

**SV300**

**Ventilator**

**Operator's Manual**



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# 6 Ventilation

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## 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

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- **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

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### WARNING

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- **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

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- **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.
- O<sub>2</sub> flow sensor test: test the flow sensor in O<sub>2</sub> 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/cmH<sub>2</sub>O)
- Tube resistance (cmH<sub>2</sub>O/L/s)
- O<sub>2</sub> 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;
- O<sub>2</sub> Supply Failure: indicates that O<sub>2</sub> supply is insufficient when O<sub>2</sub> sensor test or O<sub>2</sub> flow sensor test is being carried out;
- Monitoring Off: indicates that sensor monitoring function may not be switched on when O<sub>2</sub> sensor test is being carried out.

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## NOTE

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- **Nebulization is disabled in V-A/C, V-SIMV, PRVC-SIMV, AMV and PRVC modes when patient type is pediatric.**
  - **When O<sub>2</sub> supply type is low-pressure, pressing the [Nebulizer] key will not activate nebulizer, rather display the prompt message [Fail to Start with Low Pressure O<sub>2</sub> 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 FiO<sub>2</sub>.**
  - **The ventilator switches off the nebulizer flow when the inspiratory flow is less than 15 L/min.**
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## 9.5 O<sub>2</sub> ↑ (O<sub>2</sub> enrichment)

O<sub>2</sub> ↑ is also called as O<sub>2</sub> enrichment. It means to deliver oxygen with concentration higher than normal level within the specified time period. In the adult patient group, the O<sub>2</sub> enrichment function delivers 100 % oxygen. In the pediatric patient group, the O<sub>2</sub> enrichment function delivers 1.25 times of the current oxygen concentration or 100 %, whichever is less.

Press the [O<sub>2</sub> ↑ Suction] key and the ventilator starts oxygen enrichment. The indicator light for [O<sub>2</sub> ↑ 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 [O<sub>2</sub> %] parameter setup quick key field.

When the 2-minute period of oxygen enrichment is up or the [O<sub>2</sub> ↑ Suction] key is pressed again, the ventilator terminates oxygen enrichment.

## NOTE


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- **O<sub>2</sub> ↑ (oxygen enrichment) is disabled in Standby status.**
  - **When O<sub>2</sub> supply type is low-pressure, pressing the [O<sub>2</sub> ↑ Suction] key will not activate oxygen enrichment, rather display the prompt message [Fail to Start with Low Pressure O<sub>2</sub> Supply].**
  - **Removing the patient tubing during oxygen enrichment will start suction function. Refer to section 9.6 Suction.**
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## 10.7 AUDIO PAUSED

### 10.7.1 Set AUDIO PAUSED

Push the  key to pause audio alarm of currently active alarms for 120 seconds.

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#### WARNING

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


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#### NOTE

- Under AUDIO PAUSED status, all the alarm indicators work normally except audible alarm tones.
- Under AUDIO PAUSED status, if a new technical or physiological alarm occurs, the AUDIO PAUSED status terminates automatically and audible alarm tones start again.
- When the 120 s countdown time is up, the AUDIO PAUSED status terminates and audible alarm tones start again.



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### 10.7.2 Terminate AUDIO PAUSED

Under AUDIO PAUSED status, pushing the  key or triggering a new alarm will terminate the AUDIO PAUSED status and restore audible alarm tones. The AUDIO PAUSED icon and 120s countdown will disappear from the screen at the same time.

## 10.8 Recent Alarm

When there are currently active alarms, if the number is displayed before alarm messages, it indicates there are multiple all active alarm messages. By selecting the alarm message field, you can view active alarm messages, alarm occurrence time and alarm priority in the accessed most recent alarm window. Up to 9 alarm messages are displayed.

The icon  is displayed when all active alarms are cleared and there are no currently active alarms. By pushing the icon , you can view the most recent inactive alarms in the accessed window (up to 9 alarm messages are displayed). You can also clear the most recent inactive

alarms with the  button.

| <b>Audio indicator</b> |  |
|------------------------|--|
| 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.  |
| <b>Connector</b>       |  |
| 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.

| <b>High-pressure oxygen inlet</b>           |  |
|---|--|
| Gas type                                    | O <sub>2</sub>   |
| 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 <sub>2</sub> are mixed. |
| <b>Low-pressure oxygen inlet</b>            |  |
| Pressure range                              | Less than 100 kPa  |
| Maximum flow                                | 15 L/min(STPD)   |
| Connector                                   | CPC quick connector  |
| <b>Inspiration module</b>                   |  |
| 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.<br>Contact your service personnel.                            |  |
| <b>Main control board</b> | Please Reset Date and Time | L                  | Button cell is available in the system. But the clock is powered down and reset.<br>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.<br>Contact your service personnel.     |  |
|                           | Technical Error 01         | M                  | Keyboard Comm Stop. Keys are faulty.<br>Contact your service personnel.                                       |  |
|                           | Technical Error 02         | M                  | Keyboard Selftest Error.<br>Contact your service personnel.   |  |
|                           | Device Failure 04          | H                  | Ctrl Module Init Error.<br>Contact your service personnel.  |  |
|                           | Device Failure 05          | H                  | Ctrl Module Comm Stop.<br>Contact your service personnel.   |  |
|                           | Device Failure 19          | H                  | Power Board Comm Stop.<br>Contact your service personnel.   |  |
|                           | Device Failure 20          | H                  | SpO <sub>2</sub> Comm Stop.<br>Restart the ventilator or contact your service personnel.                      |  |
|                           | Device Failure 21          | H                  | Pressure Sensor Zero Point Error.<br>Contact your service personnel.  |  |
|                           | <b>Monitor board</b>       | Technical Error 03 | M   | Turbine blower Temp Sensor Failure.<br>Contact your service personnel. |
|                           |                            | Technical Error 04 | M   | Buzzer Failure.<br>Contact your service personnel.                     |
| Technical Error 05        |                            | M                  | Atmospheric Pressure Sensor Failure.<br>Contact your service personnel.                                       |  |
| Technical Error 06        |                            | M                  | HEPA Pressure Sensor Failure.<br>Contact your service personnel.  |  |
| Technical Error 07        |                            | M                  | 3-way Valve Failure.<br>Contact your service personnel.   |  |
| Technical Error 08        |                            | M                  | Nebulizer Valve Failure.<br>Contact your service personnel.   |  |
| Technical Error 09        |                            | M                  | Insp. Temp Sensor Failure.<br>Contact your service personnel.   |  |
| Device Failure 01         |                            | H                  | Power Supply Voltage Error.<br>Contact your service personnel.  |  |
| Device Failure 02         |                            | H                  | Memory Error.<br>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 <sub>2</sub> 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 <sub>2</sub> O (PEEP+10 cmH <sub>2</sub> O for APRV mode) within any fully mechanical ventilation cycle.  |
|                           |   | 1. Check the ventilation parameter setup.<br>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.<br>2. Perform System Check to test the leakage.  |
| Airway Obstructed?        | H | Tube is occluded.   |
|                           |   | 1. Check and clean the patient tubing.<br>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 <sub>2</sub> O for continuous 15 s. |

|                                |   |  |   |
|--------------------------------|---|--|---|
|                                |   |  | <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check the ventilation parameter setup.</li> <li>3. Check the patient tubing for occlusion.</li> </ol>  |
| Airway Leak?                   | L |  | <p>Tube is leaky.</p> <ol style="list-style-type: none"> <li>1. Check the patient tubing for leakage.</li> <li>2. Perform System Check to test the leakage</li> </ol>   |
| Tube Disconnected?             | H |  | <p>Tube is disconnected.</p> <p>Re-connect the patient tubing.</p>  |
| Insp. Limb Airway Obstructed?  | M |  | <p>The patient tubing is bent or occluded in case of O<sub>2</sub> therapy.</p> <p>Check if the patient tubing is occluded or bent. If yes, clear it.</p>   |
| Pressure Limited               | L |  | <p>In volume mode or pressure mode when ATRC function is enabled, the pressure reaches Paw high alarm limit-5.</p> <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check the ventilation parameter setup.</li> <li>3. Check pressure high alarm limit.</li> </ol>  |
| Volume Limited                 | L |  | <p>In pressure mode, delivered gas volume exceeds the set TV high limit.</p> <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check the ventilation parameter setup.</li> <li>3. Check the alarm limits.</li> </ol>   |
| Pinsp Not Achieved             | L |  | <p>Pinsp is less than the pressure setting value by 3 cmH<sub>2</sub>O or 1/3 of the pressure setting value, whichever is less.</p> <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check TV alarm limits.</li> <li>3. Check the O<sub>2</sub> supply.</li> <li>4. Check the patient tubing for leakage.</li> <li>5. Check the HEPA filter for occlusion.</li> </ol> |
| TV Not Achieved                | L |  | <p>TV<sub>i</sub> is less than the TV setting value for a period time.</p> <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check pressure high alarm limit.</li> <li>3. Check the HEPA filter for occlusion.</li> <li>4. Check the O<sub>2</sub> supply.</li> <li>5. Check the patient tubing for leakage or occlusion.</li> </ol>                                   |
| Pressure Limited in Sigh cycle | L |  | <p>The pressure reaches Paw high alarm limit-5 in sigh cycle.</p> <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check pressure high alarm limit.</li> <li>3. Check the patient tubing for occlusion.</li> <li>4. Consider to turn off sigh.</li> </ol>   |
| O <sub>2</sub> Supply Failure  | H |  | O <sub>2</sub> pressure is low or high-pressure O <sub>2</sub> is not connected.  |

|   |   |  |   |
|---|---|--|---|
|   |   |  | <ol style="list-style-type: none"> <li>1. Check connection with O<sub>2</sub> supply.</li> <li>2. Check O<sub>2</sub> supply pressure.</li> </ol> |
| Tinsp Too Long                          | L | <p>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.</p> <ol style="list-style-type: none"> <li>1. Check the patient.</li> <li>2. Check the ventilation parameter setup.</li> <li>3. Check the patient tubing for leakage.</li> </ol>  |   |
| Please Check Exp. Flow Sensor           | H | <p>Installing the expiratory flow sensor fails.</p> <p>Contact your service personnel.</p>   |   |
| Insp. Gas Temp Too High                 | H | <p>The gas temperature exceeds 45°C. Restart the machine.</p> <ol style="list-style-type: none"> <li>1. Disconnect the patient.</li> <li>2. Clean the fan dust filter.</li> <li>3. Restart the ventilator.</li> </ol>  |   |
| Replace HEPA Filter                     | L | <p>The resistance of HEPA becomes intense.</p> <p>Contact your service personnel.</p>  |   |
| Fan Failure                             | M | <p>Fan speed error. Restart the machine if the error cannot be corrected.</p> <p>Contact your service personnel.</p>   |   |
| Flow Sensor Type Error                  | H | <p>Installation error of Air flow sensor or O<sub>2</sub> flow sensor.</p> <p>Contact your service personnel.</p>  |   |
| Blower Temperature High                 | H | <p>Turbine blower temperature exceeds the threshold.</p> <ol style="list-style-type: none"> <li>1. Check if the operating ambient temperature of the machine exceeds the maximum operating temperature specified by the vendor.</li> <li>2. Check if the fan inlet and outlet are occluded. If yes, clear the foreign substance and dust.</li> <li>3. Check the rotation of the fan. If it runs abnormally (such as abnormal sound or rotation speed), replace the fan.</li> </ol> |   |
| AMV: Cannot Meet Target                 | L | <p>Cannot meet established MV%</p> <ol style="list-style-type: none"> <li>1. Check the ventilation parameter setup.</li> <li>2. Check the alarm limits setting.</li> </ol>   |   |
| O <sub>2</sub> Sensor Unconnected       | L | <p>The O<sub>2</sub> sensor is not connected.</p> <p>Connect the O<sub>2</sub> sensor.</p>   |   |
| Please Replace O <sub>2</sub> Sensor.   | M | <p>The O<sub>2</sub> sensor is used up.</p> <p>Replace the O<sub>2</sub> sensor.</p>   |   |
| Please calibrate O <sub>2</sub> sensor. | L | <p>Calibrate the O<sub>2</sub> sensor.</p> <p>Calibrate O<sub>2</sub> concentration.</p>   |   |
| Please perform pressure calibration.    | H | <p>Calibrate the pressure sensor.</p> <p>Contact your service personnel.</p>   |   |
| Please perform flow                     | H | <p>Calibrate the flow sensor.</p>  |   |

# 11 Cleaning and Disinfection

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## **WARNING**

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- Obey applicable safety precautions.
  - Read the material safety data sheet for each cleaning agent.
  - Read the operation and service instructions for all disinfection equipment.
  - Wear gloves and safety glasses. A damaged O<sub>2</sub> sensor can leak and cause burns (contains potassium hydroxide).
  - Reuse of undisinfected reusable accessories or components may cause cross-contamination.
  - To prevent leaks, avoid damaging any component in case of disassembling and reassembling the breathing system. Ensure the correct installation of the system. Make sure of the applicability and correctness of the cleaning and disinfection methods.
  - Disassemble and reassemble the breathing system as described in this manual. If you need further disassembly and reassembly, contact us. Improper disassembling and reassembling may cause breathing system to leak and compromise normal system use.
  - Seeping liquid into the control assembly can damage the equipment or cause personal injury. When cleaning the housing, ensure that no liquid flows into the control assemblies and always disconnect the equipment from the AC mains. Reconnect the AC mains after the cleaned parts are fully dry.
  - To avoid sticky residuals, do not use talc, zinc stearate, calcium carbonate, corn starch, or equivalent materials. These materials can go into the patient's lungs and airways and cause irritation or injury.
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## **CAUTION**

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- To prevent patient exposure to disinfection agents and to prevent premature deterioration of parts, use the cleaning and disinfection methods and agents recommended in this section.
  - To reduce the risk of electrical shock, disconnect electrical power from the ventilator before cleaning and disinfection.
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## NOTE

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- **Clean and disinfect the equipment as required before it is put into use for the first time. Refer to this chapter for the cleaning and disinfection methods.**
  - **To help prevent damage, refer to the manufacturer's data if you have questions about a cleaning agent.**
  - **Do not use organic, halogenated, or petroleum based solvents, anesthetic agents, glass cleaners, acetone, or other harsh cleaning agents.**
  - **Do not use abrasive cleaning agents (such as steel wool, silver polish, or cleaner).**
  - **Keep all liquids away from electronic parts.**
  - **Do not permit liquid to go into the equipment housings.**
  - **Cleaning solutions must have a pH of 7.0 to 10.5.**
  - **After cleaning and disinfection is completed, run System Check before using the equipment. Use the equipment only when System Check is passed.**
  - **The expiration valve assembly, inspiration safety valve assembly, and patient hose of the gas pathways through the ventilator can become contaminated with body fluids and expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.**
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## 11.1 Methods for Cleaning and Disinfection

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### CAUTION

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- **The process for autoclave sterilization of the ventilator inspiration safety valve assembly and the ventilator expiration valve assembly have been tested and found to be in compliance with ISO 17664:2017. Compliance to ISO 17664:2017 only applies when bacterial filters are used to filter the air. Filters must be properly installed on the inspiratory and expiratory ports.**
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Different parts of the ventilator can be disinfected by different methods. You need to select the appropriate method to clean and disinfect the parts based on the actual situations to avoid cross-contamination between the ventilator user and the patient.

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

| Parts  | Recommended frequency          | Cleaning  |   | Disinfection |   |   |   |
|--|--------------------------------|---|---|--------------|---|---|---|
|  |                                | ①   | ② | A            | B | C | D |
| <b>Ventilator Housing</b>  |                                |   |   |              |   |   |   |
| Ventilator external surface (including housing, power cord, supply gas hose) | Each patient                   | ①   |   | A or D       |   |   |   |
| Trolley and support arm  | Each patient                   | ①   |   | A or D       |   |   |   |
| Touch screen   | Each patient                   | ①   |   | A or D       |   |   |   |
| Fan dust filter  | Every four weeks/as necessary* | ②   |   | <b>B</b>     |   |   |   |
| Main unit air outlet dust filter   | Every four weeks/as necessary* | ②   |   | <b>B</b>     |   |   |   |
| Air intake dust filter   | Every four weeks/as necessary* | ②   |   | <b>B</b>     |   |   |   |
| <b>Ventilator inspiration safety valve assembly</b>                          |                                |   |   |              |   |   |   |
| Inspiration safety valve assembly  | as necessary*                  |   | ② | B or C       |   |   |   |
| <b>Ventilator expiration valve assembly</b>                                  |                                |   |   |              |   |   |   |
| Expiration valve membrane (silicone)   | Each patient/weekly            |   | ② | B or C       |   |   |   |
| Expiration valve assembly (except membrane)                                  | Each patient/weekly            |   | ② | B or C       |   |   |   |
| <b>Ventilator patient tubing (reusable)</b>                                  |                                |   |   |              |   |   |   |
| Patient tubing (including water trap, Y piece, adapter)                      | Each patient/weekly            |   | ② | B or C       |   |   |   |
| <b>Other</b>   |                                |   |   |              |   |   |   |
| Mainstream CO <sub>2</sub> sensor  | Each patient/weekly            | Refer to the cleaning and disinfection methods provided by the mainstream CO <sub>2</sub> vendor. |   |              |   |   |   |
| SpO <sub>2</sub> sensor  | Each patient/weekly            | Refer to the cleaning and disinfection methods provided by the attached package insert.           |   |              |   |   |   |
| SpO <sub>2</sub> sensor cable  | Each patient/weekly            | Refer to the cleaning and disinfection methods provided by the attached package insert.           |   |              |   |   |   |
| Nebulizer  | Each patient/weekly            | Refer to the cleaning and disinfection methods provided by the nebulizer vendor.                  |   |              |   |   |   |
| Humidifier   | Each patient/weekly            | Refer to the cleaning and disinfection methods provided by the humidifier vendor.                 |   |              |   |   |   |

| Parts  | Recommended frequency | Cleaning |   | Disinfection |   |   |   |
|--|-----------------------|----------|---|--------------|---|---|---|
|  |                       | ①        | ② | A            | B | C | D |
| <b>Cleaning methods (Wipe and Bath Immersion) :</b>  |                       |          |   |              |   |   |   |
| ① Wipe: wipe with a damp cloth immersed in alkalescent detergent (soap water, etc.) or alcohol solution and then wipe off the remaining detergent with a dry lint free cloth.  |                       |          |   |              |   |   |   |
| ② Immersion: flush with water first and then immerse it in alkalescent detergent (soap water, etc.) (water temperature 40°C recommended) for approximately three minutes. Finally clean with water and dry completely. |                       |          |   |              |   |   |   |
| <b>Disinfection methods:</b>   |                       |          |   |              |   |   |   |
| A: Wipe: wipe with a damp cloth immersed in medium- or high-efficiency detergent and then wipe off the remaining detergent with a dry lint free cloth.   |                       |          |   |              |   |   |   |
| B: Immersion: immerse it in medium- or high-efficiency detergent for more than 30 minutes (recommended time). Then clean with water and dry completely.  |                       |          |   |              |   |   |   |
| C: Steam autoclave at 134°C for 10 to 20 minutes (recommended time).   |                       |          |   |              |   |   |   |
| D: Ultraviolet radiation for 30 to 60 minutes (recommended time).  |                       |          |   |              |   |   |   |

As necessary\*: shorten the cleaning and disinfection intervals if the equipment is used in dusty environment to ensure that the equipment surface is not covered by dust. Clean and disinfect the inspiration safety valve assembly only when the patient's exhaled gas may contaminate the inspiratory limb. For disassembling and installation methods, refer to **10.2.2**.

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

| Name   | Type                              |
|--|-----------------------------------|
| Ethanol (75%)  | Moderately efficient disinfectant |
| Isopropanol (70%)  | Moderately efficient disinfectant |
| Glutaraldehyde (2%)  | Highly efficient disinfectant     |
| Ortho-Phthalaldehyde disinfectant (such as Cidex <sup>®</sup> OPA) | Highly efficient disinfectant     |
| Soap water (pH value of 7.0~10.5)                                  | Rinsing agent                     |
| Clean water  | Rinsing agent                     |
| Steam autoclave*   | Highly efficient disinfection     |

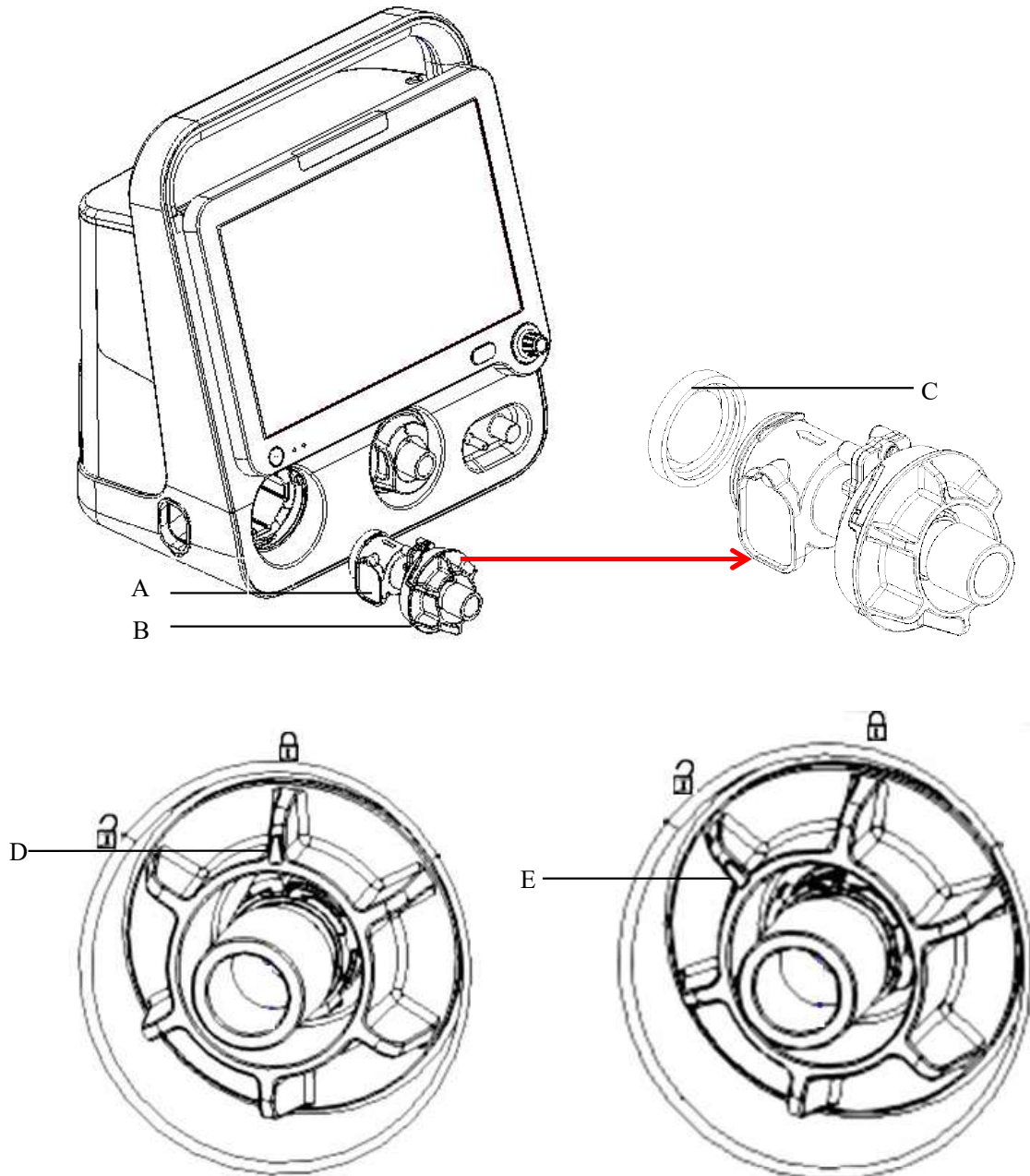
Steam autoclave\*: The recommended temperature of this disinfection method is 134°C (273°F).



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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

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### 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 O<sub>2</sub> concentration is formed in the upstream of inspiration valve after Air and O<sub>2</sub> 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 O<sub>2</sub>. Filter (F3) filters foreign substance in the high-pressure O<sub>2</sub> supply. Regulator (REG) regulates and stabilizes the pressure of high-pressure O<sub>2</sub> 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 O<sub>2</sub>, low-pressure O<sub>2</sub>, and low-pressure Air. The high-pressure O<sub>2</sub> and low-pressure O<sub>2</sub> converge before mixing with Air. High-pressure O<sub>2</sub> and low-pressure O<sub>2</sub> cannot be used at the same time. Flow sensor (Q1) is placed at the common outlet of low-pressure O<sub>2</sub> and high-pressure O<sub>2</sub> to monitor O<sub>2</sub>. Room air enters the machine after passing through filter (F1) and HEPA filter (F2).

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Turbine blower (Blower) inhales the room air and externally connected O<sub>2</sub> 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 O<sub>2</sub> are inhaled by the turbine blower after going through the first level of labyrinth chamber (SD1). The mixed gas of Air and O<sub>2</sub> 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 O<sub>2</sub> 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. O<sub>2</sub> sensor (OS) monitors O<sub>2</sub> 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.