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User's Manual

MV2000[SU:M] Ventilator System

CE 0470

This User Manual may be revised for the improvement of the product, without prior notification.
Images in this User Manual may differ from the actual product.

User Manual

This User Manual is provided to users with MV2000[SU:M] Ventilator product.

Since this User Manual is compatible with MV2000[SU:M] Ventilator, it may not be used with other products manufactured by our company. In case of loss or damage in the User Manual, you may refer to MEK-ICS web site for downloading the manual file.

URL: http://www.mek-ics.com

MV2000[SU:M] User Manual includes precautions and risks to users prior to use of ventilator. Please read all precautions for use thoroughly before operating the product.

You may quickly find wanted information using the table of contents during operation.

If you have any inquiries on details of the product, contact our company or visit Customer Service Center.

Notice

Warranty

Contents included in this document may be changed without announcement.

Our company is not responsible for any problems and damages caused from use of performance or data different from the details of this document.

Revision History

Part and revision numbers in this document represent current version.

The revision number is not changed if subordinate documents are modified or supplemented.

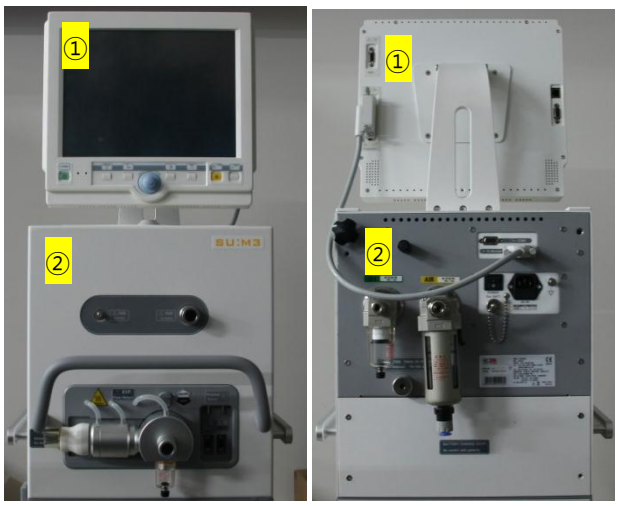
The revision number is only changed in case of change in part numbers or technical matters.

1. Introduction

1.1 Device Outline

This chapter provides guidelines for correct use of the product and summarized information on the MV2000[SU:M] ventilator system.

1.1.1 Device Illustration



1.1.2 Device Configuration

MV2000[SU:M] ventilator is composed of the following.

1) User Interface

- Configures ventilation mode and displays patient measurement data with alarms

2) Main

- Mixes supplied gas
- Delivers and exchanges gas

1.1.3 Use

MV2000[SU:M] ventilator is a device designed to treat and monitor insufficient ventilation or patients suffering respiratory insufficiency.

1.1.4 User

MV2000[SU:M] ventilator must be used by the following users.

- Medical professionals
- Individuals who received training on the use of this device
- Individuals who have experience in treatment of respiratory diseases

1.1.5 Environment

MV2000[SU:M] ventilator must be used in the following environments.

- Hospitals
- Facilities and institutions with the purpose of providing medical service
- Transportation of patients within hospitals or medical institutions

1.1.6 Service Guideline

CAUTION

- Regular Inspection
  MV2000[SU:M] ventilator must be regularly inspected by a trained professional.
- Inspection Record
  All matters related to inspection of MV2000[SU:M] ventilator shall be recorded in accordance to regulations by hospital, local government, and national government.

1.1.7 Exceptions for Legal Responsibilities

- Inappropriate environment
  Our company is not responsible for safe operation of MV2000[SU:M] ventilator if environment described in this Manual is not followed.
- Service by a non-professional
  If this product is serviced or repaired by an individual who did not complete relevant

training, our company is not responsible for safe operation of MV2000[SU:M].

1.2 Warning, Caution, Important and Reference Matters

Symbols are indicated on the interior and exterior of the product and in this User Manual.
The symbols represent important cautions and advice to the user. Please read the following symbols carefully and be well informed of them for the use and storage of the product.

DANGER

This symbol represents "DANGER."

It is associated with possible matters that may greatly harm the product or the patient, or might even cause the patient's death.

WARNING

This symbol represents "WARNING."

It is associated with possible matters that may harm or cause irreversible damage to the product or the patient..

CAUTION

This symbol represents "CAUTION."

It is associated with possible matters that may damage the product or harm the patient.

ATTENTION

This symbol is associated with safety issues that the user should give attention to and be well informed of before using the product. How to use the product is described in each section of this manual

NOTE

This symbol is associated with issues you should note regarding the surrounding environment or additional references to the descriptions in this manual. It does not pertain to possible damages to the product or the patient.

1.2.1 Summary

This booklet summarizes functions and characteristics of the MV2000[SU:M] ventilator system. Since not all details of MV2000[SU:M] are included in this booklet, do not use this booklet as a document for training.

WARNING

- Always perform pre-checking prior to connecting the ventilator to a patient.
- In case of the following, stop the use of ventilator and contact service assistant.
  → If unordinary screen shows up
  → If an alarm cannot be settled
  → If the device creates abnormal sound
  → If the device is operating abnormally or shows unexpected failure
- The ventilator must always be maintained vertical during use.
- If the ventilator is connected to a patient,
  → Carefully monitor the patient.
  → Prepare for reserve ventilators for easier use.
  → Do not raise or separate expiratory part.
  → Always check setting and measurement values displayed on the screen.
- MV2000[SU:M] ventilator must be operated by an experienced user in accordance to guidelines given in this booklet.
- Do not cover the ventilator in any way. This may cause errors in its functions.
- Expiratory part of the ventilator and expiratory may be contaminated.

CAUTION

- Device for prevention of dry lung tissues, such as disposable humidifier or humidifier, must always be used.
- Refer to installation guideline for ventilator system and options for accurate assembly.
- When separating or transporting the ventilator or its parts, refer to User Manual or request our company. Always take care in transportation.
- Be careful when handling tube, connector, and patient tube parts. Use of support arm can reduce weight of tube inflicted on the patient.
- Do not renovate or remove any part of the ventilator.
- If the product is repaired after not following the uses described in this booklet, our company is not responsible for safe operation of ventilator MV2000[SU:M].

1.2.2 Cautions for Storage

WARNING

1) Do not store the product in a place exposed to humidity..

2) Do not store the product in a place exposed to directsunlight.

3) Do not store the product in a place near a heating device.

4) Do not store the product in a place with extreme thermal variation.
(Proper Temperature range is -15℃ ~ 50℃ and humidity range is 10% ~ 90%)

5) Do not store the product in a very humid place or in a place with poor ventilation.

6) Do not install or place the product where it may fall or be dropped.
Do not store the product in a place that may cause the patient any harm.
Do not store the product in a place where the product could be exposed to extreme impact or vibration.

7) Do not store the product in a place where the product could be exposed to chemicals or explosive gases.

8) Be careful to prevent dirt, especially metal materials, from getting inside the product.

9) If the product dysfunctions, do not disassemble the product yourself.
Only MEKICS' service personnel and designated service technicians are authorized to disassemble the product for repair or battery replacement. If you disassemble the product yourself, you will not receive any service for the product.

10) Turn off the product when you will not be using the product for a while.

1.2.3 Cautions for Use

WARNING

1) This product is extremely dangerous when used or stored in places exposed to chemical substances or explosive gases.
2) Battery may explode when using the product under flame or high temperature.
3) Do not disassemble or dismantle the product. Our company will not take any responsibility on disassembled products.
4) Read this manual prior to use and check settings for various sensors and devices. This product should only be used by an authorized individual with sufficient knowledge about patient monitoring devices.
5) The product must be verified regularly to check for accurate operation.
6) Do not use one product on two patients simultaneously.
7) Do not use in places exposed to humidity.
8) It is extremely dangerous to use the product with wet hands.
9) Do not use the product under direct sunlight.
10) Do not use the product in places with large temperature fluctuations. Temperature range is 10°C ~ 40°C and humidity range is 10% ~ 90%.

11) Do not use the product nearby electric heating devices.
12) Do not use the product under high humidity or ventilation problem.
13) Do not use the product in places with excessive impact or vibrations.
14) Take care to prevent dusts, especially metal substances from entering the product.

CAUTION

1) This product is used to determine patient status. Other clinical information must be used together for accurate diagnosis.
2) Take care not to cause pain on patients from tightening of sensors. Also, take care not to tangle patients with sensor cables.
3) If measurement values displayed on the screen are considered inaccurate, measure another patient for comparison.

1.2.4 Precautions for Electric Safety

WARNING

1) The rated power input for this product is AC 100~240V / 10A / 50–60Hz.
2) Connect the power plug to an AC power outlet with an earth terminal.
3) Note that neither the company nor any representative of the company will be responsible for any issues arising from the use of any power source out of the rated power input.
4) Only authorized personnel who are trained to service the product may disassemble the product. Note that neither the company nor any representative of the company will be responsible for any electric shock, short circuit or product damage caused by unauthorized disassembly. Failure to comply will cancel the product warranty and make the product ineligible for service.

5) If the power cord or sensor cable is damaged, immediately stop using the product and replace the power cord or cable. Using the product when the power cord or sensor cable is damaged may cause an electric shock, short circuit, current leakage or product damage.
6) Do not bump or move the product while the power cord or sensor cable is connected to it. This may cause patient injuries or product malfunctions.
7) When using the product with other devices, use a separate AC power source for the other devices to ensure the patient's safety.
8) Do not use an anti-electrostatic or conductive tube for the product.
9) Auxiliary equipment and accessories provided by MEKICS are qualified items that meet electrical safety standards. The use of other companies' products or unproven items may cause injury to the patient or product damage.

CAUTION

1) Only use auxiliary equipment provided by the MEKICS Head Office or MEKICS' designated representatives.

ATTENTION

1) This product uses 12V / 7Ah lead (Pb) battery.
2) When charging battery, connect the AC cable. Take care to prevent metal substances from contacting the battery charging terminal.

1.2.5 Precautions for Electronic Safety

This product acquired electronic safety standard, CLASS II-A.

WARNING

1) A strong electromagnetic wave may affect the performance of the product.
2) Basically, the product is designed to not suffer functional disorders by surrounding electromagnetic waves. Notwithstanding, strong electromagne -tic waves may cause the product to malfunction. This may include displaying incorrect calculation values, disappearance of measurements and noises affecting the wave pattern. If such errors continue, contact the MEKICS Technical Service Center or authorized dealers for assistance
3) If used by a patient with pace maker, a professional individual with all required expert knowledge must operate the product.
4) Electromagnetic waves generated from an MRI device may influence the measurement values of the product.

2. System Outline

2.1 Ventilator Configuration

Setting values of the ventilator can be configured using touch pad, key, or encoder.

Parameters related to ventilation are always measured and can be adjusted. Gas supply can be controlled to obtain objective values (flow, volume and pressure) through difference between actually measured parameters and setting or calculated values.

MV2000[SU:M] ventilator has two gas modules (O_2, air). Gas can be supplied through hospital's medical gas supply system or compressor and gas container.

> ⚠ **CAUTION**
> When not moving the ventilator, wheels must be fixated using lock.

In order to prevent movement of the ventilator from carelessness, check whether the ventilator is fixated to the correct position on the cart.

1) User Interface (Screen)
2) Patient Unit (Main Body)
3) Mobile Cart
4) Inspiration Outlet
5) Expiration Inlet

2.2 User Interface – Connection, Label, Symbol

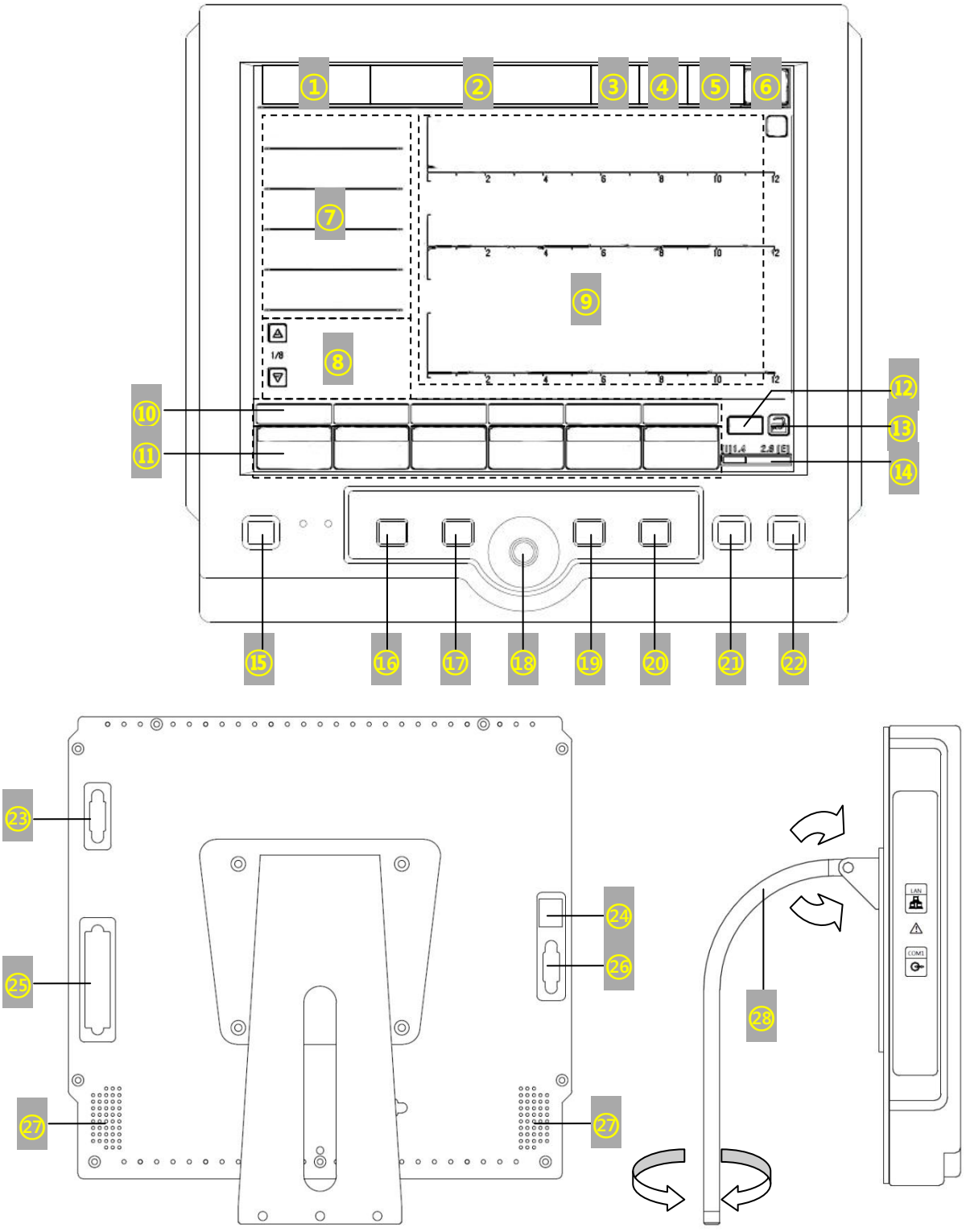
User interface is composed of the following.
- Touch Screen
- Fixed Keys
- Encoder (Rotational Dial)

2.2.1 User Interface Configuration

Refer to the user interface diagram on the next page to check for location of the following.

1) Display of current ventilation mode
2) Alarm display and alarm message window
3) Status icon
4) Date, time, O_2 100% display
5) Nebulizer On/Off display
6) Ventilation mode setting
7) Measurement value display
8) Pad to view diverse measurement values
9) Waveform window
10) Three parameter waveforms, pressure/flow, and flow/volume loop display
11) Various menu to operate ventilator MV2000[SU:M]
12) Pad to add or change setting values
13) Power supply (AC - green, BATT – orange)
    Touch key lock/unlock
14) I:E graph
15) System On/Off switch
    Standby key is used during operation of the product. Standby state is a state in which all things except the ventilator are turned on.
16) Manual inspiration
17) O_2 100%
18) Encoder
    Encoder is used to select menu or parameter. Also, encoder is used to adjust values and save adjusted values by clicking.
19) Exit (Cancel button)
20) Run (Accept)
    Execute or run operation
21) Alarm silence
    Alarm does not make sound for 2 minutes.
22) Alarm reset
    Reset alarms.
23) External VGA out port
    An external monitor can be connected for larger screen or additional screen.
24) LAN port
    RJ45 cable is used to communicate with external devices.
25) Connector between screen and main body
    Connector connects the screen from main body using cable.
26) RS232 serial port
    Serial port is used for DSC software upgrade and communication with COM.
27) Speaker
28) Screen panel support

2.2.2 User Interface Diagram



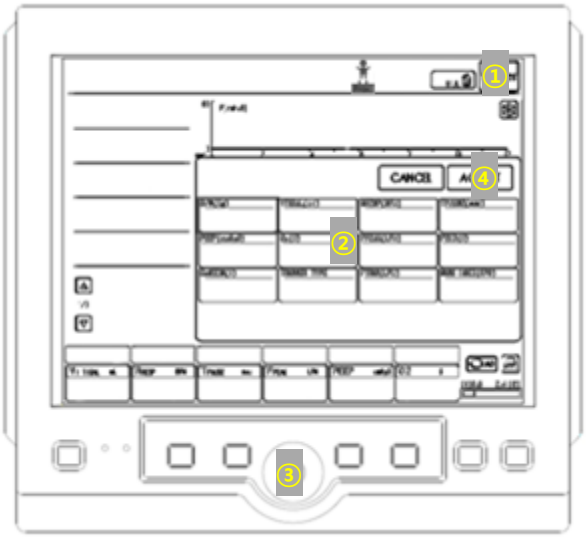
2.2.3 User Interface Symbol

Symbol	Description
	On/Off Switch, Standby – Transition to standby state or display of ventilator on/off state IEC417-5009
 MANUAL	Manual Inspiration Key – Inspiration is applied to the patient every time Manual Inspiration Key is pushed.
O_2 100%	100% O_2 Mode – Displays 100% O_2 mode. Turned on/off using O_2 100% key.
	EXIT Key – Removes menu window from the screen.
RUN 	RUN Key – Used to run the ventilator using values in ventilator set.
 2MIN	Alarm 2MIN – Mutes auditory alarm signal for two minutes.
	Alarm RESET – Resets existing alarms.
	AC Power – Displays that the device is operating under AC power.
	Battery check – Displays that the device is operating with battery, as well as remaining battery state.
	Inspiration Hold – Measures compliance and resistance by adding one second to inspiration hold time.
	Expiration Hold – Auto PEEP is measured after maintaining expiration hold for two seconds.
	Alarm Sound Off or Mute – Displays alarm sound off or mute. This can be turned on/off using 2MIN key.
	Touch Key Lock – Keys on the touch screen are locked by pushing key lock. They are unlocked by pushing again.
	Freeze – Freezes currently displayed graph. In case of trend screen, encoder can be used to view saved trend values.
	Adult – Displays male, female, pediatric and neonate mode.
	Proximal – Displays whether a proximal sensor is connected.

2.3 User Interface Usage

The following is the general method of using user interface, according to the sequence.

2.3.1 Touch Screen Setting



Ventilator Setting Method:

1) Open ventilation mode setting window by pushing ventilator mode (Modes) on top of the screen.
2) Push the parameter to configure and activate it. Once activated, Blue frame is turned white, and values can then be changed.
3) Rotate the encoder to find wanted value. Push the encoder again or touch activated parameter window again in order to settle adjusted value. When parameter turns blue, new setting has been saved.
4) Push Accept to operate new setting values and Cancel to cancel.

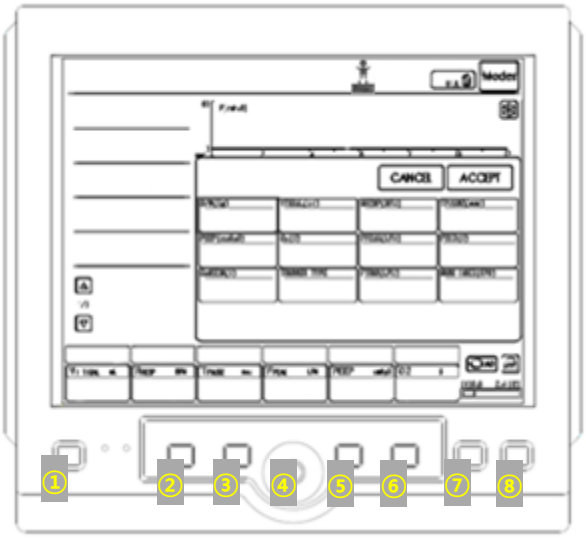
> ⚠ **ATTENTION**
> Do not use sharp tools to use touch screen.

2.3.2 Encoder Setting

Ventilator Setting Using Encoder

1) Rotate the encoder to find wanted menu.
2) Select by push the encoder. Once activated, Blue frame is turned white, and values can then be changed.
3) Rotate the encoder to find wanted value.
4) Push the encoder again or touch activated parameter window again in order to settle adjusted value.
5) When parameter turns blue, new setting has been saved.
6) Push Accept to operate new setting values and Cancel to cancel.

2.3.3 Fixed Keys



User interface has the following fixed keys.

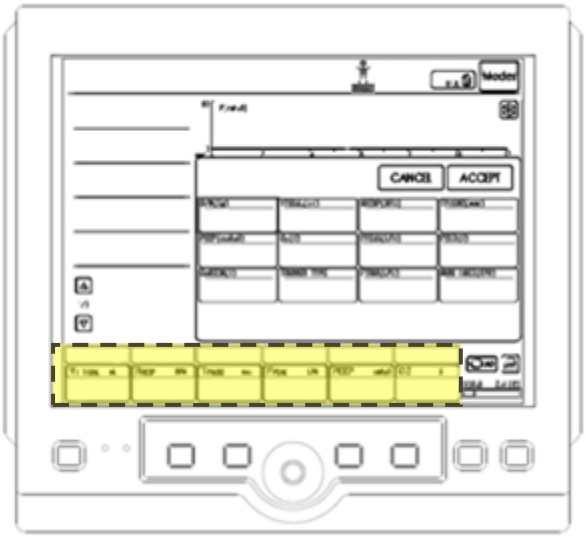
1) On/Off Switch, Standby
2) Manual Inspiration
3) O_2 100%
4) Encoder
5) Exit
6) Run
7) Alarm Silence (2min)
8) Alarm Reset

> ⚠ **ATTENTION**
> When using special vent function, user must always monitor the patient carefully.

2.3.4 Direct Access Button

Bottom of user interface has direct access buttons that can directly adjust 6 setting parameters. Parameter corresponding to each button is automatically selected based on ventilation mode.

Direct Access Button Use

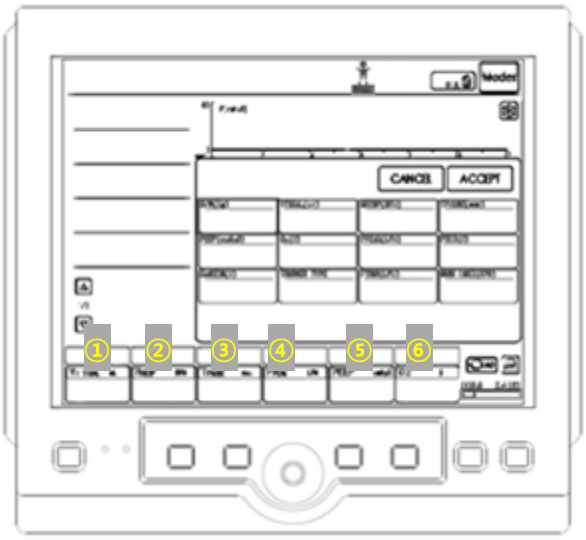


In order to adjust ventilation mode parameter,

1) Activate by touching the wanted direct access button.
2) Use the encoder to configure values.
3) Touch again to deactivate.

> ⚠ NOTE
> When parameters are changed using direct access button, changed values are applied since the next breath. Here, there is no button to confirm user's intentions such as Accept button on touch screen.

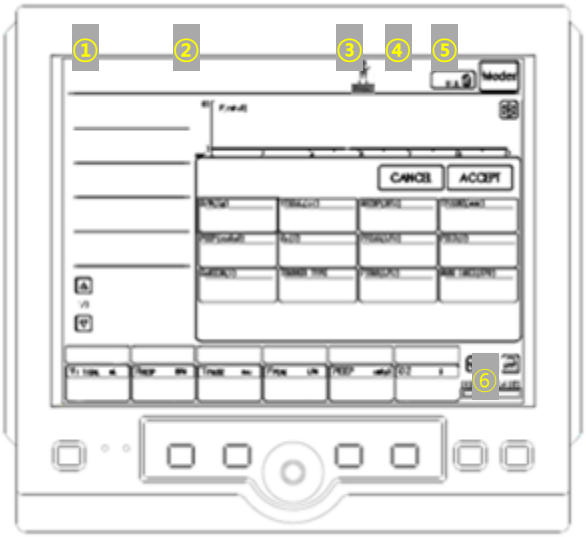
2.3.5 Menu Key



6 menu keys are positioned on the bottom of user interface. These keys can be touched for activation. Description on each menu is as follows.

1) Monitoring – Comprehensively displays data measured in each mode.
2) Graphic – Configures screen layout and trend timing (Waveform – Pressure, Flow, Volume / Loop – P-V, V-F, P-F / Trend – VE MIN, PMEAN, PPEAK, VTE, CL, RA).
3) Tools – Uses Insp.Hold and Exp.Hold functions.
4) Events – Events that occur during operation of the ventilator can be seen.
5) System – Composed of operating environment, patient information input, date change, and various calibration settings.
6) Alarms – This menu is used to configure various alarms on measurement values.

2.3.6 Status (System Information Window)



User interface displays current status of the ventilator.

Types of status displayed are as follows.

1) Current ventilation mode display
2) Alarm display and alarm message window
3) Ins, Exp hold, Adult & Proximal sensor Icon
4) Date, time and O_2 100% display
5) Nebulizer On/Off display
6) Power supply (AC - green, BATTERY – orange)
   Touch key lock/unlock
   I:E graph

> ⚠ **CAUTION**
> When external 12V DC power is used, insert internal battery for safe and normal operation.

2.4 Patient Unit – Connection, Label, Symbol

Patient unit (main body of the ventilator) is composed of the following parts.

- Gas supply and connection part
- Power supply and connection part
- Accessory connection part

2.4.1 Patient Unit Configuration

Refer to the patient unit diagram on the next page to check for location of the following parts.

A

A1. Nebulizer Port
A2. Inspiration Outlet
A3. Expiration Outlet
A4. Expiration Inlet
A5. Handle for Moving
A6. SpO_2, $EtCO_2$ Connector

B

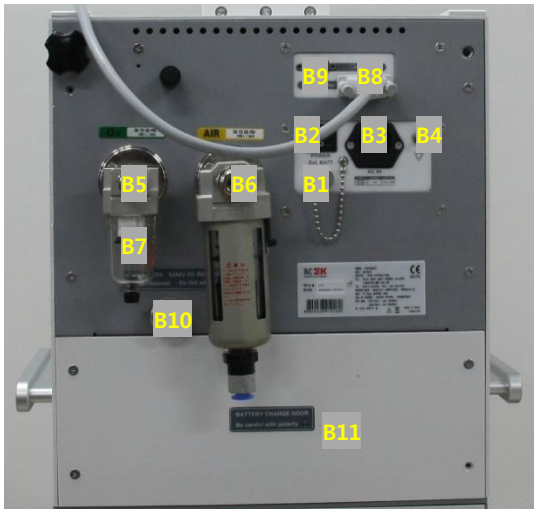
B1. External Battery Port
B2. Main Power Switch
B3. AC Power Inlet
B4. Ground Terminal
B5. O_2 Gas Inlet
B6. Air Gas Inlet
B7. Water Trap
B8. Connector between Screen and Main Body
B9. RS232 Communication Terminal
B10. Tank Safety Air Relief
B11. Battery Cover

C

C1. Safety Air Relief
C2. Body Handle

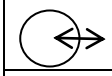
A

B



C

2.4.3 User Interface Symbol

Symbol	Description
	Power On/Off – These symbols are used in power switch. "I" indicates power on. "O" indicates power off. IEC 601-1
	Equipotentiality – This symbol indicates terminal that does not require ground potential for connecting system parts to create equipotentiality. IEC601-1, IEC 417-5021
	Attention, Consult accompanying documents This symbol indicates that user must consult accompanying document (User Manual) prior to operation. IEC 601-1
EXT. BATT	EXT. BATT – This symbol indicates external battery for vehicles.
AC IN	This symbol indicates external power (AC) connection part. IEC 417-5534Pr
TO Monitor 	Monitor Connector – This symbol indicates connection to user interface and cable.
RS232 	RS232 / Serial Port – This symbol indicates data communication connection.
	Heater – Heater heats the exp part during ventilation to prevent moisture. Be careful about high temperature heat.

2.5 Transportation and Storage in Hospitals

2.5.1 Prior to Transportation

Check the following matters before transporting the ventilator whether, the ventilator is connected to a patient, or not

- Check whether patient unit and user interface are firmly fixed and locked.
- Check whether accessories such as modules and humidifier are firmly fixed.
- Check the connection of gas container and amount of gas in the container.
- Check whether battery is sufficiently charged.
- Check whether the ventilator operates properly.
- Check for damages in the mobile cart.
- If medical portable compressor MC200 is used, make sure it is firmly fixed to prevent movement during transportation.

2.5.2 During Transportation

Check the following matters before transporting the ventilator whether, the ventilator is connected to a patient, or not

- Use the handle on the main body.
- Move slowly the bed and ventilator. During transportation, be careful about pulling or movement of tubes connected to the patient.
- When moving or changing location of support arm, be careful about pulling or movement of tubes connected to the patient
- When passing through obstacles such as door threshold, be careful not to tilt the mobile cart.

2.5.3 Transportation Between Hospitals

MV2000[SU:M] ventilator can be used during transportation of patients between hospitals.

2.5.4 Storage

- When storing ventilator, always connect to main power source for battery to be charged sufficiently.
- Do not discard battery and O2 cell with ordinary wastes.
- Do not expose the ventilator to a temperature below -15℃ (-5℉) or above +50℃ (+122℉).
- Do not expose the ventilator to a relative humidity above 90%.

3. Power Supply

3.1 Outline

MV2000[SU:M] ventilator has auto transition function for rated voltage. The ventilator automatically adjusts to 100-120 AC or 220-240 AC power.

To prevent damages in ventilator setting and stored information upon suspension of AC power (main power) supply, power source is automatically converted to 12V DC power (battery). Check charging status of battery frequently.

> **NOTE**
> Battery can be replaced if necessary, even during the use of ventilator.

Also, the ventilator can be used by connecting to an external 12V DC power. Here, similar to internal battery, power source is automatically converted to external 12V DC power upon suspension of AC power supply. Ventilator setting and stored information are preserved.

3.1.1 Power Supply Specification

Rated voltage range
110-120V, 220-240V, AC 50-60Hz

Internal battery
Battery spec is 12V, 7Ah.

External 12V DC power
12.0V ~ 15.0V, 10A, battery for vehicles

> **CAUTION**
> When using external 12V DC power, internal battery must be attached for safe operation of the ventilator.

Power Consumption

Rated Voltage	Power Consumption
100-120 AC 50/60Hz, 10A	84W max
200-240 AC 50/60Hz, 5A	84W max

3.1.2 Battery Information Summary

Battery Life	Since Manufacture Date
Quantity	1 EA
Operation Time	About 3 hours (if used continuously)
Charging Time	About 4 hours
Storage Temperature (Individual Storage)	15-20℃ (59-68°F)

3.2 Battery Status Display Screen

When the ventilator is operated using battery, remaining operation time of the battery is displayed on the bottom right corner of the screen.

When battery state is low, battery icon on the bottom right is displayed in red color. Here, battery should be replaced or, if possible, connect the ventilator to main power source.

Information on battery module inserted in the ventilator is displayed as follows.

Display	Status	Description
	Full Charging	100% charged
	80% Charging	80% charged
	50% Charging	50% charged
	20% Charging	20% charged
 	Low Charging	If remaining battery is low, the icon is displayed on the screen. In order to protect the battery, beep sound is created and power is automatically turned off after about 5 minutes.

3.3 Alarm and Safety Devices

Battery status is always monitored by the ventilator. Check the following precautions.

3.3.1 Warnings

- Check the battery prior to use for safe battery backup operation.
- If low battery is displayed, battery must be quickly replaced.
- Long-term storage may cause reduction in battery capacity. Do not leave battery module unattached or stored for long time. If it is necessary to store a battery for short time, fully charge the battery and store at low temperature (15-20℃ or 59-68℉) under dry environment.
- Stored or unused battery must be charged before using.
- Disposed batteries must be handled in accordance to local regulations. Do not discard them with ordinary wastes.
- After replacing with new battery, check the status of new battery for safe operation.
- Battery may not be fully charged upon initial supply of the product. Use user interface to check charging status. If necessary, connect the ventilator to main power source to charge the battery prior to use.
- Discharged battery must always be charged for use.
- When the ventilator is not in use, it must always be connected to main power source to charge the battery.

3.3.2 AC Power Supply Failure

If there is no AC power supply or power outlet is disconnected, the ventilator automatically operates using battery.

4. Operation Method

4.1 Operation Sequence Summary

The following is summarized operation sequence of MV2000[SU:M] ventilator.

1) Check of pre-use
2) Select the patient type.
3) Input patient information in the system menu.
4) Select ventilation mode.
5) Configure parameters for the selected ventilation mode.
6) If necessary, check and adjust alarm range in the alarm menu.
7) Connect the ventilator to the patient and push Accept button in ventilation mode to start ventilation.
8) During ventilation, user can make or change the settings as below.
9) Parameter setting can be seen or changed using direct access button.

Refer to the following section for detailed description on individual sequence of ventilator operation.

4.2 Pre-Use Check

Test and measurement items during pre-use check process are as follows.

- Gas supply status
- System function inspection
- Internal block leakage
- Pressure sensor
- Flow sensor
- O2 cell
- Battery status
- Leakage and compliance of patient tube

WARNING

- Always perform pre-use check prior to connecting the ventilator to the patient.
- Do not connect the ventilator to the patient in case of functional errors.
- When ventilator is in operation, do not raise or separate expiratory cassette. If necessary, take these actions in standby mode or with the ventilator turned off.

4.2.1 Start Up

1. Connect power and gas supply line.

- AC power
- Air, O_2 gas

2. Turn on the ventilator.

3. The ventilator will inspect system function status, pressure sensor, flow sensor, and gas supply status.

4. Once inspection is completed, the stand-by screen will appear.

4.2.2 Auto transition Between AC Power and Battery Power

During pre-use check, auto transition between AC power and battery power from suspension or reconnection of AC power supply must be tested.

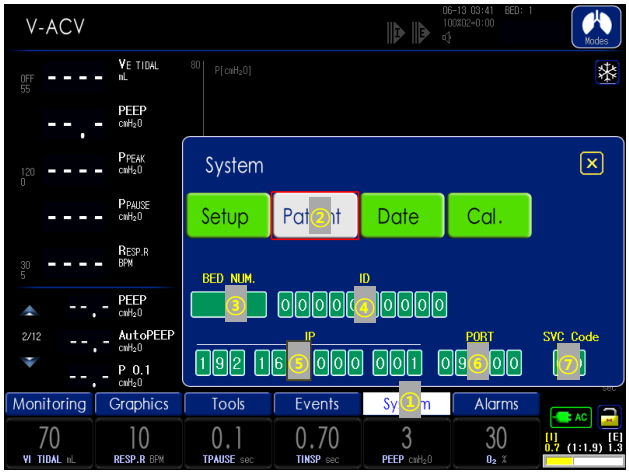
- Check icon on the screen to see whether the ventilator is in AC mode.
- Unplug the AC plug to block power source.
- Check whether icon is changed to battery mode. If there is no problem in icon change, reconnect the AC plug.

> ⚠ **CAUTION**
> If the product is turned off during transition to battery mode, re-inspect after charging or replace the battery.

4.2.3 Tube Inspection for Patients

1) Connect patient tubes including humidifier and nebulizer. If humidifier is used, water tank in the humidifier must be filled with distilled water.
2) Block Y piece and operate the product. Check for tube leakage.
3) Operate the product after connecting test lung to Y piece. Check the status of patient tubes and ordinary operation.

4.3 Patient Information Input

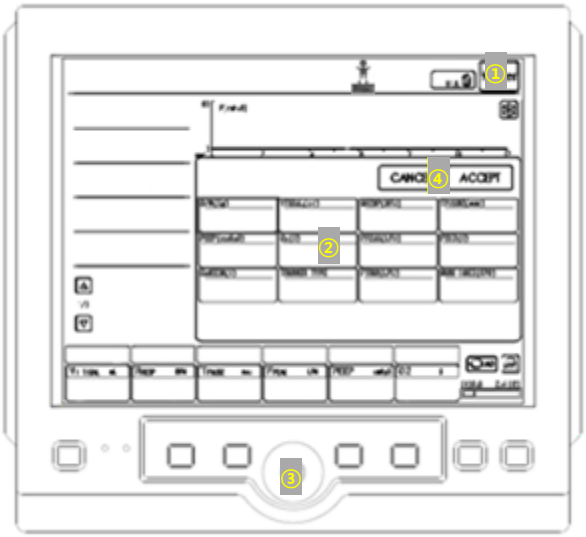


1) Select system menu on the bottom of user interface.
2) Enter patient menu.
   In input window of the patient information, the following information can be entered or modified.
3) Bed number
4) Patient ID number
5) IP address for communication (external connection using LAN)
6) Port number for communication (external connection using LAN)
7) Password (password (77) for IP and port input)

After completion of input and modification, return to stand-by screen and enter the patient's height. Body weight and setting values for each mode are defined based on internal calculations.

> NOTE
> Input and modification can be done using the same method as setting configuration using touch screen. Encoder can also be used.

4.4 Ventilation Mode and Parameter Setting



Ventilation Mode and Parameter Setting

1) Push Mode.
2) Select the mode to use in the activated ventilation mode window. Once a ventilation mode is selected, parameters required for the selected mode are displayed.
3) Select parameters for which values must be changed, and use the encoder to adjust their values. After adjusting the parameter, re-select the parameter for deactivation or push the encoder to save the adjusted value.
4) Once setting value is saved, push Accept button to operate with saved value or push Cancel to cancel.

4.5 Alarm Setting

Alarm Setting

1. Touch the alarms button on the bottom of user interface.
2. Select alarm value to adjust.
3. Rotate the encoder to change and modify the value.
4. Touch the value again or push the encoder to save changes.
5. Alarm values can be automatically configured using alarm auto button.

> NOTE
> Consider alarm auto function prior to application in a patient. If auto function is inappropriate, configure alarms directly. Alarm auto function is configured based on the patient's body weight.

4.6 Starting Ventilation

As in 4.4, select ventilation mode, configure parameters, and touch Accept button to operate the ventilator.

If standby key is pushed during operation of the ventilator, window pops up to ask whether to move to standby mode. The ventilator converts to standby mode once Standby button is pushed. Push X on the top right corner to cancel.

4.7 Change in Patient Type

MV2000[SU:M] ventilator can select among four patient type in standby mode.

- Male (Adult)
- Female (Adult)
- Pediatric
- Neonate (Infant)

> **NOTE**
> When patient type is changed, the following default values or setting values are changed.
> - Default alarm values
> - Alarm setting range
> - Default parameter values
> - Parameter range

> **NOTE**
> Default values of the ventilator system on adults and infants can arbitrarily be changed by user.

> **NOTE**
> Always check alarm setting after changing the range of patient.

4.8 Change in Setting Parameter

In order to change setting parameters during ventilation, push the speed button.

To adjust parameters of ventilation mode,

1) Activate the parameter by touching the wanted speed button.
2) Configure wanted value using encoder.
3) Touch again to deactivate.

> **NOTE**
> New setting values are applied after deactivation of corresponding parameter button.

4.9 Measurement Sensor Calibration

If the ventilator is continuously used for long time, measurement values may slightly differ. Measurement sensors must be calibrated.

Calibration of measurement sensor:

1. Select system in the menu on the bottom of user interface. Select Cal. among sub menu.
2. The following sensors must be calibrated.
   - Flow Zeroing
   (Flow Sensor Offset)

   - Exp. Flow Gain
   (Expiratory Flow Sensor Balance)

   - Adult Prox. Flow Gain
   (Adult Proximal Flow Sensor Balance)

   - Neo. Prox. Flow Gain
   (Neonate Proximal Flow Sensor Balance)

   - O_2 Cell Cal.(O_2 Sensor)

   - Leak Test

   - $EtCO_2$ Zeroing($EtCO_2$ Module)

4.9.1 Flow Zeroing

Flow zeroing is an automatic offset adjustment function on inspiratory and expiratory flow sensor. Calibration starts by pushing Start button after rotating the encoder. Calibration is completed after a moment.

4.9.2 Expiratory Flow Gain

Adjust the balance of inspiration flow and expiration flow. Ratio of inspiration volume to expiration volume can be adjusted. If you

expiratory flow gain' value increase, expiratory measured value is increased.

4.9.3 Adult/Neonatal Proximal Flow Gain

Adjust the balance of inspiration and proximal flow. Connect proximal sensor to inspiratory outlet port and select menu will start the calibration. Calibration is completed after a moment.

4.9.4 O_2 Cell Calibration

O2 cell may show incorrect O_2 concentration due to natural consumption of O_2 cell with longer use. Therefore, O_2 concentration can be fixed through calibration. With air supply connected, rotate the encoder and select 21% menu to start with 21% O_2 calibration. Calibration is completed after a moment.

While 100% O2 is being supplied, 100% O_2 calibration can be started by rotating the encoder and selecting 100% menu. Calibration is completed after a moment.

> **NOTE**
> If O2 cell has been expired, replace the cell before performing calibration.

4.9.5 Leakage Test

Analysis of leakage and compliance is conducted. First, directly connect the breathing circuit to inspiratory port and expiratory port. Rotate the encoder and push Start menu to start calibration. Analysis ends after a moment.

4.9.6 $EtCO_2$ Zeroing

If the ventilator has EtCO2 module, calibration is performed. Rotate the encoder and push Start to start with EtCO2 calibration. EtCO2 calibration is completed after a moment.

4.10 Separation of Ventilator from Patient

In order to separate the ventilator and stop ventilation,

1) Separate the ventilator from the patient.
2) Push standby key to convert to standby mode.
3) Once ventilation stops, push Power button to turn off the ventilator.
4) When power is turned off, turn off the main power switch on the back of the main body.

5. Monitor and Information Saving

5.1 Measurement Value Display

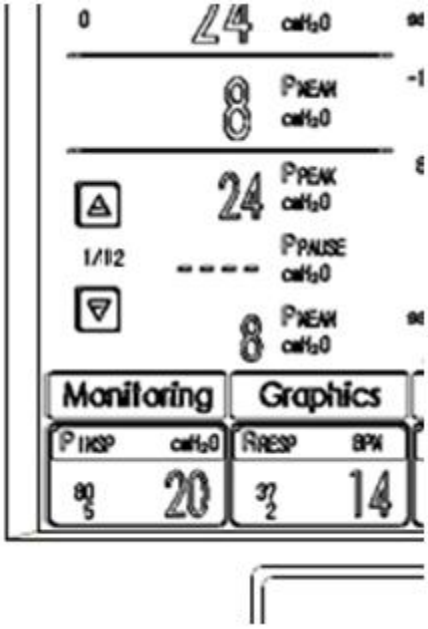
Measurement and calculation values during ventilation are displayed.
This Section includes descriptions on screen display, additional display window on measurement and calculation values, and list of all values displayed.

5.1.1 Measurement Value Screen

Measured parameters and the following details are displayed on left side of the screen.

1) Alarm Limit
2) If value lies outside upper and lower limits of Alarm Limit, the value is displayed in red.
3) If value cannot be measured, it is displayed as '----'.
4) Parameters displayed on measurement value screen can be changed in connection with monitoring menu.

5.1.2 Additional Measurement Display Screen



To see more measurement values,

1) Touch the arrows pointing up and down on the bottom left corner of the screen.
2) Measurement values can be seen up to a maximum of 12 pages.
3) Check monitoring menu to see measurement values at once.

5.1.3 List of Measurement and Calculation Values

P PEAK	cmH_2O	Maximum inspiratory pressure
P PAUSE	cmH_2O	Pressure during end-inspiratory pause
P MEAN	cmH_2O	Mean airway pressure
PEEP	cmH_2O	Positive end expiratory pressure
Auto PEEP	cmH_2O	Difference between measured PEEP and configured PEEP
P 0.1	cmH_2O	Indicator for respiratory drive
VI TIDAL	mL	Inspiratory tidal volume (per breath)
VE TIDAL	mL	Expiratory tidal volume (per breath)
VE MIN	LPM	Expiratory minute volume (per minute)
PEEP H	cmH_2O	High PEEP
PEEP L	cmH_2O	Low PEEP
F PEAK	LPM	Maximum inspiratory flow
RESP.R	BPM	Respiration
RR SPONT	BPM	Respiration rate in spontaneous breath
VEMIN SPONT	LPM	Expiratory volume per min in spontaneous breath
TI	sec	Inspiration time
TE	sec	Expiration time
I : E		Inspiration to expiration ratio
Exp.Flow	LPM	Expiration flow
RSBi	b/min/mL	Rapid shallow breathing index
O_2	%	Oxygen concentration in volume %
CL	mL/ cmH_2O	Compliance
RA	cmH_2O /s	Resistance
WOBv	J/L	Work of Breathing Ventilator
PR	BPM	Pulse Rate
SpO2	%	Oxygen saturation in blood
EtCO2	mmHg	End tidal carbon dioxide
Ins	mmHg	Inspiratory carbon dioxide
RESP	RPM	Respiration through $EtCO_2$
VI CO_2	ml	Inspiratory CO_2 Tidal Volume
VE CO_2	ml	Expiratory CO_2 Tidal Volume
VE MIN CO_2	ml	Expiratory Minute CO_2 Volume
VE STROKE	ml	Expiratory CO_2 Tidal Volume
H.Freq	Hz	Frequency

5.2 Waveform Display

When SpO_2 and $EtCO_2$ options are connected, color-wise waveforms are displayed on the screen as follows. Up to four waveforms can be displayed on the screen.

- Pressure vs. time
- Flow vs. Time
- Volume vs. Time
- SpO_2 vs. Time
- $EtCO_2$ vs. Time

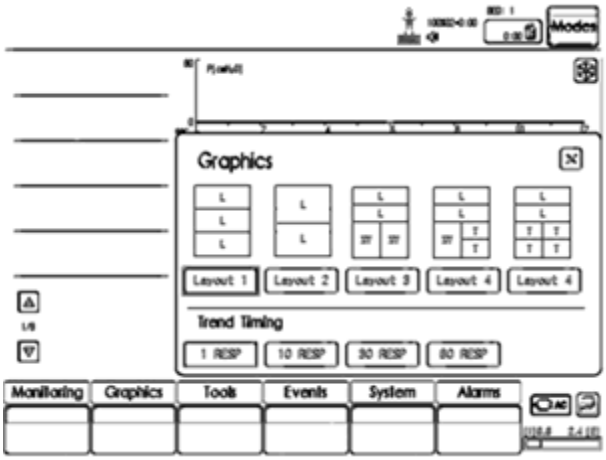
5.2.1 Characteristics

Waveforms are displayed on the screen as follows. Measured parameter values are displayed according to time axis.

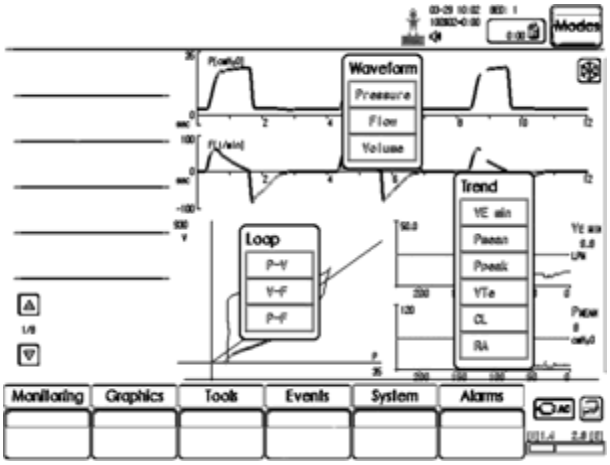
- Parameter and scale are displayed on Y axis.
- Pressure vs. time graph is displayed in dark pink.
- Flow vs. time graph is displayed in dark sky-blue.
- Volume vs. time graph is displayed in white.
- SpO_2 vs. time graph is displayed in yellow.
- $EtCO_2$ vs. time graph is displayed in white.

5.2.2 Waveform Setting and Change

Layout and trend timing of waveform can be configured and changed through [Graphics] menu on the bottom of user interface.



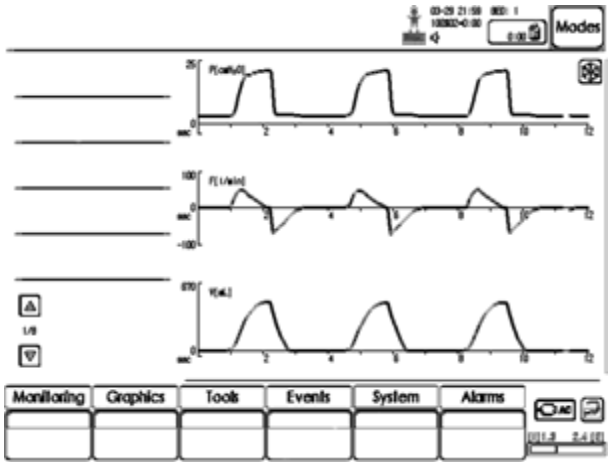
To change displayed graphs, touch waveform. The following window appears for each graph, allowing user to select wanted graphs.



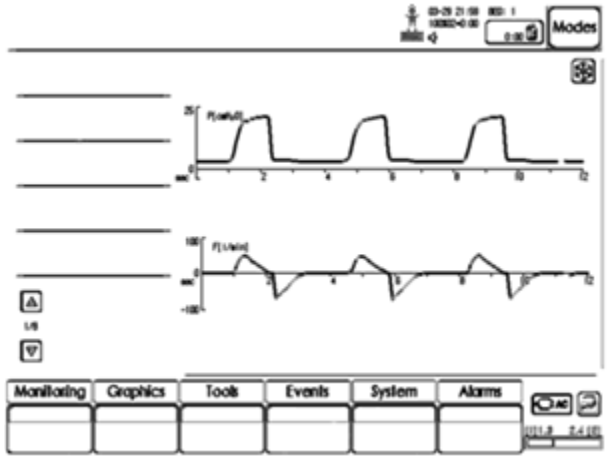
- Waveform : Pressure, Flow, Volume
  If SpO_2 and $EtCO_2$ modules are connected through option, two additional graphs can be viewed.
- Loop : P-V, V-F, P-F
- Trend : VE min, Pmean, Ppeak, VTe, CL, RA

There are five screen layouts available as follows.

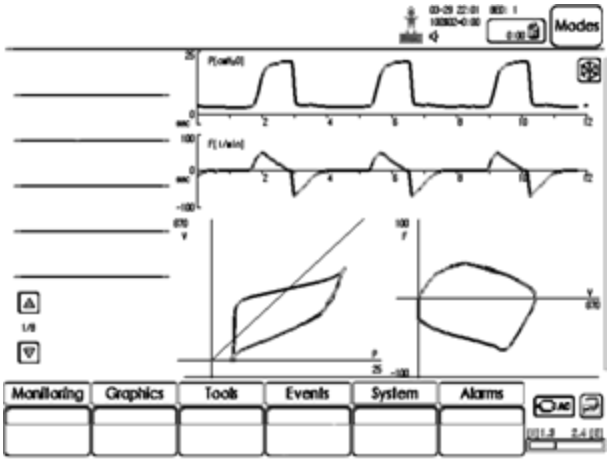
- Layout 1: Three waveform graphs are displayed among pressure, flow, volume, SpO_2 and $EtCO_2$.



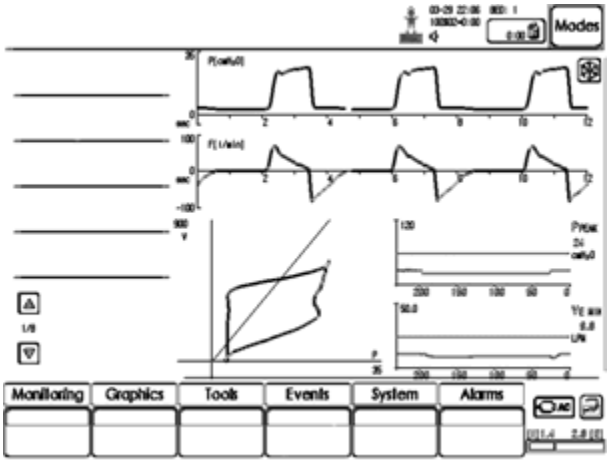
- Layout 2: Two waveform graphs are displayed among pressure, flow, volume, SpO_2 and $EtCO_2$.



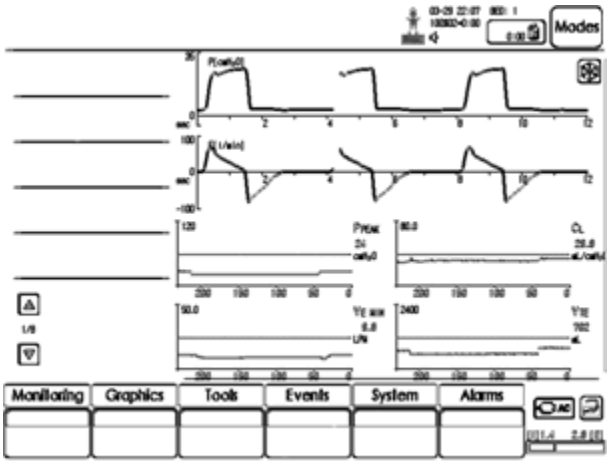
- Layout 3: Two waveform graphs are displayed among pressure, flow, volume, SpO2 and EtCO2. Two loops are displayed among P-V, V-F and P-F.



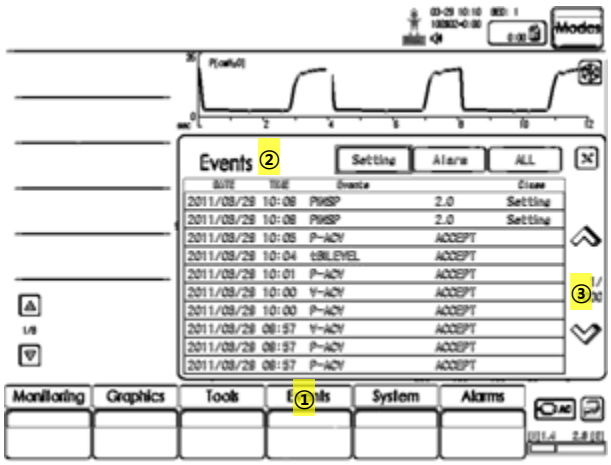
- Layout 4: Two waveform graphs are displayed among pressure, flow, volume, SpO_2 and $EtCO_2$. One Loop graph is displayed among P-V, V-F and P-F. Two trend graphs are displayed.



- Layout 5: Two waveform graphs are displayed among pressure, flow, volume, SpO_2 and $EtCO_2$. Four trend graphs are displayed.



5.3 Event Log

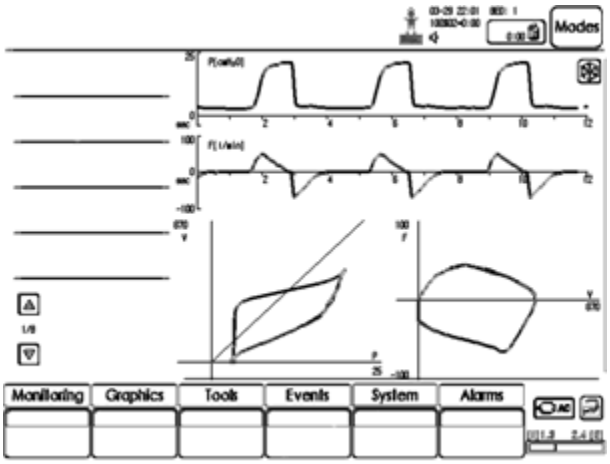


To check the event log:

1) Select events menu on the bottom of user interface.
2) All recorded events can be seen in events menu.
   A. Setting: History of changes in setting is recorded.
   B. Alarm: History of alarms is recorded.
   C. ALL: History of setting changes and alarms are recorded. All events can be seen.
3) Use arrows on the right side to search through the list of events.

5.4 Loop

Loops function displays the relationship among Pressure-Flow, Flow-Volume, and Pressure-Volume as graphs.



Refer to Section 5.2.2 for loops graph setting.

5.5 Trend

Trend value is saved every time the patient respires. Trend timing configured in graphics menu refers to the step in which trend data can be searched.

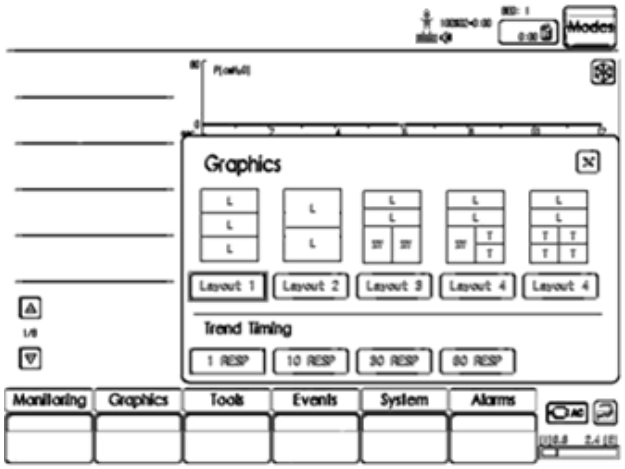
Trend timing in graphics menu can be configured as follows.

- 1RESP
- 10RESP
- 30RESP
- 60RESP

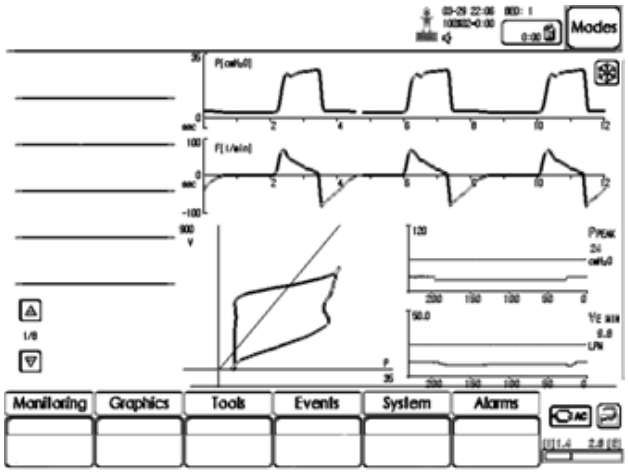
If 1 RESP is designated, Trend data can be searched at every respiration.

Refer to Section 5.2.2 for trend graph. Trend graphs can be seen using Layout 4 and Layout 5.

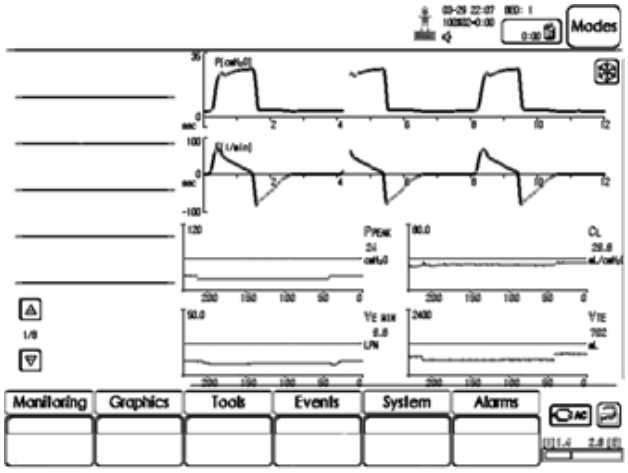
Trend Setting and Graph Sequence Diagram



- Graphics menu



- Layout 4



- Layout 5

6. Ventilation Mode and Function

6.1 Introduction

Diverse ventilation modes can be used in MV2000[SU:M] Ventilator System. This Chapter describes the ventilation modes, their settings, and associated safety information.

Refer to technical specifications for description on default settings and range of each parameter for the system.

> **NOTE**
>
> MV2000[SU:M] Ventilator System is delivered according to the following setting method.
> - Setting of parameters are based on minute volume or Tidal Volume
> - Setting of parameters are based on I:E ratio or inspiration time

6.1.1 Warnings

> **NOTE**
>
> Not all warnings below are applied to all ventilation modes.

> **WARNING**
>
> - Alarm setting for each ventilation mode must be configured appropriately. In particular, be careful for the following alarms.
>   - Minute volume or tidal volume
>   - Apnea alarm
> - In order to prevent risk of self-triggering, do not configure trigger sensitivity as too high (sensitive).
> - Be careful about upper pressure alarm setting to protect the patient's lungs from excessive pressure.
> - Excessive inspiratory pressure can cause swelling of abdomen or aspiration. It may also be a cause of excessive leakage (only applied in Mask Mode).

6.1.2 Types of Ventilation

The ventilator provides the following ventilations.

1. Controlled Ventilation
2. Supported Ventilation
3. Spontaneous Breathing/CPAP

It also allows for combined ventilator control or support. Spontaneous breathing efforts are sensed during controlled ventilation (ex: SIMV functionality).

The AutoVent functionality continuously adapts to the patient's breathing capability.

When required, all ventilation is provided for mandatorily. When the patient is able to initiate a breath, the ventilator supports and monitors the patient's breathing capability and controls ventilation only if required.

6.1.3 Ventilation Control Method

Ventilation is controlled by the following elements.

A. Pressure and Volume

B. Pressure

C. Flow/Volume

Pressure and Volume

This method guarantees constant inspiratory tidal volume per respiration by controlling pressure and flow. Inspiratory pressure level is maintained constant during each breath. (PRVC, Volume Support).

Pressure

Pressure level configured during inspiration time is maintained constant.(Pressure control, Pressure Support)

Flow/Volume

Tidal volume per respiration is maintained constant during inspiration time by flow / volume control. Inspiratory flow is maintained constant during breath(Volume Control)

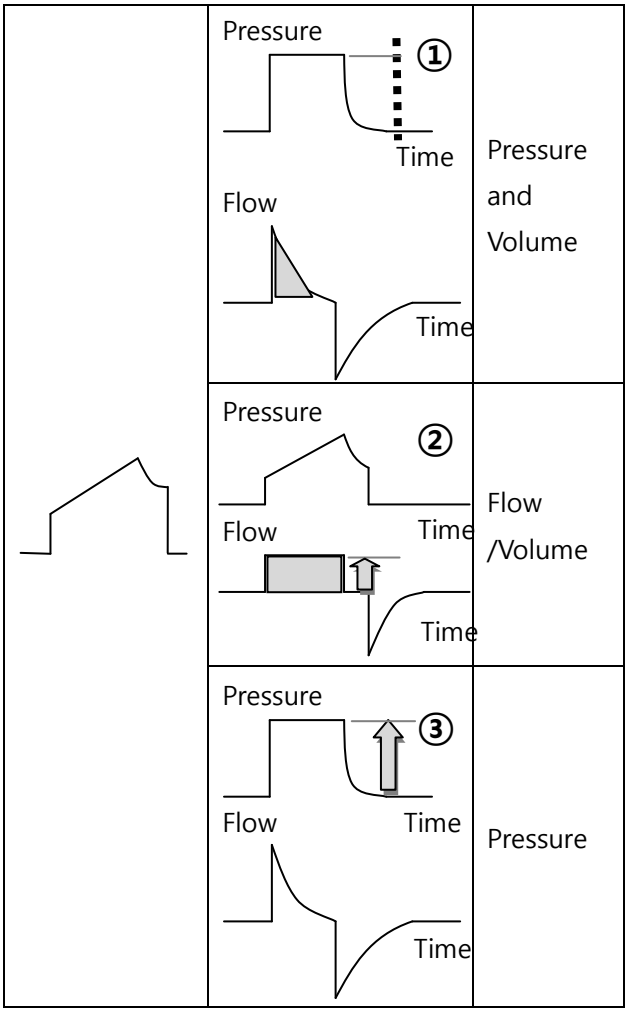
Extra Flow and Extra breaths

If demanded flow by the patient can be triggered during inspiration time, additional flow is delivered. Also, if the patient's effort for ventilation coincides with conditions of trigger sensitivity, tidal volume is delivered from the ventilator.

Timing

Timing in controlled ventilation mode is determined by configured time. Timing in supported ventilation is decided by the patient's effort for ventilation and configured inspiratory cycle off.

6.1.4 Summary of Ventilation Modes



1. Pressure Regulated Volume Control (PRVC)

(Volume control ventilation by auto pressure control)

While maintaining configured tidal volume, controlled ventilation is delivered at constant inspiratory pressure for each breath depending on the lung status of the patient. Flow is delivered using decelerating method.

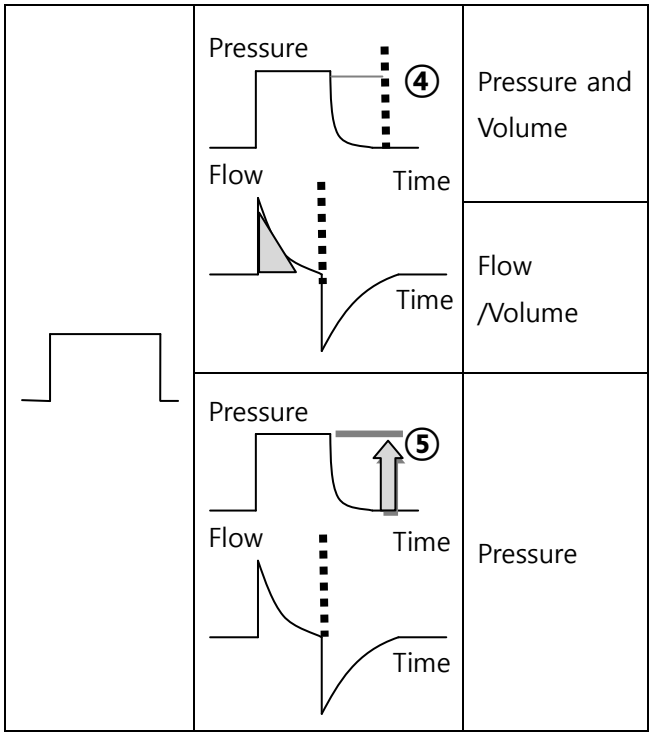
2. Volume Control (VC)

(Controlled ventilation by volume method)

While maintaining configured tidal volume, mechanical ventilation is delivered using constant flow pattern method.

3. Pressure Control (PC)

(Controlled ventilation by pressure method)
Mechanical ventilation is delivered using decelerating flow pattern method according to configured pressure level.

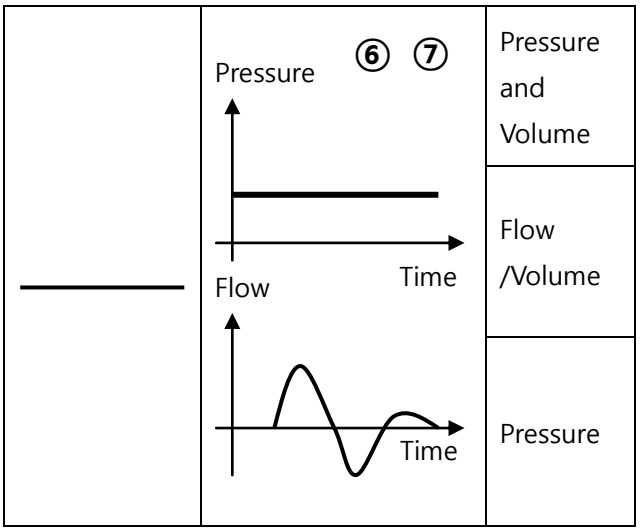


4. Volume Support (VS)

(Volume support ventilation method by auto pressure control)
Supported ventilation is delivered by constant inspiratory pressure according to the patient's effort for respiration. Delivered volume is monitored, and inspiratory pressure is automatically adjusted as necessary. Patient decides the number of respirations and inspiratory time. Flow is delivered using decelerating method.

5. Pressure Support (PS)

(Supported ventilation by pressure method)
Supported ventilation is delivered based on configured pressure level according to the patient's effort for respiration. Patient decides the number of respirations and respiration time. Flow pattern is delivered using decelerating method.



6. Spontaneous Breathing

If the patient obtains sufficient volume in volume support, spontaneous breathing can be permitted without support by the ventilator.

7. Spontaneous breathing / CPAP

(Spontaneous breathing through maintenance of positive airway pressure)
Spontaneous breathing of the patient occurs when inspiratory pressure level is configured as zero in pressure support.

O_2 Stream

Spontaneous breathing on a set flow level(High flow). The flows that exceed patient demands at various minute volumes. O_2 Stream affects CO_2 ventiatlion, efficient oxygenation, work of breathing and energy cost of gas conditioning.

AutoVent

The ventilator continuously adapts to the patient's breathing capability and allows the patient to better interact with the ventilator. The ventilator automatically shifts between controlled ventilation, supported ventilation and spontaneous ventilation.

Each controlled ventilation mode has a corresponding support mode.

Volume Control ←---→ Volume Support
PRVC ←---→ Volume Support
Pressure Control ←---→ Pressure Support

When the patient is making a breathing effort, the ventilator immediately switches to a support mode of ventilation. If the patient is not making any breathing effort, the ventilator will return to the controlled mode and deliver controlled breaths.

Synchronized Intermittent Mandatory Ventilation (SIMV)

The ventilator provides mandatory breaths which are synchronized with the patient's spontaneous efforts at a preset rate. The mandatory breaths can be Volume Control, Pressure Control or PRVC breaths.

tBiLevel

tBiLevel is pressure controlled breathing, giving the patient the opportunity of unrestricted spontaneous breathing. Two pressure levels are set together with the individually set duration of each level. Spontaneous efforts can be assisted by pressure support.

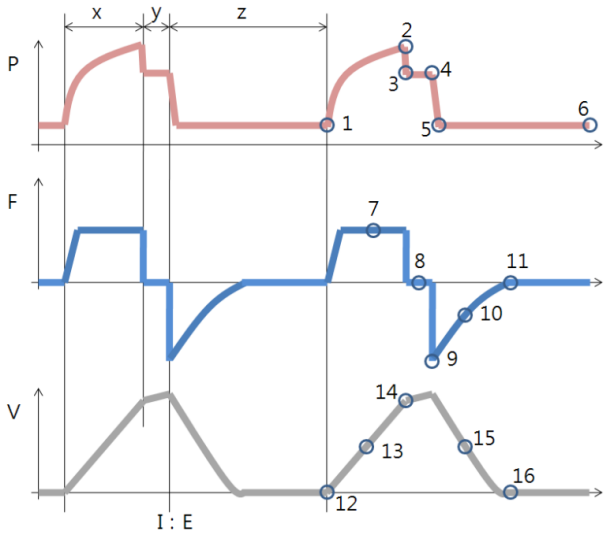
TCPL

A peak inspiratory pressure is set by the operator, and during inspiration gas flow is delivered to achieve that set pressure.
The volume of gas delivered to the patient in this TCPL varies depending on pulmonary mechanics such as compliance of stiffness of the lungs.

6.2 Waveform Description

The graphic display for flow, pressure and volume is displayed in waveforms. Patterns for flow, pressure and volume differ directly according to each ventilation mode.

6.2.1 Volume Control



Pressure-Time Waveform

X. Inspiration time

Y. Pause time

Z. Expiration time

1. Start of Inspiration
2. Peak inspiratory pressure
3. Early inspiratory pause pressure
4. End inspiratory pause pressure
5. Early Expiratory pressure
6. End Expiratory pressure

Flow-Time Waveform

X. Inspiration time

Y. Pause time

Z. Expiration time

7. Peak inspiratory flow
8. Zero flow phase
9. Peak expiratory flow
10. Slope decelerating expiratory limb
11. End expiratory flow

Volume-Time Waveform

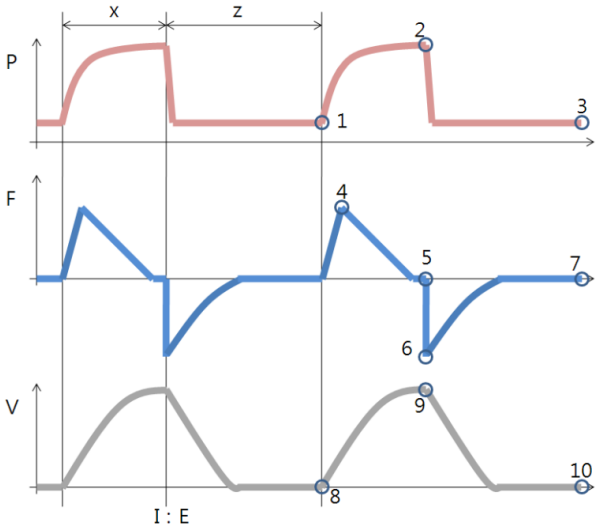
X. Inspiration time

Y. Pause time

Z. Expiration time

12. Start of Inspiration
13. The Slope displays inspiratory tidal volume per respiration
14. End Inspiration
15. The Slope displays expiratory tidal volume per respiration
16. End expiration

6.2.2 Pressure Control



Pressure-Time Waveform

X. Inspiration time

Z. Expiration time

1. Start of Inspiration
2. Peak inspiratory pressure
3. End Expiratory pressure

Flow-Time Waveform

X. Inspiration time

Z. Expiration time

4. Peak inspiratory flow
5. End inspiratory flow
6. Peak expiratory flow
7. End expiratory flow

Volume-Time Waveform

X. Inspiration time
Z. Expiration time

8. Start of Inspiration
9. End Inspiration
10. End expiration

6.3 Setting Parameter Description

6.3.1 Trigger Function

Trigger sensitivity determines the patient's effort during breath to induce ventilation from ventilator.

Trigger sensitivity can be configured using flow trigger(FTRIG) or pressure trigger(PTRIG) method. In general, flow trigger method can reduce the patient's effort for breath.

Trigger sensitivity should be configured as high as possible without resulting in self(auto)-triggering. Such setting increases patient-triggered ventilation and reduces auto-cycling by the ventilator.

Pressure trigger can be configured within the range of 0.5 ~ 20 cmH2O (pressure trigger setting is also related to PEEP setting).

Flow trigger refers to the amount of bias flow that must be inhaled by the patient to induce new breath.

⚠ WARNING

- The trigger sensitivity bar has different colors based on the setting. A light blue bar indicates a normal setting for flow. A red bar indicates that triggering is required for flow.

The ventilator continuously delivers a gas flow during expiration, which is measured in the expiratory channel.

1. Inspiration

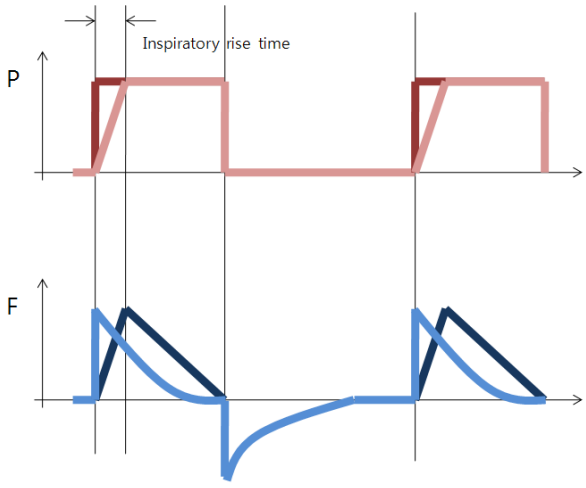
   Bias flow during expiration is 8 l/min.

⚠ WARNING

- If the trigger sensitivity is set too high, a self triggering (auto-triggering) condition may be reached. This condition can also be reached if there is leakage in the breathing system.
- Triggering will then be initiated by the system and not by the patient. This should always be avoided by decreasing the trigger sensitivity.

6.3.2 Inspiratory Rise Time

(Time adjustment from starting point of inspiration to time of peak flow or peak pressure)



At the starting point of inspiration for each breath, it can be adjusted the arrival time to peak flow or peak pressure as second or percent of respiratory cycle. If rise time is high, increased flow/pressure and it is displayed through flow and pressure waveforms

Inspiratory rise time is applicable in Pressure Control, PRVC, SIMV-Pressure Control.
Configuration of inspiratory rise time is 0.1 ~ 0.5sec.

In general, rise time must be configured higher than default system value in order to deliver comfortable ventilation to the patient in support mode.

6.3.3 Respiration Rate

Respiration rate refers to the number of respirations or breaths per minute. The respiratory rate is also used for calculation of tidal volume if the ventilator is configured for Minute volume setting.

6.3.4 Apnea Time

Apnea time refers to set apnea time until beginning of controlled ventilation in Spont mode. Range of setting is 2 ~ 60sec.

6.3.5 PEEP

Setting range of Positive End Expiratory Pressure (PEEP) is 0 ~ 45cmH2O. PEEP is maintained in the alveoli and may prevent the collapse of the airways.

6.3.6 I:E Ratio / Inspiratory Time

Inspiratory time setting in MV2000[SU:M] ventilator can be done in the following two methods.

- I:E ratio (regardless of change in respiration)
- Setting of inspiration time (regardless of change in respiration)

Once inspiration time is configured in the ventilator, pause time and inspiratory rise time are automatically changed. Change in I:E ratio according to inspiration time and pause time is displayed in information window on the bottom right corner of user interface.

6.3.7 Volume Level Setting

During initial setting for each mode of MV2000[SU:M] ventilator, volume of air supplied to the patient can be configured by adjusting inspiratory tidal volume.

6.3.8 Controlled / Supported Pressure Level

In controlled pressure mode, inspiratory pressure (P. INSP) can be configured. Supplementary pressure (P. SUPP) can be configured in supported Pressure Support, SIMV modes and tBiLevel.

6.3.9 O_2 Concentration

The setting range of O_2 concentration is 21 ~ 100%.
There is also an absolute minimum limit of alarm is 18% O_2 which is independent of operating setting. If the value reaches below this point, O_2 fail alarm will sound.
The screen only displays O_2 concentration of 21% or higher. The alarm is delayed 60 seconds after changing the O_2 concentration setting.

6.3.10 Proximal Sensor On/Off

This option must be used for low flow pressure / flow supplemented patients who require precise flow measurements and tube compensation such

as premature and neonate patients.
It is safe to use this function in supported ventilation below 200ml.
Appropriate sensor (for adults, for infants) must be used depending on the patient.

6.3.11 Mask On/Off

This option can be turned On/Off in all modes except for O_2 stream and HFV.
Once turned On, leakage compensation ability is increased.

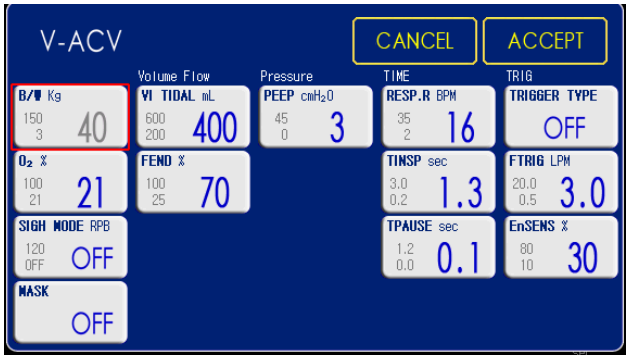
6.3.12 Previous Mode

1. Time when previous mode was inactivated
2. Name of the previous mode
3. Press the pad Show previous mode to recall the previous accepted ventilation mode.
4. Activate the previous used ventilation mode settings by pressing the Accept pad.

6.4 V-ACV
(Volume Controlled Ventilation)

Volume control mode is based on mechanical ventilation method and the ventilator delivers configured tidal volume to the patient.

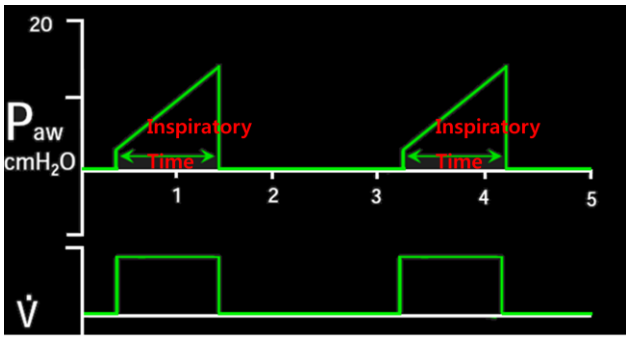
VACV mode is a mode that controls mechanical ventilation of the patient based on air volume. It controls inspiratory and expiratory times by force.



The following parameters are configured in VACV mode.

1. Tidal Volume(ml)
2. Respiratory Rate(b/min)
3. Pause Time(sec)
4. PEEP(cmH_2O)
5. Oxygen Concentration(%)
6. Inspiratory Time(sec)
7. End Flow(%)
8. Inspiratory Trigger Sensitivity(%)
9. Trigger Flow/Trigger Pressure
10. Trigger Setting(lpm/ cmH_2O)
11. Sigh Mode
12. Mask Mode(On/Off)

The airway pressure is dependent on the tidal volume, inspiration time and the resistance and compliance of the respiratory system. The set tidal volume will always be delivered. An increase in the resistance and decrease in compliance will lead to an increased airway pressure. To protect the patient's lungs from excessive pressure, it is very important to set the upper pressure limit to a suitable value.



It is possible for the patient to trigger extra breaths if they can overcome the pre-set trigger sensitivity. It is also possible for the patient, by their own inspiratory efforts, to receive a higher inspiratory flow and Tidal Volume during an inspiration than pre-set.

During volume control ventilation, peak flow is determined after configuration of tidal volume and inspiratory time. Also in addition to the above two items, end flow and plateau are items that influence peak flow.

Volume Control assures a preset tidal volume with constant flow during a preset inspiratory time at a preset frequency.

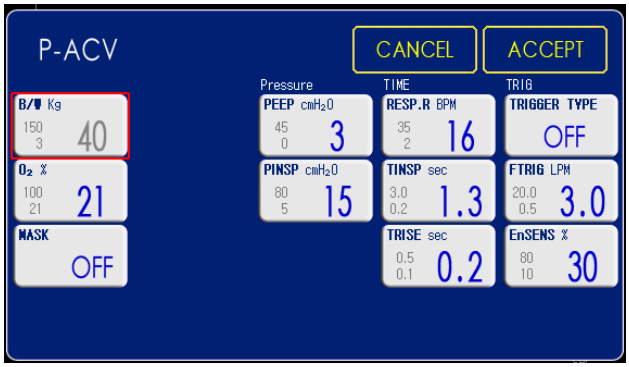
When the preset tidal volume is delivered and after the preset pause time.

I:E ratio is determined by items that influence inspiratory time and by respiratory rate.

When changing setting values of I:E ratio or items that influence inspiratory time, breath timing bar is displayed to show changes in cycle time, inspiratory time, expiratory time and I:E ratio.

6.5 P-ACV
(Pressure Controlled Ventilation)

Pressure control mode uses mechanical ventilation method.
PACV is a mode that controls mechanical ventilation of the patient based on pressure.



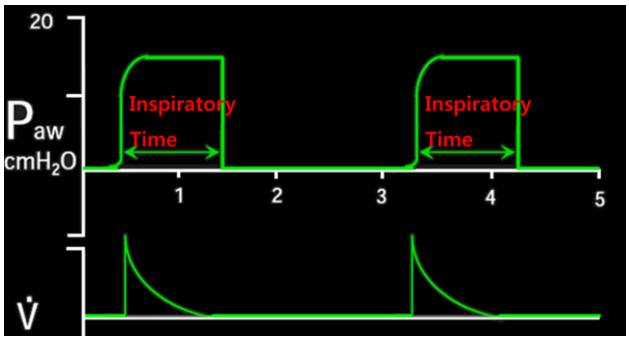
The following parameters are configured in PACV mode.

1. Inspiration Pressure(cmH_2O)
2. Inspiration Time(sec)
3. Respiratory Rate(b/min)
4. PEEP(cmH_2O)
5. Oxygen Concentration(%)
6. Inspiration Rise Time(sec)
7. Inspiratory Trigger Sensitivity(%)
8. Trigger Flow/Trigger Pressure
9. Trigger Setting(lpm/ cmH_2O)
10. Mask Mode(On/Off)

The delivered volume is dependent upon the pressure above PEEP, lung compliance and resistance in the patient tube system and airways. This means that the Tidal Volume can vary.

As the delivered tidal volume can vary it is very important to set alarm limits for Minute Volume to adequate levels.

When pressure control ventilation is provided by mandatory breath in assist / control mode, inspiratory pressure is configured. Since pressure is maintained constant during inspiration, flow pattern is shown in the form of ramp. Plateau function cannot be used.



Pressure Control assures that the preset inspiratory pressure level is maintained constantly during the entire inspiration.

The preset pressure level is controlled by the ventilator. The resulting volume depends on the set pressure level, inspiration time and the patient's lung mechanical properties during each breath.

Since exhalation valve is active exhalation valve, airway pressure control becomes more active and precise. Accordingly, exhalation valve is used to control increase in pressure caused by talking or coughing of the patient during inspiration. It also allows the patient to spontaneously breathe.

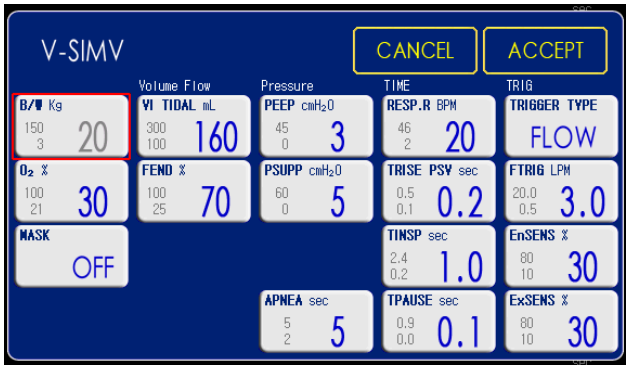
If the pressure increases to the set upper pressure limit, the expiratory valve opens and the ventilator switches to expiration.

6.6 V-SIMV
(Volume based Synchronized Intermittent Mandatory Ventilation)

V-SIMV is a mode that controls ventilation based on volume according to spontaneous ventilation of the patient. In other words, this mode combined control and pressure support/ spontaneous function allows for preset mandatory breaths synchronized with the patient's breathing.

Spontaneous ventilation is done using configured time period or mechanical ventilation is paralleled based on air volume if there is no spontaneous breathing.

The spontaneous/pressure supported breaths are defined by the setting for Pressure Support.



The following parameters are configured in VSIMV mode.

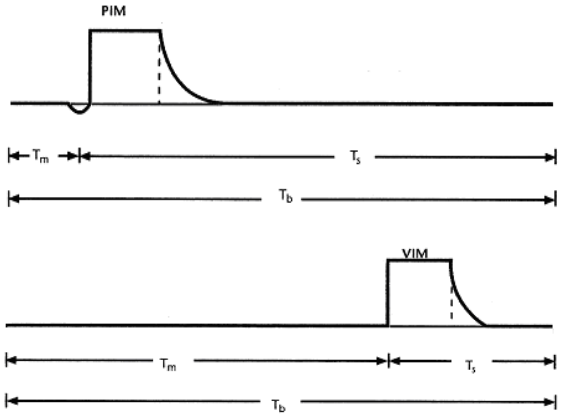
1. Tidal Volume(ml)
2. Respiratory Rate(b/min)
3. Pause Time(sec)
4. PEEP(cmH_2O)
5. Oxygen Concentration(%)
6. Inspiratory Time(sec)
7. End Flow(%)
8. Inspiratory Trigger Sensitivity(%)
9. Expiratory Trigger Sensitivity(%)
10. Trigger Flow/ Trigger Pressure
11. Trigger Setting(lpm/ cmH_2O)
12. Pressure Support(cmH_2O)
13. Trise Pressure Support(cmH_2O)
14. APNEA(sec)
15. Mask Mode(On/Off)

SIMV mode is a mode in which mandatory breath and spontaneous breath are mixed.

SIMV mode guarantees one mandatory breath for each SIMV cycle. Mandatory breath is either **P**atient Initiated **M**andatory (PIM or assisted mandatory) breath or **V**entilator **I**nitiated **M**andatory (VIM or controlled mandatory) breath.

As in the following figure, each SIMV breath cycle is divided into two parts. One is mandatory interval (Tm) and another is spontaneous interval (Ts). Once PIM breath is delivered, mandatory interval ends and spontaneous interval (Ts) begins.

If PIM breath does not occur until the end of mandatory interval, VIM breath is provided to the patient as soon as mandatory interval ends and spontaneous interval begins.



In SIMV mode, SIMV breath cycle is determined by configured respiration. If respiratory rate is configured as 12 times, SIMV breath cycle is 5 seconds. Mandatory interval is smaller value either 10 seconds or 0.6 x SIMV breath cycle. Mandatory

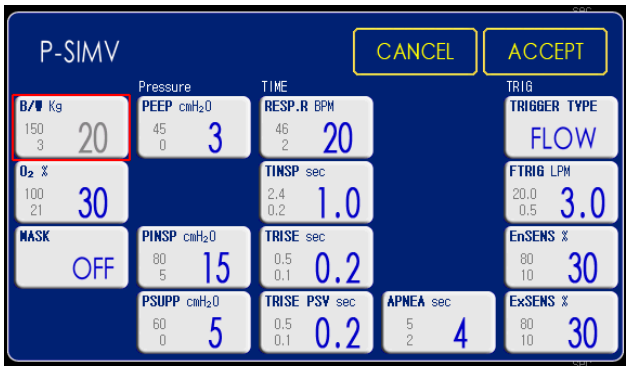
interval can be shortened depending on PIM breath.

6.7 P-SIMV
(Pressure based Synchronized Intermittent Mandatory Ventilation)

This mode controls ventilation based on pressure according to spontaneous ventilation by the patient. In other words, this mode combined control and pressure support/spontaneous function allows for preset mandatory breaths synchronized with the patient's breathing.

Mechanical ventilation is paralleled based on air volume according to spontaneous ventilation or in case there is no spontaneous ventilation using configured time period.

The spontaneous/pressure supported breaths are defined by the setting for Pressure Support.



The following parameters are configured in P-SIMV mode.

1. Inspiration Pressure(cmH_2O)
2. Inspiration Time(sec)
3. Respiratory Rate(b/min)
4. PEEP(cmH_2O)
5. Oxygen Concentration(%)
6. Inspiration Rise Time(sec)
7. Inspiratory Trigger Sensitivity(%)
8. Expiratory Trigger Sensitivity(%)
9. Trigger Flow/Trigger Pressure
10. Trigger Setting(lpm/ cmH_2O)
11. Trise Pressure Support(cmH_2O)
12. Pressure Support(cmH_2O)
13. APNEA(sec)
14. Mask Mode(On/Off)

6.8 SPONT
(Spontaneous Ventilation)

This mode provides pressure support based on spontaneous ventilation.

If there is no spontaneous ventilation for configured time while operating in this mode, mode is automatically converted to the mode (V-ACV or P-ACV) configured in Apnea Backup.

Mode returns to spontaneous ventilation once the patient breathes three times spontaneously in 10 seconds.

The following parameters are configured in SPONT mode.

1. PEEP(cmH_2O)
2. Oxygen Concentration(%)
3. Inspiratory Trigger Sensitivity(%)
4. Expiratory Trigger Sensitivity(%)
5. Trigger Flow/Trigger Pressure
6. Trigger Setting(lpm/ cmH_2O)

7. Pressure Support(cmH_2O)
8. Trise Pressure Support(cmH_2O)
9. Apnea Mode(V-ACV/P-ACV)
10. Apnea Time(sec)
11. Mask Mode(On/Off)

Once the patient's intention for spontaneous ventilation reaches sensitivity, flow is provided to the patient. Pressure is maintained between sensitivity setting value and pressure level 1 cmH_2O below sensitivity setting.

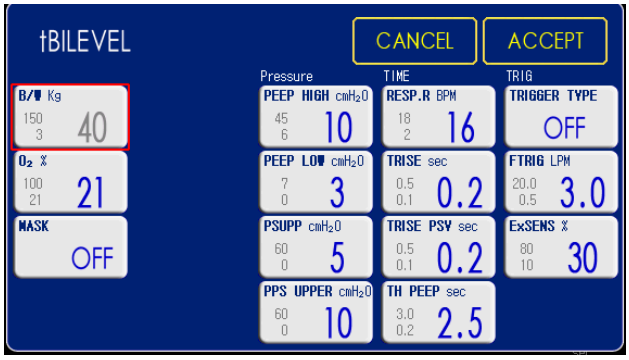
Once pressure becomes 1 cmH_2O larger than PEEP, exhalation valve is opened to begin expiration.

If the patient falls in apnea during SPONT mode, Apnea Alarm is created by the device and Apnea Ventilation (V-ACV mode or P-ACV mode) is automatically started. This Apnea Ventilation is operated according to items configured by user.

The mode returns to Spontaneous Mode if the patient shows two spontaneous breaths in 10 seconds.

6.9 tBiLEVEL (Spontaneous Ventilation)

tBiLevel is pressure controlled breathing that allows the patient the opportunity of unrestricted spontaneous breathing. Two pressure levels are set together with the individually set duration of each level. Spontaneous breathing efforts can be assisted by pressure support.



The following parameters are configured in tBiLEVEL mode.

1. High PEEP Time(sec)
2. Respiratory Rate(b/min)
3. High PEEP(cmH_2O)
4. Low PEEP (Base Pressure) (cmH_2O)
5. Oxygen Concentration(%)
6. Expiratory Trigger Sensitivity(%)
7. Trigger Flow/Trigger Pressure
8. Trigger Setting(lpm/ cmH_2O)
9. Pressure Support(cmH_2O)
10. Upper Pressure Support(cmH_2O)
11. Inspiration Rise Time(sec)
12. Rise time in Pressure support(sec)
13. Mask Mode(On/Off)

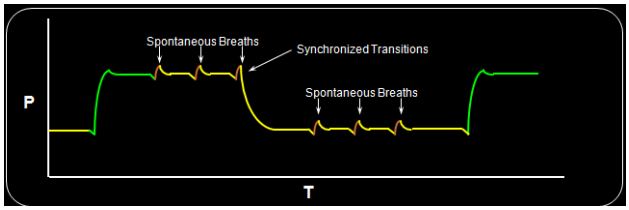
tBILEVEL mode is a mixed mode in which both mandatory breath and spontaneous breath can occur.

Though it is similar to SIMV mode in that it is a mixed mode, it differs from SIMV in that there is no spontaneous section. That is, spontaneous breath can occur at any time.

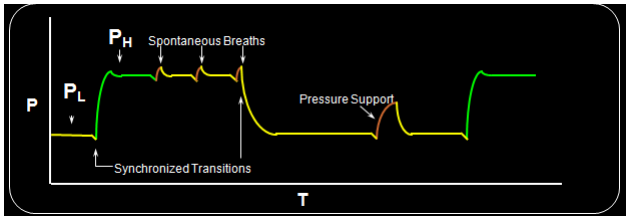
Two levels of PEEP are provided to the patient in tBiLEVEL mode. High level PEEP is called $PEEP_{HiGH}$ and low level PEEP is called $PEEP_{LOW}$. Inspiration of mandatory breath is when $PEEP_{LOW}$ is converted to $PEEP_{HIGH}$. Expiration is when $PEEP_{HIGH}$ is converted to $PEEP_{LOW}$.

Therefore, all mandatory breaths in tBILEVEL mode are pressure control ventilation. The Transition interval is short time in before and after of each transition period. In this interval if the patient intends to breath, the transition time can be quickened or slowed according to the breathing pattern.

Setting items include respiratory rate, $PEEP_{HIGH}$, and $PEEP_{LOW}$. Support pressure is additionally configured using pressure support ventilation.



It is possible to synchronize the transition from $PEEP_{HIGH}$ to $PEEP_{LOW}$ with the patient's respiratory cycle. Also at $PEEP_{LOW}$, the spontaneous breath is pressure supported



In all spontaneous breaths occurring in tBiLEVEL mode, 1.5 cmH_2O pressure supports is automatically provided. If user wants higher level of pressure support, pressure support ventilation can be configured. If the value of support pressure + $PEEP_{LOW}$ is larger than $PEEP_{HIGH}$, pressure support ventilation corresponding to the difference occurring during spontaneous breath in $PEEP_{HIGH}$ state is provided. This can be seen in the following figure.

When using tBiLEVEL mode, spontaneous breath can be supported at any time, reducing fighting between the device and patient. Therefore, frequency of inevitable sedation can be reduced, resulting in reduction of treatment cost and quicker recovery of the patient. Also, the patient's comfort can be enhanced by providing pressure support ventilation on all spontaneous breaths.

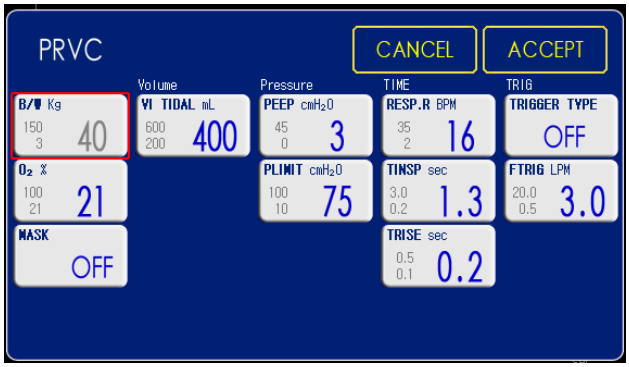
6.10 PRVC (Pressure Regulated Volume Controlled Ventilation)

Pressure Regulated Volume Control (PRVC) is a mechanical ventilation mode based on auto pressure control. Constant volume is maintained through target volume and pressure limit setting.

The ventilator delivers a pre-set Tidal Volume. The pressure is automatically regulated to deliver the pre-set volume but limited to 1 cmH_2O below the set pressure limit.

PRVC assures a set target minute ventilation to the patient. The target volume is based upon settings for Tidal Volume, frequency and inspiration time.

The inspiratory pressure level is constant during each breath, but automatically adapts in small increments breath-by-breath to match the patient's lung mechanical properties for target volume delivery.



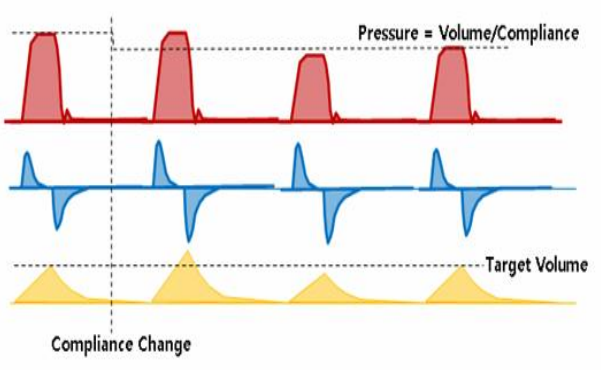
The following parameters are configured in PRVC mode.

1. Tidal Volume(ml)
2. Inspiration Time(sec)
3. Respiratory Rate(b/min)
4. PEEP(cmH_2O)
5. Oxygen Concentration(%)
6. Inspiration Rise Time(sec)
7. Trigger Flow/Trigger Pressure
8. Trigger Setting(lpm/ cmH_2O)
9. Pressure Limit(cmH_2O)
10. Mask Mode(On/Off)

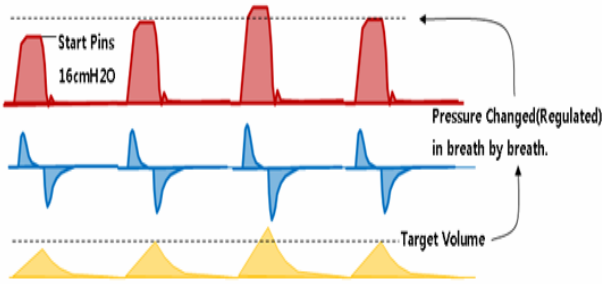
Despite advantages of pressure mode, instability of not guaranteeing inspiratory volume, caused by long-term or acute change in patient's respiratory status or long-term change in lung compliance, is removed.

The ventilator delivers configured tidal volume. Pressure maintained for supply of configured tidal volume is automatically adjusted within the range of pressure limit.

The first breath of a start sequence is a volume-controlled test breath with pressure of 16cmH_2O. The measured pause pressure of this breath is then used as the pressure level for the following breath.



During the breathing, the pressure regulated according to compliance changing of patient.



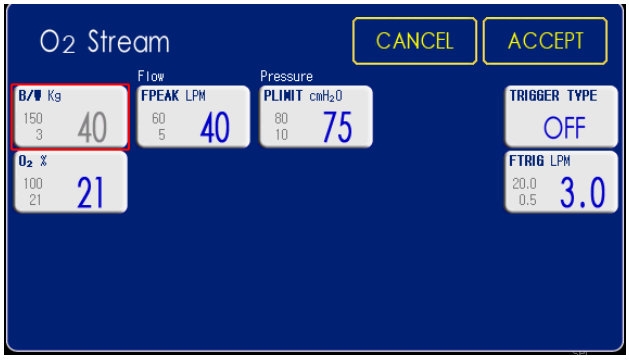
6.11 O_2 Stream

This mode can be used for nasal CPAP and high flow therapy. This mode controls a micro-miniature flow along with adjusting O_2 flow.

The conventional CPAP must be used with a humidifier in order to a patient' breathing air should be moisture, but O_2 Stream flows O_2 gas at the same time with air, the breathing air will be easy for a patient's nasal and lung.

O_2 Stream supports a positive airway pressure on the control flow to reduce the dead space at a patient's lung.

Peak pressure is limited using Pressure Limit(P_limit) for safer application to the patient.



The following parameters are configured in O2 stream mode.

1. Inspiratory Peak Flow(Lpm)
2. Pressure Limit(cmH_2O)
3. Oxygen Concentration(%)
4. Trigger Flow/Trigger Pressure
5. Trigger Setting(lpm/ cmH_2O)

6.12 AutoVent

Though it is a single mode, this mode is actively operated according to the status of the patient throughout ACV → SIMV → Spont modes while guaranteeing minute volume.

Optimal WOB(Work of Breathing) is found in prescribed respiration per minute. Medical staff manages the patient using three values including %MinVol, PEEP and O2. This guideline includes weaning induction.

If self-breathing of the patient is strong, operation is conducted as Spont + PS (5cmH2O minimum) + 10 seconds apnea time. The patient's respiration is reduced or non-breathing over 10 seconds is automatically controlled.

Advantages and limitations of AutoVent mode are as follows.

1. Advantages
   1) Patient is managed without transition between CMV, SIMV, and Spont modes. Convenience of mode management and simplification of patient information can be accomplished.

   2) Since minute volume is guaranteed without risks in weaning induction such as non-breathing, this mode is relatively safe against non-breathing.

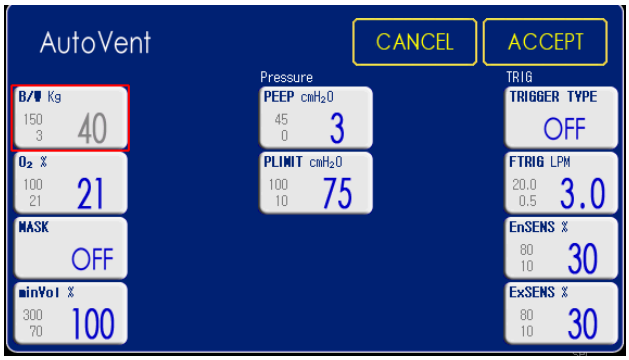
   3) Based on monitoring result on gas concentration in blood and respiration gas concentration of the patient, relatively stable patient management is made possible through simplified algorithm for %Vmin, PEEP, and O2 concentration.

2. Limitations
   1) Since this mode includes a completely different concept than existing modes, training on the new method is required. There is a possibility of mistaking this mode as a universal mode with lack of training, leading to inappropriate patient management.

   2) Patient management is still required since operation becomes unstable by auto-triggering.

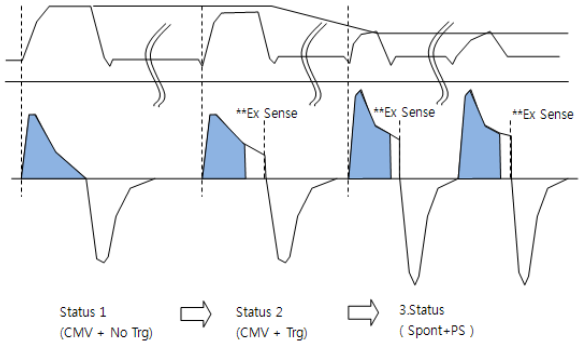
   3) Since WOB can be increased or optimized based on decision of %Vmin, patients must be managed using new training and guidelines compared to existing modes.

   4) Optimization of respiratory gas concentration and gas concentration in blood through monitoring can be difficult compared to general modes (limitation in adaptation to individual conditions of patients).



The following parameters are configured in AutoVent mode.

1. PEEP(cmH_2O)
2. Trigger Flow/Trigger Pressure
3. Trigger Setting(lpm/ cmH_2O)
4. Oxygen Concentration(%)
5. Pressure Limit(cmH_2O)
6. Inspiratory Trigger Sensitivity(%)
7. Expiratory Trigger Sensitivity(%)
8. minVol(%)
9. Mask Mode(%)



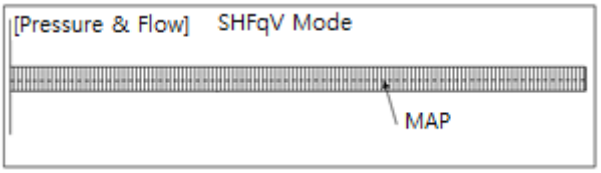
6.13 SHFV (Single High Frequency Ventilation)

High Frequency Ventilation was developed with the ideal of providing "gentle breathing" for every patient from newborn infants to seniors.

This mode is high frequency ventilation mode with single frequency.

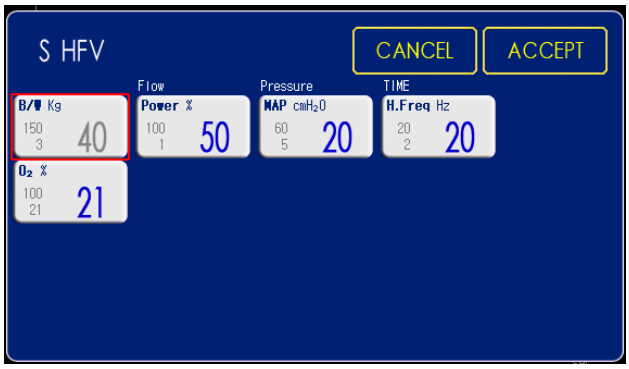
Frequency range: 2 ~ 20Hz.

The adult case sets4~8Hz(240~480bpm) and Infant case sets 10~15Hz(600~900bpm). Select appropriate setting according to patient condition and clinician's decision.



According to the patient' lung, you select the MAP. If you increase the amplitude of the Pman and Pmin, Paw should be greater than the amplitude of 1/2.

Power doesn't have the unit and determine the minimum and maximum power. When the power increases, the amplitude of the pressure and flow rate is increased. But the amplitude of the pressure increase, if Paw is low, the amplitude will be limited by Paw.



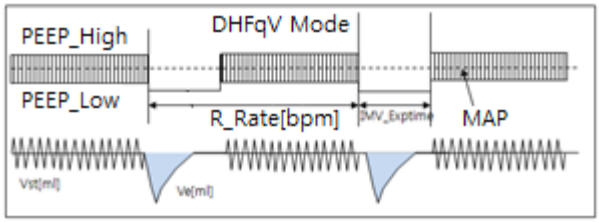
The following parameters are configured in SHFV mode.

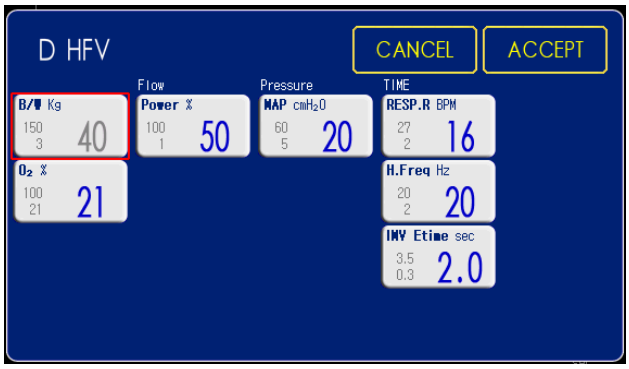
1. Power(%)
2. MAP(cmH_2O)
3. Frequency Range(Hz)
4. Oxygen Concentration(%)

6.14 DHFV (Dual High Frequency Ventilation)

Insufficient ventilation volume of SHFV mode can be supplemented intermittently using exhalation time.

During expiratory time, it is available measuring EtCO2. Increasing CO_2 exhalation at insufficient ventilation of Single HFV.





The following parameters are configured in DHFV mode.

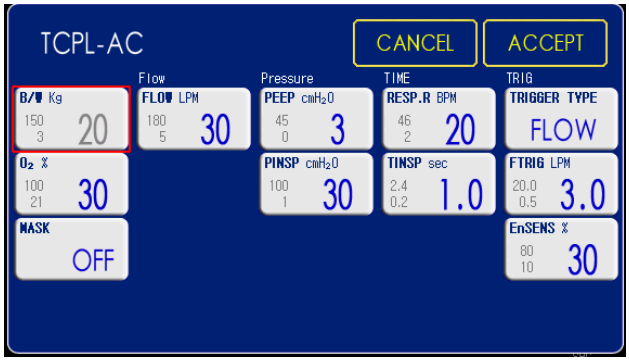
1. Power(%)
2. MAP(cmH_2O)
3. Respiratory Rate(b/min)
4. Frequency Range(Hz)
5. IMV time(sec)
6. Oxygen Concentration(%)

6.15 TCPL-AC
(Time Cycled Pressure Limited-Assist Control)

A peak inspiratory pressures is set by the operator, and during inspiration gas flow is delivered to achieve that set pressure, hence the term pressure-limited(PL).

The volume of gas delivered to the patient in this TCPL varies depending on pulmonary mechanics such as compliance of stiffness of the lungs.

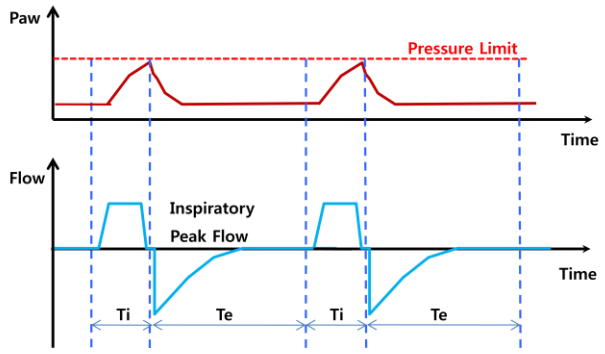
At low compliance('stiff lungs') such as occurs early in the course of respiratory distress syndrome(RDS), a given pressure generates lower tidal volume.



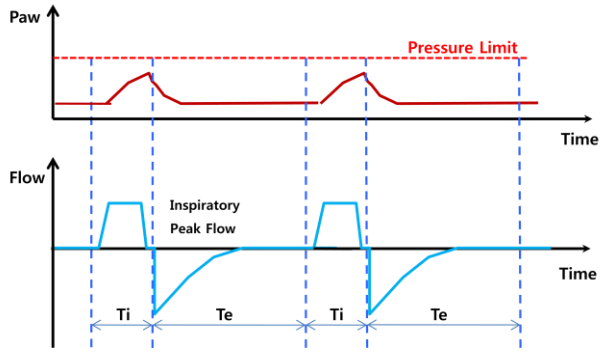
The following parameters are configured in TCPL-AC mode.

1. Flow(lpm)
2. Respiratory Rate(b/min)
3. PEEP(cmH_2O)
4. Oxygen Concentration(%)
5. Inspiratory Pressure(cmH_2O)
6. Inspiratory Time(sec)
7. Inspiratory Trigger Sensitivity(%)
8. Trigger Flow/ Trigger Pressure
9. Trigger Setting(lpm/ cmH_2O)
10. Mask Mode(On/Off)

The following case shows pressure and flow changes according to time when high flow and low compliance.

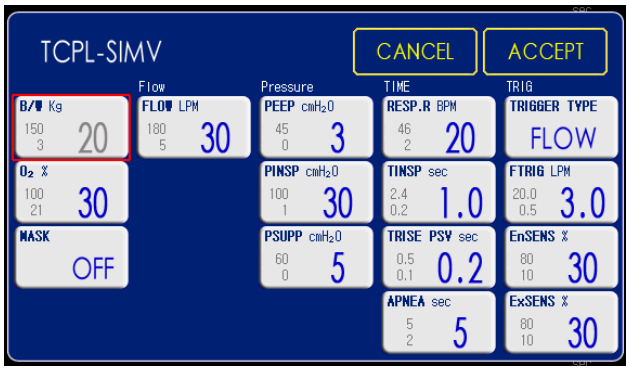


The following case shows pressure and flow changes according to time when low flow and high compliance. It can't be to reach the pressure limit.



6.16 TCPL-SIMV (Time Cycled Pressure Limited-Synchronized Intermittent Mandatory Ventilation)

TCPL-SIMV mode is similar to one the TCPL-AC mode and the mode assist the patient's spontaneous breathing.

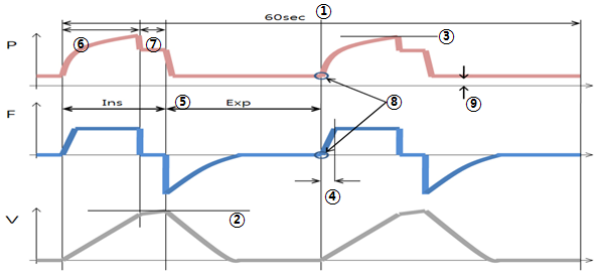


The following parameters are configured in TCPL-SIMV mode.

1. Flow(lpm)
2. Respiratory Rate(b/min)
3. PEEP(cmH_2O)
4. Oxygen Concentration(%)
5. Inspiratory Pressure(cmH_2O)
6. Inspiratory Time(sec)
7. Inspiratory Trigger Sensitivity(%)
8. Expiratory Trigger Sensitivity(%)
9. Trigger Flow/ Trigger Pressure
10. Trigger Setting(lpm/ cmH_2O)
11. Pressure Support(cmH_2O)
12. Trise Pressure Support(cmH_2O)
13. Apnea(sec)
14. Mask Mode(On/Off)

6.17 Ventilation Parameter Outline

When ventilation mode is selected, parameters related to the configured ventilation mode are displayed on the screen. The following parameters are related to all ventilation modes.



1. Respiratory Rate (RR)
   Respiratory rate is used to calculate the number of mechanical respirations or target volume (b/min).

2. Tidal Volume (VT)
   Volume per respiration or target volume (mL)

3. Minute Volume (Vmin)
   Volume per minute or target minute volume

4. Inspiratory Pressure Level

5. Inspiratory Rise Time
   Arrival time from the start of each respiration to flow / pressure peak

6. I:E Ratio (I:E)
(Inspiration time + Pause time): Expiration time

7. Inspiration Time
   Delivered time to patient of flow or pressure

8. Pause Time
   Temporary pause time during which flow or pressure is halted without delivery

9. Trigger Flow/Trigger Pressure
- Trigger Flow is that the amount of bias flow can gradually be reduced for induction of ventilation.
- Trigger Pressure is that pressure must be created below the configured PEEP through inhalation of excessive bias flow to induce ventilation.

10. PEEP
   Positive end expiratory pressure (cmH_2O)

7. Alarm

7.1 Introduction

MV2000[SU:M] ventilator includes an alarm system for the patient's safety. In case of the following problems, alarm sound is created with screen display.

- Breathing problem, ex: Apnea
- Power problem, ex: Battery mode
- Gas problem, ex: Reduced gas pressure

This Chapter describes general response method, sequence of alarm setting (refer to Chapter 4 Operation Method for details), range of alarm setting, and list.

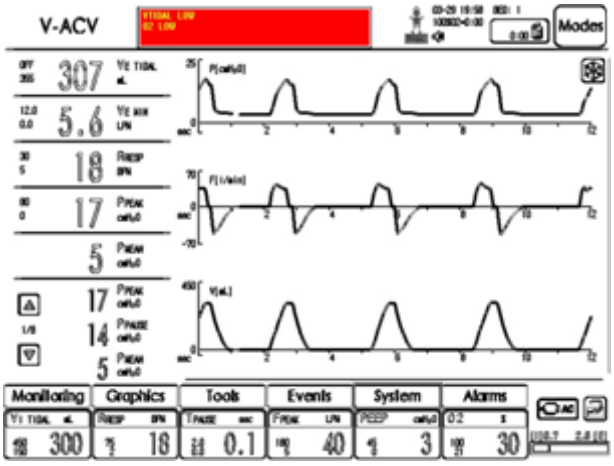
Refer to Chapter 8 Alarm Message for details on causes and solutions to all alarms.

> **WARNING**
> Potential risk can be increased if default alarm values applied to ventilators or other similar devices used in same place differ from each other.

> **ATTENTION**
> If an alarm occurs, measures must be taken by a medical professional with experience in ventilator treatment or an individual trained with MV2000[SU:M] ventilator.

7.1.1 Alarm Display

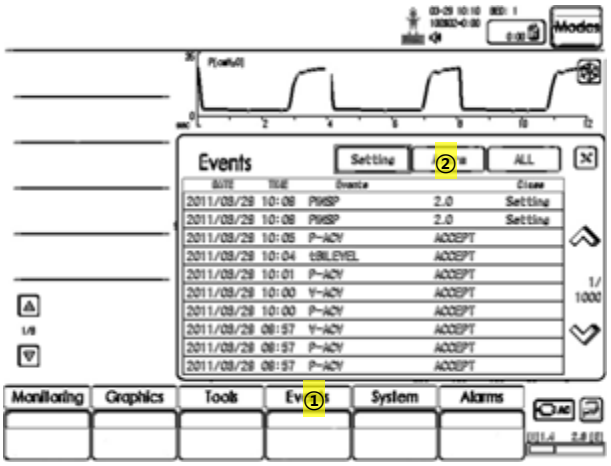
If an alarm occurs, it is displayed on the screen with a message as follows.



1) Alarm message window flickers and displays the cause of alarm.
2) Measurement value window corresponding to the alarm will flicker.

7.2 Alarm Removal

7.2.1 View Current Alarms



More than one alarm can be checked through alarm message displayed on top of the screen. To check more alarms,

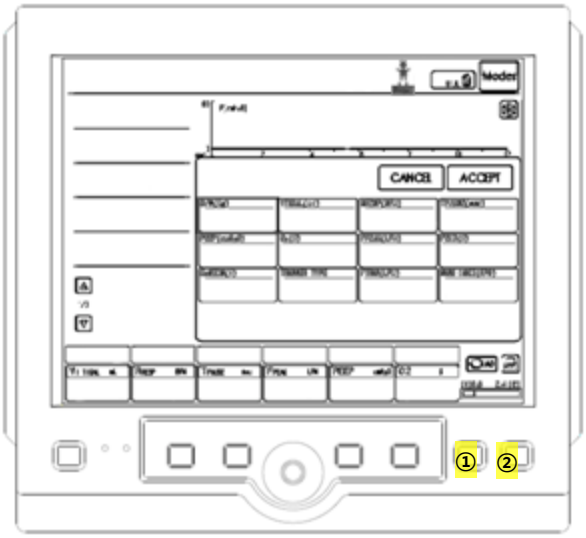
1) Choose Events menu on bottom of the screen.
2) Select Alarms among sub menu of Events to see all recent alarms.

7.2.2 Alarm Removal

Current alarm messages and alarm actions can be canceled by pushing Alarm Reset button among fixed keys at the bottom of the monitor.

Also, alarm action is automatically canceled if the alarm condition is settled.

> **NOTE**
> Alarm sound can be muted without settling current alarms. However, sound may operate intermittently depending on the situation.



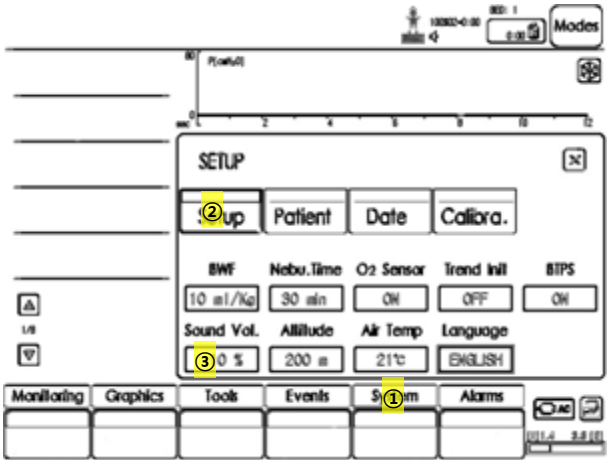
1) Alarm Silence (2 min)
2) Alarm Reset

7.2.3 Pausing Alarm Sound

If Alarm Silence button is pushed among fixed keys at the bottom of the monitor,

- Current alarms become silenced or muted for two minutes.
- Bell icon appears on the message window with remaining time for mute.
- Sound is muted for two minutes every time Alarm Silence button is pushed.

7.2.4 Alarm Sound Volume Control



1) Select System button among menu buttons located at the bottom of user interface.
2) Select Setup in the System menu.
3) Activate sound volume by touching Sound Vol. Adjust the volume of alarm sound. Once adjustment is complete, touch again to deactivate the window.

7.3 Alarm Setting

This Section explains alarm screen display, alarm setting

7.3.1 Alarm Screen Display

Configured alarms values are displayed on the left side of the screen and in measurement value window at the bottom. Among displayed alarm values, value above is the upper limit and value below is the lower limit.

7.3.2 Alarm Setting

Select Alarms among menu at the bottom of the screen when configuring alarm values. A new menu called Alarm Set appears. This menu can be used to configure alarms.

Item	Range	Default	Unit	Step
VE TIDAL HIGH	OFF, 5~2500	OFF	mL	10
VE TIDAL LOW	0~2500	50	mL	10
VE MIN HIGH	0.1~50	12	LPM	0.1
VE MIN LOW	0.0~49.9	1.2	LPM	0.1
R RESP HIGH	3~180	30	BPM	1
R RESP LOW	2~179	5	BPM	1
P PEAK HIGH	1~120	80	cmH_2O	1
P PEAK LOW	0~119	0	cmH_2O	1
O_2 HIGH	OFF, 1~100	OFF	%	1
O_2 LOW	0~100	20	%	1
AIR LEAK	OFF, 50~500	300	mL	10
Apnea	2~60	20	sec	1
SpO_2 HIGH (optional)	OFF, 52~99	OFF	%	1
SpO_2 LOW (optional)	OFF, 51~99	81	%	1
PR HIGH (optional)	30~250	150	BPM	5
PR LOW (optional)	25~245	50	BPM	5
$EtCO_2$ HIGH (optional)	0~10.0	6.0	mmHg	0.1
$EtCO_2$ LOW (optional)	OFF, 0~9.9	OFF	mmHg	0.1
INS HIGH (optional)	0~10.0	3.0	mmHg	0.1
INS LOW (optional)	OFF, 0~9.9	OFF	mmHg	0.1
RESP HIGH (optional)	3~150	30	BPM	1
RESP LOW (optional)	2~149	5	BPM	1

8. Alarm Message

8.1 Introduction

This Chapter describes alarms and measures on each alarm message.

NOTE

Contact service assistant for most of technical errors.

WARNING

When conducting an act that can bring risks to the patient such as replacement of O_2 cell, always separate the ventilator from the patient.

CAUTION

When the ventilator is in operation, do not raise or separate expiratory cassette. However, it may be separated in stand-by mode.

8.2 Alarm and Error Message

When an alarm message occurs, check current mode and settle the problem immediately.

No	Alarm Message	Occurrence (Immediate / Separate)	Criteria
1	Apnea	After apnea time	Only operated in Spont mode If there is no respiration within configured apnea time.
2	Backup Mode	After apnea time	Only operated in Spont mode Apnea occurs to notify backup mode operation. Alarm continues to sound during VENT (VACV/PACV mode) operation(Backup mode operates if Apnea mode is operated in Spont mode) Mode is switched to Spont mode in case of two spontaneous breaths in 10 seconds
3	Obstruct	Immediate	When inspiration outlet or expiration inlet are blocked
4	Expiratory Minute Volume High	One minute after Vent operation	If configured value or default alarm limit is exceeded If there is an increase in the patient's effort for breathing If self-triggering (auto cycling) of the ventilator occurs If alarm setting is inappropriate This alarm is operated one minute after Vent mode operation.
5	Expiratory Minute Volume Low	One minute after Vent operation	If configured value or default alarm limit is exceeded If there is little effort by the patient to breathe If there is leakage around cuff If there is leakage in the patient's tube line If alarm setting is inappropriate This alarm is operated one minute after Vent mode operation.
6	Pressure High	Immediate	If high pressure exceeds setting or default alarm limit If tube line is twisted or blocked If a mucus or secretion blocks endotracheal tube or airway If the patient coughs or fights with ventilator If inspiratory flow is extremely high If alarm setting is inappropriate If expiratory filter is blocked

No	Alarm Message	Occurrence (Immediate / Separate)	Criteria
7	Pressure Low	Immediate	If low pressure exceeds setting or default alarm limit If there is leakage around cuff If there is leakage in the patient's tube line If alarm setting is inappropriate Spontaneous breathing is not applied
8	Respiratory Rate High	After taking mean value on four respirations	If respiratory rate is too high If auto triggering occurs If higher than setting alarm limit
9	Respiratory Rate Low	After taking mean value on four respirations	If respiratory rate is too low If trigger sensitivity setting is inappropriate If lower than setting alarm limit
10	Tidal Volume High	Immediate	If setting or default alarm limit is exceeded If there is an increase in the patient's effort to breathe If self-triggering (auto cycling) of the ventilator occurs If alarm setting is inappropriate
11	Tidal Volume Low	After taking mean value on Vtidal of three respirations	If setting or default alarm limit is exceeded If there is leakage around cuff If there is leakage in the patient's tube line If alarm setting is inappropriate Spontaneous breathing is not applied
12	O_2 High	One minute after Vent mode or O_2 alarm setting	If higher than setting alarm limit
13	O_2 Low	One minute after Vent mode or O_2 alarm setting	If lower than setting alarm limit
14	Gas Supply Pressure Low	Immediate	In case supplied gas pressure is lower than 3psi or impurities are included in inlet filter
15	Circuit Open	Immediate	If inspiratory flow is above 8Lpm and exp pressure below 3cmH2O is maintained over 10 seconds, or over 8L is supplied If circuit is easily opened or PEEP bundle
16	Air Gas Fail	Immediate	If tank pressure is over 10 seconds and under 10psi After failure of air supply gas, gas supply is checked every two minutes for automatic recovery
17	O_2 Gas Fail	Immediate	If tank pressure is over 10 seconds and under 10psi After failure of O_2 supply gas, gas supply is checked every two minutes for automatic recovery

No	Alarm Message	Occurrence (Immediate / Separate)	Criteria
18	Circuit Leakage	After three consecutive respirations	Linked to leakage volume (mL) configured by user Used when the difference between insp volume and exp volume is larger than leakage volume configured by user Circuit leakage alarm occurs if difference between insp and exp volumes occurs during three consecutive respirations Note: NIV and Spont mode do not apply.
19	Vent Inop.	Immediate	If air gas and O_2 gas are not supplied and tank pressure is under 5psi. If battery usage is under 5 minutes If there is no respiration during time for three respirations in Vent mode Note: This may occur once during initial operation of product.
20	Low Battery Voltage	Immediate	Remaining battery is 5 minutes
21	O_2 Cell failure	Immediate	If O_2 is detected below 18% If O_2 cell fails(However, screen only displays 21% or above).

9. Supplementary Devices

9.1 MEKICS Humidifier VH-2600

Use of heating humidifier in treatment of patients can be beneficial.

Refer to user manual by the corresponding manufacturer for structure and usage of humidifier.

WARNING

- Heating type humidifier must be turned off when using nebulizer. Failure to turn off may influence the particle size of absorption drug.
- Unexpected increase in gas temperature may result from use of unauthorized humidifier.

CAUTION

- Since water can be formed in the tube when heating type humidifier is used, water trap must be connected to expiratory tube line.
- During operation, water trap must be checked frequently and emptied accordingly.

ATTENTION

- Since use of soft tube with extremely high compliance can affect functions of the ventilator, use tubes supplied by our company if possible.
- Supplementary accessories connected to the patient's tube can influence patient pressure.

9.2 $EtCO_2$ (Option)
(End Tidal CO_2 Concentration)

$EtCO_2$ sensor displays expiratory end CO_2 concentration as a graph.

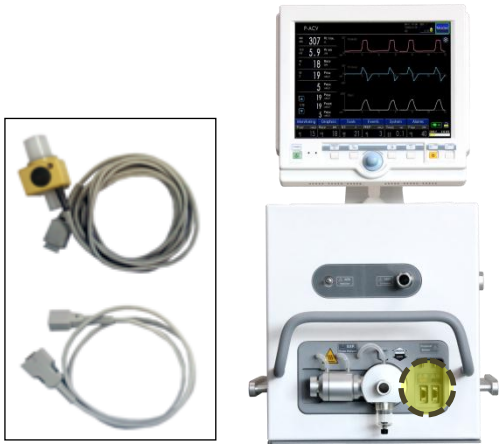
As a device that consecutively measures $EtCO_2$ concentration during expiration to predict pCO_2 (CO_2 concentration in blood), the sensor is an important means to monitor appropriate inspiration and expiration states. Also, since the sensor is a means to determine respiratory diseases such as asthma based on extraction of various parameters from capnograph wave, it is also used for diagnosis.

WARNING

Only use CO2 components certified by our company.

9.2.1 $EtCO_2$ Connection Method

1) Connect $EtCO_2$ sensor cable to the socket on which $EtCO_2$ label is attached on the right side of MV2000[SU:M] ventilator.
2) Connect the $EtCO_2$ sensor to the patient.
3) Measurement values are displayed by selecting $EtCO_2$ graph from Graph Selection menu.



9.2.2 $EtCO_2$ Calibration

1) Select System in the menu at the bottom of user interface.
2) Select Calib. menu among System menu.
3) Perform $EtCO_2$ calibration in Calib. menu.

9.3 SpO_2 (Option)
(Pulse Oximeter Oxygen Saturation)

Oxygen saturation shows the degree of concentration of hemoglobin that transports oxygen in the artery. That is, it displays the degree of currently transported amount compared to oxygen transportable by hemoglobin as a percentage. It does not show the amount of carboxyhemoglobin or methemoglobin hemoglobin from hemoglobin disorder.

WARNING

- Only use SpO_2 sensor certified by MEKICS. If a different product is used, there may be a problem in performance.
- Only use SpO_2 sensor certified by MEKICS. If a different product is used, there may be a problem in performance.
- Sensor should not be used on parts with artery catheter or vein syringe.
- Do not use damaged SpO_2 sensor or optical device.
- Since the sensor is not waterproof, do not place in water and solvent or clean excessively.
- Do not sterilize the sensor with ultraviolet ray, direct sunlight, steam or hydrogen peroxide.

CAUTION

- Do not use the sensor to patients with allergic symptoms to SpO2 sensor.
- Immediately remove the sensor if the patient calls for discomfort.

ATTENTION

Inaccurate values and waves can result as below if sensor is used incorrectly.

- When sensor not certified by MEKICS is used or sensor is used incorrectly
- Functional disorder in hemoglobin
- When sensor is excessively exposed to medical light (especially xenon light), bilirubin light, fluorescent light, infrared heating device, or direct sunlight
- Excessive movement by the patient
- Use of high frequency electric surgical instrument or cardiac resuscitator
- Pulse of venous blood
- Measured at a spot where blood pressure is measured, pressure bandage is used, artery catheter is used, or sensor is used inside blood vessel
- Measured at a spot where blood pressure is measured, pressure bandage is used, artery catheter is used, or sensor is used inside blood vessel
- When there is arterial occlusion nearby the sensor
- When the patient is experiencing cardiac arrest or shock

Heart rate may be inaccurate in the following situations.

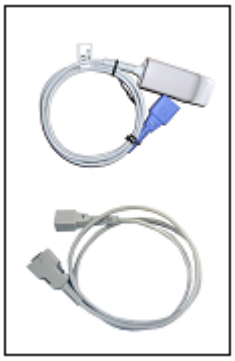
- When sensor is tightened too much
- When sensor receives excessive medical light, bilirubin light or sunlight
- When measured with pressure bandage or at a spot pressured by cuffs

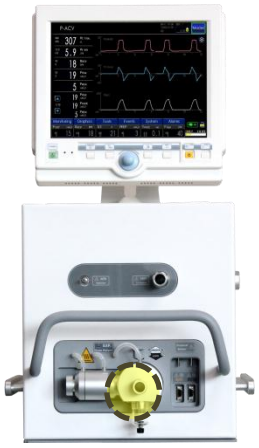
The sensor may show performance problems when exposed to excessive medical light (especially xenon light), bilirubin light, fluorescent light, infrared heating device, or direct sunlight. In order to prevent excessive light, follow the instructions for use. Use opaque substances to prevent the sensor from being exposed to external light sources. Computed values may become inaccurate if surrounding environment is too bright.

Since movement of the patient can cause problems, check whether the sensor is being operated safely. Adhesive-type sensor can be used to reduce measurement errors from patient's movement.

9.3.1 SpO_2 Connection Method

1. Connect SpO_2 sensor cable to the socket on which SpO_2 label is attached on the right side of MV2000[SU:M] ventilator.
2. Place a finger on the SpO_2 sensor.
3. Wait for a moment until SpO_2 measurement values are displayed as a graph.





10. Initial Screen Configuration

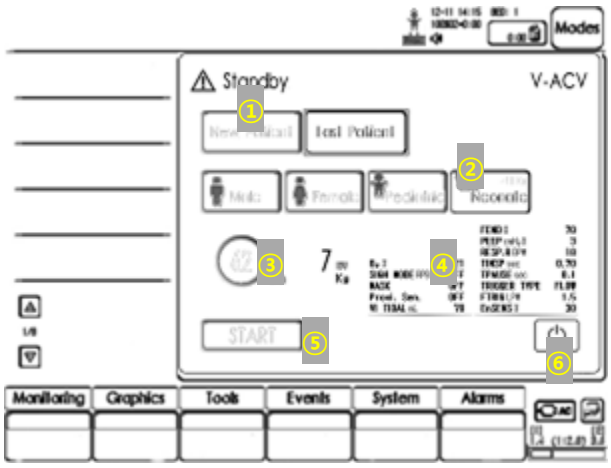
10.1 Introduction

When MV2000[SU:M] ventilator is operated, it is operated in stand-by mode. User can configure and change the following default values.

- Patient (New or Last)
- Patient Range (Adult or Neonate)
- Height and Body Weight of Patient
- Ventilation Mode (Including Setting Parameters)

10.2 Start-Up Configuration

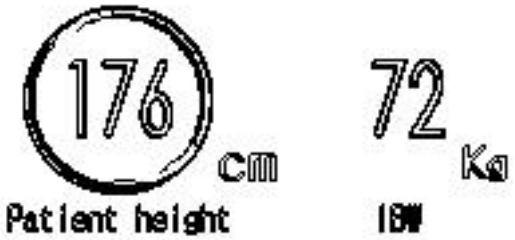
Initial screen of MV2000[SU:M] is as follows.



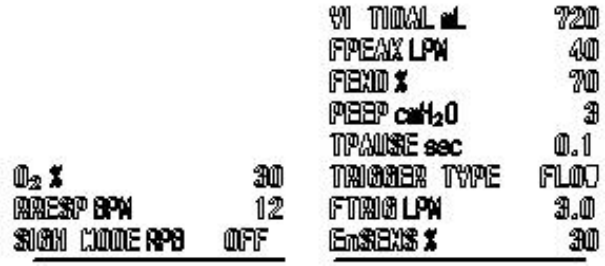
1. Add a new patient or load recent patient setting.

2. Select appropriate patient range according to age and gender.

3. If height of the patient is decided according to age and gender, PBW (predicted body weight) is automatically calculated.

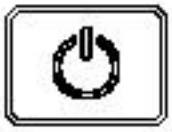


4. Touch measurement screen to move to mode setting screen and configure related parameters. Touch Modes button on the top right corner to change ventilation mode and configure parameters.



5. Ventilation begins after configuring all parameters with patient information and touching Start button.

6. Touch the following button to turn the power Off.



NOTE

In the initial standby screen, various menu at the bottom can also be used in addition to setting patient information and parameters. Matters required for ventilation can be configured through System menu.

10.3 System Setting

System menu is composed of Setup menu that configures operating conditions of the ventilator, Patient menu that configures patient information, Date menu that decides date and time, and Calibration menu that configures various calibrations.

10.3.1 Setup

The following parameters are configured in Setup menu.

1. BWF
   - Configure air volume (mL) per Kg of the patient's body weight (B/W).
   - Range: 5 ~ 15 mL/kg

2. Nebulizer Time
   - Configure usage time of nebulizer.
   - Range: 10 ~ 180 min

3. O_2 Sensor
   - Configure the use of O2 cell, whether to enable or disable the sensor.
   - Enable: O2 gas is used when O2 cell is normal.
   - Disable: This is when there is no O2 gas, lifespan of O2 cell has expired, or O2 cell can not be used for a different reason. There is no influence on supply of O_2 gas.

4 Trend Init

- Initialize trend data.

5. BTPS

- BTPS is an abbreviation of "**B**ody **T**emperature and **P**ressure **S**aturated with Water Vapor" and refers to the state in which physical factors that influence air volume inside body are taken into consideration. This function compensates for volume of air supplied, considering difference between body temperature and external temperature with altitude above sea level.
- Range
  OFF: BTPS function is turned OFF.
  Auto DRY: Selected if using without humidifier.
  Auto Humid: Selected if using with humidifier.

6. Sound Vol.

- Decide alarm sound volume for the ventilator.
- Range: 10 ~ 100 %

7. Graph speed

- Configure waveform graph sweep speed.
- Settings: x1, x2, x4, x8, x16

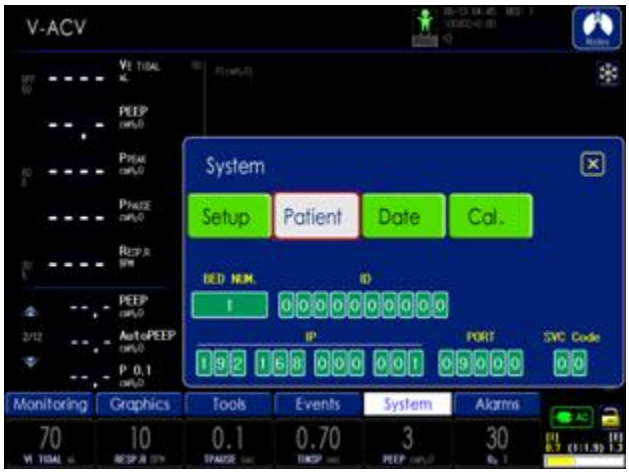
8. CO_2 Unit

- Configure CO_2 Unit.
- Settings: % or mmHg

9. Language

- Configure the language to be used.
- The supported language is English, Russian, Spanish and Chinese.

10.3.2 Patient



Patient information is entered in Patient menu, and the following parameters are configured. Refer to 'Chapter 4 Operation Method' for details.

1. BED Num

- Designate patient's bed number.

2. ID

- Input patient's ID number.

3. IP

- Input IP address for external connection using LAN.

4. PORT

- Input port number for external connection using LAN.

5. PASSWORD

- Configure password (77) for IP and port input.

10.3.3 Date

Ventilator's date is configured in Date menu. MAIN and PNEU SW version, operation time of ventilator, and remaining O_2 % are displayed.

Date configuration sequence is Year, Month, Day, Hour and Minute.

10.3.4 Calibration

In Calibration menu, sensors used in MV2000[SU:M] ventilator are calibrated. Refer to 'Chapter 4 Operation Method' for details.

11. Technical Specification

11.1 System

11.1.1 General

MV2000[SU:M] ventilator selected and acquired the following international standards.

Standards

- EN60601-1:1990
- EN60601-1-1:2001
  (Electromechanical Safety)
- EN60601-1-2:2001
  (Electromagnetic Compatibility Requirement and tests)
- IEC60601-2-12:2001
  (Particular requirements for the safety of lung ventilators for medical use)

Electromagnetic compatibility (EMC)

According IEC60601-2, 2nd Edition

11.1.2 Operating Conditions

- Operating Temperature Range
  : 10 to 40 ℃ (50~104℉)
- Operating Atmospheric Pressure
  : 700 to 1060 mbar (10.2 ~15.4psi)
- Operating Altitude
  : -443~ 3048 m (-1350~ 10,000ft)
- Relative humidity
  : 10 to 90%

11.1.3 Non-operating Conditions

- Storage temperature
  : -15 to 50 ℃
- Storage relative humidity
  : 10 to 90%
- Storage Atmospheric Pressure
  : 500 to 1060 mbar (7.3 ~15.4psi)
- Storage Altitude
  : Up to 6560m (20,000ft)

11.1.4 Power Supply

- AC input voltage
  : 100-120 VAC, 10A, 50/60Hz
  : 200-240 VAC, 5A, 50/60Hz
- AC input FUSE Rating
  : 250V / 6.3A
- Power consumption
  : 84W max
- External DC input voltage
  : 12V/7A Pb battery
- Internal Battery
  : 12V/7A Pb battery
  : Operating time – 3 hours
  : Recharge time – 4 hours

11.2 Ventilator

11.2.1 General

Dimensions (mm)

- Main unit: W330 X D250 X H400
- Display monitor : W310 X D48 X H280
- Cart : W480 X D570 X H770

Weight (kg)

- Device : 37kg(with Battery)
- Cart : 20kg

11.2.2 Gas Supply

- Gas Quality
  Gases supplied must be appropriate to medical gas standards.

- O_2 and air supply Pressure range
  :35 ~ 90 psi

- Oxygen sensor life
  :1,000,000 Vol.% h

- Safety pressure Pneumatic
  :30 psi +/- 10 %

- Inspiration Pressure Limit
  :100 cmH_2O +/-10%

11.2.3 Patient System Connectors

- Conical fittings (mm)
  : Inspiratory limb connector - ISO 22mm male
  : Expiratory limb connector - ISO 22mm male

- Air and Oxygen inlets
  : DISS male / female

11.3 Alarms

Item	Range	Unit
VE TIDAL HIGH	OFF, 5~2500	mL
VE TIDAL LOW	0~2500	mL
VE MIN HIGH	0.1~50	LPM
VE MIN LOW	0.0~49.9	LPM
R RESP HIGH	3~180	BPM
R RESP LOW	2~179	BPM
P PEAK HIGH	1~120	cmH2O
P PEAK LOW	0~119	cmH2O
O_2 HIGH	OFF, 1~100	%
O_2 LOW	0~100	%
AIR LEAK	OFF, 50~500	mL
Apnea	2~60	sec
SpO_2 HIGH (optional)	OFF, 52~99	%
SpO_2 LOW (optional)	OFF, 51~99	%
PR HIGH (optional)	30~250	BPM
PR LOW (optional)	25~245	BPM
$EtCO_2$ HIGH (optional)	0~10.0	mmHg
$EtCO_2$ LOW (optional)	OFF, 0~9.9	mmHg
INS HIGH (optional)	0~10.0	mmHg
INS LOW (optional)	OFF, 0~9.9	mmHg
RESP HIGH (optional)	3~150	BPM
RESP LOW (optional)	2~149	BPM
Wall O2/Air pressure fail	-	-
Obstructed Tube	-	-
Ventilator in-operation	-	-
Circuit open	-	-

11.4 Ventilation Modes

11.4.1 Controlled Ventilation

Volume Control (VACV)

- Volume Assist Controlled Ventilation

Mechanical ventilation is controlled based on air volume, adjusting inspiratory and expiratory times by force.

Pressure Control (PACV)

- Pressure Assist Controlled Ventilation

This mode controls mechanical ventilation of the patient based on pressure.

Pressure Regulated Volume Control (PRVC)

-Pressure Regulated Volume Controlled Ventilation

Despite advantages of pressure mode, instability of not guaranteeing inspiratory volume, caused by long-term or acute change in patient's respiratory status or long-term change in lung compliance, is removed.

Time Control Pressure Limited (TCPL)
- A peak inspiratory pressures is set by operator, and during inspiration gas flow is delivered to achieve that set pressure. Especially it is recommended mode to neonatal patients.

11.4.2 Supported Ventilation

SPONT
- Spontaneous Ventilation

This mode provides pressure support based on spontaneous ventilation.

tBiLEVEL
- Spontaneous Ventilation

Identical to SPONT mode, but only upper PEEP exists.

11.4.3 Combined Ventilation

VSIMV
(Volume Based Synchronized Intermittent Mandatory Ventilation)
This mode controls ventilation based on air volume according to spontaneous ventilation of the patient.

PSIMV
(Pressure Based Synchronized Intermittent Mandatory Ventilation)
This mode controls ventilation based on pressure according to spontaneous ventilation by the patient.

11.5 Communication / Interface

Serial Port
RS-232C – isolated
For Upgrade Firmware Main Board, Pneumatic Board
Baud rate: 115,200bps

Standard I/O Communication Port

Monitor
12.1" TFT LCD
Resolution: 800 X 600

11.6 Service

WARNING
- A/S on the device must be carried out by an experienced expert trained by our company.
- A/S on the device must be carried out after separating the ventilator from the patient.

CAUTION
Only use parts supplied by our company.

11.7 Accessories

11.7.1 Standard Accessories

- High Pressure Hose

Air Gas / Yellow (P/N : 141400020)

O_2 Gas / Green (P/N : 141400030)

-Display Panel Cable (P/N :142401900)

-O_2 Cell (P/N:140500660) : Installed inside

- PEEP Silicone Plate (P/N : 140601420)

- Test Lung (P/N :140602600)

- Operation Manual (P/N : 141700610)

-Power Cord (P/N : 140600530)

3m, 220VAC

-Fuse (P/N : 141300170)

Inlet 50T 6.3A 250V 20mm

-Wrench Driver (P/N : 140800720)

-Circuit Arm Fix Knob (P/N :140403490)

-53010(O-Ring) (P/N : 142100400)

O-Ring for PEEP Module

-53030(O-Ring) (P/N: 142100410)

O-Ring for PEEP Module

-Monitor Fix Bolt (P/N: 140800330)

M5x12mm Wrench Bolt(For Monitor)

-Body Cover (P/N: 150000160)


MEK

11.8 Setting Parameter

	Setting range	Default
Predicted Body Weight	~ 150 kg	-
Tidal Volume	5 ml ~ 2500 ml	
Inspiratory Pressure	5 ~ 80 cmH_2O	-
Pressure Support	0 ~ 60 cmH_2O	5 cmH_2O
Respiratory Rate	2 ~ 150 bpm	-
Inspiratory time	0.2 ~ 9.9 sec	-
Plateau Time (Pause Time)	0 ~ 2 sec	0.1 sec
PEEP	0 ~ 45 cmH_2O	3 cmH_2O
High PEEP(t-Bilevel)	3 ~ 45 cmH_2O	10 cmH_2O
Low PEEP(t-Bilevel)	0 ~ 42 cmH_2O	3 cmH_2O
Inspiratory Pressure limit(PRVC/O_2 Stream®)	10 ~ 80 cmH_2O	-
Minute Volume(AutoVent®)	70 ~ 300 %	-
Inspiratory Flow rate(O2 Stream®)	5 ~ 40 lpm	-
Enable inhalation trigger(En-sense)	10 ~ 80 %	30 %
Exhalation trigger Sensitivity(Ex-trig)	10 ~ 80 %	30 %
F-end	25 ~ 100 %	70 %
Inspiratory Rising Time	0.1 ~ 0.5 sec	0.2 sec
Inspiratory Rising Time PSV	0.1 ~ 0.5 sec	0.2 sec
Trigger sensitivity Pressure	OFF, 0.5 ~ 20 cmH_2O	3 cmH_2O
Trigger sensitivity Flow	OFF, 0.5 ~ 20 L/min	3 lpm
O_2 %	21 ~ 100 %	30 %
Sigh, Tidal volume	Off, 30/60/90/120	
BTPS	OFF, Auto Dry, Auto Humid	
MASK	ON, OFF	
Proximal Sensor	ON, OFF	
Power(Single/Dual High Frequency Ventilation)	1 ~ 100 %	
MAP(Single/Dual High Frequency Ventilation)	5 ~ 60 cmH_2O	20 cmH_2O
Frequency(Single/Dual High Frequency Ventilation)	2 ~ 20 Hz	20 Hz
IMV Ex duration(Dual High Frequency Ventilation)	0.3 ~ 6.0 sec	2.0 sec
ExRate(Dual High Frequency Ventilation)	2 ~ 120 bpm	12 bpm

	Setting range	Default

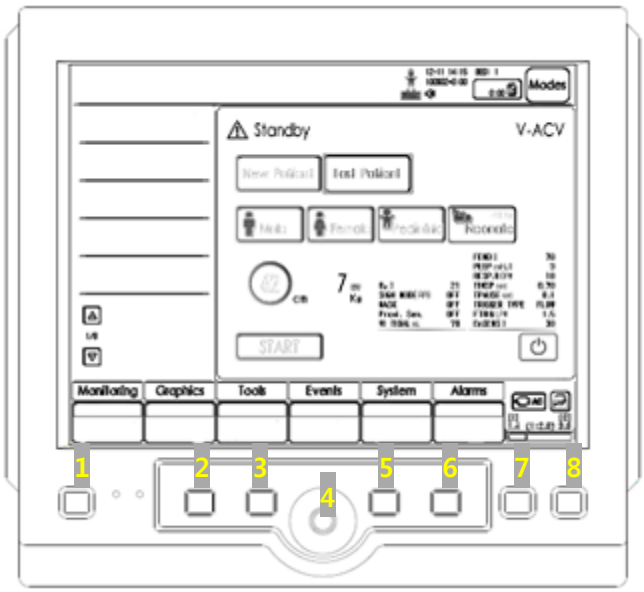
Nebulizer	10 ~ 180min	Off
Inspiration pause	-	Measures lung compliance, resistance, elasticity, Time constant
Expiration pause	-	Measures auto-PEEP
Manual Inspiration	-	Delivers one mandatory breath
100% O_2	-	Delivers 100% oxygen for 3 minutes
Key lock	-	Key&Touch Lock
Graph freeze	-	Freezes waveform & loop graphs
Alarm silence	-	Turns off alarm sound for 2 minutes
Alarm reset	-	Clear active alarms

※ Measurement Condition

1. Pressure
   A. ±(1.7 + 4% of the actual reading) cmH_2O
2. Volume
   A. ±15 % (Tidal Volume >100ml)
   B. ±20ml (Tidal Volume ≤100ml)
3. Rate
   A. ±2 bpm
4. O_2
   A. 3%
5. Inspiratory Time
   A. ±10%

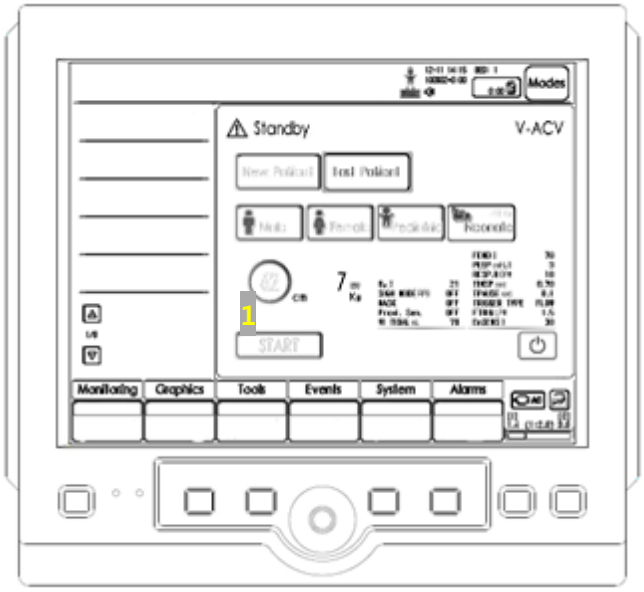
12. Summary of Screen Usage

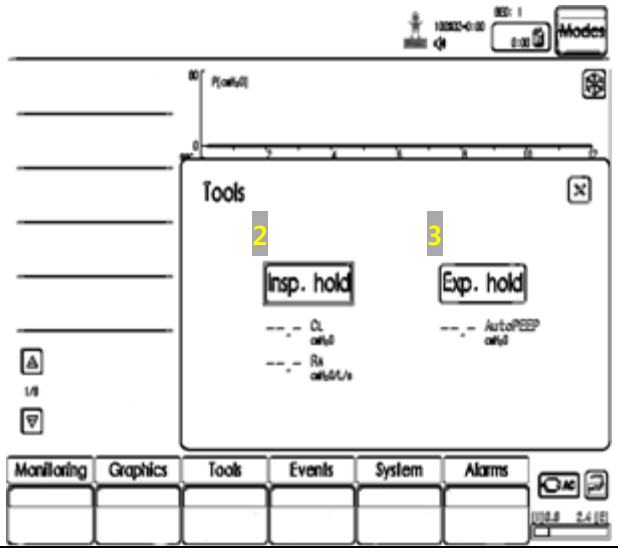
12.1 Fixed Keys



1) On/Off Switch, Standby	To turn power ON, push this button for 0.5 second. To turn power OFF, push this button during VENT mode operation for 10 seconds. If the device is not in operation, power is turned OFF by pushing for 5 seconds. The device enters stand-by mode by pushing the button during VENT mode operation.
2) Manual Inspiration	Inspiration is manually carried out once using current setting values by pushing this button.
3) O_2 100%	100% oxygen is supplied for three minutes by pushing 100% O_2 key. Concentration is automatically returned to original oxygen concentration after three minutes. If O_2 100% button is pushed again during three minutes of 100% oxygen supply, 100% O_2 supply is terminated and original concentration is returned.
4) Encoder	Rotate the encoder to select wanted menu or wanted setting value. Sub menu is selected or setting value is saved by pushing the encoder.
5) Exit	This button is used with encoder and touch key to operate menu or to clear the touch window.
6) Run	This button is used for final operation of the ventilator using values in ventilator set.
7) Alarm Silence (2min)	Auditory signal of alarm is muted for two minutes.
8) Alarm Reset	This is operated upon reset of alarm. Alarm light is turned off.

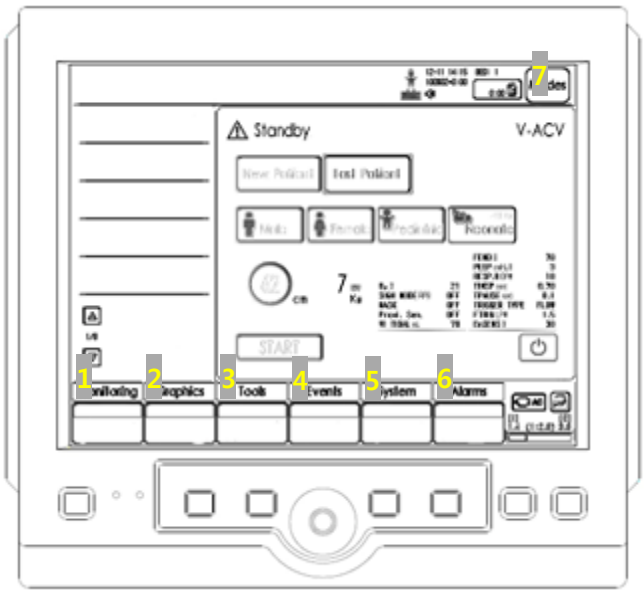
12.2 Special Function Keys





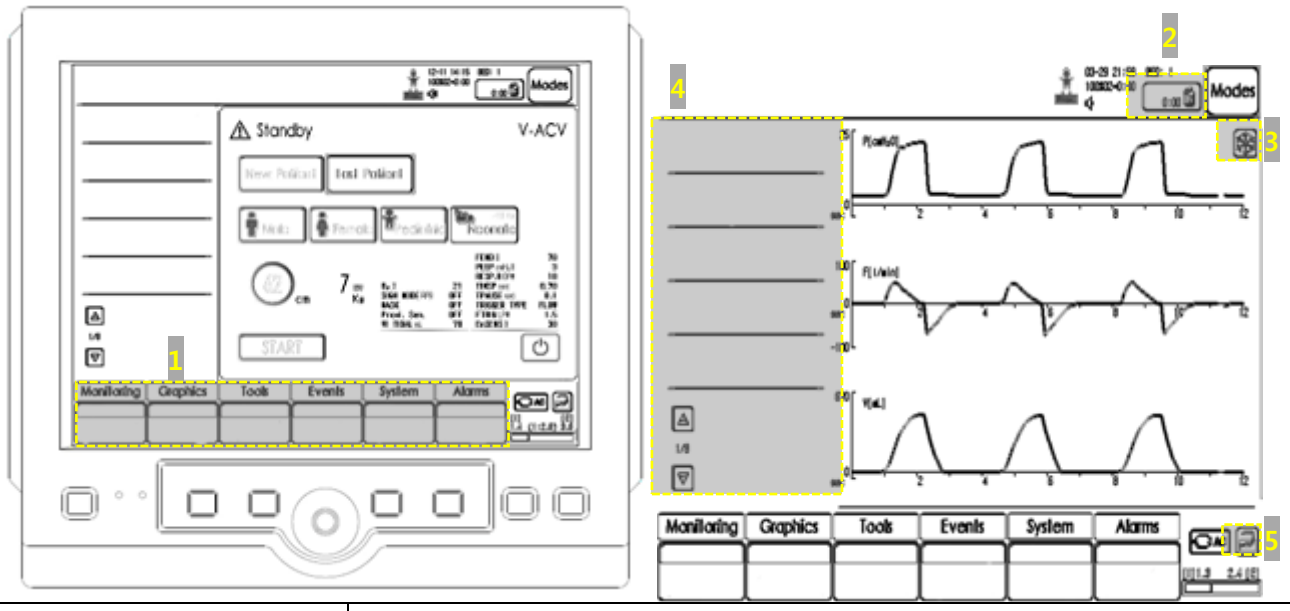
1) START	START button executes ventilation on the patient using current setting.
2) Insp.Hold (Inspiratory Hold)	This can be executed in Tools menu among menu at the bottom. Temporary hold function is operated after inspiration whenever button is pushed by user. Compliance and resistance are measured after maintaining hold for one second. Inspiration end pressure of lung can be accurately measured using this function. It can be used during x-ray or to determine static compliance, static resistance, elastance and time constant calculation.
3) Exp.Hold (Expiratory Hold)	This can be executed in Tools menu among menu at the bottom. Temporary hold function is operated after expiration whenever button is pushed by user. Auto PEEP is measured after maintaining hold for one second. Expiration end pressure of lung can be accurately measured using this function.

12.3 Menu Keys



1) Monitoring	Comprehensively shows data measured in each mode.
2) Graphics	Configures screen layout and trend timing.
3) Tools	Uses inspiration hold and expiration hold functions.
4) Events	Events that occur during operation of the ventilator can be checked.
5) System	Composed of operation condition setting, patient information, date, and various calibration settings.
6) Alarms	This menu is used to configure various alarms on measurement values.
7) Modes	If Modes is pushed to select ventilation mode, setting window for corresponding ventilation mode appears. Accept / Cancel can be used to save or cancel the selected ventilation mode. If Accept button is pushed, new ventilation starts as configured by user. If Cancel button is pushed, existing ventilation is maintained.

12.4 Screen Touch Pads



1) Direct Access	When changing setting values during ventilation, setting values for each ventilation mode can be changed.
2) Nebulizer	Nebulizer is turned On/Off using touch pad.
3) Freeze	If Freeze pad is pushed, graph freezes temporarily. Trend value can be searched in trend screen.
4) Measurement Value	Measurement values during ventilation are displayed. More measurement values can be seen by touching arrows. Use [Monitoring] menu to see values at once.
5) Touch Screen key Lock	Push Key Lock pad to disable all touches on the screen. Touches are enabled by pushing Key Lock once again.

13. MV2000[SU:M] Series Features

		SU:M1	SU:M2	SU:M3
Mode	V-ACV	○	○	○
	P-ACV	○	○	○
	SIMV	○	○	○
	SPONT	○	○	○
	Apnea Backup	○	○	○
	Mask Ventilation (Non-Invasive)	○	○	○
	TCPL		○	○
	PRVC		○	○
	tBiLevel		○	○
	AutoVent		○	○
	HFV(SHFV/DHFV)			○
Optional	O_2 Stream (with Nasal Cannula)	○	○	○
	Hemo Dynamics (with SpO_2 and $EtCO_2$)	○	○	○
	Proximal Sensor (Adult & Neonate)	○	○	○

Appendix 1. Introduction

Unless specifically mentioned, operation and information on MV2000[SU:M] ventilator shall be based on details of this User Manual.

This Annex describes sterilization and maintenance of the ventilator.

Warning, Caution, and Important Matters

> ⚠ **WARNING**
> **The mark above is "WARNING."**
> The mark warns users on precautions that may cause great or irrecoverable damage to devices and patients.

> ⚠ **CAUTION**
> **The mark above is "CAUTION."**
> The mark warns users on precautions that may cause damage to devices and patients.

> ⚠ **ATTENTION**
> **The mark above is "ATTENTION."**
> The mark indicates information and tips on for use and easy connection of components.

> **NOTE**
> **The mark above is "NOTE."**
> The mark describes relevant items and additional information. Contents included in the note mark do not damage patients and devices.

Overall Outline

Since there are diverse sterilization methods by different medical institutions, our company cannot provide a specific sterilization method that satisfies all medical institutions. In addition, our company is not responsible for the effects of sterilization process performed while configuring patient treatment.
Our company recommends using devices and methods described in this Annex. Unless certified by our company, we do not guarantee compensation for damages in the device or parts using methods not recommended here.

> ⚠ **CAUTION**
> - All users must always be aware of risks of contaminated parts when separating and cleaning the ventilator.
> - All disposable parts must be handled according to disposal method of each hospital or disposed using eco friendly methods.

ATTENTION

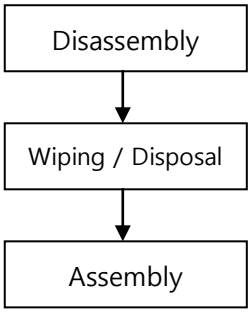
- When handling ventilator parts, follow infectious substance management guideline by each hospital.
- If possible, immediately clean the device after use. Always clean before sterilization or disinfection. When drying, make sure there are no blood and impurities on parts and device.
- Water quality may influence cleaning and sterilization. Our company recommends use of drinking water quality as minimal water quality.
- Our company recommends use of bacteria filters or equivalent devices in order to reduce spread of bacteria from patients to expiratory cassette. Use of such filters and devices can reduce risk of infection. Lifespan of the product can be extended by reducing cleaning process of expiratory cassette.

Appendix 2. Cleaning / Sterilization

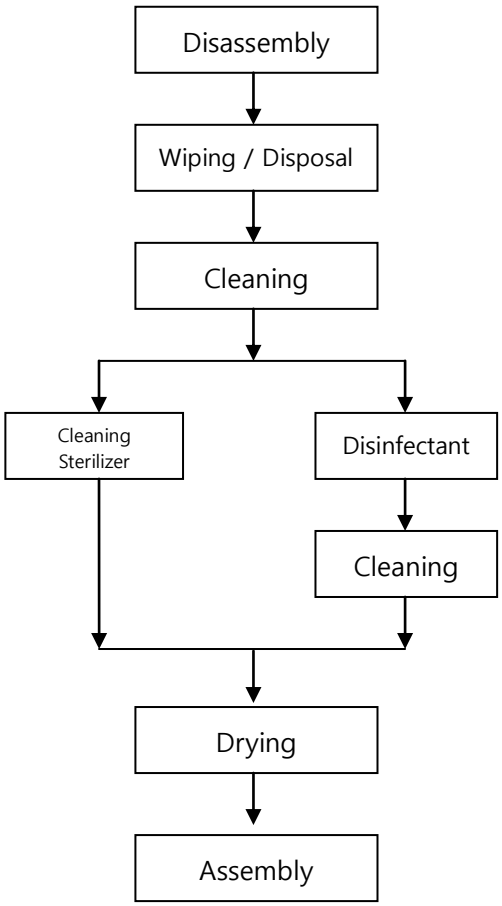
Appendix 2.1. Summary of Cleaning / Sterilization Process

This Appendix provides summary of cleaning, sterilization, and disinfection processes.

Cleaning process using bacteria filter



Cleaning process without using bacteria filter



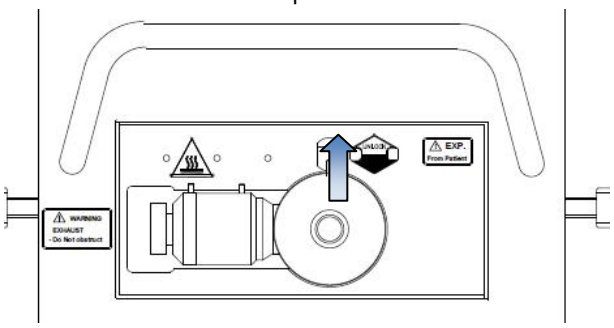
Appendix 2.2. Preparation / Disassembly

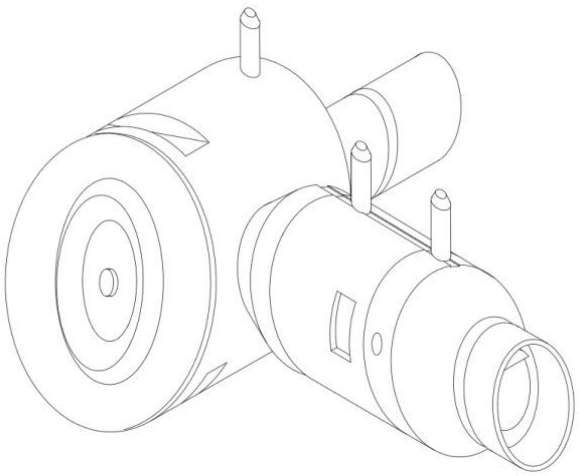
Appendix 2.2.1 Preparation

- Turn off the power of ventilator using switch button on the back of main body.
- Separate main power and gas hoses from the ventilator.
- Turn off the power of surrounding devices and separate them from the ventilator.

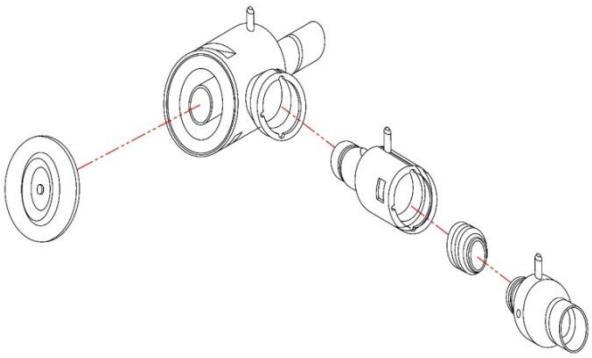
Appendix 2.2.2 Expiratory Cassette Separation

- Separate all silicon hoses connected to expiratory cassette.
- After raising the lock handle, pull the cassette bundle forward for separation.





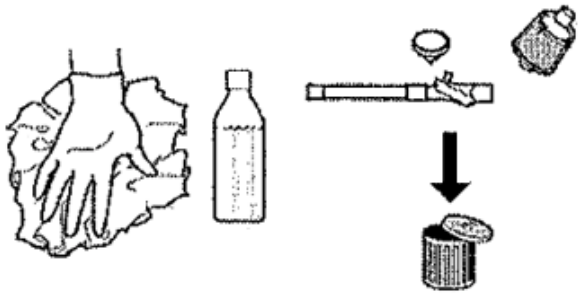
- Cassette is separated by rotating the junction marked in the drawing below.
- Disassemble the cassette as in the drawing.



Appendix 2.3. Wiping / Disposal

Appendix 2.3.1. Wiping

Wipe ventilator and all parts using soft cloth with detergent or disinfectant.



CAUTION

Do not place battery, $EtCO_2$ module and SpO_2 sensor in any solution.

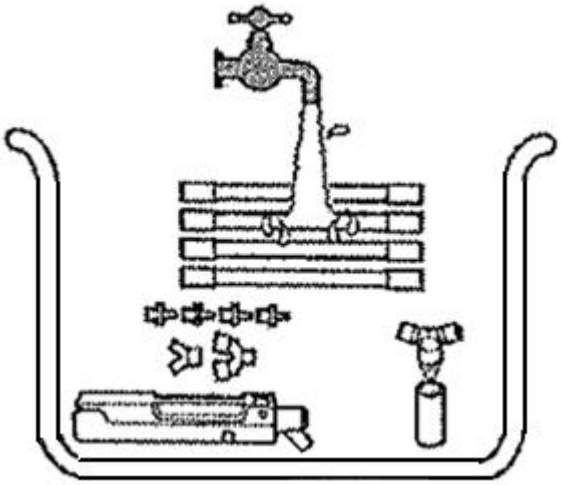
NOTE

In case of severe degree of contamination, ethyl alcohol (70%) or isopropyl alcohol (70%) is used. Avoid contact with electronic connectors.

Appendix 2.3.2 Disposal

- Bacteria filters
- Humidifier / HME (disposable humidifier)
- Disposable tube

Appendix 2.3.3. Cleaning Before Sterilization



If cleaning process is not included prior to sterilization using cleaning sterilizer, take the following steps.

- Place parts in water (<35℃/95℉) and clean.
- Make water pass through the parts.

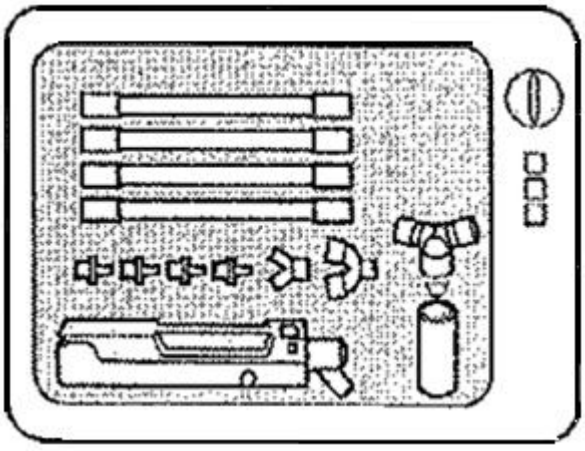
ATTENTION

Cleaning of cassette immediately after use is another effective method of sterilization. Cleaning can easily remove contaminants and reduce risks of cross infection between patients.

Appendix 2.4 Sterilization Process

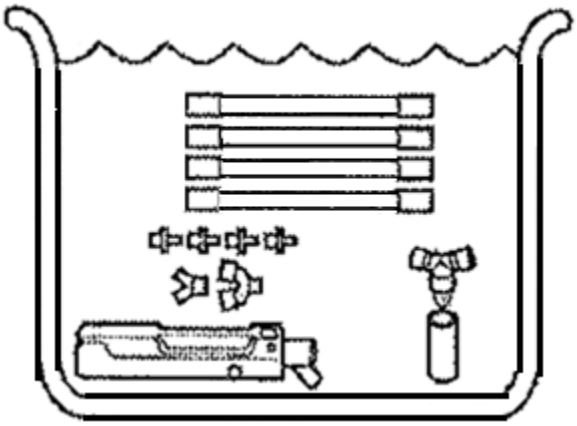
> **ATTENTION**
> - Since expiratory cassette is a precise part, it must be handled carefully.
> - All parts must be dried after sterilization.

Appendix 2.4.1 Cleaning Sterilizer



- Clean all parts in a cleaning sterilizer at temperature of 85-95℃ (185-203℉).

Appendix 2.4.2 Disinfectant



Place parts in one of the following disinfectants.

- Alcohol (ethyl or isopropyl alcohol 70%)
- CidexOPA

- Hexanios G+R
- Aniosyme DD1
- Gigazyme Plus
- Anioxide 1000

> **ATTENTION**
> Follow recommendations and guidelines by the manufacturer. Failure to do so may cause damage on the product.

Appendix 2.4.3 Rinsing After Sterilization

- Rinse sufficiently with water to remove all disinfectants from parts. Clean parts in running water.
- Turn upright, shake horizontally, and tilt.
- Repeat the above step at least 5 ~ 7 times.

> **ATTENTION**
> Chemical precipitates may influence the patient, induce leakage, or damage parts.

Appendix 2.4.4 Drying Method

Expiratory cassette must be dried before use.
Dry the cassette using the following method.

- Repeat shaking and tilting of expiratory cassette 5 ~ 7 times.
- Dry expiratory cassette in a dryer of up to 70℃ (158℉) for one hour.
- If there is no dryer, air dry expiratory cassette for 12 ~ 24 hours.

> **CAUTION**
> Since inside of expiratory cassette can be damaged, do not dry expiratory cassette using high pressure gas.

> **NOTE**
> If drying process is carried out by cleaning sterilizer, no separate drying is required.

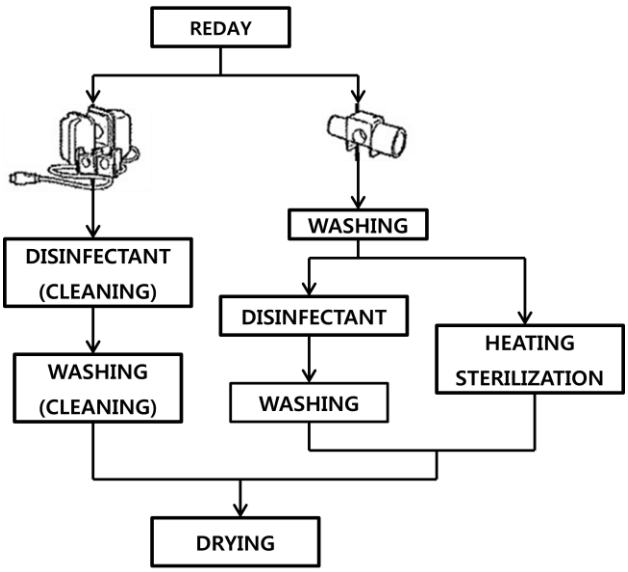
Appendix 2.5 Assembly

- Assemble expiratory cassette in the reserve sequence as disassembly.

> **WARNING**
> - Make sure that expiratory cassette makes "clicking" sound during assembly.
> - After cleaning and sterilization, record it in a log according to the hospital's regulation.
> - Once assembly is complete, perform pre-use check using test lung.
> - If the product does not operate properly, re-check assembly of expiratory cassette and verify connection of tubes.

Appendix 2.6 EtCO2 Module Cleaning / Sterilization

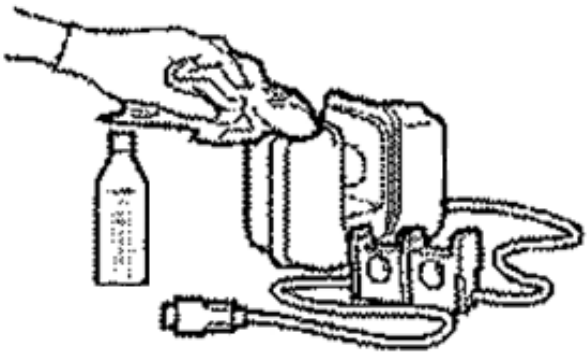
Clean and sterilize after using on a patient or dispose according to the hospital's policy.



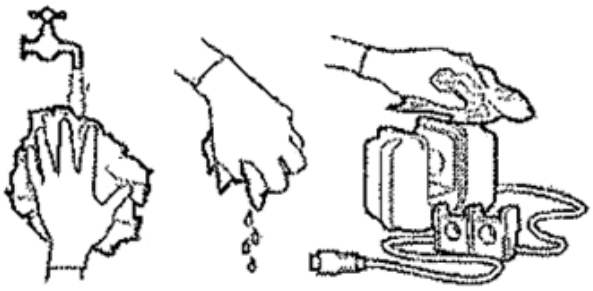
Appendix 2.6.1 Preparation

- Separate $EtCO_2$ from the ventilator.

Appendix 2.6.2 $EtCO_2$ Module Body



- Wipe the main body using soft cloth with disinfectant (Cidex OPA or isopropyl alcohol 70%).



- After cleaning and sterilization, wipe the module using soft cloth soaked in water.
- Module must be dried after cleaning and sterilization.

Appendix 2.6.3 Airway Adapter

Airway adapter can be disinfected or sterilized.

ATTENTION

Do not place EtCO2 module in solutions like water.

- Place airway adapter in Cidex OPA solution during sterilization.
- Clean airway adapter using distilled water.
- Airway adapter must be dried and wiped before re-using.

ATTENTION

Follow recommendations and guidelines of the manufacturer on the use of disinfectants.

- Airway adapter for adults can be sterilized for 4 ~ 7 minutes at 134℃ (273°F) in accordance to sterilization regulation of each hospital.
- After sterilization process, adapter must be dried prior to use.

Appendix 2.7. Accessories

MEKICS Humidifier VH-2600

Refer to User Manual of MEKICS Humidifier for details on cleaning and sterilization methods.

Appendix 3. Maintenance

Appendix 3.1. Preventive Maintenance

The device must be regularly inspected. Preventive maintenance included in service manual is carried out in case the amount of use of the ventilator is smaller than ordinary use. Receive at least one inspection per year from the technical team of our company. In general, a ventilator is expected to run about 5,000 hours per year.

Always clean inspiratory channel prior to preventive maintenance. Inspiratory cleaning must be performed by a trained expert.

Appendix 3.2. Battery Replacement

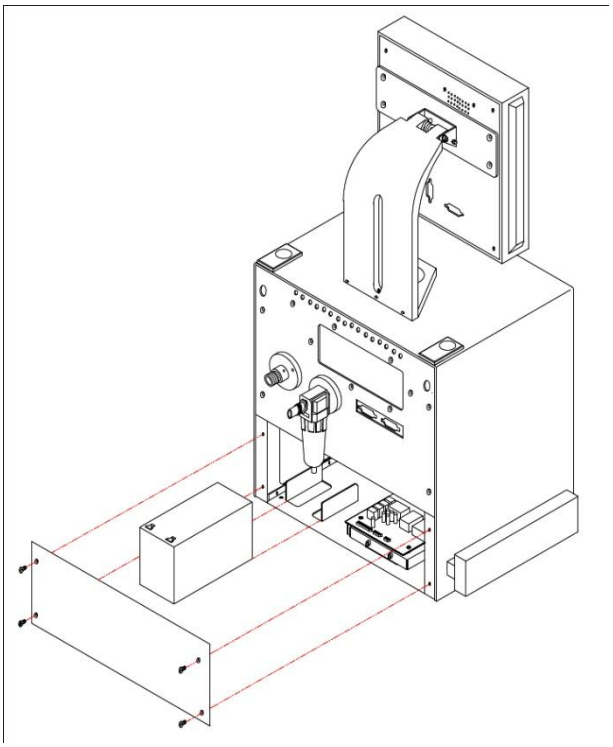
Internal battery is used to supply power to the product when the patient is moving. Battery is automatically charged when external commercial power is supplied. Once commercial power supply is terminated or power supply is suspended accidentally, power is automatically switched to internal battery. Remaining battery is indicated on the LCD monitor.

If there is a problem in commercial power or patient must be transported while the product is in operation, battery must be charged. Replace the battery if it is considered inadequate.

If voltage is inappropriate, measurement value may result in errors. If battery is low, connect to commercial power.

In case of abnormality in battery, contact [Sales / Customer Service] to receive necessary service.

Refer to the following diagram for battery replacement.



WARNING

Be careful about polarity when replacing battery. Connect (+) to red and (-) to black (if polarity is mistaken, it may damage the product).

Since current is high, battery may explode from short circuit and cause harm on human body.

Use rated voltage and current (12V ⎓, 7A).

Appendix 3.3. Accessories

Fischer & Paykel Humidifier MR850

Refer to User Manual of Fischer & Paykel Humidifier for details on cleaning and sterilization methods.

Appendix 3.4. Warranty Period

- This product was manufactured based on strict quality management and testing process of our company.
- Compensation criteria for product repair and replacement are as announced in "Consumer Injury Compensation Rule" by the Economic Planning Board.
- Warranty period for this product is regulated as one year since installation. However, warranty period for LCD, battery and O2 sensor is six months.
- If the product shows defects under normal use during warranty period, our customer service team will repair defects free of charge during warranty period.
- Prescribed service fees are levied after repair in the following cases.
  - Defect from natural disasters such as fire, earthquake and lightning
  - Defect from inappropriate movement or carelessness in use of the product after installation
  - Defect from repair or renovation made by an individual other than service agents designated by MEKICS
- Preparations for repair requests
  - If defect occurs, immediately stop the use and check details on the defect in this manual.
  - Before contacting our company's customer service team for repair request, please check model name, manufacture number, purchase date and problem.

> ⚠ **CAUTION**
> If defect is caused by inappropriate handling or careless management of the product, the manufacturer and its sales agencies are not responsible for any damages.

Please contact the following numbers and addresses to receive various services and products or to contact the Sales Department of our company.

[Manufacturer / Customer Service Team]

MEK ICS Co., Ltd.

144-3 Sangdaewon-dong Jungwon-gu Seongnam, Gyeonggi Province

5F, 5th Woorim Lions Valley, Buliding A

Sales: +82-70-7119-2520

Customer Service: +82-70-7119-2552

FAX: +82-31-735-2761

Web site: http://www.mek-ics.com

E-mail:customer@mek-ics.com

We are also receiving customer complaints through MEK ICS web site. If you experience any discomforts or improvements to be made on the product, please feel free to contact our company or its customer service team at any time.