

TV80

Respirator

Operator's Manual






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- if authorized Mindray personnel have been the only ones to carry out all installation operations, expansions, changes, modifications and repairs of the product;
- The electrical installation of the relevant room complies with the requirements of applicable local and national regulations;
- that the product is used as indicated in the instructions for use.

WARNING: It is important that the hospital or company using this equipment implement a reasonable maintenance plan. Failure to do so could result in equipment failure or personal injury.

NOTE: This equipment should only be used by trained and qualified clinical professionals.

NOTE: If there is any contradiction or ambiguity between the English version and this version, the English version shall prevail.

Warranty

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Mindray's obligations and responsibilities under this warranty do not include transportation or any other expenses, nor liability for delays or direct, indirect, or consequential damages resulting from the application or improper use of the product or accessories not approved by Mindray. The company is also not responsible for repairs performed by individuals other than authorized Mindray personnel.

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- Malfunction or damage caused by improper operation or repair carried out by unauthorized or unqualified service personnel.
- Malfunction of the equipment or of a part whose serial number is not easily readable.
- Other reasons not caused by the equipment itself or a part.

Customer Service Department

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Notification of adverse events

As a healthcare provider, you may inform SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. if adverse events occur, and also the competent authorities in the country where the user or patient is located.

These events include deaths, illnesses, and serious injuries related to the device. Furthermore, as part of our quality control program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests that you report any device malfunctions or errors. This information is requested to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. supplies only the highest quality products.

Prologue

Objective of the manual

This manual contains the instructions necessary to use the product safely and according to its intended function and use. Following the instructions in this manual is a prerequisite for proper product operation and performance, and ensures the safety of patients and technicians.

This manual is based on the complete configuration and, therefore, some of its content may not apply to your product. If you have any questions, please contact us.

This manual is part of the product. It should always be kept near the equipment so that it can be easily consulted when needed.

NOTE: **If your equipment has any features not included in this manual, please refer to the latest English version.**

Recipients

This manual is intended for medical professionals who are expected to have a working knowledge of procedures, practice, and terminology in the field of medicine for the supervision of critically ill patients.

Operator responsibilities

The proper functioning of the respirator can only be guaranteed if it is used in accordance with the information provided in this manual and if maintenance is performed by authorized Mindray personnel. Failure to comply with this information will void all warranty claims.

Only qualified and properly trained personnel may use the respirator. All operators must consult this operator's manual, as well as any additional documentation. They must also comply with all WARNINGS, PRECAUTIONS, and NOTES described in this manual.

Illustrations

All illustrations in this manual are provided for illustrative purposes only. They may not necessarily match the configuration or data displayed on the ventilator.

Conventions

- The **italicized** text is used in this manual to cite the chapters and sections being referenced.
- [] is used to indicate text from the screen.
- ÿ is used to indicate usage procedures.

Password

A password must be entered to access the different menus of the ventilator.

- System menu: 1234

Index

Intellectual Property Declaration.....	i
Manufacturer's liability	i
Warranty	ii
Disclaimers	ii
Customer Service Department.....	ii
Notification of adverse events	iii
Prologue	iii
Index.....	1
Security	1 - 1
Safety Information	1 - 2
Warnings	1 - 2
Precautions.....	1 - 7
Notes.....	1 - 10
Device symbols	1 - 11
Respirator symbols/packaging/labeling.....	1 - 11
Interface symbols	1 - 13
Basic concepts	2 - 1
Introduction	2 - 2
Intended use.....	2 - 2
Product description.....	2 - 2
Product appearance.....	2 - 3
Front view.....	2 - 3
Rear view	2 - 5
Installation and connections	3 - 1
Main unit installation.....	3 - 2
Power supply connection.....	3 - 3
Module Installation	3 - 4
Gas supply connection	3 - 5
Installation of the support arm.....	3 - 7
Installation of the intravenous pole.....	3 - 8
Pump bracket installation	
Patient tube placement.....	3 - 10
Humidifier Installation	3 - 11
Installing the humidifier on the respirator	3 - 12
Installing the humidifier on the hanging bracket.....	3 - 13
Electronic nebulizer installation.....	3 - 14
Installation of the backup gas cylinder	3 - 17
Base Installation	3 - 18
Attachment to the rail system	3 - 19
User interface.....	4 - 1
Monitor controls	4 - 2
Waveform Display	4 - 5
PulmoSight Status	4 - 6
PulmoSight Adjustment	4 - 7
Large Number Display.....	4 - 7
Measured values display.....	4 - 7

Spirometry screen	4 - 8
History.....	4 - 9
Graphical trends	4 - 10
trends.....	4 - 11
Settings Trends.....	4 - 12
Log.....	4 - 12
Freezing.....	4 - 13
Freeze State	4 - 13
State.....	4 - 13
Screenshot.....	4 - 14
Lock.....	4 - 14
System Settings	5 - 1
USB.....	5 - 2
Screen.....	5 - 2
Data	5 - 2
Settings	5 - 3
Data.....	5 - 3
Basic Settings.....	5 - 4
Setting	5 - 4
Setting.....	5 - 4
Setting.....	5 - 4
Setting.....	5 - 4
Setting.....	5 - 4
Setting.....	5 - 5
Setting	5 - 5
Period.....	5 - 5
Setting.....	5 - 5
Setting.....	5 - 6
Settings	5 - 6
Screen.....	5 - 6
Brightness	5 - 6
Volume	5 - 6
Layout	5 - 6
Color	5 - 7
Mode.....	5 - 7
Settings.....	5 - 8
Date	5 - 8
Language.....	5 - 8
Unit.....	5 - 8
Password	5 - 8
Adjusting the ventilator location.....	5 - 8
management.....	5 - 9
settings.....	5 - 9
settings.....	5 - 10
system information.....	5 - 15
View open source information.....	5 - 16
mode.....	5 - 16
Selecting shortcut keys for tools.....	5 - 16

Factory service settings	5 - 16	Calculating oxygen consumption.....	5 - 16
Start of ventilation.....	6 - 1		
System startup	6 - 2		
System Check.....	6 - 2	Patient Information Management.....	6 - 4
Information Management.....	6 - 4	Adjusting Patient Information on the Ventilator.....	6 - 4
Information on the Ventilator.....	6 - 4	Retrieving Patient Information from the ADT Server.....	6 - 4
ADT Server.....	6 - 4	Retrieving Patient Information via the Monitor.....	6 - 5
Monitor.....	6 - 5	Ventilation Type.....	6 - 5
Type.....	6 - 5	Invasive Ventilation.....	6 - 5
Ventilation.....	6 - 5	Non-invasive ventilation (NIV).....	6 - 5
Non-invasive ventilation (NIV).....	6 - 5	Adjusting the ventilation type.....	6 - 6
Adjusting the ventilation type.....	6 - 6	Ventilation mode.....	6 - 6
Ventilation mode.....	6 - 6	Ventilation mode and parameter settings.....	6 - 6
Ventilation mode and parameter settings.....	6 - 6	VA/ C	6 - 8
C	6 - 8	PA/C	6 - 9
PA/C	6 - 9	V-SIMV	6 - 10
V-SIMV	6 - 10	P-SIMV	6 - 11
P-SIMV	6 - 11	CPAP/PSV	6 - 12
CPAP/PSV	6 - 12	PSV-S/T	6 - 14
PSV-S/T	6 - 14	PRVC.....	6 - 15
PRVC.....	6 - 15	PRVC-SIMV	6 - 16
PRVC-SIMV	6 - 16	DuoLevel	6 - 18
DuoLevel	6 - 18	APRV.....	6 - 19
APRV.....	6 - 19	VS.....	6 - 20
VS.....	6 - 20	AMV	6 - 21
AMV	6 - 21	CPRV.....	6 - 23
CPRV.....	6 - 23	nCPAP	6 - 26
nCPAP	6 - 26	Apnea Ventilation	6 - 26
Apnea Ventilation	6 - 26	Oxygen Therapy	6 - 27
Oxygen Therapy	6 - 27	Other Ventilation Settings.....	6 - 30
Other Ventilation Settings.....	6 - 30	Sighs.....	6 - 30
Sighs.....	6 - 30	Leak Compensation	6 - 30
Leak Compensation	6 - 30	IntelliCycle.....	6 - 32
IntelliCycle.....	6 - 32	Alarm Settings.....	6 - 33
Alarm Settings.....	6 - 33	Ventilation Start	6 - 33
Ventilation Start	6 - 33	Ventilation parameters.....	6 - 33
Ventilation parameters.....	6 - 33	Entering standby state.....	6 - 37
Entering standby state.....	6 - 37	Shutting down the system.....	6 - 38
Shutting down the system.....	6 - 38	Neonatal ventilation	7 - 1
Neonatal ventilation	7 - 1	Safety Information	7 - 2
Safety Information	7 - 2	Connecting the Patient Tube to the Flow Sensor	7 - 3
Connecting the Patient Tube to the Flow Sensor	7 - 3	Starting Ventilation	7 - 3
Starting Ventilation	7 - 3	Backup ventilation.....	7 - 3
Backup ventilation.....	7 - 3	Adjusting the monitoring switch	7 - 4
Adjusting the monitoring switch	7 - 4	Zeroing the neonatal flow sensor	7 - 4
Zeroing the neonatal flow sensor	7 - 4		

Carbon dioxide (CO₂) control	8 - 1
Introduction	8 - 2
Sideflow CO ₂ Module.....	8 - 5 Performing the
Leak Test.....	8 - 5 Preparing for
Measurement.....	8 - 5 CO ₂
Settings	8 - 7
Measurement Limitations.....	8 - 8
Troubleshooting	8 - 8 Sensor
Zeroing	8 - 8
Sensor calibration	8 - 9
Direct Flow CO ₂ Module	8 - 9 Preparation
for Measurement.....	8 - 9 CO ₂
Settings	8 - 11
Measurement Limitations.....	8 - 12
Sensor zeroing	8 - 12
Sensor calibration	8 - 13
Troubleshooting CO ₂ Modules	
8 - 13 Troubleshooting Sideflow CO ₂ Modules.....	8 - 13
Troubleshooting Directflow CO ₂ Modules	8 - 13
Pulse Oxygen Saturation (SpO₂) Monitoring	9 - 1
Introduction	9 - 2
SpO ₂ Safety Information	
PR Adjustment	9 - 5
QRS Volume Adjustment	9 - 5 PR Origin
Adjustment	9 - 5 Show/Hide
PR	9 - 6
Limitations in measurement	9 - 6
SpO ₂ Troubleshooting.....	9 - 7 BeneVision N1
Patient Monitor.....	10 - 1
Introduction	10 - 2
Monitor interfaces.....	10 - 2
Implementation of monitoring	10 - 3
Monitoring parameters.....	10 - 3
ECG Monitoring.....	10 - 4
Invasive Blood Pressure (IBP) Monitoring.....	10
- 5 Non-invasive Blood Pressure (NIBP) Monitoring.....	10
- 6 Respiratory (Resp) Monitoring.....	10
- 7 Temperature (Temp) Monitoring.....	10
- 8 Additional Tools for Ventilation.....	11 - 1 Manual
Breath Hold/Inspiration.....	11 - 2

O2y (Oxygen Enrichment)	11 - 2
Suction	11 - 3
Expiratory retention.....	11 - 4 Static PV
loop.....	11 - 4
Recruitment Tools (IS)	11 - 5
History.....	11 - 6
Ventilator Weaning Tools.....	11 - 6 Displaying Help
Information.....	11 - 6 Spontaneous Breathing Trial
(SBT).....	11 - 7
History.....	11 - 7
Patient-ventilator asynchrony	11 - 8
Alarms.....	12 - 1
Introduction	12 - 2
Alarm Categories.....	12 - 3 Alarm
Priority Levels.....	12 - 3 Alarm
Signals.....	12 - 3
Alarm light.....	12 - 3
Audible alarms	12 - 4
Alarm messages.....	12 - 4 Flashing
alarm numeric values.....	12 - 5 Alarm status
symbol.....	12 - 5
Adjusting the alarm volume.....	12 - 5
Adjusting alarm management.....	12 - 6 Setting
alarm limits.....	12 - 6
Automatic alarm limits	12 - 6
AUDIO PAUSED.....	12 - 7
PAUSED AUDIO Adjustment	12 - 7
PAUSED AUDIO Termination	12 - 7
Current alarms	12 - 7
Recent alarm.....	12 - 8
ALARM DEACTIVATED.....	12 - 9
Alarm reset	12 - 9
Resetting physiological alarms.....	12 - 9 Resetting technical
alarms.....	12 - 9
Alarm tests	12 - 10
Energy loss.....	12 - 10 Pva too
high.....	12 - 10 Pressure too
low.....	12 - 10 TVe too
low.....	12 - 10 TVe too
high	12 - 10
MVe too low.....	12 - 11 O2 supply
failure.....	12 - 11
PEEP too low.....	12 - 11 Airway
obstructed	12 - 11 FiO2 too
high.....	12 - 11
FiO2 too low.....	12 - 11 EtCO2 too
high.....	12 - 12
EtCO2 too low.....	12 - 12

SpO2 too high.....	12 - 12 SpO2 too
low.....	12 - 12 SpO2
Unsaturated	12 - 13
PR too high	12 - 13
PR too low.....	12 - 13 Tube
disconnected.....	12 - 13
Network disconnected.....	12 - 13
When an alarm occurs.....	12 - 13
Cleaning, Disinfection, and Sterilization	13 - 1 Methods of Cleaning,
Disinfection, and Sterilization.....	13 - 3 General Guidelines for Cleaning,
Disinfection, and Sterilization.....	13 - 6 Manual
Cleaning	13 - 6 Manual
Disinfection	13 - 6
Sterilization	13 - 6
Disassembly and assembly for processing	13 - 6 Expiratory
valve and diaphragm assembly.....	13 - 7 HEPA filter and dust filter
components.....	13 - 8 Main unit air inlet dust
cover	13 - 9 Patient
tubing	13 - 9
Humidifier	13 - 10
Electronic nebulizer	13 - 13
Direct flow CO2 module.....	13 - 14 Visual
inspection	13 - 14
Maintenance	14 - 1
Repair Policy.....	14 - 2 Maintenance
Program.....	14 - 2 Pressure and Flow
Zeroing.....	14 - 4 Flow Rate
Calibration.....	14 - 4
Calibration of O2 concentration	14 - 5
CO2 Calibration.....	14 - 6
Side-flow CO2 module.....	14 - 6 Direct-flow
CO2 module.....	14 - 7 Battery
maintenance.....	14 - 7
Battery information.....	14 - 8
Battery Preparation.....	14 - 8 Checking
Battery Performance	14 - 9 Battery
Storage	14 - 9
Battery recycling.....	14 - 10 Electrical
safety inspection.....	14 - 10 Water
condensation on the flow sensor.....	14 - 11 Preventing
water condensation.....	14 - 11 Emptying
condensate.....	14 - 12
Accessories.....	15 - 1
Theory of operation.....	A - 1
Principle of the pneumatic circuit	A - 2
Pneumatic circuit diagram	A - 2 List of
components	A - 3 Definition of
symbols.....	A - 4

Overview of the pneumatic circuit system.....	A - 4
Electrical system	A - 6
Structural diagram of the electrical system	A - 6
List of components.....	A - 7
Product Specifications	B - 1
Safety specifications	B - 2
Environmental specifications.....	B - 3
Power supply requirements.....	B - 3
Physical specifications.....	B - 4
Pneumatic system specifications	B - 6
Respirator Specifications.....	B - 7
Respirator accuracy	B - 10
Alarm.....	B - 13
Adjustable alarms	B - 13
Internal alarms.....	B - 14
Additional settings and tools.....	B - 14
CO2 module specifications.....	B - 15
Sidestream CO2 Module	B - 15
Direct flow CO2 module.....	B - 17
SpO2 Module Specifications	B - 18
Monitor Specifications.....	B - 20
ECG Specifications	B - 21
Respiratory Specifications.....	B - 24
Temperature specifications	B - 25
IBP Specifications PR	B - 26
Specifications NIBP	B - 27
Specifications Signal Output	B - 27
Specifications	B - 30
EMC	C - 1
EMC	C - 2
Compliance with radio regulations	C - 9
Alarm messages	D - 1
Physiological alarm messages.....	D - 2
Respirator parameters.....	D - 2
CO2 Module	D - 3
SpO2 Module.....	D - 4
Technical alarm messages	D - 5
Power supply board.....	D - 5
Main control board.....	D - 6
Monitor board	D - 7
CO2 Module	D - 11
SpO2 Module.....	D - 12
Module Module	D - 13
Factory Defaults	E - 1
Ventilation parameters.....	E - 2
Configuration.....	E - 3
System settings.....	E - 3
Alarms	E - 4

History.....	E - 5
Additional settings and tools.....	E - 5
O2 therapy.....	E - 6
CO2 module.....	E - 6
SpO2 Module	E - 7
Others	E - 7
Abbreviations, symbols and units of measurement	F - 1
Abbreviations.....	F - 2
Symbols.....	F - 4
Units of measurement.....	F - 5
Cross-references	F - 6
Software Instructions	G - 1

1.0

Security

Safety Information.....	1-2
Device symbols.....	1-11

1.1 Security information

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

CAUTION: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, equipment failure, property damage, or loss.

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

1.1.1 Warnings

WARNING: The ventilator must be operated and used only by authorized medical personnel with the necessary training. Unauthorized or untrained personnel must never be allowed to operate the ventilator. The ventilator must be operated strictly according to the operator's manual.

WARNING: The equipment, cables, and accessories must be inspected before use. use to ensure its safe and proper functioning.

WARNING: To avoid the risk of electric shock, this equipment must Connect only to a power outlet with protective grounding terminals. Do not use the outlet if it is not connected to a protective grounding terminal. Temporarily power the equipment with lithium-ion batteries.

WARNING: Use the external power supply before the batteries run out.

WARNING: Do not use the equipment in the presence of flammable materials or Keep away from explosives to prevent fires or explosions. If using O2, keep the respirator away from ignition sources.

WARNING: Do not place the respirator next to a barrier that could impede the flow of cold air, as this could cause the equipment to overheat.

WARNING: Do not open the device casing, as you may receive an electric shock. Electrical. Only authorized service personnel trained by the manufacturer may carry out maintenance and upgrade operations on the equipment.

WARNING: Adjust the volume and alarm limits according to the actual situation. of the patient. Do not rely solely on the audible alarm system to monitor a patient. Setting the alarm volume to a low level can create a dangerous situation for the patient. Always be attentive to the patient's actual clinical condition.

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

WARNING: Comply with all applicable local regulations and legislation or hospital rules regarding waste disposal when disposing of packaging material. Keep out of reach of children.

WARNING: All personnel must be aware that disassembly or cleaning of Some parts of the respirator may pose a risk of infection.

WARNING: The service menu can only be used if the equipment is not connected to a patient.

WARNING: Positive pressure ventilation can produce some side effects, such as barotrauma, hypoventilation, hyperventilation, etc.

WARNING: Use of the respirator near high-voltage electrosurgical equipment Frequency, defibrillators, or shortwave therapy equipment can negatively affect the normal functioning of the ventilator and endanger the patient.

WARNING: Do not use masks or conducting patient tubes or antistatic products should be worn when using high-frequency surgical equipment, as burns may occur.

WARNING: To avoid the risk of fire in the presence of sufficient oxygen, do not use the respirator in a hyperbaric chamber.

WARNING: If the equipment's internal monitoring system fails, you must Have an alternative plan in place to ensure an adequate level of monitoring. The ventilator operator is responsible for the patient's proper ventilation and safety under all circumstances.

WARNING: As required by international regulations and legislation The oxygen concentration must be monitored when using the equipment with a patient. If the ventilator is not configured with this monitoring function or if this function is disabled, use a monitor that meets the requirements of ISO 80601-2-55 for oxygen concentration monitoring.

WARNING: All analog or digital products connected to this system They must have certification of compliance with the specified IEC standards (such as IEC 60950-1 for data processing equipment and IEC 60601-1 for electromedical equipment). All configurations must comply with the current version of IEC 60601-1. Personnel connecting optional equipment to the I/O signal port will be responsible for configuring the medical system and ensuring its compliance with IEC 60601-1.

WARNING: Do not touch the patient while connecting the peripheral equipment using I/O signal ports to prevent leakage currents to the patient from exceeding the requirements specified by the standard.

WARNING: This equipment is not suitable for use in a partner environment.

WARNING: If the respirator's gas supply inlet system fails or malfunctions, contact the manufacturer immediately for service personnel to repair the respirator.

WARNING: The respirator should not be used with helium or mixtures containing helium.

WARNING: Remove the support arm before moving the respirator to prevent it from tipping over.

WARNING: The respirator's oxygen-gas mixer is grease-free and therefore does not require degreasing. Do not use lubricants containing oil or grease; grease contamination of the rubber hose assemblies must be avoided. Lubricants containing oil or grease may ignite or explode when exposed to high concentrations of O₂.

WARNING: The maximum hose pressure is 1.4 MPa at 21°C. Check that the gas supply pressure matches the hose requirements before using the equipment.

WARNING: Hose connectors have a standardized gas terminal depending on the type of gas. Different types of gases or gases with different pressures should not be interchanged.

WARNING: The hose may deteriorate rapidly if exposed to acidic or alkaline substances or ultraviolet rays.

WARNING: Do not hang two or more hose assemblies together.

WARNING: The respirator arm supports a maximum of 1 kg, so products exceeding this weight should not be hung on it.

WARNING: After installing the respirator or replacing the main control board, the altitude must be reset. After changing the altitude setting, recalibrate the flow rate (factory default).

WARNING: When disconnecting quick connectors, use both hands to avoid possible injury caused by a sudden release of pressure.

WARNING: Do not block the respirator's air intake.

WARNING: To avoid interruption of the respirator's operation due to electromagnetic interference, do not place it near other devices or stack it with them. If you must use it near other devices or stack it, check that the respirator is functioning correctly with the settings you will be using it with.

WARNING: Ensure the respirator is securely attached to the cart or placed on a safe and firm surface to avoid injury and damage to the equipment.

WARNING: Move the respirator carefully when navigating around obstacles or passing through gaps somewhere (like, for example, a door threshold) to prevent it from tipping over or getting damaged.

WARNING: Engage the brake when the respirator is in place to prevent unexpected movements and damage to the equipment.

WARNING: Avoid using contaminated air. When the equipment activates the Air supply for ventilation; harmful substances may enter the patient's tube if the air is contaminated.

WARNING: When an alarm [Technical Error **] is activated, remove the equipment. Record the error code and contact the customer service department immediately to prevent patient injury caused by equipment failure.

WARNING: Do not splash liquid onto the respirator to avoid malfunction.

WARNING: A vacuum cleaner can cause the gas to heat up. To reduce the To control the temperature of the gas inside the patient's tubes and prevent personal injury, ensure that the length of the patient tube from the humidifier to the tube connector is greater than 1.2 m.

WARNING: The internal battery is used temporarily if there is any doubt about the integrity of the protective earthing conductor or protective earthing system.

WARNING: Nebulizers or humidifiers can increase the resistance of the breathing system filters. For this reason, the operator must monitor the filter for increased resistance and blockage.

WARNING: Nebulization may affect the accuracy of the respirator's ventilation.

WARNING: In the case of non-invasive ventilation, the tidal volume The patient's actual expiratory rate is different from that monitored by the ventilator due to leaks around the face mask.

WARNING: Check if the alarm limits have been set correctly before starting ventilation.

WARNING: Always connect the equipment to an easily accessible power outlet if using external power, so that it can be unplugged quickly and easily in the event of a failure.

WARNING: Modifying this equipment is not permitted.

WARNING: Stop using the respirator immediately and contact customer service when the alarm is triggered. sound.

WARNING: Store the flow sensor cable securely to avoid the risk of entanglement of the patient or unintentional extubation.

WARNING: System leaks, such as a leak caused by an uncuffed endotracheal tube, can affect airflow readings, among other parameters, pressure, CO2 production, and other respiratory mechanics parameters.

WARNING: When the ventilator is connected to the patient, do not remove or replace the fuse or perform any other maintenance. These operations must be performed when the patient is not using the ventilator.

WARNING: Make sure the AC power cord is unplugged before removing or replacing the fuses.

WARNING: There may be danger if different preset values are used. alarm for the same equipment, or for a similar one, in any area. Read the manual to confirm the respirator's preset alarm settings before use.

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

WARNING: A ventilator failure can lead to an increase in oxygen inside the ventilator and thus pose a fire risk.

WARNING: If necessary, contact the manufacturer for the circuit diagram, parts list, and calibration instructions for the product or other information related to equipment maintenance.

WARNING: When the equipment is connected to other electrical equipment with specific functions, if it cannot be determined from the specifications of each piece of equipment whether the combination is dangerous (e.g., electric shock caused by the accumulation of leakage current), contact the manufacturer or experts in this field at the hospital to ensure that the necessary safety of all the equipment in the combination is not compromised.

WARNING: Handle the power cord and accessories carefully.
Avoid patient apnea, cable entanglement, or electrical interference.

WARNING: The copyright of the software on this device is the exclusive property of the company. No organization or individual may infringe upon it, including by tampering, copying, or sharing, in any way or form without authorization.

WARNING: Use caution when moving or placing the respirator on a slope above 10°. Before moving, make sure to remove the items from the basket and the IV pole.

WARNING: This device is intended for use by a single patient only.
time.

WARNING: Do not touch the patient during defibrillation; otherwise, you could cause serious injury or death.

WARNING: At an ambient temperature of 40°C, the maximum temperature of the The surface of the respiratory mask can exceed 41 °C but not 43 °C.

WARNING: Do not connect a multi-outlet power adapter to the device.
no additional extension cable.

WARNING: To avoid high-voltage electric shocks, the respirator must
Disconnect from the AC power source and remove the batteries
before disassembling the respirator.

WARNING: All spare parts, accessories and consumables are original parts
manufactured by Mindray or recognized by Mindray.

WARNING: Do not use the respirator or sensors during the MRI.
Magnetic resonance imaging (MRI). The induced current could cause
burns to the patient.

WARNING: Refer to the humidifier operator's manual for installation and use instructions.

WARNING: Do not perform CO2 zeroing in direct sunlight.

WARNING: The respirator can only function if it is securely mounted.
in an ambulance, a fixed-wing aircraft, or a helicopter.

1.1.2 Precautions

CAUTION: The respirator should only be inspected and repaired on a routine basis.
by trained service personnel.

CAUTION: Always have an emergency respirator ready for
to ensure patient safety.

CAUTION: There must always be a person present to attend to and monitor the
operation of the equipment once the ventilator is connected to the
patient.

CAUTION: During operation of the respirator, do not disassemble the valve.
expiration unless it is in standby mode.

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

CAUTION: Dispose of the equipment and its accessories at the end of their useful
life in accordance with applicable local laws and regulations
or hospital rules.

CAUTION: The electromagnetic field may affect equipment performance.
Therefore, other devices used in the vicinity of the equipment must
comply with the relevant EMC requirements. Potential sources of
interference include mobile phones, X-ray machines, and MRI
devices, as these can emit high levels of electromagnetic radiation.

CAUTION: This system may function correctly with the following levels:
Interference levels are indicated in this manual. Higher levels of interference
may trigger alarms and even stop automatic ventilation. Keep the equipment away
from high-intensity electric fields that may cause the system to emit false alarms.

CAUTION: Ensure that the voltage and frequency of the power supply

Ensure that the power supply voltages are within the ranges specified on the equipment label or in this manual before connecting the equipment to a power source.

CAUTION: Always install or move the machine carefully to avoid falling, collision, violent vibration, or other damage caused by external mechanical force.

CAUTION: Check reusable patient tubing several times for damage or leaks before use. If found, do not use.

CAUTION: Unplug the respirator to electrically isolate the respirator circuits of all electrodes of the input power supply.

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

CAUTION: Healthcare personnel are responsible for ensuring that the adjustments of the respirators are suitable.

CAUTION: Make sure the respirator is set for the correct type of Use the appropriate patient tubing with the correct patient tubing to avoid potential injury. Ensure the system is checked before use with a patient.

CAUTION: Perform a zeroing of the pressure before using the respirator, or when the measured values show deviations.

CAUTION: Ensure the ventilator's ventilation parameters are properly set before starting ventilation to avoid injury to the patient.

CAUTION: If performing ventilation with a mask, do not use high airway pressure. High airway pressure can cause gastric distension.

CAUTION: In non-invasive ventilation, if peak pressure (P_{peak}) > 33 cmH₂O, the risk of gastric insufflation may increase. If ventilation is performed at these pressures, consider using an invasive ventilation mode.

CAUTION: Use only medical-grade approved hoses for connecting oxygen supplies to the respirator to reduce the risk of fire.

CAUTION: Ensure there is ventilation at the back of the respirator to reduce the risk of fire.

CAUTION: Turn off the oxygen supply when the ventilator is not in use. ventilation mode to reduce the risk of fire.

CAUTION: Do not store the respirator in an environment with a temperature Above 50°C for a prolonged period. Such an environment can damage the internal batteries or shorten their lifespan.

CAUTION: Use original packaging materials to ship the respirator.

CAUTION: Use only the specified fuses or fuses of the same type, voltage rating, and current rating to prevent the risk of fire. Contact customer service when a fuse needs replacing.

CAUTION: The respirator is intended for use in the patient environment.

CAUTION: The system should not be connected to multi-outlet power strips or cables. extension.

CAUTION: Before moving the ventilator, make sure the wheels and brakes are working properly and that the main unit is locked to the cart.

CAUTION: If the respirator is used in a toxic or infectious environment, the patient
The patient must inhale 100% medical-grade oxygen to prevent toxic substances or viruses from entering the breathing gas. The patient should be immediately moved to a breathable environment to avoid inhaling toxic or infectious gases when spontaneous breathing resumes.

CAUTION: To ensure that the backup battery is available when the
When the ventilator is operating in the emergency transfer scenario, keep the battery in place while the ventilator is running.

CAUTION: For safety reasons, always keep the battery fully charged.
Even when using an external power source, a sudden power outage may result in data loss.

CAUTION: Check the oxygen cylinder pressure before using it for
Avoid insufficient oxygen supply during use.

CAUTION: When using the device in an environment with very high temperatures
High temperatures prevent air from entering the lungs. Adjust the oxygen concentration to 100%. If the patient inhales superheated gas, lung injury will occur. The patient should be moved immediately to a breathable environment to prevent lung injury from inhaling superheated gases.

CAUTION: Do not use the equipment outside the specified environmental range and
Gas supply (or electrical power supply). The equipment's operation may not meet specifications.

CAUTION: Install the respirator in the protective stand and protective pack for
outdoor emergency transfer scenarios. When using the respirator in an ambulance, it can be installed and secured using the protective stand. When using the respirator indoors, accessories can be selected according to the needs.

CAUTION: The ventilator is electrically powered and controlled electronically, and is driven by the aspirator motor to form a stable mixture of air and oxygen. For further information, see A.1 Principle of the pneumatic circuit. The delivered tidal volume or minute volume and O₂ concentration are affected by the pressure at the patient connector.

CAUTION: Some settings are password protected. Changes to Passwords must be set by authorized personnel. If you need a password to access these features, please contact the appropriate staff.

CAUTION: Dry the equipment immediately after it rains or gets wet. water splashes.

CAUTION: The respirator's external air outlets should not be located in areas with electrical components.

CAUTION: Dirt caused by dust may compromise integrity Functionality of the device. Do not use the respirator without a dust filter.

1.1.3

Grades

NOTE: Place the respirator and its components in a location where it is easy to monitor, handle, and maintain.

NOTE: Keep this manual near the equipment so you can easily refer to it whenever needed.

NOTE: The equipment software has been developed in accordance with the IEC 62304 standard, with the potential risks of program errors minimized.

NOTE: This manual describes the product in order to fully cover its functions and configuration options, and the product you purchased may not be compatible with these functions or configuration options.

NOTE: When the oxygen supply is insufficient, the ventilator automatically switches to suction mode to supply ambient air to the patient.

NOTE: Under normal operating conditions, the operator should stand in front of the equipment.

NOTE: The ventilator returns to normal 10 seconds after defibrillation.













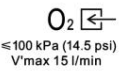
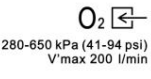








NOTE: Based on the clinical and residual risk assessment findings, no known side effects are expected in the intended patients during or after the use of this medical device. No special preparations are required from the operator. Furthermore, any remaining risks are disclosed in the relevant chapter of this manual as warnings or precautions.






















NOTE: The time that elapses between two uses from the minimum or maximum storage temperature until the respirator is ready for normal operation is approximately 1 hour.

NOTE: The time elapsed from start-up until the ventilator is ready for normal operation does not exceed 25 seconds.

1.2 Device symbols

1.2.1 Respirator symbols/packaging/labeling

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Caution		Warning
	Fuse		Grounding
	Battery LED		AC/DC power supply
	RS-232 connector		VGA output connector
	Expiration connector		Patient monitor switch buckle BeneVision N1
	USB connector		Network connector
	Oxygen supply connector low pressure		High pressure O2 supply connector
	Blockade/ Unlock		Do not push
	Inspiration connector		AUDIO PAUSED key
	Date of manufacture		Manufacturer
	Keep dry		Temperature limit

	Humidity limit		Atmospheric pressure limit
	This part upwards		Fragile, handle with care
	Recyclable		Stacking limit
	Respirator gas inlet		Respirator gas outlet
	Serial number		Unique device identifier
	Type BF applied part, defibrillation-proof		Rechargeable battery
	Class II Equipment		Key On Hold
	Medical device		Consult the manual/ brochure instructions
	Flow sensor		DC power connector polarity
	CF type applied part, defibrillation-proof		Equipotentiality
	Authorized representative in the European Community		

IP22

IP22: protected against the entry of foreign objects not less than 12.5 mm and against access to dangerous parts with a finger; protected against the harmful effects of vertically falling water drops with the device tilted at any angle up to 15°.

IP34

IP34: protected against the penetration of foreign bodies not less than 2.5 mm and against access to dangerous parts with a tool; protects against the harmful effects of water splashes.



The following definition of the WEEE label applies only to EU Member States. This symbol indicates that the product is not considered household waste. Ensuring proper disposal of the product will help prevent potential negative consequences for the environment and human health. For detailed information on product return and recycling, please consult the retailer where you purchased the product.











* In system products, this label will only be attached to the main unit.






This product is supplied with a CE marking in accordance with the regulations set out in Regulation (EU) 2017/745 or Council Directive 93/42/EEC on medical devices. The number next to the CE marking (0123) is the number of the EU notified body that certifies compliance with the requirements of the regulation.

1.2.2 Interface symbols

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	AUDIO PAUSED		Alarm limits disabled
	Recent alarms		Number of alarms
	Alarm settings		Screenshot
	USB connected		USB disconnected
	Invasive ventilation		Non-invasive ventilation
	Network connected		Network disconnected
	WLAN connected		WLAN disconnected
	5G connected		5G disconnected
	Adjust brightness/ screen volume in day mode		Adjust brightness/ screen volume in night mode

	Adult		Pediatric
	Freezing		Newborn
	Alarm reset		Bluetooth
	Battery display (disconnected from external power source)		Battery indicator (connected to the external power supply)
	Mode icon abroad		Without battery

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

SHAPE GEOMETRIC	MEANING	COLOR of SECURITY	COLOR of CONTRAST	COLOR OF GRAPHIC SYMBOL
	Prohibition	Red	White	Black
	Mandatory Blue Action		White	White
	Warning	Yellow	Black	Black

2.0

Basic concepts

Introduction.....	2-2
Product appearance.....	2-3

2.1 Introduction

2.1.1 Intended use

2.1.1.1 Intended purpose

The ventilator is designed to provide assisted ventilation and respiratory support to patients.

2.1.1.2 Intended users

The ventilator should only be used by authorized medical personnel who have been properly trained in its use. The instructions in the Operator's Manual must be strictly followed.

2.1.1.3 Patient population

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

2.1.1.4 Indicated diseases

In cases requiring prolonged ventilation and respiratory support in patients with apnea or respiratory failure, these patients are wholly or partially dependent on this equipment. This product is intended for use in intensive care settings within a professional healthcare facility, or during transport within a professional healthcare facility and emergency medical services environment, such as in ambulances or aircraft, etc.

2.1.1.5 Contraindications

There are no contraindications for this equipment. However, in the case of some specific illnesses, it is necessary to administer certain treatments to facilitate mechanical ventilation with a ventilator, or special ventilation modes must be adopted to prevent potential injury to the patient.

2.1.2 Product description

The ventilator consists of a main unit (which includes the pneumatic circuit, the electronic system, the mechanical structure, the screen, the CO₂ module and the SpO₂ module), a cart and a support arm.

The ventilator is intended for use in the patient's environment. Connect the patient to the ventilator using the breathing tube. Applied ventilator parts include SpO₂ module accessories, CO₂ module accessories , patient tubing, and masks.

2.2 Product appearance

2.2.1 Front view

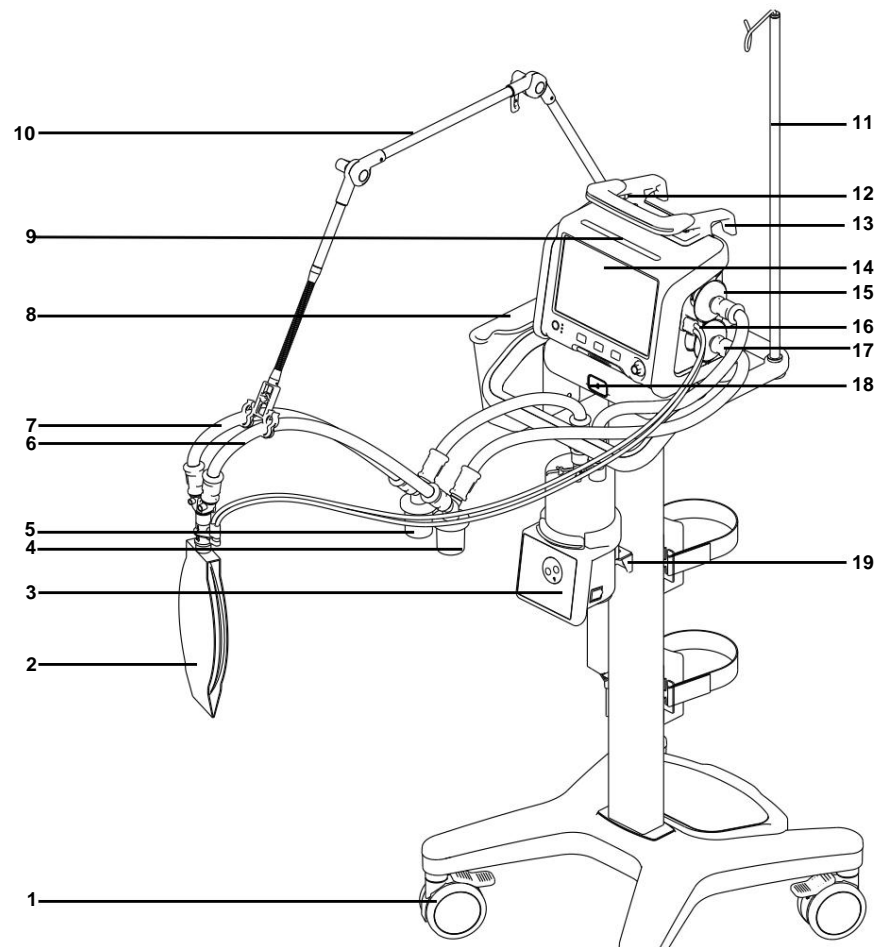


Figure 2-1 Front view

COMPONENT NO.	DESCRIPTION
1	Wheel and brake The ventilator has four wheels and all of them have brakes.
2	Test lung It is used to perform system checks or flow calibration.
3	Humidifier /
4	Expiratory water collector Collect the condensed water in the exhalation tube.
5	Inspiratory water collector Collect the condensed water in the inhalation tube.
6	Exhalation tube /

Table 2-1 List of components

COMPONENT NO.	DESCRIPTION
7	Inhalation tube /
8	Storage basket /
9	Alarm indicator /
10	Support arm The patient's tubes hang from it.
11	Intravenous post /
12	Handle It is used to transport the respirator.
13	Hook It is used to hang the respirator on the hospital bed or on the rail system.
14	Monitor /
15	Inspiratory filter /
16	Flow sensor port /
17	Expiratory filter /
18	Cart unlock button /
19	Humidifier stand It is used to install the humidifier.

Table 2-1 List of components

2.2.2 Rear view

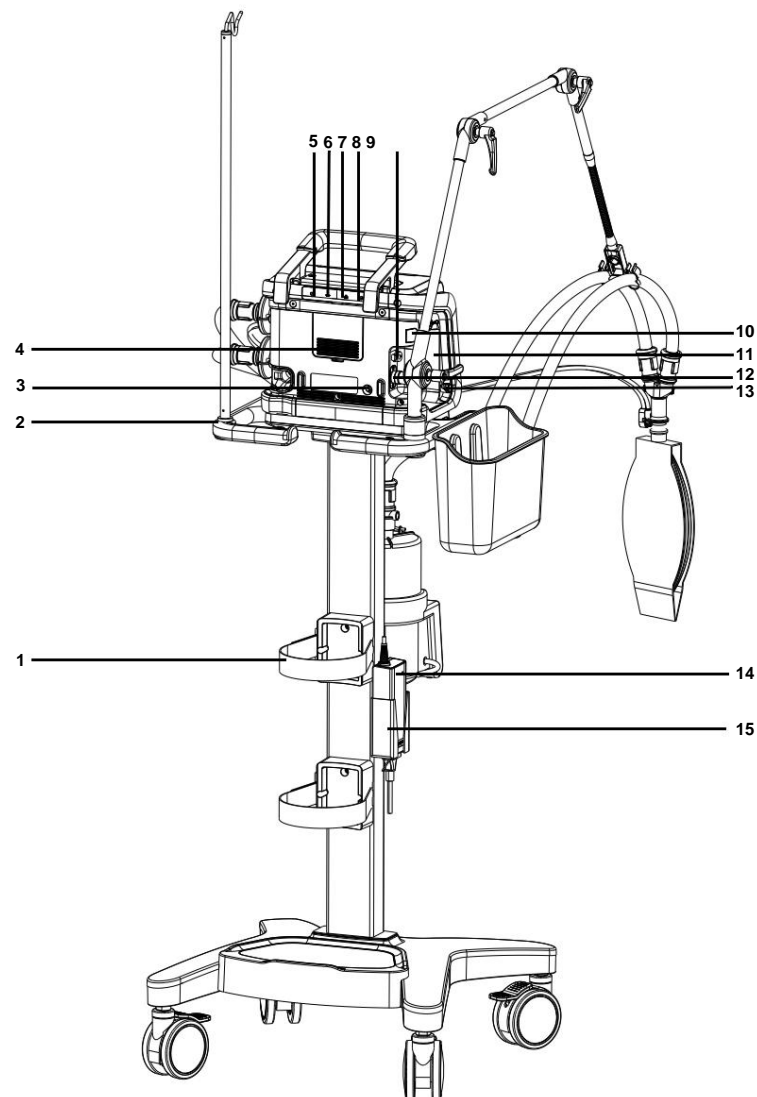


Figure 2-2 Rear view

COMPONENT NO.		DESCRIPTION
1	Cylinder fixing clamp	It is used to secure the gas cylinder.
2	Rear handle of the cart	/
3	Equipotentiality terminal/regulator	Eliminates the ground potential difference between different equipment to ensure safety.
4	HEPA filter inlet	/

Table 2-2 List of components

COMPONENT NO.	DESCRIPTION
5 VGA connector	D-sub connector; complies with RS343 electrical standards. It outputs video signals with the same content to a TV, projector, or display device.
6 USB connector	Type A connector, compliant with USB 2.0 standard. It can update the ventilator software; export the captured screen, configuration information, and historical data (such as patient data, alarm logs, and calibration tables); transfer configuration data between machines of the same type; provide power to the electronic nebulizer; and connect to a mouse or USB drive. The intended data flow is between the ventilator and the USB drive. The connector must be used by designated service personnel.
7 Network connector	RJ45 connector, compatible with 10M/100M wired networks, and compliant with IEEE 802.3. It can be connected to a PC to perform software updates and synchronize the time with an external device via the SNTP protocol. It complies with Mindray's internal protocol, the HL7 protocol, and the SNTP protocol. The intended data flow is between the PC and the ventilator. The connector must be used by designated service personnel.
8 RS-232 connector	DB9 connector with TTL serial port. It can be connected to external medical equipment to enable communication between the ventilator and the external equipment; connect to calibration devices (such as VT Plus or PF300) or a monitor and synchronize the time with the monitor. It complies with the serial protocol and Mindray's internal protocol. The intended data flow is from the ventilator to the monitor or calibration device. The connector must be used by designated service personnel.
9 Supply inlet Low pressure O2	It connects to the low-pressure O2 supply.
10 DC power connector	/

Table 2-2 List of components

COMPONENT NO.	DESCRIPTION
11	Slot for module Insert and identify the CO2 module , SpO2 module , and BeneVision N1b patient monitor mentioned in this manual.
12	Supply inlet High pressure O2 It connects to the high-pressure O2 supply.
13	Patient monitor switch buckle / BeneVision N1
14	AC Adapter /
15	AC adapter holder /

Table 2-2 List of components

a. In addition to the wired network, the ventilator is also configured with a wireless network. Wireless network-

Brica and cellular mobile network: **Cellular mobile network:**

It can connect to and communicate with the central surveillance system.

Compatible 4G operating frequencies: LTE FDD: B1/B3/B7/B8/B20/B28A, LTE TDD: B38/B40/B41, WCDMA: B1/B8, and GSM: B3/B8.

Compatible 5G operating frequency: 5G NR: n1/n2/n3/n5/n7/n8/n12/n20/n28/n38/n40/n41/n48/n66/n71/n77/n78/n79, LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B9/B12/B13/B14/B17/B18/B19/B20/B25/B26/B28/B29/B30/B32/B66/B71, LTE-TDD: B34/B38/39/B40/B41/B42/B48.

It complies with Mindray's internal protocol.

The intended information flow is from the ventilator to the central monitoring system.

The cellular mobile network must be used by the specified service personnel.

Wireless network:

It can connect to the external medical and information device; it complies with the IEEE 802.11 a/b/g/n/ac technical standard and synchronizes the time with the external device using the SNTP protocol.

It complies with Mindray's internal protocol, the HL7 protocol, and the SNTP protocol.

The intended information flow occurs between the ventilator and the external information device.

The wireless network should be used by the specified service personnel.

b. It is also called N1. See the BeneVision N1 operator's manual for more information. information.

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3.0

Installation and connections

Main unit installation	3-2
Power supply connection.....	3-3
Module Installation	3-4
Gas Supply Connection	3-5 Support
Arm Installation	3-7 IV Pole
Installation.....	3-8 Pump Bracket
Installation.....	3-9 Patient Tube
Installation.....	3-10
Humidifier Installation	3-11
Electronic nebulizer installation.....	3-14
Installation of the backup gas cylinder	3-17
Base Installation.....	3-18
Attachment to the rail system	3-19

WARNING: Do not use masks or conducting patient tubes or antistatic products should be worn when using high-frequency surgical equipment, as burns may occur.

WARNING: To ensure optimal respirator performance, Whenever accessories or components such as patient tubing, humidifier, or filter are replaced, the system must be rechecked.

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

3.1 Main unit installation

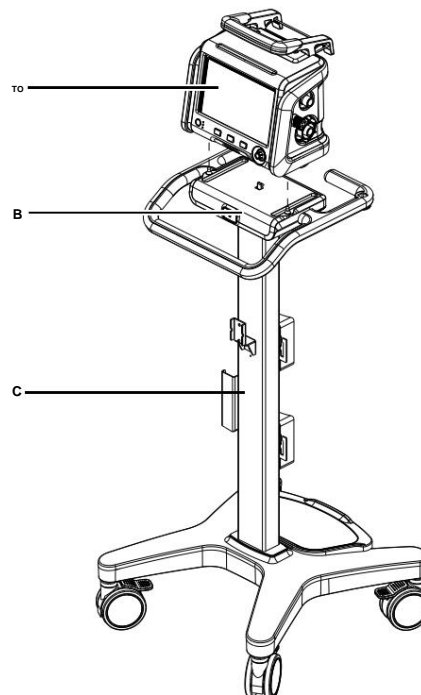


Figure 3-1 Main unit installation

- A.** Main unit
- B.** Car unlock key
- C.** Carro

Installation steps:

Securely place the main unit in the cart, aligning it with the two positioning pins.

To remove the main unit from the cart, first press the cart unlock key, and then lift the main unit with one hand.

WARNING: When the cart is used during transport, the respirator is powered by the internal battery.

3.2 Power supply connection

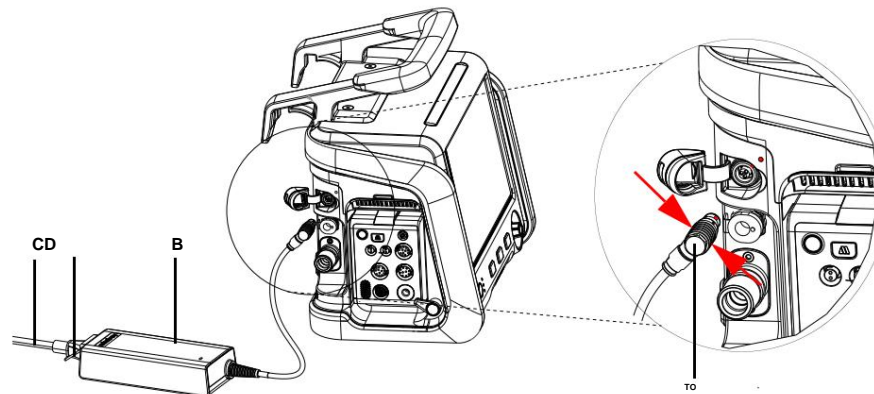


Figure 3-2 Power supply connection

- A. DC power input connector
- B. AC Adapter
- C. Adapter AC power cord
- D. Power supply anti-disconnection hook

1. Align the red dot on the DC power input connector with the red dot next to the power interface on the main unit. When you hear a "click," the connector is installed in place.
2. Plug one end of the AC power cord into the AC adapter, Secure the power cord with an anti-disconnect hook and plug the other end into the AC power outlet.

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

WARNING: Do not use the AC adapter outdoors.

NOTE: When the BeneVision N1 patient monitor (hereafter referred to as N1) is connected to the ventilator, the ventilator can charge N1 when it is powered on, but it cannot charge N1 when the ventilator is powered off. In this case, you can remove N1 from the ventilator and use the AC adapter supplied with N1 to charge it.

3.3 Module installation

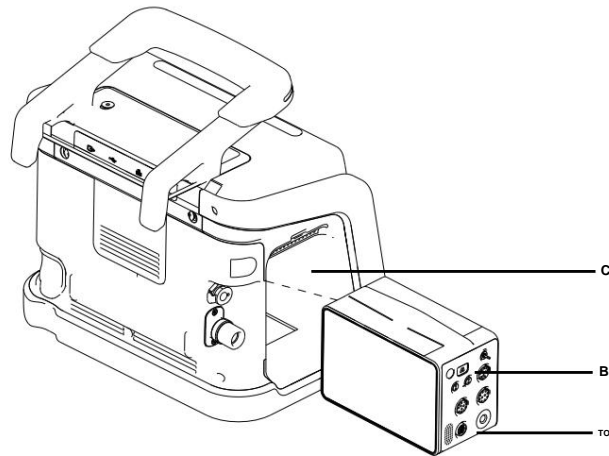


Figure 3-3 Module Installation

- A. Secure the bottom of the module
- B. Module
- C. Module slot

This device allows for module replacement without interrupting operation. In other words, you can connect or disconnect a module without turning off the ventilator.

- **Connecting the module:** Align the module with the corresponding slot and insert it until the lock located at the bottom of the module clicks into place. After connecting the module, check if the module's indicator light is on or off. If it is not on, reinsert the module.
- **Module disconnection:** After lifting the lock, pull the module out and Remove it.

NOTE: For more information about the BeneVision N1 patient monitor, please refer to the N1 operator's manual.

3.4 Gas supply connection

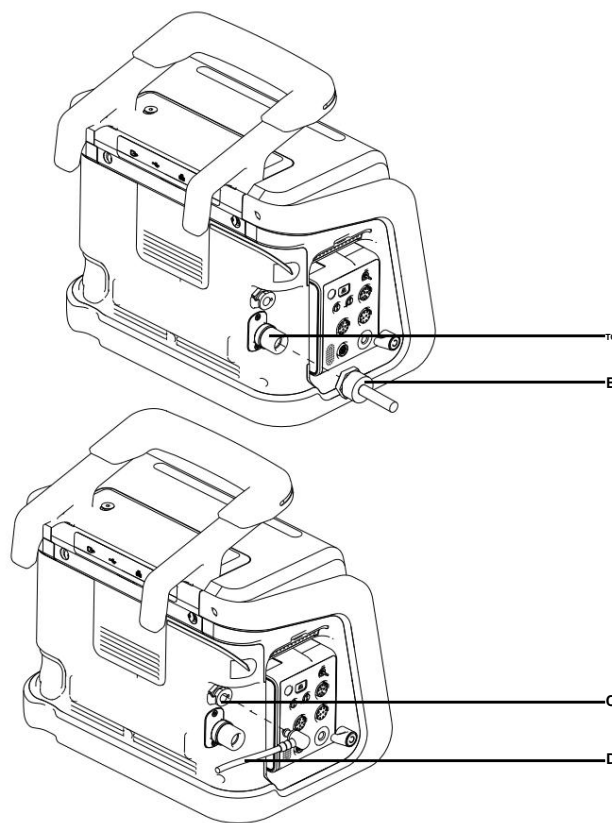


Figure 3-4 Gas supply connection

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

This respirator provides two types of gas supply connections: high pressure O₂ and low pressure O₂.

When the respirator is connected to the high-pressure O₂ supply, the gas supply pressure is 280 to 650 kPa under normal operating conditions.

A gas supply pressure below 280 kPa will affect the ventilator's performance and may even stop ventilation. A gas supply pressure between 600 and 1000 kPa will affect the ventilator's performance but will not pose any danger due to the high-pressure gas. Connect the high-pressure O₂ supply as follows.

1. Before connecting the gas supply hose, check that the sealing ring on the gas supply connection is in good condition. If the sealing ring is damaged, do not use the hose. Replace the sealing ring to prevent leaks.

2. Align the connector with the high-pressure O₂ supply inlet located on the respirator and insert it.
3. Make sure the gas supply hose is connected correctly at the gas supply inlet and tighten the pipe nut with the hand.

When the respirator is connected to a low-pressure oxygen supply, the flow rate of the low-pressure oxygen supply must not exceed 15 L/min. To reduce the risk of fire, do not use a low-pressure oxygen supply that provides a flow rate greater than 15 L/min.

To connect the low-pressure O₂ supply, align the low-pressure O₂ supply hose with the low-pressure O₂ supply connector and insert it. A click will indicate that the gas supply hose is inserted in position.

Press the metal dome of the low-pressure O₂ supply connector to remove the gas supply hose.

WARNING: Examine the O₂ supply connector carefully and ensure it is not leaking. If there is a significant gas leak, the ambient air O₂ concentration will exceed the normal O₂ concentration, resulting in a potentially dangerous oxygen-enriched environment.

WARNING: Position the O₂ supply hose carefully and avoid exposing it to an environment where it may be easily damaged by cuts or heat.

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

WARNING: To prevent oxygen buildup in and around the respirator, ensure that the low-pressure O₂ supply is disconnected when the respirator is not in use.

CAUTION: When the respirator is powered by a humidifier. When using an oxygen concentrator, never use it with a humidifier. Before using the respirator, you must drain or remove the humidifier system supplied with the concentrator.

CAUTION: Adjusting the oxygen concentration is not valid when using the low-pressure O₂ supply. To avoid potential patient injury, use the low-pressure O₂ supply only when it can provide sufficient oxygen.

CAUTION: Before starting ventilation, make sure that the appropriate oxygen source, either high-pressure oxygen (HPO) or low-pressure oxygen (LPO), has been selected during setup; see 5.3.10 Setting the O₂ supply type.

CAUTION: To avoid possible injury to the patient, make sure that it has an emergency O₂ supply (e.g., a gas cylinder) in case the low-pressure O₂ supply fails.

CAUTION: The low pressure O₂ supply hose assembly must meet the requirements of ISO 5359.

3.5 Installation of the support arm

WARNING: To prevent possible injury to the patient due to accidental extubation, check the joints of the support arm and secure them if necessary.

NOTE: The maximum load that the support arm can support is 1 kg.

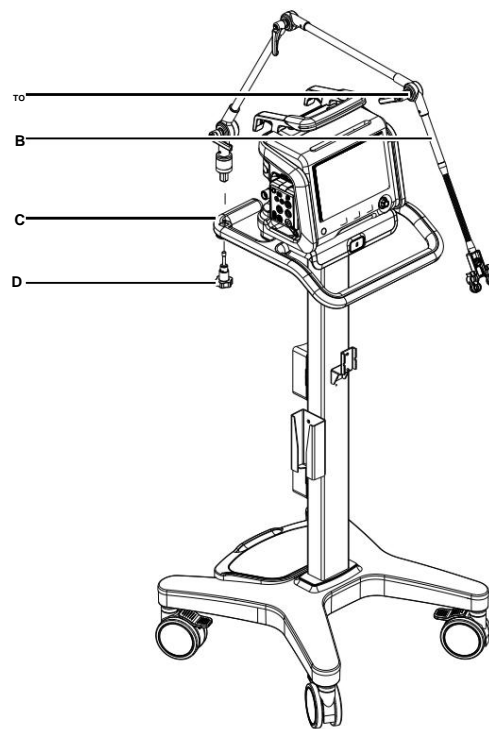


Figure 3-5 Installation of the support arm

- A. Support arm joint
- B. Support bar
- C. Installation hole
- D. Lock nut

1. Align the support arm with the installation hole and tighten the nut blockade.
2. Adjust the support arm.
 - a. Loosen the crank on the support arm joint.
 - b. Adjust the support bar to the desired position and tighten the handle at the joint.
3. Place the patient tubes in the tube hook.

3.6 Insertion of the intravenous pole

NOTE: The maximum load of the intravenous pole is 1 kg.

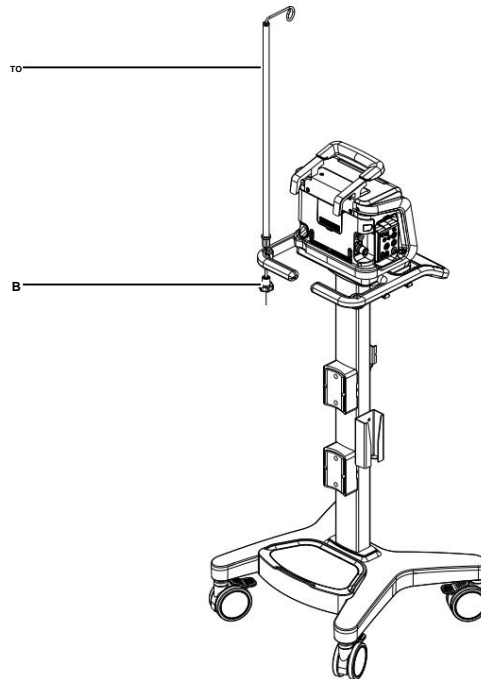


Figure 3-6 Installation of the intravenous pole

- A. Intravenous post
- B. Lock nut

Align the IV pole with the installation hole and tighten the locking nut.

3.7 Pump bracket installation

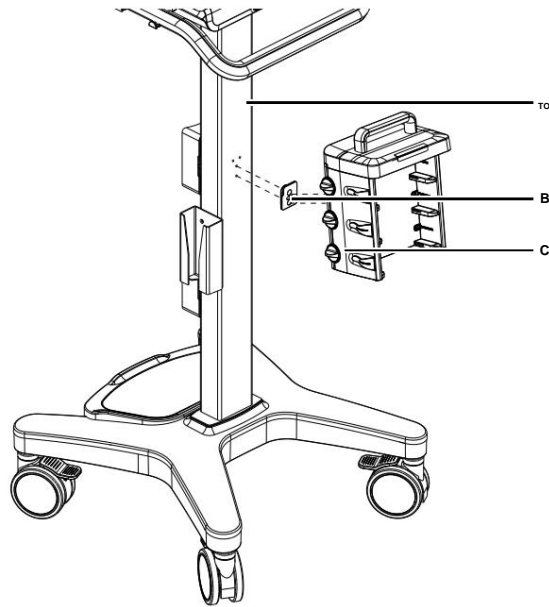


Figure 3-7 Pump Support Installation

- A. Carro
- B. Pump support
- C. Infusion pump or syringe pump

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

Note: This ventilator does not support simultaneous installation of an infusion pump/syringe and humidifier.

3.8 Patient tube placement

WARNING: To reduce the risk of bacterial contamination or damage
Physically, carefully remove and install the bacteria filter.

WARNING: To avoid contamination of the respirator or the patient,
Always use a bacterial filter between the respirator and the patient's inspiratory end.

WARNING: To prevent condensation, keep the flow meter tube pointing upwards when installing and using it.

CAUTION: The use of an expiratory filter may lead to a significant increase in expiratory resistance. Excessive expiratory resistance can impair ventilation and increase the patient's work of breathing and intrinsic PEEP.

CAUTION: Patient tubes must meet the requirements of the ISO 5367 standard.

CAUTION: Bacterial filters must meet the requirements of the ISO 23328-1 and ISO 23328-2 standards.

CAUTION: The heat and moisture exchanger (HME) must comply with the requirements of ISO 9360-1 and ISO 9360-2.

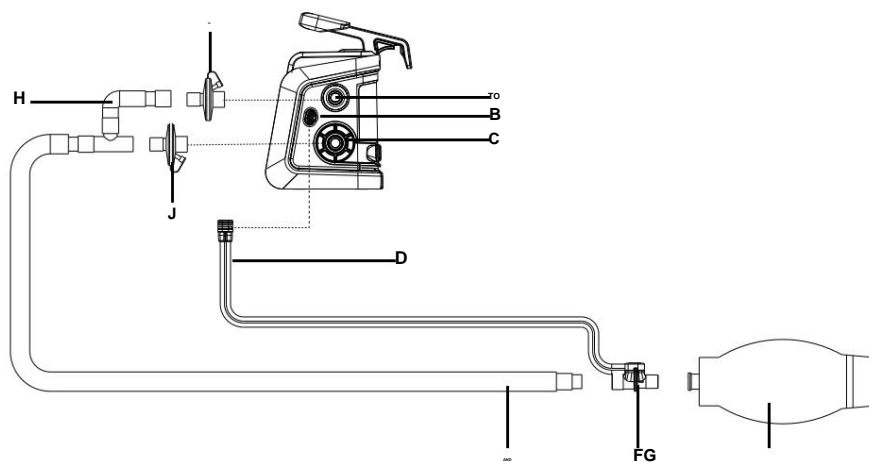


Figure 3-8 Patient Coaxial Tube Installation

- | | |
|--|--|
| A. Inspiratory port | B. Flow sensor port |
| C. Expiratory port | D. Flow sensor sampling line |
| E. Patient tubes | F. Flow sensor |
| G. Test lung | H. Coaxial connector of patient tube I |
| I. Inspiratory port bacteria filter | J. Filter for bacteria in the expiratory port |

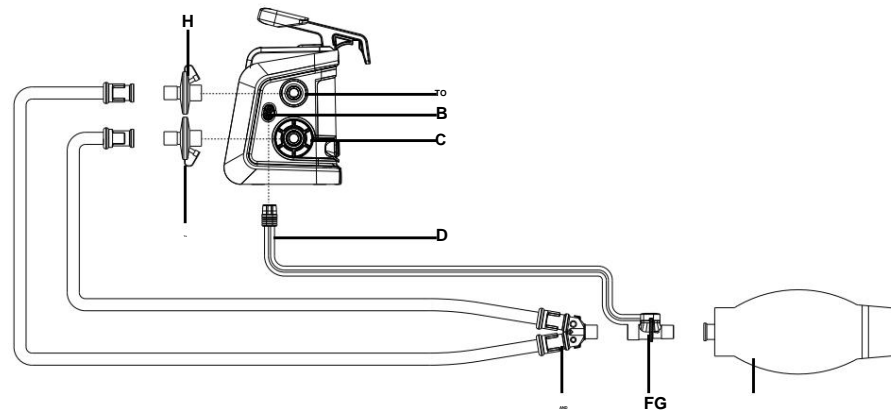


Figure 3-9 Installation of the dual-ended patient tube

- | | |
|-----------------------------|-------------------------------------|
| A. Inspiratory port | B. Flow sensor port |
| C. Expiratory port | D. Flow sensor sampling line |
| E. Patient tubes | F. Flow sensor |
| G. Test lung | H. Inspiratory filter |
| H. Expiratory filter | |

1. Mount the bacteria filters on the inspiratory and expiratory ports.
2. Connect one end of the patient tube to the bacteria filter and the other to the sensor of flow.
3. Connect the flow sensor sampling line to the flow sensor port of the respirator.
4. Connect the other end of the flow sensor to the test lung.

3.9 Humidifier installation

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

WARNING: To avoid possible injury to the patient and damage to the equipment, **Make sure the humidifier is set to the correct temperature and humidity.**

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

3.9.1 Installing the humidifier on the respirator

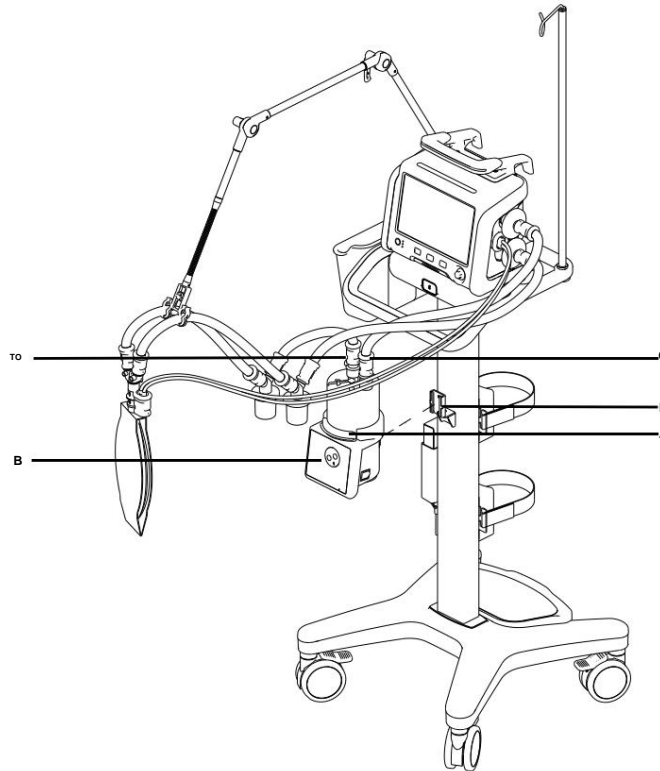


Figure 3-10 Humidifier Installation on the Respirator

- A. Humidifier outlet
- B. Humidifier
- C. Humidifier inlet
- D. Humidifier support slot
- E. Humidifier mounting plate

1. Align the humidifier mounting plate with the slot in the humidifier bracket and slide the humidifier in. Tighten the screws.
2. Mount the filters on the inspiratory and expiratory ports.
3. Connect the inspiratory filter to the humidifier inlet using the tubing.
4. Connect the humidifier outlet to the water collector using the tubing. Then, connect the water collector to the Y-piece using the tubing.
5. Connect the breather filter to the water collector using the tubing. Then, connect the water collector to the Y-piece using the tubing.
6. Place the patient tubes on the hook of the support arm.

Ventilator breathing system (VBS) frequency range:

Inspiratory and expiratory gas passage resistance: 0 to 6 cmH₂O/ (l/s) with a flow rate of 60 l/min. BSV compliance: 0 to 5 ml/cmH₂O.

3.9.2 Installing the humidifier on the hanging bracket

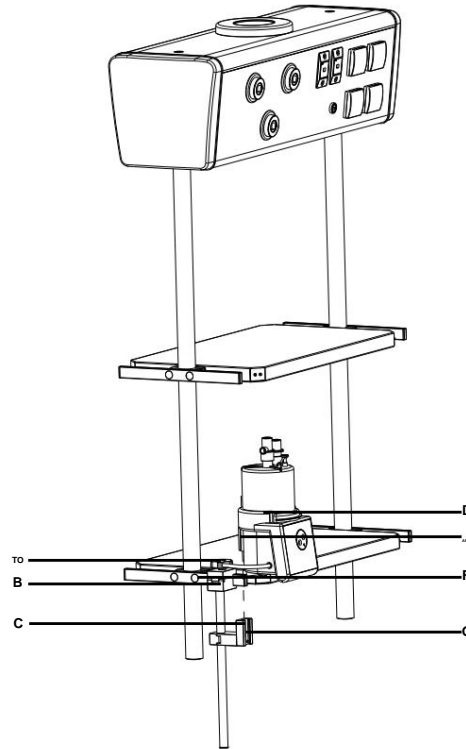


Figure 3-11 Installation of the humidifier on the hanging bracket

- A. Assembly block control
- B. Mounting block
- C. Screw
- D. Humidifier
- E. Humidifier mounting plate
- F. Vigueta
- G. Humidifier support slot

1. Release the mounting block handle. Place the mounting block onto the hanging support beam.
2. Tighten the mounting block knob.
3. Align the humidifier mounting plate with the slot in the bracket humidifier, and slide the humidifier inwards.
4. Tighten screw C.
5. Patient Tube Installation. For further details, see section **3.8 Patient Tube Installation**.

WARNING: Before installing the humidifier, make sure the humidifier connector is positioned lower than the breathing connectors on the ventilator and the patient.

3.10 Electronic nebulizer installation

NOTE: Install the specified nebulizer. The nebulizer assembly and installation steps described in this section are for reference only. Refer to the operating instructions included with the nebulizer for proper installation and use.

NOTE: To prevent the expiration valve from clogging due to nebulized medications, use only medications approved for nebulization and regularly check and clean the expiration valve diaphragm or replace it. For disposable expiration valves, inspect them frequently and replace them as needed.

NOTE: Do not use a heat and moisture exchange (HME) in the patient tubing during nebulization.

NOTE: Nebulizing medication can increase the resistance of the exhalation filter or clog it. Check the filter frequently and replace it if the exhalation resistance increases.

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

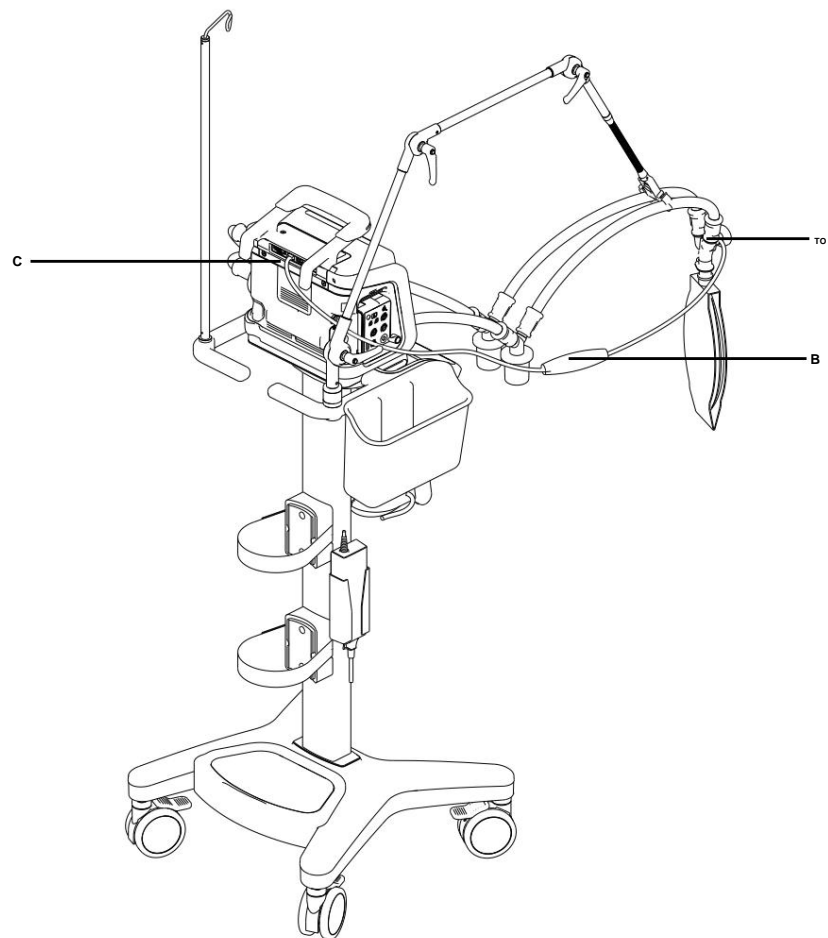


Figure 3-12 Electronic nebulizer installation

- A. Nebulizer
- B. USB Controller
- C. USB connector

1. Insert the USB connector of the USB controller into the USB connector located under the screen.
2. Connect the nebulizer to the patient tubing. Refer to the operator's manual for the nebulizer for detailed information.

During nebulization, the patient inhales the aerosolized medication for treatment purposes.

WARNING: Keep the electronic nebulizer upright while connecting it to the patient tubing.
This position prevents patient secretions and condensation from contaminating the nebulizer's aerosol generator and ensures proper nebulization.

WARNING: Refer to the instructions for use included with the nebulizer for instructions on how to install and use the nebulizer.

WARNING: Remove the direct-flow CO2 module adapter from the patient tubing before initiating nebulization. CO2 cannot be measured in an environment with aerosolized medication.

WARNING: Remove the neonatal flow sensors from the patient tubing before initiating nebulization. Neonatal flow cannot be controlled in an aerosol environment.

**WARNING: Do not use nebulized medications while using this device.
Neonatal flow sensor. Accumulated drug may damage the neonatal flow sensor.**

**WARNING: The aerosol medication may clog the exhalation valve and flow sensor.
Check and clean these components after nebulization.**

WARNING: When using the electronic nebulizer, pay attention to the nebulizer connection to avoid interrupting nebulization.

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

**CAUTION: Remove the nebulizer after nebulization is complete.
Otherwise, ventilation may be affected.**

CAUTION: Remaining nebulized medication affects the surrounding air.

3.11 Installation of the backup gas cylinder

CAUTION: Make sure the emergency gas cylinder is equipped with a pressure relief valve.

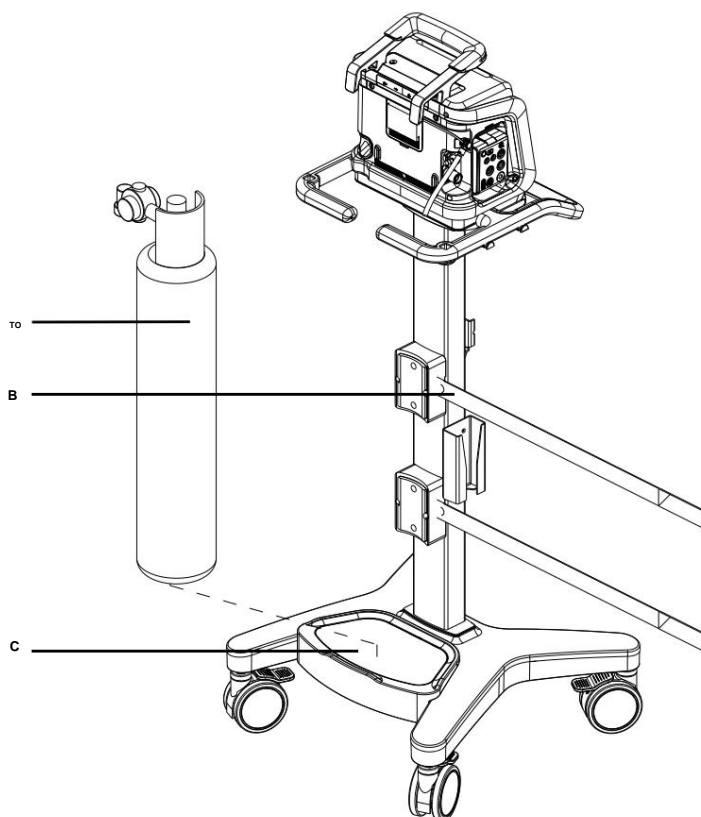


Figure 3-13 Installation of the reserve gas cylinder

- A. Emergency gas cylinder
- B. Cylinder clamping piece
- C. Base of the cart

1. Place the emergency gas cylinder at the base of the cart.
2. Secure the gas cylinder using the cylinder clamping piece.

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

3.12 Base Installation

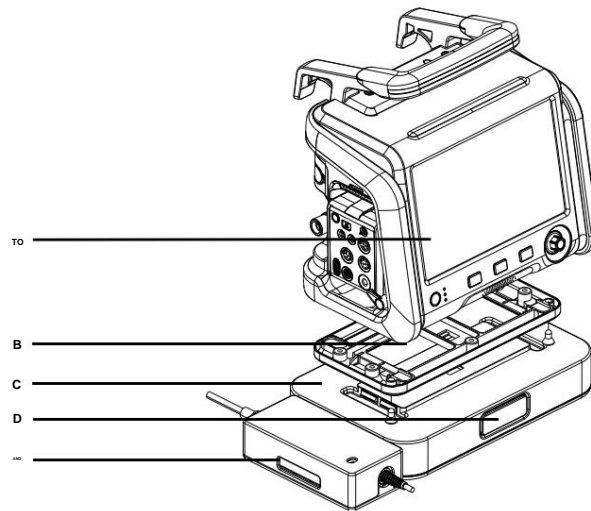


Figure 3-14 Base Installation

- A. Main unit
- B. Converter
- C. Base
- D. Unlock button
- E. AC Adapter

1. Secure the main unit and converter with screws.
2. Align the main unit with the slot on the base and place it on the base.
3. Connect the AC adapter.

To remove the main unit from the base, press the base's unlock button with one hand and lift the main unit with the other simultaneously.

When the respirator is subjected to bumps or jolts (such as in an ambulance), secure it with a base to prevent excessive movement or accidental dropping of the equipment during transport.

3.13 Attachment to the rail system

This device can be attached to rail systems or stretcher bars with diameters no greater than 38 mm using a rail bracket. During installation, ensure a minimum distance of 120 mm between the rail and the wall. Position the device appropriately for the patient.

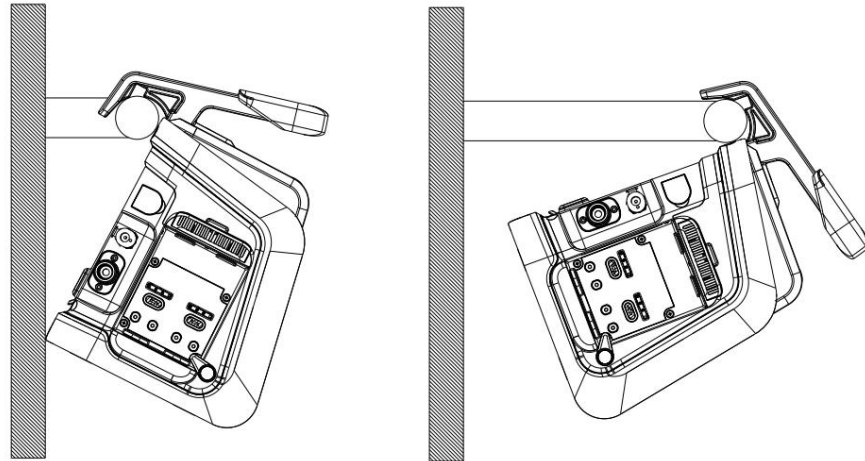


Figure 3-15 Attachment to the rail system

WARNING: When transporting the respirator with the rail support, respect the distance requirements to the wall and use other methods (such as the base or fixing bracket) to secure or protect the device and prevent it from being accidentally loosened and falling.

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4.0

User interface

Monitor controls	4-2
Waveform display.....	4-5
Large Number Display.....	4-7
Display of measured values	4-7
Spirometry screen.....	4-8
History.....	4-9
Freezing	4-13
Screenshot.....	4-14
Screen lock	4-14

4.1 Monitor controls

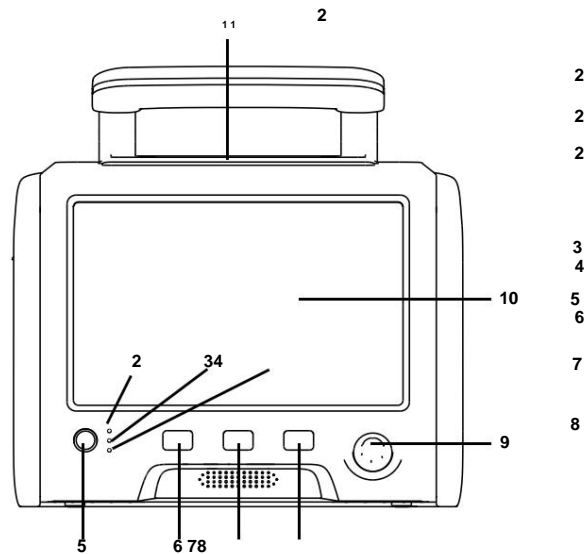


Figure 4-1 Monitor controls

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

1. Alarm Indicator The alarm

indicator shows different alarm levels with different colors and flashing frequencies when an alarm is triggered.

2. External power indicator

- Power On: when the respirator is connected to a power supply external.
- Off: when the respirator is not connected to any external power supply.

3. Ambient light sensor


When the screen brightness is set to automatic, the system automatically adjusts the screen brightness based on the intensity of the ambient light.

4. Battery indicator

- On: indicates that the battery is charging or is fully charged and that the respirator is working with the external power supply.
- Intermittent: indicates that the ventilator's power supply is coming from the battery.
- Off: indicates that the ventilator is not connected to a power supply external power supply, which does not have a battery installed or the battery is faulty.

5. Power switch (with indicator)

You can press the key to turn the system on or off. The indicator light comes on when the ventilator is turned on and turns off when it is turned off.

6. Outdoor Mode/Battery Level Indication: When the ventilator is on, this button displays the icon to enter/exit outdoor mode. When the ventilator is off, this button displays the remaining battery level icon.  Press this



7. Screen lock button

Press the screen lock button to lock or unlock the screen.

8. AUDIO PAUSED key

Press this button to initiate AUDIO PAUSE for 120 seconds; this will silence any active alarm tones.

The system automatically exits AUDIO PAUSE after 120 seconds and resumes alarm tones.

If a new alarm is triggered while AUDIO PAUSE is active, the system automatically exits AUDIO PAUSE and the new alarm tone sounds. You can press the button again while AUDIO PAUSE is active to cancel the AUDIO PAUSE mode.

9. Control unit

Press the control knob to select a menu item or confirm a setting. Turn the control knob right or left to scroll through menu items or change settings.

10. Monitor (touchscreen)

The monitor displays the ventilator system's software interface. You can select options and change settings by touching the screen.

The ventilator screen displays ventilation parameters and pressure/flow/volume waveforms, etc. A general overview of the main screen is shown below.

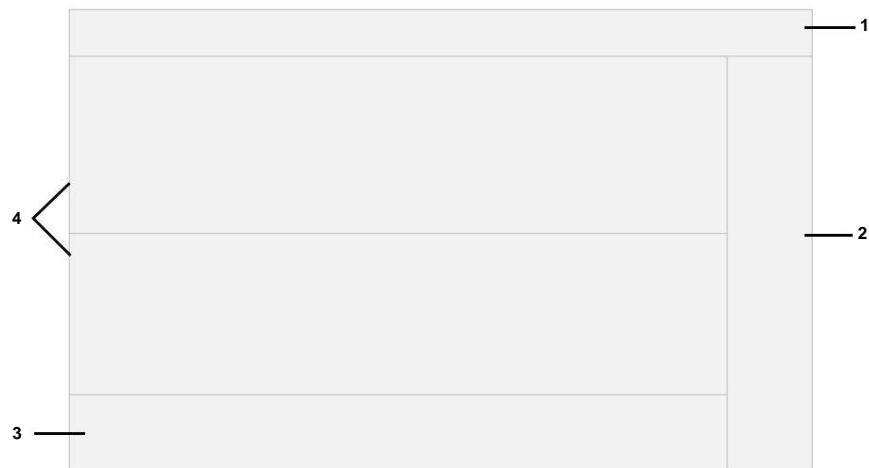


Figure 4-2 Main Screen

No.	SCREEN MAJOR	DESCRIPTION
1	Icon field	<p>It displays the following information:</p> <ul style="list-style-type: none"> • Ventilation mode icon: Shows the ventilation mode Current ventilation. Adjustment of the ventilation mode is allowed. • Ventilation type icon: displays the icon  when the ventilation type is non-invasive; shows the icon when the ventilation type is invasive. • Patient type icon. • Alarm message icon: Includes physiological alarms, technical alarms and warning messages, as well as the number of current alarms and warning messages. Select the field to display the list of all active alarms. • When the physical key AUDIO PAUSED is selected, and the 120-second paused audio icon appears.  countdown begins • Network status icon: displays the icon  when The [Network Type] is [WLAN] or [BED_ACTIVE_ZONE]; it displays the icon  when the [Network Type] is [LAN]; when the  displays the icon [Network Type] is [5G]. • USB status icon: The icon  It lights up when the The system is connected to an identifiable USB device. By selecting this icon, you can export the screen data and transfer the settings of the open interface. • Bluetooth icon. • System clock icon. • Power status icon. In the service menu, when the [Display remaining battery time] switch is on, the system displays the battery runtime; when it is off, the system displays the percentage of battery power remaining. <p>NOTE: The remaining battery time is an estimate and may be affected by many factors. It is for physician reference only.</p> <ul style="list-style-type: none"> • Oxygen consumption control icon: Displays the oxygen consumption rate (L/min) or the remaining oxygen supply time from the gas cylinder. In the service menu, when the [Display Remaining Oxygen Bottle Time] switch is on, the system displays the remaining oxygen supply time; when it is off, the system displays the oxygen consumption rate.

Table 4-1 Main Screen

2	Programmable key field	Displays system check, patient information, alarm settings, NIBP start/stop, alarm reset, freeze, screenshot, O2 suction, manual, menu, and programmable standby keys.
3	Ventilation mode field and parameter settings	Displays the keys to configure ventilation modes and parameters.
4	Waveform display field/ spirometry/ values/ large numbers	The top section displays waveforms and large numbers related to the BeneVision N1 patient monitor. The bottom section displays waveforms related to the ventilator, spirometry, monitored values, or large numbers.

Table 4-1 Main Screen

4.2 Waveform display

Once ventilation is started, the ventilator defaults to the waveform display, as shown in the following figure.

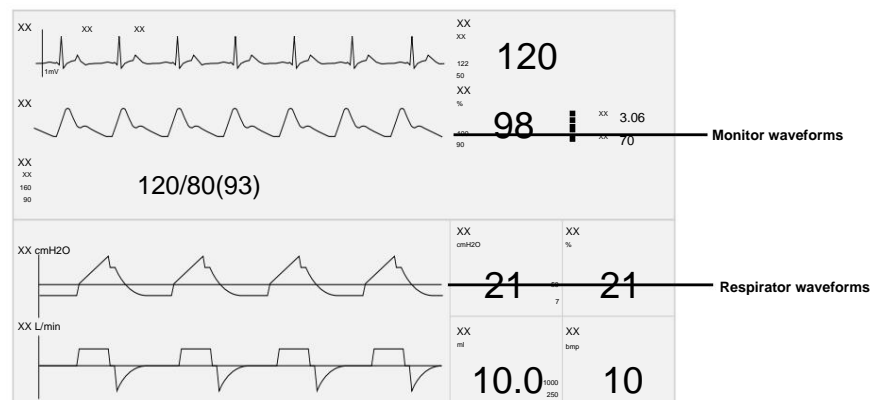


Figure 4-3 Waveform display (with N1)

When the ventilator is not equipped with the BeneVision N1 patient monitor, the waveform display is shown as follows.

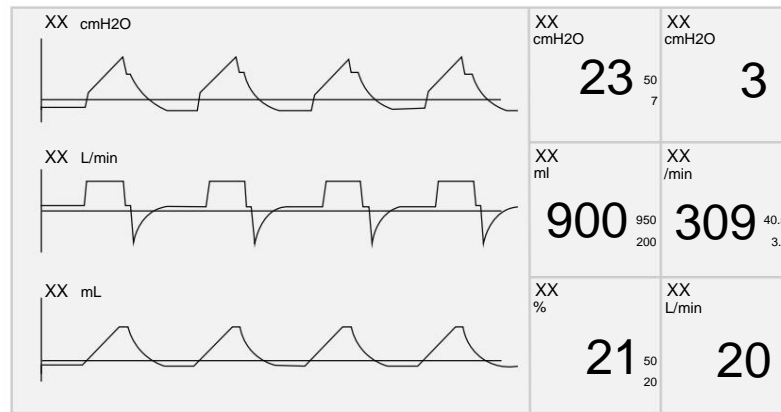


Figure 4-4 Waveform display (without N1)

4.2.1 PulmoSight Status

The brightness and darkness of the lung icon represents the inspiratory and expiratory process. During inhalation, the lungs appear bright. During exhalation, they are dark.

STATE OF PULMOSIGHT	PULMOSIGHT STATUS DESCRIPTION	
	Normal distensibility.	High resistance. Thickened airway borders.
	High distensibility. The outline of the alveoli is thinner.	Low distensibility. The outline of the alveoli is thicker.
	Lots of volume.	Low volume.

Table 4-2 PulmoSight Status

4.2.2

Adjust PulmoSight , and then

Select the key from  adjust **[Ref. distension]** and **[Ref. resistance]**.

the menu. There are three ways to adjust the parameters:

- Select the parameter adjustment areas and modify them directly.
- Select the **[Restore Default Values]** key and the system will automatically load the default values corresponding to the current patient type.
- Select the **[Current Use]** key and use the monitored values from distensibility and resistance shown on the screen.

4.3

Large number display

Select **[Menu]** $\dot{\bar{y}}$ **[Screen]** $\dot{\bar{y}}$ **[Selection Screen]**.

- Select **[Monitor]** $\dot{\bar{y}}$ **[Large Numeric Display]** to adjust the mode of monitor screen display;
- Select **[Respirator]** $\dot{\bar{y}}$ **[Large Numerical Display]** to adjust the mode of respirator screen display;

Once the setup is complete, open the screen as shown below.

In addition to selecting the menu button, you can also swipe the screen to navigate between displays. When the BeneVision N1 patient monitor is inserted into the ventilator, you can swipe the ventilator or monitor interface separately to switch between them.

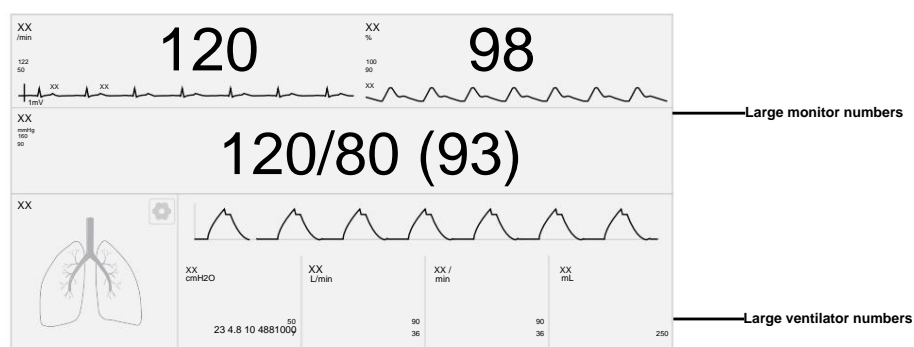


Figure 4-5 Large Number Display

4.4

Display of measured values

Select **[Menu]** $\dot{\bar{y}}$ **[Screen]** $\dot{\bar{y}}$ **[Selection Screen]** $\dot{\bar{y}}$ **[Value Screen]** to open the interface as shown below.

XX cmH2O	23	XX L/min	5.6	XX / min	798	XX cmH2O/L/s	1:1	XX mmHg	0.3
XX cmH2O	20	XX L/min	5.2	XX / min	201	XX cmH2O/L/s	1.00	XX mmHg	6.1
XX cmH2O	15	XX L/min	0.0	XX / min	7.8	XX mL/cmH2O	39	XX mmHg	0.4
XX cmH2O	3	XX L/min	0.0	XX / min	15	XX cmH2O/L/s	48	XX	11.00
XX cmH2O	3.0	XX L/min	0.0	XX / min	12	XX	5	XX	43
XX cmH2O	8.0	XX L/min	802	XX / min	3	XX	6	XX	28

Figure 4-6 Display of measured values

4.5 Spirometry screen

Select **[Menu]** $\dot{\bar{y}}$ **[Screen]** $\dot{\bar{y}}$ **[Selection Screen]** $\dot{\bar{y}}$ **[Spirometry Screen]** to access the screen shown below.

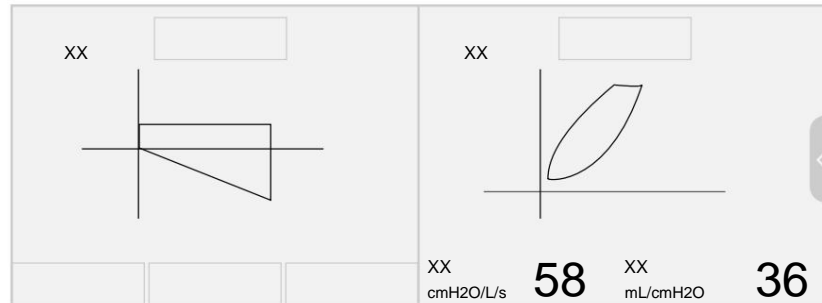


Figure 4-7 Spirometry screen

Spirometry loops reflect the patient's ventilation and lung function, as well as compliance, overdistension, leaks in the breathing system, and airway occlusions.

The system provides pulmonary function loops, including **[Pva-volume]**, **[Flow-volume]**, and **[Flow-Pva] loops**, whose data are collected from pressure, flow, and volume waveform data. When a direct flow CO₂ module is configured, a **[V-CO₂] curve can be displayed**.

Up to two types of spirometric loops can be displayed simultaneously. To select the desired loop:

1. Select **[Menu]** $\dot{\bar{y}}$ **[Screen]** $\dot{\bar{y}}$ **[Selection Screen]** $\dot{\bar{y}}$ **[Screen of]** **[spirometry]** on the main screen.
2. Adjust the desired loop or the V-CO₂ loop to be displayed.

The ventilator provides a reference loop function. Selecting **[Guard ref.]** saves the current breathing cycle loop as a reference loop and displays the time it was saved. Selecting **[Display ref.]** and a specific time displays the reference loop saved at that time.

By selecting **[Show ref.]** and then selecting **[OFF]**, you can hide the reference loop that is being displayed.

The ventilator stores up to 5 reference loops. If 5 reference loops have already been saved, the system automatically deletes the oldest reference loop and saves the current breathing cycle loop as the reference loop if **[Guard ref.] is selected again**.

Select the **[Check Ref.]** key to display the reference loop check menu.

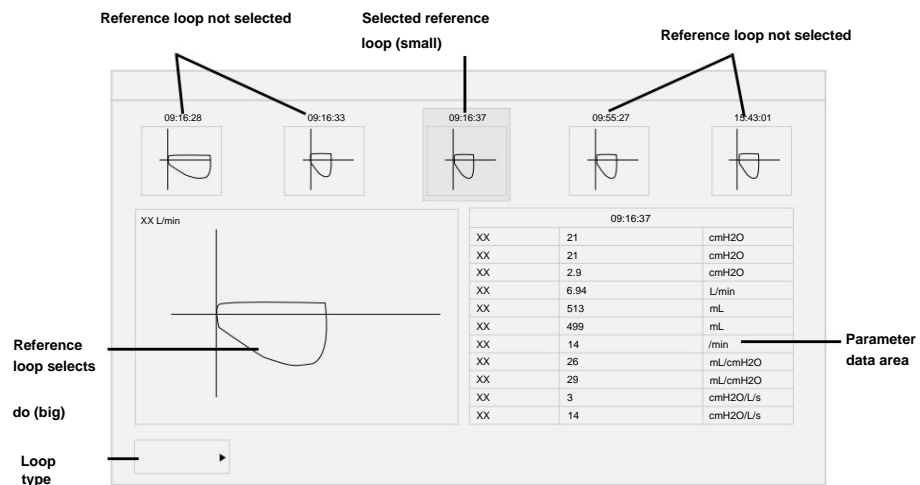


Figure 4-8 Reference Loop Review

- **Reduced loop windows:** These reduced-size graphic windows display the reference loops. The reference loops (up to 5) are shown From oldest (left) to most recent (right). Information about the selected reference loop is highlighted in blue.
- **Large loop window:** This graphics window displays an enlarged view of the selected reference loop.
- **Loop type:** When selecting loop type, you can choose the type of loop that will be used. review.
- **Parameter data area:** This area displays data of the monitored parameters related to the saved reference loops.

4.6 Record

Select the **[Menu]** **[History]** key on the screen and the following interface will appear.

The interface can display tabular, graphical, and adjustment trends, as well as the event log.

4.6.1 Graphic trends

Trend graphs record the trend of parameter values. This is represented as a curve. Each point on the curve corresponds to the value of the physiological parameter at a specific time. Trend graphs also record parameter alarm events. The trend graph data is displayed

by default at one-minute intervals, unless zoom is selected.

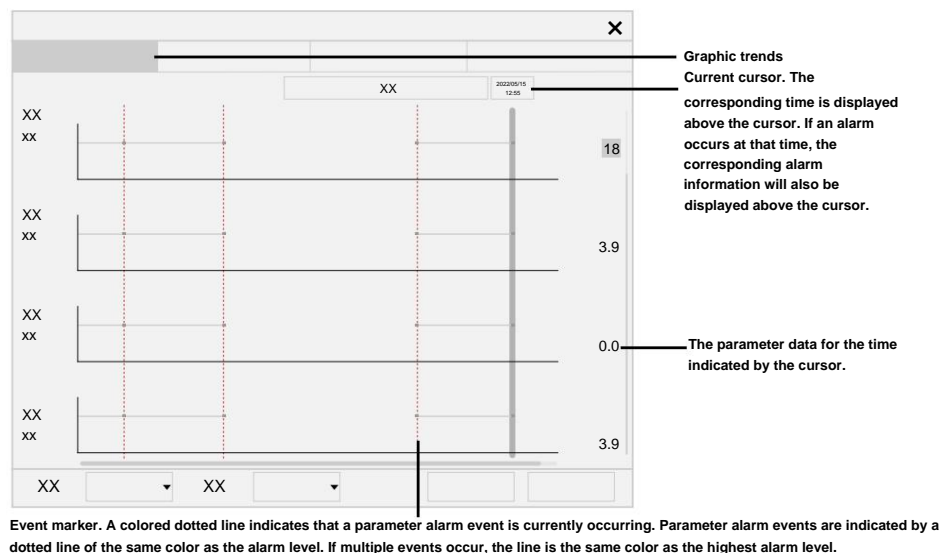


Figure 4-9 Graphic Trends

4.6.1.1 About graphic trends

- In a trend graph, the horizontal coordinates show the time and date.
- In a trend graph, the vertical coordinates show the data of the parameters.
- In a trend graph, the most recent trend data is shown on the far right.
- The system does not save graphical trend data from standby mode.
- The system can display 120 hours of continuous trend data.
- If, at the time of saving the trend record, a parameter data has an associated alarm condition, the graphical trends will highlight it in the color corresponding to the alarm.
- Select **[Previous Event]** to move the cursor to the previous event from the current position.
- Select **[Next Event]** to move the cursor to the next event from the current position.

4.6.1.2 Zoom

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

4.6.1.3 Show group

In the graphical interface, you can adjust **[Group]** to **[Pres.]**, **[Vol.]**, **[Time]**, **[Gas]**, **[SpO2]**, **[Other]** and **[All]**.

4.6.2 Tabular trends

In the tabular trends interface, you can view a patient's monitoring parameter data and events. If no resolution is configured, trends will be displayed based on data with a default interval of one minute.

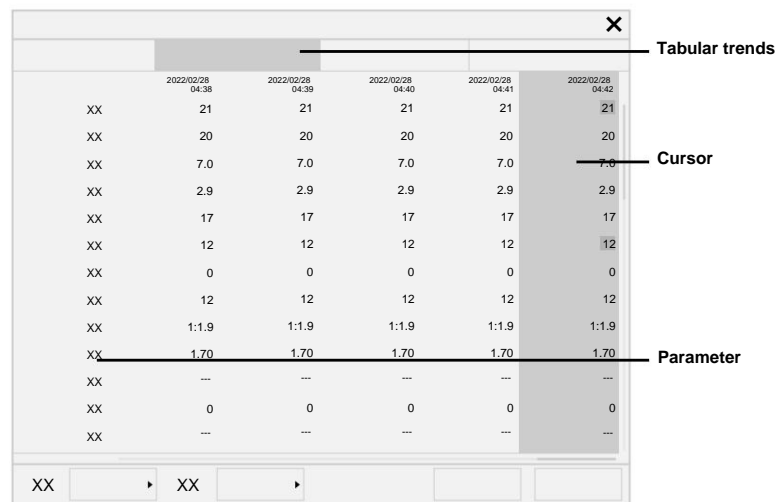


Figure 4-10 Tabular trends

4.6.2.1 About tabular trends

- Tabular trends show the date and time on the horizontal axis.
- Tabular trends show parameter data on the vertical axis.
- Tabular trends show the most recent trend data on the far right.
- Tabular trends are not saved when the computer is on standby.
- The system can display 120 hours of continuous trend data.
- Yes, when saving the trend record, the data of a parameter
If it has an associated alarm condition, the tabular trends will highlight it in the color corresponding to the alarm.
- Select **[Previous Event]** to move the cursor to the previous event from the current position.
- Select **[Next Event]** to move the cursor to the next event from the current position.

4.6.2.2 Interval

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

4.6.2.3 Show group In the table interface, you can set **[Group]** to **[Pres.]**, **[Vol.]**, **[Time]**, **[Gas]**, **[SpO2]**, **[Other]** and **[All]**.

4.6.3 Adjustment Trends The adjustment trends function is used to record ventilation mode and parameter settings.

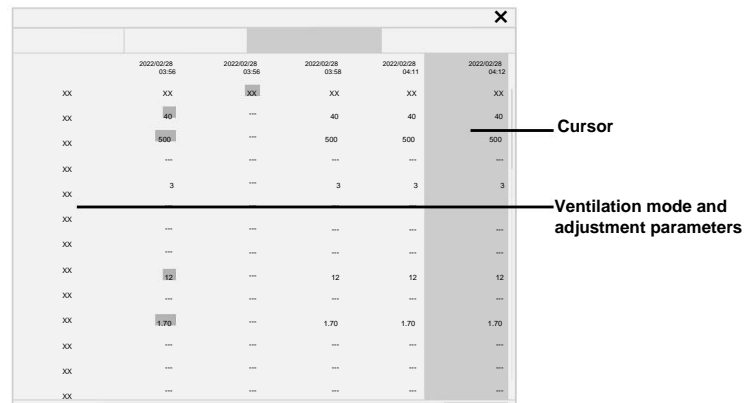


Figure 4-11 Adjustment Trends

4.6.3.1 About adjustment trends

- The adjustment trends show the date and time on the horizontal axis.
- The adjustment trends show the ventilation mode and adjustment parameter on the vertical axis.
- The adjustment trends display the most recent trend data on the far right.

4.6.4

Event Log The event log records

events such as power on/off, ventilation mode setting, ventilation parameter setting, technical alarm, physiological alarm, standby status, ventilation start, new patient, tools, default settings management, calibration, system check, PulmoSight setting, paused alarm audio, and O2 therapy event .

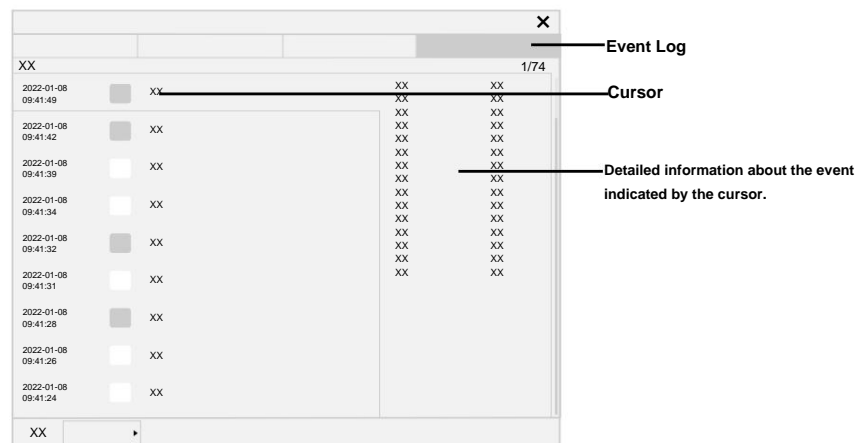


Figure 4-12 Event log

4.6.4.1 About event logging

- The event log displays the most recent entries at the top.
- The system can store up to 10,000 event log entries.

NOTE: The system can store up to 10,000 event log entries. When the number of events exceeds 10,000, the oldest event will be deleted and the most recent one saved.

4.6.4.2 Filtered

In the Event Log window, you can adjust **[Filter]** to **[High Alarms]**, **[Medium Alarms]**, **[Low Alarms]**, **[All Alarms]**, **[Function Info]** and **[All Events]**.

4.7 Freezing

The freeze function pauses the real-time updating of spirometry waveforms and loops on the screen, allowing you to closely examine the patient's condition at that specific moment. The reviewed data consists of spirometry waveforms and loops generated in the 60 seconds prior to the freeze function being activated.

4.7.1 Access to the frozen state

When the system is in a non-wait and non-freeze state, pressing the key will display the message **[Freeze On. Press Freeze to Unfreeze]** on the screen, and the system will enter freeze mode. All displayed waveforms and loops will be frozen, meaning they will not be updated. Data in the parameter area will be updated as usual. In freeze mode, the **[Guard Ref.]** key is disabled, and it is not possible to save a loop as a reference loop. However, you can view reference loops that have already been saved. In freeze mode, with the cursor selected, you can rotate the control knob clockwise or counterclockwise. reverse direction to move the cursor and view the waveform or spirometry loops.

4.7.2 Exit from frozen state


In freeze mode, press the key to exit freeze mode.


If no operation is performed on the respirator in the frozen state for more than three (3) minutes, the system will automatically exit the frozen state.


4.8 Screenshot

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

4.9 Screen lock

Press the key  on the home screen to enter locked mode, and the message **[Screen locked. Press Lock button to unlock screen.] will appear**. During the screen lock period, only the keys

 [O2ÿ Aspirac]

 and are activated. The touchscreen, control panel, and other features will be deactivated. keys. Press this key again to unlock the screen.

5.0

System settings

Export to USB.....	5-2
Data transfer.....	5-3
Basic settings.....	5-4
Display settings	5-6
System settings	5-8
Selecting shortcut keys for tools.....	5-16
Factory Service Settings



5.1 Export to USB

The ventilator's export function offers the possibility of exporting some data or settings to a USB device.

5.1.1 Screen export

Exporting the screen means exporting a saved screenshot of the respirator. The exported file is saved in "jpg" format. This respirator can save up to 50 screenshots.



To export a screenshot:

1. Insert the USB device into the respirator's USB port. The key  it is highlighted on the main screen.
2. When selecting the key , The system opens the **[Data Transfer] interface**.
3. In the open interface, first select the **[Exp screen capture]** tab and then Next, click the **[Exp Screen Capture] key**. The system performs a check to verify that there is sufficient storage space available on the USB device. If there is enough space, the system begins exporting the screen.
4. Once the export is complete, select **[Remove USB device]** to remove the USB device.

5.1.2 Data Export

Exporting data means exporting demographic data, current adjustment parameters, current alarm limits, trend data, etc. from the ventilator.

To export data:



1. Insert the USB device into the respirator's USB port. The key  it is highlighted on the main screen.
2. When selecting the key , The system opens the **[Data Transfer] interface**.
3. In the open interface, select the **[Export data]** tab and then the **[User Export] key**. The system performs a check to verify that sufficient storage space is available on the USB device. If there is sufficient space, the system will export the data, including patient information, current parameter settings, current alarm limits, history data, etc. The exported data format is "html".
4. If you need to export calibration data, the event log, and the self-test log in addition to the data mentioned above, select the **[Export to Factory]** tab and enter the password. The system will check that sufficient storage space is available on the USB device. If enough space is available, the system will begin exporting the data. The exported data is encrypted in the "blg" format.
5. Once the export is complete, select **[Remove USB device]** to remove the USB device.

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



5.1.3 Transfer of settings

You can export or import settings when the ventilator is in standby mode.

To export the settings:

1. Ensure the equipment is in standby mode.
2. Insert the USB device into the respirator's USB port. The key will be highlighted on the main screen. .
3. When selecting the key , The system opens the **[Data Transfer] interface**.
4. Select **[Transf a just predet]** ÿ Enter system password ÿ **[Export default settings]** in the open interface. The system performs a check to verify that there is sufficient storage space available on the USB device. If there is enough space, the system saves the current and default settings of the computer to the USB device.
5. Once the export is complete, select **[Remove USB device]** to remove the USB device.

To import the settings:

1. Ensure the equipment is in standby mode.
2. Insert the USB device into the respirator's USB port. The key is highlighted on the main screen .
3. When selecting the key , The system opens the USB configuration interface.
4. Select **[Transf a just predet]** ÿ Enter system password ÿ **[Import preset]** in the open interface. The system loads the respirator settings saved on the USB device.
5. Once the export is complete, select **[Remove USB device]** to remove the USB device.

5.2 Data transfer

The ventilator can transfer data in the following ways.

• Transfers data via wireless or wired network:

1. Select the **[Bed Number Settings]** interface of the bedside ventilator and this ventilator, enter the same department, room number and bed number to pair the bedside ventilator with this ventilator.
2. Select **[OK]**, and the message **[Do you want to synchronize the parameters of] [Ventilation of the bedside ventilator?]** will appear.
3. Select **[Detail]** to view the details of the respirator parameters of head.
4. Select **[Ok]** to synchronize patient information and bedside ventilator ventilation parameters with this ventilator.

• Transfer data through the BeneVision N1 patient monitor:

1. Insert the BeneVision N1 patient monitor into the ventilator and the message **[Do you want to synchronize the bedside ventilator ventilation parameters?]** on the screen.

2. Select **[Detail]** to view the details of the respirator parameters of head.
3. Select **[OK]** to synchronize patient information and parameters monitor ventilation with this respirator.

The ventilator supports automatic breakpoint recovery. During transfer, ventilator data (including monitoring parameters and parameter adjustment trends) will be saved to the BeneVision N1 patient monitor. Upon returning to the department after the transfer, connect the BeneVision N1 patient monitor to the bedside ICU monitor, and the ventilator data saved on the BeneVision N1 patient monitor during the transfer will be uploaded to the central monitoring system (CMS) for continuous data recording throughout the transfer process.

5.3 Basic settings

5.3.1 TV/IBW Adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Define **[TV/IBW]**: Set the appropriate ratio. The system calculates the volume default current (TV) in ventilation mode depending on **[TV/IBW]**.

5.3.2 IBW/height adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Adjust **[IBW/height]** and toggle between **[IBW]** and **[Height]**. With the ventilator in standby mode, define the ideal body weight or height. The system automatically calculates the preset TV, f, and apnea values in ventilation mode based on the defined IBW or height and sex.

5.3.3 Tinsp/I:E Adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Adjust **[Tinsp/I:E]** and toggle between **[Tinsp]** and **[I:E]**. Depending on **[Tinsp/I:E]**, adopt the corresponding Tinsp or I:E ventilation settings for VA/C, PA/C, PRVC, CPRV, and DuoLevel ventilation modes (when the DuoLevel time parameter is [f]).

5.3.4 Flow adjustment/Tpause(%)

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Adjust **[Flow/Tpause(%)]** and alternate between **[Flow]** and **[Tpause(%)]**. Use the corresponding ventilation settings for VA/C, V-SIMV, or CPRV ventilation mode, according to **[Flow/Tpause(%)]**.

5.3.5 DuoLevel Adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Set **[DuoLevel Set]:** **[Talt]** or [f].

- In the case of DuoLevel ventilation mode, the control parameters of Adjustable times are **[Talt]** and **[Tbaj]** if **[Ajust DuoLevel]** is set to **[Talt]**.
- In the case of DuoLevel ventilation mode, the control parameters of Adjustable times are **[f]** and **[Tinsp]** if **[Ajust DuoLevel]** is set to **[f]** and **[Tinsp/I:E]** is set to **[Tinsp]**.
- In the case of DuoLevel ventilation mode, the adjustable time control parameters are **[f]** and **[I:E]** if **[Ajust DuoLevel]** is set to **[f]** and **[Tinsp/I:E]** is in **[I:E]**.

5.3.6 Invasive apnea mode adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Define **[Invasive Apnea Mode]: [Volume Control]** or **[Pressure Control]**. In the case of invasive ventilation in V-SIMV, P-SIMV, PRVC-SIMV, CPAP/PSV, PSV, VS, Duolevel and APRV modes, the adjustable apnea ventilation control parameter is **[VCapnea]** if **[Invasive Apnea Mode]** is set to **[Volume Control]**, and it is **[$\dot{\bar{y}}$ Papnea]** if **[Invasive Apnea Mode]** is set to **[Pressure Control]**.

5.3.7 Leakage compensation adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Adjustment **[Leak Compensation]:** (activated) or (Off). When the switch is on, the respirator provides leak compensation.

5.3.8 Adjustment of the O₂% increase during the O₂ $\dot{\bar{y}}$ period

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Ventilation]**.
2. Define **[Increase O₂% in O₂ $\dot{\bar{y}}$]:** establish the oxygen enrichment of in accordance with the different types of patients. After the start of oxygen enrichment, the system compares "the current oxygen concentration + the oxygen enrichment" with "100 vol.%" and starts ventilation according to the lower of the two values.

5.3.9 Oxygen sensor control adjustment

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

1. Select **[Menu]** $\dot{\bar{y}}$ **[Set]** $\dot{\bar{y}}$ **[O₂ Sensor]**.
2. [Monitor] Setting : (Off). (activated) or (Off). When the switch is on, the oxygen concentration of the patient's inhaled gas can be monitored. If you do not need the oxygen concentration monitoring function provided by the ventilator, you can turn it off. In this case, the warning message **[O₂ Monitor Off]** is displayed on the screen. After disconnecting oxygen sensor monitoring, the ventilator deactivates the corresponding warning and alarm messages.

CAUTION: It is possible to turn off the oxygen concentration monitoring. To avoid potential patient injury, it is recommended not to leave the oxygen concentration monitoring turned off continuously.

NOTE: The total system response time for monitoring oxygen concentration does not exceed 18 seconds.

NOTE: It takes approximately 3 minutes from when the ventilator is switched on until the oxygen concentration monitoring performance specified in section B.7 Ventilator Accuracy of this manual is achieved.

5.3.10 Adjustment of the type of O2 supply

1. Select **[Menu]** $\dot{\bar{y}}$ **[Settings]** $\dot{\bar{y}}$ **[Gas Supply]**.
2. Set **[O2 Supply Type]** to **[HPO]** or **[LPO]**.




5.4 Screen settings

5.4.1 Choose screen

Select **[Menu]** $\dot{\bar{y}}$ **[Screen]** $\dot{\bar{y}}$ **[Selection Screen]**.





- When the patient monitor is not connected, you can adjust the ventilator display to **[Waveform Display]**, **[Large Number Display]**, **[Value Display]** or **[Spirometry Display]**.
- When the patient monitor is connected, you can adjust the patient monitor display to **[Waveform Display]** or **[Large Numerical Display]** in addition to the ventilator display.

5.4.2 Adjusting screen brightness

1. Select **[Menu]** $\dot{\bar{y}}$ **[Display]** $\dot{\bar{y}}$ **[Brightness/Volume]**.
2. Select today and  to the corresponding default screen brightness.
3. If the previous screen brightness is not satisfactory, adjust **[Brightness]** directly.  It appears darker and brighter.  If the respirator is battery-powered, you can select a less bright screen to conserve battery life.



NOTE: Select **[Brightness/Volume]** $\dot{\bar{y}}$ **[Auto]**. When **[Auto]** is set to (on), the respirator will automatically adjust the screen brightness based on the ambient light intensity.

5.4.3 Adjusting the volume of the keys

1. Select **[Menu]** $\dot{\bar{y}}$ **[Display]** $\dot{\bar{y}}$ **[Brightness/Volume]**.
2. Select today and switch  to the corresponding default volume key.
3. If the volume of the previous key is not satisfactory, adjust **[Volume]** directly.  It means a lower volume,  it means a higher volume, and  it means the volume is off.

5.4.4 Screen layout adjustment

1. Select **[Menu]** $\dot{\bar{y}}$ **[Display]** $\dot{\bar{y}}$ **[Screen Adjustment]**.
2. Select the corresponding icons to define the number of waves to be sample and waveform tracing method.

3. If you need to adjust the specific waveform and measured values in each Position, set **[Dispos config switch]** to select the  (activated). Next, waveform or measured value on the main screen and define the required waveform or measured value name in the displayed interface. If you need to disable this function, set **[Dispos config switch]** to (off). 
4. Select **[Default Values]** when it is necessary to restore the settings defaults.

5.4.5 Color adjustment

1. Select **[Menu]** \ddot{y} **[Display]** \ddot{y} **[Color]**.
2. Adjust the display colors of the parameters. The wave colors, parameters, spirometry loops, and parameter alarm limits are Linked. If you adjust the color of a waveform or parameter, the color of its corresponding parameter or waveform also changes. The alarm boundary color of the associated parameter will be a darker shade of the set color.

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

WAYS of VIBE	PARAMETER	LOOP of SPIROMETRY ASSOCIATED	LIMITS OF ALARM ASSOCIATES
Pva	Ppeak, Pmean, Pplat, PEEP PV loop or FP loop. pva		
Flow	MVi, MVe, MVleak, MVspn, TVe, TVi, TVe spn, ftotal, fmand, fspn, Tve/IBW, I:E, Tinsp	FV Loop	MVe, TV, ftotal
Volume.	/	/	/
/	FiO2	/	FiO2
CO2	EtCO2, VDaw, VDaw/TVe, Vtalv, MValv, slopeCO2, MVCO2, VeCO2, ViCO2	V-CO2 Curve	EtCO2
Pleti	SpO2, PR	/	SpO2, PR

Table 5-1 Color Adjustment

5.4.6 Outdoor mode setting

Outdoor mode is a configuration mode used when moving Patients outdoors. When the ventilator is in outdoor mode, the background color of the new interface is the inverse of the original interface and cannot be changed.

Press the Outdoor Mode key located below the main screen to access outdoor mode. When the ventilator is on, this key displays the remaining power icon; when the ventilator is off, this key displays the remaining power icon.



5.5 System settings

5.5.1 Setting the time and date

1. Select **[Menu]** › **[System]** › Enter system password › **[Settings]** › **[Date and time settings]**.
2. Adjust **[Date]**, **[Time]**, **[Time Zone]** and **[Daylight Saving Time]**.
3. Set **[Date Format]** to **[YYYY-MM-DD]**, **[MM-DD-YYYY]**, or **[DD-MM-YYYY]**.
4. Adjustment **[24 h]**: (activated) or (deactivated).

5.5.2 Language setting

1. Select **[Menu]** › **[System]** › Enter system password › **[Settings]** › **[Language/Unit]**.
2. Adjust **[Language]** as needed.
3. Restart the respirator to activate the selected language.

5.5.3 Unit adjustment


1. Select **[Menu]** › **[System]** › Enter system password › **[Settings]** › **[Language/Unit]**.
2. Adjust the relevant units as needed:
 - Adjustment **[Pressure Unit]**: **[cmH2O]**, **[hPa]** or **[mbar]**.
 - Setting **[CO2 Unit]**: **[mmHg]**, **[kPa]** or **[% vol.]**.
 - Adjustment **[Height Unit]**: **[cm]** or **[inch]**.
 - Adjustment **[Weight Unit]**: **[Kg]** or **[lb]**.
 - Setting **[WOB Unit]**: **[J/min]** or **[J/L]**.
 - Setting **[Gas supply pressure]**: **[kPa]**, **[psi]** or **[bar]**.
 - Adjust **[Minimum alarm volume]** to an appropriate value.

5.5.4 Password change

1. Select **[Menu]** › **[System]** › Enter system password › **[Settings]** › **[Change passwords]**.
2. Enter your current password.
3. Enter the new password.
4. Confirm the password, i.e., re-enter the new password.

5.5.5 Adjusting the respirator's location

1. Select **[Menu]** › **[System]** › Enter system password › **[Fan location]**. The system displays the device ID in the open interface.
2. Set **[Fan Name]**, **[Center]** or **[Department]**.
3. Set **[Room No.]** or **[Bed No.]**.

- Selecting **[Fixed]**, **[Room No.]** and **[Bed No.]** will lock them and they cannot be changed in the **[Patient Settings]** menu. For more information about the **[Patient Settings]** menu, see **6.3.1 Setting Patient Information on the Ventilator**.
- Selecting **[Mobile]**, **[Room No.]**, and **[Bed No.]** will unlock them and allow them to be modified in the **[Patient Settings]** menu. For more information For information on the **[Patient Settings]** menu, see **6.3.1 Adjusting Patient Information on the Ventilator**.
- Select **[Mobile]**, you can adjust **[Automatic Bed Number Retrieval]** to (on) or (off).  When the wired network is connected and the switch is turned on, the ventilator automatically obtains the patient's room number and bed number.

5.5.6 Patient management

1. Select **[Menu]** → **[System]** → Enter system password → **[Patient Management]**.
2. Select **[Field]**. In the interface that opens, configure the desired field in the **[Patient Settings]** menu. For more information about the **[Patient Settings]** menu, see **6.3.1 Adjusting Patient Information on the Ventilator**.
3. Select **[ADT Consultation]**. In the interface that opens, set **[Search Patient]** to **[All Patients]** or **[Patients in Current Service]**. Additionally, configure the desired field in the **[Search Patient]** menu. For more information about the menu **[Search patient]**, see **6.3.2 Obtaining patient information from the ADT server**.
4. Select **[Discharge Patient]**. On the open interface, set **[Clear Room and Bed Number on Discharge]** to (On) or the switch is on. If **[Room Number]** and **[Bed Number]** are **[Mobile]**, the ventilator will clear the room and bed numbers. When the switch is off, the patient's room and bed numbers are retained by the ventilator when the patient is discharged.

5.5.7 Default settings

The respirator provides the following types of adjustments:

- Factory default settings. These are the values of the adjustment elements. factory defaults.
- User default settings. You can change the ventilator's default settings according to the current settings during ventilation and save the changed settings as user defaults.
- Recent settings. In the actual application, operators can change some Settings. The ventilator saves these settings in real time. The stored settings are the latest. After the ventilator is turned on, they are loaded. automatically apply the latest settings.
- Current settings, i.e., the current settings of the ventilator.

5.5.7.1 Save current settings

You can change the respirator's default settings according to the settings during ventilation and save the changed settings as default settings.

1. Select **[Menu]** ÿ **[System]** ÿ Enter system password ÿ **[Values predetermined.]**.
2. Select **[Use current settings]** to save the current settings as default settings.

Note: The **[Use current settings]** function is valid for both the ventilator and the BeneVision N1 patient monitor.

5.5.7.2 Restore factory default settings

You can manually restore the factory default settings if necessary when the device is in standby mode.

1. Select **[Menu]** ÿ **[System]** ÿ Enter system password ÿ **[Values predetermined.]**.
2. Select **[Restore factory default settings]** to restore the factory default settings.

Note: The **[Restore factory default settings]** function is valid for both the ventilator and the BeneVision N1 patient monitor.

5.5.7.3 Applying the default settings

When the ventilator is used with a new patient after it has been switched on, the system loads the corresponding default settings according to the selected patient type.

NOTE: It records information automatically saved by the system, including monitored trends, event logs (including alarm logs), adjustment trends, patient settings, and equipment settings (including alarm settings). When this data is changed, the system automatically stores the modified data in the main board's flash memory chips. When the ventilator is restarted, the data is automatically restored.

5.5.8 Network adjustment

CAUTION: Design, installation, debugging, and maintenance
Wireless network maintenance must be performed by Mindray service personnel or authorized technicians.

CAUTION: Always deploy the wireless network in accordance with the local wireless regulations.

CAUTION: It is recommended to always use the 5G frequency band that is possible. There are more sources of interference in the 2.4G frequency band.

CAUTION: Private access points and wireless routers are not permitted. These devices can cause radio interference and result in the loss of ventilator and CMS data.

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

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

CAUTION: Prevent unauthorized users from accessing network authentication information, such as the password.

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

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

CAUTION: The maximum number of ventilators connected to a single access point is 16 for this ventilator. Too many ventilators connected to the same access point may cause a network disconnection.

CAUTION: Radio frequency interference may cause wireless network disconnection.

CAUTION: Disconnection from the network may result in CMS data loss and malfunctions. Check on the patient in case of network disconnection and reconnect as soon as possible.

CAUTION: Ensure the IP address settings of The respirator is correct. Modifying network settings may cause network disconnection. Contact service personnel if you have any problems configuring the IP address.

5.5.8.1 Network type adjustment





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

5.5.8.2 LAN/WLAN settings

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]** › **[Network configuration]**.
2. Select **[LAN Setting]** or **[WLAN Setting]** to configure the items related to the interface that appears.

5.5.8.3 Central station adjustment

The ventilator can be connected to the central monitoring system (CMS) via a network connection to transmit ventilation mode, ventilation control parameters, ventilation monitoring parameters, tools, and alarm information from the ventilator to the CMS. The alarm delay from the ventilator to the CMS does not exceed 3 seconds. You can view patient ventilation data and alarms in the CMS. For detailed information, please refer to the CMS operator manual.

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]** › **[Network configuration]**.
2. Select **[Central Station Settings]** to adjust the related items in the interface that appears.
 - Set **[Network Disconnection Alarm]** to (on) or (off).  
When this function is activated, the ventilator will emit an alarm when it is disconnected from the CMS, e-Gateway, or monitor.
 - Set **[Select CMS]** to (on) or function is  **on**, the central  (deactivated). When this monitoring system of the ventilator can be selected.
- Select **[Add central station]** to adjust the relevant central station elements to be added in the interface that appears.

5.5.8.4 Remote control system adjustment

The ventilator can also be connected to the remote control system via a network interface (wired or wireless) to control ventilation mode settings, ventilation parameters, alarms, and tools. When control is initiated through the system, the ventilator's controlled function is active for a maximum of 3 seconds. The ventilator alarm delay to the remote control system does not exceed 3 seconds. To connect to the remote control system, follow these steps. For more information, refer to the Mindray Remote Control System Operator's Manual.

1. Select **[Menu]** › **[System]** › Enter system password › **[Set]** › **[Authorization Code]** on the controlled respirator to create or view the controlled respirator authorization code.
2. Enter the authorization code for the controlled ventilator into the remote control system. Upon confirmation, the remote ventilator control authorization is complete.
3. On the **[Bed Number Settings]** screen of the controlled ventilator, press the **[Start Access]** button to initiate remote access to the ventilator.
4. The ventilator can be remotely controlled after entering the username and password into the remote control system. At this point, the controlled ventilator will flash its alarm light and display the warning message **[Being accessed by remote device]**.
5. The remote control system can control the respirator's ventilation mode settings, ventilation parameters, alarms, and tools.

6. To cancel remote control, press the **[Stop Access] button** on the respirator controlled to end the remote control.

WARNING: Other users should not operate the remote control system software when the controlled respirator is being operated.

WARNING: After the ventilator creates a new patient or is powered off and restarted, the remote control function is restored to its default disabled state. The user must click the **[Start Access] button** on the ventilator again to initiate remote control and re-establish the remote control's connection with the ventilator in the remote control system.

WARNING: When the ventilator is remotely controlled, the physiological waveforms, physiological parameters, and alarm information displayed on the remote control system are for reference only and cannot be used directly as a basis for clinical treatment. Before clinical intervention, the results observed on the remote control system must be confirmed on the controlled ventilator.

WARNING: If the data displayed on the remote control system is abnormal or questionable, check the patient's vital signs in other ways before confirming that the remote control system and ventilator are functioning normally.

WARNING: The waveforms, parameters, and alarm information displayed by the remote control system are derived from network-connected devices. When the network connection is abnormal, data transmitted from the ventilator to the remote control system may be lost or delayed. In this case, closely monitor the patient.

WARNING: There may be risks when the remote control system changes the ventilation mode, sets ventilation parameters, and changes the ventilator's alarm limits.

Consult the respirator operator's manual before using it.

WARNING: To use the remote control system software, at a minimum the following are required: ventilator, patient monitor, video surveillance system, and central monitoring system.

WARNING: The remote control function does not support remote power off, standby mode entry, or standby mode exit.

CAUTION: The length of the network cable connected to the respirator must not exceed 100 meters. Otherwise, the network signal may be too weak, causing data transmission or display errors.

CAUTION: To ensure network security and stability, make sure the LAN connecting the remote control system and the ventilator is a closed network environment, and connection to the Internet or other external networks is not permitted.

CAUTION: If necessary, contact us for information on remote control system maintenance. If you detect any problems with the remote control system, contact service personnel.

NOTE: The remote control system only supports existing functions of the controlled ventilator, including ventilation mode setting, ventilation parameters, oxygen therapy, spontaneous breathing test (SBT), sigh, IntelliCycle, manual breathing, inspiration hold, and alarm limits.

NOTE: The remote control system is primarily used in scenarios with risks of transmissibility or radiation, such as isolation rooms. The interface style of the remote control system is essentially the same as that of the self-contained breathing apparatus (SCBA). The range of parameters and the adjustment and configuration methods are also the same as those of the SCBA, simplifying user operation.

NOTE: The remote control system does not support remote control operations on life monitoring products.

5.5.8.5 Device detection setting

Adjust the multicast parameters so that the ventilator and monitor, as well as the ventilator and the central monitoring system, can detect each other. Only internal devices within the same multicast group can detect each other.

1. Select **[Menu]** ∩ **[System]** ∩ Enter system password ∩ **[Interface]**.
2. Select **[Device Detection]** to adjust the related items and check the network connection status on the interface that appears.

5.5.8.6 Information security adjustment

1. Select **[Menu]** ∩ **[System]** ∩ Enter system password ∩ **[Interface]**.
2. Select **[Information Security]** to adjust **[Connection Encryption Type]** in the interface that appears.
 - [Private Encryption Only]:** Mindray's private encryption is used to encrypt transmitted data. Devices connected using SSL (Secure Socket Layer) encryption are not supported.
 - [SSL encryption priority]:** Devices that support SSL encryption will preferably connect in SSL encryption mode, and devices that are not compatible with SSL encryption, they connect in private encryption mode.

5.5.8.7 ADT Adjustment

The ADT application gateway is typically deployed on eGateway. You can receive patient information from the hospital's ADT server through the ADT application gateway.

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]**.
2. Select **[ADT]** to adjust the related elements in the interface that appears.

5.5.8.8 SNTP Adjustment

SNTP is used to synchronize the ventilator's time with the server.

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]**.
2. Select **[SNTP]** to define the related elements in the interface that it appears. Once the adjustments have been made, you can select **[Test]** to test the connection status.

5.5.8.9 HL7 Adjustment

It can transmit real-time data, waveforms, and ventilator alarms to the hospital server via the HL7 protocol.

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]**.
2. Select **[HL7]** to adjust the related elements in the interface that it appears. Once the adjustments have been made, you can select **[Test]** to test the connection status.

5.5.8.10 Standard setting

You can connect an external monitor via the serial port.

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]**.
2. Select **[Series]** to adjust **[Protocol]** on the interface that appears.

5.5.8.11 VGA Adjustment

You can project the screen if you activate the VGA function.

1. Select **[Menu]** › **[System]** › Enter system password › **[Interface]**.
2. Select **[VGA]** to adjust the **[VGA Video Signal]** switch.

5.5.9 System information visualization

5.5.9.1 Version Information

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

5.5.9.2 Configuration information

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

5.5.9.3 Maintenance information

Select **[Menu]** › **[System]** › Enter system password › **[System Info]** › **[Maintenance]** to view the total system operating time, system start time, time of last CO₂ calibration, time of last O₂ sensor calibration, time of last flow sensor calibration, time remaining until next backup air supply maintenance, and time of last maintenance.

5.5.10 View open source information

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

5.5.11 Access to storage mode

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

5.6 Selecting a shortcut key for tools

1. Select **[Menu]** › **[Screen]** › **[Direct access key configuration]**.
2. Select the required shortcut key from the menu that appears. The system adds the shortcut keys one by one in the order of selection.

5.7 Factory service settings

Only company-authorized maintenance personnel can access the **[Service]** tab. For more information, please contact the company's Customer Service Department.

5.8 Calculation of oxygen consumption

This ventilator is capable of monitoring the oxygen consumption rate. Enter the current cylinder pressure and volume and initiate ventilation to control the oxygen cylinder for the remaining oxygen supply time. Before transporting the patient, it is necessary to check the current oxygen consumption data in the icon field on the main screen and estimate the transport duration and current oxygen capacity to ensure an adequate oxygen supply to the patient.

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

WARNING: The oxygen consumption calculation method is only feasible when there are no gas leaks at the patient end of the ventilator. If there is a gas leak in the patient tubing (for example, if the patient is wearing a ventilation mask), oxygen consumption will increase. Estimate oxygen consumption based on the patient's actual clinical condition.

Oxygen consumption is calculated as follows:

- Oxygen cylinder supply

Oxygen volume = Cylinder volume × Cylinder pressure.

For example, for a cylinder volume of 2 l and a cylinder pressure of 145 bar, the oxygen volume will be 290 l.

- Remaining gas supply time

Remaining gas supply time (min) = Oxygen volume (l) ÷ Oxygen consumption rate (l/min).

For example, in typical working mode, let's assume the cylinder volume is 2 l and the oxygen consumption rate is 5 l/min, then the remaining gas supply time will be 58 min.


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6.0

Start of ventilation

System startup	6-2
System verification.....	6-2 Patient
information management.....	6-4 Ventilation
type	6-5
Ventilation mode	6-6
Other ventilation settings.....	6-30 Alarm
settings.....	6-33
Initiation of ventilation.....	6-33
Ventilation parameters.....	6-33
Entering standby state.....	6-37 Shutting
down the system.....	6-38

6.1 System Power On

1. Plug the power cord into the power outlet. Make sure the external power indicator light is on.
2. Press the key. 
3. The alarm indicator light flashes yellow and red alternately and, Next, the system performs an automatic check of the speaker and doorbell.
4. A home screen and a self-check progress bar appear. The system check screen is shown below.

NOTE: When the ventilator is started, the system detects whether the audible alarm tones and alarm light function are working properly. If so, the alarm light flashes yellow and red sequentially, and the speaker and buzzer emit self-test tones. Otherwise, do not use the device and contact customer service immediately.

6.2 System verification


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

CAUTION: Before performing the system check, disconnect the patient of the team and make sure that it has a backup ventilation mode to ensure the patient's ventilation.

To access the system verification screen:

- After the system starts, it automatically enters the screen of Wait. Select the **[System Check]** key while in standby mode to access the system check screen.
- In the non-waiting state, select the **[Standby]** key and enter the standby state after confirmation. Then, in the standby state, select the **[System Check]** key to access the system check screen.

The system check screen displays the time of the last check and the overall check result.

Select the key to view information about the last ventilator system check, including the items and results of the check. 

Connect the gas supply, the proximal flow sensor, and lock the patient tube as illustrated. Then select **[Continue]** to start the test . element by element.

Elements of system verification:

- Vacuum cleaner test: check the speed of the vacuum cleaner.
- O2 flow sensor test : Check the flow sensor at the O2 end.
- Inspiratory flow sensor test

- Pressure sensor test: Check the pressure at the inspiratory ports and the expiratory pressure sensor.
- Expiratory valve test • Safety valve test
- Leakage (ml/min)
- O2 sensor test

The results of the system check may be:

- Approved: indicates that the item check has finished and passed correctly.
- Failure: indicates that the item has been checked but has not been overcome.
- Cancel: indicates that the item check has been cancelled.
- No gas supply: indicates that the O2 supply is not connected.
- Monitoriz desac: indicates that the sensor monitoring function cannot be activated when the O2 sensor test is being performed .
- No sensor: indicates that the flow sensor is not connected.
- Inverted sensor: indicates that the flow sensor is connected backwards.
- Sensor error: indicates that the oxygen sensor may not be working.

The results of the self-checks are indicated as follows after the completion of all elements of the self-check:

- Approved: all items tested have passed the test.
- Partial approval: some elements have not passed the test, however, mechanical ventilation is allowed.
- Ventilation disabled error: some important elements have not passed the test and mechanical ventilation is not permitted.
- Large leak, unvented: fails the flow sensor test
If the expiratory pressure sensor test, the expiratory valve test, or the safety valve test fails, mechanical ventilation is not permitted.
- Cancel: some elements of the test have been cancelled and others have passed test successfully.

When a system check is in progress, the system displays "**[Working]**" on the right side of the currently analyzed check item. At this point, selecting the "**[Skip]**" key immediately stops the check on that item and proceeds to examine the next check item. Selecting the "**[Stop]**" key stops the check.

of the current element and that of the remaining elements; then, **[Cancel]** is displayed.

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

Once all items have been checked, selecting **[Repeat]** starts a new series of checks. Selecting **[En esp]** exits the checks and enters standby mode.

6.3 Patient information management

NOTE: Adjust the patient information as needed. Device ventilation will not be affected if you do not adjust the patient information.

6.3.1 Adjusting patient information on the ventilator

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

- Select the patient type icon and adjust **[Sex]**, **[Height]/[IBW]**, and **[Ventilation Type]** in the **[Patient Settings]** menu. To change the patient information for a new patient, select the **[New Patient]** key in the **[Patient Settings]** menu, and then configure **[Sex]**, **[Height]/[IBW]**, and **[Ventilation Type]**.
- When modifying **[Sex]**, **[Height]** or **[IBW]**, the adjustment of **[VC]**, **[VCapnea]**, **[f]** and **[fapnea]** will change accordingly, as well as the TV alarm upper limit, TV alarm lower limit, MV alarm upper limit, and MV alarm lower limit.
- Select **[More]** and adjust **[Bed No.]**, **[Last Name]**, **[First Name]**, **[Date of Birth]**, **[With Mark]** or **[Custom Field]** in the open interface, etc. The settings shown here may be affected by **5.5.6 Patient Management**.

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

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

6.3.2 Obtaining patient information from the ADT server

The ventilator can connect to the ADT server (admission, discharge, transfer) via eGateway, and the ventilator can upload patient information from the ADT server.

To upload patient information from the ADT server, follow the procedure shown below:

1. Connect the network cables.
2. Select **[Menu]** → **[System]** → Enter system password → **[Settings interface]**.
3. Select the **[LAN Settings]** tab, and adjust **[IP Config]**, **[IP Address]**, **[Subnet Mask]**, and **[Gateway]** on the open interface. The open interface will also display the respirator's MAC address.
4. Select the **[eGateway]** tab and set **[eGateway]** to (enabled) in the open interface. Then, set the **[IP Address]** for both the eGateway and ADT. Adjusting the **[Port]** is usually not necessary, but you can change it if needed.
5. Ensure that the network status is **[Connected]** on the **[eGateway]** tab.
6. Select the patient type field on the main screen and open the menu patient adjustments.
7. Select **[Search Patient]**, enter **[Center]**, **[Department]**, **[Room No.]**, **[Bed No.]**, **[First Name]**, **[Last Name]**, **[Patient ID]** or **[Visit Number]** in the open interface. The settings shown here may be affected by **5.5.6 Patient Management**.

8. Select **[Consultation]**. A pop-up list of all patients who meet the consultation criteria will then appear.

9. Select a patient from the patient list, and then select

[Import]. Imported data includes patient ID, visit number, last name, bed number, room number, department, and center.

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

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

6.3.3 Obtaining patient information through the monitor

The ventilator can automatically obtain patient information from the BeneVision N1 patient monitor when the monitor is inserted.

6.4 Type of ventilation

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

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

6.4.1 Invasive ventilation

Invasive ventilation involves ventilating the patient through a manual airway (endotracheal tube [ET] or tracheal tube). Ventilation modes activated in invasive ventilation:

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

6.4.2 Non-invasive ventilation (NIV)

NIV involves ventilating the patient through a nasal or face mask instead of a ET tube or tracheal tube. Ventilation modes activated in NIV:

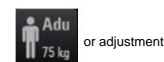
- Adult and pediatric patients: ventilation modes CPAP/PSV, PA/C, P-SIMV, DuoLevel, APRV and PSV-S/T.
- Neonatal patients: ventilation modes PA/C, PSV, nCPAP and PSV-S/T.

CAUTION: Do not use NIV in patients who are not breathing or have irregular spontaneous breathing. NIV provides supplemental ventilation assistance to patients with regular spontaneous breathing.

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

6.4.3 Adjusting the ventilation type

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



6.5 Ventilation mode

NOTE: During the expiratory phase, the ventilator does not automatically generate negative pressure. However, negative pressure can be generated when the patient inhales air.

NOTE: The user can set a high-pressure alarm limit. If the pressure reaches the high-pressure alarm limit during the inspiratory phase, a high-level alarm [Pva very high] is triggered. The ventilator opens the expiratory valve and switches to the expiratory phase until the airway pressure reaches the preset PEEP value. If the airway pressure exceeds the high-pressure alarm limit of +5 cmH₂O (adjustable pressure limit), the ventilator opens the safety valve to release pressure, allowing it to drop to 3 cmH₂O for 0.5 seconds.

NOTE: Since negative pressure can occur during closed suctioning, causing erroneous ventilator activation, it is recommended that pressure-controlled ventilation mode (PA/C mode or P-SIMV mode) be used first, in which ventilation activation can be disabled. The operator should finalize ventilation parameter adjustments according to the patient's condition.

NOTE: During the inspiratory phase, if the waveforms turn red, it means the patient is experiencing spontaneous inspiration or that support ventilation has been activated in V-SIMV, P-SIMV, PRVC-SIMV, CPAP/PSV, DuoLevel, APRV, VS, AMV, nCPAP, or PSV-S/T mode. When the patient triggers spontaneous breathing, a red triangle appears below the waveform to indicate the onset of spontaneous inspiration.

6.5.1 Ventilation mode and parameter settings

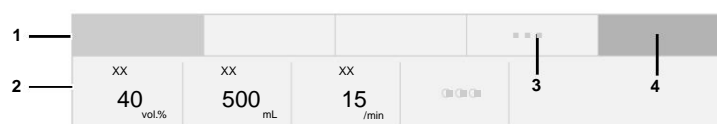


Figure 6-1 Ventilation mode and parameter settings

1. Ventilation mode field

Displays the keys to configure the ventilation modes.

2. Parameter configuration hotkey field

Displays the ventilation parameter settings corresponding to the mode of Ventilation. Select to view mode parameter settings. Select to display all parameter settings for the mode, including sigh function parameters. Ventilation parameters

They may vary depending on the ventilation mode.

3. Custom ventilation mode key

Select the custom fan mode key to open the fan mode settings menu. In the menu that opens, set the fan mode to be displayed in area 1. The system adds the fan modes one by one in the order you select them.

4. CPRV ventilation mode area (adjustable)

Select the custom key Ventilation Mode to open the ventilation mode settings menu. In the access menu, set **[RCPV]** to (on), and then the CPRV ventilation mode will be displayed in area 4. Set **[RCPV]** to (disabled), and the CPRV ventilation mode will not be displayed in area 4.

Adjusting the ventilation mode:

1. In the ventilation mode area, select the ventilation mode key
Required. The ventilation parameters that can be adjusted in this mode are shown in the open menu.
2. Select the key for the ventilation parameter you wish to adjust.
3. Press the control knob and turn it to adjust the selected parameter to the corresponding value.
4. Press the control knob again to confirm the setting.
5. Adjust the other parameters in a similar way.
6. Select the **[Ok]** key once the parameter settings are complete.

To set the hotkey ventilation parameters:

1. In the parameter configuration hotkeys field, select the ventilation parameter you wish to adjust.
2. Press the control knob and turn it to adjust the selected parameter to the corresponding value.
3. Press the control knob to confirm the setting.
4. Adjust the other parameters in a similar way.

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

1. In the ventilation mode configuration field, select VA/C, V-SIMV or CPRV ventilation mode.
2. Select the **[Additional]** or **[More]** tab in the open window.
3. Select **[Ok]** when the setup is complete.

6.5.2 VA/C

VA/C is volume-controlled/assisted ventilation mode. In VA/C mode, the patient is delivered a specific tidal volume over a defined period of gas delivery. During the expiratory phase, VA/

C supports the activation of synchronization. That is, when the ventilator detects a The inspiratory effort of the patient provides the next mechanical ventilation in advance.

The following figure shows typical waveforms in VA/C mode.

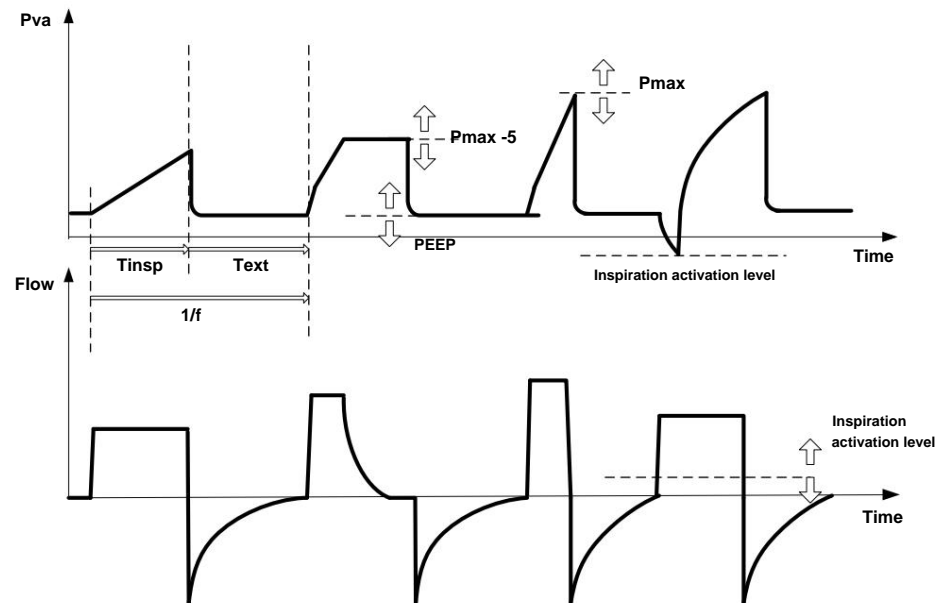


Figure 6-2 VA/C

In VA/C mode, the following basic ventilation parameters must be adjusted:

[O2%]:	Oxygen concentration
[VC]:	Tidal volume
[Tinsp] or [I:E]:	Inspiratory time or the relationship between inspiratory time and expiratory time
[F]:	Breathing rate
[PEEP]:	Positive end-expiratory pressure
[Assist]:	Connect and disconnect activation
[F-Trig] or [P-Trig]:	Inspiration activation level
[Tpause(%)] or [Flow]:	Percentage of inspiratory pause time or flow delivered to the patient during the inspiratory phase
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-1 VA/C

6.5.3 PA/C

PA/C is pressure-controlled/assisted ventilation mode. In PA/C mode, the pressure in the patient's airway increases to the preset pressure level during the pressure rise time of the inspiratory phase and is maintained at this level until the inspiration time has elapsed. The system then switches to expiratory mode. When the airway pressure is maintained at the preset pressure level

As pre-set, the supplied gas flow exhibits a deceleration pattern and varies with the patient's lung resistance and compliance. During the inspiratory phase, when the delivered gas volume exceeds the upper tidal volume alarm limit, the system immediately switches to the expiratory phase. Synchronization can be activated during the expiratory phase. That is, when the ventilator detects an inspiratory effort from the patient, it delivers the next mechanical ventilation immediately.

The following figure shows typical waveforms in PA/C mode.

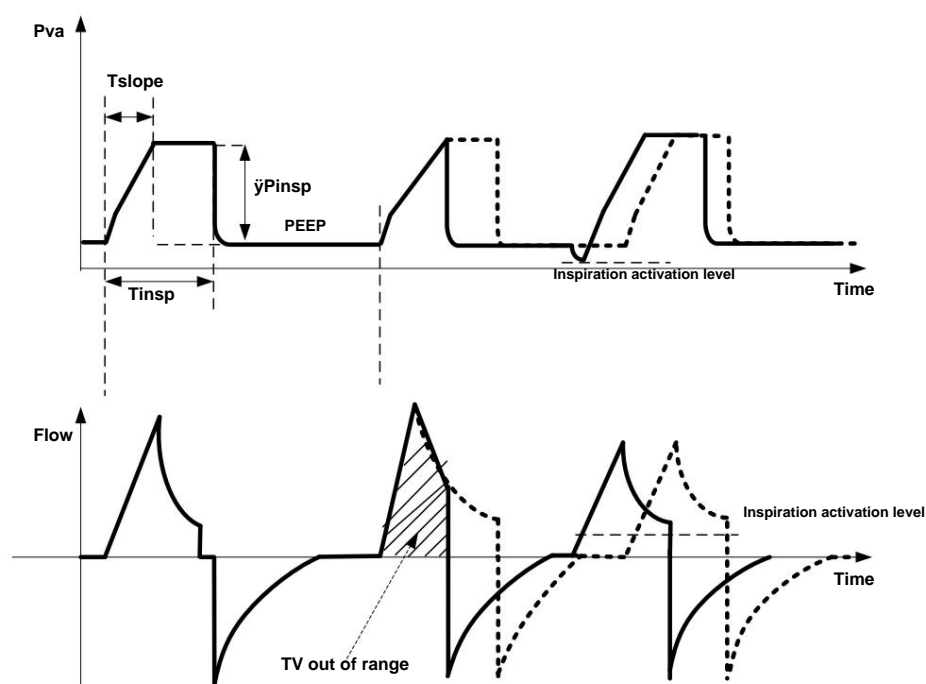


Figure 6-3 PA/C

In PA/C mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[yPinsp]:	Inspiratory pressure
[Tinsp] or [I:E]:	Inspiration time or relationship between inspirational time/ expiratory
[F]:	Breathing rate
[PEEP]:	Positive end-expiratory pressure
[Assist]:	Connect and disconnect activation
[F-Trig] or [P-Trig]:	Inspiration activation level
[Tpend]:	Pressure rise time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-2 PA/C

6.5.4 V-SIMV

V-SIMV is volume-synchronized intermittent mandatory ventilation mode. It delivers the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation rate. The mandatory ventilation mode is volume-controlled mode (VA/C mode). If the patient is triggered within the trigger interval, the ventilator delivers one mandatory volume-controlled breath. A mandatory volume-controlled breath is also delivered once if the patient is not triggered by the end of the trigger interval.

Spontaneous breathing or pressure support breathing is possible outside the activation interval. The activation interval duration is 5 seconds for adults and 1.5 seconds for pediatric and neonatal patients. If the expiratory time is shorter than the activation interval, the activation interval encompasses the expiratory time. Typical waveforms in V-SIMV + PSV mode are shown in the following figure.

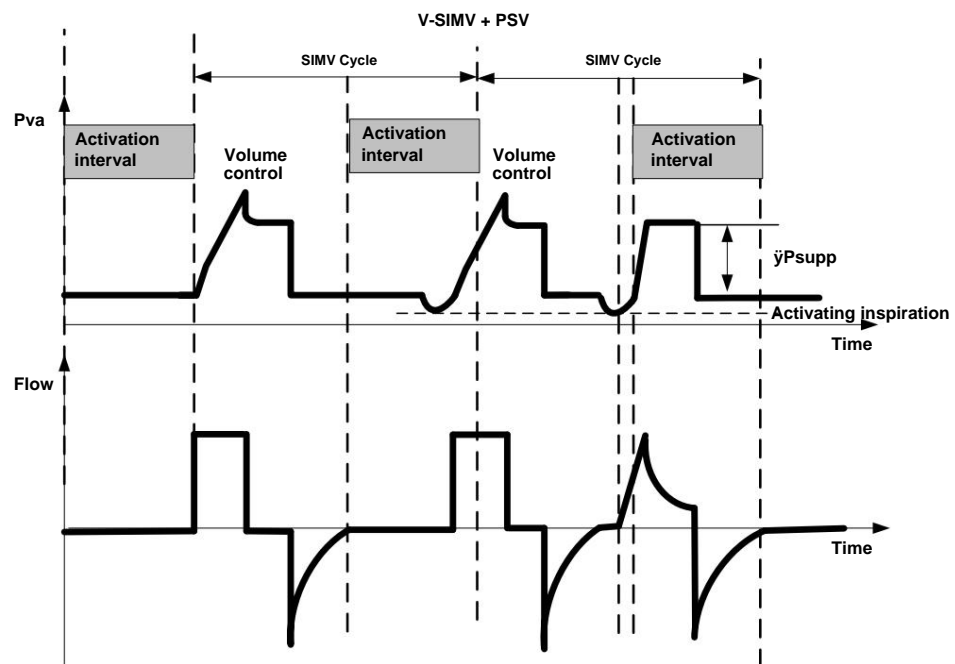


Figure 6-4 V-SIMV

In V-SIMV mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[VC]:	Tidal volume
[Tinsp]:	Time for inspiration
[fsimv]:	Mandatory respiratory rate
[Tpause(%)] or [Flow]:	Percentage of inspiratory pause time or flow delivered to the patient during inspiration
[Psupp]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure

Table 6-3 V-SIMV

[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[Vent apnea]:	Apnea ventilation switch
[VCapnea] or [ÿPapnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-3 V-SIMV

6.5.5

P-SIMV

P-SIMV is the pressure-synchronized intermittent mandatory ventilation mode. It provides the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation rate. The mandatory ventilation mode provided is pressure-controlled mode (PA/C mode). If the patient is triggered within the trigger interval, the ventilator delivers one mandatory pressure-controlled breath. A mandatory pressure-controlled breath is also delivered once if the patient is not triggered by the end of the trigger interval. Spontaneous breathing or pressure support breathing is possible outside the trigger interval. The trigger interval duration is 5 seconds for adults and 1.5 seconds for pediatric and neonatal patients. If the expiratory time is shorter than the trigger interval, the trigger interval encompasses the expiratory time. Typical waveforms in P-SIMV + PSV mode are shown in the following figure.

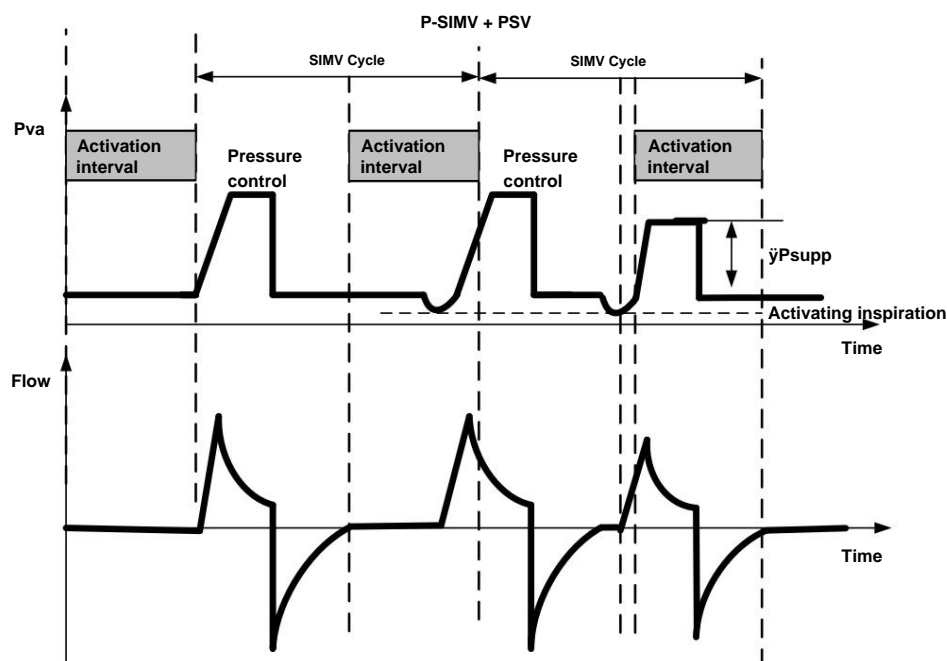


Figure 6-5 P-SIMV

In P-SIMV mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[\dot{y} P _{insp}]:	Inspiratory pressure
[T _{insp}]:	Time for inspiration
[f _{simv}]:	Mandatory respiratory rate
[T _{pend}]:	Pressure rise time
[PEEP]:	Positive end-expiratory pressure
[Exp%]:	expiration activation level
[\dot{y} P _{aux}]:	Pressure support level
[F-Trig] or [P-Trig]:	Inspiration activation level
[Vent apnea]:	Apnea ventilation switch
[VC _{apnea}] or [\dot{y} P _{apnea}]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[f _{apnea}]:	Apnea ventilation rate
[T _{insp apnea}]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-4 P-SIMV

6.5.6

CPAP/PSV

PSV is pressure support ventilation mode. The system delivers PSV when it detects that the patient's inspiratory effort reaches the activation level. The user can adjust the pressure rise time and pressure support level. At the beginning of the inspiratory phase, the patient's airway pressure rises to the preset pressure level within the defined rise time and is maintained at this pressure level until the patient's inspiratory flow reaches the expiratory trigger level. In PSV mode, when the airway pressure is maintained at the preset pressure level, the delivered gas flow slows and varies with the patient's lung resistance and compliance.

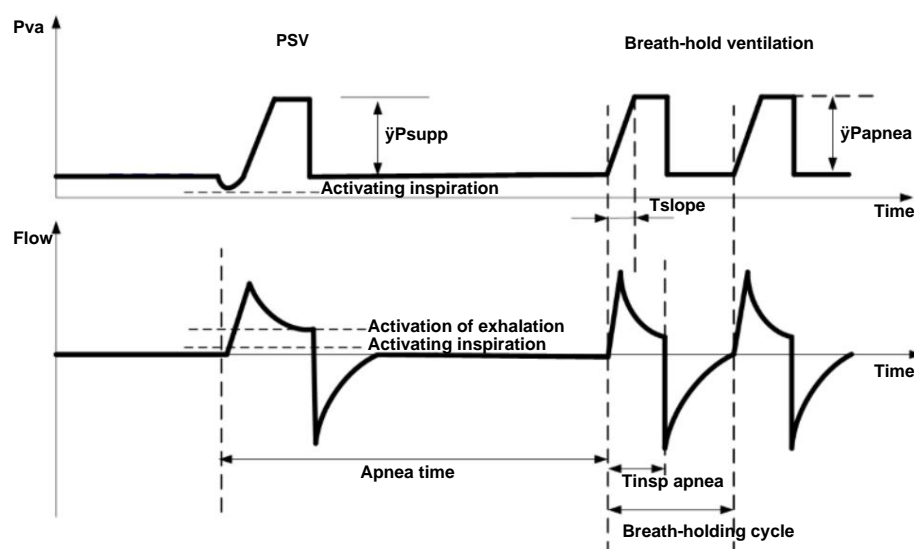


Figure 6-6 PSV

CPAP is the continuous positive airway pressure ventilation mode. Airway pressure is maintained at the user-set positive pressure level throughout the ventilation cycle. The patient breathes spontaneously and determines their own respiratory rate, tidal volume, and expiratory time. The system initiates apnea ventilation when it detects that the period of time during which the patient does not perform continuous spontaneous breathing exceeds the preset apnea time.

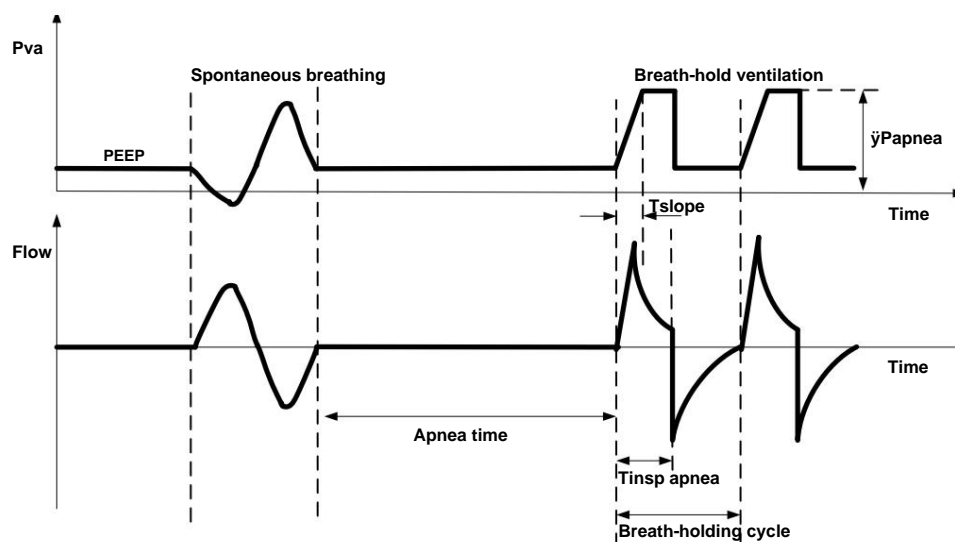


Figure 6-7 CPAP

In CPAP/PSV mode, the following basic ventilation parameters need to be adjusted for invasive ventilation:

[O ₂ %]:	Oxygen concentration
[\dot{y} Paux]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[VCapnea] or [\dot{y} Papnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-5 CPAP/PSV in invasive ventilation

In CPAP/PSV mode, the following basic ventilation parameters need to be adjusted for non-invasive ventilation (NIV):

[O2%]:	Oxygen concentration
[\dot{y} Paux]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[Ti max]:	Maximum inspiration time
[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[VCapnea] or [\dot{y} Papnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-6 CPAP/PSV in non-invasive ventilation

6.5.7 PSV-S/T

PSV-S/T mode is the spontaneous or synchronized pressure support ventilation mode, which means that the system initiates pressure support ventilation (PSV) once it detects an inspiratory effort from the patient that reaches the activation level. The user can adjust the pressure rise time and pressure support level. At the beginning of the inspiratory phase, the patient's airway pressure rises to the preset pressure level within the set time and is maintained at that pressure level until the patient's inspiratory flow reaches the expiratory trigger level.

In PSV-S/T ventilation mode, when the system detects that the patient is not breathing within the preset maximum respiratory cycle (60 s/respiratory rate), the system initiates mandatory ventilation. The duration of mandatory ventilation is subject to [f] and [Tinsp]. When the system detects that the patient is breathing within the preset maximum respiratory cycle (60 s/respiratory rate), the system initiates pressure support ventilation.

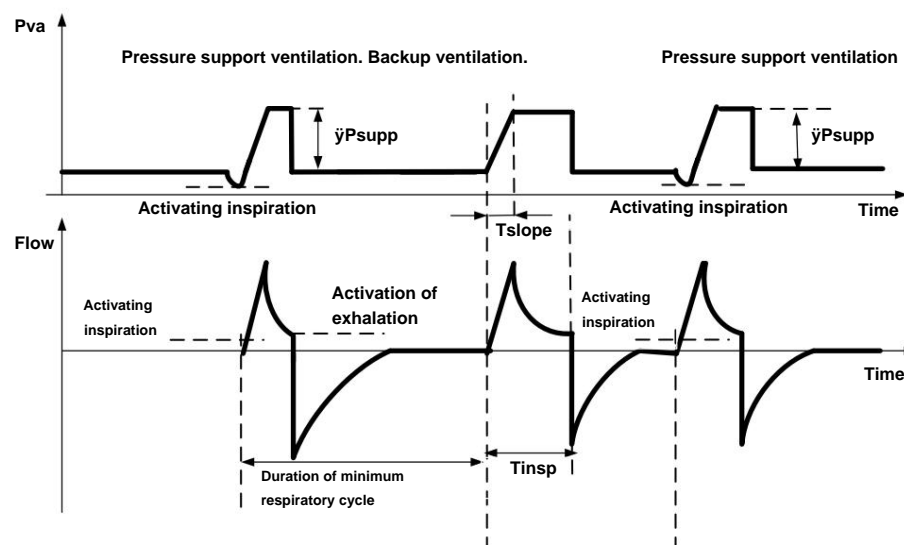


Figure 6-8 PSV-S/T

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

[O2%]:	Oxygen concentration
[Paux]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[F]:	Frequency of mandatory ventilation
[Tinsp]:	Inspiration time of mandatory ventilation
[Ti max]:	Maximum inspiratory phase time (only applies to one) ventilation period with pressure support)
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-7 PSV-S/T

6.5.8

PRVC

PRVC is pressure-regulated volume-controlled ventilation. The set tidal volume can be delivered by ventilation with

Pressure control. In PRVC mode, a relatively low pressure level is maintained as much as possible during the inspiratory phase, ensuring that the delivered gas volume equals the preset tidal volume. The peak pressure (Ppeak) value varies depending on the tidal volume setting and the patient's lung resistance and compliance. The ventilator pressure setting increase cannot exceed 10 cmH₂O during the first 3 cycles and cannot exceed 3 cmH₂O afterward.

during each of the following cycles. The maximum pressure cannot exceed the upper limit of the pressure alarm, set at 5 cmH₂O.

The first PRVC delivered is the experimental ventilation mode. The gas delivery pressure for the first cycle is 10 cmH₂O + PEEP to calculate the compliance and resistance of the system and the patient's lungs, as well as to calculate the pressure level based on the patient's condition. Subsequently, this pressure level will be used as the set point for tidal volume control.

the following ventilation cycles.

The following figure shows the typical waveforms in PRVC mode.

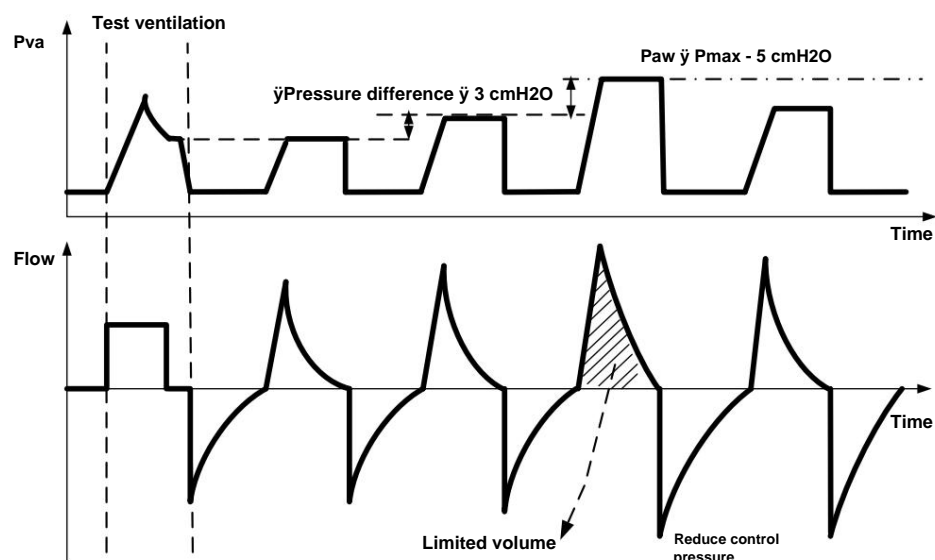


Figure 6-9 PRVC

In PRVC mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[VC]:	Tidal volume
[T _{insp}] or [I:E]:	Inspiratory time or the relationship between inspiratory time and expiratory time
[F]:	Breathing rate
[PEEP]:	Positive end-expiratory pressure
[Assist]:	Connect and disconnect activation
[F-Trig] or [P-Trig]:	Inspiration activation level
[Tpend]:	Pressure rise time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-8 PRVC

6.5.9 PRVC-SIMV

PRVC-SIMV is a synchronized intermittent pressure-regulated, mandatory, volume-controlled ventilation mode. It provides the minimum number of mandatory breaths based on the preset intermittent mandatory ventilation rate. The mechanical ventilation mode provided is volume mode (PRVC mode). If the patient is triggered within the trigger interval, the ventilator delivers one mandatory volume-controlled breath. The mandatory PRVC breath is also delivered once if it is not initiated by the end of the trigger interval. Spontaneous breathing or pressure support breathing is possible outside the trigger interval. The trigger interval duration is 5 seconds for adults and 1.5 seconds for pediatric and neonatal patients. If the expiratory time is shorter than the trigger interval, the trigger interval encompasses the expiratory time.

The following figure shows the typical waveforms in PRVC-SIMV + PSV mode.

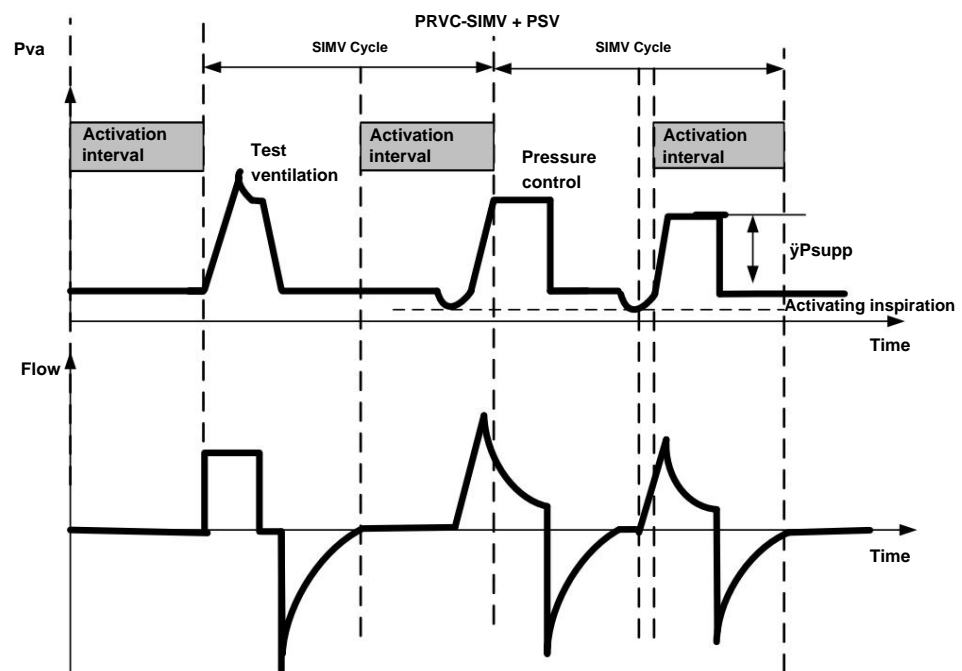


Figure 6-10 PRVC-SIMV

In PRVC-SIMV mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[VC]:	Tidal volume
[Tinsp]:	Time for inspiration
[fsimv]:	Mandatory respiratory rate
[yPaux]:	Pressure support level
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[Vent apnea]:	Apnea ventilation switch
[VCapnea] or [yPapnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-9 PRVC-SIMV

6.5.10 DuoLevel

DuoLevel is a dual-level positive airway pressure ventilation mode. In DuoLevel mode, the ventilator delivers positive airway pressure at two different pressure levels alternately during ventilation.

mechanical or spontaneous breathing. The patient can breathe spontaneously at any pressure level.

During the low-pressure phase, it is possible to adjust the pressure.

of support. The activation interval is available during the high and low pressure phases. It could originate from the transition from high to low pressure or vice versa. The activation interval during the low

pressure phase corresponds to the last 5

seconds of low pressure time (T_{low}) while the activation interval

During the high pressure phase, this corresponds to the last 1/4 of the high pressure time (T_{high}).

Within the activation interval of the low pressure phase, the activation

Inspiratory activation is transformed into high-pressure gas delivery. Within the activation interval of the

high-pressure phase, expiratory activation is transformed into

Low-pressure gas delivery. The activation interval duration is 5 s for adults and 1.5 s for pediatrics and

neonates. If the expiratory time is shorter than the activation interval, the activation interval encompasses

the expiratory time. Typical waveforms in DuoLevel mode are shown in the following figure.

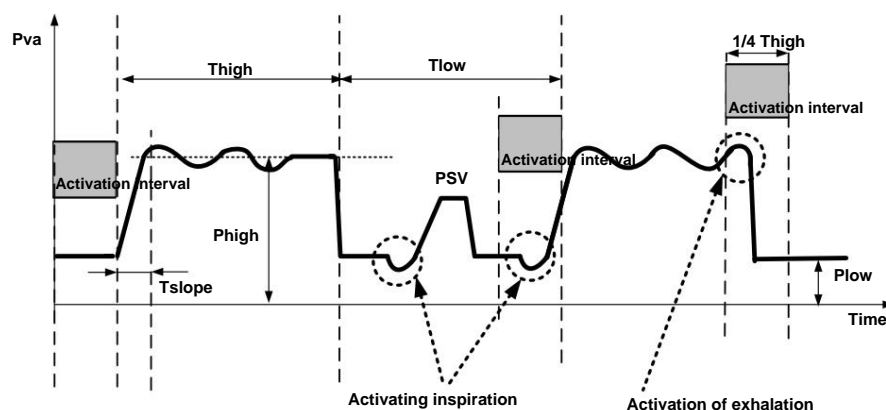


Figure 6-11 DuoLevel

In DuoLevel mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[Palt]:	High pressure
[Talt] or [f]:	High pressure time or respiratory rate
[Pbal]:	Low pressure
[Tbal], [Tinsp] or [I:E]:	Low pressure time, inspiration time or ratio between inspiration time and expiration time or inspiration/expiration ratio
[yPaux]:	Pressure support level
[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level

Table 6-10 DuoLevel

[Tpend]:	Pressure rise time
[VCapnea] or [yPapnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-10 DuoLevel

6.5.11 APRV

APRV is the airway pressure release ventilation mode.

It can be considered as a short-period periodic pressure of the airways in CPAP mode.

The following figure shows the typical waveforms in APRV mode.

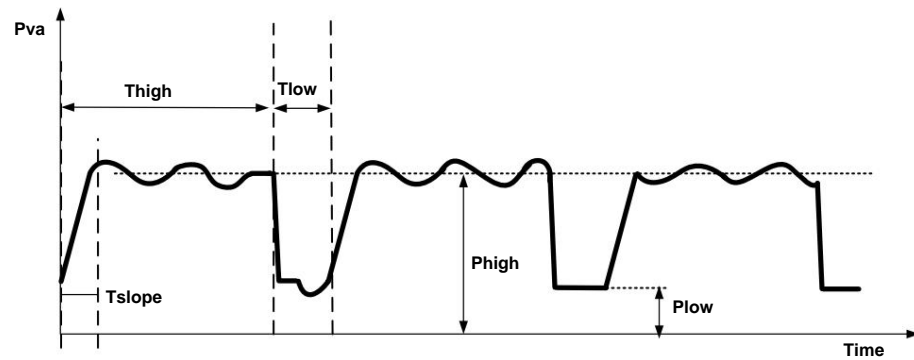


Figure 6-12 APRV

In APRV mode, the following ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[Palt]:	High pressure
[Talt]:	High pressure time
[Pbaj]:	Low pressure
[Tbaj]:	Low pressure time
[Tpend]:	Pressure rise time
[VCapnea] or [yPapnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[F-Trig] or [P-Trig]:	Inspiration activation level

Table 6-11 APRV

6.5.12VS

VS refers to volume support ventilation, which means the system initiates volume support ventilation when it detects that the patient's inspiratory effort reaches the preset inspiratory trigger level. This mode adjusts pressure support levels based on the patient's lung resistance, compliance, and inspiratory effort to ensure the patient receives the preset tidal volume. In this mode, the duration of the inspiratory and expiratory phases is controlled by the patient. The system initiates apnea ventilation when it detects that the period of time during which the patient does not perform effective continuous spontaneous breathing exceeds the preset apnea time.

The first ventilation (VS) is the experimental ventilation mode. The gas supply pressure for the first cycle is $10 \text{ cmH}_2\text{O} + \text{PEEP}$ to calculate the compliance and resistance of the system and the patient's lungs, as well as to calculate the pressure support level based on the patient's condition. Subsequently, this pressure support level will be used to regulate tidal volume control.

the following ventilation cycles. The ventilator pressure increase must not exceed $10 \text{ cmH}_2\text{O}$ during the first 3 cycles and $3 \text{ cmH}_2\text{O}$ during each subsequent cycle. The maximum pressure must not exceed the upper pressure alarm limit, set at $-5 \text{ cmH}_2\text{O}$.

The following figure shows typical waveforms in VS mode.

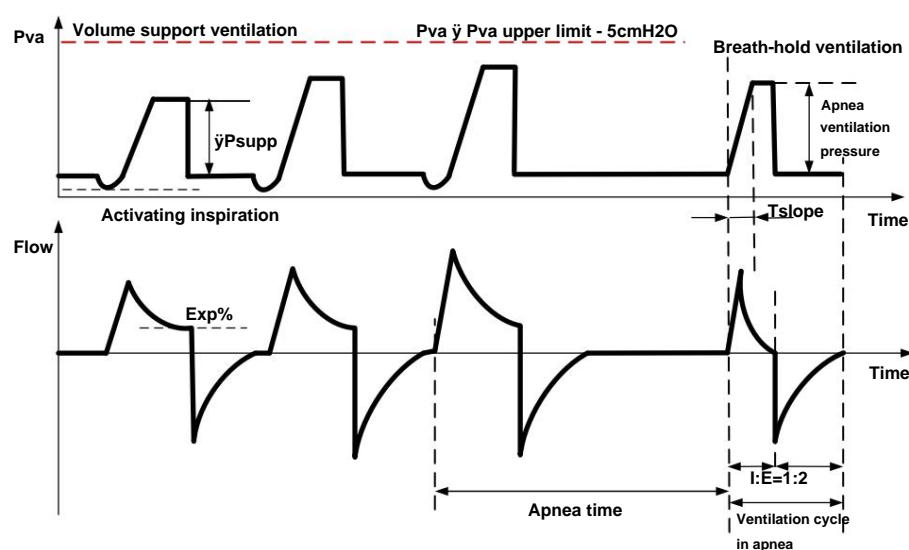


Figure 6-13 VS

In VS mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[VC]:	Tidal volume
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration activation level

Table 6-12 VS

[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[VCapnea] or [yPapnea]:	Tidal volume or inspiratory pressure in the apnea ventilation cycle
[fapnea]:	Apnea ventilation rate
[Tinsp apnea]:	Breath-hold time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-12 VS

6.5.13 AMV

AMV refers to adaptive minute volume ventilation, a ventilation mode that adjusts patient ventilation based on the minimum work of breathing (WOB). The user only needs to input the patient's ideal body weight (IBW) and the percentage of the desired minute ventilation volume; the ventilator will then calculate the tidal volume and respiratory rate using the minimum WOB and the Otis equation. It will also adjust the I:E ratio based on the measured pulmonary time constant. AMV is only suitable for ventilation

pediatric and adult.

Otis equation:

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

Where, f is the respiratory rate below the minimum WOB, MV is the target ventilation volume, V_d is the patient's physiological dead space volume, and RC_{exp} refers to a pulmonary time constant. a is a waveform coefficient; for a sinusoidal wave, a = 2√2/60.

This is the formula for calculating the target ventilation volume:

Target ventilation volume MV = Minute volume % × f_{default} × TV/IBW × IBW/1000

Where, TV/IBW refers to the current volume in relation to ideal body weight, IBW is the ideal body weight, f_{default} is a group of default values related to IBW, values which are listed below:

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

Table 6-13 Relationship between IBW and f_{default}

The first three AMV cycles are the experimental PCV ventilation mode for calculating the patient's lung compliance and resistance. The initial ventilation parameters are:

Adjustment parameters of the experimental ventilation cycle for adults

IBW (kg)	P _{insp} (cmH ₂ O)	T _{insp} (s)	f(/min)
10-29	15	1.15	
30-39	15	1	14
40-59	15	1.12	
60-89	15	1.10	
90-99	18	1.5	10
≥100	20	1.5	10

Table 6-14 Adjustment Parameters (Adults)

Adjustment parameters for the pediatric experimental ventilation cycle

IBW (kg)	P _{insp} (cmH ₂ O)	T _{insp} (s)	f(/min)
3-5	15.4	3.0	
6-8	15.6	2.5	
9-11	15.6	2.0	
12-14	15.7	2.0	
15-20	15.8	2.0	
21-23	15.9	1.5	
24-29	15	1.15	
30-35	15	1	14

Table 6-15 Adjustment Parameters (Pediatrics)

After three experimental ventilations, the automatic adjustment phase begins. Based on the minimum WOB principle, ensure that the actual minute volume is as close as possible to the preset minute volume value. Mandatory ventilation is administered if the patient is not breathing spontaneously. Supportive ventilation is administered if the patient resumes spontaneous breathing.

The following figure shows the typical waveforms in AMV mode.

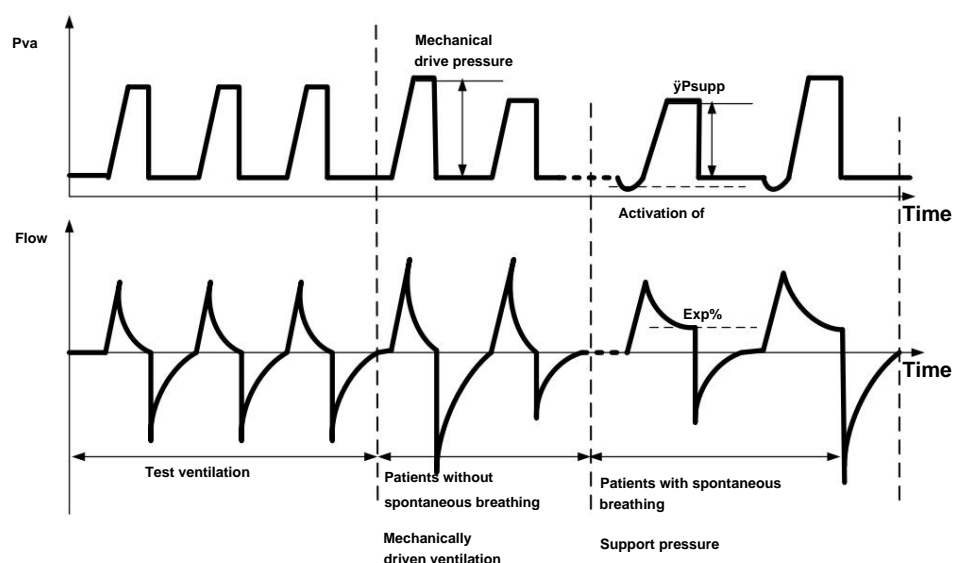


Figure 6-14 AMV

In AMV mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[VM%]:	Percentage of volume per minute
[PEEP]:	Positive end-expiratory pressure
[F-Trig] or [P-Trig]:	Inspiration activation level
[Exp%]:	expiration activation level
[Tpend]:	Pressure rise time
[IntelliCycle]:	Activate or deactivate the IntelliCycle function

Table 6-16 AMV

6.5.14

CPRV

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

CPRV refers to cardiopulmonary resuscitation ventilation, that is, a ventilation mode applied during the resuscitation procedure cardiopulmonary resuscitation (CPR) and can be rapidly activated during this procedure to provide the patient with mechanical ventilation at the appropriate time, while avoiding patient injury caused by frequent activations of ventilation and overventilation that occur during CPR.

CPRV mode is based on VA/C mode, with inspiration disabled, the inspired oxygen concentration (FiO₂) set to 100% by default, the I:E ratio set to 1:2 by default, and PEEP set to 0 cmH₂O by default. The user can initiate ventilation immediately after setting the patient type and IBW parameters. Volume-controlled ventilation is delivered at the preset rate and tidal volume. The user can also adjust the tidal volume and respiratory rate.

The following figure shows the typical waveforms in CPRV mode.

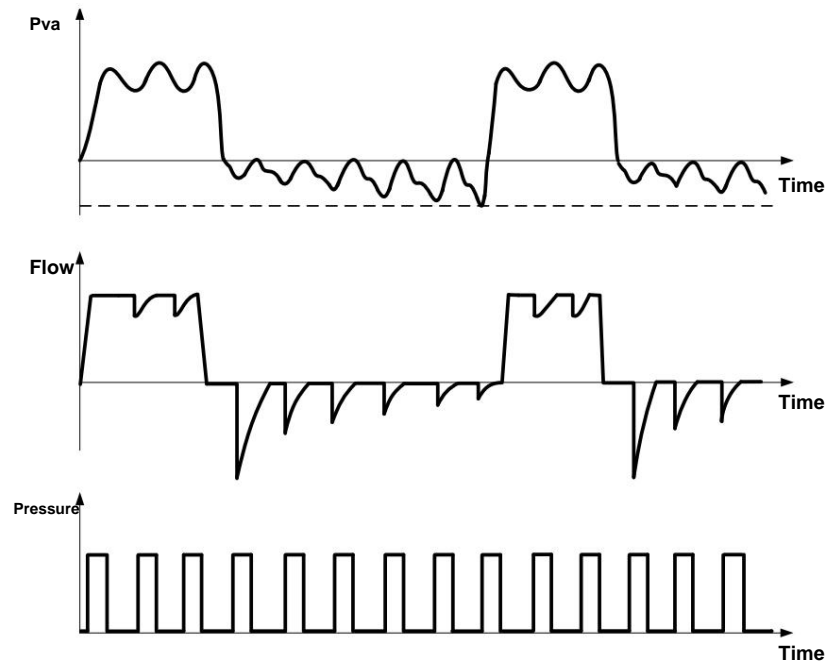


Figure 6-15 CPRV

In CPRV mode, the following basic ventilation parameters need to be adjusted:

[VC]:	Tidal volume
[F]:	Breathing rate
[O2%]:	Oxygen concentration
[T_{insp}] or [I:E]:	Inspiratory time or the relationship between inspiratory time and expiratory time
[PEEP]:	Positive end-expiratory pressure
[T_{pause}(%)] or [Flow]:	Percentage of inspiratory pause time or flow delivered to the patient during the inspiratory phase
[Compression warning]:	Compression warning switch
[Compression f]: [EtCO₂ reference line]:	The reference line for the upper and lower alarm limits of expiratory EtCO ₂ .

Table 6-17 CPRV

You can adjust the ventilator to the Resus view when rescuing the patient. The Resus view has the following features:

- Visualization of parameter values and waveforms related to the revival.
- Cardiopulmonary resuscitation (CPR) quality monitoring (available for the BeneVision N1 patient monitor equipped with Mindary SpO₂).

The Resus view is designed for adult patients only, not for pediatric or neonatal patients. Select the **[CPRV] button**, configure the basic ventilation parameters, and then click **[OK]** to enter the Resus view.

WARNING: In Resus view, all physiological alarms and some technical alarms are deactivated.

WARNING: Leave Resus's sight as soon as resuscitation is complete to resume normal patient monitoring.

After entering Resus view, the ventilator can monitor the Cardiopulmonary Resuscitation Quality Index (CQI). The CQI function is based on SpO₂ monitoring. The CQI monitoring unit obtains the pulse signal from the patient's peripheral blood vessel via the SpO₂ sensor, generates the plethysmographic waveform, calculates the CQI through post-analysis, and provides the CQI trend.

The CQI function is intended to assess the effect of CPR in adult patients. The CQI should be used in conjunction with the patient's medical history, the cause of the heart attack, other diagnostic findings, and clinical judgment.

CQI monitoring is intended for adult patients suffering a myocardial infarction who require cardiopulmonary resuscitation (CPR). CQI monitoring is contraindicated for patients unfit for SpO₂ monitoring.

For patients suffering from the following condition, CQI monitoring should be used with caution.

- Fingertip defect
- Dyes at the measurement site, such as methylene blue, indigo carmine, enamel of nails, etc.
- Arterial blood flow too low to be measured due to a drug vasoconstrictor or Raynaud's phenomenon, etc.
- Severe anemia
- Elevated levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb)

The physician must make a judgment in conjunction with the patient's clinical signs and symptoms.

CAUTION: Use the recommended SpO₂ sensor and apply it in a suitable place.

CAUTION: Avoid moving the measurement location when using the SpO₂ sensor .

CAUTION: Position the SpO₂ sensor correctly. If the sensor

The SpO₂ sensor is incorrectly positioned or an incorrect SpO₂ sensor is being used.
Incorrect, an erroneous CQI could occur. For more information, see 9.6 Measurement Limitations.

NOTE: A license is required for the CQI function.

The CQI monitoring displays the compression rate, CQI value, and trend. Click on the CQI monitoring parameters area to access the **[Demo CPR]** interface to view the CQI trend and the definition of high-quality or low-quality CPR. A CQI value above 60% indicates good peripheral circulation and CPR quality; a CQI value below 60% indicates poor peripheral circulation and CPR quality.

6.5.15nCPAP

nCPAP is nasal continuous positive airway pressure ventilation. The nCPAP mode should only be used with neonates and is only available in [unclear - possibly "infant hospitals"].

NIV mode. Airway pressure is maintained at the pressure level

Positive pressure is set by the user throughout the ventilation cycle. The patient breathes spontaneously and determines their own respiratory rate, tidal volume, and breathing time.

The following figure shows the typical waveforms in nCPAP mode.

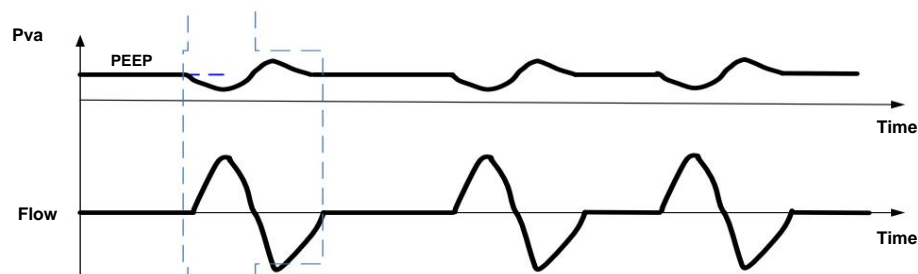


Figure 6-16 nCPAP

In nCPAP mode, the following basic ventilation parameters need to be adjusted:

[O2%]:	Oxygen concentration
[PEEP]:	Positive end-expiratory pressure
[\dot{y} PmanInsp]:	Inspiratory pressure of the manual breathing cycle
[TmanInsp]:	Inspiration time of the manual breathing cycle

Table 6-18 nCPAP

6.5.16 Breath-hold ventilation

Apnea ventilation mode is a backup ventilation mode that activates when the ventilator detects patient apnea in CPAP/PSV, VS, V-SIMV, P-SIMV, PRVC-SIMV, DuoLevel, and APRV modes. Ventilation can only be exited in

Apnea in the following circumstances: when the patient's spontaneous breathing is detected twice consecutively, the ventilation mode is switched on or the apnea ventilation is disconnected (in SIMV modes).

This ventilator has two apnea ventilation modes: volume-controlled apnea ventilation and pressure-controlled apnea ventilation.

Volume-controlled apnea and pressure-controlled apnea ventilation are

Compatible with non-invasive ventilation. During non-invasive ventilation, only pressure-controlled apnea ventilation is compatible.

In volume-controlled apnea ventilation, tidal volume, respiratory rate, and inspiratory time in the apnea ventilation cycle can

Set to apnea-compatible ventilation mode. After initiating ventilation

In apnea, the ventilator begins ventilation in VA/C mode with the tidal volume, breathing rate, and inspiration time set in the apnea ventilation cycle (the values of other setting parameters are not modified).

In pressure-controlled apnea ventilation, the inspiratory pressure, respiratory rate, and inspiratory time in the apnea ventilation cycle can

Set to apnea-compatible ventilation mode. After initiating ventilation

In apnea, the ventilator begins PA/C ventilation with the inspiratory pressure, breathing rate, and inspiratory time set in the apnea ventilation cycle (the values of other setting parameters are not modified).

CAUTION: We suggest you start apnea ventilation in SIMV mode.

6.5.17

Oxygen therapy

Oxygen therapy is a method for increasing the concentration of oxygen in the airways at a normal pressure through simple tube connections. Oxygen therapy is a medical measure that can increase the concentration of oxygen in the alveolar gas and facilitate oxygen diffusion to increase PaO₂ and SpO₂ saturation and reduce or correct hypoxia by increasing the oxygen concentration of the inspired gas. Oxygen therapy is a method for preventing or treating hypoxia by providing an oxygen concentration higher than that of air.

WARNING: O₂ therapy can only be used in spontaneously breathing patients.

WARNING: During O₂ therapy , only O₂ concentration , FiO₂, O₂ flow , SpO₂ and pulse rate are monitored.

WARNING: During O₂ therapy , all physiological alarms are blocked, except for the O₂ concentration physiological alarms .

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

WARNING: Use an external SpO₂ monitoring system for patients dependent solely on an O₂ concentration

A major definite deterioration will not be recognized. Otherwise, a deterioration in the patient's condition will not be recognized.

WARNING: Use only oxygen masks or nasal cannulas for O₂ therapy. Do not use masks for non-invasive ventilation (NIV). The use of unsuitable masks may pose a risk to the patient.

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

6.5.17.1 Preparation for O₂ therapy

WARNING: Do not use antistatic or conductive masks, hoses, or tubing on patients. The use of such materials increases the risk of electric shock to the patient and the risk of release into oxygen-enriched atmospheres.

- Use of nasal cannula for O₂ therapy

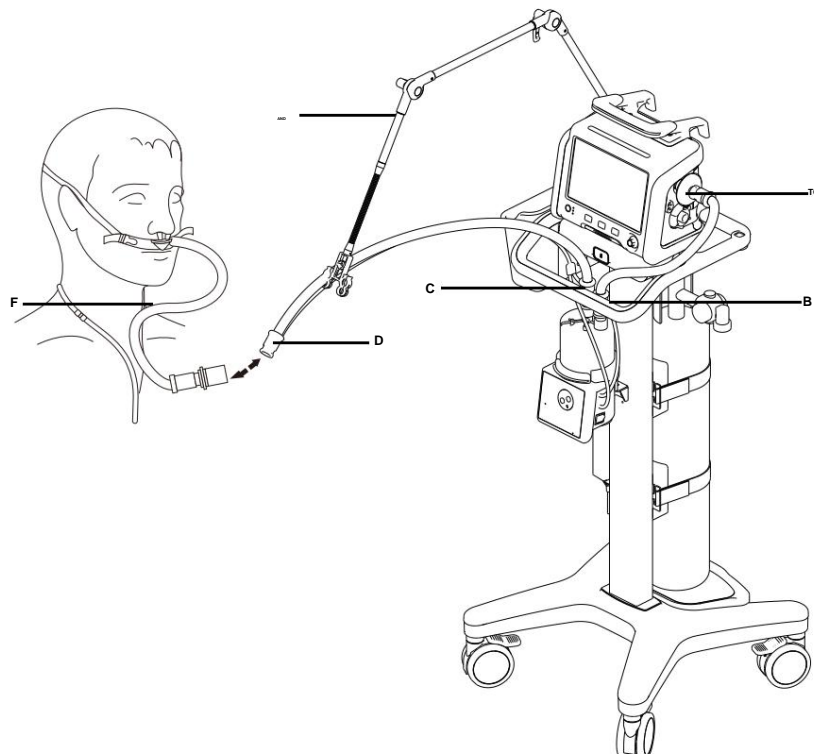


Figure 6-17 Use of nasal cannula for O₂ therapy

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

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

6.5.17.2 Switch to O₂ therapy

WARNING: The device should only be used under the supervision of qualified medical personnel, so that they can call for help immediately if any malfunction occurs or if the patient's spontaneous breathing is insufficient.

WARNING: This breather is a high-flow device and should only be connected to a piping installation that allows the required flow indicated at the terminal outlets, in order to avoid exceeding the flow capacities of the piping and minimize the risk of the breather interfering with the operation of adjacent equipment.

1. Select the **[O₂ Therapy]** key in the ventilation mode area. The screen displays the ventilation parameters that can be adjusted in ventilation mode.
2. Adjust **[Flow]** and **[O₂%]** to the appropriate values as needed.
3. Select **[Ok]** after adjusting the values.

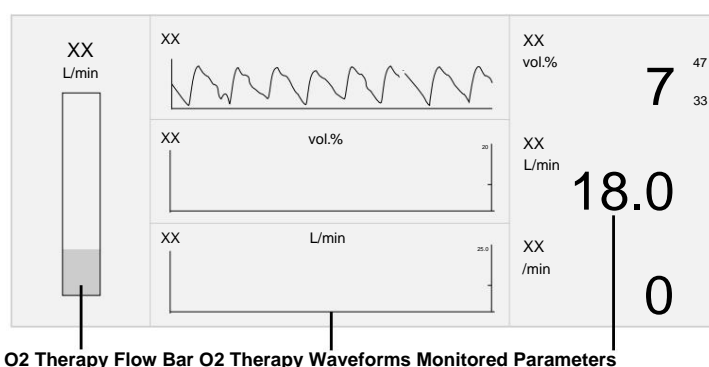





Figure 6-18 O₂ therapy screen

6.5.17.3 Stopwatch/ O₂ therapy time

Select the Stopwatch/ O₂ Therapy Time area in the upper left corner.

The stopwatch can be stopped by pressing the keys  . The time that

The display on the stopwatch can be reset to zero by selecting the key .

The timer can be started by entering the required time in minutes in **[O₂ Duration]**. When the time is up, the system emits a sound, but the oxygen supply is not interrupted.

6.5.17.4 Discontinuation of O₂ therapy

During O₂ therapy, select the **[En esp]** key to enter standby mode after confirmation or select other ventilation modes to turn off the O₂ therapy function.

6.6 Other ventilation settings

6.6.1

Sighing The

function of sighing can prevent lung collapse as it helps the alveoli to reopen.

The sigh pressure function can be activated in VA/C, PA/C, PRCV, V-SIMV, P-SIMV, PRVC-SIMV, and AMV modes. After activation of the sigh pressure function, PEEP (positive end-expiratory pressure) intermittently increases by the preset **[\dot{y} int.PEEP]**. **[Interval]** refers to the time interval between two sigh phases. **[Sigh cycles]** refers to the number of sigh cycles during each sigh phase.

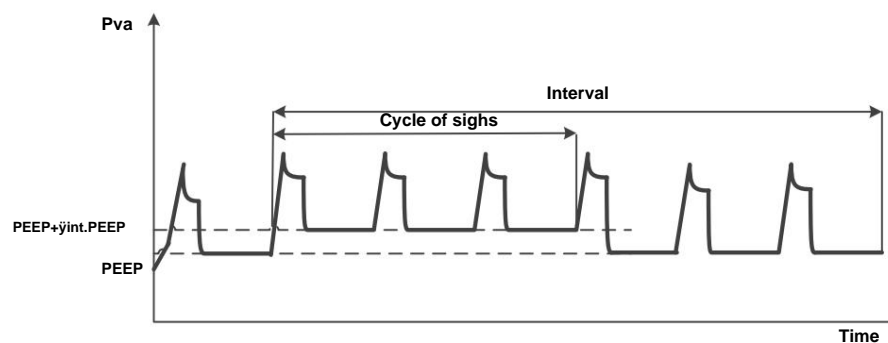


Figure 6-19 Sighs

The following parameters of the sigh function need to be set:

[Susp]:	Activate the sighing function
[Interval]:	Time interval between two phases of sighs
[Susp cycles]:	Cycles of sighs
[\dot{y}int.PEEP]:	Increased PEEP during the sigh cycle

Table 6-19 Sighs

6.6.2

Leakage compensation

Leaks in the breathing circuit and mask can cause the volume of gas delivered to the patient's lungs to be less than the set value. Leaks can also cause false inspiratory activation or make it difficult to switch between inspiration and expiration.

The ventilator includes a leak compensation function. The ventilator updates the leak amount at the end of each breathing cycle based on the difference between the inspired and expired tidal volumes, and this leak amount can be used to calculate the real-time leak flow rate for the next breathing cycle.

During the expiratory phase, the base flow is regulated to compensate for leaks and maintain the PEEP valve. To prevent false inspiratory activation, the flow activation mechanism relies on compensated flow. The maximum compensated flow Leakage rates are 65 l/min for adult patients, 45 l/min for pediatric patients, and 15 l/min for neonates.

In volume-controlled ventilation mode, the delivered gas volume is the sum of the V_t setting and the amount of leakage. Leak compensation in ventilation invasive: the upper limit of leakage compensation is 80% of the V_t setting.

In pressure-controlled ventilation mode, the ventilator regulates flow to compensate for leaks and maintain inspiratory pressure. However, the upper limit of the compensation is limited by the upper V_t limit. The ventilator does not increase flow and displays the alarm message **[Volume Limited]** when the flow exceeds the upper V_t limit (if you want to achieve maximum leak compensation, you can disable the upper V_t limit).

Leakage compensation

The ventilator determines the difference between the flow supplied during inspiration and the flow measured during expiration.

This difference provides a measure of the amount of leakage and the respirator displays it as the leak volume per minute MV_{leak} .

The ventilator can compensate for this loss in ventilation with volume control.

Example: tidal volume setting $V_t = 600$ ml, 10% leakage in the tube.

No leak compensation

The ventilator delivers 600 ml. This is referred to as the inspiratory tidal volume (V_{ti}). During inspiration, 60 ml are lost and 540 ml reach the lungs.

540 ml are exhaled, and again, 40 ml are lost due to leakage. A volume is measured. 500 ml flow on the expiratory side and is indicated as V_{te} .

With a ventilation rate of 10 breaths per minute, a

The minute volume is 6.0 L/min during inspiration and 5.0 L/min during expiration. The lung is ventilated with a mean ventilation (MV) of 5.4 L/min.

Without leak compensation, the set V_t determines the volume delivered by the ventilator.

With leak compensation

With automatic leak compensation, the ventilator delivers 660 ml based on the leak volume measured per minute, instead of the set 600 ml.

The lungs hold 600 ml and the inspiratory tidal volume shown TV is 600 ml.

The 500 ml volume measured on expiration is shown without compensation, even though leak compensation is activated.

The minute volume measured during expiration is 5.0 l/min and is also not compensated.

If this were not the case, expiratory leak compensation could inhibit the low minute volume alarm. The ventilator should always sound an alarm if the volume per minute is too low.

With leak compensation, the established TV determines the volume to be administered to the patient.

In this example, it has been simplified:

In fact, the calculated leak correction takes into account the existing pressures in the hose system. During inspiration, a greater percentage of volume is lost than during expiration because the pressure during inspiration is higher.

The leak volume per minute shown, MVleak, is based on the mean pressure Pmean.

The minute leak volume, MVleak, also includes inspiratory leaks. account. The sum of the minute volume MV + the minute leak volume value MVleak is therefore greater than the inspiratory minute volume administered to the patient.

Unlimited volume compensation is not appropriate.

The ventilator compensates for losses of up to 100% of tidal volume established.

Due to technical tolerances, a small leakage of volume per minute may be indicated even if the hose system is airtight.

6.6.3

IntelliCycle

IntelliCycle's synchronization enhancement technology promotes synchronization between the patient and the ventilator throughout the ventilation cycle (inspiratory activation, the increase in inspiratory pressure and the expiratory activation phase). This technology combines the characteristics of the patient's respiratory system to adjust the parameters of inspiration activation, expiration activation and Tslope, reducing the frequent adjustment of the ventilator settings during ventilation, relieving the workload of medical staff and improving synchronization between patient and ventilator.

Inspiratory triggering synchronization refers to the ventilator, which is in ventilation mode with [F-Trig]/[P-Trig], enabling triggering of inspiration and the start-up of IntelliCycle. It can trigger inspiration according to real-time monitoring of the patient's inspiratory effort by analyzing the waveform, which can reduce activation delay time, activation work, ineffective activation and automatic activation.

The adjustment of inspiratory pressure increase refers to the ventilator, which is in ventilation mode with [Tpend] and IntelliCycle startup, can set [Tpend] to the optimum value based on the patient's pressure waveforms to suit the patient's flow needs, which can accelerate the pressure increase or reduce excess pressure effectively to reduce the patient's work of breathing (WOBpat).

The synchronization of expiratory activation refers to the ventilator, which is located in In ventilation mode with [Exp%] and IntelliCycle startup, you can adjust the [Exp%] threshold to the optimum value based on the patient's flow and pressure waveforms to improve expiratory trigger synchrony and reduce premature or delayed termination time.

NOTE: **The IntelliCycle function is only suitable for adult and pediatric patients, excluding neonates.**

6.7 Alarm settings

Select the **[Alarm]** key on the main screen to define the ventilation alarm limit and the module alarm limit in the open menu. Additionally, You can set the alarm volume and view the most recent alarms. See **12.0 Alarms** for more details.

6.8 Start of ventilation

WARNING: Before administering ventilation to the patient, check that the oxygen concentration of the supplied gas matches the set value.

WARNING: Switch to manual ventilation immediately if the ventilator is not working properly and cannot continue to provide ventilation to the patient.

Select the **[Start Ventilation]** key in standby mode; the system will begin ventilating the patient according to the settings you have set.

6.9 Ventilation parameters

WARNING: As required by applicable regulations, oxygen concentration must be monitored when using this equipment with a patient. If the ventilator is not configured with this monitoring function or if this function is switched off, use a monitor that meets the requirements of ISO 80601-2-55 for monitoring oxygen concentration.

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

NOTE: The tidal volume and minute volume displayed on the ventilator and the associated calculated parameters are in BTPS mode.

ADJUSTMENT PARAMETER DESCRIPTION

VC	The volume of gas that the patient inhales or exhales each time during resting breathing.
Flow	Flow provided to the patient during the inspiration phase
O2%	The percentage of oxygen volume in the gas mixture supplied to the patient.
I:E	The relationship between inspiratory and expiratory time.

Table 6-20 Ventilation parameters

PEEP	Positive end-expiratory pressure.
Palt	Phigh is the level of high pressure at which the patient can breathe spontaneously, and it is an absolute value.
ÿPinsp	It is a relative pressure value related to PEEP.
Pbaj	Plow is the low pressure level at which the patient can breathe spontaneously.
ÿPaux	Pressure support level in pressure control mode. This value is related to PEEP or Plow.
Tpend	Controls pressure increase in pressure mode.
Tpause(%)	Percentage of time that the gas supply remains paused during the inspiratory time within the inspiratory phase.
VM%	It is used for calculating the target minute volume. The target minute volume is equal to the ideal minute volume x MV%.
F	The number of mechanically controlled breaths delivered to the patient in one minute.
fsimv	Mandatory breathing rate adjustment in SIMV mode.
Talt	Thigh is the time the ventilator will maintain the high pressure level.
Tbaj	Tlow is the time the ventilator will maintain the low pressure level.
Tinsp	Inspiration time in a respiratory cycle.
Ti max	Maximum inspiratory phase time
F-Trig/P-Trig	Pressure activation and flow activation included. When the activation level is detected, the ventilator enters the inspiratory phase. When F-Trig is active, in During the final stage of exhalation, the ventilator delivers a Baseflow is the flow from the inspiratory end to the expiratory end. Baseflow is essential for activation. of the flow. In non-invasive ventilation, the ventilator automatically adjusts the baseline flow from 0 L/min to a maximum flow to maintain PEEP and establish a reference for patient arousal. The maximum flow is 65 L/min. min for adult patients, 45 l/min for pediatric patients and 15 l/min for neonates. In invasive ventilation, the ventilator automatically adjusts the baseline flow of 3 L/min to a maximum flow to maintain PEEP and establish a reference for patient arousal. The maximum flow is 20 L/min.
Exp%	Inspiratory termination level. The ventilator switches to the expiratory phase when the inspiratory flow decreases to the peak flow*Exp%.

Table 6-20 Ventilation parameters

Assist	It is used to activate or deactivate assisted activation. When this function is activated, the patient can activate mechanical ventilation at the end of expiration.
Vent apnea	Activates or deactivates the apnea ventilation function.
ÿPapnea	It is the inspiratory pressure during ventilation in Apnea occurs when the pressure mode for apnea ventilation is selected. It is a value related to PEEP or Plow.
breath-holding	Adjusting the breathing rate in apnea ventilation mode.
Capnea	It is the tidal volume delivered during apnea ventilation when the volume mode for apnea ventilation has been selected.
Tinsp apnea	Inspiration time set in apnea ventilation mode.
ÿPmanInsp	Pressure value relative to PEEP or low pressure level in the inspiration phase of manually activated ventilator-controlled ventilation.
TmanInsp	Duration of the inspiration phase during ventilation controlled by the manually activated respirator.
Susp	Activate or deactivate the sigh function.
Interval	It is the adjustment value of the time interval between two groups of sighing ventilation.
Suspended cycles	It is the adjustment value for the number of cycles of each group of sighing ventilation.
ÿint.PEEP	Intermittent increase of PEEP, added during the sigh cycle.
Patient size	Choose between adult, pediatric, and infant.
IBW	It is used to calculate the ideal minute volume for the patient.
Compression Notice	Compression warning switch.
Comp. f	The number of compressions in one minute.
IntelliCycle	Activate or deactivate the IntelliCycle function
PARAMETER MONITORED	DESCRIPTION
Peak	The maximum pressure value in a respiratory cycle.
Pmest	Airway pressure during the inspiratory pause.
Pmed	The average pressure value in a respiratory cycle.
PEEP	Positive end-expiratory pressure.
VCi	The current volume inspired by a cycle.
VCE	The tidal volume expired in one cycle.
VCE esp	Spontaneous expired tidal volume in one cycle.

Table 6-20 Ventilation parameters

VCe/IBW	The tidal volume supplied in relation to ideal body weight.
MVe	The cumulative expiratory tidal volume in one minute.
MVi	Cumulative inspiratory tidal volume in one minute.
VMesp	The spontaneous expired tidal volume accumulated in one minute.
VMfuga	The accumulated leak (inspiratory volume minus volume expiratory) in one minute.
% drain	Percentage of gas leakage volume of the total respirator volume.
I:E	Relationship between inspiration time and expiration time in a cycle.
Tinsp	Duration of the inspiratory phase.
total	The cumulative number of breaths in one minute.
fmand.	The cumulative number of mechanical breaths in a minute.
fesp	The cumulative number of spontaneous breaths in a minute.
Ri	Inspiratory resistance encountered by gas as it flows through the airways during breathing.
Re	Expiratory resistance encountered by gas as it flows through the airways during breathing.
Cstat	Static compliance of the respiratory system: the ease with which the patient's lungs fill during mechanical ventilation.
Cdin	Dynamic compliance of the respiratory system: the ease with which the patient's lungs fill during mechanical ventilation. It is calculated during the inspiratory phase.
RSBI	Rapid and shallow breathing index: ratio between fspn and TVe spn (measured in liters).
WOB	Respiratory work: work required to deliver a determined volume of gas to the patient's lungs in one cycle.
RCesp	Patient expiratory time constant: resistance multiplied by distensibility.
P0.1	Occlusion pressure drops in the first 100 ms when the patient begins to breathe spontaneously.
PEEPi	Intrinsic positive end-expiratory pressure (the PEEPi value shown does not include PEEP).
PEEPtot	Total PEEP.
FiO2	The percentage of oxygen in the patient's inspired gas.
EtCO2	The concentration of CO2 measured at the end of expiration.

Table 6-20 Ventilation parameters

VDaw	Dead space of the airways.
VDaw/VCe	Relationship between airway dead space and tidal volume.
Vtalv	Alveolar current ventilation.
VMalv	Alveolar ventilation per minute.
pendCO2	Upward slope of CO2.
VeCO2	Volume of CO2 exhaled.
ViCO2	Volume of inspired CO2 .
VMCO2	Volume per minute of carbon dioxide
SpO2	Oxygen saturation (SpO2)
FP	Pulse rate
IP	Perfusion index
Power	The driving pressure exerted on the respiratory system during mechanical ventilation is the result of Pplat minus PEEP.
MPrs	The mechanical energy of the respiratory system is the energy exerted by the respirator on the respiratory system in one minute.

Table 6-20 Ventilation parameters

6.10 Enter standby state

If the BeneVision N1 patient monitor is not connected to the ventilator, select the **[On]** key and access the On Hold screen after confirmation.


When the BeneVision N1 patient monitor is connected to the ventilator, select the **[En esp]** key to perform the following operations:

- Select **[Stop Monitor]** to enter monitor standby mode.
- Select **[Stop Respirator]** to enter standby mode of the respirator.
- Select **[Stop All]** to enter standby mode for the monitor and the respirator.

WARNING: To avoid possible injury to the patient due to lack of assisted ventilation, ensure that an alternative means of ventilation is available before accessing the Standby mode. You must confirm that no patient is connected to the ventilator before entering standby mode.

WARNING: To avoid possible injury to the patient or damage to the breathing circuit due to gas overheating, turn off the humidifier when entering standby mode.

6.11 Turn off the system

Press the key in  standby mode to disconnect the system.

In non-standby mode, pressing the key will prompt the system to **[Enter Standby mode to exit the system.]**. Select **[OK]**; the system will remain in non-standby mode. Select the **[Standby]** key to access the standby interface after confirmation. Then, select the key in standby mode to



disconnect the system.

7.0

Neonatal ventilation

Safety Information.....	7-2
Connecting the Patient Tube to the Flow Sensor	7-3
Starting Ventilation.....	7-3
Backup ventilation.....	7-3
Adjusting the monitoring switch

7.1 Security information

WARNING: Inspect the neonatal flow sensor before use. Do not use the neonatal flow sensor if the sensor body, tubing, or connector is damaged or obstructed.

WARNING: Do not use the neonatal flow sensor if its tubing is kinked.

WARNING: Before using the neonatal flow sensor for ventilation, perform a system check after configuring all necessary ventilation components. Configuration includes the neonatal tubing, the neonatal flow sensor, and any necessary patient circuit fittings. If a fault is detected in the neonatal flow sensor during the system check, inspect the patient circuit and the neonatal flow sensor for leaks or blockages. If necessary, replace the neonatal flow sensor.

WARNING: After performing the system check, do not add or remove any accessories from the circuit so as not to alter the distensibility and resistance of the system.

WARNING: If an error occurs in the neonatal flow sensor, stop using it until it has been corrected.

WARNING: The neonatal flow sensor measures gas flow from the side where the patient's Y-piece is located. However, the actual flow delivered to the patient is affected by system leaks between the patient and the neonatal flow sensor.

WARNING: Install the neonatal flow sensor according to the instructions provided in this manual.

WARNING: Do not place the neonatal flow sensor in a position where the tubing or wires can become tangled, knotted, or easily disconnected. Doing so could result in hypercapnia or hypoxemia.

WARNING: Do not apply pressure to the neonatal flow sensor by pulling on its tubing or twisting it. Doing so increases the risk of it becoming disconnected or disassembled.

WARNING: Do not install the neonatal flow sensor in the patient's tubing if the sensor is not connected to the corresponding respirator connector.

WARNING: Excessive moisture in the neonatal flow sensor tubing
This can affect the accuracy of measurements. Periodically check the tube and sensor to prevent excessive moisture or the accumulation of secretions.

WARNING: Install the neonatal flow sensor according to the instructions provided in this manual. Incorrect sensor installation will result in misinterpretation of the data or incorrect ventilator settings. Reusing the disposable neonatal flow sensor may result in cross-contamination. The neonatal flow sensor is disposable and cannot be reused.

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

NOTE: In non-invasive ventilation, the neonatal flow sensor is deactivated.

7.2 Connecting the patient tube to the flow sensor

See section 3.8 Patient Tube Installation.

7.3 Start of ventilation

WARNING: Before administering ventilation to the patient, check that the oxygen concentration of the supplied gas matches the set value.

WARNING: Switch to manual ventilation immediately if the respirator is not functioning properly and cannot continue to provide ventilation to the patient.

1. For patient information settings, see 6.3 Patient Management patient information.
2. For ventilation type settings, see 6.4 Ventilation Type.
3. For ventilation mode settings, see 6.5 Ventilation Mode.
4. For alarm settings, see 12.0 Alarms.
5. Select the **[Start ventilation]** key in standby mode; the system will begin ventilating the patient according to the established settings.

7.4 Backup ventilation

If the neonatal flow sensor fails, the ventilator switches to standby ventilation mode if the current ventilation mode is VA/C, PRVC, PRVC-SIMV, V-SIMV, or VS. During standby ventilation, the user must take timely corrective action, including replacing the neonatal flow sensor or using external flow monitoring.

During standby ventilation, the ventilator operates in pressure mode with an delivered inspiratory pressure equal to PEEP + 15 cmH₂O. Other ventilation parameters are identical to those of the original ventilation mode.

When the neonatal flow sensor returns to normal, the ventilator automatically returns to the original ventilation mode.

7.5 Adjusting the monitoring switch

1. Select **[Menu]** ÿ **[Settings]** ÿ **[New Module]**.
2. Set **[Monitor]** to (activated) or (deactivated).

7.6 Resetting the neonatal flow sensor

Zero the neonatal flow sensor when the measured value shows a large Deviation. Zeroing can be performed both in standby mode and during the ventilation process. See section **14.3 Pressure and Flow Zeroing** for zeroing methods.

8.0

Carbon dioxide (CO₂) control

Introduction.....	8-2
Sideflow CO ₂ Module.....	8-5
Direct flow CO ₂ module	8-9
CO ₂ Troubleshooting	8-13

8.1 Introduction

CO₂ monitoring is a continuous, non-invasive technique for determining the concentration of CO₂ in a patient's airways by measuring the absorption of infrared (IR) light at a range of specific wavelengths.

It has its own absorption characteristics, and the amount of light that passes through the gas probe depends on the concentration of the CO₂ being measured. When a specific band of infrared light passes through respiratory gas samples, some of the infrared light will be absorbed by the CO₂ molecules. The amount of IR light transmitted after passing through the respiratory gas sample is measured by a photodetector. The CO₂ concentration is calculated from the amount of IR light measured.

The respiration frequency range of the sideflow CO₂ module is 0 to 150 min, and the data sampling frequency is 100 Hz. The highest values relative to the time-domain CO₂ waveform are used for the EtCO₂ concentration reading.

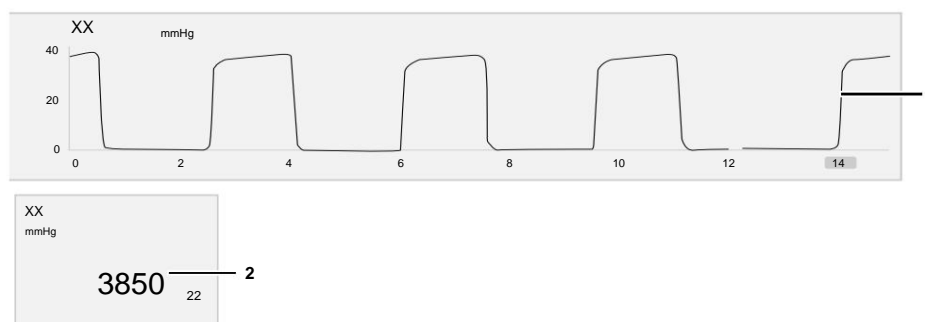
The breathing frequency range of the direct flow CO₂ module is 0 to 150 min, and the data sampling frequency is 100 Hz. The EtCO₂ concentration reading is taken from the peak of the exhaled CO₂ waveform (average selection: 1 breath, 10 seconds, 20 seconds).

Method used to determine the respiratory rate range: Use a valve to alternate between two sample gases at different frequencies (simulating the specified respiratory rate range). Record the EtCO₂ value at each frequency. By plotting the relationship between the end-expiratory EtCO₂ value and the respiratory rate, the respiratory rate range for EtCO₂ measurement accuracy that meets specifications can be determined.

The side-flow CO₂ module features automatic barometric pressure compensation (the system automatically measures the barometric pressure to which the device is exposed). However, the direct-flow CO₂ module does not include this feature. In the direct-flow CO₂ module, the default barometric pressure is 760 mmHg. The barometric pressure must be changed in

function of the actual situation.

CO₂ monitoring is used to monitor the patient's respiratory status and guide their ventilation. The measurement provides:



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

Regarding the direct flow CO₂ module, in addition to the aforementioned CO₂ and EtCO₂ waveform parameters, it also provides the function of pulmonary ventilation status.

1. V-CO₂ Curve

2. Monitored parameters:

- VDaw: airway dead space.
- VDaw/TVe: ratio between airway dead space and volume current.
- Vtalv: alveolar tidal ventilation.
- MValv: alveolar ventilation per minute.
- slopeCO₂: upward slope of CO₂.
- MVCO₂: volume per minute of carbon dioxide.
- VeCO₂: CO₂ expiratory volume.
- ViCO₂: inspiratory CO₂ volume.

Some monitored parameters of the direct flow CO₂ module may be inaccurate in the following situations. The affected parameters include VDaw, VDaw/TVe, Vtalv, MValv, slopeCO₂, MVCO₂, VeCO₂, and ViCO₂.

- System leaks
- The patient's ventilation is unstable.
- High-frequency ventilation (HFV)
- Respiratory rate greater than 35/min
- Neonatal patient
- Type of non-invasive ventilation
- Other circumstances that cause erroneous measurements of CO₂, O₂ and flow

In addition to measurement with the direct flow and lateral flow modules, CO₂ measurement can also be performed with the BeneVision N1 monitor configured with the CO₂ module.

WARNING: Ensure that the cardiopulmonary condition is stable for
to obtain **the most accurate CO₂ measurement** possible.

WARNING: CO₂ measurements are not compatible with patient transport using a fixed-wing or rotary-wing helicopter.

WARNING: When placing tubes such as those used for sample collection, avoid tangling the tube in the patient's throat to prevent apnea.

NOTE: CO₂ cannot be measured in an environment with aerosolized medication. Sampling and monitoring of the CO₂ module They are deactivated when the nebulizer function is started.

NOTE: As required by applicable international standards and regulations, oxygen concentration must be monitored when using the equipment with a patient. If the ventilator is not configured with this monitoring function, use a monitor that meets the requirements of the applicable international standards for oxygen concentration monitoring.

NOTE: When the measured RQ value is outside the range of 0.6–1.3, it is not a reliable reference value. Check for measurement error or if the patient is not in a stable condition.

NOTE: The CO₂ module has an automatic alarm suppression function. The CO₂ module only generates physiological alarms when respiratory waves are detected. When using the CO₂ module to monitor a patient, ensure that the device is properly connected to the patient.

As shown in the following figure, from left to right: sideflow CO₂ module, directflow CO₂ module and BeneVision N1 patient monitor.

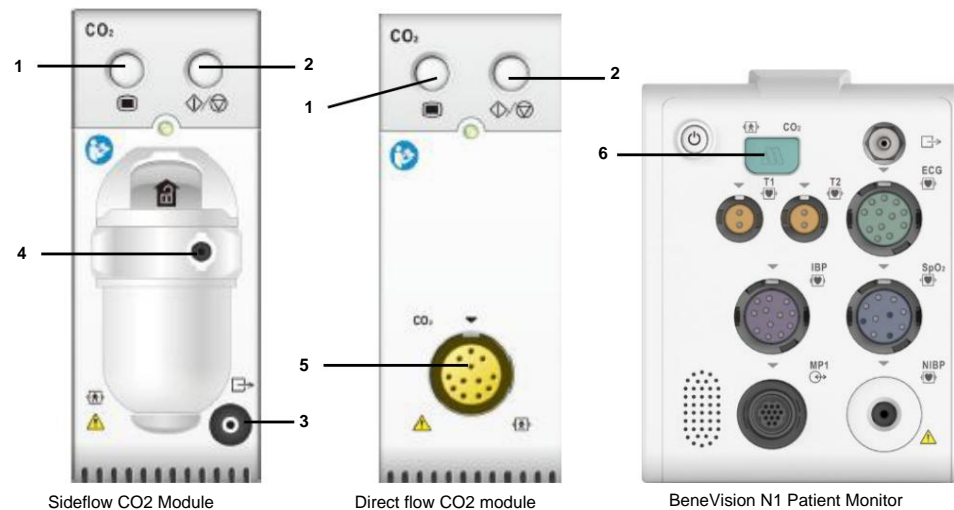


Figure 8-1 Modules

1. CO₂ settings menu
2. Measurement/Standby key
3. Gas outlet
4. CO₂ water collector intake
5. CO₂ sensor connector
6. CO₂ adapter connector

8.2 Sideflow CO₂ Module

NOTE: This section is applicable only if the ventilator is configured with a **side-flow CO₂ module**.

8.2.1 Performing the leak test

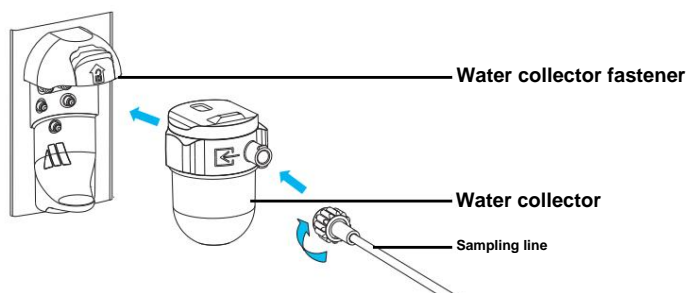
The purpose of the leak test is to check if the airway is in good condition Status. When using the side-flow CO₂ module for CO₂ measurement, a CO₂ leak test must be performed before each measurement. The leak test steps are shown below:

1. Connect the measuring accessories.
2. Wait for the module to finish warming up, then bend the sampling line to block the airway. The alarm message **[CO₂ sampling line blocked]** will then appear on the screen.
3. Block the gas inlet for another minute.
4. Select **[Menu]** → **[System]** → **[Maintenance]** → Enter the password of the system.
5. Select the **[Module]** → **[CO₂]** tab.
6. Check the current flow and the alarm message.

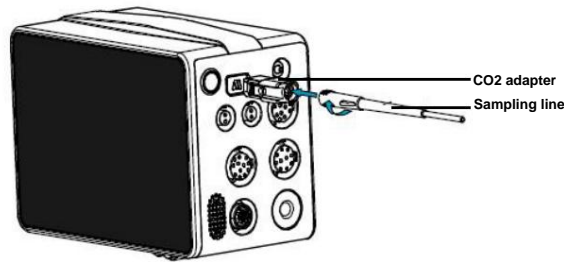
If the **current flow rate** is less than 10 ml/min and the alarm message **[CO₂ sample line blocked]** persists, the module is not leaking. If the alarm message **[CO₂ sample line blocked]** disappears, or the flow rate is greater than or equal to 10 ml/min, the module is leaking. In this case, contact service personnel for assistance.

8.2.2 Preparation for measurement

1. Select the appropriate gas sampling line and water collector according to the patient category.
2. Connect the gas sampling line.
 - When using the water collector for measurement, install the water collector in the water collector holder, connect one end of the sampling line to the water collector and the other end to the patient.



- When using the BeneVision N1 patient monitor for measurement, connect one end of the sampling line to the CO₂ adapter and the other end to the patient.



3. Connect an exhaust pipe to the module's gas outlet to discharge the gas to waste gas elimination system.
4. By default, the CO2 module is in measurement mode.
When the CO2 module is connected, the message **[Start CO2]** appears, and the measurement can begin.

NOTE: To prolong the life of the water collector and CO2 module, disconnect the water collector and deactivate CO2 monitoring, when CO2 monitoring is not required.

NOTE: It takes approximately 2 minutes from when the ventilator is switched on until the sideflow CO2 monitoring performance specified in section B.10 of this manual is achieved .

NOTE: Lateral flow CO2 measurement , with the specified accessories, can be used on intubated and non-intubated adult, pediatric, and neonatal patients. A respiratory gas sample is taken from the patient's breathing circuit using an airway adapter and a gas sampling line.

NOTE: The sampling gas taken by the respirator's side-flow CO2 module is a mixture of air and oxygen, and can be released through the gas outlet into the operating environment.

NOTE: When it comes to the water collector and sampling line, the relevant biological hazard regulations must be followed.

NOTE: Do not block this connector when sampling gas is being emitted from the CO2 module gas outlet.

CAUTION: The water collector gathers condensation droplets from the sampling line, preventing them from entering the module. If the collected water reaches a certain amount, it must be emptied to prevent airway obstruction. Dispose of the collected fluids according to hospital or local regulations.

CAUTION: The water collector has a filter that prevents bacteria, steam, and secretions from entering the module. After long-term use, dust or other substances may affect the filter's performance or even block the airways. In this case, replace the water collector. It is recommended to replace the water collector once a month. Alternatively, replace the water collector if it is found to be leaking, damaged, or contaminated.

CAUTION: When using the CO2 adapter with the BeneVision N1 patient monitor, ensure compatibility between the CO2 adapter and the sampling line before use. The CO2 adapter is designed to connect to an Oridion CO2 sampling line .

8.2.3 CO2 adjustments



8.2.3.1 Establishing CO2 settings

When **[Monitor]** is set to (on), the CO2 module is put into Operation. The ventilator displays CO2 parameters and waveforms and generates technical and physiological alarms related to the CO2 module. When the **[Monitor]** function is set to (off), the CO2 module enters standby mode. The ventilator does not display CO2 parameters and waveforms.

nor does it generate physiological alarms related to the CO2 module.

The CO2 module's standby mode is related to the ventilator's standby mode:

- If the ventilator enters standby mode, the CO2 module also does.
- If the ventilator exits standby mode, the CO2 module resumes the CO2 operating mode it was in before standby mode.
- The fact that the CO2 module enters or exits standby mode does not affect in no way to the respirator.

To manually enter or exit standby mode, select the **[Menu]** key $\dot{\text{y}}$ **[Adjust]** $\dot{\text{y}}$ **[CO2]** and adjust **[Monitor]** to  (deactivated) or  (activated).

In standby mode, the functional components of the CO2 module, such as the gas pump and infrared source, are automatically deactivated to prolong the module's lifespan.

8.2.3.2 BTPS Compensation Adjustment

CO2 measurement provides:

1. ATPD: Ambient temperature and pressure, dry gas
2. BTPS: body temperature with saturated pressure

CO2 readings will be relatively higher in the presence of moisture. Therefore, the module uses different formulas in each situation to calculate the partial presence of CO2:

$$\text{ATPD: } P_{\text{CO}_2} (\text{mmHg}) \dot{\text{y}} (\text{CO}_2 \text{ vol} \dot{\text{y}}) \dot{\text{y}} P_{\text{amb}} / 100$$

$$\text{BTPS: } P_{\text{CO}_2} (\text{mmHg}) \dot{\text{y}} \text{CO}_2 (\text{vol} \dot{\text{y}}) \dot{\text{y}} (P_{\text{amb}} \dot{\text{y}} 47) / 100$$

P_{CO_2} Where, = partial pressure, $\text{vol} \dot{\text{y}}$ = CO2 concentration, = pressure P_{amb} environmental and the unit is mmHg.

In the case of the CO2 module, BTPS compensation is activated or deactivated in depending on the actual situation. The adjustment method is as follows:

1. Select the **[Menu]** key $\dot{\text{y}}$ **[Adjust]** $\dot{\text{y}}$ **[CO2]**.
2. Adjust **[BTPS Compensation]** to  (activated) or  (disabled) in BTPS or ATPD.

8.2.3.3 Zero adjustment for 30 seconds from zeroing

1. Select the **[Menu]** key \rightarrow **[Adjust]** \rightarrow **[CO2]**.
2. Set **[Zero for 30 seconds from reset]** to **[ON]** or **[OFF]**. When the function is activated, the related parameters of the CO2 module will not be valid during the initial 30 seconds of the CO2 module reset . When the function is deactivated, the related parameters of the CO2 module will be normal in the initial 30 seconds of the CO2 module reset .

8.2.3.4 Unit adjustment

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

8.2.3.5 Waveform adjustment

To adjust the waveform, refer to **5.4.4 Adjusting the screen layout**.

8.2.4 Measurement limitations

The accuracy of measurements may decrease due to:

- A leak or an internal leak of the sampling gas.
- Mechanical shocks.
- Cyclic pressure greater than 10 kPa (100 cmH2O)
- Another source of interference (if available)

The accuracy of the measurement can be affected by the breathing rate and the I/E ratio as follows:

- When EtCO2 is within specifications for a respiratory rate of ≥ 60 /min and an I/E ratio $\geq 1:1$, the accuracy of the EtCO2 measurement meets the defined specifications.
- When EtCO2 is within specifications for a respiratory rate of ≥ 30 /min and an I/E ratio $\geq 2:1$, the accuracy of the EtCO2 measurement meets the defined specifications.

8.2.5 Troubleshooting

If the CO2 module sampling system is not working correctly, check that the sampling line is not kinked. If it is not, remove the sampling line from the water collector. Then, if a message appears on the screen indicating a

A malfunctioning airway indicates that the water collector is clogged. In this case, the water collector must be replaced.

If this warning message does not appear, it means the sampling line is clogged. The sampling line must be replaced.

8.2.6 Sensor zeroing

The purpose of zeroing the sensor is to eliminate the effect of baseline deviation on the readings during measurement, in order to ensure accurate measurement.

In the case of the CO2 module, a zero calibration is performed automatically. When the CO2 module is zeroed, it stops measuring CO2 and a message appears in the CO2 parameter area. If necessary, the user can also perform a manual zeroing: select **[Menu]** **[Calibration]** **[CO2 in maintenance]** and then select **[Zero CO2 in operation]**. It is not necessary to disconnect the sensor from the breathing system when performing a zeroing.

Once the zero calibration is complete, the CO2 module reacquires CO2 readings. During the reacquisition period, "---" appears in the CO2 numerical area. Valid data will reappear 30 seconds after zero calibration begins.

Automatic zero calibration will not start under the following conditions:

- The physiological alarms related to CO2 are active.
- The apnea alarm is activated.
- No breathing has been detected for more than 30 seconds.

NOTE: During automatic zeroing, the CO2 module temporarily stops measuring.

8.2.7 Sensor calibration

For the side-flow CO2 module, calibration must be performed annually or whenever the measured value deviates significantly. For further information, see section **14.0 Maintenance**.

NOTE: When calibrating the CO2 module, connect the calibration gas to the waste gas disposal system.

8.3 Direct flow CO2 module

NOTE: This section is applicable only if the respirator is configured with a **direct flow CO2 module**.

8.3.1 Preparation for measurement

1. Connect the sensor to the CO2 module.
2. By default, the direct flow CO2 module is in measurement mode. When the CO2 module is inserted, the warning message **[Heat CO2 sensor]** appears on the screen.
3. Once the warm-up is complete, connect the sensor to the IV adapter respiratory.
4. Perform a zero calibration as explained in **8.3.4 Sensor Zeroing**.
5. Once the zero calibration is complete, connect the airways as shown sample below.

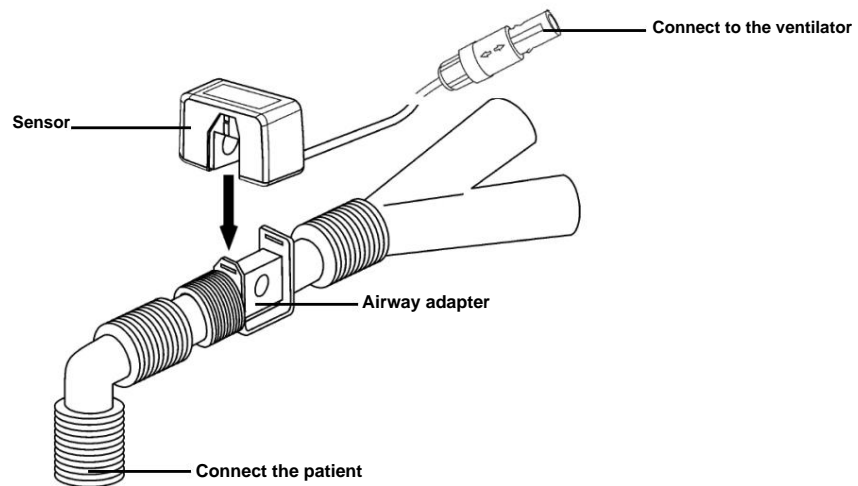


Figure 8-3 Airway Connection

6. Check for airway leaks and take measurements of CO2.

WARNING: Always check the integrity of the breathing tube of the Patient verifying that the CO2 waveform displayed on the ventilator screen is correct after inserting the airway adapter.

WARNING: If the CO2 waveform is abnormal, examine the CO2 airway adapter . Replace it if necessary.

WARNING: Do not use the CO2 sensor if it appears damaged or is not functioning properly. Contact Customer Service.

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

WARNING: Examine the CO2 sensor periodically for excess moisture and buildup of secretions.

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

CAUTION: To prevent premature failure of the CO2 sensor, the CO2 monitoring function is deactivated from the moment the nebulization function is activated until one minute after nebulization is complete. The medication

Its viscosity may contaminate the airway adapter window. It is recommended to remove the CO2 sensor and airway adapter from the pneumatic circuit.

NOTE: Always place the sensor on the adapter in a vertical position to prevent fluid accumulation in the adapter's windows. High concentrations of fluid in these areas will obstruct gas analysis.

NOTE: Approximately 2.5 minutes should elapse from when the CO2 measurement is switched on until the direct flow CO2 monitoring performance specified in section B.10 of this manual is achieved.


NOTE: Direct flow CO2 measurement can be used, with the specified accessories, with intubated and non-intubated adult, pediatric and neonatal patients.

NOTE: Make sure to adjust the barometric pressure correctly before using the direct flow CO2 module. If the settings are incorrect, the CO2 reading will be inaccurate.

NOTE: To avoid dead spaces, place the sensor and airway adapter as close to the patient as possible.

8.3.2 CO2 adjustments



8.3.2.1 Establishing CO2 settings

When **[Monitor]** is set to (on), the CO2 module is put into Operation. The ventilator displays CO2 parameters and waveforms and generates technical and physiological alarms related to the CO2 module. When the **[Monitor]** function is set to standby mode, the ventilator does not  (deactivated), the CO2 module enters the display CO2 parameters and waveforms.

nor does it generate physiological alarms related to the CO2 module.

The CO2 module's standby mode is related to the ventilator's standby mode:

- If the ventilator enters standby mode, the CO2 module also does.
- If the ventilator exits standby mode, the CO2 module resumes the CO2 operating mode it was in before standby mode.
- The fact that the CO2 module enters or exits standby mode does not affect in no way to the respirator.

To manually enter or exit standby mode, select the **[Menu]** key \ddot{y} **[Adjust]** \ddot{y} **[CO2]** and adjust **[Monitor]** to  (deactivated) or  (activated).

During standby mode, the functional components of the CO2 module, such as the infrared source, are automatically deactivated to prolong the module's lifespan.

8.3.2.2 Zero adjustment for 30 seconds from zeroing

1. Select the **[Menu]** key \ddot{y} **[Adjust]** \ddot{y} **[CO2]**.
2. Set **[Zero for 30 seconds from reset]** to **[ON]** or **[OFF]**. When the function is activated, the related parameters of the CO2 module will not be valid during the initial 30 seconds of the CO2 module reset. When the function is deactivated, the related parameters of the CO2 module will be normal in the initial 30 seconds of the CO2 module reset.

8.3.2.3 Unit adjustment

1. Select **[Menu]** \ddot{y} **[System]** \ddot{y} Enter system password \ddot{y} **[Set]**.
2. Setting **[Unit CO2]**: mmHg, kPa or vol.%

8.3.2.4 Waveform adjustment

To adjust the waveform, refer to **5.4.4 Adjusting the screen layout**.

8.3.3 Limitations in measurement

The accuracy of measurements may decrease due to:

- A leak or an internal leak of the sampling gas.
- Mechanical shocks.
- Cyclic pressure greater than 10 kPa (100 cmH2O)
- Another source of interference (if available)


8.3.4 Sensor zeroing

The purpose of zeroing the sensor is to eliminate the effect of baseline deviation on the readings during measurement, in order to ensure accurate measurement.

In the following situations, it is necessary to zero the sensor:

1. The adapter is changed.
2. Reconnect the sensor to the module.
3. If the sensor is not set to the optimal measurement mode, the ventilator
The warning message **[Zero CO2 required] is displayed**. In this case, check if the airway adapter is blocked. If a blockage is detected, clean or replace the adapter.

To reset the sensor, proceed as follows:

1. Connect the sensor to the CO2 module.
2. Select the **[Menu]** key \ddot{y} **[Adjust]** \ddot{y} **[CO2 Module]** and then adjust **[Monitor]** to  (activated).
3. Once warm-up is complete, connect the sensor to a clean, dry airway adapter. The adapter must be open to the air and isolated from sources of CO2, including the ventilator, the patient's breathing, and your own breathing.
4. Select the **[Menu]** \ddot{y} **[Calibration]** \ddot{y} **[CO2 in maintenance]** key and, Next, select the **[Start]** key corresponding to the CO2 reset on the right side of the screen. The screen displays **[P zero in CO2 exec]**.
5. A normal reset takes approximately 15 to 20 seconds. This message disappears once the reset is complete.

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

WARNING: Improper zeroing of the direct flow CO2 sensor may result in incorrect data display. During zeroing, the airway adapter and CO2 sensor must not be connected to the patient's tubing.

WARNING: Do not rely on readings during CO2 zeroing .

8.3.5 Sensor calibration

For the direct-flow CO2 module, calibration is not required. The system sends the altitude data to the direct-flow CO2 module for calibration compensation. Please contact Customer Support if calibration is necessary.

8.4 CO2 Troubleshooting

This section lists problems that may occur. If you experience problems using the equipment or accessories, consult the table below before requesting technical support. If the problem persists, contact service personnel.

8.4.1 Troubleshooting the side-flow CO2 module

PROBLEM	SOLUTION
EtCO2 measurements too low	<ol style="list-style-type: none"> 1. Ventilate the room if the ambient CO2 concentration is too high. 2. Check for leaks in the sampling line and the connectors. 3. Check the patient's condition.

Table 8-1 Troubleshooting the Side-Flow CO2 Module

8.4.2 Troubleshooting the Direct Flow CO2 Module

PROBLEM	SOLUTION
High initial value	<ol style="list-style-type: none"> 1. Check the patient's condition. 2. Check the sensor.

Table 8-2 Direct Flow CO2 Module Troubleshooting

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9.0

Pulse oxygen saturation (SpO₂) monitoring

Introduction.....	9-2
SpO ₂ Safety Information	9-3
Preparation for measurement.....	9-3
SpO ₂ Adjustment.....	9-4
PR Adjustment.....	9-5
Limitations in measurement	9-6
Troubleshooting SpO ₂ problems	9-7

9.1 Introduction

SpO2 monitoring is a non-invasive technique used to measure heart rate and blood oxygen levels based on the absorption of selected light waves. The light generated by the sensor passes through the tissue and is converted into electrical signals by the sensor's photodetector. The SpO2 module processes the electrical signal and displays the numerical values, waveform, and pulse rate.

This device has been calibrated to display functional oxygen saturation. You can use the BeneVision N1 patient monitor and SpO2 module to measure SpO2.

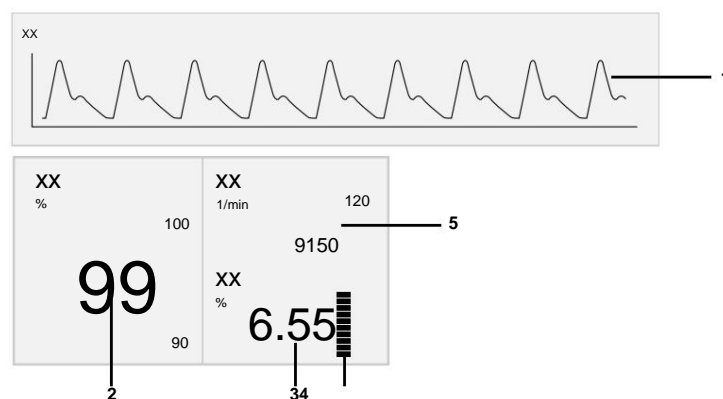


FIGURE 9-1 SpO2 Waveforms and Parameters

1. Plethysmographic waveform: visual indication of the patient's pulse. The shape of the waveform has not normalized.
2. Arterial blood oxygen saturation (SpO2): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
3. Perfusion Index (PI): This provides the numerical value of the pulsatile component of the measured signal originating from the arterial pulse. The PI is an indicator of pulse strength. You can also use this value to assess the quality of the SpO2 measurement. A value greater than 1 is optimal; a value between 0.3 and 1 is acceptable; a value less than 0.3 indicates low perfusion. Reposition the SpO2 sensor or place it in a more suitable location. If perfusion remains low, choose another method for measuring oxygen saturation, if possible.
4. Perfusion indicator: the pulsatile component of the measured signal originating from the arterial pulse.
5. Pulse rate (derived from the plethysmographic waveform): beats detected per minute.

NOTE: The Mindray SpO2 connector can only be connected to the Mindray SpO2 extension cable .

NOTE: A functional tester or SpO2 simulator cannot be used to evaluate the accuracy of an SpO2 module or SpO2 sensor.

NOTE: A functional tester or SpO2 simulator can be used to determine the accuracy of the pulse rate.

NOTE: The SpO2 simulator cannot be used to validate the accuracy of the oxygen saturation monitor and SpO2 sensor. The accuracy of the oxygen saturation monitor and SpO2 sensor must be validated with clinical data.

NOTE: Qualification and regulatory compliance tests must be performed in accordance with ISO 80601-2-61 on the respirator, SpO2 probe and probe extension cable to be used with the respirator.

9.2 SpO2 safety information

WARNING: If you observe a trend indicating deoxygenation of the patient, you should analyze blood samples with a blood gas analyzer to fully understand the patient's condition.

WARNING: Do not use the SpO2 monitor or sensors during an MRI scan or in an MRI environment. Induced current could cause burns.

WARNING: Prolonged continuous monitoring may increase the risk of unwanted changes in skin characteristics, such as irritation, redness, blisters, or burns.

Inspect the sensor application site every two hours and reposition the sensor if the skin quality changes. Change the application site every four hours. For neonates, patients with poor peripheral blood circulation, or sensitive skin, check the sensor application site more frequently.

WARNING: Setting alarm limits to extreme values can reduce the effectiveness of the alarm system. For example, a high oxygen level can predispose a premature infant to retrolental fibroplasia. Setting the SpO2 high alarm limit to 100% is equivalent to turning off the SpO2 alarm.

CAUTION: Use only the SpO2 sensors and cables specified in this Manual. Follow the instructions regarding the SpO2 sensors and heed all warnings and precautions.

9.3 Preparation for measurement

Prepare to monitor SpO2:

1. Select an appropriate sensor based on the module type, category, and patient type.
2. Clean the contact surface of the reusable sensor.
3. Remove nail polish from the application area, if necessary.
4. Place the sensor on the patient.

5. Select a suitable extension cable according to the connector type and plug the cable into the SpO2 connector.
6. Connect the sensor cable to the extension cable.

CAUTION: Select a sensor that matches the measurement site. If the sensor is too loose, light leakage may occur. If the sensor is too tight, venous pulse may occur, and the measurement value may be inaccurate.

CAUTION: When the ambient temperature is high, pay special attention. Pay attention to measurement sites with poor perfusion. Excessively high ambient temperatures can damage the sensor where it is worn for extended periods.

CAUTION: Do not place the SpO2 sensor on the same limb as a NIBP cuff, arterial catheter, or intravascular line.

CAUTION: For neonatal patients, ensure that the sensor and extension cable connectors are outside the isolation box. Moisture may cause inaccurate measurements.

9.4 SpO2 adjustment

9.4.1 SpO2 monitoring adjustment

Select the **[Menu]** $\bar{\bar{y}}$ **[Set]** $\bar{\bar{y}}$ **[SpO2 Sensor]** key , and then set **[Monitor]** to (on).

(deactivated) or

9.4.2

Sensitivity Adjustment: The SpO2 value

displayed on the ventilator screen is the average of the data collected over a specific time period. The sensitivity, from highest to lowest, indicates the average time, from short to long.

Select the **[Menu]** key $\bar{\bar{y}}$ **[Adjust]** $\bar{\bar{y}}$ **[SpO2 Sensor]** , and then set **[Sensitivity]** to **[High]**, **[Medium]** , or **[Low]**. If **[Sensitivity]** is set to **[High]**, the patient monitor is more sensitive to weak signals. If monitoring critically ill patients with very low pulse rates, **[High] is strongly recommended**. If monitoring non-critically ill patients who tend to move around a lot, noise or invalid signals may occur.

In this case, it is recommended that the sensitivity be **[Med]** or **[Low]**, so that they can to filter out interference caused by movement and thus ensure the stability of the measurement.

9.4.3 Adjusting the volume of the heartbeat

Select the **[Menu]** key $\bar{\bar{y}}$ **[Adjust]** $\bar{\bar{y}}$ **[SpO2 Module]**. Adjust the heartbeat volume by sliding the cursor on the screen. The heartbeat volume has 10 adjustment levels; the 10th It is the maximum volume.

9.4.4 Adjusting the sweep speed

Select the **[Menu]** $\bar{\bar{y}}$ **[Adjust]** $\bar{\bar{y}}$ **[SpO2 Module]** key to adjust **[Sweep Speed]** to **[12.5 mm/s]** or **[25 mm/s]**.

9.4.5 NIBP Simulation Adjustment

NIBP Simul can only be configured when the BeneVision N1 patient monitor is inserted into the ventilator. If NIBP and SpO2 are measured in the same limb of a
In patients with NIBP, **[simult. NIBP]** must be activated to ensure that physiological SpO2 alarms are not altered during NIBP measurement. If **[simult. NIBP]** is activated, the low perfusion caused by the NIBP measurement will result in an inaccurate SpO2 measurement and trigger a physiological SpO2 alarm during NIBP measurement.

Select the parameter area or the SpO2 waveform area to access **[SpO2] ÿ [Alarm]** , and then set **[simult. PANI]** to **[ON]** or **[OFF]**.

9.4.6 Show/Hide PI

You can configure whether to display PI only when the BeneVision N1 patient monitor is inserted into the ventilator. You can select the parameter area or the SpO2 waveform area to access **[SpO2] ÿ [Adjust]** and then turn **[Display PI]** on or off.

9.5 PR adjustment

PR can only be adjusted when the BeneVision N1 patient monitor is inserted into the ventilator.

9.5.1 QRS volume adjustment

When the alarm source is set to PR, the monitor emits a QRS sound.
function of pulse rate. To adjust the QRS volume, do the following:

Select the parameters area or the SpO2 waveform area and choose **[SpO2] ÿ [FP] ÿ [Adjust]**. Adjust **[QRS Volume]** to an appropriate value.

When valid SpO2 measured values are available , the system will adjust the tone according to the SpO2 value.

9.5.2 Adjustment of PR origin

The current valid pulse source is displayed in the PR parameters area. The pulse frequency of this pulse source has the following characteristics:

- The alarm is monitored by the system and provided as a source of effective alarm.
- It is stored in the monitor's database and can be reviewed in the graphical/tabular trends. In the graphical trends, the color of the PR curve matches that of the current PR source parameter.
- Sent to the CMS over the network (if one exists).

To configure the PR source, do the following:

Select the parameters area or the SpO2 waveform area, choose **[SpO2] ÿ [FP] ÿ [Adjust]**, select **[FP Source]** and then select a suitable PR source from the drop-down list box.

NOTE: The [PR Source] menu displays the currently available PR sources from top to bottom by priority. If you select [Auto], the system will automatically select the first option as the PR source. If the current PR source is unavailable, the system will automatically change [PR Source] to [Auto]. When you select [IBP], the system will automatically select the first pressure label as the PR source.

9.5.3 Show/Hide PR

You can configure whether to display PR in the SpO2 parameter area in the following steps:

Select the parameters area or the SpO2 waveform area to enter [SpO2] ÿ [PF] ÿ [Adjust]. Enable or disable [FP Display].

9.6 Limitations in measurement

If you are unsure of the accuracy of the measurement results, examine the patient's vital signs using other methods, and then the SpO2 monitor and sensor. During the measurement process, the following factors may affect the accuracy of the measurement:

- Physiological characteristics of the patient:
 - Cardiac arrest
 - Hypotension
 - Dark pigmented skin
 - Crash
 - Severe vasoconstriction
 - Hypothermia
 - Severe anemia
 - Ventricular septal defects (VSD)
 - Venous pulsations
 - Poor perfusion
- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Elevated bilirubin levels
- Vasospastic disease, such as Raynaud's disease, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell disease, etc.
- Hypocapnic or hypercapnic conditions
- Birthmarks, tattoos, skin discoloration, skin moisture, deformed or abnormal fingers, etc.

- Interfering substances:
 - Intravascular dyes (such as indocyanine green, methylene blue, indigo carmine, etc.)
 - Dyes applied to the area of measurement, such as nail polish.

- Environmental conditions:
 - Excessive ambient light
 - Electrosurgical equipment
 - Defibrillation (may cause an inaccurate reading for a short period of time)
 - Excessive patient/sensor movement
 - Electromagnetic field
 - Arterial catheters and intra-aortic balloon

- Others
 - Improper placement of the SpO2 sensor or use of an incorrect SpO2 sensor
 - Blood pressure cuff or measuring device on the same limb as the SpO2 sensor.

9.7 Troubleshooting SpO2

This section lists problems that may occur. If you experience problems using the equipment or accessories, consult the table below before requesting technical support. If the problem persists, contact service personnel.

PROBLEM	SOLUTION
Neither the numerical area nor the waveform area of SpO2 is visible in the main screen (BeneVision N1 used)	<ol style="list-style-type: none"> 1. Check that SpO2 is set to display in the [Screen Adjustment] menu. 2. Check that the SpO2 parameter switch is turned on. 3. Check that the SpO2 sensor cable and extension cable connections are tight. Replace the SpO2 sensor or extension cable if necessary.
It appears OFF in place of the numerical values and a straight line in the waveform area (SpO2 modulus used)	<ol style="list-style-type: none"> 1. Select [Menu] ÷ [Set] ÷ [SpO2 Sensor] to check if the SpO2 monitoring switch is turned on. 2. Check that the SpO2 sensor cable and extension cable connections are tight. Replace the SpO2 sensor or extension cable if necessary.

Table 9-1 SpO2 Troubleshooting

PROBLEM	SOLUTION
The hyphens appear in place of the numbers.	<ol style="list-style-type: none"> 1. Check that the SpO2 sensor cable and extension cable connections are tight. Replace the SpO2 sensor or extension cable if necessary. 2. Reconnect the SpO2 sensor if the alarm [SpO2 sensor off] appears. 3. Check the PI value. If the PI value is too low, adjust the SpO2 sensor, or apply the sensor to the site with the best perfusion. 4. Move the sensor to a place with less light or cover the sensor with a cloth if the alarm [SpO2 sensor desc] appears.
Low amplitude SpO2 signal (BeneVision N1 used)	<ol style="list-style-type: none"> 1. The SpO2 sensor and NIBP cuff are placed on the same limb. Change the monitoring site if necessary. 2. Check the PI value. If the PI value is too low, adjust the SpO2 sensor, or apply the sensor to the site with the best perfusion. 3. Check the sensor and its application location.
The SpO2 value is inaccurate	<ol style="list-style-type: none"> 1. Check the patient's vital signs. 2. Check for conditions that may cause inaccurate SpO2 readings. 3. Check that the ventilator, monitor, SpO2 module or MPM are working properly.

Table 9-1 SpO2 Troubleshooting

10.0

BeneVision N1 Patient Monitor

Introduction.....	10-2
Monitor Interfaces.....	10-2
Implementation of monitoring.....	10-3
Monitoring parameters.....	10-3

10.1 Introduction

The BeneVision N1 patient monitor (hereinafter referred to as N1) facilitates monitoring of the patient's electrocardiogram (ECG, including ST segment measurement and arrhythmia analysis), respiration (RESP), body temperature (TEMP), pulse blood oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), and invasive blood pressure (IBP, including variation).

pulse pressure (PPV) and carbon dioxide (CO₂).

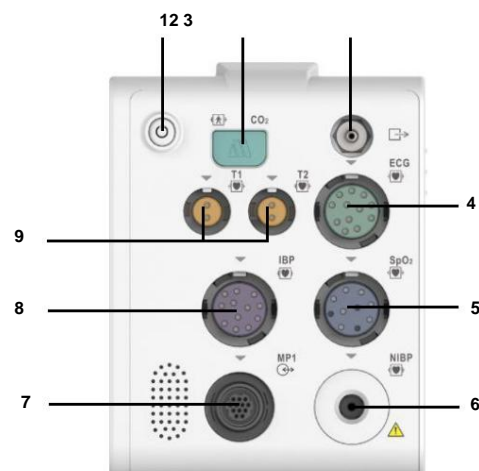
This ventilator can be used in conjunction with the N1. When used in combination with the N1 patient monitor, this ventilator provides the following functions:

- Transmit patient information, parameter settings, and alarm settings between N1 and the ventilator.
- Display N1 parameter information on the respirator interface.

For detailed operating instructions on the BeneVision N1 patient monitor, refer to the N1 Operator's Manual.


10.2 Monitor interfaces

The interfaces of the BeneVision N1 patient monitor are shown in the following diagram.



No.	DESCRIPTION	No.	DESCRIPTION
1.	Power switch	6	NIBP cuff connector
2	Sideflow CO ₂ sampling line connector	7	Multifunction connector: analog output and defibrillation synchronization signal
3	Gas outlet		
4	Cable connector ECG	8	IBP sensor connector
5	Sensor connector SpO ₂	9	Temperature probe connector

10.3 Implementation of monitoring

1. Place the BeneVision N1 patient monitor into the module slot ventilation.
2. Select whether you want to transfer ventilation parameters and other data from the monitor to the ventilator.
3. Check the patient information and patient settings, etc. Make sure the alarm limit, patient type, and other information are correct.
4. Configure the monitor:
 - Select **[Menu]** **]** **[Display]** **]** **[Selection Display]** to adjust the monitor interface display mode to **[Wave Display]** or **[Large Numeric Display]**.
 - Select **[Menu]** **]** **[Monitor]** to set the parameter layout, waveform display, and other monitor interface settings.
 - In the interface **[Menu]** **]** **[Monitor]**, when the **[Monitor]** is  (Disabled), Not all monitor functions are available on the ventilator.
5. Start monitoring. See the relevant section on monitor parameters for more details.

WARNING: If a patient is being moved, do not unplug the monitor of BeneVision N1 patient before the synchronization of configuration data between the N1 and the ventilator is complete; otherwise, patient information and data may be inconsistent.

WARNING: During patient transfer, if you unplug the BeneVision N1 patient monitor while the patient's historical data is being loaded, the patient's historical data for this ventilator will be incomplete.

WARNING: After completing the patient data transfer, check the settings on the BeneVision N1 patient monitor (especially patient type, stimulation status, alarm limit, etc.) and verify that they are all applicable to the patient.

10.4 Monitoring parameters

When the BeneVision N1 is inserted into the ventilator, there are some functional differences compared to using the N1 alone. The specific configuration differences are shown below.

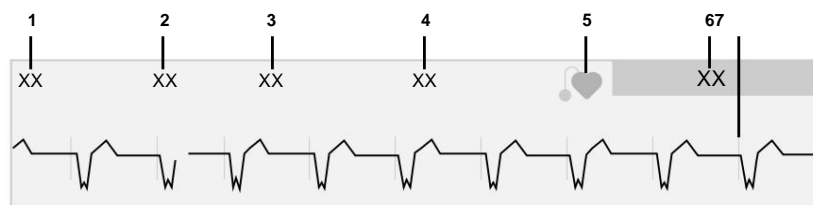
PARAMETERS of MONITORING OF N1 USE WITH RESPIRATOR	N1 USE ONLY	
ECG	<p>1. Without QT/QTc measurements, 12 ECG analysis function leads and view of FA;</p> <p>2. No ST graphics window;</p> <p>3. The 6-lead placement cannot be used for derivation</p> <p>12-lead ECG; 4. Only displays a maximum of 3 ECG waveforms.</p>	<p>1. With QT/QTc measurements, 12-lead ECG analysis function and AF view;</p> <p>2. With ST graphics window;</p> <p>3. The 6-lead placement can be used to generate 12 leads</p> <p>ECG (D12L);</p> <p>4. Displays a maximum of 12 ECG waveforms.</p>
IBP	<p>1. Without PEAP monitoring;</p> <p>2. The IBP module cannot be used in one slot;</p> <p>3. Monitors two invasive blood pressures.</p>	<p>1. With monitoring of PEAP;</p> <p>2. One can use a IBP module of a slot;</p> <p>3. Monitor four invasive blood pressures.</p>
NIBP	Just like using N1 alone	
Resp	Just like using N1 alone	
Temp	Just like using N1 alone	

10.4.1 ECG monitoring

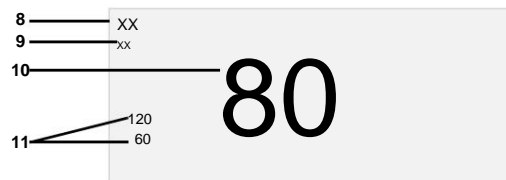
The electrocardiogram (ECG) measures and records the electrical activity of the heart. Its monitoring provides 3-, 5-, 6-, and 12-lead ECG monitoring, arrhythmia analysis, and ST segment analysis. When the BeneVision N1 patient monitor is inserted into the ventilator, it does not support the 6-lead placement for generating a 12-lead ECG (D12L). Furthermore, it does not provide QT/QTc measurements, 12-lead ECG analysis, or atrial fibrillation (AF) view. The ventilator cannot display the ST segment graphic window. For more information

For detailed information about the ECG, please refer to the BeneVision N1 patient monitor operator's manual.

The following figures show the ECG waveform and numerical areas:



No.	DESCRIPTION	No.	DESCRIPTION
1	ECG lead label of the displayed waveform	5	Pacemaker status: Yes [Pacemaker] is set to [Yes] . If [Pacemaker] is displayed is set to [No], it is shown.
2	Waveform gain of ECG	6	Alert message
3	ECG filter mode	7	Rhythm pulse mark: Yes Pacemaker is set to Yes, rhythm pulse markers " " corresponding to the detected rhythm pulse are displayed in each shape ECG waveform.
4	Filter slot status		



No.	DESCRIPTION	No.	DESCRIPTION
8	Parameter label	10	FC Value
9	FC Unit	11	Heart rate alarm limits

When monitoring the ECG, you can choose the screen you want.

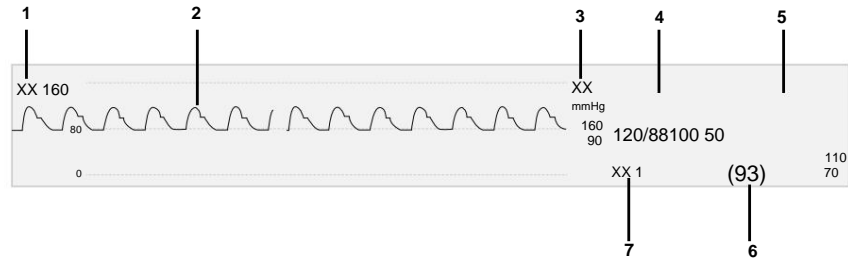
- For 3-lead ECG monitoring, only the normal display is available.
- For 5-lead, 6-lead, or 12-lead ECG monitoring, in addition to the normal display, it can show a maximum of 3 waveforms in screen.

10.4.2 Invasive blood pressure monitoring (IBP)

This patient monitor can monitor two invasive blood pressures.

IBP monitoring is intended for adult, pediatric, and neonatal patients. The device is not compatible with PEAP monitoring, the single-slot module, or the PICCO module. For more detailed information about IBP, please refer to the BeneVision N1 Patient Monitor Operator's Manual.

The IBP measurement is displayed on the monitor as a waveform and numerical pressures. For blood pressure, the numerical area for IBP shows the pressure. Systolic, diastolic, and mean arterial pressures are displayed. For venous pressure, the numerical area of the PPI (Proximal Blood Pressure Index) shows only the mean arterial pressure. The following figure shows the waveform and numerical data for arterial pressure.



No.	DESCRIPTION	No.	DESCRIPTION
1	Pressure label 5		Diastolic pressure
2	Waveform	6	Average pressure
3	Pressure unit7		PPV Measurement
4	Systolic pressure		

10.4.3

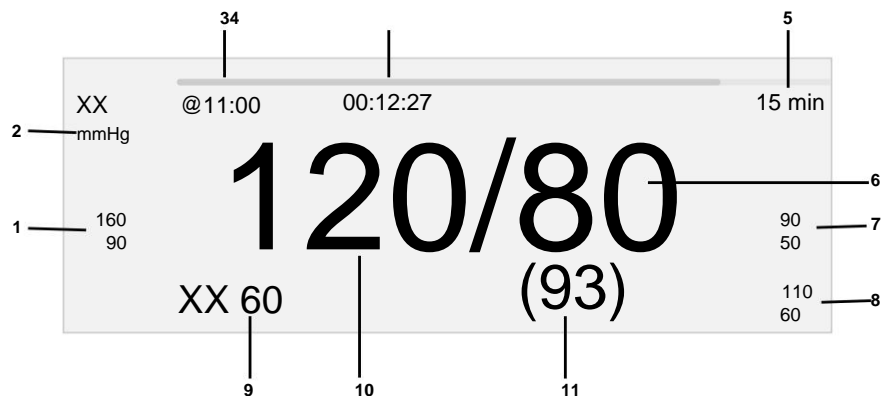
Non-invasive blood pressure monitoring (NIBP)

The monitor uses the oscillometric method to measure non-invasive blood pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations in the arterial wall. The oscillometric device uses a blood pressure cuff to detect these oscillations.

like small pulsations in the cuff pressure. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

NIBP monitoring is intended for adult, pediatric, and neonatal patients. For more detailed information about NIBP, please refer to the BeneVision N1 Patient Monitor Operator's Manual.

The NIBP screen only displays numerical data.



No.	DESCRIPTION	No.	DESCRIPTION
1	Pressure alarm limits systolic	7	Diastolic blood pressure alarm limits
2	NIBP unit: mmHg or kPa	8	Average pressure alarm limits
3	The last hour of measurement of the NIBP	9	Pulse rate
4	Time until the next measurement (for Auto mode and mode Sequence)	10	Systolic pressure
5	Measurement mode: For automatic NIBP, the interval is displayed; for Sequence mode, the current phase and interval are displayed.	11	Average pressure (displayed once the measurement is complete) or cuff pressure (displayed during the measurement)
6	Diastolic pressure		

10.4.4 Respiratory monitoring (Resp)

Impedance breathing is measured across the chest. When the patient breathes or ventilates, the volume of air in the lungs changes, causing impedance changes between the electrodes. The respiratory rate (RR) is calculated from these impedance changes, and a respiratory waveform appears on the patient monitor screen.

Respiratory monitoring is intended for adult, pediatric, and neonatal patients. For more detailed information about Resp, please refer to the BeneVision N1 Patient Monitor Operator's Manual.



No.	DESCRIPTION	No.	DESCRIPTION
(1)	Response waveform gain	(4)	Frequency respiratory rate (RR)
(2)	Derivation label respiratory	(5)	Source of FR
(3)	Alarm limits		

10.4.5 Temperature monitoring (Temp)

The monitor can continuously monitor the patient's skin and core temperatures. It uses thermally sensitive resistors (thermistors). These operate on the principle that the electrical resistance of a thermistor changes with temperature. The thermistors measure this change in resistance and use it to calculate the temperature.

They can simultaneously monitor two temperature points and calculate the difference between them.

Temperature monitoring is intended for adult, pediatric, and neonatal patients. For more detailed information about Temp, please refer to the BeneVision N1 Patient Monitor Operator's Manual.

The following figure shows the numerical area for Temp for temperature monitoring with the monitor. Your display may be configured differently.



No.	DESCRIPTION	No.	DESCRIPTION
1	Temperature location	4	Temperature value
2	Unit of temperature	5	Temperature difference (ΔT): Difference between two temperature locations. Only displayed when ΔT is enabled.
3	Alarm limits		

11.0

Additional tools for ventilation

Manual breath-holding/inspiration	
O ₂ (Oxygen Enrichment)	11-2
Suction.....	11-3
Retention of exhalation.....	11-4
Static PV Loop	11-4
Recruitment Tools (IS)	11-4
Tools for gradual weaning from the respirator.....	11-5
Patient-ventilator asynchrony.....	11-5

11.1 Manual breath-holding/inspiration

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

During the exhalation phase, if you press and release the **[Manual]** key within a short period of time, the ventilation system will deliver a breath to the patient based on of the current ventilation mode.

NOTE: If the **[Manual Resp]** key is pressed during the inspiratory phase, manual respiration cannot be initiated.

NOTE: The manual breathing function is disabled in CPAP mode. Manual breathing is enabled when apnea ventilation occurs.

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

At any stage of respiration, press and hold the **[Manual] key**. If the ventilator is in the expiratory phase, it will perform inspiratory hold at the end of the next cycle; if the ventilator is in the inspiratory phase, it will perform breath-hold.

Inspiratory pause at the end of the cycle. When the breath-hold function is activated, the message **[Inspiratory pause active]** will appear on the screen. Release the **[Manual] key**. The ventilator ends the inspiratory hold function.

The inspiration hold function is active for a maximum of 30 seconds (for adult and pediatric patients) or 5 seconds (for neonatal patients). If the **[Manual]** key is pressed and the maximum time is exceeded, the ventilator will end the hold function from inspiration automatically.

During inspiration hold, the ventilator automatically calculates the Cstat and Pplat values and displays the calculation results in the warning message box.

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

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

NOTE: The expiratory hold function is disabled in CPAP mode. The expiratory hold function is enabled when apnea ventilation occurs.

11.2 O₂ (Oxygen enrichment)

O₂ is also called O₂ enrichment. It means that oxygen is supplied at a concentration higher than the normal level within the specified time period. The oxygenation level can be set by selecting **[Menu] y**

[Adjust] y [Ventilation]. The default oxygen enrichment level is 60% for adult and pediatric patients, and 10% for neonatal patients.

Press the **[O₂ Aspirac]** key and the ventilator will start oxygen enrichment. At that moment, the indicator light for the **[O₂ Aspirac]** key will illuminate, and the remaining oxygen enrichment time will be displayed. Oxygen enrichment remains active for a maximum of two minutes. During oxygen enrichment, the currently set oxygen concentration is displayed in the **[O₂%]** parameter setting quick-key field .

When the 2-minute oxygen enrichment period ends or the **[O₂ Aspirac]** key is pressed again, the ventilator ends oxygen enrichment.

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

NOTE: When the O₂ supply type is low pressure, pressing the **[O₂ Aspirac]** key will not activate oxygen enrichment, but the message **[Error starting with low O₂ supply pressure]** will appear.

NOTE: The system cannot initiate O₂ (oxygen enrichment) in the static PV loop test process.

NOTE: When the alarm **[O₂ supply failure]** is triggered , press the **[O₂ Aspirac]** key , O₂ is deactivated and **[O₂ supply failure]** appears . **O₂ deactivated.**].

NOTE: If the O₂ process triggers the alarm **[O₂ supply failure]**, O₂ It stops.

NOTE: If you remove the patient's tubes during oxygen enrichment, the suction function will start. See section 11.3 Suction.

11.3 Suction

The ventilator detects the procedure of disconnecting or reconnecting the patient's tubes when the ICU staff performs the suctioning maneuver on the patient. The ventilator begins oxygen enrichment before and after aspiration. and disables related alarm messages during aspiration.

1. Press the **[O₂ Aspirate]** key. The system delivers oxygen enrichment to the patient and monitors whether the patient's tubing is disconnected during the 120-second oxygen enrichment period. Disconnect the patient's tubing during this time.
2. After disconnecting the patient's tubes, the system indicates **[The patient has [Disconnected. Reconnect the patient when suctioning is complete.]** The system stops ventilating the patient. In this case, you can apply manual suction to the patient.
3. Reconnect the patient tubing after suctioning. When the patient connection is detected, the system delivers oxygen enrichment to the patient for 120 seconds.

During oxygen enrichment periods, pressing the **[Stop aspiration]** key can end the procedure.

NOTE: The system cannot initiate O₂ aspiration in standby, O₂ therapy , or CPRV modes .

11.4 Holding your breath

Expiratory retention means manually extending the expiratory phase time and preventing the patient from inhaling for a specified period of time.

Select the **[Tool]** key, then press and hold the **[Expiratory Pause]** key. The ventilator initiates the expiratory hold function, and **[Expiratory Pause Active]** appears on the display. Release the **[Expiratory Pause]** key. The ventilator ends the function.

Expiratory hold. Expiration is maintained for a maximum of 30 seconds (for adults and pediatric patients) or 5 seconds (for neonates). If the **[Expiratory Hold]** key is pressed for longer than the maximum or released, the ventilator automatically terminates the expiratory hold function.

NOTE: There is at least one inspiratory phase between two expiratory retentions.

NOTE: The system does not respond to the exhalation hold key if it is in standby, oxygen therapy, nCPAP, or CPRV modes.

11.5 Static PV loop

Mechanical ventilation adjusted with optimal PEEP can improve oxygenation and alveolar mechanics, and reduce lung injury. By plotting the static pressure-volume loop, the static PV loop is the method used to determine optimal PEEP based on characteristic points of the static PV loop. With this function, the clinician can determine the optimal PEEP for the patient.

NOTE: The static PV loop function is deactivated in the following cases: in standby mode; when the patient size is pediatric or neonatal; in CPAP/ventilation modes

PSV, VS, NIV or apnea; during O₂ (oxygen enrichment); within one minute after aspiration; within one minute after the most recent PV loop measurement.

NOTE: The static PV loop is not recommended when there are large leaks or when the patient is breathing spontaneously. The relevant feature points provided by the static PV loop function are for reference only.

NOTE: If no operation is performed in the static PV loop window for three minutes, the measurement window automatically exits.

1. Select **[Menu]** $\dot{\bar{y}}$ **[Tools]** $\dot{\bar{y}}$ **[Basic]**.
2. Select **[Bucl PV est]** to access the static PV loop window.
3. Read the notes related to the static PV loop on the information screen.
4. Select **[Procedure]**, and adjust the parameters Pstart, Flow Rate, Pmax, and Vlimit on the Procedure screen. The system acquires the value of the Tmax parameter according to the calculation formula and displays it on the Procedure screen.
 - Flow: gas delivery and expiration flows of the static PV loop.
 - Pstart: initial pressure of the static PV loop.

- Pmax: maximum pressure that the static PV loop can reach.
 - Vlimit: maximum volume that the static PV loop can reach.
 - Tmax: maximum measurement time required to complete the loop measurement static PV.
5. Select **[Start]** and the system will begin measuring the static PV loop. If selecting **[Det insp]** during measurement will immediately stop the measurement test on the inspiratory limb and begin the measurement on the expiratory limb. Selecting **[Susp]** during measurement will abort the measurement immediately.
 6. Once the measurement is complete, the system opens the Analysis screen. You can set the desired positions of **[Cursor 1]** and **[Cursor 2]**. When you select **[Cursor 1]** or **[Cursor 2]**, the selected cursor turns green. You can move the cursor position using the control knob to determine the characteristic points. The system also displays the volume and pressure values in the inspiratory and expiratory limbs corresponding to the selected position.

of the cursor and shows the compliance of these branches.
 7. Click **[History]** to select the desired loop from the list. The system only displays the history loop you are currently viewing.
 8. Select **[Ref. Loop]** to choose the desired loop from the list. The system displays the reference loop you are viewing, as well as the current loop.

11.6 Recruitment tools (IS)

Lung recruitment is a protective ventilation strategy of the lungs. A pressure higher than the average is administered to the airways during mechanical ventilation and maintained for a certain period of time, so that the most collapsed alveoli can be reopened and atelectasis secondary to a small tidal volume can be avoided.

The IS recruitment ventilation function uses a pressure ventilation method constant to perform a recruitment maneuver in a single cycle.

NOTE: Ventilation is used in the IS recruitment maneuver pure oxygen or oxygen of a high concentration.

NOTE: The IS recruitment maneuver is not recommended if there are signs of spontaneous breathing in the patient.

NOTE: The IS recruitment maneuver should be discontinued if the patient's physiological state is not normal.

NOTE: The IS function cannot be used in the following situations: with neonatal patients; during sucking; and during O2 therapy.

1. Select **[Menu]** \hat{y} **[Tools]** \hat{y} **[Basic]** \hat{y} **[IS]** to enter the screen of pulmonary recruitment tools.
2. Select the **[Note] interface**, and read the notes related to the recruitment tool on the open screen.
3. Select the **[Procedure]** interface and configure these two parameters: **[Pressure Maintenance]** and **[Wait Time]**. Adjusting the recruitment maneuver parameters:

- [Maint. pressure]:** maintaining the pressure of the recruitment process pulmonary.

- [Waiting time]:** duration of the pulmonary recruitment process.

4. Press the **[Start]** key and the system will initiate IS ventilation. After the waiting time has elapsed, IS ventilation will automatically end. Press the **[Stop]** key during IS ventilation and the recruitment maneuver will stop immediately.

11.6.1 History

1. Select **[Tools]** ÿ **[Advanced]** ÿ **[IS]** to enter the screen of pulmonary recruitment tools.
2. Select **[History]** to view all recruitment history information of the patient.

11.7 Tools for gradual weaning from the ventilator

WARNING: The ventilator only provides trends and parameter changes to assist healthcare professionals in conducting weaning reviews and spontaneous breathing trials, and does not indicate whether weaning can be performed or has been successful. Healthcare professionals must make decisions and take action based on the patient's clinical status.

If the patient's condition improves after a certain period of ventilator use, the ventilator should be gradually weaned to restore spontaneous breathing. Before weaning, a weaning assessment and spontaneous breathing trials should be performed, depending on the patient's condition. The patient's respiratory status and vital signs should be thoroughly examined during the assessment of the feasibility and appropriateness of weaning.

The ventilator provides data on the dynamic trend and changes in the parameters listed below: TVe/IBW, fspn, MVe, RSBI, EtCO₂, SpO₂, PR, SpO₂/FiO₂. Users can set normal ranges for TVe/IBW, fspn, RSBI, EtCO₂, SpO₂, and PR, and observe changes in these parameters. During ventilator weaning, users can observe changes in parameter trends and assess the patient's vital signs and respiratory status.

the goal is to be able to make the right decision about whether withdrawal is appropriate or not.

NOTE: The SBT function cannot be used in CPRV, NIV, standby, O₂ therapy modes or when the apnea alarm is activated.

11.7.1 Displaying help information

1. Select **[Tool]** ÿ **[Advanced]** ÿ **[Withdrawal]** to enter the ventilator weaning assist tool screen.
2. Select **[Information]** to check the basic principle of the ventilator weaning support tool and precautions.

11.7.2 Spontaneous breathing test (SBT)

Spontaneous Breathing Trial (SBT): Users can define and initiate the SBT, and the ventilator performs PSV ventilation according to these parameters, while displaying real-time values and trends for ventilator weaning criteria. If the criteria exceed the preset range, PSV ventilation automatically terminates, and the original ventilation mode is restarted. When the monitor transmits SpO₂ and EtCO₂ data to the ventilator's SBT tool, the monitor icon appears in the SBT parameter area.

1. Select **[Menu]** **[Tool]** **[Basic]** **[Withdrawal]** to enter the ventilator weaning assist tool screen.
2. Adjust **[PEEP]**, **[yPaux]**, **[FiO₂]** and **[Duration]** (adjustment range: 20 min to 240 min) and **[Tolerance]** (adjustment interval: 100 s to 300 s).
3. Press the **[Criteria]** key to enter the judgment indicator settings screen.
You can return to the SBT screen after adjusting these parameters. Alternatively, you can press the **[Auto Limit]** key; the ventilator will automatically change the judgment parameters according to the algorithm. The algorithm is as follows:

BOUNDARIES	FORMULA
Upper limit of fspn	1.5x monitored fspn value, not exceeding 160 /min
Lower limit of fspn	0.5x monitored fspn value
Upper limit of TVe/IBW	15ml/kg
Lower limit of TVe/IBW	4 ml/kg
RSBI	$105 \text{ l}/(\text{l}\cdot\text{min})$
Upper limit of EtCO ₂	Mean EtCO ₂ value + 10 mmHg
Lower limit of EtCO ₂	Adult: 15 mmHg; pediatric: 20 mmHg
Upper limit of SpO ₂	100%
Lower limit of SpO ₂	90%
High PR limit	1.2x monitored PR value, not exceeding 300/min
PR lower limit	0.8x monitored PR value, not exceeding 15/min

Table 11-1 Alarm Limits

4. Select the **[Start]** key to start the SBT system and display the time.
Remaining SBT. If you select the **[Stop]** key during the SBT, the system will end the SBT and return to the original ventilation mode. When the countdown finishes, the system ends the SBT and returns to the original ventilation mode. If any of the withdrawal criteria exceed the preset range and the duration exceeds the tolerance time during the SBT, the system ends the SBT and returns to the original ventilation mode. If the apnea alarm is triggered, the system ends the SBT and returns to the original ventilation mode.

11.7.3 Record

1. Select **[Menu]** **[Tool]** **[Basic]** **[Withdrawal]** to enter the ventilator weaning assist tool screen.
2. Select **[History]** to view all patient history withdrawal information.

11.8 Patient-ventilator asynchrony

The patient-ventilator asynchrony tool is used to identify and collect patient-ventilator events during mechanical ventilation, and provide related guidance based on the identified results to help users adjust parameter settings in order to reduce the occurrence of asynchrony.

of patient-ventilator asynchrony events.

NOTE: The patient-ventilator asynchrony function only identifies and collects statistics on three types of patient-ventilator asynchrony events: ineffective effort, double triggering, and insufficient flow. It does not collect statistics on other types of patient-ventilator asynchrony events that occur in clinical settings.

NOTE: The patient-ventilator asynchrony function is not a tool for diagnosis or treatment, and cannot replace the clinician's professional judgment.

NOTE: The patient-ventilator asynchrony function is not applicable to neonatal patients.

To quantify the incidence of patient-ventilator asynchrony, the following indicators are used for statistical calculation:

- Asynchrony Index (AI%) = $\frac{\text{Times of various types of patient-ventilator asynchrony}}{\text{Number of respiratory cycles} + \text{Number of ineffective effort cycles}} \times 100\%$;
- Ineffective effort (IE%) = $\frac{\text{Times of ineffective effort}}{\text{Number of respiratory cycles}} \times 100\%$;
- Double shot (DT%) = $\frac{\text{Double shot times}}{\text{Number of respiratory cycles} + \text{Number of ineffective effort cycles}} \times 100\%$;
- Flow insufficiency (FS%) = $\frac{\text{Times of flow insufficiency}}{\text{Number of respiratory cycles} + \text{Number of ineffective effort cycles}} \times 100\%$.

Alarms

Introduction.....	12-2
Alarm Categories.....	
12-3 Alarm Priority Levels.....	12-3 Alarm
Signals	12-3
Adjusting the alarm volume.....	12-5
Setting alarm limits	12-6
AUDIO PAUSED	12-7
Current alarms.....	12-7
Recent alarm.....	12-8
ALARM DEACTIVATED.....	12-9
Alarm reset.....	12-9
Alarm tests	12-10
When an alarm occurs.....	12-13

12.1 Introduction

The alarms are triggered by an abnormal vital sign or by technical problems with the ventilator, and are shown to the user through audible and visual indications.

NOTE: When the ventilator is started, the system detects whether the audible alarm tones and alarm light function are working properly. If so, the alarm light will flash yellow and red sequentially, and the speaker and buzzer will emit self-test tones. If not, do not use the equipment and contact us immediately.

NOTE: When several alarms of different priorities are generated simultaneously, the ventilator selects the highest priority alarm and emits audible and visual indications accordingly.

NOTE: If one or more alarms of the same level are triggered, the alarm messages are displayed according to the sequence of the triggered alarms.

NOTE: When the ventilator is accidentally turned off, if it is turned back on within 60 seconds, the ventilator will automatically restore the last settings. If power is lost for more than 120 seconds, the ventilator will automatically load the user settings before shutting down. The ventilator can automatically restore the last settings or automatically load the user settings before shutting down within 60 to 120 seconds.

NOTE: The ventilator restores the last settings if it is restarted after a power failure.

WARNING: There may be a potential hazard if different alarm settings are used for the same or similar equipment in the same area, for example, an intensive care unit or a cardiac operating room.

WARNING: If the BeneVision N1 patient monitor is connected to the central monitoring system (CMS) or other monitors, alarms may occur and be controlled remotely. Remote suspension, inhibition, or resetting of monitor alarms via the CMS or other means. Monitors can pose a potential hazard. For more information, refer to the operator manuals for the CMS and the other monitors.

WARNING: When monitoring patients who are not continuously attended by a clinical operator, properly configure the alarm system and adjust the alarm parameters according to the patient's condition.

12.2 Alarm categories

Depending on the type, ventilator alarms are divided into three categories: physiological alarms, technical alarms, and warning messages.

1. Physiological alarms

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

2. Technical alarms

Technical alarms, also called system status alarms, are activated. Technical alarm messages are displayed in the alarm message field. This can be caused by a device malfunction or data distortion due to mechanical problems or improper operation.

3. Warning messages

In reality, the indication messages are not alarm messages. In addition to the technical and physiological alarm messages, the ventilator displays some messages with information about the system status. This type of message is included in the warning message category and is usually displayed in the warning message area.

12.3 Alarm priority levels

The ventilator alarms are divided into three categories based on the severity of the situation: high priority alarms, medium priority alarms, and low priority alarms.

The priorities of all alarms are factory preset and are not user-configurable.

12.4 Warning signs

When an alarm is triggered, the respirator alerts the user through a series of audible or visual alarm indications.

- Alarm light
- Audible alarms
- Alarm messages
- Intermittent numeric data

Among them, the alarm light, audible alarm tones, and alarm messages differentiate the alarm priority in different ways.

12.4.1 Alarm light

If a technical or physiological alarm is triggered, the corresponding alarm will flash. The color and flashing speed depend on the alarm's priority.

- High priority alarms: The light flashes rapidly in red.
- Medium priority alarms: the light flashes slowly in yellow.
- Low priority alarms: the light turns blue without flashing.

12.4.2 Acoustic alarms

The ventilator uses different alarm tone patterns depending on the alarm priority:

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

A-weighted sound pressure level for audible alarm signals:

- Operator position: 1 meter from the front and 1.5m above the respirator.
- A-weighted sound pressure level: not less than 45 dB and not more than 85 dB.
The high priority alarm volume is not less than 60 dB at the default alarm volume level.

12.4.3 Alarm messages

When an alarm is triggered, an alarm message appears in the ventilator's alarm message field. The alarm message uses a different background color depending on the alarm's priority:

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

The exclamation marks (!) before the alarm message correspond to the alarm priority as follows:

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

When a high-priority, exclusive alarm occurs, the original ventilator alarm and warning information are pushed back. The high-priority, exclusive alarm information will cover the ventilation mode display area.

original and of the patient category icon. See the following figure:

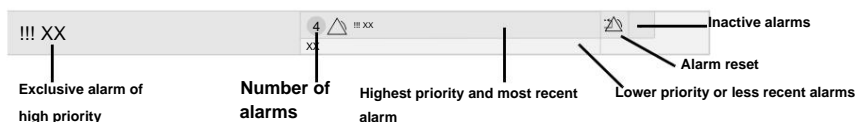


Figure 12-1 Exclusive high priority alarm

When the BeneVision N1 patient monitor is inserted into the ventilator, the monitor and ventilator alarms are displayed on two separate lines. The first line shows alarms related to the monitor, and the second line shows alarms related to the ventilator.






Exclusive high-priority alarms include **[Device Failure]**, **[Tube Disconnected?]**, **[SpO2 Desatration]**, **[Asystole]**, **[Ventr. Fibr./Ventr. Tachy.]**, **[Ventr. Tachy.]**, **[Ventr. Bradycardia]**, **[Extreme Tachy.]**, **[Apnea]**, **[System OFF. Connect External Source.]** and **[Very High PVA]**. If one of these alarms occurs, see **D.0 Alarm Messages** to take the appropriate measures.

12.4.4 Flashing alarm numerical values

If an alarm is triggered by a violation of an alarm limit, the numerical value of the alarm measurement parameter flashes at a predetermined frequency.



12.4.5 State of alarm symbol

In addition to the alarm indicators mentioned above, the ventilator uses the following symbols to indicate the alarm status:

-  indicates that the alarm sound has been paused and the alarm system is found in PAUSED AUDIO mode.
-  this icon is displayed next to alarm messages, the ventilator indicates that multiple alarm messages are present and shows the number. The alarm message uses a different background color depending on the alarm's priority. A red background indicates a high priority level for multiple alarm messages, while a yellow background indicates a medium priority level. You can view active alarms by selecting the alarm messages field.
-  Indicates that there are deactivated alarms whose activation condition has been removed. Tapping this icon will display the most recent inactive alarms (up to 9 alarm messages) on the open screen. You can also clear the most recent alarms using the **[Reini]** key.
-  indicates that a parameter alarm is closed and the alarm signal is on ALARM MODE OFF.
-  indicates that the monitor's alarm system has been reset.

12.5 Adjusting the alarm volume

To adjust the alarm volume:

1. Select the **[Alarm]** $\dot{\bar{y}}$ **[Audio]** key.
2. **[Volume alarm]** setting :  Indicates the lowest volume. The  indicates the highest volume alarm volume is limited by the lowest volume and cannot be lower than the lowest. If there are no alarms, the system will emit the low-priority alarm tone once at the alarm volume you set when adjusting the volume.




To adjust the minimum alarm volume.

1. Select **[Menu]** $\dot{\bar{y}}$ **[System]** $\dot{\bar{y}}$ Enter system password $\dot{\bar{y}}$ **[Set]**.
2. Adjust **[Minimum alarm volume]** to an appropriate value.

WARNING: Do not rely solely on the audible alarm system when using the ventilator.

Setting the alarm volume to a low level can create a dangerous situation for the patient. Monitor the patient closely and continuously.

12.6 Alarm management settings

1. Select the **[Alarm]** key $\dot{\bar{y}}$ **[Set]** $\dot{\bar{y}}$ **[Alarm Management]**.
2. Set it to (On) or  (On). The root  (Off). When the switch is on  cause of alarm activations and disappearances will be analyzed and managed to prevent unnecessary and annoying alarms. Alarms are clearer to reduce alarm fatigue.

12.7 Set alarm limits

CAUTION: If the upper pressure alarm limit of 60 cmH₂O is not required under clinical conditions, it is recommended to set the upper pressure alarm limit to 60 cmH₂O or less to prolong the service life of the spare air supply and battery.

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

NOTE: When using the respirator, always pay attention to whether the alarm limits for the various parameters are set to the appropriate values.

Select **[Alarms]** $\dot{\bar{y}}$ **[Ventilation Limits]** or **[Module Limits]**, or select the flashing active monitored values to adjust the alarm limits related to the respirator or the module.

12.7.1 Automatic alarm limits

Select **[Alarms]** $\dot{\bar{y}}$ **[Ventilation Limits]** $\dot{\bar{y}}$ **[Auto Limits]**, and the ventilator will update the alarm limits for the parameters based on the monitored value. The relationship appears in the following table.

ALARM LIMIT	ADJUSTMENT FORMULA
PVA upper limit	Mean peak pressure + 10 cmH ₂ O or 35 cmH ₂ O, whichever is greater
Lower pressure limit of the respiratory tract	PEEP + 4 cmH ₂ O
Upper limit of MV	1.5x MVe monitored value
Lower limit of MV	Monitored value of 0.6xMVe
High TV limit	1.5x average TVe value
Low TV limit	0.5x average TVe value
Upper limit of ftotal	1.4 x total frequency monitoring value, not exceeding 160/min
Lower limit of ftotal	Monitored value of 0.6xftotal
Apnea time	15 s

Table 12-1 Automatic Alarm Limits of the Ventilator


The value used to calculate the average uses either the monitoring value of the last eight ventilation cycles or the monitoring value in one minute, whichever is higher.
minor.

If the calculated alarm limit is higher than the upper threshold of the setting range or lower than the lower threshold, the corresponding threshold is used as the automatic alarm limit.

If the BeneVision N1 patient monitor is connected to the ventilator, the monitor's alarm limits are automatically adjusted. Refer to the BeneVision N1 patient monitor operator's manual for more details.

12.8 AUDIO PAUSED


12.8.1 AUDIO PAUSED setting

After pressing the key, the ventilator  and monitor enter AUDIO mode PAUSED simultaneously. The paused audio time is 120 seconds, and the current alarm sound can be turned off. When the 120-second countdown ends, the PAUSED AUDIO state ends and the audible alarm tones are restored.

WARNING: Pay close attention to the patient and the ventilator to ensure that no alarm messages are ignored during the AUDIO PAUSED period. There may be risks to the patient or equipment if the alarm condition continues and no action is taken.

NOTE: In the AUDIO PAUSED state, all alarm indicators function normally except for the audible alarm tones.

12.8.2 End of PAUSED AUDIO

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

12.9 Current alarms

When alarms are currently active, if a number appears before the alarm messages, it indicates that multiple alarm messages are active. Selecting the alarm messages field displays the messages for active alarms, the time they occurred, and their priority in the open alarm window. For certain alarms, select the right-hand triangle button to view relevant help information.

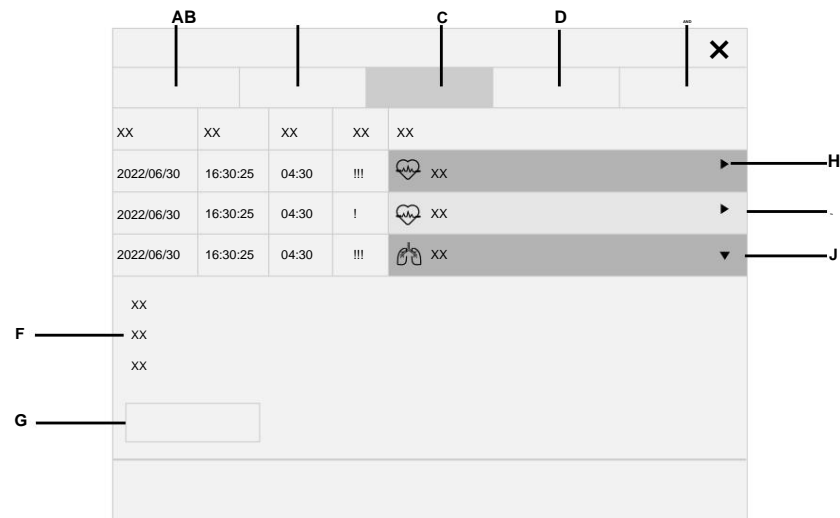


Figure 12-2 Help Information

- A. Setting alarm limits for ventilation parameters
- B. Setting alarm limits for monitoring parameters
- C. Current alarms
- D. Recent alarms
- E. Alarm volume configuration and alarm management
- F. Help information
- G. Associated information

Select the key to open the corresponding settings menu.

H. Help Information Key Press this

key to display help information in the window that appears. Press this key again to close the help information window.

I. Ventilator-related alarms (displayed as)



J. Alarms related to the BeneVision N1 patient monitor (displayed as



12.10 Recent alarm

The icon will appear if there is a deactivated alarm (alarms) whose activation condition has been removed. By pressing the icon, you can view recently deactivated alarms in the open window. You can also delete recently deactivated alarms by pressing the **[Reini]** key.

12.11 ALARM DEACTIVATED

When the alarm limit is set to **[OFF]** or the alarm is disabled, the system will display an ALARM OFF icon showing the alarm limits of the parameters, and the corresponding physiological alarms will be closed.

Specifically, the alarm message, alarm light, audible alarm tones, and flashing numerical alarm values for this physiological alarm will be turned off.

**WARNING: Turning off the alarms may endanger the patient.
Handle them with care.**

12.12 Alarm Reset


Press the **[Reset Alarm]** hotkey to reset the alarm system. When the alarm system is reset, the alarm reset icon appears in the system status field.

NOTE: The alarm reset function is only valid for the monitor alarm, but not for the ventilator alarm.

NOTE: If a new alarm is triggered after the alarm system has been reset, the alarm reset icon will disappear and the alarm light and alarm tone will be reactivated.


12.12.1 Resetting physiological alarms

Physiological alarms present different alarm indicators when the alarm system is reset:

- The alarm sound is silenced.
- A check mark  appears before the alarm message.
- The color of the numeric parameter background corresponds to the alarm priority, but the numeric parameter does not flash.

12.12.2 Resetting technical alarms

Technical alarms present different alarm indicators when the alarm system is reset:

- Some technical alarms are being erased. The monitor is not providing any alarm indications.
- Some technical alarms are replaced by warning messages.
- For some technical alarms, the alarm is silenced and a checkmark  appears before the alarm message.

For more details on the indications of technical alarms when the alarm system is reset, refer to the BeneVision N1 operator's manual.

12.13 Alarm tests

12.13.1 Energy loss

1. Connect the respirator to AC power and press the power button.
2. Once the system has started, and if the battery is fully charged, Disconnect the external power supply.
3. Connect a test lung to the ventilator and start normal ventilation.
4. The ventilation time is approximately 5 hours for a ventilator configured with one battery, and approximately 10 hours for a ventilator configured with two batteries. When the battery power is depleted, the alarm **[System OFF. Connect external power source.] is activated.**
5. Reconnect the external power supply.
6. Verify that the alarm has been reset and that the respirator is receiving power from the AC source again.

12.13.2 Very high PVA

1. Once the ventilator system has started normally, connect a Test lung on ventilator and begin ventilation.
2. Set the Pva alarm upper limit to Current Peak + 5 cmH₂O.
3. Firmly squeeze the test lung during inspiration.
4. Check that the **[Pva very high]** alarm is activated, the ventilator performs an exhalation cycle, and the airway pressure drops to the PEEP level.

12.13.3 Pressure too low

1. Once the ventilator system has started normally, connect a Test lung on ventilator and begin ventilation.
2. Set the Pva low alarm limit to Peak + 5 cmH₂O.
3. Check if the **[Pva too low]** alarm is activated.

12.13.4 TVe too low

1. Once the ventilator system has started normally, connect a Test lung on ventilator and begin ventilation.
2. Adjust the TV alarm low limit to be higher than the current TVe. Verify that the alarm **[VCe very low]** is activated.

12.13.5 TVe too high

1. Once the ventilator system has started normally, connect a Test lung on ventilator and begin ventilation.
2. Adjust the TV alarm upper limit to be lower than the current TVe. Verify that the alarm **[VCe very high]** is activated.

12.13.6 MVe too low

1. Once the ventilator system has started normally, connect a Test lung on ventilator and begin ventilation.
2. Adjust the MV alarm lower limit to be higher than the current MV. Verify that the **[MVe very low]** alarm is activated.

12.13.7 Oxygen supply failure

1. Connect the respirator to the high-pressure O2 supply and define the O2 supply type on the respirator's high-pressure O2 supply .
2. Shut off the high-pressure O2 supply and check if the **[O2 supply failure]** alarm has been activated.

12.13.8 PEEP too low

1. Remove the expiration valve membrane and install the expiration valve.
2. Once the ventilator system has started normally, connect a Test lung on ventilator and begin ventilation.
3. Set the PEEP to 30 cmH2O. Verify that the **[PEEP too low]** alarm is activated.

12.13.9 Obstructed airway

1. Once the ventilator system has started normally, connect a Connect the test lung to the ventilator and put it in pressure mode to start ventilation.
2. Disconnect the patient tube from the test lung and cap the patient tube with the leak-proof plug.
3. Verify that the alarm **[Inspiratory branch blocked?]** is triggered after several respiratory cycles.
4. Connect the patient tube to the test lung and verify that this alarm is triggered. It resets automatically.

12.13.10 FiO2 too high

1. Connect the ventilator to the low-pressure O2 supply . Adjust the type of O2 supply to LPO.
2. Connect a test lung to the ventilator and start ventilation.
3. Set the FiO2 alarm upper limit to be lower than the recorded value of the current O2 concentration after ventilation has stabilized.
4. Verify that the **[FiO2 very high]** alarm is activated. Resume the supply of reserve air once the test has been carried out.

12.13.11 FiO2 too low

1. Connect the respirator to the high-pressure O2 supply . Adjust the type of O2 supply to HPO.
2. Connect a test lung to the ventilator and start ventilation.

3. Disconnect the high-pressure O₂ supply once ventilation is stable.
4. Verify that the **[Very Low FiO₂]** alarm is activated.

12.13.12 EtCO₂ too high

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the CO₂ test module and place the CO₂ test module in operating mode.
3. Once the CO₂ heating is complete and the CO₂ module enters Operating mode, supply between 3% and 7% standard CO₂ gas. Connect the sampling port of the side-flow CO₂ module or the airway adapter of the direct-flow CO₂ module. Set the EtCO₂ high alarm limit to be lower than the standard gas concentration.
4. Verify that the **[EtCO₂ very high]** alarm is activated.

12.13.13 EtCO₂ too low

1. Connect the CO₂ test module and place the CO₂ test module in operating mode.
2. Connect a test lung to the ventilator and start ventilation.
3. Once the CO₂ heating is complete and the CO₂ module enters Operating mode, supply between 3% and 7% standard CO₂ gas. Connect the sampling port of the side-flow CO₂ module or the airway adapter of the direct-flow CO₂ module. Set the EtCO₂ alarm lower limit to be higher than the standard gas concentration.
4. Verify that the **[EtCO₂ very low]** alarm is activated.

12.13.14 SpO₂ too high

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SpO₂ sensor and activate the SpO₂ monitoring function.
3. Connect the SpO₂ sensor to your index finger, set the SpO₂ alarm limit Desat as 0%, set the SpO₂ low alarm limit as 0% and the SpO₂ high alarm limit as 2%.
4. Check that the **[SpO₂ too high]** alarm is activated.

12.13.15 SpO₂ too low

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SpO₂ sensor and activate the SpO₂ monitoring function.
3. Connect the SpO₂ sensor to your index finger, set the SpO₂ alarm upper limit to 100% and the upper limit of the SpO₂ alarm at 98%.
4. Hold the wrist with the other hand to press the pulse until the SpO₂ reading is below 98% and verify that the **[Very Low SpO₂]** alarm is activated.

12.13.16 SpO2 Desat

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SpO2 sensor and activate the SpO2 monitoring function.
3. Connect the SpO2 sensor to your index finger and set the high alarm limit to SpO2 as 100%, the lower alarm limit of SpO2 at 98%, and SpO2 Desat at 98%.
4. Hold the wrist with the other hand to press the pulse until the SpO2 reading is less than 98% and verify that the **[SpO2 desat]** alarm is activated.

12.13.17 PR very high

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SpO2 sensor and activate the SpO2 monitoring function.
3. Connect the SpO2 sensor to your index finger and set the PR alarm upper limit to 15 1/min.
4. Verify that the **[PR very high]** alarm is activated.

12.13.18 PR too low

1. Connect a test lung to the ventilator and start ventilation.
2. Connect the SpO2 sensor and activate the SpO2 monitoring function.
3. Connect the SpO2 sensor to your index finger and set the PR alarm upper limit to 300 rpm and the low alarm limit of PR at 298 rpm.
4. Verify that the **[PR very low]** alarm is activated.

12.13.19 Tube disconnected

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

12.13.20 Network disconnected

1. Once the ventilator system has started up normally, connect the ventilator to a test lung and begin ventilation. Connect the ventilator to the remote control system.
2. Disconnect the network between the ventilator and the remote control system.
3. Verify that the **[Network disconnected]** alarm is activated.

12.14 When an alarm occurs

When an alarm occurs, proceed as follows:

1. Check the patient's condition.
2. Determine the alarm parameter or alarm category.
3. Identify the source of the alarm.

4. Take the necessary actions to eliminate the alarm situation.
5. Ensure that the alarm condition is corrected.

For more details on how to troubleshoot alarms, see **D.0 Alarm Messages**.

WARNING: To prevent potential patient injury when alarms are active, ensure the patient receives adequate ventilation. Identify and eliminate the causes of the alarms. Readjust alarm limits only when they no longer reflect current conditions.

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

13.0

Cleaning, disinfection and sterilization

Cleaning, disinfection and sterilization methods	13-3
General guidelines for cleaning, disinfection and sterilization	13-6
Disassembly and assembly for processing	13-6

WARNING: Take applicable safety precautions.

WARNING: Read the material safety data sheet for each cleaning agent.

WARNING: Read the user and service manual for all disinfection equipment.

WARNING: Wear gloves and safety glasses. A damaged O2 sensor may leak and cause burns (contains potassium hydroxide).

WARNING: Reusing the breathing system or reusable accessories without disinfecting them may result in cross-contamination.

WARNING: To prevent leaks, take care not to damage the components.
in case of disassembling and reassembling the breathing system.
Verify the correct installation of the system. Ensure the applicability and correctness of the cleaning, disinfection, and sterilization methods.

WARNING: Disassemble and reassemble the breathing system as explained in this manual. If you require further disassembly and reassembly, please contact us.
Improper disassembly and reassembly may cause leaks in the breathing system and compromise its normal operation.

WARNING: If water gets into the control assembly, it can damage the equipment or cause personal injury. When cleaning or disinfecting the housing, make sure no liquid enters the control assemblies and always unplug the equipment from the AC power source.
Reconnect the AC power supply when the cleaned parts are completely dry.

WARNING: To avoid sticky residue, do not use talc.
Zinc stearate, calcium carbonate, corn starch, or equivalent substances. These materials can enter the patient's lungs and airways and cause irritation or injury.

CAUTION: To avoid patient exposure to disinfecting agents and premature deterioration of the pieces, use the cleaning and disinfection methods and agents recommended in this section.

CAUTION: To reduce the risk of electric shock, disconnect the respirator from the power source before cleaning and disinfecting it.

NOTE: Clean, disinfect, and sterilize the equipment as required before putting it into operation for the first time. Refer to this chapter for cleaning, disinfection, and sterilization methods.

NOTE: To avoid damage, consult the manufacturer's data if you have any doubts about a cleaning agent.

- NOTE:** Do not use organic, halogenated or petroleum-derived solvents, anesthetic agents, glass cleaners, acetone or other harsh cleaning agents.
- NOTE:** Do not use abrasive cleaning agents (such as steel wool or silver cleaners).
- NOTE:** Keep all liquids away from electronic components.
- NOTE:** Do not allow liquid to enter the equipment casings.
- NOTE:** Cleaning solutions should have a pH of 7 to 10.5.
- NOTE:** Once cleaning, disinfection and sterilization are complete, perform the system check before using the equipment. Use the equipment only if it passes the check.
- NOTE:** Once cleaning, disinfection, and sterilization are complete, check the components for damage or cracks (e.g., the expiratory valve diaphragm). If any are found, replace the component appropriately.

13.1 Cleaning, disinfection and sterilization methods

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

Some parts of the respirator can be cleaned, disinfected, and sterilized. Different parts of the respirator must be disinfected using different methods. You must select the appropriate method for cleaning, disinfecting, and sterilizing the parts.

function of real situations to avoid cross-contamination between the respirator user and the patient.

This table shows our cleaning, disinfection, and sterilization methods recommended for respirator parts, including first-time use and use after many times.

PARTS	INTERVAL OF FREQUENCY RECOMMENDED	METHODS		
		CLEANING MANUAL	DISINFECTION MANUAL ON	STERILIZATION
RESPIRATOR CASING				
External surface of the respirator (including the housing, the plug-in module housing, and the gas supply hose)	Before each patient	Y	A or C	No

Table 13-1 Cleaning and Disinfection Methods

Cart, IV pole, and support arm	Before each patient	ÿ	A or C	No
AC Adapter	Before each patient	ÿ	A or C	No
Base	Before each patient	ÿ	A or C	No
Touchscreen	Before each patient	ÿ	A or C	No
HEPA air intake dust filter	Every four weeks or according to as necessary*	2	B	No
RESPIRATOR EXPIRATION VALVE ASSEMBLY (REUSABLE)				
Expiratory valve membrane (silicone)	Before each patient/ weekly	2	BD	
Expiration valve assembly (excluding diaphragm)	Before each patient/ weekly	2	BD	
FLOW SENSOR (REUSABLE)				
Flow sensor	Before each patient/ weekly	2	BD	
OTHERS				
Patient tubes	Before each patient/ weekly	Refer to the cleaning and disinfection methods provided by the patient tube supplier.		
Direct flow CO2 module	Before each patient/ weekly	Consult the cleaning and disinfection methods provided by the direct flow CO2 supplier.		
SpO2 sensor	Before each patient/ weekly	Refer to the cleaning and disinfection methods provided in the accessory manual.		
Sensor cable SpO2	Before each patient/ weekly	Refer to the cleaning and disinfection methods provided in the accessory manual.		
Electronic nebulizer	Before each patient/ weekly	Consult the nebulizer supplier for cleaning and disinfection methods.		
Humidifier	Before each patient/ weekly	Consult the humidifier supplier for cleaning and disinfection methods.		

Table 13-1 Cleaning and Disinfection Methods

Patient monitor BeneVision N1	Before each patient/ weekly	Refer to the cleaning and disinfection methods provided in the BeneVision N1 operator's manual.
----------------------------------	-----------------------------------	---

Cleaning methods:

1. Cleaning: Clean with a damp cloth dipped in alkalizing detergent (soapy water, etc.), then remove detergent residue with clean water and a dry lint-free cloth

2. Immersion: Rinse it first with water, then immerse it in Use an alkalizing detergent (soapy water, etc.) for the time recommended by the manufacturer. Then rinse thoroughly with water.

Disinfection methods:

A: Cleaning: Wipe with a damp cloth dipped in disinfectant, then wipe off any remaining disinfectant with clean water and a dry, lint-free cloth.

B: Immersion: Immerse it in disinfectant for 30 minutes (recommended time).

Next, rinse with clean water and dry completely.

C: Ultraviolet radiation between 30 and 60 minutes (recommended time).

Sterilization methods:

D: Sterilize with steam in an autoclave at a maximum of 134 °C for 10 to 20 minutes (recommended time).

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

Table 13-1 Cleaning and Disinfection Methods

The following table indicates the cleaning and disinfecting agents and the autoclave process that can be used on the respirator.

NAME	GUY
Ethanol (75%)	Intermediate level disinfectant
Isopropanol (70%)	Intermediate level disinfectant
Glutaraldehyde (2%)	High-level disinfectant
Orthophthalaldehyde disinfectant (as Cidex®OPA)	High-level disinfectant
Water and soap (pH value of 7-10.5)	Cleaning product
Clean water*	Cleaning product
Steam autoclave* Clean	Sterilization

water*: the quality of the water must never be lower than that of drinking water.

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

NOTE: It is recommended to consult the manufacturer's instructions for use.

NOTE: The expiration valve and flow sensor are only applicable to the high-level disinfectant (orthophthalaldehyde disinfectant only) and the steam autoclave.

Table 13-2 Cleaning and Disinfecting Agents

13.2 General guidelines for cleaning, disinfection and sterilization

Before proceeding with cleaning, disassemble the respirator parts in accordance with section 12.3. Clean and disinfect or sterilize the parts according to the following general guidelines for manual cleaning, manual disinfection and sterilization.

Check the product for visible dirt and repeat the cleaning and disinfection process. If necessary, check the product for visible damage and replace it if needed.

13.2.1 Manual cleaning

1. Clean or soak the parts according to the above table of methods cleaning, disinfection and sterilization.
2. Clean off any remaining disinfectant with clean water and a dry, lint-free cloth.
3. Disinfect or sterilize the part, continue with the disinfection procedures/ proper sterilization.

13.2.2 Manual disinfection

1. After cleaning, do not reassemble the part.
2. Clean or immerse the parts according to the above table of cleaning, disinfection and sterilization methods (ultraviolet radiation for specified parts).
3. Clean with clean water and a dry, lint-free cloth or rinse with clean water. then let the pieces dry completely.
4. Inspect all parts and replace them if they are damaged.

13.2.3 Sterilization

1. After cleaning, do not reassemble the part.
2. Sterilize the parts in a steam autoclave according to the above table of cleaning, disinfection, and sterilization methods.
3. Let the pieces dry completely.
4. Inspect all parts and replace them if they are damaged.

Reassemble the parts according to **13.3 Disassembly and assembly for processing** and perform the necessary tests. And perform any required tests.

13.3 Disassembly and assembly for processing

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

13.3.1 Expiration valve and diaphragm assembly

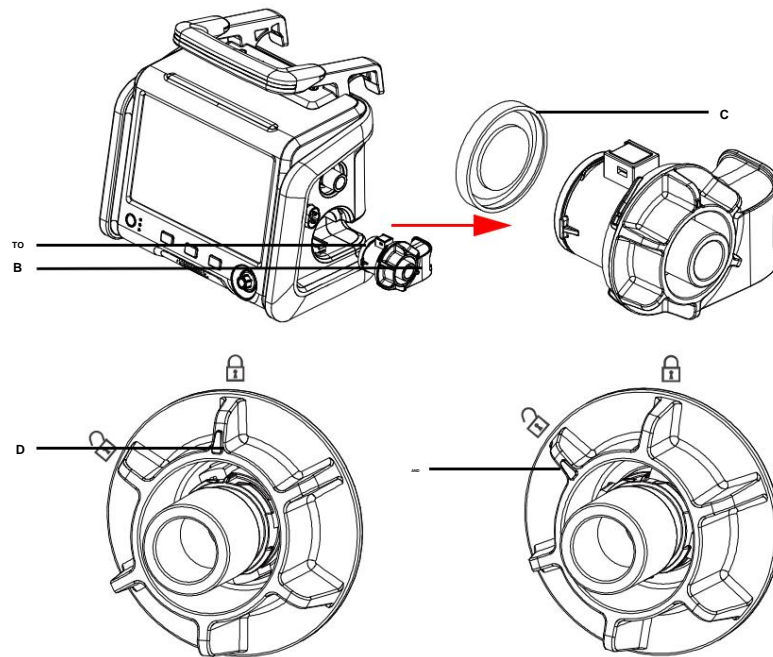



Figure 13-1 Expiration valve and diaphragm assembly

- A. Expiration valve assembly
- B. Expiration valve steering wheel
- C. Expiratory valve membrane
- D. Exhalation valve blocked
- E. Exhalation valve unlocked

• Disassembly:

1. Turn the exhaust valve steering wheel until the arrow

The steering wheel indicator aligns with the . Next, extract the horizontal position of the expiration valve assembly.

2. Remove the expiration valve membrane.

• Assembly:

1. Place the expiration valve diaphragm into the valve assembly expiration.

2. Make sure the indicator arrow on the steering wheel is aligned with the

Position. Insert the safety valve assembly into the corresponding connector on the respirator in a horizontal position and fully into place. Then, turn the exhalation valve handwheel clockwise (and push the handwheel in the direction the valve is installed).

exhalation) until the indicator arrow on the steering wheel is aligned with the position .

13.3.2 HEPA filter and dust filter components

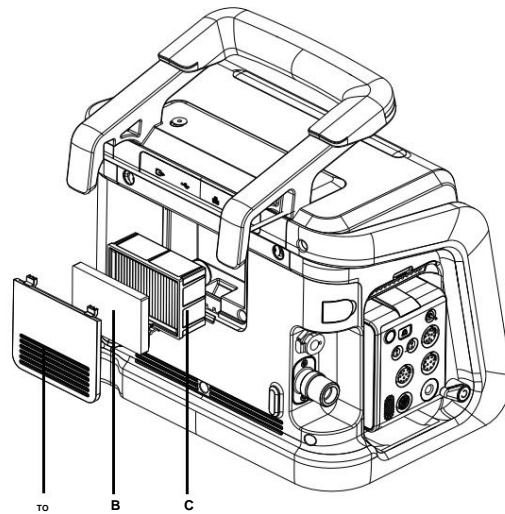


Figure 13-2 HEPA filter and dust filter

- A. HEPA air inlet grille
- B. HEPA air intake dust filter
- C. HEPA Filter

• Disassembly:

1. Pull the two latches on the HEPA air intake/outlet grille to remove the rack.
2. Pull the HEPA filter lock to remove it. If it is necessary to remove the air intake dust filter, grasp the air filter with two fingers and pull it out.

• Assembly:

1. Align the HEPA filter with the corresponding slot and push in the direction the HEPA filter is installed. Secure the HEPA filter lock.
2. Check if the closure over the HEPA filter has been installed correctly.
3. Close the HEPA air intake grille.

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

CAUTION: Do not operate the respirator if it is not equipped with a **HEPA filter. Otherwise, the device's inspiration end and the patient's tubing will be contaminated.**

13.3.3 Dust cover for the main unit's air inlet

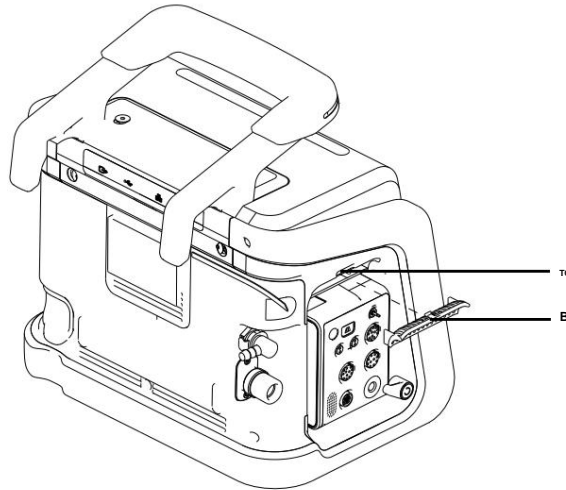


Figure 13-3 Main unit air inlet dust cover

- A. Slot
- B. Dust cover

- **Disassembly:**

Press the slot to remove the dust cover from the air inlet.

- **Assembly:**

Insert the dust cover directly into the slot.

13.3.4 Patient tubes

WARNING: To reduce the risk of bacterial contamination or damage **Physically, carefully remove and install the bacteria filter.**

CAUTION: When removing reusable patient tubes, disconnect them from the ventilator connectors, do not pull on them.

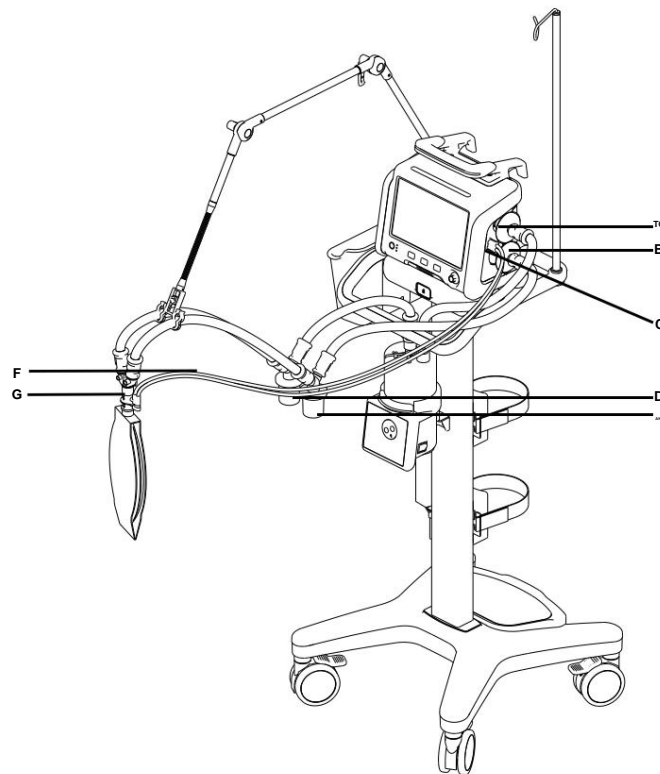


Figure 13-4 Patient Tubes

- A. Inspiratory filter
- B. Expiratory filter
- C. Flow sensor tube connector
- D. Inspiratory water collector
- E. Expiratory water collector
- F. Flow sensor tube
- G. Flow sensor

• Disassembly:

Remove the tubes from the patient one by one.

• Assembly:

See section **3.8 Patient Tube Installation**.

13.3.5 Humidifier

NOTE: **The humidifier must meet the requirements of ISO 8185.**
The humidifier assembly and the installation and disassembly steps described in this section are for reference purposes only.

13.3.5.1 Humidifier in the respirator

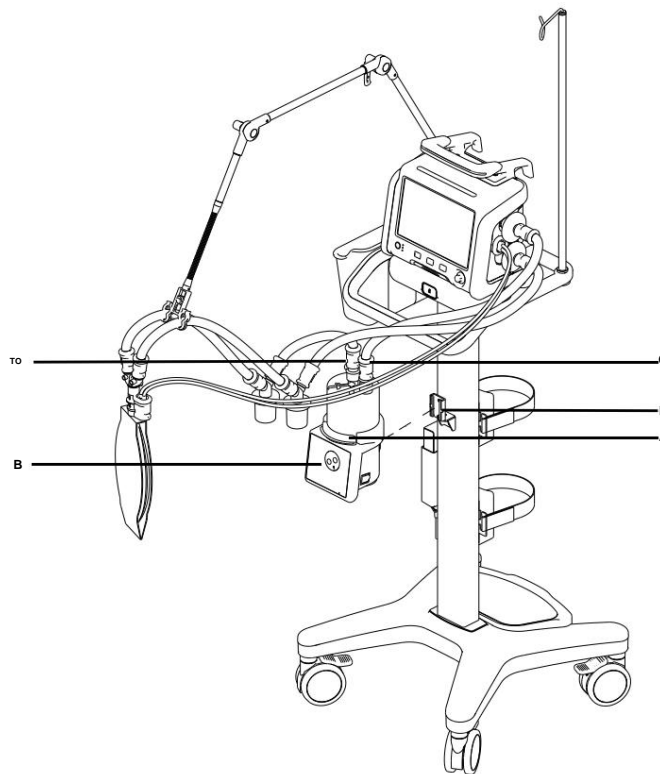


Figure 13-5 Humidifier in respirator

- A. Humidifier outlet
- B. Humidifier
- C. Humidifier inlet
- D. Humidifier support slot
- E. Humidifier mounting plate

- Disassembly:

1. Disconnect the humidifier tubes.
2. Remove the screw.
3. Lift the humidifier to remove it from the fixed seat of the humidifier holder.

- Assembly:

Refer to section **3.9.1 Humidifier Installation on the Respirator.**

13.3.5.2 Humidifier on hanging support

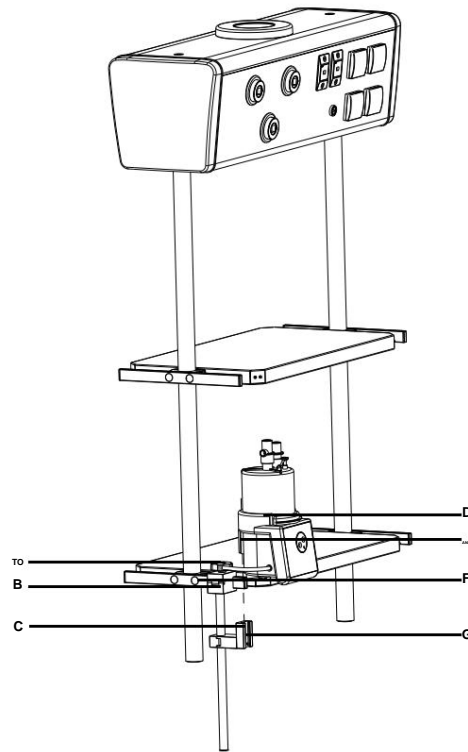


Figure 13-6 Humidifier on hanging bracket

- A. Assembly block control
- B. Mounting block
- C. Screw
- D. Humidifier
- E. Humidifier mounting plate
- F. Vigueta
- G. Humidifier support slot

• **Disassembly:**

1. Disconnect the humidifier tubes.
2. Remove the screw.
3. Lift the humidifier to remove it from the fixed seat of the humidifier holder.

• **Assembly:**

Refer to section **3.9.2 Installing the humidifier on the hanging bracket.**

WARNING: Before installing the humidifier, make sure the connector of the
**The humidifier is located lower than the breathing
connectors of the ventilator and the patient.**

13.3.6 Electronic nebulizer

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

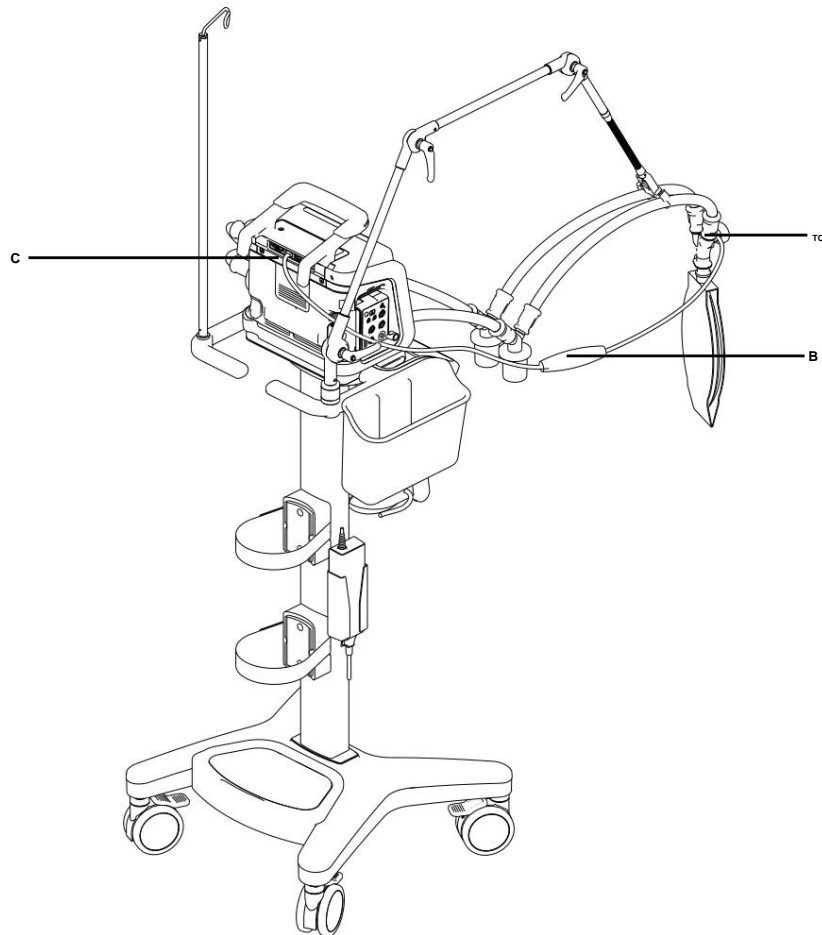


Figure 13-7 Electronic Nebulizer

- A. Nebulizer
- B. USB Controller
- C. USB connector

• Disassembly:

1. Remove the USB connector from the USB controller.
2. Remove the nebulizer tube from the nebulizer and remove the nebulizer.

- Assembly:

See section 3.10 Electronic nebulizer installation.

WARNING: Always keep the nebulizer in a vertical orientation while it is in the patient circuit. This position helps prevent patient secretions and condensation from contaminating the nebulizer's aerosol generator and ensures proper nebulization.

WARNING: Refer to the nebulizer operator's manual for instructions on installing and using the nebulizer.

13.3.7

Direct flow CO2 module

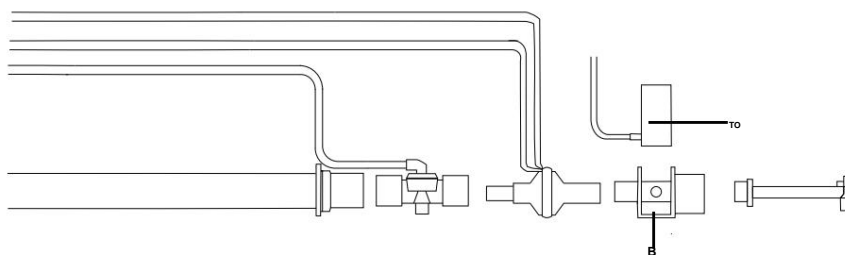


Figure 13-8 Direct Flow CO2 Module

A. CO2 sensor

B. CO2 airway adapter

- Disassembly:

Remove the CO2 airway adapter by pulling it vertically.

- Assembly:

Insert the CO2 sensor into the CO2 adapter vertically.

13.3.8

Visual inspection

After disassembly, inspect the components for damage, wear, and deterioration. The visual inspection criteria are that there should be no damage, creaking, or other noises. Deformations. If the components are damaged, worn, or torn, contact service personnel.

14.0

Maintenance

Repair Policy.....	14-2 Maintenance
Program.....	14-2 Pressure and Flow
Zeroing.....	14-4 Flow Rate
Calibration.....	14-4
Calibration of O2 concentration	14-5
CO2 Calibration.....	14-6
Battery Maintenance.....	14-7
Electrical safety inspection	14-10 Water
condensation on the flow sensor	14-11

14.1 Repair policy

WARNING: Follow infection control and safety procedures. The equipment used may contain blood and other biological fluids.

WARNING: Moving parts and removable components may **This poses a risk of pinching or crushing. Use caution when moving or replacing system parts and components.**

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

Do not use a respirator that is not functioning properly. All repairs and service operations must be performed by an authorized service representative. Replacement and maintenance of the parts listed in this manual may be performed by a competent and trained person with repair experience.

of devices of this nature.

After performing a repair, test the respirator to confirm that it is functioning correctly according to specifications.

NOTE: No repairs should ever be carried out by a person who has no experience in repairing devices of this nature.

NOTE: Replace the damaged parts with components manufactured or sold by us. Then, test the unit to ensure it meets the manufacturer's published specifications.

NOTE: Please contact the Customer Service Department for technical assistance.

NOTE: For more information about the product, please contact us. We can provide documentation for some parts depending on the specific situation.

14.2 Maintenance program

INTERVAL	PART/ACCESSORY PROCEDURE	
Before each patient or as needed	Patient tubing (including mask, inspiratory filter, flow sensor, expiratory valve, and membrane)	Perform pressure and flow zeroing (see 14.3); perform the self-check of the system (see 6.2); perform the calibration of the flow sensor (see 14.4); replace them with disinfected or sterilized parts or new disposable parts.
As needed	Expiration valve	Replace the expiration valve if it is damaged (see 13.3.1).
	Calibration of CO ₂	Calibrate the CO ₂ module when the CO ₂ measurement value shows a large deviation (see 14.6).
	Flow sensor	Replace the flow sensor if it is damaged.

Table 14-1 Maintenance Program

INTERVAL	PART/ACCESSORY	PROCEDURE
Several times a day or as needed	Patient tubes	Check for water accumulation in the patient tube and water collection systems. Empty any accumulated water (see 13.3.4). Inspect the parts to see if they are damaged. Replace them if necessary (see 13.3.4).
During cleaning and adjustment	Respirator	Inspect the parts to see if they are damaged. Replace them as needed.
Daily or as needed	Respirator	Clean external surfaces (see 13.1).
Before each use or after continuous use for two weeks.	Full respirator	Perform a system self-test and check the breathing system resistance and leaks (see 6.2).
Monthly or as needed	Air intake dust filter	Check for dust buildup on the dust filter or dust cover.
	HEPA, main unit air intake dust cover	Clean or replace as needed (see 13.3).
Check every 6 months and replace every three years	Lithium-ion battery	Check the charge and discharge of the lithium-ion battery every 6 months and replace it every three years. Contact us for a replacement.
Annually, every 5000 hours, or as needed	Respirator	Please contact the Customer Service Department for preventative maintenance.
	Ultrasonic oxygen sensor	Calibrate the ultrasonic oxygen sensor if necessary. Contact Customer Service for a replacement if the oxygen sensor fails.
	HEPA air intake filter	Replace it (see section 13.3).
	Expiratory valve membrane	Check the expiration valve diaphragm. Contact us to replace it when necessary.
	Backup alarm system	Check the duration of the backup alarm system's alarm (doorbell). If it is too short, contact us. us.
	Sealing ring of the fountain gas	Check the gas source sealing ring. Contact us to replace it if necessary.

Table 14-1 Maintenance Program

INTERVAL	PART/ACCESSORY PROCEDURE	
Every 6 years or as needed	Clock module battery	Replace the clock module battery. Please contact the Customer Service Department for a replacement.
Every 20,000 hours	Vacuum cleaner box. Please contact the Customer Service Department for a replacement.	

Table 14-1 Maintenance Program

For maintenance of the BeneVision N1 patient monitor, refer to the BeneVision N1 operator's manual.

14.3 Pressure and flow reset

Zero the pressure and flow when the monitored pressure or flow value varies considerably. Zeroing can be performed both in standby mode and during ventilation.

1. Press the **[Menu]** \bar{y} **[Calibration]** \bar{y} **[Zero Calibration]** key , and then
Select the **[Start]** key corresponding to zero pressure and flow on the right side. The pressure and flow zeroing process begins, and the message **[Zero calibration in progress]** appears.
2. Once the zeroing process is successful, the message **[P zero completed]** is displayed. Otherwise , the zeroing failure message is displayed.
In this case, you must perform the zeroing process again.

14.4 Flow rate calibration

NOTE: Do not perform any calibration when the unit is connected to the patient.

NOTE: Do not perform flow calibration when using a low-pressure oxygen source.

NOTE: During calibration, do not use the pneumatic parts. Take special care not to move or press on the patient tubes.

NOTE: Ensure the system is in standby mode. If it is not, press the **[Standby]** key to enter the **[Startup]** screen.
wait.

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

Calibrate the flow sensor if the measured value varies considerably from its setting or when it has been replaced.

Perform the following steps to calibrate the flow:

1. Connect one end of the patient tube to the ventilator and leave the other end open.
into the air.

2. Select the **[Menu]** $\dot{\bar{y}}$ **[Calibration]** $\dot{\bar{y}}$ **[Flow Rate Calibration]** key and, Next, select **[Start]** on the right. Flow rate calibration begins and a **[Calibrating]** warning message appears.



3. During calibration, calibrate the reverse flow by reversing the flow sensor. Proximal as indicated by the system. If necessary, reverse the flow sensor to the first position to calibrate the original airflow.
4. If you select **[Stop]**, the current calibration will be terminated and the message **[Calibration stopped. Calibration not completed.]** will appear.
5. After the calibration is performed successfully, the warning message is displayed. **[Calibration complete!]**. Otherwise, a message will appear indicating a Calibration failure. In this case, you must perform the calibration again.

NOTE: In case of calibration failure, check for any relevant malfunction alarms and, if present, troubleshoot the problem. If the failure persists or a significant measurement deviation occurs after troubleshooting, replace the flow sensor and repeat the above steps. If the measurement deviation remains significant, contact authorized service personnel.

14.5 Calibration of O₂ concentration

- NOTE:** Do not perform any oxygen concentration calibration when the unit is connected to the patient.
- NOTE:** Do not perform oxygen concentration calibration when using a low-pressure oxygen source.
- NOTE:** Make sure the system is in standby mode. If it is not, press the **[Standby]** key to enter the standby screen.

Calibrate the oxygen concentration when the measured oxygen concentration shows a large deviation from the settings or when the oxygen sensor self-test fails.

Perform the following steps to calibrate the oxygen concentration:

1. Ensure that the high-pressure O₂ supply is connected.
2. Press the **[Menu]** key $\dot{\bar{y}}$ select **[Calibration]** $\dot{\bar{y}}$ **[O₂ Calibration]** and, at Next, select **[Start]** on the right. The O₂% calibration begins and the **[Calibration]** warning message appears .

3. During calibration, if you select **[Stop]**, the ongoing calibration stops and the message **[Calibration stopped. Calibration not completed.]** is displayed.

4. After the calibration is performed correctly, the warning message is displayed. **[Calibration complete!]**. Otherwise, a message will appear indicating a Calibration failure. In this case, you must perform the calibration again.

NOTE: In case of calibration failure, check for any relevant malfunction alarms and, if present, resolve the issue. Then, perform the calibration again. If the error persists, contact service personnel or us.

NOTE: Increasing the pressure periodically by 10 kPa (100 cmH2O) has no effect on the accuracy of oxygen concentration monitoring.

14.6 CO2 calibration

14.6.1 Sideflow CO2 Module

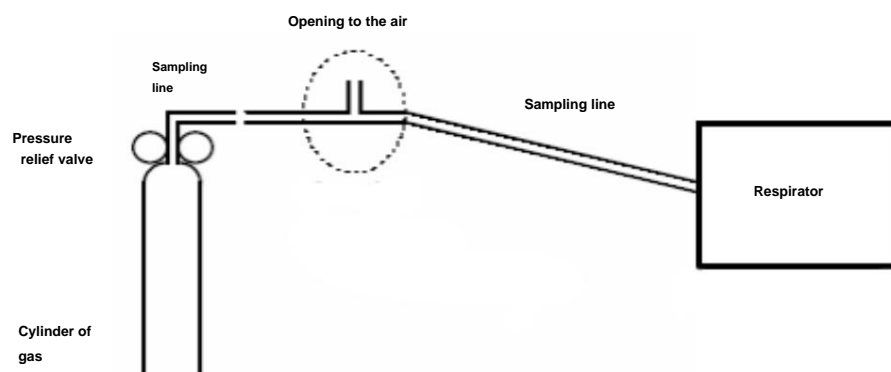
NOTE: Ensure the system is in standby mode. If it is not, press the **[Standby]** key to enter the **[Startup]** screen. wait.

Prepare the following before performing the calibration:

- Gas cylinder: cylinders filled with 3% to 7% CO2
- T-connector
- Sampling line

Follow these steps to perform CO2 calibration :

1. Check the airway and make sure there are no leaks or obstructions.
Make sure the CO2 module has already warmed up or started up.
2. Select **[Menu]** \bar{y} **[Calibration]** \bar{y} **[CO2 in maintenance]** and then select the **[Zero Calibration]** key.
3. After zeroing, connect the gas cylinder to the sampling line using the T-connector, as shown below. Check that the airway is not leaking.



4. Expose the sampling line to standard CO₂ by opening the cylinder pressure relief valve.
5. Write the standard CO₂ concentration in the corresponding box of the window.
6. The CO₂ concentration measured in the window is displayed. When the
Once the measured CO₂ concentration stabilizes, select **[Calibration]** to calibrate the CO₂ module .
The message **[Calibration] appears**.
7. After the calibration is performed successfully, the warning message is displayed.
[Calibration complete!]. Otherwise, the message **[Calibration error] is displayed**.
Try again.] In this case, you must perform the calibration again.

14.6.2 Direct flow CO₂ module

In the case of the direct-flow CO₂ module, calibration is not required. The system sends the altitude to the direct-flow CO₂ module for calibration compensation.

14.7 Battery maintenance

**WARNING: The lithium-ion battery has a lifespan of 3 years. Once
Once the lithium-ion battery has reached the end of its useful life, replace it.**

**WARNING: The respirator activates the battery over-temperature alarm when the battery temperature exceeds
55°C during battery use. The battery power supply will be interrupted.**

It stops when the battery temperature is outside the range of -20 to 60 °C.

**WARNING: Ventilation stops if the internal batteries are fully charged
downloaded and there is no external supply available.**

CAUTION: The batteries can only be charged through this respirator.

**NOTE: Use the batteries at least once a month to prolong their lifespan. Charge the
batteries before they are depleted.**

**NOTE: Inspect and replace batteries regularly. Battery life depends on the frequency
and duration of use. For a lithium-ion battery with regular maintenance**

**With proper storage, the expected lifespan is approximately 3 years. For
other models used more intensively, the expected lifespan may be shorter.**

**NOTE: In case of battery failure, please contact us or ask a service technician
to replace it. Do not replace the battery without authorization.**





**NOTE: When the alarm message [System OFF. Connect external source.] appears on
the ventilator, it indicates that the ventilator can still perform mechanical
ventilation for at least 30 minutes.**

Prepare to use manual ventilation for the patient.

**This alarm also indicates that the remaining battery capacity is
insufficient and that the respirator should be connected to an external
power source immediately.**

The ventilator is designed to operate on battery power in the event of a power outage. If the ventilator is connected to an external power source, the batteries charge regardless of whether the ventilator is switched on. In the event of a power outage, the ventilator will automatically switch to its internal batteries. If the external power source is restored within the specified period, the power supply will automatically switch from the batteries to the external power source to ensure continued operation of the system.

The battery icon on the screen indicates the battery status as follows:

- : indicates that the external power supply is connected. The respirator is receiving power from the external power supply. The solid green portion represents the current battery charge level relative to its maximum charge level.
- : indicates that the external power source is not connected. The respirator is powered by the integrated batteries. The solid green portion represents the current battery charge level relative to its maximum charge level.
- : This indicates that the external power source is not connected. The ventilator is powered by its built-in batteries. The battery capacity is low and needs to be charged immediately.
- : indicates that there is no battery installed.

If the internal battery capacity is limited, the alarm **[System closed. Connect external power supply.]** will activate and a warning menu will appear.

In this case, connect an external power source to the respirator.

14.7.1 Battery Information

Inspect and replace batteries regularly. Battery life depends on the frequency and duration of use. For a lithium-ion battery with proper maintenance and storage, the expected lifespan is approximately 3

years. In other models for more intensive use, the expected lifespan may be shorter. We recommend replacing lithium-ion batteries every 3 years.

To ensure maximum battery capacity, follow these instructions:
use:

- Check battery performance once every six months.
It is necessary to check the performance of the batteries before carrying out a repair in the ventilator or when the batteries are thought to be the cause of the ventilator failure.
- Prepare the batteries when they have been used for three months or when the operating time of the batteries is noticeably shorter.

14.7.2 Battery preparation

Prepare the batteries before using them for the first time. The following describes a Complete battery preparation cycle: uninterrupted charge, followed by uninterrupted discharge until the ventilator shuts off, and then uninterrupted charge again. Prepare the batteries regularly to prolong their lifespan.

NOTE: **Prepare the batteries when they have been used for three months or when the battery operating time is noticeably shorter.**

NOTE: Over time, battery capacity will decrease. For older batteries, the full battery icon does not indicate that the battery capacity or operating time still meets the specified requirements. When preparing batteries, replace them when their operating time is noticeably shorter.

Follow these steps to prepare the batteries:

1. Disconnect the patient from the ventilator and turn off the ventilator.
2. Connect the respirator to the external power source and charge the batteries continuously for at least 10 hours.
3. Disconnect the external power supply. Let the respirator operate on powered by batteries until the respirator is turned off.
4. Reconnect the respirator to the external power source and charge the battery continuously for at least 10 hours.
5. The preparation of the batteries is complete.

14.7.3

Battery performance check

Check battery performance once every six months. Battery performance should also be checked before performing any repairs. the ventilator or when the batteries are suspected of being the cause of the ventilator failure. Battery performance will decrease over time.

Perform the following steps to check battery performance:

1. Disconnect the patient from the ventilator and turn off the ventilator.
2. Connect the respirator to the external power source and charge the batteries continuously for at least 10 hours.
3. Disconnect the external power supply. Let the respirator operate on powered by batteries until the respirator is turned off.
4. The operating time of the batteries reflects their performance.

If the battery operating time is noticeably shorter than that indicated in the specifications, replace the batteries or contact service personnel.

NOTE: If the operating time of the batteries is too short after they have been fully charged, the batteries may be damaged or defective.

NOTE: If there is obvious damage to the batteries or if the batteries fail to charge, replace and recycle them properly.

14.7.4

Battery storage

When storing batteries, make sure the battery electrodes do not get into Avoid contact with metal objects. For prolonged storage, store batteries in a cool environment and maintain a battery charge level of at least 40% and 60%.

Storing batteries in a cold environment can slow down battery degradation. Ideally, batteries should be stored in a cool environment at 15°C (60°F). Do not store batteries outside the ambient temperature range of -20°C (-4°F) to +60°C (140°F).

Remove the batteries from the respirator if it will not be used for an extended period. If you don't, the batteries will over-discharge and the battery charging time will increase noticeably. Fully charge the batteries once every 2 months and keep the battery power between 40% and 60%. Fully charge the batteries before use.

NOTE: Remove the batteries from the device if it will not be used for an extended period of time.

NOTE: Prolonged storage of batteries above 38°C (100°F) greatly shortens battery lifespan.

14.7.5 Battery recycling

If there is obvious damage to the batteries or if they fail to charge, replace and recycle them properly. The size of the replacement battery must not exceed 140 mm x 90 mm x 20 mm (length x width x height). Dispose of batteries according to local regulations governing the disposal of these products.

WARNING: Do not disassemble the batteries, throw them into fire, or short-circuit them. They may catch fire, explode, or leak, causing injury.

14.8 Electrical safety inspection

NOTE: Perform an electrical safety inspection after carrying out maintenance operations. Before performing the electrical safety inspection, ensure that all covers, panels, and screws are properly installed.

NOTE: It is recommended that electrical safety tests be carried out by the manufacturer or a specialized company. Electrical safety inspections should be performed annually.

1. Perform the protective earth resistance test:

- a. Connect the analyzer probes to the device's ground terminal on the AC power cord and screw.
- b. Test the grounding resistance with a current of 25 A.
- c. Check that the resistance is less than 0.1 ohms (100 mohms).
- d. If the resistance is greater than 0.1 ohms (100 milliohms) but less than 0.2 ohms (200 milliohms), disconnect the AC power cord and connect the probe that was previously plugged into the grounding terminal of the AC power cord to the ground contact of the electrical outlet. Repeat steps a through c.

2. Perform the following earth leakage current tests:

- normal polarity
- reverse polarity

- Normal polarity with open neutral
- Reverse polarity with open neutral

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

3. Perform the following current leakage tests on the patient:

- normal polarity
- reverse polarity
- Normal polarity with open neutral
- Reverse polarity with open neutral
- Normal polarity with open ground
- Reverse polarity with open ground
- Electrical network at the applied part (network at AP), normal polarity
- Electrical network at the applied part (network at AP), reverse polarity

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

NOTE: Ensure the safety analyzer is approved by certified entities (UL, CSA, or AAMI, among others). Follow the analyzer manufacturer's instructions.

14.9 Water condensation on the flow sensor

14.9.1 Prevent water condensation

The warm, humid gas exhaled by the patient condenses as it flows along the expiratory tubing. The condensed water remains on the tubing wall and eventually enters the water collector. When the patient's exhaled gas reaches the expiratory valve, condensation may appear on the valve and the proximal flow sensor, compromising the flow sensor's measurement accuracy.

Check for condensation on the expiration valve and proximal flow sensor when an abnormal flow waveform or fluctuation is detected.

Unstable tidal volume. If water condensation is present, wipe it off before use. Check for water in the exhaled water collector while using the respirator. If condensation is present, empty it promptly. Water condensation in

The expiration valve can be reduced by using a bacteria filter between the expiration tube and the expiration valve.

14.9.2 Drain condensate water

If there is condensation inside the expiratory valve and proximal flow sensor, remove the expiratory valve and flow sensor, and drain the water. Then, replace them all for use.

WARNING: Ensure all parts of the breathing system are dry each time you clean and disinfect or clean and sterilize the breathing system.

WARNING: Check for water accumulation in the expiration valve when you detect an abnormal flow waveform or unstable tidal volume fluctuation.

If there is condensation inside the expiratory valve and proximal flow sensor, clean it.

15.0

Accessories

WARNING: Use only the accessories specified in this chapter. The use of other accessories may result in erroneous measured values or damage to the equipment.

WARNING: Disposable accessories should not be reused. Reuse may decrease performance or cause cross-contamination of the next patient.

WARNING: Check if the accessories and their packaging are damaged. If you detect any damage, do not use them.

WARNING: Parts intended to come into contact with patients must meet the biocompatibility requirement of ISO10993-1 to avoid any adverse reaction resulting from such contact.

WARNING: Disposal of accessories must comply with applicable waste control regulations.

WARNING: The user must purchase legally marketed products for other accessories that must implement the functions of the equipment.

NOTE: All listed accessories are validated for use with this specific ventilator. The hospital is responsible for ensuring ventilator and accessory compatibility before use. Incompatible parts may result in decreased performance.

NOTE: The accessory material of the CO₂ and SpO₂ module that comes into contact with patients has been biocompatibility tested and verified to comply with ISO 10993-1.

ACCESSORIES DESCRIPTION		PART NO.
Patient tubing kit (includes breathing tubes, connectors, water collector, etc.)	Reusable circuit for adults	115-094299-00
	Reusable circuit for adults	040-007376-00
	Reusable pediatric circuit	115-094300-00
	Reusable pediatric circuit	040-007377-00
	Reusable neonatal circuit	040-007368-00
	Disposable circuit for adults	040-001884-00
	Adult Circuit (Disposable/Sensor/Connector) 115-096080-00	
	Disposable pediatric circuit	040-001886-00
	Pediatric Circuit (Disposable/Sensor/Connector) 115-096081-00	
	Disposable neonatal circuit	040-002751-00
	Neonatal Circuit (Disposable/Sensor/Connector)	115-096082-00
	Disposable adult/pedal breathing circuit (coaxial, 1.8 m)	040-006596-00
	Coaxial Circuit (Disposable/Sensor/Connector)	115-096083-00
	Disposable coaxial breathing circuit set with expiratory valve and flow sensor (10 units)	115-094000-00
	Reusable circuit for adults (without water collector) 115-094270-00	
Reusable circuit for adults (without water collector)040-007378-00		
Reusable pediatric circuit (without water collector) 115-094271-00		
Reusable pediatric circuit (without water collector)040-007379-00		
Humidifier tube kit	Disposable circuit with individual heating for infants (Jike)	040-002172-00
	Disposable heated circuit for adults (Jike)	115-018063-00
	Disposable heated circuit for infants (Jike)	115-028490-00
	Disposable circuit for adults (F&P/water chamber)	040-002892-00
	Disposable infant circuit (F&P/water chamber)040-002891-00	
	Reusable heated circuit for adults (Jike)	115-094337-00
	Breathing tubes (Evatherm/heating)	040-002338-00
	Reusable circuit with individual heating for infants (F&P)	040-000711-00
	Reusable circuit with individual heating for adults (F&P)	040-000715-00
	Heat and moisture exchanger	040-001571-00
Filter	Disposable bacteria filter	040-001831-00
	Electric nebulizer	040-003539-00

Table 15-1 List of accessories

Face mask	Disposable face mask, small, with headband 115-093936-00	
	Disposable face mask, medium size, with headband 115-093937-00	
	Disposable face mask, large, with headband 115-093938-00	
	Reusable face mask, small, with headband 115-093942-00	
	Reusable, medium-sized face mask with headband	115-093948-00
	Reusable, large face mask with headband 115-093949-00	
Nasal cannula	Nasal cannula (small) (10)	115-094759-00
	Nasal cannula (medium) (10)	115-094760-00
	Nasal cannula (large) (10)	115-094761-00
	Nasal cannula, adult, small	040-007358-00
	Nasal cannula, adult, medium	040-007359-00
	Large adult nasal cannula	040-007360-00
	Oxygen Therapy Mask for Oxygen Therapy (Large, Adult) 040-002365-00	Oxygen therapy mask (small, child) 040-002366-00
Nasal cannula (small) (10)		115-037829-00
Nasal cannula (small) (10)		115-094759-00
Nasal cannula (medium) (10)		115-037830-00
Nasal cannula (medium) (10)		115-094760-00
Nasal cannula (large) (10)		115-037831-00
Nasal cannula (large) (10)		115-094761-00
Nasal cannula, adult, small		040-002376-00
Nasal cannula, adult, small		040-007358-00
Nasal cannula, adult, medium		040-002377-00
Nasal cannula, adult, medium		040-007359-00
Large adult nasal cannula		040-002378-00
Large adult nasal cannula		040-007360-00
Pediatric nasal cannula		040-005920-00
Nasal cannula, infant		040-005803-00
Nasal cannula, neonate		040-005802-00
Test lung		Test lung (adult)040-000744-00
	Test lung (neonate)040-000745-00	

Table 15-1 List of accessories

Humidifier kit (including humidifier, water reservoir, heated patient tubing, etc.)	Jike SH330/EU	115-018049-00
	Jike SH330/India	115-018050-00
	Jike SH330/USA/110V	115-018051-00
	Jike SH330/United Kingdom	115-018053-00
	Jike SH330/USA/220 V	115-018054-00
	Jike SH330/BR/230 V	115-032096-00
	Jike SH330/BR/110V	115-032097-00
	Jike SH530/Heating/EU	115-018056-00
	Jike SH530/Heating/India	115-018057-00
	Jike SH530/Heating/USA/110V	115-018058-00
	Jike SH530/Heating/United Kingdom	115-018060-00
	Jike SH530/Heating/USA/220 V	115-018061-00
	Jike SH530/Heating/EU/Infant	115-028494-00
	Jike SH530/Heating/India/Infant	115-028496-00
	Jike SH530/Heating/United Kingdom/Infant	115-028498-00
	Jike SH530/Heating/US110/Infant	115-028500-00
	Jike SH530/Heating/US220/infant	115-028502-00
	Jike SH530/Heating/BR/230 V	115-032098-00
	Jike SH530/Heating/BR/110V	115-032099-00
Jike SH530/Heating/BR230/Infant	115-032100-00	
Jike SH530/Heating/BR110/infant	115-032101-00	
Humidifier water reservoir	Disposable water chamber for Jike humidifier 040-002173-00	
	Reusable water chamber for Jike 040-001530-00 humidifier	
Supply hose assembly gas	Respirator oxygen hose accessory kit (German)	115-008257-00
	Respirator oxygen hose accessory kit (French)	115-008259-00
	Respirator oxygen hose accessory kit (Australian)	115-008261-00
	Respirator Oxygen Hose Accessory Kit (US/Dual Connector/ DISS)	115-008209-00
	Respirator oxygen hose accessory kit (British)	115-008201-00

Table 15-1 List of accessories

Module accessories	Direct flow CO2 accessory kit (disposable)	115-091760-00
CO2	Direct Flow CO2 Accessory Kit (Reusable) 115-093194-00	
	Disposable main CO2 adapter , adult/pedal, 10 You.	125-000280-00
	Reusable primary CO2 adapter , adult/pedic. Disposable	040-006830-00
	primary CO2 adapter , neonatal, 10 You.	125-000281-00
	Reusable primary CO2 adapter , neonatal	040-006831-00
	Sideflow CO2 Module Accessory Kit (Adult/Pediatric)	115-024752-00
	Sideflow CO2 Module Accessory Kit (Neonatal)	115-024753-00
	Direct flow CO2 module	6800-30-50487
	Sideflow CO2 Module	115-037385-00
Module accessories	SpO2 accessory kit /additional/reusable	0651-30-77014
SpO2*	SpO2/ped/reusable accessory kit	0651-30-77015
	SpO2/Neonatal/Reusable Accessory Kit	0651-30-77016
	SpO2 Module	115-015016-00
	Flow Sensor Reusable Flow Sensor Kit (Adult/Pediatric, Differential Pressure Type)	115-090657-00
	Disposable flow sensor kit (adult/pediatric, differential pressure type)	115-090659-00
	Disposable flow sensor kit (neonate, differential pressure type)	115-090660-00
	Disposable flow sensor kit (adu/ped/10 kits) 115-094093-00	
	Disposable flow sensor kit (neonatal/10 kits) 115-094094-00	
Expiration valve	Reusable exhalation valve	115-085487-00
	Disposable exhalation valve/10 units.	115-093994-00
	Reusable exhalation valve (neonate)	115-089491-00
	Disposable exhalation valve (neonatal/10 units) 115-094971-00	
Accessories for newborns	nCPAP accessory kit (neonate)	115-041555-00
Power adapter	AC power adapter (100-240 V)	022-000599-00
	DC power adapter, with power cord (12-28 V)	022-000646-00
Lithium-ion battery	Lithium-ion battery kit	115-079845-00
	Lithium-ion battery kit	115-096070-00

Table 15-1 List of accessories

Power cable	AC adapter power cord (Brazil) 009-003699-00	
	AC adapter power cord (UK United)	009-003701-00
	AC adapter power cord (US/ 110 V)	009-003702-00
	AC adapter power cord (EU)	009-003703-00
	AC adapter power cord (India) 009-010943-00	
	AC adapter power cord (AUS)	009-004941-00
	Adapter AC power cord (ZA)	009-015291-00
	AC adapter power cord (US/ 220 V)	009-015324-00
Arm of support	Support arm	034-000652-00
Car	Car	045-005884-00
HEPA filter	HEPA filter	082-004174-00
Dust filter Air intake dust filter		048-011379-00
Base	Ventilation coupling, with adapter	115-094147-00
	Protective cover for the tube	048-011547-00
Protective cover for the tube		
Intravenous post	Intravenous post	034-000653-00
Basket of accessories	Accessory basket	043-012949-00
Pump support	BeneFusion tDS Transport Base Station with cart support	115-094570-00
fall arrest rope	fall arrest rope	048-012017-00
Pressure reducer	Pressure reducer, 3/4" (DIN 477)/DIN	082-004343-00
	Pressure reducer, 5/8BE (BS 341)/DIN	082-004344-00
	Pressure reducer, CGA 540/DISS	082-004345-00
	Pressure reducer, Pin Index (CGA 870)/DIN	082-004346-00
	Pressure reducer, Pin Index (CGA 870)/DIN	082-004347-00
Adapter mounting base kit	Adapter mounting base kit	115-095424-00

Table 15-1 List of accessories

*:

The pulse oximetry probes and probe cable extenders listed for this device have been validated and tested in accordance with ISO 80601-2-61.

The SpO₂ sensor material that comes into contact with patients or the insole has been biocompatibility tested and found to comply with ISO 10993-1.

The wavelength emitted by the sensors is between 600 nm and 1000 nm. The maximum photoelectric output power consumption of the sensor is less than 18 mW.

Information on wavelength range and maximum photodynamic output consumption can be especially useful for healthcare personnel, for example, for healthcare personnel who perform photodynamic therapy.

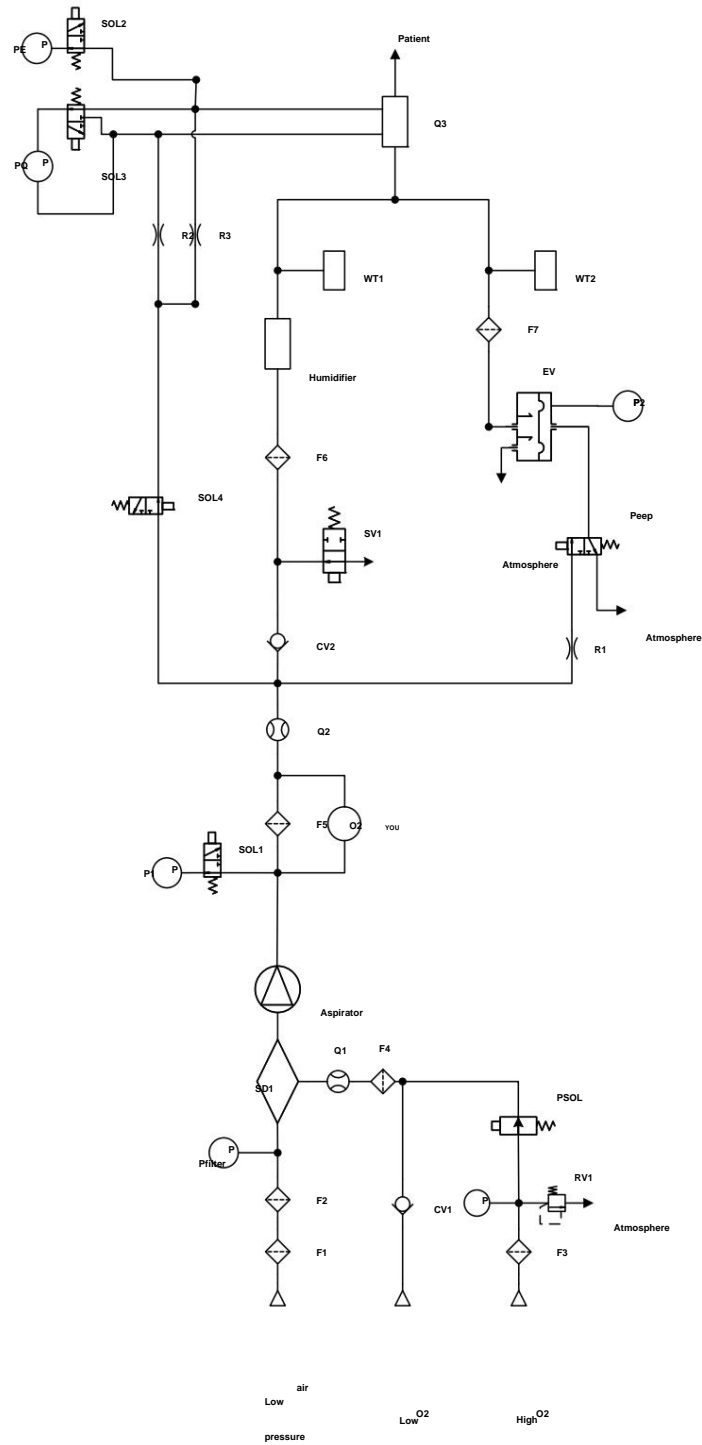
For information on ECG accessories, Resp accessories, Temp accessories, NIBP accessories, and IBP accessories used with the BeneVision N1 patient monitor, please refer to the BeneVision N1 patient monitor operator's manual. To purchase these accessories, please contact our company.

A.0 **Theory of operation**

Principle of the pneumatic circuit.....	A-2
Electrical system	A-6

A.1 Principle of the pneumatic circuit

A.1.1 Pneumatic circuit diagram



A.1.2 List of components

SYMBOLS	NAME	SYMBOLS	NAME
Low air pressure inlet	Low air pressure inlet	Aspirator	Aspirator
Low pressure O2 inlet	Low pressure O2 inlet	P1, P2	Pressure sensor
High entry O2 pressure	High entry O2 pressure	SOL1, SOL2, SOL3, SOL4	Three-way valve pressure reset
F1	Coarse filter	YOU	O2 sensor
F2	HEPA filter	CV2	Valve retention
Pfilter	Vacuum sensor	SV1	Valve security
SD1	Mixing chamber of air/oxygen	F6	Inspiration port filter
CV1	Valve retention of the entrance of gas supply	R1, R2, R3	Endurance
F3	Input filter high pressure O2	PEEP Proportional PEEP Control Valve	
PS1	EV Pressure Sensor Expiration Valve		
RV1	Relief valve pressure	Q3	Proximal flow sensor
PSOL	Valve solenoid proportional	PQ	Sensor difference of pressure
F4, F5	Filter mesh	PE	Pressure sensor proximal
WT1, WT2	Water collector	F7	Hole filter expiration
Q1, Q2	Flow sensor		

Table A-2 List of components

A.1.3 Definition of the symbols

















	Gas supply		Filter
	Pressure regulating valve		Switch valve (double position, two-way solenoid valve)
	O2 sensor		Pressure sensor
	Check valve		Endurance
	Dual position, three-way solenoid valve		Flow sensor
	Vacuum sensor air inlet		Solenoid valve proportional
	Vacuum cleaner heat exchanger		Aspirator
	Water collector		Humidifier

Table A-3 Symbols

A.1.4 Overview of the pneumatic circuit system

This product is a respirator that is electronically operated and controlled. Oxygen is supplied through the high- or low-pressure oxygen port. Air is drawn from the ambient atmosphere using the vacuum created by the aspirator motor. The logical structure diagram of the pneumatic circuit system is shown in the following figure. The system consists of six parts: gas supply subsystem, aspirator subsystem, inspiration branch subsystem, pressure monitoring subsystem, patient tube subsystem, and expiratory valve subsystem.

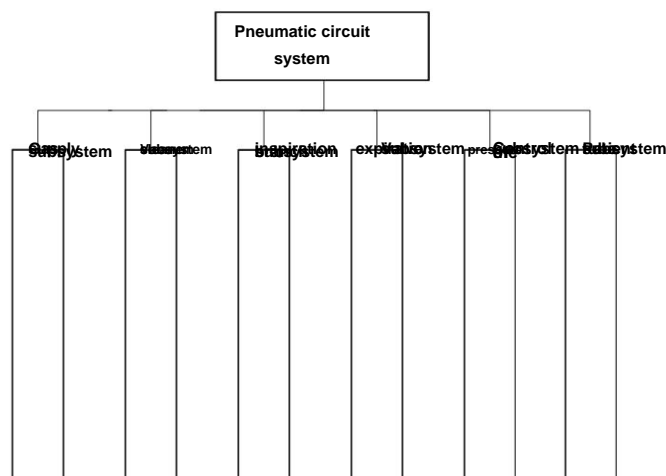


Figure A-2 Structural diagram of the pneumatic system

The gas supply subsystem is the first part of the pneumatic circuit. Its main function is to draw air and oxygen from external sources into the machine. Because the external gas supply pressure is high and unstable and may contain impurities, a dedicated filter is provided in the gas supply subsystem to remove these impurities from the air and oxygen. A pressure relief valve is also provided in the high-pressure gas supply circuit to protect the precision solenoid valve and flow sensor in the flow control module at the rear end. A pressure sensor is also included.

to control the gas supply pressure, as well as a check valve to prevent gas backflow within the respirator to other external gas supplies. The gas supply inlet connector has been designed as an optional NIST type/ DISS to avoid connection errors.

The main function of the aspirator subsystem is to mix pure oxygen and air into different proportions, thus controlling the oxygen concentration of the outlet gas and the speed of the aspirator, thereby achieving precise control of the gas flow and pressure.

The inspiration branch subsystem is designed to control concentration of oxygen, control the flow rate of the main branch, and release pressure from the safety valve. The O₂ sensor is used to monitor the oxygen concentration of the outlet gas in the aspirator subsystem. A high-precision flow sensor is provided in the main branch to monitor the outlet gas flow rate in the aspirator subsystem. Additionally, a safety valve is equipped to relieve pressure in the patient tubing in case of excessively high pressure due to a abnormal use, in order to ensure patient safety.

The pressure monitoring subsystem includes pressure monitoring At the machine end, monitoring includes patient end pressure, PEEP control pressure, and proximal flow sensor differential pressure. A sampling circuit purge function is provided to prevent damage from humidified gas entering the machine through the sampling tube.

The patient tubing subsystem, as the ventilator's peripheral pneumatic circuit, primarily serves to connect the ventilator to the patient and humidify the patient's inhaled gas. This subsystem connects the humidifier's filter and water reservoir to the patient's face mask. The filter's precision is 0.3 μm , effectively preventing bacteria and water vapor from entering the ventilator from the tubing.

The gas supplied by the ventilator is discharged through the expiratory valve subsystem. This subsystem is equipped with expiratory PEEP control and PEEP pressure monitoring.

A.2 Electrical system

A.2.1 Structural diagram of the electrical system

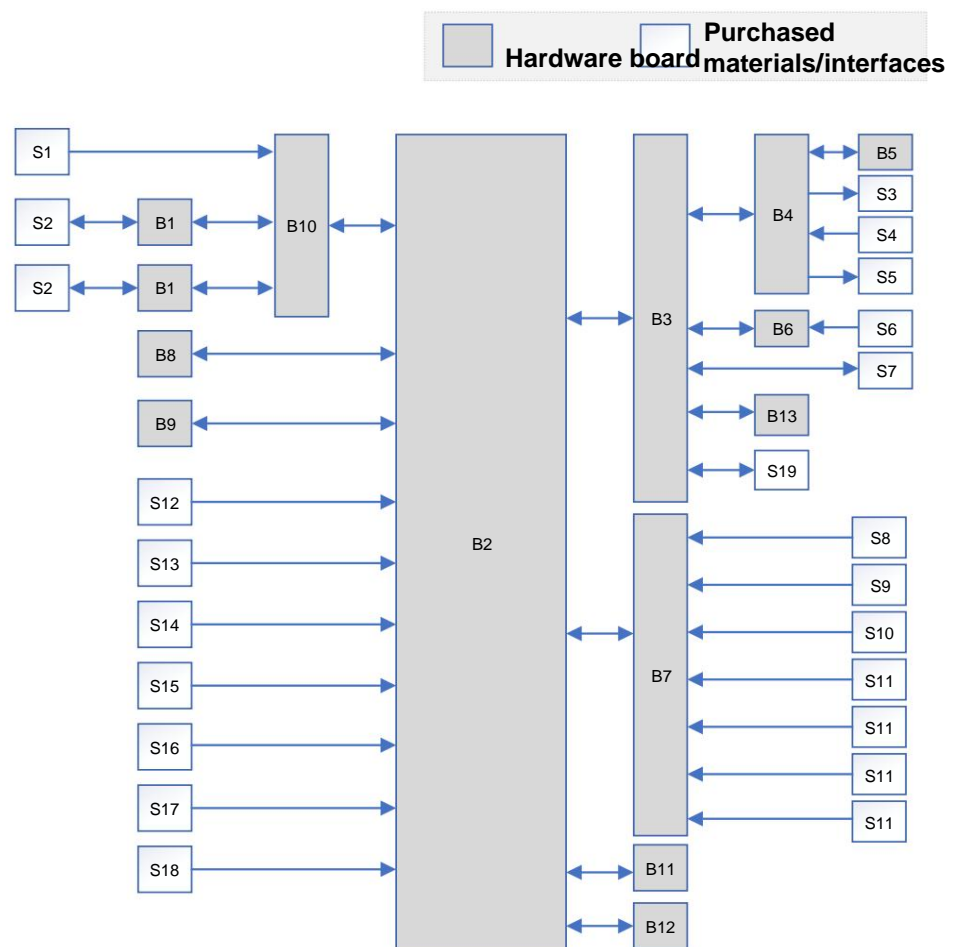


Figure A-3 Structural diagram of the electrical system

A.2.2 List of components

No.	NAME	No.	NAME
S1	DC input socket	S8	Oxygen branch flow sensor
S2	Battery	S9	Branch flow sensor major
B1	S10 Battery Adapter Plate Proportional PEEP Valve		
B2	Monitor board	S11	3-way valve
B8	Vacuum sensor plate	S12	Aspirator
B9	Gas supply pressure sensor plate	S13	Ultrasonic O2 sensor
B3	Main control board	S14	Proportional oxygen valve
B4	Keyboard	S15	Safety valve
B5	Alarm light plate	S16	Energy capacitor
B6	4G/5G carrier card	S17	Backup vacuum cleaner
S3	Speaker	S18	Power radiator breather
S4	Encoder	B10	Power supply board
S5	Ink screen	B11	External interface board
S6	4G/5G Module	B12	Plug-in box backplate
S7	Touch and display module	B13	Bluetooth module
B7	Sensor adapter plate	S19	WiFi Module

Table A-4 List of components

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B.0

Product specifications

Safety Specifications	B-2 Environmental
Specifications.....	B-3 Electrical Power
Requirements.....	B-3 Physical
Specifications.....	B-4 Pneumatic
System Specifications	B-6 Respirator
Specifications.....	B-7 Respirator
Accuracy.....	B-10
Alarm.....	B-13
Additional Settings and Tools.....	B-14 CO2 Module
Specifications.....	B-15 SpO2 Module
Specifications.....	B-18 Monitor
Specifications.....	B-20

The ventilator is already integrated with an expiratory volume monitor, a pressure measuring device, a pressure release device, a built-in alarm system, an O2 monitor, a CO2 monitor, an SpO2 monitor, an ECG monitor, a Resp monitor, a Temp monitor, an IBP monitor, and a NIBP monitor.
Of them:

- The expiratory volume monitor, pressure measuring device and pressure release device comply with ISO 80601-2-12 and ISO 80601-2-84 standards.
- The alarm system complies with IEC 60601-1-8.
- The O2 monitor complies with ISO 80601-2-55.
- The CO2 monitor complies with ISO 80601-2-55.
- The SpO2 monitor complies with ISO 80601-2-61.
- The ECG monitor complies with IEC 60601-2-27.
- The temperature monitor complies with ISO 80601-2-56.
- The IBP monitor complies with the IEC60601-2-34 standard.
- The NIBP monitor complies with IEC 80601-2-30.
- The gas supply hose assembly complies with ISO 5359.

B.1 Safety specifications

Classified by type of protection against electric shocks	Respirator: Class I device with internal electrical power supply (connected to AC adapter); Class II device with internal power supply (connected to DC adapter)
Classified by the degree of protection against electrical shocks	Respirator: Mixed applied piece type BF and CF. Respiratory circuit and CO2: Type BF. SpO2: Type CF. BeneVision N1 Patient Monitor: Mixed applied part type BF and CF, where ECG, Resp, Temp, SpO2, NIBP and IBP are CF type, while CO2 is applied part BF.
Classified by degree of protection against harmful water ingress	Respirator: IP34 Coupling: IP22 AC adapter: IP22 DC Adapter: IP33
Classified according to sterilization and disinfection methods recommended by the manufacturer	Respirator: Disinfection and sterilization methods of the device recommended by the manufacturer.
Classified according to safety level when using flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide	Not applicable to an environment containing flammable anesthetic gas
Classified according to the mode of operation	Continuous operating equipment
If the equipment has applied parts that support protection against the shock effect of defibrillation	All applied parts support protection against the defibrillation shock effect

Table B-1 Safety Specifications

If the equipment has signal output or input components	With signal input and output components
Permanently installed equipment or equipment not permanently installed	Equipment installed on a non-permanent basis
Level of movement	Portable device (without cart)
	Mobile device (with cart)
	Fixed device (with coupling)

Table B-1 Safety Specifications

B.2 Environmental specifications

MAIN UNIT			
Element	Temperature (°C)	Relative humidity (non-condensable)	Pressure barometric (kPa) ¹
Operation	-20 to 50	From 5% to 95% of relative humidity	Adult: 37.6 to 110 Neonate: 60 to 110
Storage -20 to 60		From 10% to 95% of relative humidity	60 to 110

Table B-2 Environmental Specifications

1. Note: The outlet pressure from 37.6 kPa to 60 kPa should reach 35 cmH₂O, the outlet pressure from 60 kPa to 110 kPa should reach 60 cmH₂O.

CAUTION: The device may not meet operating specifications if stored or used outside the specified temperature and humidity ranges. If device performance degrades due to aging or environmental conditions, contact service personnel.

NOTE: When using the respirator with other medical devices, refer to the environmental specifications stated in the instructions for the corresponding medical device.

B.3 Power supply requirements

EXTERNAL AC POWER SUPPLY	
Input voltage	100 to 240V~
Input frequency	50/60 Hz
Input current	2.2 to 1.0 A
Fuse	T3,15 A/250 V
AC waveform	Sine wave
EXTERNAL DC POWER SUPPLY	
Input voltage	12a 28 V
Input current	15 to 6.5 A

Table B-3 Electrical Power Requirements

INTERNAL BATTERY	
Number of batteries	One or two
Battery Type	Lithium-ion battery
Nominal battery voltage	14.4 VCC
Battery capacity	6600 mAh with a single battery 13,200 mAh with two batteries
Charging time	No more than 3 hours from 0% to 90% when the ventilator is powered by a new battery in an off or standby state; or no more than 6 hours from 0% to 90% when the ventilator is powered by two new batteries in an off or standby state.
Minimum battery operating time	330 min (powered by a fully charged old battery according to ISO 80601-2-12); 660 min (powered by two old batteries fully charged according to ISO 80601-2-12). Note: The operating condition of the respirator complies with ISO 80601-2-12.

Table B-3 Electrical Power Requirements

B.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)
TOTAL DIMENSIONS	
Dimensions	<p>* Dimensional error: ±10 mm</p>

Table B-4 Physical Specifications

Weight	<p>Approximately 6.5 kg (including the main unit) 35kg (entire machine including BeneVision N1 patient monitor)</p> <p>Note: The main unit does not include the BeneVision N1 patient monitor. The complete machine includes the main unit (with one battery), the display, and the cart, but excludes the patient tubing, module, support arm, and humidifier.</p>
WHEEL	
Wheel	Four wheels. All wheels have brakes.
MONITOR	
Guy	TFT screen
Dimensions	10.1"
Resolution	1280 × 800 pixels
Glow	Adjustable
LED INDICATOR	
Alarm LED One (blue, yellow, and red)	When high-priority alarms occur, it flashes red; when medium-priority alarms occur, it flashes yellow; when (low priority alarms, flashes blue).
Power LED external	One (green; lights up when the power supply (external is connected).
Battery indicator light	One (green; lit when batteries are installed and the external power supply is connected; flashes when powered by batteries; turns off when no batteries are installed or when the respirator is switched off).
Operating status LED	One, specifically, is the backlight on the power switch key (green; it lights up when the computer is on and turns off when the computer is off).
AUDIO INDICATOR	
Speaker	It emits alarm and key tones; it supports multi-level tone modulation. The alarm tones meet the requirements of IEC 60601-1-8.
Audible alarm	It emits auxiliary alarm tones if the speakers are not working correctly.
CONNECTOR	
Network connector	It is a connector that allows you to connect the equipment to a PC to perform software updates and to an external medical data device.
USB connector	Use the USB device to perform ventilator software updates, export captured screens, export configuration information and historical data (such as patient data, alarm logs, calibration tables), transfer configuration data between machines of the same type, and connect the electronic nebulizer with a USB interface.

Table B-4 Physical Specifications

RS-232 connector	It connects to the external calibration device to calibrate the pressure. A device can be connected via this connector. external medical device for communicating with the ventilator.
VGA connector	It outputs VGA video signals with the same content as the main screen and connects to the external screen (supports screens with a resolution of 1280*800).
Bluetooth	Connect to and communicate with the external device.
5G	Connect to and communicate with the external device.
WiFi	Connect to and communicate with the external device.
Alarm output	
Alarm delay time from the monitor to the remote equipment	The alarm delay time from the monitor to the remote equipment is ≈ 3 seconds, measured at the monitor's signal output connector.
Alarm signal sound pressure level range	45 dB(A) to 85 dB(A) within a range of one meter

Table B-4 Physical Specifications

B.5 Pneumatic system specifications

HIGH PRESSURE O₂ SUPPLY	
Type of gas	Oxygen
Gas supply pressure range	280 kPa to 650 kPa
Average inflow in 10 s of each gas at 280 kPa	<200 l/min
Input connector	NIST or DISS
Nominal flow requirement 200 l/min	
LOW PRESSURE O₂ SUPPLY	
Gas supply pressure range	≈ 100 kPa
Input connector	Quick connector that supports self-sealing
Flow	≈ 15 l/min
INSPIRATION MODULE	
Out of inspiration	15mm/22mm coaxial tapered connector
Safe respiratory system pressure	Under normal and single-failure conditions, the airway pressure should not exceed 120% of the maximum operating pressure or exceed the high-pressure alarm limit of 20 cmH ₂ O.
EXPIRATION MODULE	
Expiration outlet	15mm/22mm coaxial tapered connector

Table B-5 Pneumatic System Specifications

SYSTEM CONFORMITY AND RESISTANCE	
Accordance	<p>Disposable circuit for adults (includes inspiratory safety valve, bacteria filter, disposable adult patient tubing, water collector, expiratory valve and adult/pediatric flow sensor): $\dot{y}4$ ml/cmH₂O;</p> <p>Reusable adult circuit (includes inspiratory safety valve, bacteria filter, reusable adult patient tubing, water collector, expiratory valve, Y-piece connector and adult/pediatric flow sensor): $\dot{y}2$ ml/cmH₂O;</p> <p>Disposable pediatric circuit (includes inspiratory safety valve, bacteria filter, disposable pediatric tubing, water collector, expiratory valve and adult flow sensor) pediatric): $\dot{y}2$ml/cmH₂O;</p> <p>Pediatric reusable circuit (includes inspiratory safety valve, bacteria filter, pediatric reusable tubing, water collector, expiratory valve, Y-piece connector and adult/pediatric flow sensor): $\dot{y}2$ ml/cmH₂O;</p> <p>Disposable neonatal circuit (includes inspiratory safety valve, bacteria filter, disposable neonatal tube, water collector, expiratory valve, Y connector and neonatal flow sensor): $\dot{y}1$ ml/cmH₂O.</p>
Resistance of inspiration	<p>Not exceeding 6 cmH₂O at a flow rate of 60 l/min (adult patient tube)</p> <p>Not exceeding 6 cmH₂O at a flow rate of 30 l/min (pediatric patient tube)</p> <p>Not exceeding 6 cmH₂O at a flow rate of 5 l/min (neonatal patient tube)</p>
Resistance to exhalation	<p>Not exceeding 6 cmH₂O at a flow rate of 60 l/min (adult patient tube)</p> <p>Not exceeding 6 cmH₂O at a flow rate of 30 l/min (pediatric patient tube)</p> <p>Not exceeding 6 cmH₂O at a flow rate of 5 l/min (neonatal patient tube)</p>
MAXIMUM FLOW	
Maximum flow $\dot{y}280$ l/min	
DEAD SPACE OF THE FLOW SENSOR	
Flow sensor dead space	Disposable/reusable, adult/pediatric: $\dot{y}20$ ml, neonate: $\dot{y}2$ ml.

Table B-5 Pneumatic System Specifications

B.6 Respirator specifications

CONTROLLED PARAMETERS			
Parameter	Range	Step size	Unit
Flow (O ₂ Therapy)	Adult/Pediatric: 2 to 80 Newborn: 2 to 20	1 l/min	
O ₂ %	21 to 100	1	% vol.

Table B-6 Respirator Specifications

VC	Adult: 100 to 4000 Pediatric: 20 to 300 Newborn: 2 to 100	100 to 4000: 10 50 to 100: 1 10 to 50: 0.5 2 to 10: 0.1	ml
\dot{y} Paux	0 to 80	1	cmH2O
PEEP	0 to 50	1	cmH2O
\dot{y} int.PEEP	deactivated, 1 to 40	1	cmH2O
Palt	0 to 80	1	cmH2O
Pbaj	0 to 50	1	cmH2O
\dot{y} Pinsp	1 to 80	1	cmH2O
\dot{y} Papnea	1 to 80	1	cmH2O
F	Adult/Pediatric: 1 to 100 Newborn: 1 to 150	1	/min
fsimv	1 to 60	1	/min
I:E	4:1 to 1:100.5/		
Tinsp0.10 to 10.00		0.10 to 1.00: 0.01 1.00 to 10.00: 0.05	s
Tpend	0.00 to 2.00	0.05	s
Talt	0.10 to 30.00	0.10 to 1.00: 0.01 1.00 to 30.00 0.05	s
Tbaj	0.20 to 30.00	0.20 to 1.00: 0.01 1.00 to 30.00 0.05	s
Exp%	Automatic, from 1 to 85	1 to 5: 1 5 to 85: 5	%
F-Trig	Adult/Pediatric: 0.5 to 20.0, disabled Neonate: 0.1 to 5.0	0.1	l/min
P-Trig-20,0 to -0.5, deactivated		0.5	cmH2O
Tpause(%)	deactivated, 5 to 605		%
Capnea	Adult: 100 to 4000 Pediatric: 20 to 300 Newborn: 2 to 100	100 to 4000: 10 50 to 100: 1 10 to 50: 0.5 2 to 10: 0.1	ml
breath-holding	Adult/Pediatric: 1 to 100 Newborn: 1 to 150	1	/min
Tinsp apnea	0.10 to 10.00	0.10 to 1.00: 0.01 1.00 to 10.00: 0.05	s
VM%	25 to 350	1	%
Flow	Adult: 6 to 180 Pediatric: 6 to 30	10 to 180: 1.0 6 to 10: 0.1	l/min
PEEP (nCPAP mode)	0 to 50	1	cmH2O

Table B-6 Respirator Specifications

MONITORED PARAMETERS			
PARAMETER	RANGE	RESOLUTION	UNIT
FiO2	15 to 100	1	% vol.
VCI0 to 6000 (BTPS)		<100 ml: 0.1 ≥100 ml: 1	ml
VCe			
VCe esp			
VM	Adult/Pediatric: 0.0 to 100.0	<10.0 l/min: 0.01	l/min
VMesp	Neonate: 0.0 to 30.0	≥10.0 l/min: 0.1	
VMfuga			
Peak-20 to 120		Absolute value <10 cmH2O: 0.1	cmH2O
Pmest		Absolute value ≥ 10 cmH2O: 1	
Pmed			
PEEP	0 to 120	<10 cmH2O: 0.1 ≥10 cmH2O: 1	cmH2O
total	0 to 200	1	/min
fmand.			
fesp			
Tinsp0.00 to 60.00	0.01s		
I:E	150:1 to 1:150	0.1	/
WOB	0.00 to 100.00	0.01 J/min	
	0.00 to 20.00	0.01 J/l	
% drain	0 to 100	1	%
Rio to 600		1	cmH2O/ (l/s)
Re			
Cstat	0 to 300	<10ml/cmH2O: 0.1 ≥10 ml/cmH2O: 1	ml/cmH2O
Cdin			
RSBI	0 to 9999	11/(l•min)	
RCesp0.00 to 10.00	0.01s		
Flow (O2 Therapy)	0.0 to 100.00.1		l/min
PEEPi0 to 80		0.1	cmH2O
PEEPtot	0 to 120	0.1	cmH2O
P0.1-20,0 to 0,00,1			cmH2O
Power	0 to 120	<10 cmH2O 0.1 ≥10 cmH2O: 1	cmH2O
MPrs	0.00 to 100.00	0.01 J/min	
	0.00 to 20.00	0.01 J/l	

Table B-6 Respirator Specifications

B.7 Respirator accuracy

ACCURACY OF CONTROL	
Flow (O ₂ Therapy)	2 l/min to 3 l/min: ± 2 l/min 3 l/min to 80 l/min: $\pm(2$ l/min + 10% of the set value)
FiO ₂	$\pm(3$ vol. % + 1 % of the established value)
VC	Adult/Pediatric: 20 ml to 4000 ml: $\pm(10$ ml + 10% of the established value) Newborn: 2 ml to 3 ml: ± 2 ml 3 ml to 100 ml: $\pm(2$ ml + 10% of the established value)
\dot{y} Paux	$\pm(2$ cmH ₂ O + 5% of the established value)
\dot{y} Pinsp	$\pm(2$ cmH ₂ O + 5% of the established value)
PEEP	0 cmH ₂ O to 2 cmH ₂ O: \pm set value (Error is not greater than 2 cmH ₂ O when PEEP is set to 0 cmH ₂ O). 2 cmH ₂ O to 50 cmH ₂ O: $\pm(2$ cmH ₂ O + 5% of the established value)
Palt	0 cmH ₂ O to 2 cmH ₂ O: \pm set value (Error is not greater than 2 cmH ₂ O when P _{high} is set to 0 cmH ₂ O). 2 cmH ₂ O to 80 cmH ₂ O: $\pm(2$ cmH ₂ O + 5% of the established value)
Pbaj	0 cmH ₂ O to 2 cmH ₂ O: \pm set value (Error is not greater than 2 cmH ₂ O when the P _{low} is set to 0 cmH ₂ O). 2 cmH ₂ O to 50 cmH ₂ O: $\pm(2$ cmH ₂ O + 5% of the established value)
f ₁ /min at 100/min: ± 1 /min	Another interval: $\pm 2\%$ of the established value
fsimv	± 1 /min
I:E	2:1 to 1:4 10% of the established value Another interval: $\pm 2\%$ of the established value
T _{insp}	± 0.10 or $\pm 10\%$ of the stated value, whichever is greater
T _{alt}	0.10 s 0.20 s: \pm set value 0.20 sa 30.00 s: ± 0.20 so $\pm 10\%$ of the established value, whichever is greater
T _{baj}	± 0.20 or $\pm 10\%$ of the stated value, whichever is greater
F-Trig	Adult/Pediatric: 0.5 l/min to 1.0 l/min: \pm set value 1.0 l/min to 20.0 l/min: $\pm(1$ l/min + 10% of the set value) Newborn: 0.1 l/min to 1.0 l/min: +1.0/-0.1 l/min 1.0 l/min to 5.0 l/min: $\pm(1$ l/min + 10% of the set value)
P-Trig	-1.0 cmH ₂ O to -0.5 cmH ₂ O: \pm set value -20.0 cmH ₂ O to -1.0 cmH ₂ O: $\pm(1.0$ cmH ₂ O + 10% of the established value)
Exp%	1% to 10%: \pm set value (absolute error) 10% to 85%: $\pm 10\%$ (absolute error)
T _{pause} (%)	$\pm 5\%$ (absolute error, not applicable if T _{pause} (%) is less than 0.1 s)

Table B-7 Respirator Accuracy

Tpend	0.00 s 0.20 s: \pm set value (The error is no greater than 0.10 s when Tslope is set to 0.00 s). 0.20 sa 2.00 s: ± 0.20 so $\pm 20\%$ of the established value, whichever is greater
\dot{y} Papnea	$\pm(2 \text{ cmH}_2\text{O} + 5\%$ of the established value)
Capnea	Adult/Pediatric: 20 ml to 4000 ml: $\pm(10 \text{ ml} + 10\%$ of the established value) Newborn: 2 ml to 3 ml: $\pm 2 \text{ ml}$ 3 ml to 100 ml: $\pm(2 \text{ ml} + 10\%$ of the established value)
breath-holding	1/min to 100/min: $\pm 1/\text{min}$ Another interval: $\pm 2\%$ of the established value
Tinsp apnea	± 0.1 or $\pm 10\%$ of the stated value, whichever is greater
VM%	$\pm 10\%$ (absolute error) or $\pm 10\%$ of the established value, whichever is greater.
\dot{y} int.PEEP	1 cmH ₂ O to 2 cmH ₂ O: \pm established value 2 cmH ₂ O to 40 cmH ₂ O: $\pm(2 \text{ cmH}_2\text{O} + 5\%$ of the established value)
Flow	$\pm 20\%$ of the established value
PEEP (nCPAP mode)	0 cmH ₂ O to 2 cmH ₂ O: \pm set value (Error is not greater than 2 cmH ₂ O when PEEP [nCPAP mode] is set to 0 cmH ₂ O). 2 cmH ₂ O to 50 cmH ₂ O: $\pm(2 \text{ cmH}_2\text{O} + 5\%$ of the established value)
MONITORING ACCURACY	
FiO ₂ *	$\pm(2.5 \text{ vol.}\% + 2.5\%$ of the actual reading)
VCi	Adult/Pediatric:
VCe	0ml to 100ml: $\pm(10\text{ml} + 3\%$ of the actual reading)
VCe esp	100 ml to 6000 ml: $\pm(5 \text{ ml} + 8\%$ of the actual reading) Newborn: 0ml to 6000ml: $\pm(2\text{ml} + 8\%$ of the actual reading)
Adult/Pediatric VMA:	$\pm(0.2 \text{ l/min} + 10\%$ of the actual reading)
VMesp	Neonate: $\pm(0.15 \text{ l/min} + 8\%$ of the actual reading)
VMfuga	
Peak pressure $\pm (2 \text{ cmH}_2\text{O} + 4\%$ of the actual reading)	
Pmest	
Pmed	
PEEP	
Flow (O ₂ Therapy)	$\pm(2 \text{ l/min} + 10\%$ of the actual reading)
total	$\pm 1 \text{ /min}$ or 5% of the actual reading, whichever is greater.
fmand.	
fesp	
Tinsp	$\pm 0.05 \text{ s}$
I:E	$\pm 6\%$ (not applicable if Tinsp or Texp is less than 50 ms)

Table B-7 Respirator Accuracy

WOB	$\pm(1 \text{ J/min} + 15\% \text{ of the actual reading})$
	$\pm(0.20 \text{ J/l} + 10\% \text{ of the actual reading})$
% drain	$\pm 10\%$ (absolute error)
Ri0 cmH2O/(l/s) at 20	cmH2O/(l/s): $\pm 10 \text{ cmH2O/(l/s)}$;
Re	20 cmH2O/(l/s) to 600 cmH2O/(l/s): $\pm 50\%$ of actual reading
Cstat	$\pm 10 \text{ ml/cmH2O}$ or $\pm 20\%$ of the actual reading, whichever is greater
Cdin	
RSBI	$\pm 20 \text{ l/(l}\cdot\text{min)}$ or $\pm 15\%$ of the actual reading, whichever is greater
RCesp	$\pm(0.20 \text{ s} + 20\% \text{ of the actual reading})$
PEEPi	$\pm(2 \text{ cmH2O} + 4\% \text{ of the actual reading})$
PEEPtot	$\pm(2 \text{ cmH2O} + 4\% \text{ of the actual reading})$
P0.1	$\pm(2 \text{ cmH2O} + 4\% \text{ of the actual reading})$
Power	$\pm(2 \text{ cmH2O} + 4\% \text{ of the actual reading})$
MPrs	$\pm(1 \text{ J/min} + 15\% \text{ of the actual reading})$
	$\pm(0.20 \text{ J/l} + 10\% \text{ of the actual reading})$

Table B-7 Respirator Accuracy

FiO2*: The deviation test method for achieving accuracy in testing specified in ISO 80601-2-55 can ensure that the measurement accuracy complies with the requirements of this table.

B.8 Alarm

B.8.1 Adjustable alarms

ALARM SETTINGS				
PARAMETER		ADJUSTMENT RANGE	ADJUSTMENT OF THE STEP LENGTH NOTES	
Pva	High alarm limit	10 cmH ₂ O to 85 cmH ₂ O	1 cmH ₂ O	Set the high alarm limit so that it is higher than the lower alarm limit.
	Low alarm limit	deactivated, 1 cmH ₂ O at 80 cmH ₂ O		
VC	High alarm limit	Adult: deactivated, 110 ml to 6000 ml; Pediatric: deactivated, 25 ml to 600 ml; Neonate: deactivated, 3ml at 200 ml.	3ml to 100ml: 1ml, 100ml to 6000ml: 5ml.	
	Low alarm limit	Adult: deactivated, 50 to 5995 ml; Pediatric: deactivated, 10 to 595 ml; Neonate: deactivated, 1 ml at 195 ml.	1ml to 100ml: 1ml, 100ml to 6000ml: 5ml.	
F	High alarm limit	deactivated, 2/min to 160/min 1/min		
	Low alarm limit	deactivated, 1/min to 159/min		
VM High	alarm limit	Adult: 0.20 l/min to 100.0 l/min; Pediatric: 0.20 l/min to 60.0 l/min min; Neonate: 0.02 l/min to 30.0 l/min, in ventilation mode nCPAP can be turned off.	0.02 to 1.0: 0.01 l/min, 1.0 to 100.0 l/min: 0.1 l/min.	
	Low alarm limit	Adult: 0.10 l/min to 50.0 l/min; Pediatric: 0.10 l/min to 30.0 l/min min; Neonate: from 0.01l/min to 15.0 l/min min, in NIV mode, can be disconnected.	0.01 to 1.0: 0.01 l/min, 1.0 to 50.0 l/min: 0.1 l/min.	

Table B-8 Adjustable Alarms

FiO2 High	alarm limit (in low pressure O2 delivery mode)	20 vol. % to 100 vol. %	1 vol. %	In low pressure O2 supply mode , set the high alarm limit so that it is greater than the lower alarm limit.
	Low alarm limit (in low pressure O2 supply mode)	18 vol. % to 98 vol. %		
Tapnea		5 to 60 seconds, in nCPAP ventilation mode, It can be deactivated.	1 s	The error is ± 3 s.

Table B-8 Adjustable Alarms

Note: When the alarm limit in the table above is deactivated, the screen interface will display the deactivated alarm icon.



B.8.2 Internal alarms

PARAMETER		ALARM CONDITION	GRADES
FiO2 High Alarm Limit	High Alarm Limit	Internal alarm limit: min (set value of FiO2 + max (7 vol. % or set value of FiO2 x 10%), 100 vol. %).	Set the high alarm limit so that it is higher than the lower alarm limit.
	Low alarm limit	Internal alarm limit: max (18 vol.%, set FiO2 value less max (7 vol.%, set FiO2 value x 10))	

Table B-9 Internal Alarms

B.9 Additional settings and tools

SETTINGS AND TOOLS
Holding your breath
Manual breathing
Oxygen enrichment
Suction
Sighs
Holding your breath
Static PV loop
Recruitment tool
Tools for gradual weaning from the ventilator
Dynamic lung display function
Patient-ventilator asynchrony

Table B-10 Adjustments and Additional Tools

B.10 CO2 module specifications

B.10.1 Sidewall CO2 Module

SIDE FLOW CO2 MODULE		
Regulations		Complies with ISO 80601-2-55: 2018
Measurement range: 0.0 vol. % to		20.0 vol. % (0 mmHg to 152 mmHg)
Absolute CO2 Accuracy * Total Accuracy Mode:		0 to 40 mmHg: ± 2 mmHg 41 to 76 mmHg: $\pm 5\%$ of the reading 77 to 99 mmHg: $\pm 10\%$ of the reading 100 to 150 mmHg: $\pm (3 \text{ mmHg} + 8\% \text{ of the reading})$ >150 mmHg CO2: unspecified
Inaccuracies in the specifications are affected by respiratory rate and I:E ratio. EtCO2 accuracy is within specifications with a respiratory rate \dot{y} 60 rpm and an I/E ratio \dot{y} 1:1, or with a respiratory rate \dot{y} 30 rpm and an I/E ratio \dot{y} 2:1.		
Deviation from accuracy		The test method of ISO 80601-2-55 can ensure measurement that the accuracy of the measurement meets the requirements of this table.
Resolution 0.1 vol. % (1 mmHg)		
Sample flow rate		The sampling flow rate is 50 ml/min when using the BeneVision N1 patient monitor; The sampling flow rate is 120 ml/min or 90 ml/min when using the CO2-3 module.
Flow tolerance of the sample		$\pm 15\%$ or ± 15 ml/min, whichever is greater.
Setup time		Maximum 90 s
march		Typical 20s
Up time	Use of monitor of patient BeneVision N1	Measured with a standard Oridion sampling line: $\dot{y} 250$ ms at 50 ml/min; Measured with an extended Oridion sampling line: $\dot{y} 280$ ms at 50 ml/min.
	Using the CO2-3 module	Measured with a DRYLINE II neonatal water collector and a 2.5-meter neonatal sampling line: $\dot{y} 330$ ms at 90 ml/min; Measured using a DRYLINE II adult water collector and a 2.5-meter adult sampling line: $\dot{y} 300$ ms at 120 ml/min.
Total time of response from system	Use of monitor of patient BeneVision N1	Measured with a standard Oridion sampling line: $\dot{y} 5.0$ sa 50 ml/min; Measured with an extended Oridion sampling line: < 6.5 sa 50 ml/min.
	Using the CO2-3 module	Measured using a DRYLINE II neonatal water collector and a 2.5-meter neonatal sampling line: $\dot{y} 4.5$ sa 90 ml/min; Measured using a DRYLINE II adult water collector and a 2.5-meter adult sampling line: $\dot{y} 5.0$ sa 120 ml/min.

Table B-11 Sidewall CO2 Module

Water collector cleaning time	<p>CO2 water collector cleaning time</p> <p>Water collector for adult/pediatric patients: \bar{y}26 hours at 120 ml/min;</p> <p>Water collector for neonatal patients: \bar{y}35 hours at 90 ml/min.</p> <p>Note:</p> <p>(1) Experimental condition: the sampling gas temperature is 37°C, the ambient temperature is 23°C and the relative humidity of the sampling gas is 100%.</p> <p>(2) the water collector cleaning time \bar{y} 26 hours or 35 hours means that the liquid level will not exceed the maximum line in 26 hours or 35 hours respectively.</p>
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Table B-11 Sideflow CO2 Module

LIMITS OF ALARM (WEARING CO2-3 MODULE) RANGE		SIZE OF PASSED	GRADES
Upper limit of EtCO2 alarm	2 to 152 mmHg	1 mmHg	Adjust the upper alarm limit to be higher than the lower limit.
Lower alarm limit of EtCO2	0 to 150 mmHg		

Table B-12 Sideflow CO2 Alarm Limits

LIMITS OF ALARM (WEARING BENEVISION N1) RANGE		SIZE OF PASSED	GRADES
EtCO2 alarm upper/lower limit	1 to 99 mmHg	1 mmHg	The upper alarm limit is greater than the lower alarm limit by at least 2 mmHg.

Table B-13 Sideflow CO2 Alarm Limits

SIDE FLOW CO2 ENVIRONMENTAL SPECIFICATIONS			
Element	Temperature (°C)	Relative humidity (without condensation)	Barometric pressure (kPa)
Operation	5 to 40	15 to 95%	57.3 to 105.3
Storage	-20 to 60	10 to 95	57.3 to 105.3

Table B-14 Sideflow CO2 Environmental Specifications

B.10.2 Direct flow CO2 module

DIRECT FLOW CO2 MODULE	
Regulations	Complies with ISO 80601-2-55: 2018
Measurement range: 0.0 vol. % to 20.0 vol. % (0 mmHg to 150 mmHg)	
Accuracy 0.0 vol. % at 5.0 vol. % (0 mmHg to 40 mmHg): ± 0.25 vol. % (± 2 mmHg)	5.0 vol. % to 9.0 vol. % (41 mmHg to 70 mmHg) (excluding 5.0 vol. %): ± 5 % of actual reading
	9.0 vol. % to 13.0 vol. % (71 mmHg to 100 mmHg) (excluding 9.0 vol. %): ± 8 % of the actual reading
	13.0 vol. % to 20.0 vol. % (101 mmHg to 150 mmHg) (excluding 13.0 vol. %): ± 10 % of the actual reading
Deviation of the measurement accuracy	The test method of ISO 80601-2-55 can ensure that the accuracy of the measurement meets the requirements of this table.
Resolution 0.1 vol. % (1 mmHg)	
Up time	<60 ms
Total system response time	<2.0 s

Table B-15 Direct Flow CO2 Module

LIMITS OF CO2 ALARM FLOW STRAIGHT	RANGE	STEP SIZE NOTES	
EtCO2 alarm upper limit	2 to 150 mmHg	1 mmHg	Adjust the upper alarm limit to be higher than the lower limit.
Lower alarm limit of EtCO2	0 to 148 mmHg		

Table B-16 Direct Flow CO2 Alarm Limits

DIRECT FLOW CO2 ENVIRONMENTAL SPECIFICATIONS			
Element	Temperature (°C)	Relative humidity (without condensation)	Barometric pressure (kPa)
Operation	0 to 40	10 to 90%	57.3 to 105.3
Storage	-20 to 60	10 to 90%	53.3 to 107.4

Table B-17 Direct Flow CO2 Environmental Specifications

B.11 SpO2 module specifications

SPOCAL SPECIFICATIONS				
* Verification of measurement accuracy: The accuracy of SpO2 has been verified in Experiments with human subjects compared it to the reference of arterial blood sample measured with a CO-oximeter. Pulse oximetry measurements are statistically distributed and it is expected that around two-thirds of the measurements will be within the specified accuracy range compared to CO-oximeter measurements.				
Regulations	Complies with ISO 80601-2-61 standards			
Measurement range	From 0% to 100%			
Resolution	1%			
Response time	<30 s (normal perfusion, no alterations, SpO2 value changes) suddenly from 70% to 100%)			
SpO2 accuracy	Adult/Pediatric: 70% to 100%: $\pm 2\%$ Newborn: 70% to 100%: $\pm 3\%$ 0% to 69%: Not declared			
Update period from the data	30 s			
Renewal frequency 2 s				
* Studies were conducted to validate the accuracy of the pulse oximeter with SpO2 contrast sensors using a CO-oximeter. Statistical analysis of the study data shows that the accuracy (groups) is within the stated accuracy specifications. Refer to the following table.				
SENSOR TYPE	TOTAL	DATA	GROUPS	
512F (adult, finger type, reusable)	10 (4 men and 6 women)	200 pairs	1.91%	
512H (pediatric, finger type, reusable)	10 (0 men and 10 women)	200 pairs	1.95%	
The pulse oximeter with SpO2 sensors for newborns was also validated in adult subjects.				
SKIN COLOR	SEX	NUMBER	AGE (YEARS)	STATE OF HEALTH
Black	Man	1	26 \pm 3.14	Healthy
	Women	1		
Yellow	Man	3		
	Women	9		
PR SPECIFICATIONS				
Measurement range	20 rpm to 300 rpm			
Resolution	1 1/min			
Precision	± 3 1/min			

Table B-18 SpO2 Module Specifications

PI		
Measurement range: 0.05% to 20%		
Resolution 0.05 to 9.99%: 0.01%	10.0 to 20.0%: 0.1%	
Perfusion index range	0.05 to 20%	
CQI		
Measurement interval of CQI	0 to 100	Note: Only applicable to BeneVision N1 Mindray SpO2
CQI Resolution	1	
Display range of the frequency	20 cpm to 300 cpm	
Frequency resolution	1 cpm	
Speed measurement accuracy	40 cpm to 160 cpm \pm 3 cpm Other range: not specified	

Table B-18 SpO2 Module Specifications

LIMIT SPECIFICATION SPO2 ALARM		RANGE	SIZE OF PASSED	GRADES
Use of the module of SpO2-1	High limit alarm SpO2	2% to 100%	1%	Adjust the upper alarm limit to be higher than the lower limit.
	Low alarm limit of SpO2	0% to 98%		
	Alarm of desaturation	0% to 98%		/
Use of monitor of patient BeneVision N1	High limit alarm SpO2	(SpO2 lower alarm limit + 2%) to 100%	1%	Adjust the upper alarm limit to be higher than the lower limit.
	Low alarm limit of SpO2	(Desaturation alarm + 1%) a (upper alarm limit of SpO2 - 2%)		
	Alarm of desaturation	0% to (lower alarm limit of SpO2 - 1%)	1%/	

Table B-19 SpO2 Alarm Limits

LIMIT SPECIFICATION PR ALARM		RANGE	SIZE OF PASSED	GRADES
Using the module SpO2-1	PR alarm upper limit	17 /min to 300 /min	1/min	Adjust the upper alarm limit to be higher than the lower limit.
	Low alarm limit of PR	15 /min to 298 /min		
Use of the patient monitor BeneVision N1	PR alarm upper limit	PR \dot{y} 40 /min: (lower limit + 2 /min) at 40 / min PR > 40 /min: (lower limit + 5 /min) to 295 /min	PR < 40 /min: 1 / min; PR > 40 /min: 5 /min	
	Low alarm limit of PR	PR \dot{y} 40 /min: 16 / min a (upper limit - 2 /min) PR > 40 /min: 40 / min a (upper limit - 5) /min)		

Table B-19 SpO2 Alarm Limits

ENVIRONMENTAL SPECIFICATIONS OF THE SPO2 MODULE			
Element	Temperature (°C)	Relative humidity (without condensation)	Barometric pressure (kPa)
Operation	0 to 40	From 15% to 95% of relative humidity	57.0 to 107.4
Storage -20 to 60		From 10% to 95% of relative humidity	16.0 to 107.4

Table B-20 SpO2 Module Environmental Specifications

The measurement uncertainty for each disclosed tolerance is included within the specification range.

B.12 Monitor specifications

ENVIRONMENTAL SPECIFICATIONS OF BENEVISION N1			
Element	Temperature (°C)	Relative humidity (without condensation)	Barometric pressure (kPa)
Operation	0 to 40	From 5% to 95% of relative humidity	57.0 to 107.4
Storage -30 to 70		From 5% to 95% of relative humidity	16.0 to 107.4

Table B-21 Environmental Specifications of the BeneVision N1 Patient Monitor

CAUTION: Do not transport the BeneVision N1 patient monitor at a temperature below -30°C.

B.12.1 ECG Specifications

Standards	Complies with IEC 60601-2-27:2011
Set of derivations	3 leads: I, II, III 5 conductors: I, II, III, aVR, aVL, aVF, V 6 leads: I, II, III, aVR, aVL, aVF, Va, Vb 12 leads: I, II, III, aVR, aVL, aVF, V1 to V6
ECG Standard	AHA, IEC
Sensitivity of the screen	1.25mm/mV (x0.125), 2.5mm/mV (x0.25), 5mm/mV (x0.5), 10mm/mV (x1), 20 mm/mV (x2), 40 mm/mV (x4), automatic, less than 5% error
Speed of scanning	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s, less than 5% error
Bandwidth (-3 dB)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgical mode: 1 to 20 Hz ST Mode: 0.05 to 40 Hz
Relationship of rejection in mode common	Diagnostic mode: >90 dB Monitor mode: >105 dB (with the slit filter activated) Surgical mode: >105 dB (with the slit filter activated) ST Mode: >105 dB (with the slit filter activated)
50/60 Hz Slit Filter	Monitor, surgical, and ST modes: the slit filter activates automatically Diagnostic mode and high-frequency cutoff: the slit filter is manually activated/deactivated
Differential input impedance	$\geq 5 \text{ M}\Omega$
Input signal range	$\pm 8 \text{ mV}$ (peak-to-peak value)
Tolerance of electrode displacement potential	$\pm 500 \text{ mV}$
Current of detection deviation	Measuring electrode $< 0.1 \text{ }\mu\text{A}$ Drive electrode $< 1 \text{ }\mu\text{A}$
Current of deviation of entrance	$\leq 0.1 \text{ }\mu\text{A}$, (drive cable $\leq 1 \text{ }\mu\text{A}$)

Table B-22 ECG Specifications

Defibrillation protection	Withstands a load of 5000 V (360 J) without data loss or corruption Baseline recovery time <5 s (after defibrillation) Polarization recovery time <10 s Defibrillation energy absorption: $\leq 10\%$ (100 μ load)
Patient leakage current	<10 μ A
Calibration signal	1 mV (peak-to-peak value) ± 5
ESU Protection	300W cutting mode Coagulation mode 100 W Recovery time ≤ 10 s In accordance with the requirements of clause 202.6.2.101 of IEC 60601-2-27: 2011
Rhythm pulse	
Rhythm pulse markers	Rhythm pulses that meet the following conditions are labeled with a PACE marker: Amplitude: ± 2 to ± 700 mV Width: 0.1 to 2 ms Upload time: 10 to 100 μ s (not more than 10% of the pulse width) Without overflowing
Rejection of the rhythm pulse	When tested in accordance with IEC 60601-2-27: 2011: 201.12.1.101.13, the pulse meter rejects all pulses that meet the following conditions. Amplitude: ± 2 to ± 700 mV Width: 0.1 to 2 ms Upload time: 10 to 100 μ s (not more than 10% of the pulse width) Without overflowing
FC	
Measurement range Neonate	15 to 350 /min Pediatric: 15 to 350 /min Adult: 15 to 300 /min
Resolution	1/min
Precision	± 1 /min or $\pm 1\%$, whichever is greater.
Sensitivity	200 μ V (lead II)

Table B-22 ECG Specifications

FC averaging method	<p>In accordance with the requirements of clause 201.7.9.2.9.101 b) 3) According to IEC 60601-2-27: 2011, the following method is used:</p> <p>If the last 3 consecutive FR intervals are greater than 1200 In ms, the 4 most recent RR intervals are averaged to calculate the HR. Otherwise, the HR is calculated by subtracting the maximum and minimum from the 12 most recent RR intervals and then averaging them.</p> <p>The heart rate value displayed on the monitor screen does not update for more than one second.</p>														
Response to irregular rhythm	<p>In accordance with the requirements of clause 201.7.9.2.9.101 b) 4) According to IEC 60601-2-27: 2011, the heart rate after 20 seconds of stabilization is shown as follows:</p> <p>Ventricular bigeminy (A1 waveform): 80 ± 1 /min Slow alternating ventricular bigeminy (A2 waveform): 60 ± 1 /min Rapid alternating ventricular bigeminy (A3 waveform): 120 ± 1 /min Bidirectional systoles (A4 waveform): 90 ± 2 /min</p>														
Response time to change in heart rate	<p>It meets the requirements of IEC 60601-2-27: 2011: Clause 201.7.9.2.9.101 b) 5).</p> <p>From 80 to 120 /min: less than 11 s From 80 to 40 /min: less than 11 s</p>														
Time until tachycardia alarm	<p>It meets the requirements of section 201.7.9.2.9.101 b) 6) of IEC 60601-2-27: 2011.</p> <table border="1"> <tr> <td colspan="2">Waveform</td> </tr> <tr> <td>Range B1h:</td> <td><11 s</td> </tr> <tr> <td>Range B1:</td> <td><11 s</td> </tr> <tr> <td>Range B1d:</td> <td><11 s</td> </tr> <tr> <td>B2h range:</td> <td><11 s</td> </tr> <tr> <td>Range B2:</td> <td><11 s</td> </tr> <tr> <td>B2d Range:</td> <td><11 s</td> </tr> </table>	Waveform		Range B1h:	<11 s	Range B1:	<11 s	Range B1d:	<11 s	B2h range:	<11 s	Range B2:	<11 s	B2d Range:	<11 s
Waveform															
Range B1h:	<11 s														
Range B1:	<11 s														
Range B1d:	<11 s														
B2h range:	<11 s														
Range B2:	<11 s														
B2d Range:	<11 s														
High T-waveform rejection capability	<p>When the test is carried out based on clause 201.12.1.101.17 According to IEC 60601-2-27: 2011, the heart rate calculation is not affected for QRS of 1 mV amplitude and 100 ms duration, T wave duration of 180 ms and amplitude less than 1.2 mV, and QT interval of 350 ms.</p>														
Arrhythmia analysis classifications	<p>Asystole, ventricular fibrillation/ventricular tachycardia, ventricular tachycardia, ventricular bradycardia, extreme tachycardia, extreme bradycardia, ventricular rhythm, CVP/min, pauses/min, matching, bigeminy, trigeminy, R on T, running CVP, CVP, tachycardia, bradycardia, missed beat, non-pacing pacemaker, non-capture pacemaker, multiform CVP, non-pacing ventricular tachycardia, pause, irregular rhythm, atrial fibrillation, supraventricular tachycardia, SVC/ min.</p>														
ST Segment Analysis															
Measurement range	-2.0 to 2.0 mV RTI														

Table B-22 ECG Specifications

Precision	-0.8 to 0.8 mV: Beyond this range	± 0.02 mV or $\pm 10\%$, whichever is greater. Unspecified
Resolution	0.01 mV	
Alarm limit	Range	Passed
ST high	(lower limit +0.2 mV) to 2.0 mV (ST alarm mode: absolute) 0 mV to 2.0 mV (ST alarm mode: relative)	0.05 mV
ST low	-2.0 mV to (upper limit -0.2 mV) (ST alarm mode: absolute) -2.0 mV to 0 mV (ST alarm mode: relative)	
High FC	HR \dot{y} 40 /min: (lower limit + 2 / min) at 40 /min HR > 40 /min: (lower limit + 5 / min) at 295 /min	HR \dot{y} 40 /min: 1 /min HR > 40 /min: 5 /min
FC low	HR \dot{y} 40 /min: 16 /min a (high limit - 2 / min) HR > 40 /min: 40 /min a (high limit - 5 / min)	

Table B-22 ECG Specifications

B.12.2

Responsible specifications

Technique	Transthoracic impedance
Derivation	The options are referral I, II and automatic.
Excitation waveform of breathing	<300 \dot{y} A RMS, 62.8 kHz ($\pm 10\%$)
Minimum breathing impedance threshold	0.3 \dot{y}
Reference impedance range	200 to 2500 \dot{y} (using an ECG cable with a resistance of 1 k \dot{y})
Bandwidth	0.2 to 2.5 Hz (-3 dB)
Sweep speed	3mm/s, 6.25mm/s, 12.5mm/s, 25mm/s or 50mm/s, less than 10% error
Respiratory rate	
Measurement range	0 to 200 /min
Resolution	1/min

Table B-23 Responsible Specifications

Accuracy 0 to 120 /min ± 1 /min	121 to 200 /min: ± 2 /min	
Apnea alarm time: 10s, 15s, 20s, 25s, 30s, 35s, 40s		
Alarm limit	Range	Passed
High FR	Adult, pediatric: FR $\dot{y}20$: (lower limit + 2) to 20 FR >20: (lower limit + 5) to 100 Newborn: FR $\dot{y}20$: (lower limit + 2) to 20 FR >20: (lower limit + 5) to 150	FR $\dot{y}20$: 1 FR >20: 5
low FR	FR $\dot{y}20$: 0 to (high limit - 2) FR >20: 20 a (high limit - 5)	

Table B-23 Responsible Specifications

B.12.3 Temperature specifications

Regulations	Complies with ISO 80601-2-56	
Operating mode	Direct mode	
Measurement range	0 to 50°C (32 to 122°F)	
Resolution 0.1°C		
Precision	± 0.1 °C or ± 0.2 °F (excluding probe error)	
Renewal frequency	$\dot{y}1$ s	
Minimum time for accurate measurement	Body surface area: <100 s Body cavity <80 s	
Alarm limit	Range	Passed
Txx high (xx refers to the temperature location)	(lower limit +1.0) at 50.0 °C (lower limit +2.0) at 122.0 °F	0.1 °C 0.1 °F
Txx low (xx refers to the temperature site)	0.1 to (upper limit - 1.0) °C 32.2 a (upper limit - 2.0) °F	
high $\dot{y}T$	0.1 to 50.0 °C 0.2 to 90.0 °F	

Table B-24 Temperature Specifications

B.12.4 IBP Specifications

Regulations	Complies with IEC 60601-2-34: 2011.	
Technique	Direct invasive measurement	
IBP		
Measurement range	-50 to 360 mmHg (-6.7 kPa to 48.0 kPa)	
Resolution	1 mmHg (0.1 kPa)	
Precision	±2% or ±1 mmHg, whichever is greater (excluding sensor error)	
PPV		
Measurement range	From 0% to 50%.	
Pressure transducer		
Excitation voltage 5 VDC, ±2		
Sensitivity	5 μ V/V/mmHg	
Zero adjustment range	±200 mmHg	
Impedance range	300 to 3000 Ω	
Volume displacement	<0.04 mm ³ /100 mmHg	
Alarm limit	Range (mmHg)	Variation (mmHg)
Sys high	IBP \dot{y} 50: (lower limit + 2) to 50 IBP > 50: (lower limit + 5) to 355	IBP \dot{y} 50: 1 IBP > 50: 5
Medium high		
High day		
Low system	IBP \dot{y} 50: -49 to (upper limit - 2) IBP > 50: 50 to (upper limit - 5)	
Low medium		
Low day		
Art-S extreme high	Upper limit < 50: (upper limit + 1) to 360 Upper limit \dot{y} 50: (upper limit + 5) to 360	IBP \dot{y} 50: 1 IBP > 50: 5
Art-M extreme high		
Art-D extreme high		
Art-S extreme low	lower limit \dot{y} 50: -50 to (lower limit - 1) lower limit > 50: 50 to (lower limit - 5)	
Art-M extreme low		
Extreme low Art-D		

Table B-25 IBP Specifications

B.12.5 PR Specifications

PR of the NIBP module		
Measurement range	30/min to 300/min	
Resolution	1/min	
Precision	±3 /min or ±3%, whichever is greater	
PR of the IBP module		
Measurement range	25/min to 350/min	
Resolution	1/min	
Precision	±1/min or ±1%, whichever is greater	
Alarm limits range		Passed
High PR	PR \dot{y} 40 /min: (lower limit + 2 /min) at 40 /min PR > 40 /min: (lower limit + 5 /min) to 295 /min	PR \dot{y} 40 1 PR > 40 5
PR low	PR \dot{y} 40 /min: 16 /min at (upper limit - 2 /min) PR > 40 /min: 40 /min at (high limit - 5 /min)	

Table B-26 PR Specifications

B.12.6 NIBP Specifications

Regulations	Complies with IEC 80601-2-30: 2018
Technique	Oscillometry
Operating mode	Manual, Auto, STAT, Sequence
Repeat intervals in mode Car	1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min
Cycle duration in STAT mode	5 min
Maximum measurement time	Adult, pediatric 180 s Neonate: 90 s
Heart rate range	30 to 300 /min

Table B-27 NIBP Specifications

Measurement ranges (mmHg)		Adult	Pediatric Newborn born	
	Systolic:	25 to 290	25 to 240	25 to 140
	Diastolic:	10 to 250	10 to 200	10 to 115
	Average:	15 to 260	15 to 215	15 to 125
Precision	Maximum mean error: ± 5 mmHg Maximum standard deviation: 8 mmHg			
Resolution	1 mmHg (0.1 kPa)			
Pressure range Initial cuff inflation (mmHg)	Adult: 80 to 280 Pediatric: 80 to 210 Neonate: 60 to 140			
Predetermined initial cuff inflation pressure (mmHg)	Adult: 160 Pediatric: 140 Neonate: 90			
Software overpressure protection	Adult: 297 ± 3 mmHg Pediatric: 297 ± 3 mmHg Neonate: 147 ± 3 mmHg			
Hardware overpressure protection	Adult: $\dot{y}330$ mmHg Pediatric: $\dot{y}330$ mmHg Neonate: $\dot{y}165$ mmHg			
Static pressure measurement range	0 mmHg to 300 mmHg (0 kPa to 40.0 kPa)			
Pressure measurement accuracy static	± 3 mmHg (± 0.4 kPa)			

Table B-27 NIBP Specifications

Alarm limit	Range (mmHg)	Variation (mmHg)
NIBP-S high	Adult: (lower limit + 5) to 285 Pediatric: (lower limit + 5) to 235 Neonate: (lower limit + 5) to 135	NIBP \dot{y} 50 1 NIBP > 50: 5
NIBP-S low	26 to (upper limit - 5)	
NIBP-M high	Adult: (lower limit + 5) to 255 Pediatric: (lower limit + 5) to 210 Neonate: (lower limit + 5) to 120	
NIBP-M low	16 to (upper limit - 5)	
NIBP-D high	Adult: (lower limit + 5) to 245 Pediatric: (lower limit + 5) to 195 Neonate: (lower limit + 5) to 110	
NIBP-D low	11 to (upper limit - 5)	
NIBP-S extreme high	Adult: (NIBP-S upper limit + 5) to 290 Pediatric: (Upper limit of NIBP-S + 5) to 240 Neonate: (NIBP-S High Limit + 5) at 140	NIBP \dot{y} 50 1 NIBP > 50: 5
NIBP-S extreme low 25 to (upper limit of NIBP-S - 5)		
Extreme High NIBP-M Adult	(NIBP-M High Limit + 5) at 260 Pediatric: (NIBP-M upper limit + 5) to 215 Neonate: (NIBP-M High Limit + 5) at 125	
NIBP-M extremely low 15 to (lower limit of NIBP-M - 5)		
NIBP-D extreme high	Adult: (Upper limit of NIBP-D + 5) to 250 Pediatric: (Upper limit of NIBP-D + 5) to 200 Neonate: (NIBP-D High Limit + 5) at 115	
NIBP-D extremely low 10 to (lower limit of NIBP-D - 5)		

Table B-28 NIBP Alarm Limit

* Measurement accuracy verification: In both adult and pediatric patient modes, blood pressure measurements taken with this device comply with the standard for non-invasive sphygmomanometers (ISO 81060-2) was used to determine mean error and standard deviation by comparing them with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. The fifth Korotkoff sound was used as the auscultatory reference to determine the pressure. diastolic.

In neonatal patient mode, blood pressure measurements taken with this device meets the American national standard for non-invasive sphygmomanometers (ISO 81060-2) regarding mean error and standard deviation by comparison with intra-arterial measurements (according to configuration) in a population typical patient.

B.12.7 Signal output specifications

Analog ECG output	
Bandwidth (-3dB; reference frequency: 10 Hz)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgical mode: 1 to 20 Hz ST Mode: 0.05 to 40 Hz
Maximum QRS delay 25 ms (in diagnostic mode and without rhythm)	
Gain (reference frequency: 10 Hz)	1V/mV ($\pm 5\%$)
Increased rhythm. Signal amplitude	Voh $\ddot{y} 2.5V$ Pulse width 10ms $\pm 5\%$ Signal rise and fall time $\ddot{y} 100 \ddot{y} s$
IBP analog output	
Bandwidth (-3 dB; frequency of reference: 1 Hz)	0 to 40 Hz
Maximum delay of transmission	30 ms
Gain (reference frequency: 1 Hz)	1 V/100 mmHg, $\pm 5\%$.
Defibrillation synchronization pulse	
Output impedance	$\ddot{y} 100 \text{ ohm}$
Maximum delay	35 ms (peak of the R wave at the leading edge of the pulse)
Amplitude	High level: 3.5 to 5 V, $\pm 5\%$, providing a maximum output current of 10 mA; Low level: <0.5 V, receiving a maximum of 5 mA of input current.
Pulse width	100 ms $\pm 10\%$.
Maximum ascent and descent time	1 ms

Table B-29 Signal Output Specifications

C.0

CEM

EMC	C-2
Compliance with radio regulations	C-9

C.1 CEM

The TV80 respirator complies with the EMC standard IEC60601-1-2:2020.

The TV80 respirator also meets the EMC requirements of ISO 7637-2:2011, EN 13718-1:2014 Section 4.5.7, EN 1789:2020 Section 4.2.2, EN 794-3:2009 Section 36, IEC 60601-1-12:2020 Section 11, ISO 80601-2-84:2020 Section 202, RTCA DO-160G Section 20/21, MIL-STD-461G RE101/ RS101/ CS114 below.

WARNING: The use of unapproved accessories may decrease the respirator's performance.

WARNING: The use of components, accessories, probes, and cables other than those specified in the product description may result in a violation of the law. The specified ones may cause an increase in emission or a decrease in respirator immunity.

WARNING: The respirator requires special precautions regarding EMC and it must be installed and put into operation in accordance with the EMC information provided below.

WARNING: This equipment should not be used alongside other equipment or stacked with it. They, as it could cause malfunction. If such use is necessary, this equipment and the other equipment should be monitored to verify that they are functioning normally.

WARNING: The use of accessories, transducers, and cables other than those specified may cause serious harm. specified or supplied by the manufacturer of this equipment could cause an increase in electromagnetic emissions or a reduction in the electromagnetic immunity of this equipment and cause malfunction.

WARNING: Portable radio frequency communication equipment (including peripherals such as antenna cables and external antennas) must not be used within 30 cm (12 inches) of any part of the respirator, including cables specified by the manufacturer. Failure to do so may impair the performance of this equipment.

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

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

WARNING: The use of portable or mobile communication devices may decrease equipment performance.

WARNING: Use the respirator away from heat penetration equipment, diathermy, electrocautery, MRI, RFID, and security equipment (such as electromagnetic anti-theft systems and metal detectors). If any concealed radio frequency transmitters, unknown to the user, become exposed near the device and are disturbed by it (e.g., changes in scan mode or image alterations that affect diagnosis), the user must immediately take corrective measures, such as redirecting, repositioning, or shielding the device away from the radio frequency transmitter.

If the TV80 ventilator operates within the electromagnetic environment listed in TABLE CEM-1, TABLE CEM-2, and TABLE CEM-3, the ventilator will remain safe and provide the following basic performance: Vdel control accuracy, Vdel monitoring accuracy, airway pressure monitoring, CO2 accuracy, and O2 monitoring accuracy .

Mindray Guide and Declaration: Electromagnetic Emissions

The TV80 respirator is designed for use in the electromagnetic environment specified below. The customer or user of the TV80 respirator must ensure that it is used in an environment of this type.

Emissions test	Electromagnetic Environment Compliance: Guide	
Radiofrequency emissions CISPR 11	Group 1	The TV80 respirator uses radio frequency energy only for its internal function. Therefore, its radio frequency emissions are very low and are not likely to cause interference with nearby electronic equipment.
Radiofrequency emissions CISPR 11	Class B	The TV80 respirator is suitable for use in all establishments, including domestic ones and those directly connected to the public low-voltage electricity supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ intermittent emissions	Accordance	
IEC 61000-3-3		
Note: /		

Table C-1 CEM-1

Mindray Guide and Statement: Electromagnetic Immunity

The TV80 respirator is designed for use in the electromagnetic environment specified below. The customer or user of the TV80 respirator must ensure that it is used in an environment of this type.

Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment: guide
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV per contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	±8 kV per contact; ±2 kV, ±4 kV, ±8kV, ±15 kV in air	The floors must be made of wood, concrete, or ceramic. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast electrical transients/ bursts IEC 61000-4-4	±2 kV for power lines; ±1 kV for input/output lines	±2 kV for power lines ±1 kV for input/output lines	The quality of the electrical network must be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line; ±0.5 kV, ±1 kV, ±2 kV ground lines	±0.5 kV, ±1 kV line to line; ±0.5 kV, ±1 kV, ±2 kV ground lines	The quality of the electrical network must be that of a typical commercial or hospital environment.
Voltage drops, interruptions brief s and voltage variation in the IEC 61000 network input voltage- 4-11	0% of UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% of UT; 1 cycle 70% of UT for 25/30 cycles at 0°. 0% UT; 250/300 cycles	0% of UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% of UT; 1 cycle 70% of UT for 25/30 cycles at 0°. 0% UT; 250/300 cycles	The quality of the electrical network must be that of a Typical commercial or hospital environment. If needs a operation during power outages, it is recommended to power our product with a power supply system uninterrupted or with a battery.
Power frequency magnetic field (50/ 60 HZ) ICE 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields must be at the characteristic levels of a typical location in a typical commercial or hospital environment.

Note: UT is the AC mains voltage before the application of the test level.

Table C-2 CEM-2

Mindray Guide and Statement: Electromagnetic Immunity

The TV80 respirator is designed for use in the electromagnetic environment specified below. The customer or user of the TV80 respirator must ensure that it is used in an environment of this type.


Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment: guide
Radiofrequency-conducted IEC 61000-4-6	3Vrms 0.15 MHz - 80 MHz	3Vrms 0.15 MHz - 80 MHz	Portable and mobile radio frequency communication equipment should not be used closer to any part of the TV80 respirator, including cables, than the recommended separation distance calculated from the equation Applicable to the transmitter frequency. Separation distance recommended: $d = 1.2 \times \sqrt{P}$ $d = 2 \times \sqrt{P}$
	6Vrms in bands ISM and amateur radio between 0.15 MHz and 80 MHz	6 Vrms at ISM and amateur radio bands between 0.15 MHz and 80 MHz	
Radiofrequency radiation IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Where, P is the maximum nominal output power of the transmitter in watts (W) according to the transmitter manufacturer, yd is the recommended separation distance in meters (m). The field strengths of fixed radio frequency transmitters, determined by an electromagnetic study of the site, must be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	10 V/m 80MHz - 2.7GHz (for respirator function)	10 V/m	

Table C-3 CEM-3

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

Note 2: These guidelines do not apply in all cases. Absorption and reflection from structures, objects, and individuals can affect electromagnetic propagation.

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, and 14 MHz to 14.2 MHz. 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. The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM radio broadcasts, and television broadcasts, cannot be theoretically predicted with Accuracy. To assess the electromagnetic environment due to fixed radio frequency transmitters, the possibility of conducting an electromagnetic survey of the site should be considered. If the field strength measured at the location where the device is used exceeds the applicable radio frequency compliance level mentioned above, the device should be observed to verify its normal operation. If a

If the device malfunctions, additional measures may be necessary, such as reorienting or relocating it.

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

Table C-3 CEM-3

Mindray Guide and Statement: Electromagnetic Immunity

The TV80 respirator is designed for use in the electromagnetic environment specified below. The customer or user of the TV80 respirator must ensure that it is used in an environment of this type.

Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment: guide
Proximity magnetic fields	8 A/m	8 A/m	/
	30 kHz CW	30 kHz CW	
IEC 61000-4-39	65 A/m	65 A/m	
	134.4 kHz Pulse modulation	134.4 kHz Pulse modulation	
	2.1 kHz	2.1 kHz	
	7.5 A/m 13.56 MHz Pulse modulation	7.5 A/m 13.56 MHz Pulse modulation	50 kHz
	50 kHz		

Table C-4 CEM-4

Recommended separation distances between portable and mobile radio frequency communication equipment and the ventilator

The TV80 respirator is intended for use in an electromagnetic environment where radiated radio frequency disturbances are controlled. The respirator customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communication equipment (transmitters) and the respirator as recommended below, based on the maximum output power of the communication equipment. Portable and mobile radio communication equipment (e.g., two-way radios, mobile/cordless phones, and similar equipment) should not be used closer to any part of this TV80 respirator, including cables, than determined by 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	Modulation pulses 18 Hz	1,80,3		27
450	430 - 470	GMRS 460 FRS 460	FM ± 5 kHz 1 kHz sinusoidal deviation	20,3 28		
710	704 - 787	LTE Band 13,17	Modulation pulses 217 Hz	0,20,39		
745						
780						
810	800 - 960	GSM 800/900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Modulation pulses 18 Hz	20,3 28		
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMTS	Modulation pulses 217 Hz	20,3 28		
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Modulation pulses 217 Hz	20,3 28		
5240	5100 - 5800	WLAN 802.11 a/n	Modulation pulses 217 Hz	0,20,39		
5500						
5785						

Table C-5 CEM-5

Recommended separation distances between portable and mobile radio frequency communication equipment and the ventilator

The TV80 respirator is intended for use in an electromagnetic environment where radiated radio frequency disturbances are controlled. The customer or user of the TV80 respirator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communication equipment (transmitters) and the TV80 respirator as recommended below.

function of the maximum output power of the communications equipment.

Maximum rated output power of the transmitter (W)	Separation distance according to the transmitter frequency			
	150 kHz - 80 MHz Outside of the ISM and amateur radio bands $d=1,2 \sqrt{P}$	150 kHz - 80 MHz in ISM and amateur radio bands $d=2 \sqrt{P}$	80 MHz - 800 MHz $d=1,2 \sqrt{P}$	800 MHz - 2.7 GHz $d=2,3 \sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.22		1.22,3	
103.8	6.4		3.87,3	
100	12	20	12	23

For those transmitters whose maximum output power is not listed above, you can determine the recommended separation distance in meters (m) from the equation applicable to the transmitter frequency, where P equals the maximum nominal output power of the transmitter in watts (W), according to the transmitter manufacturer.

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

Note 2: These guidelines do not apply in all cases. Absorption and reflection from structures, objects, and individuals can affect electromagnetic propagation.

Table C-6 CEM-6

No.	Name	Cable length (m)	Armor or not?	Observations
1	Power cable AC	3.5	Without protector	/
2	CO2 cable	2.8	Protective	/
3	SPO2 cable	3.7	Protective	/
4	ECG	3.5	Protective	/
5	Temperature cable	2.8	Protective	/
6	Temperature cable	3.5	Protective	/
7	IBP cable	4.8	Protective	/

Table C-7 CEM-7

C.2 Compliance with radio regulations

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

Table C-8 Radiofrequency Parameter

NOTE: **Maintain a distance of at least 20 cm from the respirator when the WiFi function is in use.**

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D.0

Alarm messages

Physiological alarm messages	D-2
Technical alarm messages	D-5

This chapter lists the messages of the technical and physiological alarms.

Please note that in this chapter:

- The P column indicates the default alarm level: H means high, M medium, and L low.
- For each alarm message, the corresponding instructions are provided for
Solve the problem. If the problem persists, contact service personnel.
- To obtain alarm messages from the BeneVision N1 patient monitor, refer to the
BeneVision N1 Patient Monitor Operator's Manual.

D.1 Physiological alarm messages

D.1.1 Respirator parameters

MESSAGES FROM ALARM	P	CAUSE AND ACTION
Pva very high	H	Airway pressure exceeds the upper limit of the pressure alarm.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits. 4. Check the patient's tubes for blockages.
Pva too much low	H	The airway pressure setting is below the lower pressure alarm limit.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits. 4. Check if the patient tube is leaking or kinked.
FiO2 very high	H	The inspired O2 concentration is above the upper FiO2 alarm limit for at least 30 s.
		<ol style="list-style-type: none"> 1. Check if the HEPA filter is clogged. 2. Calibrate the O2 sensor . 3. Check the alarm limits.
FiO2 very low	H	The concentration of inspired O2 has been below the lower limit of the FiO2 alarm for at least 30 seconds, or is less than 18%.
		<ol style="list-style-type: none"> 1. Check the O2 supply connection . 2. Ensure that the O2 supply pressure is between 280 kPa and 650 kPa. 3. Calibrate the O2 sensor . 4. Check the alarm limits.
VCe very high	M	The monitored TVe value is greater than the high alarm limit of TVe for 3 continuous mechanical ventilation cycles.
		<ol style="list-style-type: none"> 1. Check the ventilation parameter settings. 2. Check the alarm limits.

Table D-1 Respirator parameters

Very low VCe	M	The monitored TVe value is less than the lower alarm limit of TVe for 3 continuous mechanical ventilation cycles.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits. 4. Check if the breathing tubes are blocked or leaking. 5. Perform a system check to test for leaks.
MVe very high		HMVe is greater than the upper alarm limit of MVe.
		<ol style="list-style-type: none"> 1. Check the ventilation parameter settings. 2. Check the alarm limits.
Very low MVe		HMVe is less than the lower alarm limit of MVe.
		<ol style="list-style-type: none"> 1. Check the ventilation parameter settings. 2. Check the alarm limits. 3. Check if the breathing tubes are blocked or leaking. 4. Perform a system check to test for leaks.
Apnea	H	The failure time to detect breathing exceeds the Tapnea value.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Manual breathing. 3. Check the apnea time setting. 4. Check if the patient's tubes are disconnected.
Ventilation apnea	H	The failure time to detect breathing exceeds the Tapnea value. Start apnea ventilation mode.
		Check the ventilation parameter settings during apnea.
Very high FR M		ftotal is greater than the upper alarm limit of ftotal.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits.
Very low FR M		ftotal is less than the lower alarm limit of ftotal.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits.
Ventilation apnea ended	L	This alarm is triggered when apnea ventilation ends. It is not necessary to process this alarm.

Table D-1 Respirator parameters

D.1.2

CO2 Module

MESSAGES ALARM	P	CAUSE AND ACTION
EtCO2 very high	M	The value of the monitored parameter exceeds the alarm limit.
		<ol style="list-style-type: none"> 1. Check the patient type. 2. Check the alarm limits.
EtCO2 very low	M	The value of the monitored parameter exceeds the alarm limit.
		<ol style="list-style-type: none"> 1. Check the patient type. 2. Check the alarm limits.

Table D-2 CO2 Module

D.1.3 SpO2 Module

MESSAGES FROM ALARM	P CAUSE AND ACTION
SpO2 very high	<p>M The SpO2 value is greater than the upper alarm limit.</p> <ol style="list-style-type: none"> 1. Check the patient's condition and ventilation settings. 2. Check the patient's inspiratory O2% . 3. Check the alarm limits.
SpO2 very low	<p>M The SpO2 value is less than the lower alarm limit.</p> <ol style="list-style-type: none"> 1. Check the patient's condition and ventilation settings. 2. Check the patient's inspiratory O2% . 3. Check the alarm limits.
SpO2 desat	<p>H The SpO2 value is less than the desaturation alarm limit.</p> <ol style="list-style-type: none"> 1. Check the patient's condition and the ventilator settings. 2. Check the patient's inspiratory O2% . 3. Check the alarm limits.
PR very high	<p>M The PR value exceeds the high alarm limit.</p> <ol style="list-style-type: none"> 1. Check the patient's condition. 2. Check the respirator settings. 3. Check the alarm limits.
PR very low	<p>M The PR value is below the lower alarm limit.</p> <ol style="list-style-type: none"> 1. Check the patient's condition. 2. Check the respirator settings. 3. Check the alarm limits.
No pulse	<p>H The patient's pulse signal is too weak and the system cannot perform the analysis.</p> <ol style="list-style-type: none"> 1. Check the patient's condition. 2. Check the SpO2 sensor and the connection at the measurement site.

Table D-3 SpO2 Module

D.2 Technical alarm messages

D.2.1 Power supply board

ALARM MESSAGES: CAUSE AND ACTION

Battery failure 1 02 H	Battery charging failure 1. Please contact the service staff.
Battery failure 1 03 H	Battery aging 1. Please contact the service staff.
Battery failure 1 04 H	Battery communication error 1. Please contact the service staff.
Battery failure 1 05 H	Battery failure 1. Please contact the service staff.
Battery failure 2 02 H	Battery charging failure 2. Please contact the service staff.
Battery failure 2 03 H	Battery aging 2. Please contact the service staff.
Battery failure 2 04 H	Battery communication error 2. Please contact the service staff.
Battery failure 2 05 H	Battery failure 2. Please contact the service staff.
High battery temperature. Connect external power supply	M The battery temperature is somewhat high during discharge. Connect to the external power supply.
High battery temperature. System deactivated.	H The battery temperature is too high during discharge. The system may be disabled. Connect to the external power supply.
Low battery. Connect external power supply.	M The remaining battery charge is less than a threshold. Connect to the external power supply.
System OFF. Connect external source.	H The battery is depleted. The system will shut down in a few minutes. Connect to the external power source immediately.
No battery detected. There is no battery in the main unit or in the backup air supply at this time.	Please contact the service staff.
Ventilation error	M Power board fan speed error. If the problem persists, restart the machine. Please contact the service staff.
Device failure 03	H Power board self-test error. Please contact the service staff.

Table D-4 Power Board

D.2.2 Main control board

ALARM MESSAGES: CAUSE AND ACTION

Reset date and time	L	The button cell battery is available in the system. But the clock is off and reset. Please reset the date and time.
Key error	L	The physical key or rotary encoder remains pressed continuously for more than 35 seconds. Please contact the service staff.
Storage Error M Storage error.		Please contact the service staff.
Device failure 04	H	Control module initialization error. Please contact the service staff.
Device failure 05		Interruption of communication with the control module. Please contact the service staff.
Device failure 19		Interruption of communication with the power board. Please contact the service staff.
Device failure 20	H	SpO2 communication stop Restart the ventilator or contact service personnel.
Device failure 22		Interruption of communication with the protection module Please contact the service staff.
Network disconnected		The ventilator is disconnected from the system. central monitoring (CMS), eGateway or the monitor. 1. Check if the network connection mode (e.g., wired/wireless network or monitor access point) of the ventilator is correct. 2. Check if the network cable between the ventilator and the central monitoring system (CMS), eGateway or monitor is connected, and if the WiFi router is working properly. 3. Check the network configuration (IP, gateway, etc.).

Table D-5 Main Control Board

D.2.3 Monitor board

ALARM MESSAGES: CAUSE AND ACTION

Technical error 04	L	Bell Error. Please contact the service staff.
Technical error 05	M	Atmospheric pressure sensor failure. Please contact the service staff.
Technical error 07	M	3-way valve error. Please contact the service staff.
Technical error 09	M	Test inspiration temperature sensor. Please contact the service staff.
Device failure 01	H	Power supply voltage error. Please contact the service staff.
Device failure 02 H		Memory error. Please contact the service staff.
Device failure 05 H		Interruption of communication with the control module. Please contact the service staff.
Device failure 06 H		Control module self-test error. Please contact the service staff.
Device failure 09 H		Pressure sensor error. Please contact the service staff.
Device failure 10 H		Safety valve failure. Please contact the service staff.
Device failure 12 H		Total failure of the inspiratory limb. Please contact the service staff.
Device failure 13	H	O ₂ end failure . Please contact the service staff.
Device failure 21	H	Error in zeroing the pressure sensor. Please contact the service staff.
Device failure 22 H		Interruption of communication with the protection module Please contact the service staff.
Device failure 23	H	Error in automatic check of the protection module. Please contact the service staff.
PEEP very high	H	Monitored PEEP exceeds PEEP + 5 cmH ₂ O (PEEP + 10 cmH ₂ O for APRV mode) in a complete ventilation cycle mechanics. 1. Check the ventilation parameter settings. 2. Check if the patient's tubes show obstructions.

Table D-6 Monitor board

PEEP very low		The patient's PEEP is less than the set value up to a certain point.
		<ol style="list-style-type: none"> 1. Check the patient's tubes for leaks. 2. Perform a system check to test for leaks.
Via insp branch obstructed?	H	The pipe is blocked.
		<ol style="list-style-type: none"> 1. Check and clean the patient's tubes. 2. Check and clean the exhalation valve.
Via insp branch obstructed?	M	The patient's tube is bent or obstructed in case of O ₂ therapy .
		Check if the patient tube is blocked or kinked. If that's the case, fix it.
Continuous airway pressure	H	The airway pressure measured by any pressure sensor is greater than the PEEP setting + 15 cmH ₂ O for 15 consecutive seconds.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check if the patient's tubes show obstructions.
Leak on track?	L	The pipe is leaking.
		<ol style="list-style-type: none"> 1. Check the patient's tubes for leaks. 2. Perform a system check to test for leaks.
Tube disconnected? H		The tube is disconnected.
		Reconnect the patient tube.
Limited pressure	L	In volume mode, the pressure reaches the Paw-5 high alarm limit.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the high limit of the pressure alarm.
Limited volume	L	In pressure mode, the volume of gas supplied exceeds the configured high TV limit.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the alarm limits.
Pinsp not reached	L	Pinsp is less than the pressure setting value by 3 cmH ₂ O or is 2/3 of the pressure setting value, whichever is lower.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the high TV limit. 3. Check the O₂ supply . 4. Check the patient's tubes for leaks. 5. Check if the HEPA filter is clogged.

Table D-6 Monitor board

VC not achieved	L	TVi is lower than the TV setting value by more than 10 ml + 10% of the adjustment value.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the high limit of the pressure alarm. 3. Check if the HEPA filter is clogged. 4. Check the O2 supply . 5. Check if the breathing tubes are blocked or leaking.
Limited pressure in suspended cycle	L	The pressure reaches the Pva-5 high alarm limit in the sigh cycle.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the high limit of the pressure alarm. 3. Check if the patient's tubes show obstructions. 4. Consider disabling the sighs function.
O2 supply failure	H	The oxygen supply is not sufficient for the normal functioning of the ventilator.
		<ol style="list-style-type: none"> 1. Check the connection to the O2 supply . 2. Check the O2 supply pressure .
prolonged tinsp	L	In PSV mode, Tinsp exceeds 4s for adults, 1.5s for pediatrics, and the maximum user-set inspiration time for neonates for 3 continuous cycles.
		<ol style="list-style-type: none"> 1. Check the patient. 2. Check the ventilation parameter settings. 3. Check the patient's tubes for leaks.
Check the flow sensor	H	Error in the installation of the expiratory flow sensor.
		Please contact the service staff.
Very high inspiratory gas temperature	H	The gas temperature exceeds 55 °C.
		<ol style="list-style-type: none"> 1. Disconnect the patient. 2. Restart the computer. Contact the specified service personnel if the problem persists.
Error in the type of internal flow sensor	H	Error in the installation of the air flow sensor or the O2 flow sensor .
		Please contact the service staff.
High vacuum cleaner temperature	H	The temperature of the backup air supply exceeds the established threshold.
		<ol style="list-style-type: none"> 1. Check if the ambient operating temperature of the equipment exceeds the maximum operating temperature specified by the supplier. 2. Check if the fan inlet and outlet are obstructed. If so, remove the foreign substance and dust. 3. Check the fan's rotation. If it is malfunctioning (abnormal noises or rotation speed), replace the fan.

Table D-6 Monitor board

VMA: Target not achieved	L	The established MV% cannot be achieved
		1. Check the ventilation parameter settings.
		2. Check the alarm limit settings.
Replace HEPA filter	L	HEPA filter clogged, increased resistance.
		Please contact the specified service personnel.
Vacuum cleaner technical error 01	M	Air supply temperature sensor error booking.
		Please contact the service staff.
Vacuum cleaner technical error 02	M	HEPA pressure sensor failure.
		Please contact the service staff.
Vacuum cleaner error 03	H	Backup air supply temperature too high
		Please contact the service staff.
Vacuum cleaner error 04	H	Backup air supply failure
		Please contact the service staff.
O2 sensor gauge.	L	The O2 sensor self-test fails.
		Calibrate the O2 concentration .
Perform calibration pressure.	H	Calibrate the sensor pressure.
		Please contact the service staff.
Perform calibration flow.	H	Calibrate the flow sensor.
		Perform flow calibration.
Excessive asynchrony	M	The total number of patient-ventilator asynchrony events exceeds 20% of the total number of ventilation cycles (configurable).
		1. Check the patient's condition and the ventilation parameter settings.
		2. Enter the patient-ventilator asynchrony interface for more details.
Sensor failure with O2	M	O2 sensor error .
		Replace the O2 sensor .
Incorrect flow sensor	H	The wrong flow sensor is being used.
		Check the flow sensor type and make sure it matches the selected patient type.
Reverse flow sensor	H	Flow sensor connected backwards.
		Reverse the flow sensor.
High O2 supply pressure	H	The O2 supply pressure is higher than the threshold value.
		1. Check the connection to the O2 supply .
		2. Ensure that the O2 supply pressure ranges between 280 kPa and 650 kPa.

Table D-6 Monitor board

D.2.4 CO2 Module

MESSAGES FROM ALARM	P CAUSE AND ACTION
Module failure CO2 01	There is an error in the zeroing of the side-flow CO2 module. The deviation of the input gain signal is too large; it exceeds the adjustable range. Please contact the service staff.
Module failure CO2 02	M CO2 Initialization Error An error occurs in the CO2 module during initialization. Please contact the service staff.
Module failure CO2 03	M CO2 Self-Check Error An error has occurred in the CO2 module during self-check. Please contact the service staff.
Module failure CO2 04	M CO2 hardware error . Please contact the service staff.
Module failure CO2 05	M CO2 communication stoppage , CO2 module failure , CO2 communication error , or communication failure It reaches 10 seconds. Please contact the service staff.
Module failure CO2 06	M Error in zeroing the direct flow CO2 module. Please contact the service staff.
High temperature sensor CO2	L The sensor temperature is too high (above 63°C). Please contact the service staff.
CO2 sample line obstructed	L The sampling line is defective or obstructed. 1. Check if the sampling line is occluded. 2. Replace the sampling line. 3. Replace the water collector.
CO2 without a trap water	L The water collector has become disconnected or is not connected correctly. Check the water collector. Reinstall the water collector.
EtCO2 out of range L	The measured values of the parameters exceed the measurement range (including the error range). 1. Perform a zeroing of the CO2 module. 2. Contact the service staff.
Replace sensor CO2	M The direct flow CO2 module sensor is faulty. Please contact the service staff.
Without CO2 sensor	L The direct flow CO2 module sensor is not connected. Connect the CO2 sensor

Table D-7 CO2 Module

D.2.5 SpO2 Module

MESSAGES FROM ALARM	P	CAUSE AND ACTION
SpO2 sensor desc	L	The connected SpO2 sensor became disconnected from the patient tube (e.g., cable disconnection or short circuit). Check the SpO2 sensor and the connection at the measurement site.
Replace sensor SpO2	M	The SpO2 sensor failed (e.g., cable disconnection or short circuit). 1. Replace the SpO2 sensor. 2. Contact the service staff.
Without SpO2 sensor	L	The main cable has been disconnected from the module. The connection between the sensor and the main cable has been broken. Check that the SpO2 cable is connected to the module.
SpO2 very weak	L	The light to which the sensor is exposed is so bright that the sensor's photodetector is absorbing light from the environment. Place the SpO2 sensor in a location with less ambient light.
No pulse SpO2	L	The SpO2 sensor cannot obtain the pulse signal (or the signal is incomplete). 1. Check the patient's condition. 2. Check the SpO2 sensor connection and the measurement location 3. Replace the SpO2 sensor.
SpO2 module error	M	SpO2 module error or SpO2 initialization error. 1. Replace the SpO2 sensor. 2. Contact the service staff.
SpO2 out of range	L	The measured values of the SpO2 parameter exceed the measurement range. 1. Replace the SpO2 sensor. 2. Contact the service staff.
PR out of range	L	The measured values of the PR parameter exceed the measurement range. 1. Replace the SpO2 sensor. 2. Contact the service staff.

Table D-8 SpO2 Module

D.2.6 Module Module

MESSAGES FROM ALARM	P CAUSE AND ACTION
Neo flow sensor out of range	H The range of the neonatal flow sensor exceeds 32 l/min. 1. Check the patient's condition and ventilation settings. 2. Change the patient type if necessary.
Monitor sensor neo flow. deactivated	M Neonatal flow sensor monitor disconnected in volume mode. Neonatal flow sensor monitor connected.

Table D-9 Module Module

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E.0

Factory Defaults

Ventilation parameters.....	E-2
Configuration.....	E-3
System settings.....	E-3
Alarms.....	E-4
History.....	E-5
Additional Adjustments and Tools.....	E-5 Oxygen
Therapy	E-6
CO2 module.....	E-6
SpO2 Module.....	E-7
Other.....	E-7

This chapter lists the most important factory default settings that the user cannot modify. If necessary, you can restore the factory default settings.

For default settings for ECG, Resp, NIBP, IBP, and Temp, refer to the BeneVision N1 Patient Monitor Operator's Manual.

E.1 Ventilation parameters

PARAMETER ADJUSTMENTS OF THE BREATHING MODE	FACTORY SETTINGS BY DEFAULT
O2%	Non-CPRV: 40 vol. %; CPRV: 100 vol.%
VC	Adult: 500 ml; Pediatric: 100 ml; Neonate: 20 ml
ÿPinsp	15 cmH2O
ÿPaux	In PSV and PSV-S/T modes: 15 cmH2O; in other modes: 0 cmH2O
PEEP	No CPRV: 3 cmH2O; CPRV: 0 cmH2O
Palt	15 cmH2O
Pbaj	3 cmH2O
F	Adult: 15/min (CPRV: 10/min); pediatric: 20/min; neonate: 40/min
I:E	Adult/pediatric: 1:2; neonate: 1:2.5
Tinsp	Adult: 1.3 s; pediatric: 1.0 s; neonate: 0.4 s
Talt	Adult: 1.3 s; pediatric: 1.0 s; neonate: 0.4 s
Tbaj	Adult: 2.7 s; pediatric 2.0 s; neonate: 1.1 s
F-Trig	Adult: 2.0 l/min; pediatric: 1.0 l/min; neonate: 0.5 l/min
P-Trig	/
ÿPapnea	15 cmH2O
Capnea	Adult: 500 ml; Pediatric: 100 ml; Neonate: 20 ml
<small>breath-holding</small>	Adult: 15/min; pediatric: 20/min; neonate: 40/min
fsimv	Adult: 5/min; pediatric: 15/min; neonate: 30/min
Tinsp apnea	Adult: 1.30 s; pediatric 1.00 s; neonate: 0.40 s
Flow	Adult: 24 l/min; pediatric: 7 l/min
Exp%	25%
Tpause(%)	Deactivated
Tpend	0.20 s
IntelliCycle	Activated
VM%	100%
ÿint.PEEP	Deactivated
Vent apnea	Activated
ÿPmanInsp	15 cmH2O
TmanInsp	Neonate: 0.4 s

Table E-1 Ventilation parameters

E.2 Configuration

CONFIGURATION	FACTORY DEFAULT VALUE
Menu - Calibration - CO2 in maintenance - CO2 %	3%
Menu - Adjustment - Ventilation - VC/IBW	7 ml/kg
Menu - Adjustment - Ventilation - IBW/height	Height
Menu - Settings - Ventilation - Tinsp/I:E	Tinsp
Menu - Adjustment - Ventilation - Flow/ Tpause(%)	Flow
Menu - Adjust - Ventilation - Adjust DuoLevel Height	
Menu - Adjustment - Ventilation - Invasive Apnea Pressure Control	
Menu - Adjust - Ventilation - Compensation leaks	Activated
Menu - Adjustment - Ventilation - Increase O2% in O2y	Adult: 60%; Pediatric: 60%; Neonatal: 10%
Menu - Settings - Neo. Module	Activated
Menu - Adjustment - O2 Sensor	Activated
Menu - Settings - Gas Supply - O2 Supply Type	HPO
Menu - Screen - Selection Screen	Wave screen
Menu - Screen - Brightness/Volume - Mode day and night	Day
Menu - Screen - Brightness/Volume - Brightness	5
Menu - Screen - Brightness/Volume - Volume key	2
Menu - Screen - Screen Adjustment - Waveform	3
Menu - Screen - Screen Adjustment - Curve Wave Trace	
Menu - Screen - Screen Adjustment - Device Configuration Switch	Activated

Table E-2 Configuration

E.3 System settings

SYSTEM	FACTORY DEFAULT VALUE
Menu - System - Date and time settings - 24 h	24 h
Menu - System - Date and Time Settings - Time format	00:00:00
Menu - System - Date and Time Settings - Date format	YYYY-MM-DD
Menu - System - Date and Time Settings - Date	2012.01.01

Table E-3 System Settings

Menu - System - Language/Unit - Language	Chinese
Menu - System - Language/Unit - Unit weight kg	
Menu - System - Language/Unit - Height Unit	cm
Menu - System - Language/Unit - Unit pressure cmH2O	
Menu - System - Language/Unit - Unit CO2 mmHg	
Menu - System - Language/Unit - Unit WOBJ/min	
Menu - System - Language/Unit - Pressure gas supply	kPa
Menu - System - Language/Unit - Volume minimum alarm	2
Menu - System - Interface - Network Type	LAN
Menu - System - Interface - LAN - IP Settings Config	DHCP
Menu - System - Interface - Station Configuration central - Select CMS	Deactivated
Menu - System - Interface - Information Security - Connection Encryption Type	SSL encryption priority
Menu - System - Interface - Serial - Protocol	None

Table E-3 System Settings

E.4 Alarms

ALARMS	FACTORY SETTINGS BY DEFAULT
Alarms - Ventilation limits - High PVA limit	50 cmH2O (in CPAP mode: 60 cmH2O)
Alarms - Ventilation limits - Low PVA limit	Deactivated
Alarms - Ventilation limits - High alarm limit volume per minute	1.5xTV
Alarms - Ventilation limits - Low alarm limit for minute volume	0.6xTV
Alarms - Ventilation limits - High alarm limit from TVE	The lower of the set value of 2xTV and the upper limit of the adjusted range
Alarms - Ventilation limits - Low alarm limit of TVE	0.5xTV set value
Alarms - Ventilation limits - Tapnea	In non-nCPAP mode: Adult and pediatric: 15 s; neonate: 10 s In nCPAP mode: Off
Alarms - Ventilation limits - High alarm limit of ftot	Deactivated
Alarms - Vent limits - Low alarm limit of ftot	Deactivated
Alarms - Module limits - High limit EtCO2 alarm	Sidewall CO2 Module : Adult/ pediatric: 50 mmHg; neonate: 45 mmHg; Direct flow CO2 module : 50 mmHg.

Table E-4 Alarms

Alarms - Module limits - EtCO ₂ alarm low limit	Adult: 15 mmHg; pediatric: 20 mmHg; neonate: 30 mmHg
Alarms - Module Limits - Disconnect	80%
Alarms - Module limits - SpO ₂ alarm high limit	100%
Alarms - Module limits - SpO ₂ alarm low limit	90%
Alarms - Module Limits - PR Alarm High Limit	Adult: 120 bpm; Pediatric: 160 bpm; Neonatal: 200 bpm
Alarms - Module Limits - PR Alarm Low Limit	Adult: 50 bpm; Pediatric: 75 bpm; Neonatal: 100 bpm

Table E-4 Alarms

E.5 Record

RECORD	FACTORY SETTINGS BY DEFAULT
Chart - Group	All
Graphic - Zoom	10 min
Table - Group	All
Table - Interval	1 min
Event Log - Filter	All events

Table E-5 History

E.6 Additional settings and tools

SETTINGS AND TOOLS	FACTORY SETTINGS BY DEFAULT
Tool. - Advanced - PV loop est- Pinic	3 cmH ₂ O
Tool. - Advanced - PV loop est - Pmax	15 cmH ₂ O
Tool - Advanced - PV loop - Flow	6 l/min
Tool. - Advanced - PV loop est - Limit	770 ml
Tool. - Advanced - PV loop est - Ref. loop	Disguise
Tools - Advanced - IS - Pressure Maintenance	Adult: 35 cmH ₂ O; pediatric: 20 cmH ₂ O
Tool - Advanced - IS - Waiting time	Adult: 30 s; Pediatric: 15 s
Tool. - Advanced - Withdrawal - PRE - PEEP	5 cmH ₂ O
Tool. - Advanced - Withdrawal - PRE - \dot{y} Paux	5 cmH ₂ O
Tool. - Advanced - Withdrawal - PRE - FiO ₂	40%
Tool - Advanced - Withdrawal - PRE - Duration 30 min	
Tools - Advanced - Withdrawal - PRE - Tolerance	180 s
Tool - Advanced - Withdrawal - Criteria - Upper limit of fspn	35 /min

Table E-6 Additional Adjustments and Tools

Tool - Advanced - Withdrawal - Criteria - Lower limit of fspn	Deactivated
Tool - Advanced - Withdrawal - Criteria - Upper limit of TVe/IBW	15 ml/kg
Tool - Advanced - Withdrawal - Criteria - Lower limit of TVe/IBW	4 ml/kg
Tools - Advanced - Withdrawal - Criteria - RSBI Upper Limit	105 1/(min*l)
Tools - Advanced - Withdrawal - Criteria - EtCO2 upper limit	Adult: 50 mmHg; pediatric: 50 mmHg; neonate: 45 mmHg
Tools - Advanced - Withdrawal - Criteria - Lower limit of EtCO2	Adult: 15 mmHg; pediatric: 20 mmHg; neonate: 30 mmHg
Tool - Advanced - Withdrawal - Criteria - SpO2 upper limit	100%
Tool - Advanced - Withdrawal - Criteria - Lower SpO2 limit	90%
Tool - Advanced - Withdrawal - Criteria - Upper limit of PR	120 /min
Tool - Advanced - Withdrawal - Criteria - Lower limit of PR	50 /min

Table E-6 Additional Adjustments and Tools

E.7 Oxygen therapy

OXYGEN THERAPY	FACTORY SETTINGS BY DEFAULT
O2 Therapy - O2%	40 vol.%
Oxygen Therapy - Flow	Adult: 25 l/min, pediatric: 8 l/min; neonate: 4 l/min

Table E-7 O2 Therapy

E.8 CO2 Module

CO2 MODULE	FACTORY SETTINGS BY DEFAULT
Menu - Settings - CO2 Module - Monitoring Activated	
Menu - Settings - CO2 Module - Comp. BTPS	Deactivated
Menu - Adjustment - CO2 Module - Off for 30 seconds since reset	Activated

Table E-8 CO2 Module

E.9 SpO2 Module

SPO2 MODULE	FACTORY SETTINGS BY DEFAULT
Menu - Settings - SpO2 Sensor - Monitoring Enabled	
Menu - Settings - SpO2 Sensor - Med Sensitivity	
Menu - Settings - SpO2 Sensor - Sweep Speed	25 mm/s
Menu - Settings - SpO2 Sensor - Volume beat	1
Menu - Settings - SpO2 Sensor - Alarm SpO2	Activated
Menu - Settings - SpO2 Sensor - PR Alarm Activated	
Menu - Settings - SpO2 Sensor - SpO2 Alarm Level	Alarm med
Menu - Settings - SpO2 Sensor - PR Alarm Level	Alarm med

Table E-9 SpO2 Module

E.10 Others

PATIENT	FACTORY SETTINGS BY DEFAULT
Weight	Adult: 70 kg; pediatric: 15.4 kg; neonate: 3 kg
Sex	Man
Height	Adult: 174cm; pediatric: 100 cm
Ventilation type	Invasive

Table E-10 Other

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F.0

Abbreviations, symbols and units of measurement

Abbreviations.....	F-2
Symbols.....	F-4
Units of measurement.....	F-5
Cross-references.....	F-6

This chapter lists only the abbreviations, symbols, and units of measurement related to the ventilator. For more information on the symbols and units of measurement related to the BeneVision N1 patient monitor, refer to the BeneVision N1 patient monitor operator's manual.

F.1 Abbreviations

ABBREVIATIONS	DESCRIPTION
VMA	Adaptive minute volume ventilation
Tinsp apnea	Inspiratory ventilation time during apnea
Vent apnea	Breath-hold ventilation
APRV	Airway pressure release ventilation
ATPD	Ambient temperature, dry gas pressure
BTPS	Body temperature with saturated pressure
Cdin	Dynamic conformity
CPAP/PSV	Continuous positive airway pressure/ Pressure support ventilation
CPR	(Cardiopulmonary Resuscitation Ventilation)
Cstat	Static conformity
Suspended cycles	Cycles of sighs
DuoLevel	DuoLevel Ventilation
EtCO ₂	Carbon dioxide at the end of exhalation
Exp%	Percentage of expiration activation
FICO ₂	Fraction of inspired carbon dioxide
FI _{O₂}	Concentration of inspired oxygen
Flow	Flow
F	Breathing rate
breath-holding	Apnea ventilation rate
fmand.	Mandatory frequency
fesp	Spontaneous frequency
fsimv	SIMV Frequency
total	Total breathing rate
Activ-F	Flow activation
I:E	Inspiratory time:expiratory time ratio
Interval	Interval
VM%	Volume per minute

Table F-1 Abbreviations

ABBREVIATIONS	DESCRIPTION
Spontaneous minute volume	
VMfuga	Leakage volume per minute
nCPAP	Nasal ventilation with continuous positive airway pressure
NIV Non-invasive ventilation	
O ₂	Oxygen
PA/C	Pressure-controlled/assisted ventilation
P _{va}	Airway pressure
PEEP	Positive end-expiratory pressure
PEEP _i	intrinsic PEEP
PEEP _{tot}	Total positive pressure at the end of expiration
P _{alt}	High pressure
ȳP _{insp}	Inspiratory pressure control level (relative to PEEP/P _{low})
Pressure limit level	
P _{baj}	Low pressure
ȳP _{manInsp}	Manual inspiration by pressure control (relative to PEEP/P _{low})
P _{med}	Average pressure
Peak	Maximum pressure
P _{mest}	Plateau pressure
PRVC	Pressure-regulated volume-controlled ventilation
PRVC-SIMV	Pressure-regulated volume-controlled ventilation: synchronized intermittent mandatory ventilation
PSV-S/T	Pressure support ventilation: spontaneous/ synchronized
P-SIMV Mandatory intermittent ventilation synchronized by pressure control	
P-Trig Pressure Activation	
ȳ _{int} .PEEP	Intermittent positive end-expiratory pressure
ȳP _{apnea}	Apnea ventilation pressure (relative to PEEP/P _{low})
ȳP _{aux}	Pressure support level (relative to PEEP/P _{low})
R _i	Resistance of inspiration
R _e	Resistance to exhalation
Susp	Sighs
T _{manInsp}	Time for manual inspiration

Table F-1 Abbreviations

ABBREVIATIONS	DESCRIPTION
Tesp	Expiration time
Talt	High pressure time
Tinsp	Time for inspiration
Tbaj	Low pressure time
Tpause(%)	Percentage of inspiratory pause time
T stable	Time of stability in the time of inspiration
Pressure increase time	
VC	Tidal volume
Capnea	Apnea tidal volume
VCe	Tidal volume expired
VCe/IBW	Tidal volume expired per ideal body weight
VCe esp	Spontaneous expired tidal volume
VCi	Inspired tidal volume
Volume.	Gas volume
VA/C	Volume-controlled/assisted ventilation
V-SIMV	Volume-Synchronized Intermittent Mandatory Ventilation
VS	Volume support ventilation
RCesp	Expiratory time constant
RSBI	Rapid shallow breathing index
WOB	Breathing work

Table F-1 Abbreviations

F.2 Symbols

SYMBOLS	DESCRIPTION	SYMBOLS	DESCRIPTION
-	less	<	less than
%	percent	>	greater than
/	by; divide; or	≤	less than or equal to
-a ÿ		≥	greater than or equal to
^	power±	×	multiplied by
+	further	©	copyright
=	equal to		

Table F-2 Symbols

F.3 Units of measurement

UNITS of EXTENT	DESCRIPTION	UNITS of EXTENT	DESCRIPTION
Ampere		amber	millibar
Ah	ampere-hours	mg	milligram
°C	centigrade	min	minute
dc	cubic centimeters	/min	per minute
cm	centimeter	ml	milliliter
cmH ₂ O	centimeter of water	mm	millimeter
dB	decibel	mmHg	millimeter of mercury
°F	Fahrenheit	ms	millisecond
g	gram	mV	millivolt
h	hour	mW	milliwatt
Hz	hertz	nm	nanometer
hPa	hectopascal	ppm	parts per million
inch	inch	s	second
kilo		V	volt
kg	kilogram	GOES	volt ampere
kPa	kilopascal	ÿ	ohm
1 liter		ÿA	microampere
lb	pound	ÿV	microvolt
meter		W	watt
mAh	microampere per hour		

Table F-3 Units of measurement

F.4 Cross-references

Manufacturer's specific designation of the ventilator ventilation modes	Systematic coding scheme for ventilation modes (ISO 19223 Pulmonary ventilators and related equipment. Vocabulary and semantics)
VA/CA/C-VC	
PA/CA/C-PC	
V-SIMV	SIMV-VC\PS
P-SIMV	SIMV-PC\PS
CPAP/PSV	CPAP/CSV-PS
PSV-S/TS/T-PS/PC	
PRVCA/C-vtPC	
PRVC-SIMV	SIMV-vtPC\PS
DuoLevel	/
APRV	IMV-PC
VS	CSV-vtPS
VMA	/
nCPAP	CPAP

Table F-4 Cross-references

G.0

Software instructions

This product uses the following commercial software. During product development, Mindray will evaluate security patches according to the development process to determine if updates are necessary.

NAME OF THE SUPPLIER	NAME OF THE COMPONENT	VERSION OF THE COMPONENT	DESCRIPTION/USE
Linux Kernel Organization, Inc	Operating system Embedded Linux	3.2.0	Operating system
Digia Plc Software base	Marco QT Open layer of secure sockets	5.2.1 1.1.0e	GUI/Application Open SSL

Table G-1 Software Information

