Lable

Contact Information

Warranty and Liability

Notice to Operators

**Unsafe Operation** - Operating the Bridge ventilator without a complete and thorough understanding of its attributes is unsafe and may cause harm to the patient. It is important that this manual be read and understood in its entirety before operating the ventilator.

**The Bridge ventilator must be operated in conjunction with continuous end tidal CO2 monitoring. Failure to do so is unsafe and prohibited.**

**The Bridge ventilator is not equipped with a battery power, and in the case of loss of external power, there is no warning system with this device. Any patient connected to the Bridge ventilator must be continuously monitored by qualified healthcare providers with full monitoring of physiologic data in critical care setting.**

**The bridge ventilator requires either an adult Jackson-Rees or Mapleson D circuit to function. The specific circuits do not accompany the Bridge ventilator and have to be obtained by the ordering physician separately.**

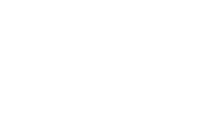
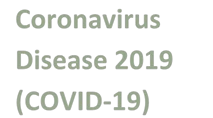
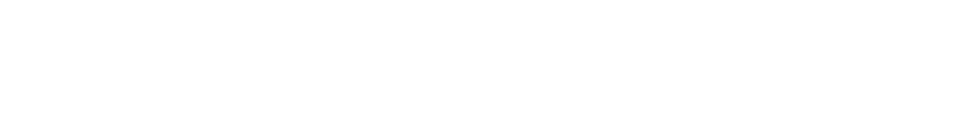
**Warnings and Cautions Section** - Read the section on **Warnings** and **Cautions** carefully before

operating the Bridge ventilator.

**Use and Maintenance** - Any questions regarding installing, operating, or maintaining the Bridge

ventilator, should be directed to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**FACT SHEET FOR HEALTHCARE PROVIDERS Coronavirus**



Emergency Use of Ventilators During the COVID-19 PandemicMarch 24, 2020 **Disease 2019**

# (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as “ventilators” in this Fact Sheet), ventilator tubing connectors, and ventilator accessories.

Certain ventilators, ventilator tubing connectors, and ventilator accessories are authorized for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

**All patients who are treated with authorized ventilators during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of Ventilators During the**

**COVID-19 Pandemic**

**What are the symptoms of COVID-19?**

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

**What do I need to know about the emergency use of ventilators?**

* Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
* Ventilators found in the list of authorized products are authorized for use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.
* For each device, healthcare providers should review the instructions for use, including device specifications, reprocessing instructions (if applicable), and other labeling information.
* During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter. Healthcare providers should review additional device specifications, labeling, and patient monitoring recommendations in these circumstances.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed*

*Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC’s webpage, *Information for Healthcare Professionals* (see links provided in “Where can I go for updates and more information” section).

**What are the known and potential benefits and risks of ventilators?**

Potential benefits of ventilators include:

* Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
* Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:

* Device malfunctions or adverse events
* Potential infectious and mechanical complications from sharing one ventilator through the use of multiplexing adapters have not been studied, and therefore caution is advised
* Risks of modified ventilator devices have not been studied, and therefore caution is advised
* Risks associated with the potential reduced requirements for alarms and monitoring of patients
* Reduced familiarity of healthcare providers with novel technologies used to treat patients

**What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?**

Alternatives to traditional ventilators that are authorized under this Emergency Use Authorization (EUA) include anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:

* Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
* Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

* A positive pressure breathing device cannot offer all of the support that a traditional mechanical ventilator can
* A positive pressure breathing device may expose others to aerosols that could be contagious
* Healthcare providers other than trained anesthesia providers may not be familiar with the operation of anesthesia equipment, and therefore should pay careful attention to the instructions for use to avoid use error

**What is an EUA?**

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as “ventilators”), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

**Where can I go for updates and more information?**

**CDC webpages:**

**General:** [https://www.cdc.gov/COVID19](https://www.cdc.gov/nCoV) **Healthcare Professionals:**

[https://www.cdc.gov/coronavirus/2019-nCoV/guidancehcp.html](https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html)

**Infection Prevention and Control Recommendations in Healthcare Settings:**

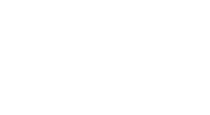
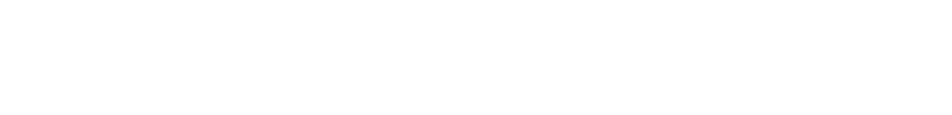
[https://www.cdc.gov/coronavirus/2019-ncov/infectioncontrol/control-recommendations.html](https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html)

**Infection Control:** [https://www.cdc.gov/coronavirus/2019ncov/infection-control/index.html](https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html)

**FDA webpages:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)  **EUAs:** (includes links to patient fact sheet and manufacturer’s instructions) [https://www.fda.gov/medicaldevices/emergency-situations-medical-devices/emergencyuse-authorizations](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)

**FACT SHEET FOR PATIENTS Coronavirus**



**Disease 2019**

**Emergency Use of Ventilators During the COVID-19 Pandemic March 24, 2020** **(COVID-19)**

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you treatment using a ventilator, anesthesia gas machine modified for use as a ventilator, or positive pressure breathing device modified for use as a ventilator (collectively referred to as “ventilators” in this Fact Sheet), ventilator tubing connectors, and/or ventilator accessory.

This Fact Sheet contains information to help you understand the benefits and risks of using ventilators, ventilator tubing connectors, and ventilator accessories for the treatment of patients during the COVID-19 pandemic. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

* **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**

* [**https://www.cdc.gov/COVID19**](https://www.cdc.gov/nCoV)

**What is COVID-19?**

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States.There is limited information available to characterize the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

**What do I need to know about the emergency use of ventilators?**

Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized under an Emergency Use Authorization (EUA) for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

A healthcare provider may choose to treat you with a ventilator if you have difficulty breathing, or other respiratory symptoms. During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter when individual ventilators are not available, or preemptively to increase the potential of single-use ventilators for multiple patients simultaneously.

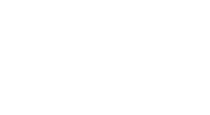
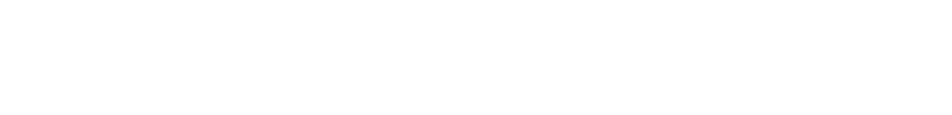
**What is an EUA?**

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as “ventilators”), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved

• **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: [**https://www.cdc.gov/COVID19.**](https://www.cdc.gov/nCoV) In addition, please also contact your healthcare provider with any questions/concerns.

1



**FACT SHEET FOR PATIENTS Coronavirus**

**Disease 2019**

**Emergency Use of Ventilators During the COVID-19 Pandemic March 24, 2020** **(COVID-19)**

or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

**What are the known and potential benefits and risks of ventilators?**

Potential benefits of ventilators include:

* Ventilator support may be effective in treating you if you have difficulty breathing, or other respiratory symptoms
* The use of a ventilator may help your condition improve and allow you to recover
* Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:

* Modified ventilator devices and techniques may have new risks associated with them that have not been studied

**What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?**

Alternatives to traditional ventilators that are authorized under this EUA include anesthesia gas machines modified for use as ventilators, and

positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:

* The device may be effective in treating you if you have difficulty breathing, or other respiratory symptoms
* The device may help your condition improve and allow you to recover
* Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

* A positive pressure breathing device cannot offer all the support a traditional mechanical ventilator can offer
* A positive pressure breathing device may expose others to aerosols that could be contagious
* Healthcare providers may not be familiar with the operation of the modified devices that are authorized

under this EUA, which could lead to use error

* **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: [**https://www.cdc.gov/COVID19.**](https://www.cdc.gov/nCoV) In addition, please also contact your healthcare provider with any questions/concerns.

2

Table of Content: Page v

Waranty…………………………………………………………………………………………………………………………………………….III

Notices………………………………………………………………………………………………………………………………………………IV

Fact Sheet for Healthcare Providers….……………………………………………………………………………………………….V-VI

Fact Sheet for Patients…………………..………………………………………………………………………………………………….VII-VIII

**Section 1 - Introduction**…………………………………………………………………………………………………………………….2

**Section 2 – Ventilator Overview**…………………………………………………………………………………………………………6

**Section 3 – Breath Types and Ventilation Mode**……………………………………………………………………………….8

**Section 4 –Using the Controls and Indicators**……………………………………………………………………………………10

**Section 5 –Controls**……………………………………………………………………………………………………………………………12

**Section 6 –Displays and Indicators**……………………………………………………………………………………………………13

**Section 7 – Monitored Data**………………………………………………………………………………………………………………14

**Section 8 – Ventilator Alarms**……………………………………………………………………………………………………………15

**Section 9 – Ventilator Checkout Tests**………………………………………………………………………………………………16

**Section 10 – Operating Procedure**……………………………………………………………………………………………………18

**Section 11 – Cleaning, Disinfecting and Sterilization**……………………………………………………………………….19

**Section 12 – Troubleshooting**………………………………………………………………………………………………………….20

**Section 1 -INTRODUCTION**

This Operator’s Manual contains detailed information and instructions which when adhered to ensure the safe and effective set up, use and simple maintenance of the Bridge ventilator.

This manual is designed for use by Respiratory Therapists or other qualified and trained personnel under the direction of a physician and in accordance with applicable state laws and regulations.

**Operator’s Safety Information**

All Operators are to read and understand the following information about Warning, Caution and Note statements before operating the Bridge ventilator.

**WARNING**

“**WARNING**”statements alert the reader to potentially hazardous situations which, if not avoided, could result in death or serious injury.

**CAUTION**

“**CAUTION**” statements alert the reader to potentially hazardous situations which, if not avoided, could result in equipment damage.

**NOTE**

“**NOTE**” statements contain additional information to assist in the proper operation of the Bridge ventilator.

**Bold Text**: Words that appear in bold text typically represent text as it appears on the ventilator itself, or used as emphasis.

**Abbreviations**: Bridge ventilator and the ventilator are used interchangeably throughout this document.

**WARNING**

**Untrained Personnel** – Only properly trained personnel should operate the ventilator. The Bridge ventilator is a restricted medical device designed for use by Respiratory Therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

**Leak Testing the Patient Breathing Circuit** – The patient circuit must be leak tested before connection to the patient. In addition, the Ventilator Checkout mode should be used to check for correct operation of the ventilator alarms. Harm to the patient or ineffective ventilation may result from failure to leak test the patient breathing circuit before connection to a patient. When using a heated humidifier, include it in the circuit when performing leak testing.

**Critical Alarms** – For safety purposes, all alarms must be checked to insure proper operation.

**Alarms Function Verification** - All alarms must be verified as functioning properly on a daily basis. If any alarm malfunctions, immediately contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Patient Monitoring** - Patients who are dependent on a ventilator should be constantly monitored by qualified personnel. Such personnel should be prepared to address equipment malfunctions and circumstances where equipment becomes inoperative. An alternative method of ventilation should be available for all patients dependent on the ventilator, and qualified personnel should be fully familiar with emergency ventilation procedures.

**Alternative Ventilation** - It is recommended that an alternative means of ventilating the patient be available at all times and that all ventilator operators be fully familiar with emergency ventilation procedures.

**Fire or Explosion** - Operation of the Bridge ventilator in the presence of flammable gases could cause a fire or explosion. Under no circumstances is the ventilator to be operated when explosive gases are present. The presence of nitrous oxide or flammable anesthetics presents a danger to the patient and operator.

**Patient Breathing Circuit Disconnection** - Inadvertent disconnection of the patient from the patient breathing circuit is dangerous.

**Personal Injury and Electric Shock** - Operation of the Bridge ventilator if any of its panels have been removed may result in electrical shock to the patient or operator.

**Audible and Visual Alarms** - Failure to immediately identify and correct audible and visual alarm situations may result in serious patient injury.

**Equipment Malfunction or Failure** - The Bridge ventilator has alarms to notify operators of certain conditions and to cease operating upon detecting possible danger. In the event of equipment failure, all ventilator operators should have an alternative method of ventilation available and be fully familiar with emergency ventilation procedures.

**Improperly Functioning Ventilator** - Operation of a ventilator that does not appear to be working properly may be hazardous. If the ventilator is damaged or malfunctions in any way, discontinue its use and immediately contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Ventilator Checkout Tests** – Be aware that no breath is delivered to the patient during this tests. Disconnect the patient from the ventilator and ventilate the patient using an alternative method before running the Ventilator Checkout tests.

**Inspired Oxygen (FIO2) Concentration** – If the patient has a variable respiratory rate, his/her minute ventilation will fluctuate. If exact concentrations of inspired oxygen (FIO2) are required to be delivered to the patient, it is recommended that an accurate oxygen analyzer with alarms be used.

**Ventilation Variables and O2 Consumption** - Variations in the patient’s minute ventilation, I:E ratio and/or ventilator setting changes or equipment status (i.e. circuit leaks) affect the consumption rate of oxygen. When warranted by a patient’s condition, it is recommended that a back-up cylinder or alternative source of oxygen be available at all times.

**Unauthorized Parts or Accessories** – Serious harm to the patient may result from the use of unauthorized parts or accessories. Only items expressly approved by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ may be used in conjunction with the Bridge ventilators.

**Ultra Violet Light Sensitivity** – The material used in the 3D-printed portions of the ventilator are not UV stable. Avoid exposure to UV light.

**Patient Circuit Accessories** - The use of accessories such as Speaking Valves, Heat-Moisture Exchangers and Filters create additional patient circuit resistance and in the event of a disconnection, may impede the generation of a Low-Pressure alarm. Ensure that the Low Pressure alarm settings accommodate these types of accessories when used in combination with patient circuits. Perform a clinical assessment to determine if an alternative monitor (i.e. a Pulse Oximeter with an audible alarm, or a Cardio Respiratory Monitor) should be used.

**MR Safety** – The Bridge ventilator is not MRI-Safe and must be avoided in MRI suits. It can cause serious damage to patients, staff and equipment in strong magnetic fields.

**Cautions**

**Ventilator Sterilization** – To avoid irreparable damage to the Bridge ventilator, do not attempt to sterilize it.

**Cleaning Agents** – To avoid damaging the ventilator’s plastic components, do not use cleaning agents containing ammonium chloride, other chloride compounds, more than 2% glutaraldehyde, phenols, or abrasive cleaners.

**Ventilator Immersion** - Do not immerse the ventilator in liquids.

**Reusable Patient Circuit Components** – There is no reusable patient circuit components. This ventilator is designed to work with Jackson-Rees or Mapleson D circuit. Please comply with all procedures as specified by the circuit’s manufacturer.

**Front Panel Cleaning** – Do not pour or spray liquid cleaners onto the front panel.

**Care of Bacterial Filters** – If bacterial filters are used in conjunction with the Bridge ventilator, comply with all procedures as specified by the filter manufacturer.

**Wet or Damp Filters** – If wet or damp filters are utilized with this device, comply with all procedures as specified by the filter manufacturer.

**Oxygen Supply Contamination** - The accuracy of the oxygen delivery capabilities of Bridge ventilator can be compromised by foreign debris contamination in the oxygen supply system. To reduce the risk of airborne contaminants entering the ventilator, ensure that any oxygen supply connected to the ventilator is clean, properly filtered and that the ventilator’s O2 Inlet Port Cap is securely installed on the O2 Inlet Port whenever the ventilator is not connected to an external oxygen supply.

**Power Outlets** – Power outlets are normally wired for a positive center contact and ground sleeve contact. Connecting the ventilator to an improperly wired outlet will cause the adapter fuse to blow and may damage the adapter or the ventilator.

**Electrical Grounding** – In the event of a loss of electrical protective ground, touching the ventilator could result in electrical shock. To ensure grounding and avoid this danger, use only the unmodified power cord originally supplied with the Bridge ventilator, maintained in good condition and connected to a properly wired and grounded electrical power outlet.

**Do not cover the ventilator** – To avoid damage to the ventilator, do not cover while operating or position relative to other objects such that the operation or performance of the ventilator may be adversely affected. Ensure that sufficient space exists around the ventilator while in use to allow free circulation of gases.

**Electrostatic Discharge** – The use of electrically conductive hoses and tubing is not recommended. The use of such materials may result in damage to the ventilator from electrostatic discharge.

**AC Power Source** - When connecting the ventilator to an AC power source, use only the approved Bridge power adapter.

**Fuse Fire Hazard** – Replacement of existing fuses with fuses with different voltage or electrical current ratings may cause a fire.

**Ventilator Checkout Tests** – The Bridge ventilator Checkout tests must be performed before initial use of the ventilator. Rerun the tests whenever a question about the ventilator’s operation arises.

**SECTION 2 – Ventilator Overview**

The Bridge ventilator is a lightweight, low-budget and open-source ventilator that is designed to provide the maximum functionality during the extreme shortage of medical supply during COVID-19 outbreak as a temporary measure to keep the patients alive until an FDA approved mechanical ventilator becomes available. The Bridge ventilator provides the following features:

* High performance ventilation in a small lightweight package.
* Gear and pinion technology allows the ventilator to operate without an external compressed gas source.
* Volume controlled mode of ventilation.
* Alarm system including high peak pressure, too high or low tidal volumes and device malfunction.
* Presets to facilitate rapid patient set-up.

**Indications for Use**

The Bridge ventilator is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation during COVID-19 outbreak when there is no FDA approved device (ventilator) is available. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients with ideal body weight of at least 50kg, who require positive pressure ventilation, delivered invasively (via endotracheal tube or trach tube). The ventilator is suitable for use on in critical care settings.

**CAUTION: Federal law restricts this device to sale by or on the order of a physician.**

**Section 3 – Breath Types and Ventilation Mode**

This Section contains information regarding the breath types available on the Bridge ventilator. It covers how breaths are initiated, limited and cycled, and when each breath is given.

The following terms are used in discussing how breaths are given:

**Initiate**: What causes a breath to be given. Breaths may be initiated by a patient trigger or by the ventilator based on the set breath rate and ventilation mode.

**Limit**: How the breath is controlled. Breaths may be limited to a maximum circuit pressure or flow.

**Cycle**: What causes the breath to be cycled from the inspiratory phase to the exhalation phase. Breaths may be cycled by the ventilator when a set time or delivered volume has been reached.

**Breath Types**

Breaths are defined by how they are initiated, limited and cycled. The breath types are Machine and Patient.

|  |  |  |
| --- | --- | --- |
|  | Machine | Patient |
| Initiated By | Ventilator | Patient |
| Limited By | Ventilator | Ventilator |
| Cycled By | Ventilator | Patient |

Breaths may be given in any of the following forms: Volume Control and Spontaneous. These breaths are given as described in the sections below.

In addition, the following parameters apply to all breaths:

* The Minimum Inspiratory Time is \_\_\_\_\_\_\_\_\_ ms.
* The Minimum Exhalation Time is \_\_\_\_\_\_\_\_\_ ms.

**Volume Control Breaths**

For Volume Control breaths, the set Tidal Volume is delivered over the set Inspiratory Time. The fresh gas flow to the Jackson-Rees or Mapleson D circuit must be set based on the manufacturer’s instruction for controlled ventilation. This fresh gas flow rate must be at least 3 times the patient’s minute volume if Jackson-Rees circuit is used and 70 ml/kg ideal body weight if Mapleson D circuit is used. Volume breaths may be only machine breaths.

**Spontaneous Breaths**

For Spontaneous breaths, please follow the manufacturer’s instruction for Jackson-Rees or Mapleson D circuit regarding fresh gas flow rate. Spontaneous breaths are patient type breaths. There is no mechanism in the Bridge ventilator to sense patient’s breaths. Perform a clinical assessment to diagnose and treat patient-ventilator desynchrony as indicated.

**Ventilation Modes**

The Bridge ventilator provides Mandatory Volume Control mode of ventilation.

Control mode ventilation is automatically selected when Bridge ventilator is turned on. In Control mode, Volume Controlled machine breaths are given at the rate specified by the Breath Rate setting. There is no mechanism to detect patient breaths as a trigger, but spontaneous patient breaths are allowed.

**Section 4 – Using the Controls and Indicators**

**Ventilator Controls**

The following diagram shows how the Bridge front panel controls and displays are arranged.

Insert a Picture of Front Panel with Arrows to Each Control

**Setting a Control**

There are 4 kinds of controls on the Bridge ventilator. They are:

* Variable Controls: Controls and alarms that have front panel displays.
* Buttons: Push buttons that perform a function.
* Set Value Knobs: Used to set control values.
* Mechanical Controls: Controls, such as Over Pressure Relief, that are hardware regulated and not operator adjustable.

The following sections describe how to set each kind of control.

**Variable Controls**

To set a variable control:

1. Select the control knob
2. Change the control value by rotating the Set Value knob. Rotate clockwise to increase and counter-clockwise to decrease the value.
3. An audible beep with confirm change from the previous value.

**Buttons**

Button control performs a function, such as ventilator checkout test or reset the tidal volume.

Push the button to activate the feature. An audible beep will confirm the push button.

**Set Value Knob**

Use the Set Value knob to set control values. To change the setting for a variable control, turn the knob clockwise or

counter-clockwise until the desired setting is reached. An audible beep will confirm the push button.

**LED Controls**

Visual alarms will be displayed as solid. A solid red LED indicates tidal volume delivery malfunction. See Section \_\_\_\_\_\_\_\_\_\_\_\_\_\_ for Ventilator Alarms for more information on this. A solid green LED light indicates optimum performance.

**Control Limiting**

The tidal volume setting may be affected by any of the following reasons:

* Tidal volume may vary to ensure a minimum inspiration time of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ms
* Tidal volume may vary to ensure a minimum exhalation time of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ms
* Tidal volume may vary to ensure peak pressure does not exceed limiting pressure of 40 cmH2O
* Inadequate fresh gas flow rate to Jackson-Rees or Mapleson D circuit can result in reduced tidal volumes

When you are updating a control and have reached a limited condition, the red control LED will turn on solid and a continuous audible alarm will sound.

**Section 5 – Controls**

This section explains how each of the Bridge ventilator front panel controls work.

**Breath Rate**

Use the Breath Rate control (RR) to establish the minimum rate of machine breaths that the ventilator will deliver per minute.

To set the Breath Rate, rotate the RR knob clockwise or counter-clockwise. The available choices for breath rates are 12, 14 and 16 breaths per minute. Upon changing the value, an audible beep confirms the change.

**Tidal Volume**

Use the Tidal Volume control knob to establish the volume of gas which the ventilator will deliver during Volume Controlled breaths. Flow is delivered constantly to the Jackson-Rees or Mapleson D circuit. Inspiratory and expiratory times are set based on the set breath rate.

**Section 6 – Displays and Indicators**

This section describes each of the Bridge ventilator front panel displays.

**Airway Pressure**

The Bridge ventilator will not show the airway pressures unless connected to an auxiliary pressure transduce and display; however, should the peak airway pressure reach 40 cmH2O, the tidal volume is reduced and the machine alarm triggered.

**External Power Indicator**

The External Power indicator shows the status of the external power and the ventilator is operating optimally from an external power source. When running from external power, the indicator shows solid green. If the red indicator is on, it indicates device malfunction (accompanied by a continuous audible alarm).

**Section 7 – Monitored Data**

This section describes each of the monitored data and how the data is calculated.

Tidal volume is derived from the stroke distance of the Bridge ventilator gear and pinion system. This was achieved empirically at the following flow rates at specific minute volumes:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Set Respiratory Rate | Set Tidal Volume | Flow Rate (L/min) | Step Distance | Actual Tidal Volume (ml) |
| 12 | Low | 15 |  | 350 |
| Med | 15 |  | 400 |
| High | 15 |  | 450 |
| 14 | Low | 15 |  | 325 |
| Med | 15 |  | 375 |
| High | 15 |  | 425 |
| 16 | Low | 15 |  | 300 |
| Med | 15 |  | 350 |
| High | 15 |  | 400 |

When the Bridge ventilator is turned on, the onboard computer will record the expected location of the ventilator plate at the end expiration as well as mid-inspiration and mid-expiration. During each respiratory cycle, these values are compared with the actual values, and any deviation will result in activation of device malfunction alarm.

**Section 8 – Ventilator Alarms**

When conditions requiring immediate operator interaction are detected by the Bridge ventilator, an alarm is generated. All alarms require some action from the operator, and the audible and visual alarms will continue until the problem is corrected.

When an alarm occurs:

* An audible alarm sounds.
* The red LED light will be lit solid.
* Depending on the alarm, other actions may be taken, such as terminating an inspiration.

When an alarm condition clears:

* The audible alarm is silenced.
* The Red LED light will be off

**WARNING**

Critical Alarms – For safety purposes, all alarms must be checked to insure proper operation.

Audible/Visual Alarms - Failure to immediately identify and correct audible/visual alarm situations may result in serious patient injury.

**Alarms**

**High Pressure**

When the pressure in the patient circuit is greater than 40 cmH2O, the malfunction alarm is generated. When this alarm occurs, any inspiration in progress is terminated. This will result in turning on of red LED light and an audible alarm, which is sustained until reset button is pressed.

**Inadequate Inspiratory Tidal Volume**

During each breath, if the step distance in the stepper motor during inspiration fails to activate the inspiratory switch, the malfunction alarm is generated. When this alarm occurs, any inspiration in progress is terminated. This will result in turning on of red LED light and an audible alarm, which is sustained until reset button is pressed.

**Inadequate Expiratory Tidal Volume**

During each breath, if the step distance in the stepper motor during expiration inappropriately activate the expiratory switch, the malfunction alarm is generated. When this alarm occurs, any inspiration in progress is terminated. This will result in turning on of red LED light and an audible alarm, which is sustained until reset button is pressed.

**Section 9 – Ventilator Checkout Test**

This Section details the test procedures used to verify the proper operation of the Bridge ventilator. These tests should be performed before the device is connected to the patient and as needed thereafter. An alternative mode of ventilation must be available during this test, and the Bridge ventilator will not provide ventilatory support during this test.

**Initial Power on Test**

Upon turning on the machine, prior to connecting to the patient, the ventilator plate will rise all the way to the top. The upper limit of the machine’s stroke distance is sensed by a sensor and saved. An audible beep occurs once this upper limit sensor is activated. Next, the down stroke is tested and upon activation of the mid-stroke sensor, a second audible beep is noted. This distance is also saved. If this initial check is free of error, the Bridge ventilator will begin delivering tidal volumes.

If any malfunction is detected in the stroke distance, the red LED with be lit solid and a continuous audible alarm sounded. The bridge ventilator will not deliver a tidal volume in the presence of a malfunction and should not be connected to a patient until the malfunction is resolved.

1. Ensure that the patient is not connected to the ventilator and an alternative method of ventilation is in use.
2. Turn on the Bridge ventilator.
3. Ensure that the AC Adapter is connected to a valid AC power source and verify that the External Power Status LEDs is illuminated (solid green).
4. The machine will begin the test automatically.
5. The ventilator plate will first rise all the way to the top. When it is at the top, an audible single beep is generated.
6. Next, the ventilator plate is lowered halfway, and will generate another single audible beep.
7. If no malfunction is detected, the ventilator plate will start delivering tidal volumes.
8. On the other hand, failure to pass this initial power on test would result in a continuous alarm and turning on the red LED solid.
9. Pressing the reset button will result in momentary turning the alarm off and repeating this initial power on test.
10. Follow the troubleshooting steps.

**Alarm Test**

1. Disconnect the patient from the ventilator and ventilate the patient using an alternative method.
2. Ensure that the AC Adapter is connected to a valid AC power source and verify that the External Power Status LEDs is illuminated.
3. Turn the RR knob to 12 and TV to low.
4. Turn the RR knob clockwise to 14 and then to 16. Turn the TV knob to med and then to high. With each change, an audible alarm (single beep) must be heard.

**Control Test**

1. Disconnect the patient from the ventilator and ventilate the patient using an alternative method.
2. Ensure that the AC Adapter is connected to a valid AC power source and verify that the External Power Status LEDs is illuminated.
3. Turn the RR knob to 12 and TV knob to low.
4. As the bridge continues to push on the inflatable bag of the Jackson-Rees or Mapleson D circuit, count the breaths in 10 seconds and multiply by 6. This should correspond to 12 breaths per minute. Repeat the procedure at RR set at 14 and 16.
5. As the TV knob is set to low, note the stroke distance of the Bridge ventilator. As you increase the TV to med and high, you should see a larger stroke distance in the machine.

**Leak Test**

1. Disconnect the patient from the ventilator and ventilate the patient using an alternative method.
2. Follow the Jackson-Rees or Mapleson D manufacturer’s recommendation regarding leak test.

**Malfunction Alarm**

1. Disconnect the patient from the ventilator and ventilate the patient using an alternative method.
2. Ensure that the AC Adapter is connected to a valid AC power source and verify that the External Power Status LEDs is illuminated.
3. Activate the top vertical limit switch by hand (by pressing on the switch in the underside of the motor).
4. This should lead to a continuous audible alarm since the machine senses a different stroke distance (delivered tidal volume) than the expected stroke distance (delivered tidal volume).
5. Press the reset button to turn off the alarm.
6. Activate the top horizontal limit switch by hand by pressing on the switch in the underside of the motor.
7. This should lead to a continuous audible alarm.
8. Press the reset button to turn off the alarm.

**Section 10 – Operating Procedures**

This section describes how to turn the Bridge ventilator on and off, and how to set up the ventilation modes.

**To Turn the Ventilator On**

1. Connect the unit to an external source of power.
   * The External Power LED is lit green to indicate the external power source connection and absence of any errors.
2. Set the on/off switch to on
   * The bridge ventilator’s stepper motor will begin moving the ventilator plate (see exhibit) all the way to the top and begin tidal volume breaths.
   * If there are any errors found, the red LED light will be lit solid and a continuous audible alarm sound.
   * In the absence of any errors, the green LED light will continue to be lit solid and no alarms will be sounded
   * Pressing the reset button will turn off the alarms and reinitiates the initial self-test.
3. Perform a leak test of the patient Jackson-Rees or Mapleson D circuit (as per manufacturer’s instruction) prior to connecting the ventilator to the patient.
4. Connect the patient circuit to the ventilator.
5. If the Power On Self Tests fail, the red LED light will be lit solid and a continuous alarm sounded.
   * Silence the alarm by pushing the Silence Reset button.
   * Discontinue use of the ventilator and immediately contact \_\_\_\_\_\_\_\_\_\_.

**Before connecting the ventilator to a patient,** **follow the checkout procedures in \_\_\_\_\_\_\_\_\_.**

**To Turn the Ventilator Off**

1. Disconnect the ventilator from the patient.
2. Switch the power switch to off. The ventilator ceases operating, the green LED light will turn off.

**Reset Button**

The reset button will turn off the continuous malfunction alarm temporarily and will initiate the Initial Power on Test. If a malfunction is detected, the continuous alarm will be sounded and the patient must be ventilated with an alternative method.

**Section 11 – Cleaning, Disinfecting and Sterilization**

**Cleaning the Ventilator**

All ventilator external surfaces should be cleaned prior to initial use. To clean the ventilator:

* Wipe the exterior surfaces of the ventilator with a clean, damp cloth. The use of an anti-bacterial cleaning solution is recommended. Be sure to wipe away any residual cleaner.
* Ensure no liquid enters the electronics box.

**CAUTION**

Ventilator Sterilization – To avoid irreparable damage to the Bridge ventilator, do not attempt to sterilize the Bridge ventilator.

Cleaning Agents – To avoid damaging the ventilator’s plastic components and front panel, do not use cleaning agents containing ammonium chloride, other chloride compounds, more than 2% glutaraldehyde, phenols, or abrasive cleaners.

Ventilator Immersion - Do not immerse the ventilator in liquids.

The Bridge ventilator is considered single-patient use. Do not attempt to use the same device on multiple patients. Follow the manufacturer’s instruction on the use of Jackson-Rees or Mapleson D circuit (also single-patient use).

**Section 12 - Troubleshooting**

Ensure that the patient is not connected to the Bridge ventilator during the troubleshooting steps and an alternative method of ventilation is utilized, as the machine will not deliver tidal volumes during the test.

A single beep denotes normal function when a parameter is set or a parameter is changed. For example, during the initial power on test, a single beep is generated to denotes recording the top of the stroke distance (expected location of the ventilator plate at the end of expiration) and the second single beep denotes the location of mid-stroke (expected location of the plate during inspiration and expiration of a specific set tidal volume. Additionally, when the control knobs are rotated to change the respiratory rate or tidal volume, a single beep denotes confirmation of a change in that parameter.

There is no silence button incorporated into the Bridge ventilator. The reset button will momentarily turn off the continuous alarm and initiates the initial power on test. If the machine does not pass this test, the continuous alarm will turn on again and the machine should not be connected to the patient.

1. The Bridge ventilator malfunction
   1. Initial Power on Test Failure
      1. Ensure there is no object obstructing the stroke path.
      2. Remove any object around the balloon of the Jackson-Rees or Mapelson D circuit.
      3. Ensure the balloon of the circuit in the center of the ventilation chamber of the Bridge.
      4. Check integrity of the sensors located under the motor bridge.

Once the above steps are taken, press the reset button to restart the Initial Power on test. If no continuous alarm is sounded, the machine has passed the test and ventilation is resumed.

* 1. Alarm Failure
     1. If the alarm test does not result in a continuous audible alarm, disconnect the machine from the patient and utilize an alternative mode of ventilatory support.
  2. Control Failure
     1. If the respiratory rate and/or tidal volume knobs fail to change the respiratory rate and tidal volume respectively, disconnect the machine from the patient and utilize an alternative mode of ventilatory support.
  3. Malfunction Alarm
     1. If the Bridge ventilator sounds a continuous alarm, follow the procedures for the Initial Power on Test Failure.
  4. Other Malfunctions
     1. For all other malfunctions, disconnect the machine from the patient and utilize an alternative mode of ventilatory support.

1. Circuit Malfunction
   1. Please follow the instructions provided by the circuit manufacturer for troubleshooting tips.