ Too Low**] alarm is activated.

9.12.14 Tube Disconnected

1. After the ventilator system is started normally, connect the ventilator to a test lung and start ventilation.
2. Disconnect the test lung.
3. Verify that the [**Tube Disconnected?**] alarm is activated.

9.13 When an Alarm Occurs

When an alarm occurs, do as follows:

1. Check the patient's condition.
2. Determine the alarming parameter or alarm category.
3. Identify the alarm source.
4. Take proper actions to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

For details about how to troubleshoot alarms, refer to **D.0 Alarm Messages**.

WARNING: To prevent possible patient injury when alarms are active, ensure that the patient receives adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.

CAUTION: Contact the Customer Service Department if the alarm persists without obvious cause.

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10.0

Cleaning, Disinfection and Sterilization

Methods for Cleaning, Disinfection and Sterilization	10-3
General Guidelines for Cleaning, Disinfection and Sterilization	10-5
Disassembling and Reassembling for Processing	10-6

-
- WARNING:** Obey applicable safety precautions.
- WARNING:** Read the material safety data sheet for each cleaning agent.
- WARNING:** Read the operation and service instructions for all disinfection equipment.
- WARNING:** Wear gloves and safety glasses. A damaged O₂ sensor can leak and cause burns (contains potassium hydroxide).
- WARNING:** Reuse of undisinfected reusable accessories or components may cause cross-contamination.
- WARNING:** To prevent leaks, avoid damaging any component in case of disassembling and reassembling the breathing system. Ensure the correct installation of the system. Make sure of the applicability and correctness of the cleaning, disinfection and sterilization methods.
- WARNING:** Disassemble and reassemble the breathing system as described in this manual. If you need further disassembly and reassembly, contact us. Improper disassembling and reassembling may cause breathing system to leak and compromise normal system use.
- WARNING:** Seeping liquid into the control assembly can damage the equipment or cause personal injury. When cleaning the housing, ensure that no liquid flows into the control assemblies and always disconnect the equipment from the AC mains. Reconnect the AC mains after the cleaned parts are fully dry.
- WARNING:** To avoid sticky residuals, do not use talc, zinc stearate, calcium carbonate, corn starch, or equivalent materials. These materials can go into the patient's lungs and airways and cause irritation or injury.
- CAUTION:** To prevent patient exposure to disinfection agents and to prevent premature deterioration of parts, use the cleaning and disinfection methods and agents recommended in this section.
- CAUTION:** To reduce the risk of electrical shock, disconnect electrical power from the ventilator before cleaning and disinfection.
- NOTE:** Clean, disinfect and sterilize the equipment as required before it is put into use for the first time. Refer to this chapter for the cleaning, disinfection and sterilization methods.
- NOTE:** To help prevent damage, refer to the manufacturer's data if you have questions about a cleaning agent.
- NOTE:** Do not use organic, halogenated, or petroleum based solvents, anesthetic agents, glass cleaners, acetone, or other harsh cleaning agents.
- NOTE:** Do not use abrasive cleaning agents (such as steel wool, silver polish, or cleaner).
- NOTE:** Keep all liquids away from electronic parts.
- NOTE:** Do not permit liquid to go into the equipment housings.

- NOTE:** Cleaning solutions must have a pH of 7.0 to 10.5.
- NOTE:** After cleaning, and disinfection and sterilization are completed, run System Check before using the equipment. Use the equipment only when System Check is passed.
- NOTE:** After cleaning, disinfection and sterilization are completed, run System Check before using the equipment. Use the equipment only when System Check is passed.

10.1 Methods for Cleaning, Disinfection and Sterilization

Some of the ventilator's parts can be cleaned, disinfected and sterilized. Different parts of the ventilator should be disinfected using different methods. You need to select the appropriate method to clean, disinfect and sterilize the parts based on the actual situations to avoid cross-contamination between the ventilator user and the patient.

This table is our recommended cleaning, disinfection and sterilization methods for the ventilator parts, including use for the first time and use after many times.

PARTS	RECOMMENDED FREQUENCY INTERVAL	METHODS		
		MANUAL CLEANING	MANUAL DISINFECTI ON	STERILIZA TION
VENTILATOR HOUSING				
External ventilator surface (including housing, and gas supply hose)	Each patient	①	A or C	No
Trolley, IV pole and support arm	Each patient	①	A or C	No
Portable gas cylinder bracket	Each patient	①	A or C	No
AC adapter	Each patient	①	A or C	No
Dock	Each patient	①	A or C	No
Touch screen	Each patient	①	A or C	No
Main unit air intake dust filter	Every four weeks/ as necessary*	②	B	No
HEPA air intake dust filter	Every four weeks/ as necessary*	②	B	No
Flow sensor	Each patient/ weekly	②	B	D
OTHER				

Table 10-1 Methods for Cleaning and Disinfection

EMS ventilator portable carrying bag and tube protective case	Each patient/ weekly	Wipe with clean water.
Patient tubing	Each patient/ weekly	Refer to the cleaning and disinfection methods provided by the patient tubing vendor.
Mainstream CO ₂ module	Each patient/ weekly	Refer to the cleaning and disinfection methods provided by the mainstream CO ₂ vendor.
Electronic nebulizer	Each patient/ weekly	Refer to the cleaning and disinfection methods provided by the nebulizer vendor.
Humidifier	Each patient/ weekly	Refer to the cleaning and disinfection methods provided by the humidifier vendor.

Cleaning Methods:

① Wipe: wipe with a damp cloth immersed in alkaline detergent (soapy water, etc.), and then wipe off the remaining detergent with clean water and a dry lint-free cloth.

② Immersion: rinse with water first, and then immerse it in alkaline detergent (soap water, etc.) for recommended time by manufacturer. Then rinse with water completely.

Disinfection Methods:

A: Wipe: wipe with a damp cloth immersed in disinfectant and then wipe off the remaining disinfectant with clean water and a dry lint free cloth.

B: Immersion: immerse it in disinfectant for 30 minutes (recommended time). Then rinse with clean water and dry completely.

C: Ultraviolet radiation for 30 to 60 minutes (recommended time).

Sterilization methods:

D: Steam autoclave at 134°C for 10 to 20 minutes (recommended time).

As necessary: shorten the cleaning, disinfection and sterilization intervals if the equipment is used in dusty environment to ensure that the equipment surface is not covered by dust.*

Table 10-1 Methods for Cleaning and Disinfection

The table below lists the cleaning and disinfecting agents and autoclaving process that may be used on the ventilator.

NAME	TYPE
Ethanol (75%)	Intermedium level disinfectant
Isopropanol (70%)	Intermedium level disinfectant
Glutaraldehyde (2%)	Highly level disinfectant
Ortho-Phthalaldehyde disinfectant (such as Cidex®OPA)	Highly level disinfectant
Soap water (pH value of 7.0~10.5)	Cleaning agent

Table 10-2 Cleaning and Disinfecting Agents

Clean water*	Cleaning agent
Steam autoclave*	Sterilization

Clean water:* The water quality must never be less than drinking water quality.

Steam autoclave:* The recommended temperature of this disinfection method is 134°C (273°F).

NOTE: It is recommend to refer to the manufacturer's directions for use.

NOTE: The flow sensor is only applicable to high level disinfectant (Ortho-Phthalaldehyde disinfectant only) and steam autoclave.

Table 10-2 Cleaning and Disinfecting Agents

10.2 General Guidelines for Cleaning, Disinfection and Sterilization

Before cleaning, disassemble the parts from the ventilator according to 12.3. Clean and disinfect or sterilize the parts as the following general guidelines for manual cleaning, manual disinfection and sterilization.

Check the product for visible soiling and repeat cleaning and disinfection if necessary. Check the product for visible damage and replace if necessary.

10.2.1 Manual Cleaning

1. Wipe or immerse parts in accordance with the above table of cleaning, disinfection and sterilization methods.
2. Wipe off the remaining disinfectant with clean water and a dry lint free cloth.
3. Disinfect or sterilize the part, continue with the appropriate disinfection/sterilization procedures.

10.2.2 Manual Disinfection

1. After cleaning, do not reassemble.
2. Wipe or immerse parts in accordance with the above table of cleaning, disinfection and sterilization methods (Ultraviolet radiation for specified parts).
3. Wipe with clean water and a dry lint-free cloth or rinse with clean water, then allow the parts to dry completely.
4. Inspect all parts, and replace if damaged.

10.2.3 Sterilization

1. After cleaning, do not reassemble.
2. Steam autoclave parts in accordance with the above table of cleaning, disinfection and sterilization methods.
3. Allow the parts to dry completely.
4. Inspect all parts, and replace if damaged.

Reassemble the parts according to **10.3 Disassembling and Reassembling for Processing** and perform any required tests. And perform any required tests.

10.3 Disassembling and Reassembling for Processing

Disassemble and reassemble the parts at the point of use or at the designated cleaning area.

10.3.1 HEPA Filter Components and Dust Filter

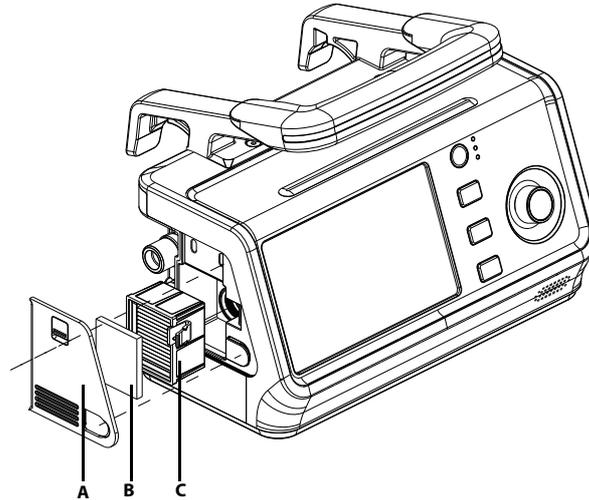


Figure 10-1 HEPA and Dust Filter

A. HEPA air intake grille

B. HEPA air intake dust filter

C. HEPA filter

• To disassemble:

1. Pull the two latches on the HEPA air inlet/outlet grille to remove the grille.
2. Pull the latch over the HEPA filter to remove. If it is necessary to remove the air intake dust filter, pinch the dust filter with two fingers and take it out.

• To install:

1. Align the HEPA filter with the corresponding slot, and push in the direction the HEPA filter is installed. Fasten the HEPA filter latch.
2. Check whether the key placement above HEPA has been installed correctly.
3. Close the HEPA air intake grille.

NOTE: Install the specified HEPA filter and air intake dust filter.

CAUTION: Do not operate the ventilator if the ventilator is not equipped with an HEPA filter. Otherwise, the inspiration end of the device and patient tubing will be contaminated.

10.3.2 Main Unit Air Intake Dust Filter

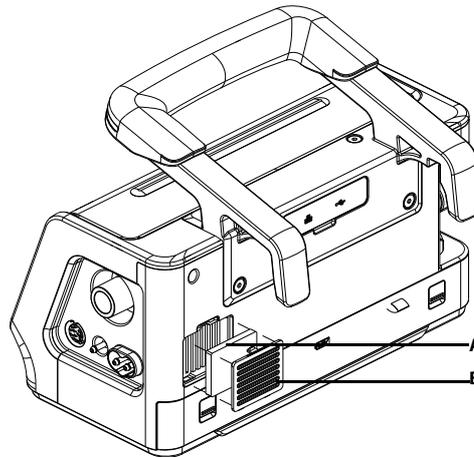


Figure 10-2 Main Unit Air Intake Dust Filter

- A.** Main unit air intake dust filter
- B.** Main unit air intake grille

- To disassemble:
 1. Pull the two latches on the main unit air intake grille to remove the grille.
 2. Pull out the main unit air intake dust filter upward.
- To install:
 1. Insert the main unit air intake dust filter into the corresponding position of the main unit.
 2. Insert the protruding supports at the bottom of the main unit air intake grille into the corresponding grooves of the main unit to fasten the latch on the grille.

10.3.3 Patient Tubing

WARNING: To minimize the risk of bacterial contamination or physical damage, remove and install the bacterial filter with care.

CAUTION: When removing the reusable patient tubing, disconnect the tubes from the ventilator connectors instead of pulling the tubes.

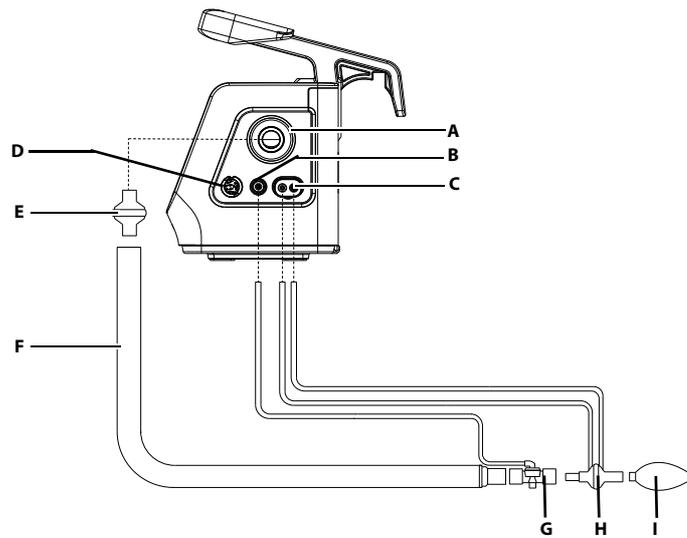


Figure 10-3 Patient Tubing

- | | |
|--------------------------------------|----------------------------|
| A. Inspiratory port | F. Patient tubing |
| B. Expiratory valve port | G. Expiratory valve |
| C. Flow sensor port | H. Flow sensor |
| D. Mainstream CO2 module port | I. Test lung |
| E. Bacteria filter | |

- To disassemble:
Pull out the patient tubing one by one.
- To install:
Refer to **3.4 Installing the Patient Tubing**.

10.3.4 Electronic Nebulizer

NOTE: Install the specified nebulizer. The nebulizer assembly, its installation and disassembling steps described in this section are only for reference.

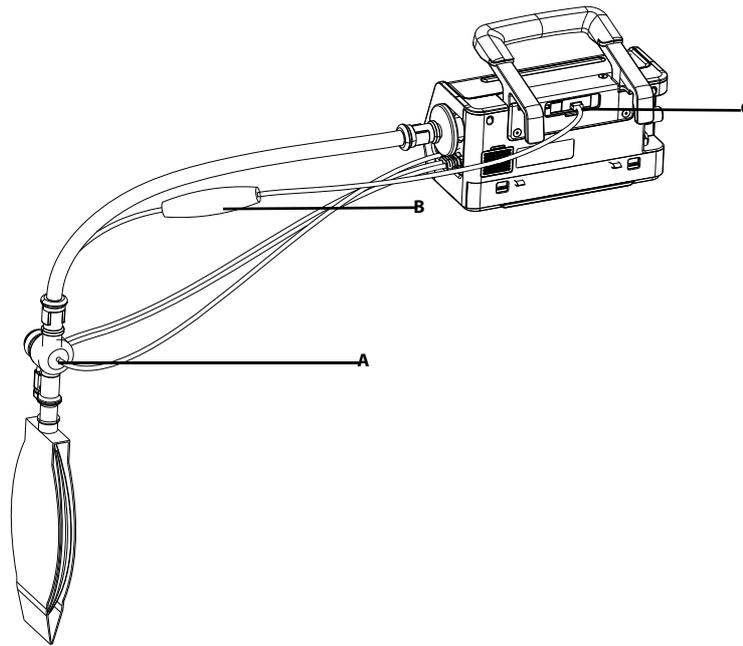


Figure 10-4 Electronic Nebulizer

- A.** Nebulizer
- B.** USB controller
- C.** USB connector

- To disassemble:
 - 1.** Pull out the USB connector of USB controller.
 - 2.** Pull out the nebulizer tube from the nebulizer and remove the nebulizer.

- To install:

Refer to **3.5 Installing the Electronic Nebulizer**.

WARNING: Always maintain the nebulizer in a vertical orientation while in the patient circuit. This orientation helps prevent patient secretions and condensate from contaminating the aerosol generator of the nebulizer and ensures proper nebulization.

WARNING: Refer to the nebulizer accompanying operator's manual to install and use the nebulizer.

10.3.5 Mainstream CO₂ Module

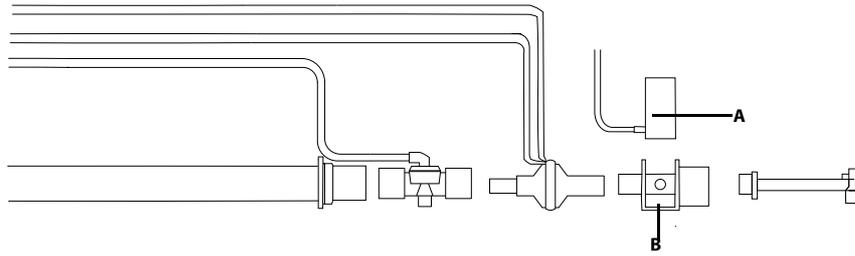


Figure 10-5 Mainstream CO₂ Module

- A.** CO₂ sensor
- B.** CO₂ airway adapter

- To disassemble:

Simply pull the CO₂ airway adapter out vertically upward.

- To install:

Install the CO₂ sensor on the CO₂ adapter vertically downward.

10.3.6 Visual Inspection

After the disassembly, inspect the components for damage, wear and tear, and the visual inspection criteria is no damage, no creak and no distortion. If the components are damaged, worn and torn, contact the service personnel.

Maintenance

Repair Policy.....	11-2
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11.1 Repair Policy

WARNING: Obey infection control and safety procedures. Used equipment may contain blood and body fluids.

WARNING: Movable parts and removable components may present a pinch or a crush hazard. Take care to move or replace system parts and components.

WARNING: Do not use lubricants that contain oil or grease, which will burn or explode when exposed to high O₂ concentrations.

Do not use malfunctioning ventilator. Have all repairs and services done by an authorized service representative. Replacement and maintenance of the parts listed in this manual may be undertaken by a competent, trained individual having experience in the repair of devices of this nature.

After repair, test the ventilator to ensure that it is functioning properly, in accordance with the specifications.

NOTE: No repair should ever be attempted by anyone not having experience in the repair of devices of this nature.

NOTE: Replace damaged parts with components manufactured or sold by us. Then test the unit to make sure that it complies with the manufacturer's published specifications.

NOTE: Contact the Customer Service Department for service assistance.

NOTE: For further information about the product, contact us. We can provide documents about some parts depending on the actual condition.

11.2 Maintenance Schedule

INTERVAL	PART/ACCESSORY	PROCEDURE
Each patient or as necessary	Patient tubing (including mask, inspiratory filter, flow sensor, expiration valve and membrane)	Perform pressure and flow zeroing (refer to 11.3); perform system self check (refer to 6.2); perform flow sensor calibration (refer to 11.4); replace with disinfected or sterilized parts or new disposable parts.
As necessary	Expiration valve	Replace the expiratory valve if it is damaged (refer to 10.3.1).
	Flow sensor	Replace the flow sensor if it is damaged.
Several times a day or as necessary	Patient Tubing	Check the patient tubing for water build-up. Empty water build-up if there is (refer to 10.3.3). Inspect the parts for damage. Replace as necessary (refer to 10.3.3).

Table 11-1 Maintenance Schedule

INTERVAL	PART/ACCESSORY	PROCEDURE
During cleaning and setup	Ventilator	Inspect the parts for damage. Replace as necessary.
Daily or as necessary	Ventilator	Clean the external surfaces (refer to 10.1).
Before each use or after continuous use of two weeks	Entire ventilator	Perform system self checking, and check the breathing system leakage (refer to 6.2).
Monthly or as necessary	HEPA air intake dust filter, main unit air intake dust filter	Check the dust filter for dust build-up. Clean or replace as necessary (refer to 10.3).
Check every 6 months and replace every three years	Lithium-ion battery	Check the charging and discharging of the lithium battery every 6 months and replace the lithium battery every three years. Contact us for replacement.
Annually, or every 5000 hours, or as necessary	Ventilator	Contact the Customer Service Department for preventive maintenance.
	Ultrasonic oxygen sensor	Calibrate the ultrasonic oxygen sensor if necessary. Contact the Customer Service Department for replacement if the oxygen sensor fails.
	Air intake HEPA filter	Replace (refer to 10.3).
	Expiration valve membrane	Check the expiration valve membrane. Contact us for replacement if necessary.
	Backup alarm system	Check the alarm duration of backup alarm system (buzzer). If it is too short, contact us.
	Gas source sealing ring	Check the gas source sealing ring. Contact us for replacement if necessary.
Every 6 years or as necessary	Battery of the clock module	Replace the battery of the clock module. Contact the Customer Service Department for replacement.
Every 20,000 hours	Blower box	Contact the Customer Service Department for replacement.

Table 11-1 Maintenance Schedule

11.3 Pressure and Flow Zeroing

Zero pressure and flow when the monitored pressure or flow value has a great deviation. Zeroing can be performed in both standby status and the process of ventilation.

1. Press the **[Menu]** key → **[Calibration]** → **[Zero Calibration]**, and then select **[Start]** key corresponding to the pressure and the flow zero on the right side.

Pressure and flow zeroing are initiated and the **[Zero Calibration Running]** message is prompted.

- After successful zeroing, the **[Zeroing Completed!]** prompt message is displayed. Otherwise, a message indicating zeroing failure will be displayed. In this case, you need to perform zeroing again.

11.4 Flow Calibration

NOTE: Do not perform calibration while the unit is connected to a patient.

NOTE: Do not perform flow calibration when low-pressure oxygen source is used.

NOTE: During calibration, do not operate the pneumatic parts. Especially, do not move or press the patient tubing.

NOTE: Ensure that the system is in Standby status. If not, push the **[Standby]** key to enter standby screen.

NOTE: It is recommended not to connect the humidifier to the ventilator before the calibration.

Calibrate the flow sensor when the measured value has a great deviation from the setting, or when the flow sensor is replaced.

Follow these steps to calibrate flow:

- Connect one side of the patient tubing with the ventilator and leave the other side open to the air.
- Select the **[Menu]** key → **[Calibration]** → **[Flow Calibration]**, and then select **[Start]** on the right-hand side. Flow calibration is initiated and the **[Calibrating]** prompt message is displayed.



- During the calibration, calibrate the reverse flow by reversing the proximal flow sensor as prompted by the system. If necessary, reverse the flow sensor to the first position to calibrate the original airflow.
- If you select **[Stop]**, the ongoing calibration will be terminated and the message **[Calibration Stopped! Calibration is unfinished.]** is displayed.
- After a successful calibration, the **[Calibration Completed!]** prompt message is displayed. Otherwise, a message indicating calibration failure will be displayed. In this case, you need to perform the calibration again.

NOTE: In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it. If it still fails or great measurement deviation occurs after troubleshooting, replace the flow sensor and repeat the above operations. If the measurement deviation is still significant, contact the authorized service personnel.

11.5 O₂ Concentration Calibration

NOTE: Do not perform oxygen concentration calibration while the unit is connected to a patient.

NOTE: Do not perform oxygen concentration calibration when low-pressure oxygen source is used.

NOTE: Ensure that the system is in Standby status. If not, push the [Standby] key to enter standby screen.

Calibrate the oxygen concentration when the measured oxygen concentration displays great deviation from the settings or when the oxygen sensor selftest fails.

Follow these steps to calibrate the oxygen concentration:

1. Ensure the high-pressure O₂ supply is connected.
2. Press the [Menu] key → Select [Calibration] → [O₂ Calibration], and then Select [Start] on the right-hand side. O₂% calibration is initiated and the [Calibrating] prompt message is displayed.
3. During the calibration, if you select [Stop], the ongoing calibration will be terminated and the message [Calibration Stopped! Calibration is unfinished.] is displayed.
4. After a successful calibration, the [Calibration Completed!] prompt message is displayed. Otherwise, a message indicating calibration failure will be displayed. In this case, you need to perform the calibration again.

NOTE: In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it. Then do the calibration again. If it still fails, contact your service personnel or us.

NOTE: Increasing to periodical pressure of 10 kPa (100 cmH₂O) has no effect upon oxygen concentration monitoring accuracy.

11.6 Mainstream CO₂ Module Calibration

For a mainstream CO₂ module, manual calibration is not required. The system sends altitude to the mainstream CO₂ module for calibration compensation.

11.7 Battery Maintenance

WARNING: The service life of lithium battery is 3 years. After the service life of lithium-ion battery expires, please replace a new one.

- WARNING:** The ventilator triggers the battery overtemperature alarm when the battery temperature exceeds 55°C during battery usage. The battery power supply is interrupted when the battery temperature is out of the range of -20~ 60°C .
- WARNING:** The ventilation stops if the internal batteries are fully discharged and no external supply is available.
- CAUTION:** The batteries can only be charged by this ventilator.
- NOTE:** Use batteries at least once every month to extend their lives. Charge the batteries before they are depleted.
- NOTE:** Inspect and replace batteries regularly. Battery life depends on how frequent and how long battery is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 3 years. For more aggressive use models, life expectancy can be shortened.
- NOTE:**
- NOTE:** When the alarm message [System DOWN. Connect Ext. Power.] is displayed on the ventilator, it indicates that the ventilator can still perform mechanical ventilation for at least 30 minutes. Please prepare to use manual ventilation for the patient. This alarm also indicates that the remaining battery capacity is insufficient and the ventilator should be connected to an external power supply immediately.

The ventilator is designed to operate on battery power whenever power supply becomes interrupted. When the ventilator is connected to the external power source, the batteries are charged regardless of whether the ventilator is currently on or not. In case of power failure, the ventilator will automatically be powered by the internal batteries. When external power source is restored within the specified time, power supply is switched from battery to external power supply automatically to ensure continuous system use.

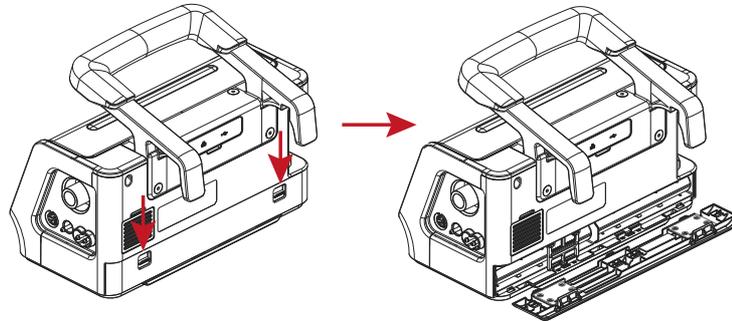
On-screen battery icon indicates the battery statuses as follows:

-  indicates that external power source is connected. The ventilator is powered by external power source. The solid green portion represents the current charge level of the batteries in proportion to its maximum charge level.
-  indicates that external power source is not connected. The ventilator is powered by built-in batteries. The solid green portion represents the current charge level of the batteries in proportion to its maximum charge level.
-  indicates that external power source is not connected. The ventilator is powered by built-in batteries. The battery capacity is low and the batteries need to be charged immediately.
-  indicates that no batteries are installed.

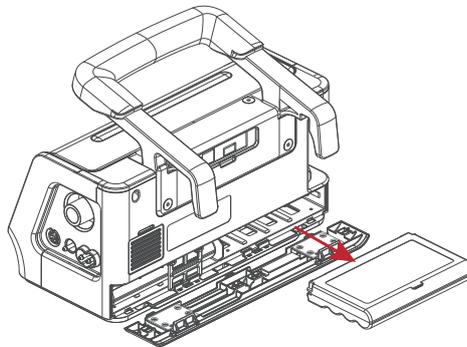
If the internal battery capacity is limited, the alarm [**System DOWN. Connect Ext. Power.**] will be triggered and a warning menu will pop-up. In this case, connect an external power source to the ventilator.

To replace the battery, follow the steps below:

1. Make sure that the ventilator is shut down.
2. Press the fastener downward with both hands to open the battery cover.



3. Remove the depleted battery from the battery slot.



4. When installing a fully charged battery, first confirm the battery orientation to ensure that it corresponds to the interface in the battery slot.
5. Press the battery by hand to ensure that it is installed in place.
6. Close the battery cover and you will hear a click, which indicates that it is closed in place.

11.7.1 Battery Guidelines

Inspect and replace batteries regularly. Battery life depends on how frequent and how long battery is used. For a properly maintained and stored lithium battery, its life expectancy is approximately 3 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing lithium batteries every 3 years.

To ensure maximum battery capacity, please adhere to the following use instructions:

- Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure.
- Condition batteries whenever they have been used for three months, or when the battery running time becomes noticeably short.

11.7.2 Battery Performance Conditioning

Condition batteries when they are put into use for the first time. A complete battery conditioning cycle is: uninterrupted charging, followed by uninterrupted discharging until the ventilator shuts off, and then uninterrupted charging. Condition batteries regularly to maintain their service lives.

NOTE: Condition batteries every time when they have been used for three months or when the battery running time becomes noticeably short.

NOTE: Over time and with the use of the battery, the actual battery capacity will decrease. For an old battery, the battery full icon does not indicate that the battery capacity or battery running time still meets the requirement specified. When conditioning batteries, replace the battery when its running time becomes noticeably short.

Follow these steps to condition batteries:

1. Disconnect the patient from the ventilator and shut down the ventilator.
2. Connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
3. Disconnect the external power source. Allow the ventilator to operate on battery power until the ventilator shuts off.
4. Re-connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
5. Battery conditioning is now completed.

11.7.3 Battery Performance Checking

Check battery performance once every six months. Checking battery performance is also required before ventilator repair is carried out or when battery is doubted to be the source for ventilator failure. Battery performance may degrade over time.

Follow these steps to check battery performance:

1. Disconnect the patient from the ventilator and shut down the ventilator.
2. Connect the ventilator to the external power source and charge the batteries uninterruptedly for at least 10 hours.
3. Disconnect the external power source. Allow the ventilator to operate on battery power until the ventilator shuts off.
4. The running time of the battery reflects its performance.

If the running time of the battery is noticeably shorter than that stated in the specifications, replace the battery or contact the service personnel.

NOTE: If the running time of the battery is too short after fully charged, the battery may be damaged already or defective.

NOTE: If obvious signs of damage are detected on the battery or the battery recharging has failed, replace the battery and recycle it properly.

11.7.4 Battery Storage

During storing batteries, ensure the battery electrodes do not get in touch with metal. In case of long-time storage, place batteries in a cool environment and keep battery power at 40% to 60%.

Placing batteries in a cool environment can delay battery aging. Ideally, batteries should be stored in a cool environment of 15°C (60°F). Do not store batteries outside the environmental range of -20°C (-4°F) to +60°C (140°F).

Remove the batteries from the ventilator if the ventilator is not used for a long time. Failure to do so will over-discharge the batteries and extend the battery charging time noticeably. Fully charge the batteries once every 2 months and keep battery power at 40% to 60%. Fully charge the batteries before use.

NOTE: Remove the batteries from the equipment if the equipment is not used for a long time.

NOTE: Long-time storage of batteries above 38°C (100°F) greatly shortens the battery life expectancy.

11.7.5 Battery Recycling

If obvious signs of damage are detected on the battery or the battery recharging has failed, replace the battery and recycle it properly. The size of the replaced battery should not be larger than 140mm × 90 mm × 20mm (Length × Width × Height). Dispose of the battery in compliance with the local laws regulating the disposal of such product.

WARNING: Do not disassemble batteries, or dispose of them in fire, or short-circuit them. They may ignite, explode and leak, causing personal injury.

11.8 Electrical Safety Inspection

NOTE: Perform an electrical safety inspection after servicing or routine maintenance. Before performing the electrical safety inspection, ensure that all the covers, panels, and screws are correctly installed.

NOTE: It is recommended that a specialized company or the manufacturer be entrusted to conduct electrical safety tests. The electrical safety inspection should be performed once a year.

1. Perform protective earth resistance test:
 - a. Plug the probes of the analyzer into the protective earth terminal of the AC power cord and the screw.
 - b. Test the earth resistance with a current of 25A.
 - c. Verify the resistance is less than 0.1ohms (100 mohms).
 - d. If the resistance is larger than 0.1ohms (100 mohms) but less than 0.2ohms (200 mohms), disconnect the AC power cord and plug the probe, that was previously plugged in the protective earth terminal of the AC power cord, into the protective earth contact of the power outlet. Repeat steps a to c.

2. Perform the following earth leakage current tests:

- normal polarity
- reverse polarity
- normal polarity with open neutral
- reverse polarity with open neutral.

Verify that the maximum leakage current does not exceed 500 μ A (0.5 mA) in the first two tests. In the final two tests, verify that the maximum leakage current does not exceed 1000 μ A (1 mA).

3. Perform the following patient leakage current tests:

- normal polarity
- reverse polarity
- normal polarity with open neutral
- reverse polarity with open neutral.
- normal polarity with open earth.
- reverse polarity with open earth.
- Mains on applied part (mains on AP), normal polarity
- Mains on applied part (mains on AP), reverse polarity

4. Verify that the maximum leakage current in the first two tests is not higher than 10 μ A (0.01 mA) on the CF type applied parts and not higher than 100 μ A (0.1 mA) on the BF type applied parts; that the maximum leakage current in the middle four tests is not higher than 50 μ A (0.05 mA) on the CF type applied parts and not higher than 500 μ A (0.5 mA) on the BF type applied parts; that the maximum leakage current in the last two tests is not higher than 50 μ A (0.05 mA) on the CF type applied parts and not higher than 5000 μ A (5 mA) on the BF type applied parts.

NOTE: **Ensure the safety analyzer is authorized by certificate organizations (UL, CSA, or AAMI etc.). Follow the instructions of the analyzer manufacturer.**

11.9 Water Condensation in the Flow Sensor

11.9.1 Preventing Water Condensation

The patient's exhaled warm and moist gas is condensed when it flows through the expiratory hose. The condensed water remains on the hose wall. When the patient's exhaled gas arrives at the expiration valve, condensed water may appear at the expiration valve and the proximal flow sensor, compromising the measurement accuracy of flow sensor.

Check the expiration valve and the proximal flow sensor for water condensation when abnormal flow waveform or unstable tidal volume fluctuation is detected. If there is water condensation, clear it before use.

Check the patient tubing for water during the use of the ventilator. If there is water condensation, empty it promptly.

11.9.2 Clearing Water Condensation

If there is water condensation inside the expiration valve and the proximal flow sensor, remove the expiration valve and flow sensor and clear the water. Then reinstall them for use.

WARNING: Ensure that all breathing system parts are dry every time when the breathing system is cleaned and disinfected or cleaned and sterilized.

WARNING: Check the expiration valve for water build-up when abnormal flow waveform or unstable tidal volume fluctuation is detected. If there is water condensation inside the expiration valve and the proximal flow sensor, clear it.

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12.0

Accessories

- WARNING:** Use only accessories specified in this chapter. Using other accessories may cause incorrect measured values or equipment malfunction.
- WARNING:** Disposable accessories can not be reused. Reuse may degrade performance or cause cross infection of the next patient.
- WARNING:** Check the accessories and their packages for damage. Do not use them if any sign of damage is detected.
- WARNING:** Parts which are intended to contact patients must comply with the biocompatibility requirement of ISO10993-1 to prevent any adverse reactions arising from such contact.
- WARNING:** Disposal of the accessories shall comply with the applicable waste control regulations.
- WARNING:** The user shall buy legally launched products for other accessories required to implement the functions of the machine.
- NOTE:** All the accessories listed are validated for use with this specific ventilator. And the hospital is responsible for ensuring the compatibility of the ventilator and the accessories before use. The incompatible parts can result in degraded performance.
- NOTE:** The CO₂ module accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

ACCESSORIES	DESCRIPTION	PN
Patient tubing kit (including breathing tubes, connectors, etc.)	Reusable adult circuit	040-006958-00
	Disposable adult circuit	040-006960-00
	Reusable pediatric circuit	040-006959-00
	Disposable pediatric circuit	040-006961-00
	Disposable adult circuit (with flow sensor)	040-007341-00
	Disposable pediatric circuit (with flow sensor)	040-007339-00
	Disposable adult circuit (with flow sensor)	115-096631-00
	Disposable pediatric circuit (with flow sensor)	115-096632-00
Filter	Heat/Moisture exchanger	040-001571-00
	Disposable bacteria filter	040-001831-00
Nebulizer	Electrical nebulizer	040-003539-00
Mask	Disposable mask, small, with head band	115-093936-00
	Disposable mask, medium, with head band	115-093937-00
	Disposable mask, large, with head band	115-093938-00
	Reusable mask, small, with head band	115-093942-00
	Reusable mask, medium, with head band	115-093948-00
	Reusable mask, large, with head band	115-093949-00
O ₂ therapy	O ₂ therapy mask (large, adult)	040-002365-00
	O ₂ therapy mask (small, child)	040-002366-00
	Nasal Cannula (small)(10)	115-037829-00
	Nasal Cannula (small)(10)	115-094759-00
	Nasal Cannula (medium)(10)	115-037830-00
	Nasal Cannula (medium)(10)	115-094760-00
	Nasal Cannula (large)(10)	115-037831-00
	Nasal Cannula (large)(10)	115-094761-00
	Nasal Cannula, Adult, small	040-002376-00
	Nasal Cannula, Adult, small	040-007358-00
	Nasal Cannula, Adult, medium	040-002377-00
	Nasal Cannula, Adult, medium	040-007359-00
	Nasal Cannula, Adult, large	040-002378-00
	Nasal Cannula, Adult, large	040-007360-00
	Nasal Cannula, Pediatric	040-005920-00
Nasal Cannula, Infant	040-005803-00	
Test lung	Test Lung (adult)	040-000744-00

Table 12-1 Accessories List

Humidifier kit (including humidifier, water tank, heated patient tubing, etc.)	Jike SH330/EU	115-018049-00
	Jike SH330/India	115-018050-00
	Jike SH330/US/110V	115-018051-00
	Jike SH330/UK	115-018053-00
	Jike SH330/US/220V	115-018054-00
	Jike SH330/BR/230V	115-032096-00
	Jike SH330/BR/110V	115-032097-00
Humidifier water tank	Disposable water chamber for Jike humidifer	040-002173-00
	Reusable water chamber for Jike humidifer	040-001530-00
Gas supply hose assembly	Ventilator oxygen hose accessories kit (German)	115-008257-00
	Ventilator oxygen hose accessories kit (French)	115-008259-00
	Ventilator oxygen hose accessories kit (Australian)	115-008261-00
	Ventilator oxygen hose accessories kit (US/dual connector/DISS)	115-008209-00
	Ventilator oxygen hose accessories kit (British)	115-008201-00
Mainstream CO ₂ module accessories	Mainstream CO ₂ accessory kit (Disposable)	115-091760-00
	Mainstream CO ₂ accessory kit (Reuse)	115-093194-00
	Disp. main CO ₂ adapter, Adu/Ped, 10 pcs	125-000280-00
	Reusable main CO ₂ adapter, Adu/Ped	040-006830-00
Flow sensor	Reusable flow sensor kit (adult/ pediatric, diff. pressure type)	115-090657-00
	Disposable flow sensor kit (adult/ pediatric, diff. pressure type)	115-090659-00
	Disposable flow sensor kit (Adu/ped/10 set)	115-094093-00
Power adapter	AC power adapter (100-240V)	022-000599-00
	DC power adapter, with power cord (12-28V)	022-000646-00
Lithium battery	Lithium battery kit	115-079845-00
	Lithium battery kit	115-096070-00
Power cord	AC power cord of adapter (Brazil)	009-003699-00
	AC power cord of adapter (UK)	009-003701-00
	AC power cord of adapter (US/110V)	009-003702-00
	AC power cord of adapter (EU)	009-003703-00
	AC power cord of adapter (India)	009-010943-00
	AC power cord of adapter (AUS)	009-004941-00
	AC power cord of adapter (ZA)	009-015291-00
	AC power cord of adapter (US/220V)	009-015324-00
Support arm	Support arm	034-000652-00
Trolley	Trolley	045-005884-00

Table 12-1 Accessories List

HEPA filter	HEPA filter	082-004173-00
Dust filter	Air intake dust filter	048-011378-00
Dock	Ventilator dock	115-093877-00
Portable gas cylinder holder	Gas cylinder holder	045-005932-00
Accessory carrying bag	Accessory carrying bag	048-011389-00
Tube protective case	Tube protective case	048-011547-00
IV pole	IV pole	034-000653-00
Pump holder	BeneFusion tDS transport docking station with trolley mount	115-094570-00
Anti-drop rope	Anti-drop rope	048-012017-00
Pressure reducer	Pressure reducer, 3/4"(DIN 477)/DIN	082-004343-00
	Pressure reducer, 5/8BE(BS 341)/DIN	082-004344-00
	Pressure reducer, CGA 540/DISS	082-004345-00
	Pressure reducer, Pin Index(CGA 870)/DIN	082-004346-00
	Pressure reducer, Pin Index(CGA 870)/DIN	082-004347-00
Adapter fixing base kit	Adapter fixing base kit	115-095424-00

Table 12-1 Accessories List

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A.0

Theory of Operation

Pneumatic Circuit Principle	A-2
Electrical System.....	A-6

A.1.2 Components List

SYMBOLS	NAME	SYMBOLS	NAME
Air Low-Pressure Inlet	Air low-pressure inlet	Blower	Blower
O2 Low-Pressure Inlet	O ₂ low-pressure inlet	P1, P2	Pressure sensor
O2 High-Pressure Inlet	O ₂ high-pressure inlet	SOL1, SOL2, SOL3, SOL4	Pressure zeroing three-way valve
F1	Roughing filter	OS	O ₂ sensor
F2	HEPA filter	CV2	Check valve
Pfilter	Vacuum sensor	SV1	Safety valve
SD1	Air/oxygen mix chamber	F6	Inspiration port filter
CV1	Check valve of gas supply inlet	R1, R2, R3	Resistor
F3	O ₂ high-pressure inlet filter	Ppeep	PEEP control proportional valve
PS1	Pressure sensor	EV	Expiration valve
RV1	Pressure relief valve	Q3	Proximal flow sensor
PSOL	Proportional solenoid valve	PQ	Pressure difference sensor
F4, F5	Filter mesh	PE	Proximal pressure sensor
Q1, Q2	Flow sensor		

Table A-2 Components List

A.1.3 Definition of Symbols

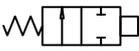
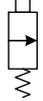
	Gas supply		Filter
	Pressure regulating valve		Switch valve (dual position, two-way solenoid valve)
	O ₂ sensor		Pressure sensor
	Check valve		Resistor
	Dual position, three-way solenoid valve		Flow sensor
	Air inlet vacuum sensor		Proportional solenoid valve
	Blower heat exchanger		Blower

Table A-3 Symbols

A.1.4 Pneumatic Circuit System Overview

This product is an electronically driven and electronically controlled ventilator. Oxygen is provided by high- or low-pressure oxygen port. Air is inhaled from the ambient atmosphere due to vacuum produced by the blower motor. The logic structure diagram of the pneumatic circuit system is shown in the figure below. The system consists of five parts: gas supply subsystem, blower subsystem, inspiration branch subsystem, pressure monitoring subsystem, and patient tubing subsystem.

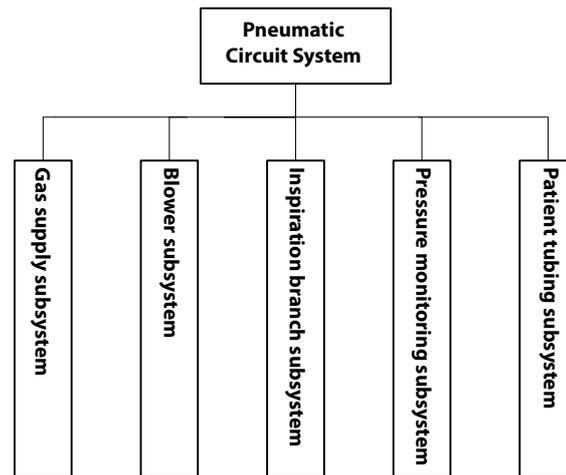


Figure A-2 Pneumatic Circuit System Structure Diagram

The gas supply subsystem is the first part of the pneumatic circuit. Its main function is to draw the air and oxygen from external sources into the machine. As the pressure of the external gas supply is high and unstable and may contain certain impurities, a dedicated filter is provided in the gas supply subsystem to filter the impurities in the air and oxygen, and a pressure relief valve is provided in the high-pressure gas supply circuit to protect the precision solenoid valve and the flow sensor in the flow control module at the back-end. Meanwhile, a pressure sensor is provided to monitor the gas supply pressure, as well as a check valve to prevent the reflux of the gas inside the ventilator to other external gas supplies. The gas supply inlet connector is designed as NIST/DISS optional type to prevent incorrect connection.

The main function of the blower subsystem is to mix pure oxygen and air in different proportions thus controlling the oxygen concentration of the output gas and blower speed, therefore achieving the precise control of gas flow rate and pressure.

The inspiration branch subsystem is designed for oxygen concentration monitoring, main branch flow rate monitoring, and safety valve pressure release. The O₂ sensor is used to monitor the oxygen concentration of the output gas in the blower subsystem. The high-precision flow sensor is provided in the main branch to monitor the flow of the output gas in the blower subsystem. Also, a safety valve is equipped for pressure relief in the patient tubing in case of excessively high pressure due to abnormal use, so as to ensure the patient's safety.

The pressure monitoring subsystem includes machine-end pressure monitoring, patient-end pressure monitoring, PEEP control pressure monitoring, and differential pressure monitoring of the proximal flow sensor. The purging function of the sampling circuit is provided to prevent damage from the entry of humidified gas into the machine through the sampling tube.

The patient tubing subsystem, as a peripheral pneumatic circuit of the ventilator, primarily serves to connect the ventilator with the patient, and the gas delivered by the ventilator is discharged via the expiration valve. The patient tubing subsystem connects the filter, and finally connects to the patient face mask. The filter accuracy is 0.3 μm, which effectively prevents the entry of bacteria and water vapor from the tubing to the ventilator.

A.2 Electrical System

A.2.1 Electrical System Structure Diagram

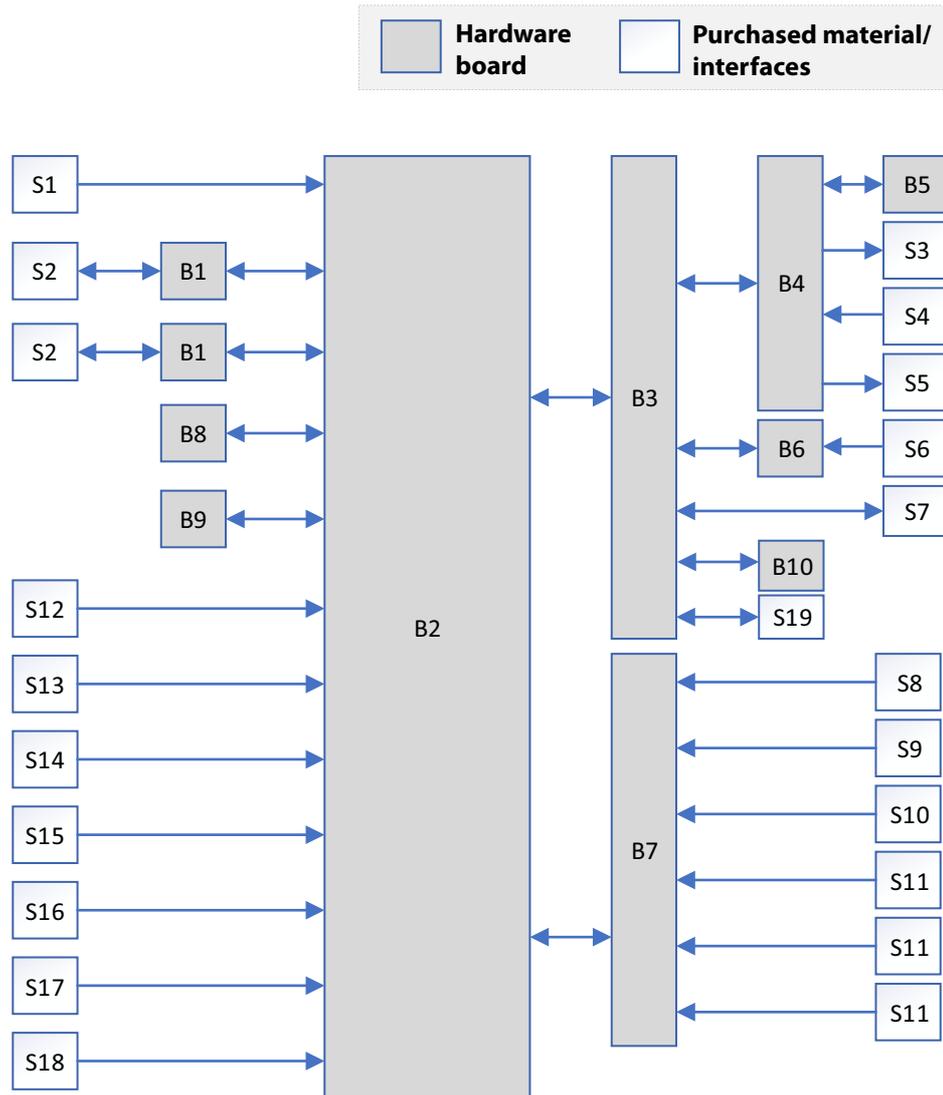


Figure A-3 Electrical System Structure Diagram

A.2.2 Components List

NO.	NAME	NO.	NAME
S1	DC input socket	B7	Sensor adapter board
S2	Battery	S8	Flow sensor of oxygen branch
B1	Battery adapter board	S9	Flow sensor of main branch
B2	Power monitor board	S10	PEEP proportional valve
B8	Vacuum sensor board	S11	3-way valve
B9	Gas supply pressure sensor board	S12	Blower
B3	Main control board	S13	Ultrasonic O ₂ sensor
B4	Key board	S14	Oxygen proportional valve
B5	Alarm lamp board	S15	Safety valve
B6	4G/5G carrier board	S16	Energy capacitance
S3	Speaker	S17	Mainstream CO ₂ module
S4	Coder	S18	Power radiator fan
S5	Ink screen	B10	Bluetooth module
S6	4G/5G module	S19	WIFI module
S7	Touch and display module	/	/

Table A-4 Components List

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Product Specifications

Safety Specifications	B-2
Environmental Specifications.....	B-3
Power Requirements	B-3
Physical Specifications	B-4
Pneumatic System Specifications	B-6
Ventilator Specifications.....	B-7
Ventilator Accuracy	B-9
Alarm	B-11
Additional Settings and Tools	B-12
CO2 Module Specifications	B-13

The ventilator is already integrated with an expiratory volume monitor, pressure measurement device, pressure release device, built-in alarm system, O₂ monitor, and CO₂ monitor. Among them:

- The expiratory volume monitor, pressure measurement device, and pressure release device comply with ISO 80601-2-12 and ISO 80601-2-84.
- The alarm system complies with IEC 60601-1-8.
- The O₂ monitor complies with ISO 80601-2-55.
- The CO₂ monitor complies with ISO 80601-2-55.
- The gas supply hose assembly complies with ISO 5359.

B.1 Safety Specifications

Classified by the type of protection against electric shock	Ventilator: Class I device with internal electrical power supply (connected with AC adapter); Class II device with internal electrical power supply (connected with DC adapter)
Classified by the degree of protection against electric shock	Ventilator: BF applied part type. Breathing circuit and CO ₂ : BF type.
Classified by degree of protection against harmful ingress of water	Ventilator: IP34 Dock: IP22 AC adapter: IP22 DC adapter: IP33
Classified by the sterilization and disinfection methods recommended by manufacturer	Ventilator: The device disinfection and sterilization methods are recommended by manufacturer.
Classified by the safety level when flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide is used	Not applicable to an environment containing flammable anesthetic gas
Classified by the operational mode	Continuous running equipment
Whether the equipment has applied parts that support protection against the defibrillation discharge effect	All applied parts support protection against the defibrillation discharge effect
Whether the equipment has signal output or input parts	With signal input and output parts
Permanently installed equipment or non-permanently installed equipment	Non-permanently installed equipment
Movement level	Portable device (without trolley)
	Mobile device (with trolley)
	Fixed device (with dock)

Table B-1 Safety Specifications

B.2 Environmental Specifications

MAIN UNIT			
Item	Temperature (°C)	Relative humidity (non-condensable)	Barometric pressure (kPa) ¹
Operating	-20 to 50	5 to 95 % R.H.	Adult: 37.6 to 110 Infant: 60 to 110
Storage	-20 to 60	10 to 95 % R.H.	60 to 110

Table B-2 Environmental Specifications

- Note: 37.6 kPa to 60 kPa output pressure should reach 35 cmH₂O, 60 kPa to 110 kPa output pressure should reach 60 cmH₂O.

CAUTION: The device may not meet the performance specifications if stored or used beyond the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.

NOTE: When the ventilator is used with other medical devices, please refer to the environmental specifications declared in the relevant medical device instructions.

B.3 Power Requirements

EXTERNAL AC POWER SUPPLY	
Input voltage	100 to 240 V~
Input frequency	50/60 Hz
Input current	2.2 to 1.0 A
Fuse	T3.15 A/250 V
AC waveform	Sinusoidal wave
EXTERNAL DC POWER SUPPLY	
Input voltage	12 to 28 V
Input current	15 to 6.5 A
INTERNAL BATTERY	
Number of batteries	One or two
Battery type	Lithium-ion battery
Rated battery voltage	14.4 VDC
Battery capacity	6600 mAh with a single battery 13200 mAh with two batteries

Table B-3 Power Requirements

Charging time	no more than 3 hours from 0% to 90% when the ventilator is powered by one new battery in powered-off status or standby status; or no more than 6 hours from 0% to 90% when the ventilator is powered by two new batteries in powered-off status or standby status.
Minimum battery run time	300 min (powered by one aged fully-charged battery according to ISO 80601-2-12); 600 min (powered by two aged fully-charged batteries according to ISO 80601-2-12). Note: Ventilator's working condition complies with ISO 80601-2-12.

Table B-3 Power Requirements

B.4 Physical Specifications

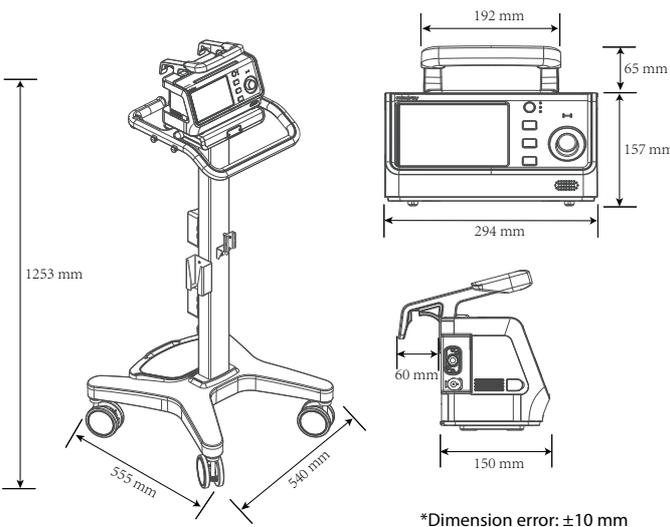
SYSTEM NOISE	
System noise	A-weighted sound pressure level (L_{pA}) \leq 48 dB(A) A-weighted sound power level (L_{WA}) \leq 56 dB (A)
OVERALL DIMENSIONS	
Dimensions	 <p>*Dimension error: ± 10 mm</p>
Weight	About 4.5 kg (including the main unit) \leq 8 kg (whole machine, including the main unit and the portable gas cylinder bracket) \leq 30 kg (whole machine, including the main unit and the trolley) Note: The whole machine includes the main unit (with one battery), display, trolley, and excludes the patient tubing assembly, support arm and humidifier.
CASTER	

Table B-4 Physical Specifications

Caster	Four casters. All casters have brakes.
DISPLAY	
Type	TFT display
Dimensions	7"
Resolution	800 x 480 pixels
Brightness	Adjustable
LED INDICATOR	
Alarm LED	One (cyan, yellow and red. When high priority alarms occur, it flashes red; when medium priority alarms occur, it flashes yellow; when low priority alarms occur, it flashes cyan.)
External power LED	One (green; lit when the external power supply is connected.)
Battery indicator light	One (green; Lit when batteries are installed and external power supply is connected; flashing when powered by batteries; extinguished when no batteries are installed or when the ventilator is powered off.)
Operating status LED	One, namely, power switch key background light (green; Lit when power on, and off when power off.)
AUDIO INDICATOR	
Speaker	Gives off alarm tones and key tones; supports multi-level tone modulation. The alarm tones comply with the requirements of IEC 60601-1-8.
Buzzer	Gives off auxiliary audio alarm in case of speaker malfunction.
CONNECTOR	
Network connector	A connector which supports connection with a PC to perform software upgrade and connection with external medical and information device.
USB connector	Use USB device to conduct ventilator software upgrade, export captured screen, export configuration information and historical data (such as patient data, alarm log, calibration table), transfer configuration data between machines of the same type, and connect the electronic nebulizer with USB interface.
Bluetooth	Connects with the external device and communicate with the external device.
5G	Connects with the external device and communicate with the external device.
WiFi	Connects with the external device and communicate with the external device.
Alarm Output	
Alarm delay time from the monitor to remote equipment	The alarm delay time from the monitor to remote equipment is ≤ 3 seconds, measured at the monitor signal output connector.
Alarm signal sound pressure level range	45 db(A) to 85 db(A) within a range of one meter

Table B-4 Physical Specifications

B.5 Pneumatic System Specifications

HIGH PRESSURE O2 SUPPLY	
Gas type	Oxygen
Gas supply pressure range	280 kPa to 650 kPa
10s average input flow for each gas at 280kpa	<200 L/min
Input connector	NIST or DISS
Rated flow requirement	200 L/min
LOW PRESSURE O2 SUPPLY	
Gas supply pressure range	≤ 100 kPa
Input connector	Quick connector which supports self sealing
Flow	≤ 15 L/min
INSPIRATION MODULE	
Inspiratory outlet	Coaxial 15 mm/22 mm conical connector
Safe pressure of the breathing system	In normal conditions and single fault conditions, the airway pressure should not exceed 120% of the maximum operating pressure or exceed the high pressure alarm limit 20 cmH ₂ O.
SYSTEM COMPLIANCE AND RESISTANCE	
Compliance	Adult disposable circuit (including inspiratory safety valve, bacteria filter, adult disposable patient tubing, expiratory valve and flow sensor): ≤ 4 mL/cmH ₂ O; Adult reusable circuit (including inspiratory safety valve, bacteria filter, adult reusable patient tubing, expiratory valve and flow sensor): ≤ 2 mL/cmH ₂ O; Pediatric/infant disposable circuit (including inspiratory safety valve, bacteria filter, pediatric/infant disposable patient tubing, expiratory valve and flow sensor): ≤ 2 mL/cmH ₂ O; Pediatric/infant reusable circuit (including inspiratory safety valve, bacteria filter, pediatric/infant reusable patient tubing, expiratory valve and flow sensor): ≤ 2 mL/cmH ₂ O.
Inspiration Resistance	Not greater than 6 cmH ₂ O at 60 L/min flow (adult patient tubing) Not greater than 6 cmH ₂ O at 30 L/min flow (pediatric/infant patient tubing)
Expiration Resistance	Not greater than 6 cmH ₂ O at 60 L/min flow (adult patient tubing) Not greater than 6 cmH ₂ O at 30 L/min flow (pediatric/infant patient tubing)
PEAK FLOW	
Peak flow	≥ 210 L/min

Table B-5 Pneumatic System Specifications

FLOW SENSOR DEAD SPACE	
Flow sensor dead space	Disposable/reusable, ≤ 20 mL.

Table B-5 Pneumatic System Specifications

B.6 Ventilator Specifications

CONTROLLED PARAMETERS			
Parameter	Range	Step size	Unit
Flow (O ₂ Therapy)	2 to 80	1	L/min
O ₂ %	21 to 100	1	Vol. %
TV	Adult: 100 to 4000 Pediatric: 20 to 300 Infant: 20 to 100	100 to 4000: 10 50 to 100: 1 20 to 50: 0.5	mL
ΔP _{supp}	0 to 60	1	cmH ₂ O
PEEP	0 to 50	1	cmH ₂ O
Δint.PEEP	OFF, 1 to 40	1	cmH ₂ O
P _{high}	0 to 60	1	cmH ₂ O
P _{low}	0 to 50	1	cmH ₂ O
ΔP _{insp}	1 to 60	1	cmH ₂ O
ΔP _{apnea}	1 to 60	1	cmH ₂ O
f	1 to 100	1	/min
f _{simv}	1 to 60	1	/min
I:E	4:1 to 1:10	0.5	/
T _{insp}	0.10 to 10.00	0.10 to 1.00: 0.01 1.00 to 10.00: 0.05	s
T _{slope}	0.00 to 2.00	0.05	s
T _{high}	0.10 to 30.00	0.10 to 1.00: 0.01 1.00 to 30.00: 0.05	s
T _{low}	0.20 to 30.00	0.20 to 1.00: 0.01 1.00 to 30.00: 0.05	s
F-Trig	0.5 to 20.0, OFF	0.1	L/min
P-Trig	-20.0 to -0.5, OFF	0.5	cmH ₂ O
Exp%	Auto, 1 to 85	1 to 5: 1 5 to 85: 5	%
T _{pause} (%)	OFF, 5 to 60	5	%
TV _{apnea}	Adult: 100 to 4000 Pediatric: 20 to 300 Infant: 20 to 100	100 to 4000: 10 50 to 100: 1 20 to 50: 0.5	mL
f _{apnea}	1 to 100	1	/min

Table B-6 Ventilator Specifications

Apnea Tinsp	0.10 to 10.00	0.10 to 1.00: 0.01 1.00 to 10.00: 0.05	s
MV%	25 to 350	1	%
Flow	Adult: 6 to 120 Pediatric: 6 to 30	10 to 120: 1.0 6 to 10: 0.1	L/min
MONITORED PARAMETERS			
PARAMETER	RANGE	RESOLUTION	UNIT
FiO2	15 to 100	1	Vol. %
TVi	0 to 6000 (BTPS)	<100 mL: 0.1 ≥ 100 mL: 1	mL
TVe			
TVe spn			
MV	0.0 to 100.0	<10.0 L/min: 0.01 ≥ 10.0 L/min: 0.1	L/min
MVspn			
MVleak			
Ppeak	-20 to 120	Absolute value <10 cmH ₂ O: 0.1 Absolute value ≥ 10 cmH ₂ O: 1	cmH ₂ O
Pplat			
Pmean			
PEEP	0 to 120	<10 cmH ₂ O: 0.1 ≥ 10 cmH ₂ O: 1	cmH ₂ O
ftotal	0 to 200	1	/min
fmand			
fspn			
Tinsp	0.00 to 60.00	0.01	s
I:E	150:1 to 1:150	0.1	/
WOB	0.00 to 100.00	0.01	J/min
	0.00 to 20.00	0.01	J/L
Leak%	0 to 100	1	%
Ri	0 to 600	1	cmH ₂ O/ (L/s)
Re			
Cstat	0 to 300	<10 mL/cmH ₂ O: 0.1 ≥ 10 mL/cmH ₂ O: 1	mL/ cmH ₂ O
Cdyn			
RSBI	0 to 9999	1	1/(L·min)
RCexp	0.00 to 10.00	0.01	s
Flow (O ₂ Therapy)	0.0 to 100.0	0.1	L/min
PEEPi	0 to 50	0.1	cmH ₂ O
PEEPtot	0 to 120	0.1	cmH ₂ O
P0.1	-20.0 to 0.0	0.1	cmH ₂ O

Table B-6 Ventilator Specifications

B.7 Ventilator Accuracy

CONTROL ACCURACY	
Flow (O ₂ Therapy)	2 L/min to 3 L/min: ± 2 L/min 3 L/min to 80 L/min: ± (2 L/min + 10% of set value)
FiO ₂	± (3 vol.% + 1% of set value)
TV	± (10 ml + 10% of set value)
ΔP _{supp}	± (2 cmH ₂ O + 5 % of set value)
ΔP _{insp}	± (2 cmH ₂ O + 5 % of set value)
PEEP	0 cmH ₂ O to 2 cmH ₂ O: ± set value (The error is not greater than 2 cmH ₂ O when the PEEP is set to 0 cmH ₂ O.) 2 cmH ₂ O to 50 cmH ₂ O: ± (2 cmH ₂ O + 5 % of set value)
Phigh	0 cmH ₂ O to 2 cmH ₂ O: ± set value (The error is not greater than 2 cmH ₂ O when the Phigh is set to 0 cmH ₂ O.) 2 cmH ₂ O to 60 cmH ₂ O: ± (2 cmH ₂ O + 5 % of set value)
Plow	0 cmH ₂ O to 2 cmH ₂ O: ± set value (The error is not greater than 2 cmH ₂ O when the Plow is set to 0 cmH ₂ O.) 2 cmH ₂ O to 50 cmH ₂ O: ± (2 cmH ₂ O + 5 % of set value)
f	± 1/min
fsimv	± 1/min
I:E	2:1 to 1:4: 10% of set value Other range: ± 2% of set value
T _{insp}	± 0.10 s or ±10% of set value, whichever is greater
T _{high}	0.10s to 0.20s: ± set value 0.20s to 30.00s: ± 0.20s or ±10% of set value, whichever is greater
T _{low}	± 0.20s or ±10% of set value, whichever is greater
F-Trig	0.5 L/min to 1.1 L/min: ± set value 1.1 L/min to 20.0 L/min: ± (1 L/min + 10% of set value)
P-Trig	-1.0 cmH ₂ O to -0.5 cmH ₂ O: ± set value -20.0 cmH ₂ O to -1.0 cmH ₂ O: ± (1.0 cmH ₂ O + 10% of set value)
Exp%	1% to 10%: ± set value (absolute error) 10% to 85%: ± 10 % (absolute error)
T _{pause} (%)	± 5% (absolute error, not applicable if T _{pause} (%) is less than 0.1s)
T _{slope}	0.00s to 0.20s: ± set value (The error is not greater than 0.10s when the T _{slope} is set to 0.00s.) 0.20s to 2.00s: ± 0.20s or ±20% of set value, whichever is greater
TV _{apnea}	± 15 mL or ±15% of set value, whichever is greater
f _{apnea}	± 1/min
ΔP _{apnea}	± (2 cmH ₂ O + 5 % of set value)
Apnea T _{insp}	± 0.1s or ±10 % of set value, whichever is greater
MV%	±10% (absolute error) or ± 10% of set value, whichever is greater.
Δ _{int} .PEEP	1 cmH ₂ O to 2 cmH ₂ O: ± set value 2 cmH ₂ O to 40 cmH ₂ O: ± (2 cmH ₂ O + 5% of set value)

Table B-7 Ventilator Accuracy

Flow	±20% of set value
MONITORING ACCURACY	
FiO ₂ *	± (2.5 vol. % + 2.5% of actual reading)
TVi	± 15 mL or ± 15% of actual reading, whichever is greater
TVe	
TVe spn	
MV	± (0.2 L/min + 10% of actual reading)
MVspn	
MVleak	
Ppeak	± (2 cmH ₂ O + 4 % of the actual reading)
Pplat	
Pmean	
PEEP	
Flow (O ₂ Therapy)	± (2 L/min + 10% of actual reading)
ftotal	± 1 /min or 5% of actual reading, whichever is greater.
fmand	
fspn	
Tinsp	± 0.05s
I:E	± 6% (not applicable if Tinsp or Texp is less than 50 ms)
WOB	± (1 J/min + 15% of actual reading)
	± (0.20 J/L + 10% of actual reading)
Leak%	± 10 % (absolute error)
Ri	0 cmH ₂ O/(L/s) to 20 cmH ₂ O/(L/s): ±10 cmH ₂ O/(L/s)
Re	20 cmH ₂ O/(L/s) to 600 cmH ₂ O/(L/s): ± 50% of actual reading
Cstat	± 10 mL/cmH ₂ O or ± 20% of actual reading, whichever is greater
Cdyn	
RSBI	±20 1/(L·min) or ±15% of actual reading, whichever is greater
RCexp	± (0.20s + 20 % of actual reading)
PEEPi	± (2 cmH ₂ O + 4% of the actual reading)
PEEPtot	± (2 cmH ₂ O + 4% of the actual reading)
P0.1	± (2 cmH ₂ O + 4% of the actual reading)

Table B-7 Ventilator Accuracy

FiO₂*: the drifting test method for testing accuracy specified in the standard ISO 80601-2-55 can ensure the measurement accuracy meets the requirement in this table.

B.8 Alarm

B.8.1 Settable Alarms

ALARM SETTINGS				
PARAMETER		SETTING RANGE	ADJUST STEP LENGTH	NOTES
Paw	High alarm limit	10 cmH ₂ O to 65 cmH ₂ O	1 cmH ₂ O	Set the high alarm limit to be greater than low alarm limit.
	Low alarm limit	OFF, 1 cmH ₂ O to 60 cmH ₂ O;	1 cmH ₂ O	
TV	High alarm limit	Adult: OFF, 110 mL to 6000 mL; Pediatric: OFF, 25 mL to 600 mL; Infant: OFF, 21mL to 200 mL.	21 mL to 100 mL: 1 mL, 100 mL to 6000 mL: 5 mL.	
	Low alarm limit	Adult: OFF, 50 to 5995 mL; Pediatric: OFF, 10 to 595 mL; Infant: OFF, 5 mL to 195 mL.	5 mL to 100 mL: 1 mL, 100 mL to 6000 mL: 5 mL.	
f	High alarm limit	OFF, 2/min to 160/min	1/min	
	Low alarm limit	OFF, 1/min to 159/min	1 /min	
MV	High alarm limit	Adult: 0.2 L/min to 100.0 L/min; Pediatric/infant: 0.2 L/min to 60.0 L/min	0.02 to 1.0: 0.01 L/min, 1.0 to 100.0 L/min: 0.1 L/min.	
	Low alarm limit	Adult: 0.1 L/min to 50.0 L/min; Pediatric/infant: 0.1 L/min to 30.0 L/min; in NIV mode, it can be set to OFF.	0.01 to 1.0: 0.01 L/min, 1.0 to 50.0 L/min: 0.1 L/min.	

Table B-8 Settable Alarms

FiO2	High alarm limit (in low pressure O ₂ supply mode)	20 vol.% to 100 vol.%	1 vol.%	In low pressure O ₂ supply mode, set the high alarm limit to be greater than low alarm limit.
	Low alarm limit (in low pressure O ₂ supply mode)	18 vol.% to 98 vol.%		
Tapnea		5s to 60s	1s	Error is ± 3s.

Table B-8 Settable Alarms

Note: When the alarm limit in the above table is set to off, the display screen interface will show the alarm off icon 

B.8.2 Internal Alarms

PARAMETER		ALARMING CONDITION	NOTES
FiO2	High alarm limit	Internal alarm limit: min (FiO ₂ set value + max (7 vol.% or FiO ₂ set value × 10%), 100 vol.%).	Set the high alarm limit to be greater than low alarm limit.
	Low alarm limit	Internal alarm limit: max (18 vol.%, FiO ₂ set value minus max (7 vol.%, FiO ₂ set value × 10%))	

Table B-9 Internal Alarms

B.9 Additional Settings and Tools

SETTINGS AND TOOLS
Inspiration Hold
Manual Breath
Oxygen enrichment
Suction
Sigh

Table B-10 Additional Settings and Tools

B.10 CO₂ Module Specifications

MAINSTREAM CO ₂ MODULE	
Measurement range	0.0 vol.% to 20.0 vol.% (0 mmHg to 150 mmHg)
Accuracy	0.0 vol.% to 5.0 vol.% (0 mmHg to 40 mmHg): ± 0.25 vol.% (± 2 mmHg)
	5.0 vol.% to 9.0 vol.% (41 mmHg to 70 mmHg) (not including 5.0 vol.%): ± 5% of actual reading
	9.0 vol.% to 13.0 vol.% (71 mmHg to 100 mmHg) (not including 9.0 vol.%): ± 8% of actual reading
	13.0 vol.% to 20.0 vol.% (101 mmHg to 150 mmHg) (not including 13.0 vol.%): ± 10% of actual reading
Measurement accuracy drift	The test method of the standard ISO 80601-2-55 can ensure the measurement accuracy meets the requirement in this table.
Resolution	0.1 vol.% (1 mmHg)
Rise time	<60 ms
Total system response time	<2.0 s

Table B-11 Mainstream CO₂ Module

MAINSTREAM CO ₂ ALARM LIMITS	RANGE	STEP SIZE	NOTES
EtCO ₂ high alarm limit	2 to 150 mmHg	1 mmHg	Set the high alarm limit to be greater than the low alarm limit.
EtCO ₂ low alarm limit	0 to 148 mmHg		

Table B-12 Mainstream CO₂ Alarm Limits

MAINSTREAM CO ₂ ENVIRONMENTAL SPECIFICATIONS			
Item	Temperature (°C)	Relative humidity (non-condensing)	Barometric pressure (kPa)
Operating	0 to 40	10 to 90%	57.3 to 105.3
Storage	-20 to 60	10 to 90%	53.3 to 107.4

Table B-13 Mainstream CO₂ Environmental Specifications

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C.0

EMC

EMC	C-2
Radio Regulatory Compliance	C-9

C.1 EMC

The TV50 Ventilator complies with the EMC standard IEC60601-1-2:2020.

The TV50 Ventilator also complies with the EMC requirements of the follow standard ISO 7637-2:2011, EN 13718-1:2014 Section 4.5.7, EN 1789:2020 Section 4.2.2, EN 794-3:2009 Section 36, IEC 60601-1-12:2020 Section 11, ISO 80601-2-84:2020 Section 202, RTCA DO-160G Section 20/21, MIL-STD-461G RE101/ RS101/ CS114.

WARNING: The use of unapproved accessories may diminish the ventilator performance.

WARNING: Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of the ventilator.

WARNING: The ventilator needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

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

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

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

WARNING: Other devices may interfere with this equipment even though they meet the requirements of CISPR.

WARNING: When the input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

WARNING: Use of portable or mobile communications devices can degrade the performance of the equipment.

WARNING: Use the ventilator away from heat penetration, diathermy, electrocautery, magnetic resonance imaging, RFID and security equipment (such as electromagnetic anti-theft system and metal detector). If some concealed RF transmitters that are not known to the user are exposed near the device and are disturbed by the device (for example, scanning mode changes or image disturbances affecting diagnosis), the user should immediately take mitigation measures, such as redirecting, repositioning or shielding away from the RF transmitter.

If the TV50 Ventilator is operated within the electromagnetic environment listed in TABLE EMC-1, TABLE EMC-2 and TABLE EMC-3 , the ventilator will remain safe and will provide the following basic performances: Vdel control accuracy, Vdel monitoring accuracy, monitoring of the airway pressure, CO2 accuracy, and O2 monitoring accuracy.

Guidance and Mindray Declaration - Electromagnetic Emissions

The TV50 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of TV50 Ventilator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The TV50 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 TV50 Ventilator is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance	
Note: /		

Table C-1 EMC-1

Guidance and Mindray Declaration - Electromagnetic Immunity

The TV50 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of TV50 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	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact; ±2 kV, ±4 kV, ±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0,5 kV, ±1 kV line(s) to line(s); ±0,5 kV, ±1 kV, ±2 kV line(s) to earth	±0,5 kV, ±1 kV line(s) to line(s); ±0,5 kV, ±1 kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	0% U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _T ; 1 cycle 70% U _T for 25/30 cycle at 0° 0% U _T ; 250/300 cycle	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT for 25/30 cycle at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC. mains voltage prior to application of the test level.

Table C-2 EMC-2

Guidance and Mindray Declaration - Electromagnetic Immunity

The TV50 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of TV50 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 0,15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands ^a between 0,15 MHz and 80 MHz	3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands ^a between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of TV50 Ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \times \sqrt{P}$ $d = 2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80MHz - 2.7GHz (for ventilator function)	10 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^b , should be less than the compliance level in each frequency range ^c . Interference may occur in the vicinity of equipment marked with the following symbol:  .

Table C-3 EMC-3

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

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

c. Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table C-3 EMC-3

Guidance and Mindray Declaration - Electromagnetic Immunity

The TV50 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of TV50 Ventilator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Proximity magnetic fields	8 A/m 30 kHz CW	8 A/m 30 kHz CW	/
IEC 61000-4-39	65 A/m 134,4 kHz Pulse modulation 2,1 kHz	65 A/m 134,4 kHz Pulse modulation 2,1 kHz	
	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	

Table C-4 EMC-4

Recommended Separation Distances Between Portable and Mobile RF, Communications Equipment and The Ventilator

The TV50 Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ventilator as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this TV50 Ventilator, including cables, than determined according to the following method:

Test frequency (MHz)	Band(MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table C-5 EMC-5

Recommended Separation Distances Between Portable and Mobile RF, Communications Equipment and The Ventilator

The TV50 Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of TV50 Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and TV50 Ventilator as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter (W)	Separation Distance According to Frequency of Transmitter			
	150kHz -80MHz Out ISM and amateur radio bands $d=1.2 \sqrt{P}$	150kHz -80MHz in ISM and amateur radio bands $d=2 \sqrt{P}$	80MHz-800MHz $d=1.2 \sqrt{P}$	800MHz-2.7GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.4	3.8	7.3
100	12	20	12	23

For transmitters at a maximum output power not listed above, the recommended separation distanced 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 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.

Table C-6 EMC-6

No.	Name	Cable length(m)	Shield or not	Remarks
1	AC power cable	3.5	Not shield	/
2	CO2 cable	2.8	Shield	/

Table C-7 EMC-7

C.2 Radio Regulatory Compliance

Service	Ban (MHz)	Modulation	Power (dBm)
RF-ID	13.56	ASK	<0 (Average)
WLAN	2412-2472 5180-5825	BPSK, QPSK, 16QAM, 64QAM, 256QAM	<20 dBm (Average) <30 dBm (Peak)
Mobile communications	<ul style="list-style-type: none"> • LTE FDD/LTE TDD 704-787, 1700-1900, 2400-2570 • WCDMA 800-960 • CDMA B1/B8 • GSM: 900/1800 5G NR	OFDM	<30 dBm (Peak)

Table C-8 RF Parameter

NOTE: Keep a distance of at least 20cm away from the Ventilator when Wi-Fi function is in use.

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D.0

Alarm Messages

Physiological Alarm Messages	D-2
Technical Alarm Messages.....	D-4

This chapter lists physiological and technical alarm messages.

Note that in this chapter:

- Column P stands for the default alarm level: H for high, M for medium and L for low.
- For each alarm message, corresponding actions are given instructing you to troubleshoot problems. If the problem persists, contact your service personnel.

D.1 Physiological Alarm Messages

D.1.1 Ventilator Parameters

ALARM MESSAGES	P	CAUSE AND ACTION
Paw Too High	H	The airway pressure exceeds the set pressure high alarm limit. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check the patient tubing for occlusion.
Paw Too Low	H	Airway pressure setting is lower than the low limit of pressure alarm. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check if the patient tubing are leaked or disconnected.
FiO ₂ Too High	H	The inspired O ₂ concentration is greater than the FiO ₂ high alarm limit for at least 30s. 1. Check the HEPA filter for occlusion. 2. Calibrate the O ₂ sensor. 3. Check the alarm limits.
FiO ₂ Too Low	H	The inspired O ₂ concentration has been lower than the FiO ₂ low alarm limit for at least 30 s or is less than 18%. 1. Check the connection of the O ₂ supply. 2. Ensure the O ₂ supply pressure is between 280 kPa and 650 kPa. 3. Calibrate the O ₂ sensor. 4. Check the alarm limits.
TVe Too High	M	The TVe monitored value is greater than TVe high alarm limit for continuous 3 mechanical ventilation cycles. 1. Check the ventilation parameter setup. 2. Check the alarm limits.
TVe Too Low	M	The TVe monitored value is less than TVe low alarm limit for continuous 3 mechanical ventilation cycles. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits. 4. Check the patient tubing for leakage or occlusion. 5. Perform System Check to test the leakage.

Table D-1 Ventilator Parameters

MVe Too High	H	MVe is greater than MVe high alarm limit. 1. Check the ventilation parameter setup. 2. Check the alarm limits.
MVe Too Low	H	MVe is less than MVe low alarm limit. 1. Check the ventilation parameter setup. 2. Check the alarm limits. 3. Check the patient tubing for leakage or occlusion. 4. Perform System Check to test the leakage.
Apnea	H	The time of failure to detect respiration exceeds Tapnea. 1. Check the patient. 2. Manual breath. 3. Check apnea time setup. 4. Check if the patient tubing are disconnected.
Apnea Ventilation	H	The time of failure to detect respiration exceeds Tapnea. Start apnea ventilation mode. Check apnea ventilation parameter setup.
ftotal Too High	M	ftotal is greater than ftotal high alarm limit. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
ftotal Too Low	M	ftotal is lower than the ftot low alarm limit. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
Apnea Ventilation Ended	L	This alarm is given when apnea ventilation ends. There is no need to process this alarm.

Table D-1 Ventilator Parameters

D.1.2 CO₂ Module

ALARM MESSAGES	P	CAUSE AND ACTION
EtCO ₂ Too High	M	The monitored parameter value exceeds the alarm limit. 1. Check the patient type. 2. Check the alarm limits.
EtCO ₂ Too Low	M	The monitored parameter value exceeds the alarm limit. 1. Check the patient type. 2. Check the alarm limits.
Apnea CO ₂	M	The time of failure to detect respiration by the CO ₂ module exceeds Apnea Tinsp. Whenever the CO ₂ apnea alarm is on, block the [EtCO ₂ Too High] alarm and [EtCO ₂ Too Low] alarm until the alarm is cleared. 1. Check the patient. 2. Check apnea time setup. 3. Check the connections of CO ₂ module sampling device.

Table D-2 CO₂ Module

D.2 Technical Alarm Messages

D.2.1 Power Board

ALARM MESSAGES	P	CAUSE AND ACTION
Battery 1 Failure 02	H	Battery 1 Charge Failure. Contact your service personnel.
Battery 1 Failure 03	H	Battery 1 Aging. Contact your service personnel.
Battery 1 Failure 04	H	Battery 1 Comm Error. Contact your service personnel.
Battery 1 Failure 05	H	Battery 1 Failure. Contact your service personnel.
Battery 2 Failure 02	H	Battery 2 Charge Failure. Contact your service personnel.
Battery 2 Failure 03	H	Battery 2 Aging. Contact your service personnel.
Battery 2 Failure 04	H	Battery 2 Comm Error. Contact your service personnel.
Battery 2 Failure 05	H	Battery 2 Failure. Contact your service personnel.
Battery Temp. High. Connect Ext. Pwr.	M	Battery temperature is a bit high during discharge. Connect to the external power supply.
Battery Temp High. Syst maybe Down	H	Battery temperature is too high during discharge. The system may be down. Connect to the external power supply.
Temp. Low. Connect Ext. Pwr.	M	Battery temperature is a bit low during discharge. Connect to the external power supply.
Temp Low. Syst maybe Down	H	Battery temperature is too low during discharge. The system may be down. Connect to the external power supply.
Low Battery. Connect Ext. Power.	M	The remaining battery power is lower than a threshold. Connect to the external power supply.
System DOWN. Connect Ext. Power.	H	Battery power is depleted. The system will shut down in a few minutes. Connect to the external power supply immediately.
Battery Undetected	H	No battery in main unit or backup air supply at present. Contact your service personnel.

Table D-3 Power Board

Ventilator Cooling Fan Failure	M	Power board fan speed abnormal. If it can not be solved, please restart the machine. Contact your service personnel.
Device Failure 03	H	Power Board Selftest Error. Contact your service personnel.

Table D-3 Power Board

D.2.2 Main Control Board

ALARM MESSAGES	P	CAUSE AND ACTION
Please Reset Date and Time	L	Button cell is available in the system. But the clock is powered down and reset. Re-set the date and time.
Key Error	L	Hardkey or rotary encoder is depressed continuously for more than 35s. Contact your service personnel.
Storage Error	M	Storage error. Contact your service personnel.
Technical Error 01	M	Keyboard Comm Stop. Contact your service personnel.
Device Failure 04	H	Ctrl Module Init Error. Contact your service personnel.
Device Failure 05	H	Ctrl Module Comm Stop. Contact your service personnel.
Device Failure 19	H	Power Board Comm Stop. Contact your service personnel.
Device Failure 22	H	Protecting Module Comm Stop. Contact your service personnel.
Network Disconnected	M	The ventilator is disconnected with the central monitoring system (CMS), eGateway or monitor. 1. Check if the network connection mode (eg. wired/ wireless network or monitor hotspot) of the ventilator is correct. 2. Check if the network cable between the ventilator and the central monitoring system (CMS), eGateway or monitor is connected, and if the WiFi router works properly. 3. Check the network setup (IP, gateway, etc.).

Table D-4 Main Control Board

D.2.3 Monitor Board

ALARM MESSAGES	P	CAUSE AND ACTION
Technical Error 04	L	Buzzer Failure. Contact your service personnel.
Technical Error 05	M	Atmospheric Pressure Sensor Failure. Contact your service personnel.
Technical Error 07	M	3-way Valve Failure. Contact your service personnel.
Technical Error 09	M	Insp. Temp Sensor Failure. Contact your service personnel.
Device Failure 01	H	Power Supply Voltage Error. Contact your service personnel.
Device Failure 02	H	Memory Error. Contact your service personnel.
Device Failure 05	H	Ctrl Module Comm Stop. Contact your service personnel.
Device Failure 06	H	Ctrl Module Selftest Error. Contact your service personnel.
Device Failure 09	H	Pressure Sensor Failure. Contact your service personnel.
Device Failure 10	H	Safety Valve Failure. Contact your service personnel.
Device Failure 12	H	Total Inspiratory Limb Failure. Contact your service personnel.
Device Failure 13	H	O ₂ Limb Failure. Contact your service personnel.
Device Failure 21	H	Pressure Sensor Zero Point Error. Contact your service personnel.
Device Failure 22	H	Protecting Module Comm Stop. Contact your service personnel.
Device Failure 23	H	Protection Module Self Check Error. Contact your service personnel.
PEEP Too High	H	Monitored PEEP exceeds PEEP + 5 cmH ₂ O (PEEP + 10 cmH ₂ O for APRV mode) within any fully mechanical ventilation cycle. 1. Check the ventilation parameter setup. 2. Check the patient tubing for occlusion.

Table D-5 Monitor Board

PEEP Too Low	M	<p>Patient's PEEP is less than the setting value to a certain extent.</p> <ol style="list-style-type: none"> 1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage
Airway Obstructed?	H	<p>Tube is occluded.</p> <ol style="list-style-type: none"> 1. Check and clean the patient tubing. 2. Check and clean the expiration valve.
Insp. Limb Airway Obstructed?	M	<p>The patient tubing is bent or occluded in case of O₂ therapy.</p> <p>Check if the patient tubing is occluded or bent. If yes, clear it.</p>
Sustained Airway Pressure	H	<p>The airway pressure measured by any pressure sensor is greater than the setting PEEP + 15 cmH₂O for 15 s consecutively.</p> <ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the patient tubing for occlusion.
Airway Leak?	L	<p>Tube is leaky.</p> <ol style="list-style-type: none"> 1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage
Tube Disconnected?	H	<p>Tube is disconnected.</p> <p>Re-connect the patient tubing.</p>
Pressure Limited	L	<p>In volume mode, the pressure reaches Paw high alarm limit-5.</p> <ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check pressure high alarm limit.
Volume Limited	L	<p>In pressure mode, delivered gas volume exceeds the set TV high limit.</p> <ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
Pinsp Not Achieved	L	<p>Pinsp is lower than the pressure setting value by 3 cmH₂O or 2/3 of the pressure setting value, whichever is less.</p> <ol style="list-style-type: none"> 1. Check the patient. 2. Check TV alarm limits. 3. Check the O₂ supply. 4. Check the patient tubing for leakage. 5. Check the HEPA filter for occlusion.
TV Not Achieved	L	<p>TVi is less than the TV setting value by more than 10 mL + 10% of the setting value.</p> <ol style="list-style-type: none"> 1. Check the patient. 2. Check pressure high alarm limit. 3. Check the HEPA filter for occlusion. 4. Check the O₂ supply. 5. Check the patient tubing for leakage or occlusion.

Table D-5 Monitor Board

Pressure Limited in Sigh cycle	L	The pressure reaches Paw high alarm limit-5 in sigh cycle. 1. Check the patient. 2. Check pressure high alarm limit. 3. Check the patient tubing for occlusion. 4. Consider to turn off sigh.
O2 Supply Failure	H	Oxygen supply is not sufficient to support normal ventilator operation. 1. Check connection with O ₂ supply. 2. Check O ₂ supply pressure.
Tinsp Too Long	L	In PSV mode, Tinsp exceeds 4s for adult, 1.5s for pediatric, and the maximum inspiration time set by the user for infants for continuous 3 cycles. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the patient tubing for leakage.
Check flow sensor	H	Installing the expiratory flow sensor fails. Contact your service personnel.
Insp. Gas Temp Too High	H	The gas temperature exceeds 55°C. 1. Disconnect the patient. 2. Restart the machine. Contact the specified service personnel if the issue persists.
Internal Flow Sensor Type Error	H	Installation error with air flow sensor or O ₂ flow sensor. Contact your service personnel.
Blower Temperature High	H	Backup air supply temperature exceeds the threshold. 1. Check if the operating ambient temperature of the machine exceeds the maximum operating temperature specified by the vendor. 2. Check if the fan inlet and outlet are occluded. If yes, clear the foreign substance and dust. 3. Check the rotation of the fan. If it runs abnormally (such as abnormal sound or rotation speed), replace the fan.
AMV: Cannot Meet Target	L	Cannot meet established MV% 1. Check the ventilation parameter setup. 2. Check the alarm limits setting.
Replace HEPA Filter	L	HEPA filter occluded, resistance increased. Contact the specified service personnel.
Blower Technical Error 01	M	Backup air supply Temp Sensor Failure. Contact your service personnel.
Blower Technical Error 02	M	HEPA Pressure Sensor Failure. Contact your service personnel.
Blower Failure 03	H	Backup air supply Temp Too High. Contact your service personnel.
Blower Failure 04	H	Backup air supply Failure. Contact your service personnel.

Table D-5 Monitor Board

Please calibrate O2 sensor	L	The O ₂ sensor selftest fails. Please calibrate O ₂ concentration.
Please perform pressure calibration.	H	Calibrate the pressure sensor. Contact your service personnel.
Please perform flow calibration.	H	Calibrate the flow sensor. Please perform flow calibration.
O2 Sensor Failure	M	O2 sensor error. Change the O2 sensor.
Wrong Flow Sensor	H	Wrong flow sensor is used. Check the flow sensor type and make sure it matches the selected patient type.
Reverse flow sensor	H	Flow sensor connected reversed. 1. Reverse the flow sensor. 2. Check if there is water in the tubes.
High O2 Supply Pressure	H	O2 supply pressure is greater than the threshold value. 1. Check connection with O2 supply. 2. Ensure the O2 supply pressure ranges from 280 kPa to 650 kPa.
Please Check Exp. Valve	H	The current of the PEEP valve is very high. The pressure at the machine end is too different from that at the PEEP valve end. 1. Check if the expiration valve is properly installed. 2. Verify the expiration valve drive line is correctly connected.
Oxygen Therapy Flow Not Achieved	M	The oxygen therapy flow rate is not reached. Check if the patient tubing is clogged or bent. If yes, unplug it.

Table D-5 Monitor Board

D.2.4 CO₂ Module

ALARM MESSAGES	P	CAUSE AND ACTION
CO ₂ Module Failure 02	M	CO ₂ Init Error. An error occurs to the CO ₂ module during initialization. Contact your service personnel.
CO ₂ Module Failure 03	M	CO ₂ self check error. An error occurred in the CO ₂ module during self check. Contact your service personnel.
CO ₂ Module Failure 04	M	CO ₂ Hardware Error. Contact your service personnel.
CO ₂ Module Failure 05	M	CO ₂ Comm Stop, CO ₂ Module Failure, CO ₂ Comm Error or communication failure reaches 10s. Contact your service personnel.

Table D-6 CO₂ Module

CO ₂ Module Failure 06	M	Mainstream CO ₂ module zeroing fails. Contact your service personnel.
CO ₂ Sensor High Temp	L	The sensor temperature is too high (above 63°C). Contact your service personnel.
EtCO ₂ Overrange	L	Parameter measured values exceed the measurement range (error range is included). 1. Perform CO ₂ module zeroing. 2. Contact your service personnel.
Please Replace CO ₂ Sensor	M	The mainstream CO ₂ module sensor is faulty. Contact your service personnel.
CO ₂ No Sensor	L	The mainstream CO ₂ module sensor is not connected. Connect the CO ₂ sensor.

Table D-6 CO₂ Module

Factory Defaults

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This chapter lists the most important factory default settings which are not user-adjustable. When necessary, you can restore the factory default settings.

E.1 Ventilation Parameters

VENTILATION MODE PARAMETER SETTINGS	FACTORY DEFAULT SETTING
O2%	Non-CPRV: 40 vol.%; CPRV: 100 vol.%
TV	Adult: 500 mL; pediatric: 100 mL; infant: 35 mL
ΔP_{insp}	15 cmH ₂ O
ΔP_{supp}	In PSV and PSV-S/T mode: 15 cmH ₂ O; in other modes: 0 cmH ₂ O
PEEP	Non CPRV: 3 cmH ₂ O; CPRV: 0 cmH ₂ O
P _{high}	15 cmH ₂ O
P _{low}	3 cmH ₂ O
f	Adult: 15/min (CPRV: 10/min); pediatric: 20/min; infant: 30/min
I:E	1:2
T _{insp}	Adult: 1.3 s; pediatric: 1.0 s; infant: 0.67 s
T _{high}	Adult: 1.3 s; pediatric: 1.0 s; infant: 0.67 s
T _{low}	Adult: 2.7 s; pediatric: 2.0 s; infant: 1.33 s
F-Trig	Adult: 2.0 L/min; pediatric: 1.0 L/min; infant: 0.5 L/min
P-Trig	/
ΔP_{apnea}	15 cmH ₂ O
T _{Vapnea}	Adult: 500 mL; pediatric: 100 mL; infant: 35 mL
f _{apnea}	Adult: 15/min; pediatric: 20/min; infant: 30/min
f _{simv}	Adult: 5/min; pediatric: 20/min; infant: 30/min
Apnea T _{insp}	Adult: 1.3 s; pediatric: 1.0 s; infant: 0.67 s
Flow	Adult: 24 L/min; pediatric: 7 L/min
Exp%	25%
T _{pause} (%)	OFF
T _{slope}	0.20 s
IntelliCycle	ON
MV%	100%
$\Delta \text{int. PEEP}$	OFF
Apnea Vent	ON

Table E-1 Ventilation Parameters

E.2 Setup

SETUP	FACTORY DEFAULT VALUE
Menu - Calibration - CO2 In Maintenance - CO2%	3%
Menu - Setup - Ventilation - TV/IBW	7 mL/kg
Menu - Setup - Ventilation - IBW/Height	Height
Menu - Setup - Ventilation - Tinsp/I:E	Tinsp
Menu - Setup - Ventilation - Flow/ Tpause(%)	Flow
Menu - Setup - Ventilation- DuoLevel Setup	Thigh
Menu - Setup - Ventilation - Invasive Apnea mode	Pressure Control
Menu - Setup - Ventilation - Leakage Compensation	ON
Menu - Setup - Ventilation - Increase O2% during O2 ↑	Adult: 60%; pediatric: 60%; infant: 10%
Menu - Setup - O2 Sensor	ON
Menu - Setup - Gas Supply - O2 Supply Type	HPO
Menu - Screen - Choose Screen	Waveforms Screen
Menu - Screen - Brightness/Volume - Day & Night Mode	Day
Menu - Screen - Brightness/Volume - Brightness	5
Menu - Screen - Brightness/Volume - Key Volume	2
Menu - Screen - Screen Setup - Waveform	3
Menu - Screen - Screen Setup - Draw Wave	Curve
Menu - Screen - Screen Setup - Layout Setup Switch	ON

Table E-2 Setup

E.3 System Settings

SYSTEM	FACTORY DEFAULT VALUE
Menu - System - Date & Time Setup - 24 h	24 h
Menu - System - Date & Time Setup - Time Format	00:00:00
Menu - System - Date & Time Setup - Date Format	YYYY-MM-DD
Menu - System - Date & Time Setup - Date	2012.01.01

Table E-3 System Settings

Menu - System - Language/Unit - Language	Chinese
Menu - System - Language/Unit - Weight Unit	kg
Menu - System - Language/Unit - Height Unit	cm
Menu - System - Language/Unit - Pressure Unit	cmH2O
Menu - System - Language/Unit - CO2 Unit	mmHg
Menu - System - Language/Unit - WOB Unit	J/min
Menu - System - Language/Unit - Gas Supply Pressure	kPa
Menu - System - Language/Unit - Minimum Alarm Volume	2
Menu - System - Interface - Network Type	LAN
Menu - System - Interface - LAN Setup - IP Config.	DHCP
Menu - System - Interface - Central Station Setup - Select CMS	OFF
Menu - System - Interface - Information Security - Encryption Connection Type	SSL Encryption Priority

Table E-3 System Settings

E.4 Alarms

ALARMS	FACTORY DEFAULT SETTING
Alarms - Vent Limits - Paw High Limit	50 cmH2O
Alarms - Vent Limits - Paw Low Limit	OFF
Alarms - Vent Limits - Minute Volume High Alarm Limit	1.5×f×TV
Alarms - Vent Limits - Minute Volume Low Alarm Limit	0.6×f×TV
Alarms - Vent Limits - TVe High Alarm Limit	The smaller one between the set value of 2×TV and the upper limit of the set range
Alarms - Vent Limits - TVe Low Alarm Limit	0.5×TV set value
Alarms - Vent Limits - Tapnea	Adult & pediatric: 15 s; infant: 10 s
Alarms - Vent Limits - ftot High Alarm Limit	OFF
Alarms - Vent Limits - ftot Low Alarm Limit	OFF
Alarms - Module Limits - EtCO2 High Alarm Limit	50 mmHg
Alarms - Module Limits - EtCO2 Low Alarm Limit	Adult: 15 mmHg; pediatric: 20 mmHg; infant: 30mmHg

Table E-4 Alarms

E.5 History

HISTORY	FACTORY DEFAULT SETTING
Graphic - Group	All
Graphic - Zoom	10 min
Tabular - Group	All
Tabular - Interval	1 min
Event Logbook - Filter	All Events

Table E-5 History

E.6 O₂ Therapy

O ₂ THERAPY	FACTORY DEFAULT SETTING
O2 Therapy - O2%	40 vol.%
O2 Therapy - Flow	Adult: 25 L/min; pediatric: 8 L/min; infant: 4 L/min

Table E-6 O2 Therapy

E.7 CO₂ Module

CO ₂ MODULE	FACTORY DEFAULT SETTING
Menu - Setup - CO2 Module - Monitoring	ON
Menu - Setup - CO2 Module - BTPS Comp	OFF
Menu - Setup - CO2 Module - Null for 30s from Zeroing	ON

Table E-7 CO2 Module

E.8 Other

PATIENT	FACTORY DEFAULT SETTING
Weight	Adult: 70 kg; pediatric: 15.4 kg; infant: 5 kg
Gender	Male
Height	Adult: 174 cm; pediatric: 100 cm
Ventilation Type	Invasive

Table E-8 Other

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Abbreviations, Symbols and Measuring Units

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F.1 Abbreviations

ABBREVIATIONS	DESCRIPTION
AMV	Adaptive Minute Ventilation
Apnea Tinsp	Inspiratory time of Apnea Ventilation
Apnea Vent	Apnea Ventilation
APRV	Airway Pressure Release Ventilation
ATPD	Ambient Temperature and Pressure Dry
BTPS	Body Temperature and Pressure Saturated
Cdyn	Dynamic Compliance
CPAP/PSV	Continuous Positive Airway Pressure/ Pressure Support Ventilation
CPRV	Cardiopulmonary Resuscitation Ventilation
Cstat	Static Compliance
Cycles Sigh	Cycles Sigh
DuoLevel	Duo Level Ventilation
EtCO ₂	End-tidal Carbon Dioxide
Exp%	Percent of Expiration Trigger
FiCO ₂	Fraction of Inspired Carbon Dioxide
FiO ₂	Inspired Oxygen Concentration
Flow	Flow
f	Breathing Frequency
fapnea	Frequency of Apnea Ventilation
fmand	Mandatory Frequency
fspn	Spontaneous Frequency
fsimv	Frequency of SIMV
ftotal	Total Breathing Frequency
F-Trig	Flow Trigger
I:E	Inspiratory Time:Expiratory Time Ratio
Interval	Interval
MV%	Minute Volume
MVspn	Spontaneous Minute Volume
MVleak	Leakage Minute Volume
NIV	Non-Invasive Ventilation
O ₂	Oxygen
P-A/C	Pressure - Assist/Control Ventilation
Paw	Airway Pressure

Table F-1 Abbreviations

ABBREVIATIONS	DESCRIPTION
PEEP	Positive End-Expiratory Pressure
PEEPi	Intrinsic PEEP
PEEPtot	Total Positive End-Expiratory Pressure
Phigh	Pressure High
ΔP_{insp}	Pressure Control Level of Inspiration (relative to PEEP/Plow)
Plimit	Pressure Limit Level
Plow	Pressure Low
$\Delta P_{manInsp}$	Pressure Control Level of Manual Inspiration (relative to PEEP/Plow)
Pmean	Mean Pressure
Ppeak	Peak Pressure
Pplat	Plateau Pressure
PRVC	Pressure Regulated Volume Control Ventilation
PRVC-SIMV	Pressure Regulated Volume Control Ventilation-Synchronized Intermittent Mandatory Ventilation
PSV-S/T	Pressure Support Ventilation-Spontaneous/Timed
P-SIMV	Pressure – Synchronized Intermittent Mandatory Ventilation
P-Trig	Pressure Trigger
$\Delta int.PEEP$	Intermittent Positive End-Expiratory Pressure
ΔP_{apnea}	Pressure of Apnea Ventilation (relative to PEEP/Plow)
ΔP_{supp}	Pressure Support Level(relative to PEEP/Plow)
Ri	Inspiration Resistance
Re	Expiration Resistance
Sigh	Sigh
TmanInsp	Time of Manual Inspiration
Texp	Time of Expiration
Thigh	Time of High Pressure
Tinsp	Time of Inspiration
Tlow	Time of Low Pressure

Table F-1 Abbreviations

ABBREVIATIONS	DESCRIPTION
Tpause(%)	Percent of Inspiratory Pause Time
Tplat	Time of Plat In Inspiratory Period
Tslope	Time of Pressure Rising
TV	Tidal Volume
TVapnea	Tidal Volume of Apnea Ventilation
TVe	Expired Tidal Volume
TVe/IBW	Expired Tidal Volume Per Ideal Body Weight
TVe spn	Spontaneous Expired Tidal Volume
TVi	Inspired tidal Volume
Volume	Gas Volume
V-A/C	Volume - Assist/Control Ventilation
V-SIMV	Volume - Synchronized Intermittent Mandatory Ventilation
VS	Volume Support Ventilation
RCexp	Expiratory time constant
RSBI	Rapid Shallow Breath Index
WOB	Work of Breathing

Table F-1 Abbreviations

F.2 Symbols

SYMBOLS	DESCRIPTION	SYMBOLS	DESCRIPTION
-	minus	<	less than
%	percent	>	greater than
/	per; divide; or	≤	less than or equal to
~	to	≥	greater than or equal to
^	power	±	plus or minus
+	plus	×	multiply
=	equal to	©	copyright

Table F-2 Symbols

F.3 Measuring Units

MEASURING UNITS	DESCRIPTION	MEASURING UNITS	DESCRIPTION
A	ampere	mbar	millibar
Ah	ampere hour	mg	milligram
°C	centigrade	min	minute
cc	cubic centimetre	/min	per minute
cm	centimeter	ml	milliliter
cmH ₂ O	centimeter of water	mm	millimeter
dB	decibel	mmHg	millimeter of mercury
°F	fahrenheit	ms	millisecond
g	gram	mV	millivolt
hr	hour	mW	milliwatt
Hz	hertz	nm	nanometer
hPa	hectopascal	ppm	part per million
inch	inch	s	second
k	kilo-	V	volt
kg	kilogram	VA	volt ampere
kPa	kilopascal	Ω	ohm
L	litre	μA	microampere
lb	pound	μV	microvolt
m	meter	W	watt
mAh	milliampere hour		

Table F-3 Measuring Units

F.4 Cross References

Manufacturer-specific naming of the ventilator's ventilation modes	Ventilation-mode systematic coding scheme (ISO 19223 Lung ventilators and related equipment — Vocabulary and semantics)
V-A/C	A/C-VC
P-A/C	A/C-PC
V-SIMV	SIMV-VC\PS
P-SIMV	SIMV-PC\PS
CPAP/PSV	CPAP/CSV-PS
PSV-S/T	S/T-PS/PC
PRVC	A/C-vtPC
PRVC-SIMV	SIMV-vtPC\PS
DuoLevel	/
APRV	IMV-PC
VS	CSV-vtPS
AMV	/

Table F-4 Cross References

G.0

Software Instructions

This product uses the following off-the-shelf software. During product development, Mindray will evaluate security patches according to the development process to determine whether updates are necessary.

VENDOR NAME	COMPONENT NAME	COMPONENT VERSION	DESCRIPTION/USE
Linux Kernel Organization, Inc	Linux embedded operating system	3.2.0	Operating System
Digia Plc	QT framework	5.2.1	GUI/Application
OpenSSL software foundation	Open secure sockets layer	1.1.0e	Open SSL

Table G-1 Software Information

