SV300/SV350/SV300 Pro/SV350 Pro

Ventilator

Table of Contents

CE 0123

For this Operator's Manual, the issue date is May, 2024.

Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this Mindray product and this manual. This manual may refer to information protected by copyright or patents and does not convey any license under the patent rights or copyright of Mindray, or of others.

Mindray intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden. Release, amendment, reproduction, distribution, rental, adaptation, translation or any other derivative work of this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

mindray, MINDRAY and MINDRAY are the trademarks, registered or otherwise, of Mindray in China and other countries. All other trademarks that appear in this manual are used only for informational or editorial purposes. They are the property of their respective owners.

Responsibility on the Manufacturer Party

Contents of this manual are subject to change without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

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.

Exemptions

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.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- 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.

Customer Service Department

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R. China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, GERMANY
Tel:	0049-40-2513175
Fax:	0049-40-255726

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.

Illustrations

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

1.0 *Safety*

1.1 Safety Information

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

CAUTION: **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury and/or product/property damage.**

NOTE: **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Warnings

WARNING: **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.**

WARNING: **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**

WARNING: **To avoid the risk of electric shock, this equipment must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect it from the power line.**

WARNING: **Use external power source (AC power or DC power) before the batteries are depleted.**

WARNING: **After the first installation of the battery, please connect the external power source until the battery is fully charged.**

WARNING: **To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetic agent, vapors or liquids. When O_2 is used, keep the ventilator away from any fire sources.**

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

WARNING: **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by us only.**

WARNING: **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. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**

WARNING: **The physiological parameters and alarm messages displayed on the screen of the equipment are for doctor's reference only and cannot be directly used as the basis for clinical treatment.**

WARNING: **To dispose of the package material, observe the applicable waste control regulations. And keep the package 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.**

WARNING: **Maintenance menu 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 high frequency electrosurgery equipment, defibrillators, or short-wave treatment equipment in the vicinity of the ventilator may interfere with its operation and pose a risk of patient injury.**

WARNING: **Do not use antistatic or conductive masks, hoses or patient tubing. They can cause burns if they are used near high frequency electrosurgery equipment.**

WARNING: **The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.**

WARNING: **If the equipment internal monitoring system malfunctions, an alternative plan must be available to ensure adequate level of monitoring. The operator of the ventilator must be responsible for patient's proper ventilation and safety under all circumstances.**

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 turned off, use a monitor which complies with the requirements of ISO 80601-2-55 for oxygen concentration monitoring.**

WARNING: **All analog or digital products connected to this system must be certified to the specified IEC standards (such as IEC 60950 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 who are responsible for 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 or replacing the oxygen cell, 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 us immediately for service by specified personnel.**

WARNING: **The ventilator shall not be used with helium or mixtures with Helium.**

WARNING: **Do not move the ventilator before removing the support arm from it, in order to avoid the ventilator getting tilted during the movement.**

WARNING: **The maximum pressure of hose is 1.4MPa@21°C and please check whether gassupply 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: **Don't cascade two or more hose assemblies together.**

WARNING: **Do not block the air intake at the rear of the ventilator.**

WARNING: **To prevent interrupted operation of the ventilator due to electromagnetic interference, avoid using the ventilator adjacent to or stack with other device. If adjacent or stacked use is necessary, verify the ventilator's normal operation in the configuration in which it will be used.**

WARNING: **To prevent possible personal injury and equipment damage, ensure that the ventilator is secured to the trolley or placed on the safe and smooth surface.**

WARNING: **To prevent possible equipment damage, avoid tipping over the ventilator when crossing thresholds.**

WARNING: **To prevent possible equipment damage, push the brake down when parking the ventilator.**

WARNING: **Avoid the use of polluted air. When the equipment uses air as gas source for ventilation, if the air is polluted, harmful substance may enter the patient tubing**

WARNING: **To prevent patient injury caused by equipment malfunction, when the alarm [Technical Error**] occurs, remove the equipment immediately, record failure code, and contact the Customer Service Department.**

WARNING: **To prevent possible ventilator malfunction, do not spill liquid onto the ventilator.**

WARNING: **A turbine can cause gas to be heated. To reduce the temperature of gas inside the tubing and prevent patient injury accordingly, ensure that the length of patient tubing from the humidifier to Y piece is greater than 1.2m.**

WARNING: **The internal electrical power source is to be used if the integrity of the protective earth conductor or the protective grounding system in the installation is in doubt.**

WARNING: **Nebulization or humidification can increase the resistance of breathing system filters, and that you need to monitor the filter frequently for increased resistance and blockage.**

WARNING: **The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer.**

WARNING: **Check if the alarm limit settings are appropriate before taking measurement.**

WARNING: **When operating the unit with the power supply unit, always connect the unit to an easily accessible outlet so that it can be unplugged quickly in the event of a malfunction.**

WARNING: **No modification of this equipment is allowed.**

WARNING: **Failure to have an alternative means of ventilation such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4) with mask can result in PATIENT death if the VENTILATOR fails.**

WARNING: **Stop using the ventilator and contact us immediately when the buzzer sounds.**

WARNING: **Under the ambient temperature of 40°C, the inspiratory pressure of the ventilator exceeds 60 cmH_2O, and the maximum temperature on the surface of breathing mask may exceed 41°C but does not exceed 43°C.**

WARNING: **When the turbine fails, the ventilator cannot supply the gas to the patient.**

WARNING: **Please place the proximal flow sensor cable correctly, to avoid patients from becoming entangled or unplanned extubation.**

WARNING: **The expiratory valve and the neonatal flow sensor can contact patient-expired gases or may become contaminated with patient body fluids.**

WARNING: **Do not cover the ventilator or place in a position that affects proper operation.**

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: **The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.**

WARNING: **It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.**

WARNING: **When using nebulization or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.**

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 maximum working pressure is ensured by the high pressure alarm limit and safety valve.**

WARNING: **Performing tracheal intubation in invasive ventilation mode may result in laryngeal oedema.**

WARNING: **Prolonged use of the ventilator may result in complications such as respiratory muscle weakness and secretion retention, but these complications are not caused by the ventilator itself.**

WARNING: **The clinical data for the safety and performance of the ventilators in vulnerable patient populations, i.e. pediatrics, neonates and pregnant/ lactating women, might be limited, even though a fair amount of clinical usages of the ventilators on these populations have been provided.**

1.1.2 Cautions

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

CAUTION: **To ensure patient safety, always prepare resuscitator for use.**

CAUTION: **Always have a special person attend and monitor the operation of the equipment once the ventilator is connected to the patient.**

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

CAUTION: **To ensure patient safety, use only parts and accessories specified in this manual.**

CAUTION: **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.**

CAUTION: **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason, ensure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**

CAUTION: **This system operates correctly at the electrical interference levels identified in this manual. Higher levels can cause nuisance alarms that may stop mechanical ventilation. Pay attention to false alarms caused by high-intensity electrical fields.**

CAUTION: **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or specified in this manual.**

CAUTION: **Always install or carry the equipment properly to avoid damage caused by dropping down, impact, strong vibration or other mechanical force.**

CAUTION: **Check whether the patient tubing is damaged or leaked repeatedly before usage. If so, don't use such tubing.**

CAUTION: **To electrically isolate the ventilator circuits from all poles of the supply mains simultaneously, disconnect the mains plug.**

CAUTION: **To minimize the risk of fire, do not use low-pressure gas tubes that are worn or contaminated with combustible materials like grease or oil.**

CAUTION: **It is the clinician's responsibility to ensure that all ventilator settings are appropriate.**

CAUTION: **To prevent possible patient injury, ensure the ventilator is set up for appropriate patient type with the appropriate patient tubing. Ensure the System Check is performed before each patient.**

CAUTION: **Perform Flow Sensor Calibration before the first use, or when the measured values have deviations.**

CAUTION: **To prevent possible patient injury, ensure the ventilation parameters are set up properly before ventilating the patient.**

CAUTION: **To ensure the accuracy of oxygen monitoring, replace an exhausted oxygen cell as soon as possible or use an external monitor that complies with ISO 80601-2-55.**

CAUTION: **A fan failure could result in oxygen enrichment inside the ventilator and a subsequent fire hazard.**

CAUTION: **To reduce the risk of explosion, do not burn the O_2 cell or force the cell open.**

CAUTION: **When ventilating with a mask, avoid high airway pressures. High pressures may cause gastric distension.**

CAUTION: **Peak pressures, exceeding 33 cmH_2O, may increase the risk of aspiration due to gastric insufflation. When ventilating with such pressures, consider using an invasive mode.**

CAUTION: **To reduce the risk of fire, use only tube systems approved for medical purposes and for use with oxygen between the oxygen source and ventilator.**

CAUTION: **To reduce the risk of fire, ensure adequate ventilation at the rear of the ventilator.**

CAUTION: **To reduce the risk of fire, switch off the oxygen source when the ventilator is not in a ventilating mode.**

CAUTION: **Avoid putting the ventilator in the storage environment of more than 50°C for a long time. Such environment may damage or shorten the battery lives of internal battery and oxygen sensor.**

CAUTION: **Use the original packing materials to ship the ventilator.**

CAUTION: **To prevent fire hazard, use only specified fuses or fuses with the same type, rated voltage, and rated current as the existing fuses. When it is necessary to replace fuses, contact the Customer Service Department.**

CAUTION: **The ventilator is suitable for use within the PATIENT ENVIRONMENT.**

CAUTION: **Additional MULTIPLE SOCKET- OUTLET or extension cord 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: **The diseases or symptoms listed below are general points to note regarding ventilator usage and are not specific to Mindray ventilator models. They are provided for reference purposes only. For specific clinical suggestions, please consult with a clinician.**

CAUTION: **When dealing with patients experiencing difficulty in mouth opening, limited oral space, and an inability to tilt backwards, priority should be given to considering nasal or oral intubation over tracheal intubation.**

CAUTION: **For patients with severe nasal or maxillofacial fractures, coagulopathy, nasal or nasopharyngeal obstruction, or basilar skull fracture, priority should be given to nasal or oral intubation over tracheal intubation.**

CAUTION: **Airway pressure levels should be properly controlled when applying mechanical ventilation to patients at high risk of barotrauma.**

CAUTION: **For patients with compromised chest wall integrity or severely impaired ventilation, mechanical dilatation may be used to stabilize the chest wall to ensure adequate ventilation.**

CAUTION: **For patients with pneumothorax, mediastinal emphysema, pulmonary bullae, pulmonary cysts, hypovolaemic shock, severe pulmonary hemorrhage, tracheoesophageal fistula, etc., the primary disease should be actively managed according to the deterioration of the disease that may occur during the mechanical ventilation process while administering mechanical ventilation.**

1.1.3 Notes

NOTE: **Put the ventilator and its accessories in a location where you can easily see the screen and access the operating controls.**

NOTE: **Keep this manual close to the equipment so that it can be obtained conveniently when needed.**

NOTE: **The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.**

NOTE: **This manual describes all features and options. Your equipment may not have all of them.**

NOTE: **When the oxygen supply is insufficient, the ventilator will automatically switch to the tubine and supply the ambient air to the patient.**

NOTE: **The ventilator is equipped with barometric pressure sensors, and has the function of barometric pressure compensation.**

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. Thus, no residual risk associated with using the medical device should be disclosed.**

2.0 *The Basics*

2.1 System Description

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 neonate 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. It is usually used in the intensive care environment in medical institutions and can be used in the hospital.

2.1.1.5 Contra-indications

There are no absolute contraindications for the use of the ventilator.

2.1.1.6 Side Effects

N/A.

2.1.2 Components

The ventilator consists of a main unit (including pneumatic circuit, electronic system, mechanical structure, software, display, CO_2 module, SpO_2 module), trolley, and support arm.

Connect the patient to the ventilator via the patient breathing circuit.

The applied part of the ventilator is breathing tubes, masks and SpO_2 sensor.

3.0 Installations and Connections

WARNING: **Do not use antistatic or conductive masks, hoses or patient tubing. They can cause burns if they are used near high frequency electrosurgery equipment.**

WARNING: **To ensure optimum performance of the ventilator, re-do System Check each time after changing the patient type, replacing the accessories or components like patient tubing, humidifier, and filter.**

WARNING: **Adding accessories or other components to the breathing system of the ventilator can increase system inspiratory and expiratory resistance.**

WARNING: **Inspect the O_2 supply connector carefully and ensure there is no leakage. If gas leakage is significant, O_2 concentration in the ambient environment will exceed normal O_2 concentration in atmosphere, resulting in potentially dangerous O_2 enriched environment.**

WARNING: **Place the O_2 supply hose carefully, avoiding exposure to the environment in which possible damage to the O_2 supply hose is easily caused by cut or heating.**

WARNING: **To reduce the risk of fire, do not use a low-pressure O_2 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 O_2 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 ventilator's oxygen control is not active when low-pressure oxygen is used. To prevent possible patient injury, use low-pressure oxygen only in cases that the low-pressure supply can provide an adequate level of oxygenation.**

CAUTION: **Before starting ventilation, ensure the appropriate oxygen source, either high-pressure oxygen (HPO) or low-pressure oxygen (LPO), was selected during configuration.**

CAUTION: **To prevent possible patient injury, ensure that an emergency backup O_2 supply (for example, a gas cylinder) is available in case the low-pressure O_2 supply fails.**

CAUTION: **The low-pressure O_2 supply hose assembly shall comply with the requirements of ISO 5359.**

WARNING: **To prevent possible patient injury due to accidental extubation, check the support arm joints and the connection security as necessary.**

NOTE: **The maximum weight of the support arm is 1 kg.**

NOTE: **The support arm can be fixed onto the handle on the either side of the ventilator.**

WARNING: **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**

WARNING: **To prevent patient or ventilator contamination, always use a bacteria filter between the ventilator and the patient inspiratory limb.**

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: **Do not reuse the bacteria filter repeatedly to prevent cross infection.**

CAUTION: **The Heat & Moisture Exchange (HME) shall comply with the requirements of ISO 9360-1 and ISO 9360-2.**

WARNING: **Please keep the sensor cable buckle upright during installation and use of the neonatal flow sensor.**

WARNING: **Hot swap is not suitable for the proximal flow sensor cable.**

WARNING: **To prevent possible patient injury and equipment damage, do not turn on the humidifier until the gas flow has started and is regulated.**

WARNING: **To prevent possible patient injury and equipment damage, ensure the humidifier is set to appropriate temperature and humidity.**

WARNING: **Follow the humidifier manufacturer's Instructions for Use (IFU) when using a humidifier with patient ventilation.**

NOTE: **The humidifier shall comply with the requirements of ISO 8185. The humidifier assembly and its installation steps described in this section are only for reference.**

WARNING: **When installing the humidifier, ensure that the humidifier connector shall be lower than the ventilator's breathing connectors and the patient.**

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 and/or the expiratory filter. For the disposable expiration valve, regularly check and replace the expiration valve as required. The occlusion time of the expiration valve is related to the type of the nebulized drugs.**

NOTE: **Do not use an HME in the patient's breathing circuit 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.**

CAUTION: **To reduce the risk of explosion, do not burn the O_2 cell or force the cell open.**

CAUTION: **Ensure that the gas cylinder is equipped with pressure-reducing valve.**

4.0 System Settings

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 23s.**

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

NOTE: **Patient type, gender, height, IBW, ventilation mode, ventilation parameters, and alarm limit settings can be saved as current settings.**

NOTE: **Records the system saves automatically include reference loop, monitored trend, event log (including alarm log), setup trend, measured values of tools (including PEEPi, NIF, P0.1, and Static PV Loop measured values), patient setup and equipment setup (including alarm setup). 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.**

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.**

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

NOTE: **The system can store up to 5000 records of Event Logbook. When a new event occurs after 5000 events are already stored, the new event overwrites the earliest one.**

5.0 Start Ventilation

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

WARNING: **To ensure optimum performance of the ventilator, re-do System Check each time after changing the patient type, replacing the accessories or components like patient tubing, humidifier, and filter.**

CAUTION: **Always run System Check before using the ventilator on a patient. 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.**

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 patient information, ventilation mode, ventilation type, monitored paremeters, controlled parameters, waveforms and alarm limits data to the eGateway.**

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

WARNING: **Incorrect tube type, ID or compensate setting can endanger the patient. Make sure to set them properly.**

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

WARNING: **The exhaled volume and exhaled CO2 of the patient can differ from the measured exhaled volume and exhaled CO2 due to leaks around the mask.**

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.**

NOTE: **At the inspiratory 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 cmH_2O (adjustable pressure limit), the ventilator opens the safety valve to release pressure, so that the airway pressure falls to less than 3 cmH_2O for continuous 0.5 s. Make sure to set high pressure alarm limit properly to ensure patient safety.**

NOTE: **The P-A/C and P-SIMV are the recommended ventilation modes for use with a closed-suction catheter during the suction. And the settings are decided by the operator according to the patient situation.**

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, AMV or APRV mode.**

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

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

NOTE: **Manual breath function is disabled in CPAP mode and is supported when apnea ventilation occurs.**

NOTE: **Manual breath is disabled in Standby status.**

NOTE: **There is at least one inspiratory phase between two expiration holds.**

NOTE: **The system responds to Exp. Hold key pressing operation only in non-standby status.**

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

NOTE: **The system responds to Insp. Hold key pressing operation only in non-standby status.**

NOTE: **Inspiration Hold function is disabled in CPAP mode and is supported when apnea ventilation occurs.**

NOTE: **CO_2 cannot be measured in the aerosolized medicament environment. CO_2 module sampling and monitoring are disabled when the nebulizer is started.**

NOTE: **Nebulizer is disabled in Standby status.**

NOTE: **Nebulization is disabled in V-A/C, V-SIMV, PRVC-SIMV, AMV and PRVC modes when patient type is pediatric.**

NOTE: **When O_2 supply type is low-pressure, pressing the [Nebulizer] key will not activate nebulizer, rather display the prompt message [Fail to Start with Low Pressure O_2 Supply].**

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

NOTE: **Nebulization may cause fluctuation in the patient's FiO_2.**

NOTE: **The ventilator switches off the nebulizer flow when the inspiratory flow is less than 15 L/min.**

NOTE: **O_2 ↑ (oxygen enrichment) is disabled in Standby status.**

NOTE: **When O_2 supply type is low-pressure, pressing the [O_2 ↑ Suction] key will not activate oxygen enrichment, rather display the prompt message [Fail to Start with Low Pressure O_2 Supply].**

NOTE: **Removing the patient tubing during oxygen enrichment will start suction function. Refer to section *NOTE: P0.1, PEEPi, and NIF are disabled after suction is activated.*.**

NOTE: **P0.1, PEEPi, and NIF are disabled after suction is activated.**

NOTE: **Suction, PEEPi, and NIF are disabled after P0.1 is activated.**

NOTE: **During P0.1 measurement, pressing the [Freeze] key does not produce freezing operation.**

NOTE: **If no operation is performed on P0.1 measurement window within three minutes, the measurement window exits automatically.**

NOTE: **If no operation is performed on NIF measurement window within three minutes, the measurement window exits automatically.**

NOTE: **During PEEPi measurement, pressing the [Freeze] key does not produce freezing operation.**

NOTE: **Manual Breath, Inspiration Hold, and Expiration Hold are disabled during PEEPi measurement.**

NOTE: **If no operation is performed on PEEPi measurement window within three minutes, the measurement window exits automatically.**

NOTE: **The Static PV Loop function is disabled in the following cases: patient type is Ped ; in CPAP/PSV ; in NIV or apnea ventilation mode ; during O_2 ↑ (oxygen enrichment) ; during P0.1 measurement ; during nebulization or suction ; within one minute after nebulization or suction ; within one minute after last static PV loop measurement.**

NOTE: **The Static PV Loop function is not recommended when there is great leakage or when the patient has spontaneous breathing. The relevant characteristic points, that the Static PV Loop function provides are only for your reference.**

NOTE: **If no operation is performed on Static PV Loop window within three minutes, the measurement window exits automatically.**

NOTE: **Pure oxygen ventilation or high-concentration oxygen ventilation is used during the SI recruitment maneuver.**

NOTE: **The SI recruitment maneuver function is not recommended in the case that the patient evidences spontaneous breathing.**

NOTE: **The SI recruitment maneuver should be suspended if the patient's physiological status is abnormal.**

NOTE: **The SI function cannot be used in the following situations: with neonate patients; during Suction; and during O_2 therapy.**

WARNING: **The ventilator only provides parameter trends and changes to aid doctors with weaning screen and spontaneous breathing trials, and does not advise or indicate whether weaning can be applied or whether weaning is successful. Healthcare providers should make decisions and take measures based on the patient's clinical conditions.**

NOTE: **The SBT function cannot be used in the CPRV, NIV, Standby, O2 Therapy**

WARNING: **ATRC may induce autotriggering. If autotriggering occurs, first check the patient, breathing circuit, and other possible causes.**

NOTE: **Incorrect tube type or ID setting can endanger the patient. Make sure to set them properly.**

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.**

WARNING: **As required by the relevant rules and regulations, oxygen concentration shall 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**

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.**

6.0 Neonatal Ventilation

WARNING: **Check the neonatal flow sensor before use. DO NOT use the neonatal flow sensor if the sensor's main body, tubing or connector is damaged or occluded.**

WARNING: **Before using the neonatal flow sensor for ventilation, please run a system check after configuration of all components required for ventilation. Configuration includes neonatal tubing, neonatal flow sensor and accessories required for the patient circuit. In the event that neonatal flow sensor failure is detected in the system check, please check the patient circuit and the neonatal flow sensor for leak and/or occlusion. Replace the neonatal flow sensor if necessary.**

WARNING: **After conducting the system check, DO NOT add or remove any accessories to or from the circuit, so as not to alter the system resistance and compliance.**

WARNING: **If a neonatal flow sensor error occurs, stop using the neonatal flow sensor until the error is fixed.**

WARNING: **The neonatal flow sensor measures the gas flow on the patient's Y piece side. However, the actual flow delivered to the patient will be affected by system leakage between the patient and the neonatal flow sensor.**

WARNING: **Install the neonatal flow sensor in accordance with the instructions provided in this manual.**

WARNING: **DO NOT place the neonatal flow sensor in a position where the tubing or cables may become easily entangled, knotted or detached. Otherwise, this may result in hypercarbia or hypoxemia.**

WARNING: **Please DO NOT apply pressure to the neonatal flow sensor by pulling the proximal flow sensor cable, or rotate the neonatal flow sensor. Otherwise, this will result in increased risk of detachment or disconnection.**

WARNING: **Please DO NOT install the neonatal flow sensor onto the patient tubing if the sensor is not connected to the corresponding ventilator connector.**

WARNING: **Install the neonatal flow sensor in accordance with the instructions provided in this manual. Sensor installation errors will result in data misinterpretation or incorrect ventilator setup. The disposable neonatal flow sensor may not be used repeatedly.**

WARNING: **Do not attempt to clean or disinfect the disposable neonatal flow sensor.**

NOTE: **In non-invasive ventilation, neonate flow sensor is disabled.**

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.**

7.0 O2 Therapy

WARNING: **During O_2 therapy, only the O_2 concentration FiO_2, O_2 flow, SpO_2, and pulse rate are monitored.**

WARNING: **During O_2 therapy, all physiological alarms are shielded except O_2 concentration and SpO_2 module physiological alarms.**

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

WARNING: **Use SpO_2 monitoring for patients who are dependent only on an increased defined O_2 concentration. Otherwise, a deterioration in the patient's condition cannot be recognized.**

WARNING: **Only use oxygen masks or nasal catheters for O_2 Therapy. Do not use masks for non-invasive ventilation (NIV). The patient may be at risk if unsuitable masks are used.**

WARNING: **O_2 therapy can only be used on patients with spontaneous breathing.**

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.**

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.**

8.0 Alarms

NOTE: **When the ventilator is started, the system detects whether audible alarm tones and alarm lamp function normally. If yes, the alarm lamp flashes red and yellow 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: **When multiple alarms of same levels occur simultaneously, the alarm messages are displayed in order of time of occurrence.**

NOTE: **The ventilator provides distributed alarm system function which is permitted to be located outside of the patient environment. The delay from the time the net port is polled by the external device, until the alarm message leaves the net port does not exceed 3 seconds.**

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: **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.**

CAUTION: **In case that high pressure alarm limit of 60 cmH_2O is not required under clinical condition, setting high pressure alarm limit to 60 cmH_2O or less is recommended so as to extend the service life of the turbine 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.**

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.**

NOTE: **Under AUDIO PAUSED status, if a new technical or physiological alarm occurs, the AUDIO PAUSED status terminates automatically and audible alarm tones start again.**

NOTE: **When the 120 s countdown time is up, the AUDIO PAUSED status terminates and audible alarm tones start again.**

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

WARNING: **Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.**

WARNING: **Use the specified nurse call cable when connecting with the hospital's nurse call system through the nurse call connection port. Failure to do so may burn the machine and produce electric shock hazard.**

WARNING: **Inspect the ventilator alarm signals periodically when using the nurse call function.**

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.**

9.0 Cleaning, Disinfection and Sterilization

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 O_2 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, 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, check whether there is any damage to or cracks on the components (e.g., expiratory valve membrane). If so, replace the component in a timely manner.**

NOTE: **The expiration valve assembly, inspiration safety valve assembly, and patient hose of the gas pathways through the ventilator can become contaminated with body fluids and expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.**

CAUTION: **The process for autoclave sterilization of parts have been tested and found to be in compliance with ISO 17664-1:2021. Compliance to ISO 17664-1:2021 only applies when bacterial filters are used to filter the air. Filters must be properly installed on the inspiratory and expiratory ports.**

NOTE: **The inspiration safety valve, expiration valve and neonatal flow sensors are only applicable to high level disinfectant ((Ortho-Phthalaldehyde disinfectant only)) and steam autoclave.**

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

CAUTION: **Do not run the ventilator if the ventilator is not equipped with HEPA filter to avoid contaminating the ventilator inspiration port and 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.**

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

NOTE: **The humidifier shall comply with the requirements of ISO 8185. The humidifier assembly, its installation and disassembling steps described in this section are only for reference.**

WARNING: **Before installing the humidifier, ensure that the humidifier connector shall be lower than the ventilator's breathing connectors and the patient.**

10.0 *Maintenance*

10.1 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. They burn or explode in high O_2 concentrations.**

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 us for service assistance.**

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

10.2 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.**

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

10.3 Oxygen 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 Standby. If not, push the [Standby] key to enter standby screen.**

NOTE: **In case of calibration failure, check for relevant malfunctioning alarm and then troubleshoot it. Then do the calibration again. In case of repeated calibration failures, replace the O_2 sensor and do the calibration again. If it still fails, contact your service personnel or us.**

NOTE: **Handle and dispose of the O_2 sensor according to your biohazard policies. Do not incinerate.**

NOTE: **Oxygen concentration monitoring does not provide automatic atmospheric pressure compensation. Do oxygen concentration calibration again when atmospheric pressure has changed.**

NOTE: **Increasing to periodical pressure of 10 kPa (100 cmH_2O) has no effect upon oxygen concentration monitoring accuracy.**

NOTE: **O_2 cell measures the partial pressure of oxygen. Increase or decrease of pressure (absolute pressure) affects the partial pressure of oxygen. Increase of pressure (absolute pressure) by 10% causes oxygen concentration to increase by 10%. Decrease of pressure (absolute pressure) by 10% causes oxygen concentration to decrease by 10%. Do oxygen concentration calibration when atmospheric pressure has changed.**

10.4 Battery Maintenance

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 2 years. For more aggressive use models, life expectancy can be shortened. We recommend replacing lithium batteries every 2 years.**

NOTE: **In case of battery failure, contact us or have your service personnel replace it. Do not replace the battery without permission.**

NOTE: **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.**

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

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.**

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.**

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.**

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

10.5 Electrical Safety Inspection

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

NOTE: **The electrical safety inspection should be performed once a year.**

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

10.6 Water Build-up in the Flow Sensor

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 build-up inside the expiration valve, clear it.**

11.0 Product Specifications

The ventilator is already integrated with expiratory volume monitor, pressure measurement device, and pressure release device. It is equipped with alarm system, O_2 monitor, CO_2 monitor and SpO_2 monitor, where:

- The expiratory volume monitor, pressure measurement device, and pressure release device comply with ISO 80601-2-12 .
- The alarm system complies with IEC 60601-1-8.
- The O_2 monitor complies with ISO 80601-2-55.
- The CO_2 monitor complies with ISO 80601-2-55.
- The gas supply hose assembly complies with ISO 5359.
- The SpO_2 monitor complies with ISO 80601-2-61.

11.1 Safety Specifications

Type of protection against electric shock	Class I equipment with internal electrical power supply.
Degree of protection against electric shock	BF, defibrillation-proof
Operating mode	Continuous
Degree of protection against hazards of explosion	Ordinary equipment, without protection against explosion; not for use with flammable anaesthetics.
Degree of protection against harmful ingress of water	Degrees of protection provided by enclosures(IP Code)—IP21 Protection Index according the EN 60529 standard: 2: Protected against solid foreign objects of 12.5 mm diameter and greater 1: Protected against vertically falling water drops
Electrical connections between the equipment and the patient	Non-electrical connections

Table 11-1

11.2 Environmental Specifications

MAIN UNIT			
Item	Temperature (°C)	Relative humidity (non-condensing)	Barometric pressure (kPa)
Operating	5 to 40	10 to 95 %	62 to 106*
Storage and transport	–20 to +60 (O_2 sensor: –20 to +50)	10 to 95 %	50 to 106

Table 11-2

The ventilator performance satisfies the specifications at barometric pressure 80 kPa to 106 kPa. The inspiration pressure of the ventilator can reach 60 cmH_2O at barometric pressure 62 kPa to 80 kPa.

11.3 Power Requirements

EXTERNAL AC POWER SUPPLY	
Input voltage	100 to 240 V
Input frequency	50/60 Hz
Input current	2.7 to 1.1A
Fuse	T3.15 AH/250 V
EXTERNAL DC POWER SUPPLY	
Input voltage	12 V
Input current	15A
INTERNAL BATTERY	
Number of batteries	One or two
Battery type	Lithium-ion battery
Rated battery voltage	14.8 VDC
Battery capacity	6600 mAh for a single battery (applicable for CE)/5800 mAh for a single battery (applicable for Korea, Japan, India, Russia, Saudi Arabia, Brazil, Indonesia and Malaysia)
Overcurrent protection	8.2 ± 5%A
Time to shutdown	10 min at least (powered by new fully-charged batteries after the first low battery alarm)
Battery run time	180 min (powered by one fully-charged battery according to the standard work condition[1]); 360 min (powered by two fully-charged batteries according to the standard work condition[1]).
	150 min (powered by one aged fully-charged battery according to the Table 201.102 with tidal volume 500 ml or 150 ml in ISO 80601-2-12); 120 min (powered by one aged fully-charged battery according to the Table 201.102 with tidal volume 30 ml in ISO 80601-2-12); 300 min (powered by two aged fully-charged batteries according to the Table 201.102 with tidal volume 500 ml or 150 ml in ISO 80601-2-12); 240 min (powered by two aged fully-charged batteries according to the Table 201.102 with tidal volume 30 ml in ISO 80601-2-12).

Table 11-3

[1]The standard work condition is:

- Ventilation mode: P-A/C ;
- ΔPinsp: 10 cmH_2O;
- f:10 bpm;
- Tslope: 0.2 s;
- I :E : 1 :2 ;
- O2%: 21 Vol.%;
- PEEP: 5 cmH_2O;
- R: 20 cmH_2O/L/s;
- C: 20 ml/cmH_2O;
- Gas supply nominal work pressure: 400±100 kPa.

11.4 Physical Specifications

SYSTEM NOISE	
System noise	A-weighted sound pressure level (LpA) ⩽ 45 dB(A) A-weighted sound power level (LWA) ⩽ 53 dB (A)
MAIN UNIT	
Dimensions	Not greater than 1365 mm×526 mm×544 mm (height×width×depth) (including the ventilator cart) Not greater than 354 mm×315 mm×255 mm (height×width×depth) (excluding the ventilator cart)
Weight	Approximately 30 kg (including the ventilator cart) Approximately 10 kg (excluding the ventilator cart)
CASTER	
Caster	4 casters. All casters have brakes.
DISPLAY	
Type	TFT LCD
Size	12.1"
Resolution	1280 x 800 pixels
Brightness	Adjustable
Touch screen	Available, anti-glare.
LED INDICATOR	
Alarm LED	One (yellow and red. When high and medium priority alarms occur simultaneously, it flashes red only).
External power LED	One (green; lit when the external power supply is connected).
Battery LED	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 external power supply is not connected.)
Operating status LED	One, namely, power switch key background light (green; lit when powered on and extinguished when powered off).
AUDIO INDICATOR	
Speaker	Gives off alarm tones and key tones; supports multi-level tone modulation. The alarm tones comply with the requirements of IEC60601-1-8.
Buzzer	Gives off auxiliary audio alarm in case of speaker malfunction.

Table 11-4

CONNECTOR	
Network connector	A connector which supports connection with a PC to perform software upgrade and connection with external medical and information device.
RS-232 connector	Connects to the external calibration device for calibrating pressure. An external medical device can be connected via this connector to communicate with the ventilator.
USB connector	Exports captured screen, conducts ventilator software upgrade, configuration information export and history data (such as patient data, alarm log, calibration table) export, configuration transfer between machines of the same type via USB device.
Nurse call connector	Connects to the hospital's nurse call system.
VGA connector	Outputs VGA video signals with the same contents to the primary display and connects to the external display (supporting display with resolution of 1280*800).

Table 11-4

11.5 Pneumatic System Specifications

NOTE: All gas volume, flow and leakage specification are expressed at STPD except those associated with the VBS which are expressed at BTPS.

HIGH-PRESSURE OXYGEN INLET	
Gas type	O_2
Pressure range	280 to 600 kPa
Rated flow requirement	No less than 120 L/min (STPD)
10 s average input flow for each gas at 280 kPa	<120 L/min
Connector	NIST or DISS
Fresh gas	Fresh gas is called after supplied Air and O_2 are mixed.
LOW-PRESSURE OXYGEN INLET	
Pressure range	Less than 100 kPa
Maximum flow	15 L/min(STPD)
Connector	CPC quick connector
INSPIRATION MODULE	
Peak flow in case of single supply gas (air)	⩾ 210 L/min(BTPS)
Pneumatic medicament nebulizer connector	Synchronous with inspiration at 6 to 9 L/min flow
Safety valve release pressure	<125 cmH2O
Inspiratory outlet (To patient port)	Coaxial 22 mm/15 mm conical connector
Response time to change in FiO_2 setting from 21% to 90% O_2 (measured at the patient wye)	⩽ 90 s for TV=500 mL, f=10 bpm, I:E=1:2 ⩽ 120 s for TV=150 mL, f=20 bpm, I:E=1:2 ⩽ 90 s for TV=30 mL, f=30 bpm, I:E=1:2

Table 11-5

EXPIRATION MODULE	
Expiratory outlet (From patient port)	Coaxial 22 mm/15 mm conical connector
SYSTEM COMPLIANCE AND RESISTANCE	
Compliance	Adult disposable circuit (including inspiration safety valve, adult disposable patient tubing, water trap, expiration valve): ≤ 4 mL/cmH_2O; Adult reusable circuit (including inspiration safety valve, adult patient tubing, water trap, expiration valve, Y piece): ≤ 2 mL/cmH_2O; Pediatric disposable circuit (including inspiration safety valve, pediatric disposable patient tubing, water trap, expiration valve): ≤ 2 mL/cmH_2O; Pediatric reusable circuit (including inspiration safety valve, pediatric patient tubing, water trap, expiration valve, Y piece): ≤ 2 mL/cmH_2O; Neonate disposable circuit (including inspiration safety valve, neonate disposable patient tubing, water trap, expiration valve, Y piece, neonatal flow sensor): ≤ 1 mL/cmH_2O.
Inspiratory resistance	Not greater than 6 cm H_2O at 60 L/min flow (adult patient tubing) Not greater than 6 cmH_2O at 30 L/min flow (pediatric patient tubing) Not greater than 6 cmH_2O at 5 L/min flow (neonate patient tubing)
Expiratory resistance	Not greater than 6 cmH_2O at 60 L/min flow (adult patient tubing) Not greater than 6 cmH_2O at 30 L/min flow (pediatric patient tubing) Not greater than 6 cmH_2O at 5 L/min flow (neonate patient tubing)
Bacterial filter	Resistance: < 2 cmH_2O at 30 L/min Particle size: Captures particles of 0.3 mm (micron) with > 99.99% efficiency Dead space: < 80 mL
LEAKAGE	
Leakage	Not greater than 200 mL/min@50 cmH_2O (adult tubing) Not greater than 100 mL/min@40 cmH_2O (pediatric tubing) Not greater than 50 mL/min@20 cmH_2O (neonate tubing)

Table 11-5

11.6 Ventilator Specifications

CONTROLLED PARAMETERS			
Parameter	**Range**	**Step**	**Unit**
O_2%	21 to 100	1	Vol. %
TV	Adult: 100 to 2000(BTPS) Pediatric: 20 to 300(BTPS) Neonate: 2 to 100(BTPS)	Adult: 10 Pediatric: 1 Neonate: 0.5	mL
f	Adult/Pediatric: 1 to 100 Neonate: 1 to 150	1	bpm
fsimv	1 to 60	1	bpm
Tinsp	0.10 to 10.0	0.05	s
I:E	4:1 to 1:10	0.5	/
Tslope	0.00 to 2.00	0.05	s
Tpause(%)	OFF, 5 to 60	5	%
PEEP	OFF, 1 to 50	1	cmH_2O
ΔPinsp	Adult/Pediatric: 5 to 80 Neonate: 1 to 80	1	cmH_2O
ΔPsupp	0 to 80	1	cmH_2O

Table 11-6

Phigh	0 to 80	1	cmH_2O
Plow	0 to 50	1	cmH_2O
Thigh	Adult/Pediatric: 0.2 to 30.0 Neonate: 0.1 to 30.0	0.1	s
Tlow	0.2 to 30.0	0.1	s
Trigger	Adult/Pediatric: 0.5 to 20.0 Neonate: 0.1 to 5.0	0.1	L/min
	-20.0 to -0.5	0.5	cmH_2O
Assist	ON, OFF	/	/
Δint.PEEP	OFF, 1 to 50	1	cmH_2O
Exp%	Adult/Pediatric: Auto, 1 to 85 Neonate: 1 to 85	1 to 5: 1 5 to 85: 5	%
ΔPapnea	Provides pressure apnea setting. Refer to ΔPinsp specification.		
fapnea	Adult/Pediatric: 1 to 80 Neonate: 1 to 150	1	bpm
TVapnea	Adult: 100 to 2000 (BTPS) Pediatric: 20 to 300 (BTPS) Neonate: 2 to 100(BTPS)	Adult: 10 Pediatric: 1 Neonate: 0.5	mL
Apnea Tinsp	0.10 to 10.00	0.05	s
MV%	25 to 350	1	%
Tube I.D.	Adult: 5.0 to 12.0 Pediatric: 2.5 to 8.0 Neonate: 2.5 to 5.0	0.5	mm
Compensate	OFF, 1 to 100	1	%
Interval	20s to 180min	20s to 59s:1s 1min to 180min:1min	/
Cycles Sigh	1 to 20	1	/
Neg.Plimit	-30 to 0	1	cmH_2O
CONTROLLED PARAMETERS (O_2 THERAPY)			
Continuous Flow	Adult/Pediatric: 2 to 80 Neonate: 2 to 20	1	L/min
O_2 Concentration	21 to 100	1	Vol.%
WEIGHT			
Pediatric	3 to 35	0.1	kg
Adult	10 to 200	1	kg
Neonate	0.2 to 15kg	0.1	kg
MONITORED PARAMETERS			
Parameter	Range	Resolution	Unit
Ppeak	-20 to 120	1	cmH_2O
Pplat			
Pmean			
PEEP	0 to 120	1	cmH_2O
TVi	0 to 4000 (BTPS)	Adult/Pediatric: 1 Neonate: $<$ 100: 0.1 $\geqslant$ 100: 1	mL
TVe			
TVe spn			

Table 11-6

MV MVspn MVleak	Adult/Pediatric: 0.0 to 100.0 (BTPS) Neonate: 0.0 to 30.0 (BTPS)	Adult/Pediatric: 0.1 Neonate: < 10.0: 0.01 ⩾ 10.0: 0.1	L/min
ftotal fmand fspn	0 to 200	1	bpm
Rinsp	0 to 600	1	$cmH_2O/(L/s)$
Rexp	0 to 600	1	$cmH_2O/(L/s)$
Cstat	0 to 300	Adult/Pediatric: 1 Neonate: < 10: 0.1 ⩾ 10: 1	mL/cm H_2O
Cdyn	0 to 300	Adult/Pediatric: 1 Neonate: < 10: 0.1 ⩾ 10: 1	mL/cm H_2O
RSBI	0 to 9999	1	1/(L•min)
WOB	0.0 to 100.0	Adult/Pediatric: 0.1 Neonate: 0.01	J/min
NIF	-45.0 to 0.0	0.1	cmH_2O
P0.1	-20.0 to 0.0	0.1	cmH_2O
PEEPi	0.0 to 80.0	0.1	cmH_2O
FiO_2	15 to 100	1	vol.%
RCexp	0.0 to 10.0	Adult/Pediatric: 0.1 Neonate: 0.01	s
TVe/IBW	0 to 50	0.1	mL/kg
Tinsp	0.00 to 60.00	0.01	s
I:E	100:1 to 1:150	0.1	/
Leak%	0 to 100	1	%
MONITORED PARAMETERS (O_2 THERAPY)			
Continuous Flow	0 to 100	1	L/min
O_2 Concentration	15 to 100	1	vol.%

Table 11-6

11.7 Ventilator Accuracy

CONTROL ACCURACY	
O_2%	± (3 Vol.% +1% of setting)
TV	Adult/Pediatric: ± (10 mL +10% of setting) (BTPS) Neonate: ±(2 mL+10% of setting) (BTPS)
f	1 to 100 /min: ±1 bpm Other range: ±2 % of setting
fsimv	±1 bpm
Tinsp	±0.1 s or ±10 % of setting, whichever is greater
I: E	2: 1 to 1: 4: ±10 % of setting Other range: ±15 % of setting

Table 11-7

Tslope	± (0.2 s+20 % of setting)
PEEP	± (2.0 cmH_2O + 5 % of setting)
ΔPinsp	± (2.0 cmH_2O + 5 % of setting)
ΔPsupp	± (2.0 cmH_2O + 5 % of setting)
Phigh	± (2.0 cmH_2O + 5 % of setting)
Plow	± (2.0 cmH_2O + 5 % of setting)
Thigh	± 0.2 s or ±10 % of setting, whichever is greater
Tlow	± 0.2 s or ±10 % of setting, whichever is greater
Trigger	± (1.0 cmH_2O + 10 % of setting) Adult/Pediatric: ± (1.0 L/min + 10 % of setting) Neonate: ± (0.2 L/min + 10 % of setting)
Δint.PEEP	± (2.0 cmH_2O + 5 % of setting)
Exp%	± 10 %
fapnea	1 to 100 /min: ± 1 bpm Other range: ±2 % of setting
ΔPapnea	± (2.0 cmH_2O + 5 % of setting)
Tvapnea	Adult/Pediatric: ± (10 mL +10 % of setting) (BTPS) Neonate: ±(2 mL+10% of setting) (BTPS)
Apnea Tinsp	± 0.1 s or ±10 % of setting, whichever is greater
Tpause(%)	±5% (absolute error, unavailable when Tinsp is less than 0.1s)
MV%	±10% (absolute error) or ± 10% of set value, whichever is greater
Neg.Plimit	± (2.0 cmH_2O + 5 % of set value)
CONTROL ACCURACY (O_2 THERAPY)	
Continuous Flow	± (2 L/min+10 % of setting) (BTPS)
O_2 Concentration	± (3 Vol.% +1 % of setting)
MONITORING ACCURACY	
Ppeak	± (2 cmH_2O + 4 % of the actual reading)
Pplat	
Pmean	
PEEP	
Tvi	Adult/Pediatric: 0 mL ~ 100 mL: ± (10 mL + 3 % of the actual reading) (BTPS); 100 mL ~ 4000 mL: ± (3 mL + 10 % of the actual reading) (BTPS) Neonate: ± (2 mL + 8 % of the actual reading) (BTPS)
Tve	
Tve/IBW	
Tve spn	
MV	Adult/Pediatric: ± (0.2 L/min + 10 % of the actual reading) (BTPS) Neonate: ± (0.15 L/min + 8 % of the actual reading) (BTPS)
MVspn	
Mvleak	
ftotal	±5 % of reading or ±1 bpm, whichever is greater
fmand	
fspn	
Rinsp	0 cmH_2O/(L/s) to 20 cmH_2O/(L/s): ± 10 cmH_2O/(L/s) Other range: ± (50% of the actual reading)
Rexp	
Cstat	± (2 mL/cmH_2O + 20 % of the actual reading)
Cdyn	

Table 11-7

RSBI	± (3 1/(L•min)+15 % of the actual reading)
WOB	± (1 J/min+15 % of the actual reading)
NIF	± (2 cmH_2O + 4 % of the actual reading)
P0.1	± (2 cmH_2O + 4 % of the actual reading)
PEEPi	No declaration
Rcexp	± (0.2 s + 20 % of the actual reading)
FiO_2	± (2.5 vol. % + 2.5 % of the actual reading)
Tinsp	± 0.05 s
I:E	± 6% (unavailable when the inspiration time or the expiration time is less than 50ms)
Leak%	± 10% (absolute error)
MONITORING ACCURACY (O_2 THERAPY)	
Continuous Flow	± (2 L/min+ 10 % of the actual reading)(BTPS)
O_2 Concentration	± (2.5 Vol. % + 2.5% of the actual reading)

Table 11-7

11.8 Alarms

11.8.1 Settable Alarms

ALARM SETTINGS				
Parameter		Setting range	Automatic threshold	Notes
TV	High limit	110 to 4000 mL, OFF (Adult) 25 to 600 mL, OFF (Pediatric) 3 to 200 mL, OFF (Neonate)	1.5 × TVe average value	High limit is greater than low limit.
	Low limit	50 to 4000 mL, OFF (Adult) 10 to 600 mL, OFF (Pediatric) 1 to 200 mL, OFF (Neonate)	0.5 × TVe average value	
MV	High limit	0.2 to 100.0 L/min (Adult) 0.2 to 60.0 L/min (Pediatric) 0.02 to 30.0 L/min (Neonate)	1.5 × MV monitored value	
	Low limit	0.1 to 50.0 L/min (Adult) 0.1 to 30.0 L/min (Pediatric) 0.01 to 15.0 L/min (Neonate)	0.6 × MV monitored value	
FiO_2	High limit	Low-pressure oxygen: 20 vol.% to 100 Vol.%	100 vol.%	
	Low limit	Low-pressure oxygen: 18 vol.% to 98 Vol.%	21 vol.%	
Paw	High limit	10 to 85 cmH_2O	Average peak pressure+10 cmH_2O or 35 cmH_2O, whichever is greater	/
ftotal	High limit	1 to 150 bpm, OFF (Adult/ Pediatric) 1 to 160 bpm, OFF (Neonate)	1.4 × ftotal monitored value, not more than 160 bpm	/
Tapnea		5 to 60s, in the nCPAP ventilation mode, it can be set to OFF.)	15s	/

Table 11-8

11.8.2 Internal Alarms

PARAMETER		ALARMING CONDITION
FiO_2	High limit	High-pressure oxygen: FiO_2 exceeds the alarm limit for at least 30s. Internally set alarm limit: min (Set value + max (7 Vol.% or set value x 10%), 100 Vol.%).
	Low limit	High-pressure oxygen: FiO_2 is lower than the alarm limit for at least 30s. Internally set alarm limit: max (18 Vol.%, set value - max (7 Vol.% , set value x 10%)). Absolute FiO_2 low limit: 18 Vol.%
Sustained Airway Pressure		Internally set alarm limit: PEEP+15 cmH_2O The alarm limit is exceeded for 15 s continuously.

Table 11-9

11.9 Additional Settings and Tools

SETTINGS AND TOOLS	SPECIFICATION
Inspiration Hold	Push and hold the Insp. Hold key to activate this function. Inspiration Hold is active for a maximum of 30s.
Expiration Hold	Push and hold the Exp. Hold key to activate this function. Expiration Hold is active for a maximum of 30s.
O_2 ↑	O_2 ↑ is delivered for a fixed 2 min. During O_2 ↑ , O_2 concentration for adult patients is 100% and that for pediatric patients is 1.25 times of the currently set O_2 concentration or 100%, whichever is less.
Suction	Phase 1: O_2 ↑ before suction. Delivering 100% O_2 lasts for a maximum of 120 s. O_2 concentration for adult patients is 100% and that for pediatric patients is 1.25 times of the currently set O_2 concentration or 100%, whichever is less. When patient disconnection is detected, the system enters next phase automatically. Phase 2: suction. Suction lasts for a maximum of 120s. When patient reconnection is detected, the system enters next phase automatically. Phase 3: O_2 ↑ after suction. Delivering 100% O_2 lasts for a maximum of 120s. O_2 concentration for adult patients is 100% and that for pediatric patients is 1.25 times of the currently set O_2 concentration or 100%, whichever is less.
Nebulizer	Supports jet nebulizer; Supports to set nebulizer time ranging from 1 to 60 min.
Manual Breath	One breath is delivered in the expiratory stage. Manual breath is not responded if one breath is delivered in the inspiratory stage or when the expiratory stage is not finished.
P0.1	The pressure drop in the first 100 ms when the patient starts spontaneous breathing.
NIF	Maximum negative pressure produced by patient's spontaneous breathing within a period of time.
PEEPi	The PEEPi measure function supports measurement of two parameters: PEEPi and Vtrap. PEEPi is the positive end-expiratory pressure produced by the trapped gas and Vtrap is the trapped gas volume.
Static PV Loop	By drawing static pressure-volume loop, Static PV Loop is the method to determine the optimal PEEP based on the characteristic points on the static PV loop.
ATRC	ATRC stands for the function of automatic tube resistance compensation. By selecting appropriate endotracheal (ET) tube or tracheostomy (Trach) tube of different diameters for the user, the ventilator can adjust gas delivery pressure automatically.

Table 11-10

SETTINGS AND TOOLS	SPECIFICATION
Sigh	The sigh function is used to open collapsed areas of the lung or to keep the lung open. The sigh function can be activated in all ventilation modes except CPAP/PSV, DuoLevel, and APRV. Each time after the sigh function is activated, ventilation is controlled based on the user-set sigh ventilation cycles and the set value of Δint.PEEP. PEEP of the sigh ventilation cycle increases Δint.PEEP level. After that, sigh is automatically switched off until next sigh time interval.
Screen Locking	Prevents ventilator settings and values displayed from being changed due to inadvertent key clicking.
O_2 Therapy	Continuous flow application with adjustable O_2 concentration and flow for patients with independent breathing and using oxygen masks.
Recruitment Tool	The lung recruitment function is a ventilation strategy to protect the lungs. Administer a pressure higher than that of the regular average airway during mechanical ventilation and maintain for a specified period of time, which can reopen more collapsed alveoli and prevent secondary atelectasis to small tidal volume.
Weaning Tool	If a patient's condition improves after using ventilator for a period of time, ventilator weaning can be exercised to restore spontaneous breathing. Before ventilator weaning is conducted, daily weaning screen and spontaneous breathing trials should be performed based on the patient's condition. The patient's breathing status and vital signs should be closely monitored in this process to evaluate whether weaning can be exercised, and whether it is successful.

Table 11-10

11.10 CO_2 Module Specifications

11.10.1 Sidestream CO_2 Module

CO_2 MODULE		
Measurement range and accuracy	Measurement range	Accuracy
	0 to 40 mmHg	±2 mmHg
	41 to 76 mmHg	±5 % of the actual reading
	77 to 99 mmHg	±10 % of the actual reading
Measurement accuracy drift	According to the test method of the standard ISO 80601-2-55, the module meets the requirement for measurement accuracy in this table.	
Resolution	1 mmHg	
Rise time	Adult water trap: < 400 ms@70 mL/min < 330 ms@100 mL/min < 300 ms@120 mL/min < 240 ms@150 mL/min Neonatal water trap: < 400 ms@70 mL/min < 330 ms@100 mL/min	

Table 11-11

Total system response time	Using neonatal water trap, neonatal sampling line: < 7.5 s @ 100 mL/min < 8 s @ 70 mL/min Using adult water trap, adult sampling line: < 7.5 s @ 150 mL/min < 8 s @ 120 mL/min < 8.5 s @ 100 mL/min < 9.5 s @ 70 mL/min
Pump rate	Adult: 70 mL/min, 100 mL/min, 120 mL/min and 150 mL/min optional. Pediatric/Neonate: 70 mL/min and 100 mL/min optional. The flow control accuracy is ±15 % of the set value or ±15 mL/min, whichever is greater.
Water trap cleaning time	Adult water trap: ⩾ 24 h@150 mL/min ⩾ 48 h@70 mL/min Neonatal water trap: ⩾ 24 h@100 mL/min ⩾ 48 h @70 mL/min

Table 11-11

SIDESTREAM CO_2 ALARM LIMITS	RANGE	STEP
$EtCO_2$ high limit	2 to 99 mmHg	1 mmHg
$EtCO_2$ low limit	0 to 97 mmHg	

Table 11-12

SIDESTREAM CO_2 ENVIRONMENTAL SPECIFICATIONS			
Item	**Temperature (°C)**	**Relative humidity (non-condensing)**	**Barometric pressure (kPa)**
Operating	5 to 40	10 to 95 %	70 to 106
Storage and transport	–20 to +60	10 to 95 %	50 to 106

Table 11-13

11.10.2 Mainstream CO_2 Module

CO_2 MODULE		
Measurement range and accuracy	Measurement range	Accuracy
	0 to 40 mmHg	±2 mmHg
	41 to 70 mmHg	±5 % of the actual reading
	71 to100 mmHg	±8 % of the actual reading
	101 to 150 mmHg	±10 % of the actual reading
Measurement accuracy drift	According to the test method of the standard ISO 80601-2-55, the module meets the requirement for measurement accuracy in this table.	
Resolution	1 mmHg	

Table 11-14

Monitored parameters	Parameters	Range	Resolution
	slopeCO2	0 to 9.99 % /L	0.01 % /L
	Vtalv	0 to 9999 mL	1 mL
	V'alv	0 to 20 L/min	0.01 L/min for < 1 L/min 0.1 L/min for ⩾ 1 L/min
	V'CO2	0 to 9999 mL /min	1 mL/min
	Vdaw	0 to 999 mL	1 mL
	Vdaw/TVe	0 to 100 %	1 %
	VeCO2	0 to 999 mL	1 mL
	ViCO2	0 to 999 mL	1 mL
Total system response time	<2.0 s		

Table 11-14

MAINSTREAM CO_2 ALARM LIMITS	RANGE	STEP
$EtCO_2$ high limit	2 to 150 mmHg	1 mmHg
$EtCO_2$ low limit	0 to 148 mmHg	

Table 11-15

MAINSTREAM CO_2 ENVIRONMENTAL SPECIFICATIONS			
Item	**Temperature (°C)**	**Relative humidity (non-condensing)**	**Barometric pressure (kPa)**
Operating	10 to 40	10 to 90 %	62 to 106
Storage and transport	–10 to +55	10 to 90 %	50 to 106

Table 11-16

11.11 SpO_2 Module Specifications

SPO_2 MODULE	
*Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come with in the specified accuracy range compared to CO-oximeter measurements.	
Measurement range	0 to 100 %
Resolution	1 %
Accuracy	70 % to 100 %: Adult/pediatric: ± 2 % (measured without motion in adult/pediatric mode) Neonate: ± 3 % (measured without motion in neonate mode) 0 % to 69 %: Not specified.
Data update period	⩽ 30 s
*Studies were performed to validate the accuracy of Pulse Oximeter with SpO_2 sensors by contrast with a CO-Oximeter. The statistical analysis of data of this study shows the accuracy (Arms) is within the stated accuracy specification. Please see the following table.	

Table 11-17

SENSOR TYPE	TOTAL	DATA	ARMS	
512F (adult, finger type, reusable)	10 (4 male&6 female)	200 pairs	1.91 %	
512H (pediatric, finger type, reusable)	10 (0 male&10 female)	200 pairs	1.95 %	
SKIN COLOR	**GENDER**	**NUMBER**	**AGE(YEARS)**	**HEALTH**
Black	Male	1	26±3.14	Healthy
	Female	1		
Yellow	Male	3		
	Female	9		
PR				
Measurement range	20 to 254 1/min			
Resolution	1 1/min			
Accuracy	±3 1/min			
Data update period	⩽ 30 s			
PI				
measurement range	0.05 %~20 %			
Resolution	0.05 ~ 9.99 %: 0.01 % 10.0 ~ 20.0 %: 0.1 %			

Table 11-17

SPO_2 ALARM LIMITS	RANGE	STEP
SpO_2 high limit	2 to 100 %	1 %
SpO_2 low limit	0 to 98 %	
Desat limit	0 to 98 %	

Table 11-18

PR ALARM LIMIT	RANGE	STEP
PR high limit	17 to 300 1/min	1 1/min
PR low limit	15 to 298 1/min	

Table 11-19

11.12 O_2 Sensor Specifications

O_2 SENSOR	
Output	9 to 13 mV at 210 hPa O_2
Range	0 to 1500 hPa O_2
100% O_2 signal deviation	100 ± 1 %
Resolution	1 hPa O_2
Expected service life	1.5 x 10^6 % for measurement (20 °C) 0.8 x 10^6 % for measurement (40 °C)
Response time (21 % air to 100 % O_2)	<15 s
Linearity	Linear 0-100 % O_2

Table 11-20

Operating temperature range	-20 °C to +50 °C
Temperature compensation	±2 % of fluctuation at 0 to 40 °C
Pressure range	50 to 200 kPa
Relative humidity	0 to 99%
100% O_2 concentration output drift	Over one year of typical value <5%
Material	White ABS
Packaging	Sealed package
EFFECT OF INTERFERING GAS	
GAS UNDER TEST	**ERROR (%O_2)**
50% He/50% O_2	<1 %
80% N_2O/20% O_2	1 % to 1.5 %
4% Halothane/28.8% O_2 /67.2% N_2O	1.5 % to 2 %
5% Sevoflurane/28.5% O_2 / 66.5% N_2O	1 % to 1.5 %
5% Enflurane/28.5% O_2 /66.5% N_2O	1.2 % to 1.8 %
5% Isoflurane/28.5% O_2 /66.5% N_2O	1.2 % to 1.8 %
5% CO_2 / 28.5% O_2 /66.5% N_2O	<1 %

Table 11-20

A.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 CO_2 and SpO_2 module accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.**

B.0 EMC

This ventilator complies with the EMC standard IEC 60601-1-2:2020.

WARNING: The use of unapproved accessories may diminish system performance.

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

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 the ventilator adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the ventilator 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 the ventilator could result in increased electromagnetic emissions or decreased electromagnetic immunity of the ventilator 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 the ventilator could result.

WARNING: Other devices may interfere with the ventilator even though they meet the requirements of CISPR. The CO2 accessories which meet CISPR 11 CLASS B requirements will also compliance EMC requirements.

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 ventilator.

WARNING: The ventilator is not intended for use in residential environments and can possibly not provide adequate protection to radio reception in such environments.

If the ventilator is operated within the electromagnetic environment listed in TABLE EMC-2, EMC-3, EMC-4 and EMC-5, the ventilator will remain safe and will provide the following basic performances: airway pressure, expired volume, PEEP, oxygen level, CO2 level, and alarm.

GUIDANCE AND MINDRAY DECLARATION - ELECTROMAGNETIC EMISSIONS		
The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The 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 A	The ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance	

Table B-1 EMC-1

GUIDANCE AND MINDRAY DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of system 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, ±8 kV, ±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 % 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	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.

Table B-2 EMC-2

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 B-2 EMC-2

GUIDANCE AND MINDRAY DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conduced RF IEC 61000-4-6	3 Vrms 0.15 MHz - 80 MHz	3 Vrms 0.15 MHz - 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\times \sqrt{P}$
	6 Vrms in ISM bands[a] between 0.15 MHz and 80 MHz	6 Vrms in ISM bands[a] between 0.15 MHz and 80 MHz	$d = 2\times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz - 2.7GHz	10 V/m 80MHz - 2.7GHz	$d = 1.2\times \sqrt{P}$ 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 B-3 EMC-3

NOTE:	**At 80 MHz and 800 MHz, the higher frequency range applies.**
NOTE:	**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 B-3 EMC-3

GUIDANCE AND MINDRAY DECLARATION - ELECTROMAGNETIC IMMUNITY			
The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Proximity magnetic fields IEC 61000-4-39	65 A/m 134.2 kHz Pulse modulation 2.1 kHz	65 A/m 134.2 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 B-4 EMC-4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND VENTILATOR						
The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 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 system, 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

Table B-5 EMC-5

710 745 780	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 -1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 -2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 -5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Table B-5 EMC-5

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND VENTILATOR

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

Rated Maximum Output power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**			
	150 kHz - 80 MHz Out ISM bands $d=1.2\sqrt{P}$	150kHz -80MHz in ISM bands $d=2\sqrt{P}$	80MHz-800MHz $d=1.2\sqrt{P}$	800MHz-2.7GHz $d=2.3\sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2.0	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: **At 80 MHz and 800 MHz, the higher frequency range applies.**

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

Table B-6 EMC-6

No.	Name	Cable Length(m)	Shield or Not	Remarks
1	Power input	3.0 m	No	/
2	Mainstream CO2 module cable	2.8 m	Yes	/
3	SPO2 cable	2.8 m	Yes	/

Table B-7 EMC-7

Item	Description
Wi-Fi	IEEE 802.11 a/b/g/n/ac
Operating frequency	2412 MHz -2472 MHz, 5180 MHz -5825 MHz
Modulation mode	BPSK/QPSK/16QAM/64QAM/256QAM
Output power (dBm)	< 20 dBm (Average) < 30 dBm (Peak)

Table B-8 Radio Regulatoty Compliance

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