

SV300

Ventilator

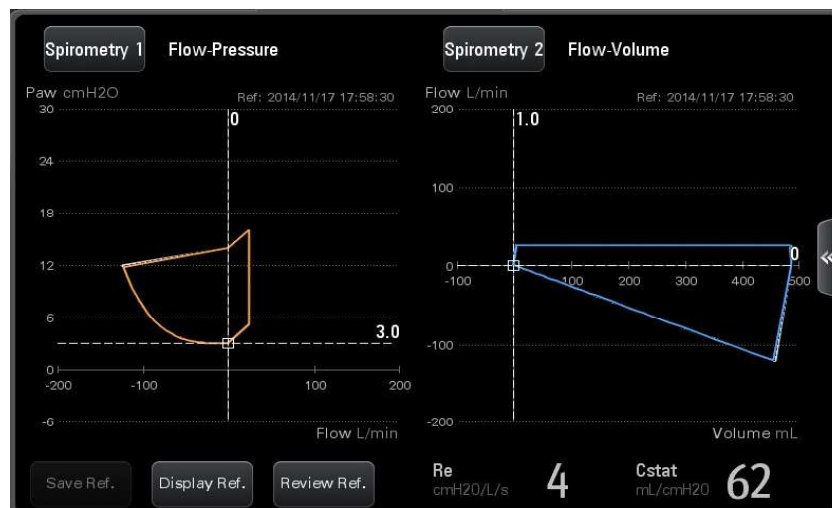
Operator's Manual



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The screen as shown below is displayed by pressing the  button.



4.6.4 Exit freeze status

In freeze status, press the **[Freeze]** key to exit freeze status. In freeze status, if no operation is performed on the ventilator for more than three (3) minutes, the system exits freeze status automatically.

4.7 Lock Screen

Press the  soft key on the main screen to enter locked status, and the **[Screen locked. Press the Lock key to unlock screen.]** prompt message is displayed. During the period of screen locked, only , O₂↑ Suction, and  key are enabled. Touch screen, control knob, and other keys are disabled. Press this key a second time to unlock the screen.

6 Ventilation

6.1 Turn on the System

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

NOTE

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



WARNING

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

- Always run System Check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use. Do not use the ventilator until necessary repairs are completed and all tests have passed.
 - Before running System Check, disconnect the patient from the equipment and ensure that a backup ventilation mode is available for patient ventilation.
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To enter the System Check screen,

- The System Check screen is accessed automatically after powering on the system.
- On the non-standby screen, select the [**Standby**] button and enter the Standby status after your confirmation. Select the [**System Check**] button in the Standby status to enter the System Check screen.

The system check screen displays the last system check time. Select the [**Details**] button to query the system check information of the ventilator system, including system check items, System Check results, and System Check time.

Connect the gas supply and block the Y piece as illustrated. Then select [**Continue**] to start System Check item by item.

System Check items include:

- Blower test: test the speed of the turbine blower.
- O₂ flow sensor test: test the flow sensor in O₂ limb.
- Inspiratory flow sensor test: test the inspiration valve and flow sensor.
- Expiratory flow sensor test: test the expiratory flow sensor.
- Pressure sensor test: test the pressure sensors at the inspiratory and expiratory ports.
- Expiration valve test
- Safety valve test
- Leakage (mL/min)
- Compliance (mL/cmH₂O)
- Tube resistance (cmH₂O/L/s)
- O₂ sensor test

System Check result can be:

- Pass: indicates that check of this item is completed and is passed;
- Fail: indicates that check of this item is completed but is failed;
- Cancel: indicates that check of this item is cancelled;
- O₂ Supply Failure: indicates that O₂ supply is insufficient when O₂ sensor test or O₂ flow sensor test is being carried out;
- Monitoring Off: indicates that sensor monitoring function may not be switched on when O₂ sensor test is being carried out.

NOTE

- **Nebulization is disabled in V-A/C, V-SIMV, PRVC-SIMV, AMV and PRVC modes when patient type is pediatric.**
 - **When O₂ supply type is low-pressure, pressing the [Nebulizer] key will not activate nebulizer, rather display the prompt message [Fail to Start with Low Pressure O₂ Supply].**
 - **Aerosolized medication may occlude the expiration valve and flow sensor. Please have them checked and cleaned after nebulization.**
 - **Nebulization may cause fluctuation in the patient's FiO₂.**
 - **The ventilator switches off the nebulizer flow when the inspiratory flow is less than 15 L/min.**
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9.5 O₂ ↑ (O₂ enrichment)

O₂ ↑ is also called as O₂ enrichment. It means to deliver oxygen with concentration higher than normal level within the specified time period. In the adult patient group, the O₂ enrichment function delivers 100 % oxygen. In the pediatric patient group, the O₂ enrichment function delivers 1.25 times of the current oxygen concentration or 100 %, whichever is less.

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

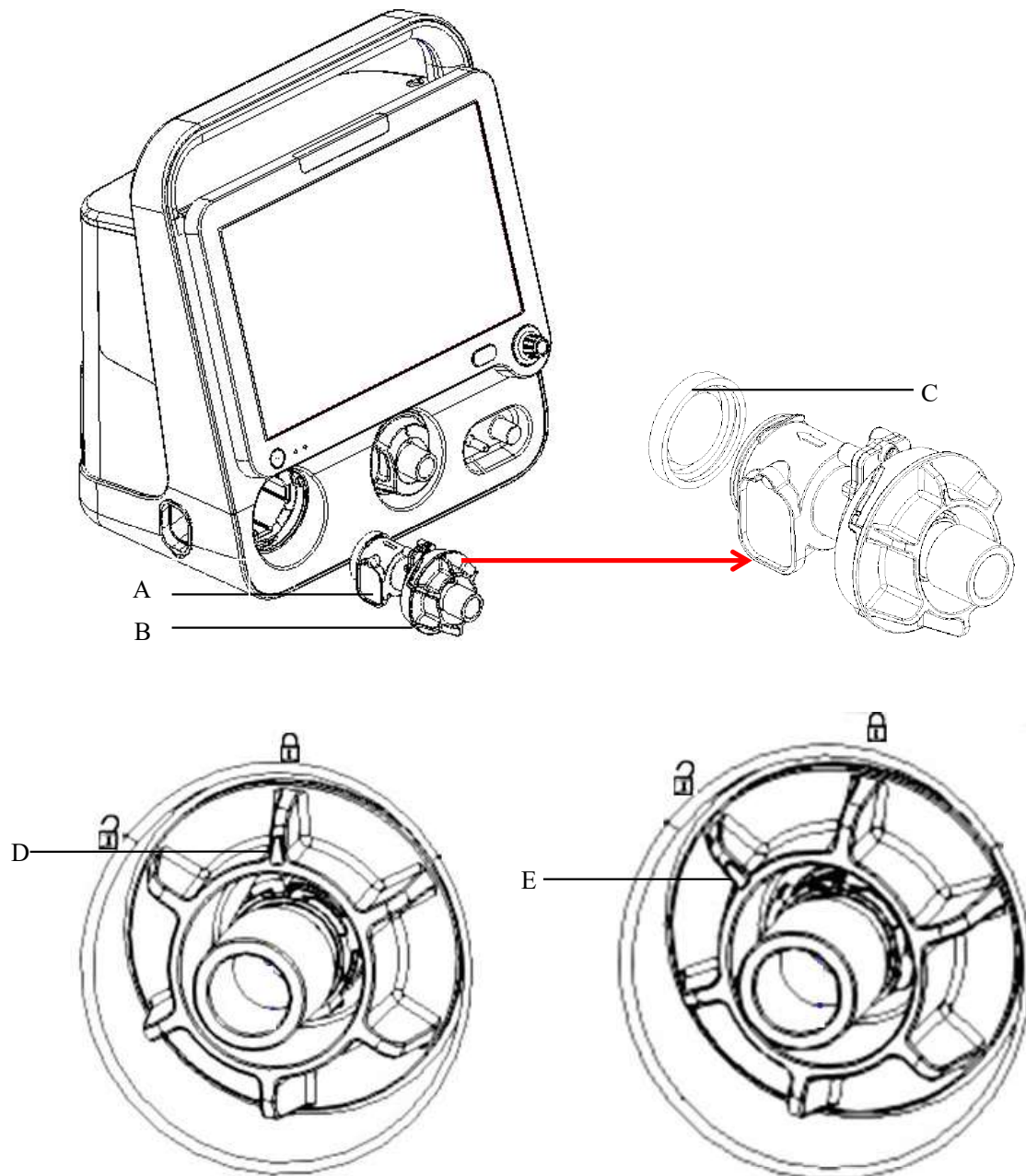
When the 2-minute period of oxygen enrichment is up or the [O₂ ↑ Suction] key is pressed again, the ventilator terminates oxygen enrichment.

NOTE

- **O₂ ↑ (oxygen enrichment) is disabled in Standby status.**
 - **When O₂ supply type is low-pressure, pressing the [O₂ ↑ Suction] key will not activate oxygen enrichment, rather display the prompt message [Fail to Start with Low Pressure O₂ Supply].**
 - **Removing the patient tubing during oxygen enrichment will start suction function. Refer to section 9.6 Suction.**
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11.2 Disassemble the Ventilator's Cleanable and Disinfectable Parts

11.2.1 Expiration Valve Assembly and Membrane



A. Expiration valve assembly

B. Expiration valve handwheel

C. Expiration valve membrane

D. Locked state of the expiration valve

E. Unlocked state of the expiration valve

■ To disassemble the expiration valve assembly:

1. Rotate the expiration valve handwheel counter-clockwise until the indicating arrow  on the handwheel aligns with the  position. Then pull out the expiration valve assembly horizontally.
2. Remove the expiration valve membrane.

■ To install the expiration valve assembly:

1. Install the expiration valve membrane onto the expiration valve assembly.
2. Ensure the indicating arrow  on the handwheel aligns with the  position. Push the expiration valve assembly into the corresponding connector on the ventilator horizontally to the end. Then rotate the expiration valve handwheel clockwise (and depress the handwheel in the direction the expiration valve is installed) until the indicating arrow  on the handwheel aligns with the  position.

A.1.2 Parts List

Symbol	Description	Symbol	Description
Air Low-Pressure Inlet	Air supply (low pressure)	SOL1	Zeroing three-way valve
F1	Dust filter (Air)	PI	Inspiratory pressure sensor
F2	HEPA filter (Air)	F6	Inspiratory pressure sensor filter
Pfilter	Vacuum sensor (Air)	Humidifier	Humidifier
O ₂ Low-Pressure Inlet	O ₂ supply(low pressure)	WT1	Water trap
CV1	Check valve	Patient	Patient
O ₂ High-Pressure Inlet	O ₂ supply(high pressure)	NCV	Nebulizer switch
F3	Filter (O ₂)	R1	Nebulizer resistor
REG	Regulator	Nebulizer	Nebulizer
PSOL	Proportional solenoid valve	WT2	Water trap
F4	Filter screen	F7	Bacteria filter (connecting to inspiratory port)
Q1	Flow sensor	Q3	Expiratory flow sensor
SD1	Level 1 mixed noise reduction chamber	F8	Bacteria filter (connecting to patient port)
Tblower	Temperature sensor	F9	Filter
Blower	Turbine blower	F10	Filter
SD2	Level 2 mixed noise reduction chamber	SOL2	Zeroing three-way valve
Heat Exchanger	Heat exchanger	SOL3	Zeroing three-way valve
Insp. valve	Inspiration valve	PQ3	Expiratory differential pressure sensor
OS	O ₂ concentration sensor	PE	Expiratory pressure sensor
F5	Filter screen	F11	Filter
Q2	Flow sensor	R2	Resistor
CV2	Check valve	R3	Resistor
SV	Safety valve	EV	Expiration valve
Atmosphere	Atmosphere	CV3	Expiratory check valve

Note: the nebulizer mentioned in this manual shall be the legal product with medical device certificate registered in the People's Republic of China. This requirement applies to nebulizers mentioned in other places than here.

A.1.3 Theory

This product is an electronically driven and electronically controlled ventilator. Oxygen is provided by high- or low-pressure oxygen port. Air is inhaled from the ambient atmosphere due to vacuum produced by the turbine motor. During the inspiratory phase, the inspiration valve opens. Gas with specific O₂ concentration is formed in the upstream of inspiration valve after Air and O₂ are mixed. Such gas becomes gas with specific flow or pressure after passing through the inspiration valve and enters the patient's lungs via inspiratory tube. During the expiratory phase, the inspiration valve is closed while the expiration valve opens. The gas reaches the expiration valve from the lungs via the expiratory tube and is finally discharged out of the human body.

When the turbine works to inhale Air from the ambient atmosphere, Filter (F1) filters dust in the Air. Filter (F2) is an HEPA filter for filtering bacteria. After the machine is used or placed for a period of time, dust or foreign substance absorbed on the surfaces of the two filters at the Air inlet can occlude the Air inlet when the dust or foreign substance is accumulated to a certain extent. This may cause insufficient Air intake of the machine and compromise the ventilation performance of the machine. Vacuum sensor (Pfilter) at the Air inlet monitors the vacuum at the Air inlet in real-time, effectively judges filter occlusion at the Air inlet, and gives the replacement prompt.

Check valve (CV1) ensures unidirectional flow of low-pressure O₂. Filter (F3) filters foreign substance in the high-pressure O₂ supply. Regulator (REG) regulates and stabilizes the pressure of high-pressure O₂ supply to ensure the stability and repetitiveness of flow outputted by the rear proportional solenoid valve (PSOL).

Filter screen (F4) is placed before the flow sensor to stabilize gas flow for the convenience of sensor measurement. Flow sensor (Q1) is a hot-wire mass flow sensor which does not require calibration.

The gas supply part includes three parallel limbs: high-pressure O₂, low-pressure O₂, and low-pressure Air. The high-pressure O₂ and low-pressure O₂ converge before mixing with Air. High-pressure O₂ and low-pressure O₂ cannot be used at the same time. Flow sensor (Q1) is placed at the common outlet of low-pressure O₂ and high-pressure O₂ to monitor O₂. Room air enters the machine after passing through filter (F1) and HEPA filter (F2).

Turbine blower (Blower) inhales the room air and externally connected O₂ and outputs them to the rear end of the inspiratory limb after compression. The turbine blower module contains two levels of labyrinth, which are located in the upstream and downstream of the turbine blower respectively. Air and O₂ are inhaled by the turbine blower after going through the first level of labyrinth chamber (SD1). The mixed gas of Air and O₂ is then compressed by the turbine blower and enters the second level of labyrinth chamber (SD2). These two levels of labyrinth chamber mix Air and O₂ and reduce noise. The turbine blower motor has a thermal conductive metal piece which conducts heat for heat dissipation via a cooling fan.

The large-diameter inspiration valve (Insp. valve) controls inspiratory pressure or flow. This valve uses voice coil motor as the driving component. In case of power failure, the valve port is automatically sealed via spring preload. When the voice coil motor takes actions, the valve port opens. Different output flows or pressures are acquired by exerting different control currents to the voice coil motor.

The outlet of large-diameter inspiration valve is connected to flow sensor (Q2) which monitors the flow in the inspiratory limb. Flow sensor (Q2) is a hot-wire mass flow sensor which does not require calibration. O₂ sensor (OS) monitors O₂ volume percentage concentration in the inspiratory limb.

Check valve (CV2) prevents patient's expired gas from polluting the components in the upstream of this valve under the single fault condition of expiratory limb being occluded.

Safety valve (SV) ensures that the pressure in the inspiratory limb is kept within the safe range and provides flow to the spontaneous inspiratory channel when the system is powered down. It is controlled by electromagnet. When the ventilator is in normal working state, the electromagnet is powered on and the safety valve is in closed state. When the pressure in the inspiratory limb exceeds the system setting pressure, the electromagnet is powered down and the safety valve is opened to release excess pressure. When the system is powered down, the electromagnet is in power-down state and the safety valve is opened by default. The patient inhales the external gas through the spontaneous inspiratory channel.

The expiration valve assembly integrates the expiration valve (EV) and flow sensor (Q3). Q3 is a diaphragm differential pressure flow sensor. It monitors the front and rear pressure and Flow Calibration processes for calibration via the differential pressure sensor PQ3. PE is an expiratory pressure sensor which monitors the airway pressure. F9, F10 and F11 are filters which protect the upstream components from being polluted by the patient's expired gas. R2 and R3 are resistors which flush weak flow introduced to the expiration valve from the gas source, preventing water vapour condensation from occluding the pressure measurement tubes. CV3 is a check valve which prevents gas from flowing in the reverse direction.

Audio indicator	
Speaker	Gives off alarm tones and key tones; supports multi-level tone modulation. The alarm tones comply with the requirements of IEC60601-1-8.
Buzzer	Gives off auxiliary audio alarm in case of speaker malfunction.
Connector	
Network connector	A connector which supports connection with a PC to perform software upgrade and connection with external medical and information device.
RS-232 connector	Connects to the external calibration device for calibrating pressure. An external medical device can be connected via this connector to communicate with the ventilator.
USB connector	Exports captured screen, conducts ventilator software upgrade, configuration information export and history data (such as patient data, alarm log, calibration table) export, configuration transfer between machines of the same type via USB device.
Nurse call connector	Connects to the hospital's nurse call system.
VGA connector	Outputs VGA video signals with the same contents to the primary display and connects to the external display (supporting display with resolution of 1280*800).

B.5 Pneumatic System Specifications

NOTE

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

High-pressure oxygen inlet	
Gas type	O ₂
Pressure range	280 to 600 kPa
Rated flow requirement	No less than 120 L/min (STPD)
Connector	NIST or DISS
Fresh gas	Fresh gas is called after supplied Air and O ₂ are mixed.
Low-pressure oxygen inlet	
Pressure range	Less than 100 kPa
Maximum flow	15 L/min(STPD)
Connector	CPC quick connector
Inspiration module	
Peak flow in case of single supply gas(air)	≥210 L/min(BTPS)

D.2 Technical Alarm Messages

Source	Alarm message	P	Cause and action
Power board	Battery 1 Failure 01	H	The temperature of battery 1 is higher than expected.
			Contact your service personnel.
	Battery 1 Failure 02	H	Battery 1 Charge Failure
			Contact your service personnel.
	Battery 1 Failure 03	H	Battery 1 Aging
			Contact your service personnel.
	Battery 1 Failure 04	H	Battery 1 Comm Error
			Contact your service personnel.
	Battery 1 Failure 05	H	Battery 1 Failure
			Contact your service personnel.
	Battery 2 Failure 01	H	The temperature of battery 2 is higher than expected.
			Contact your service personnel.
	Battery 2 Failure 02	H	Battery 2 Charge Failure
			Contact your service personnel.
	Battery 2 Failure 03	H	Battery 2 Aging
			Contact your service personnel.
	Battery 2 Failure 04	H	Battery 2 Comm Error
			Contact your service personnel.
	Battery 2 Failure 05	H	Battery 2 Failure
			Contact your service personnel.
	Battery Temp. High. Connect Ext.Pwr.	M	Battery temperature is a bit high during discharge.
			Connect to the external power supply.
	Battery Temp High. Syst maybe Down	H	Battery temperature is too high during discharge. The system may be down.
			Connect to the external power supply.
	Battery in Use	L	The current system is powered by battery. Connect to the external power supply.
			Connect to the external power supply.
	Low Battery. Connect Ext. Power.	M	The remaining battery power is lower than a threshold.
			Connect to the external power supply.
	System DOWN. Connect Ext. Power.	H	Battery power is depleted. The system will shut down in a few minutes.
			Connect to the external power supply immediately.
	Power Board Comm Stop	H	Power board communication stops.
			Contact your service personnel.

	Battery Undetected	H	Battery is not available in the current system.
			Contact your service personnel.
Main control board	Please Reset Date and Time	L	Button cell is available in the system. But the clock is powered down and reset.
			Re-set the date and time.
	Apnea Ventilation Ended	L	This alarm is given when apnea ventilation ends. There is no need to process this alarm.
	Key Error	L	Hardkey or rotary encoder is depressed continuously for more than 35s.
			Contact your service personnel.
	Technical Error 01	M	Keyboard Comm Stop. Keys are faulty.
			Contact your service personnel.
	Technical Error 02	M	Keyboard Selftest Error.
			Contact your service personnel.
	Device Failure 04	H	Ctrl Module Init Error.
			Contact your service personnel.
	Device Failure 05	H	Ctrl Module Comm Stop.
			Contact your service personnel.
	Device Failure 19	H	Power Board Comm Stop.
			Contact your service personnel.
	Device Failure 20	H	SpO ₂ Comm Stop.
			Restart the ventilator or contact your service personnel.
	Device Failure 21	H	Pressure Sensor Zero Point Error.
			Contact your service personnel.
Monitor board	Technical Error 03	M	Turbine blower Temp Sensor Failure.
			Contact your service personnel.
	Technical Error 04	M	Buzzer Failure.
			Contact your service personnel.
	Technical Error 05	M	Atmospheric Pressure Sensor Failure.
			Contact your service personnel.
	Technical Error 06	M	HEPA Pressure Sensor Failure.
			Contact your service personnel.
	Technical Error 07	M	3-way Valve Failure.
			Contact your service personnel.
	Technical Error 08	M	Nebulizer Valve Failure.
			Contact your service personnel.
	Technical Error 09	M	Insp. Temp Sensor Failure.
			Contact your service personnel.
	Device Failure 01	H	Power Supply Voltage Error.
			Contact your service personnel.
	Device Failure 02	H	Memory Error.
			Contact your service personnel.

	Device Failure 03	H	Power Board Selftest Error.
			Contact your service personnel.
	Device Failure 06	H	Ctrl Module Selftest Error.
			Contact your service personnel.
	Device Failure 07	H	Insp. Module Comm stop.
			Contact your service personnel.
	Device Failure 08	H	Exp. Module Comm stop.
			Contact your service personnel.
	Device Failure 09	H	Pressure Sensor Failure.
			Contact your service personnel.
	Device Failure 10	H	Safety Valve Failure.
			Contact your service personnel.
	Device Failure 12	H	Insp. Limb Failure.
			Contact your service personnel.
	Device Failure 13	H	O ₂ Limb Failure.
			Contact your service personnel.
	Device Failure 14	H	Turbine blower Failure.
			Contact your service personnel.
	Device Failure 15	H	Turbine blower Temp Too High.
			Contact your service personnel.
	Device Failure 16	H	Insp. Valve Disconnected.
			Contact your service personnel.
	Device Failure 17	H	Insp. Module Selftest Error.
			Contact your service personnel.
	Device Failure 18	H	Exp. Module Selftest Error.
			Contact your service personnel.
	Device Failure 21	H	Pressure Sensor Zero Point Error.
			Contact your service personnel.
	PEEP Too High	H	Monitored PEEP exceeds PEEP+5 cmH ₂ O (PEEP+10 cmH ₂ O for APRV mode) within any fully mechanical ventilation cycle.
			1. Check the ventilation parameter setup. 2. Check the patient tubing for occlusion.
	PEEP Too Low	M	Patient's PEEP is less than the setting value to a certain extent.
			1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage.
	Airway Obstructed?	H	Tube is occluded.
			1. Check and clean the patient tubing. 2. Check and clean the expiration valve.
	Sustained Airway Pressure	H	The airway pressure measured by any pressure sensor is greater than or equal to the setting PEEP+15 cmH ₂ O for continuous 15 s.

			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the patient tubing for occlusion.
	Airway Leak?	L	Tube is leaky.
			1. Check the patient tubing for leakage. 2. Perform System Check to test the leakage
	Tube Disconnected?	H	Tube is disconnected.
			Re-connect the patient tubing.
	Insp. Limb Airway Obstructed?	M	The patient tubing is bent or occluded in case of O ₂ therapy.
			Check if the patient tubing is occluded or bent. If yes, clear it.
	Pressure Limited	L	In volume mode or pressure mode when ATRC function is enabled, the pressure reaches Paw high alarm limit-5.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check pressure high alarm limit.
	Volume Limited	L	In pressure mode, delivered gas volume exceeds the set TV high limit.
			1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the alarm limits.
	Pinsp Not Achieved	L	Pinsp is less than the pressure setting value by 3 cmH ₂ O or 1/3 of the pressure setting value, whichever is less.
			1. Check the patient. 2. Check TV alarm limits. 3. Check the O ₂ supply. 4. Check the patient tubing for leakage. 5. Check the HEPA filter for occlusion.
	TV Not Achieved	L	TVi is less than the TV setting value for a period time.
			1. Check the patient. 2. Check pressure high alarm limit. 3. Check the HEPA filter for occlusion. 4. Check the O ₂ supply. 5. Check the patient tubing for leakage or occlusion.
	Pressure Limited in Sigh cycle	L	The pressure reaches Paw high alarm limit-5 in sigh cycle.
			1. Check the patient. 2. Check pressure high alarm limit. 3. Check the patient tubing for occlusion. 4. Consider to turn off sigh.
	O ₂ Supply Failure	H	O ₂ pressure is low or high-pressure O ₂ is not connected.

			1. Check connection with O ₂ supply. 2. Check O ₂ supply pressure.
	Tinsp Too Long	L	In PSV mode, Tinsp exceeds 4s for adult and 1.5s for pediatric for continuous 3 cycles. This alarm is not triggered again after pressure sensor or flow sensor failure. 1. Check the patient. 2. Check the ventilation parameter setup. 3. Check the patient tubing for leakage.
	Please Check Exp. Flow Sensor	H	Installing the expiratory flow sensor fails. Contact your service personnel.
	Insp. Gas Temp Too High	H	The gas temperature exceeds 45°C. Restart the machine. 1. Disconnect the patient. 2. Clean the fan dust filter. 3. Restart the ventilator.
	Replace HEPA Filter	L	The resistance of HEPA becomes intense. Contact your service personnel.
	Fan Failure	M	Fan speed error. Restart the machine if the error cannot be corrected. Contact your service personnel.
	Flow Sensor Type Error	H	Installation error of Air flow sensor or O ₂ flow sensor. Contact your service personnel.
	Blower Temperature High	H	Turbine blower temperature exceeds the threshold. 1. Check if the operating ambient temperature of the machine exceeds the maximum operating temperature specified by the vendor. 2. Check if the fan inlet and outlet are occluded. If yes, clear the foreign substance and dust. 3. Check the rotation of the fan. If it runs abnormally (such as abnormal sound or rotation speed), replace the fan.
	AMV: Cannot Meet Target	L	Cannot meet established MV% 1. Check the ventilation parameter setup. 2. Check the alarm limits setting.
	O ₂ Sensor Unconnected	L	The O ₂ sensor is not connected. Connect the O ₂ sensor.
	Please Replace O ₂ Sensor.	M	The O ₂ sensor is used up. Replace the O ₂ sensor.
	Please calibrate O ₂ sensor.	L	Calibrate the O ₂ sensor. Calibrate O ₂ concentration.
	Please perform pressure calibration.	H	Calibrate the pressure sensor. Contact your service personnel.
	Please perform flow	H	Calibrate the flow sensor.