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I. OWNER/USER RESPONSIBILITY

The Bunnell Incorporated equipment and the authorized accessories and supplies are designed to function as specified when operated, maintained, and serviced in accordance with approved manuals and instructions.

Your Life Pulse High-Frequency Ventilator and Patient Box(es) should be returned to the factory every 2000 hours or every year, whichever comes first, to be checked, re-calibrated, maintained, and components repaired and replaced for the equipment to operate reliably. Parts that have failed, in whole or in part, exhibit excessive wear, are contaminated, or are otherwise at the end of their useful life should not be used. Furthermore, they should be replaced immediately with parts supplied by Bunnell Incorporated or parts which are approved by Bunnell Incorporated.

Equipment, which is not functioning correctly or is otherwise in need of repair or maintenance, must not be used until all necessary repairs and/or maintenance have been completed, and a Bunnell service representative has verified that the equipment is fit and ready for use. This equipment, and any accessories or component parts, should not be modified.

The owner/user of this equipment will have the sole responsibility and liability for any damage or injury to persons or property (including the equipment itself) resulting from:

A) Operation not in accordance with the operating instructions,

B) Faulty maintenance not in accordance with the authorized maintenance instructions,

C) Repair by anyone other than a Bunnell service representative, modification of the equipment or accessories, or

D) Use of components or accessories that have either been damaged or not authorized for use with this equipment by Bunnell Incorporated.

The disposal of any Bunnell Incorporated equipment is the responsibility of the owner of that equipment. Disposal should always be in accordance with any local and/or national requirements.
II. INDICATIONS FOR USE, CONTRAINDICATIONS, AND ADVERSE SIDE EFFECTS

A. Indications for Use

The Bunnell Life Pulse High-Frequency Ventilator is indicated for use in ventilating critically ill infants with pulmonary interstitial emphysema (PIE). Infants studied ranged in birth weight from 750 to 3529 grams and in gestation age from 24 to 41 weeks.

The Bunnell Life Pulse High-Frequency Ventilator is also indicated for use in ventilating critically ill infants with respiratory distress syndrome (RDS) complicated by pulmonary air leaks who are, in the opinion of their physicians, failing on conventional ventilation. Infants of this description studied ranged in birth weight from 600 to 3660 grams and in gestational age from 24 to 38 weeks.

B. Contraindications

Use of this device is contraindicated in patients requiring tracheal tubes smaller than 2.5 mm ID.

This device is not intended for use outside of a device user facility (21 CFR 821.3 (g)).

C. Adverse Side Effects

The adverse side effects noted during the use of high-frequency ventilation include those commonly found during the use of conventional positive pressure ventilators. These adverse effects include:

1. Pulmonary air leaks such as:
   a) pneumothorax,
   b) pneumopericardium,
   c) pneumoperitoneum,
   d) pneumomediastinum, and
   e) pulmonary interstitial emphysema;

2. Intraventricular hemorrhage;

3. Necrotizing tracheobronchitis; and

4. Bronchopulmonary dysplasia
III. WARNINGS AND PRECAUTIONS

Anyone using or involved with the use of the Life Pulse High-Frequency Ventilator should study and observe the warnings and precautions listed here.

Warnings are used to indicate that there are possibilities of injury to either the operator or patient. The term Warning is also used where required by law or to meet the requirements of certain performance standards.

Precautions indicate there are possibilities of damage to the instrument or other property.

The following warnings and precautions are organized according to whether they are relevant during set-up, operation, or patient monitoring during the use of the Life Pulse.

A. Set-Up WARNINGS and PRECAUTIONS

1. **WARNING:** Use only by or on the order of a qualified physician and by persons properly trained in its operation, and only in accordance with the operator's manual.

2. **WARNING:** Do not connect any additional tubing or pressure monitors between the pressure monitoring tube of the LifePort adapter and the pressure monitoring barbed connector on the Patient Box. Doing so will destroy the Life Pulse's ability to accurately measure airway pressures and may lead to dangerously high pressures being applied to the patient.

3. **WARNING:** Do not connect 100% oxygen directly to the “Mixed Gas Input” on the rear panel of the Life Pulse, unless you intend to only deliver 100% oxygen. The Life Pulse ventilator’s external gas supply should be a mixed gas source from an air/oxygen blender. A low flow blender (0-30 L/min.) is preferred or the low flow output (2-100 L/min) from a standard blender can be used.

4. **WARNING:** A TEST cycle should be run prior to use on a patient. A standard endotracheal tube with the LifePort adapter, Test Lung, and a Humidifier Cartridge/Circuit must be properly connected to the ventilator for this test. Never initiate a TEST while the Life Pulse ventilator is connected to a patient.

5. **WARNING:** Following a successfully completed TEST of the Life Pulse, remove the LifePort adapter and endotracheal tube with Test Lung from the Life Pulse and the Patient Box. Failure to do so may result in unsafe conditions that can endanger the patient.

6. **PRECAUTION:** Use ONLY sterile water for inhalation, USP, in the Life Pulse Humidifier Cartridge. The use of deionized water or salt solutions may cause a malfunction of the water level sensors in the humidifier cartridge.

7. **WARNING:** The water inlet tube of the humidifier cartridge/circuit must be latched into the pump housing to prevent cartridge overfill and delivery of water to the patient by gravity feed.

8. **WARNING:** The water supply should be positioned at or below the level of the humidifier cartridge to decrease the potential of overfilling the cartridge by gravity feed.

9. **PRECAUTION:** The compressed gases used with the Life Pulse Ventilator must be clean and dry to prevent a ventilator malfunction or damage to the ventilator. Whenever using
external compressed air, it is recommended that an air inlet water trap be connected to the mixed gas inlet on the rear of the ventilator.

10. **WARNING:** The Life Pulse Ventilator is intended for use only with a LifePort adapter and standard endotracheal tube. The LifePort adapters are manufactured and distributed by Bunnell Incorporated.

11. **WARNING:** All patient connections to the Life Pulse circuit must only be made while the Life Pulse is in the STANDBY mode. Failure to comply may result in a high volume of gas being delivered at pressure to the patient, which may result in severe patient injury.

12. **WARNING:** The Life Pulse humidifier is intended for use only with the Bunnell patient breathing circuit.

13. **WARNING:** Continuous monitoring of tissue oxygenation and ventilation and of hemodynamic status is required for each patient being treated by the Life Pulse.

14. **PRECAUTION:** Failure to discard humidifier cartridge/circuits after one use or seven days may result in leaks, improper temperature, and water level control upon re-use.

15. **PRECAUTION:** In accordance with good medical practices, when operating critical equipment, it is recommended to have back-up equipment available. An extra Patient Box, humidifier cartridge/circuit, and LifePort adapter should be kept near the bedside of a patient receiving treatment from the Life Pulse. These items are the Life Pulse components most vulnerable to being dropped, damaged, and/or replaced.

16. **PRECAUTION:** Do not sterilize the Life Pulse ventilator. The internal components are not compatible with sterilization techniques. Refer to Section X for cleaning instructions.

17. **PRECAUTION:** Save the shipping carton for use in the event your Life Pulse is returned to Bunnell for service. Shipping a Life Pulse Ventilator in other than a factory-authorized carton may result in voiding of the warranty.

18. **WARNING:** This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause interference with radio communications and other devices in the vicinity. If this device does cause electrical interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the problem by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.

This device complies with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class I and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This device also complies with the requirements of Part 15 of FCC rules for a Class A computing device, which is designed to provide reasonable protection against such interference when operated in a commercial environment.
19. **WARNING:** If a LOSS OF PIP alarm has occurred with the READY light off, it will be necessary to press the ENTER button to resume ventilation.

**B. WARNINGS and PRECAUTIONS Pertaining to Operation of the Life Pulse**

1. **WARNING:** When the Life Pulse is connected to a patient, it is recommended that properly trained personnel be in attendance at all times to detect an alarm or other indications of a problem.

2. **WARNING:** An audible alarm indicates an anomalous condition and should never go unheeded.

3. **WARNING:** There are no alarms active while the Life Pulse is in the Standby mode. The Life Pulse is not a conventional ventilator monitor.

4. **WARNING:** The patient is not being ventilated by the Life Pulse during VENT FAULT alarms that place the Life Pulse into Standby mode. In this condition, the operator is alerted by a visual and audible alarm and the patient remains connected to a conventional ventilator.

5. **WARNING:** The Life Pulse will not detect extubation of a patient during start-up (i.e., from the time the ENTER button is pushed until the READY light is illuminated). During start-up, the ventilator may appear to be functioning normally during an extubation and will generate no audible or visual alarms.

6. **WARNING:** The Life Pulse requires at least 20 seconds before adequate ventilation is delivered. Conventional or manual ventilation should be provided during this start-up period.

7. **WARNING:** Before leaving the Life Pulse, during initial start-up and following a circuit change, a properly trained person must observe the cartridge fill with sterile water for inhalation, USP, to the second water level sensing pin and the water pump stop pumping.

8. **WARNING:** There will be no LOSS OF PIP alarm for the first 15 seconds after the ENTER button is pushed or until the READY light becomes illuminated.

9. **WARNING:** Do not press the ENTER button during a LOSS OF PIP alarm if the patient is clinically appropriate and the Servo pressure has locked at or near an established operating value. Doing so will temporarily silence the audible alarm and unlock the Life Pulse Servo pressure. This action may shut off the Servo valves and result in high-frequency breaths of decreased volume to be delivered to the patient.

10. **WARNING:** Pressing the ENTER button during an alarm will temporarily silence the audible alarm and cause the machine to restart its efforts to ventilate the patient under alarm conditions. The risk in such a procedure is that it allows an operator to restart ventilation without first correcting the existing alarm condition.

11. **PRECAUTION:** Using pens, pencils, fingernails, or other pointed objects to push the buttons on the Life Pulse front panel will damage the buttons and may cause them to fail.

12. **WARNING:** When using a conventional ventilator in tandem with the Life Pulse ventilator, the rate at which the conventional ventilator is set should not exceed 60 breaths per minute. The recommended conventional ventilator rate is 0 - 10 breaths per minute.

13. **WARNING:** Care should be taken not to tip the humidifier cartridge during removal as water could spill directly into the patient breathing circuit.
14. **WARNING:** Removal of the humidifier cartridge exposes a heater plate which may be in excess of 60 °C.

15. **WARNING:** Opening the door of the humidifier pump while the ventilator is operating, or failure to close the humidifier pump door may pressurize the water supply container.

16. **WARNING:** The humidifier Cartridge Temperature may need to be adjusted up or down from its default setting in order to provide the minimal water condensation consistent with maintenance of 100% relative humidity at the patient's body temperature. Failure to properly adjust this temperature may result in either over- or under-humidification.

17. **WARNING:** Pushing the WAIT button on the humidifier shuts off all heating elements which provide for gas warming and humidification. This condition will remain in effect so long as the light in the corner of the WAIT button is illuminated or is flashing. A brief audible alarm will occur every 30 seconds while the humidifier is in the WAIT mode.

18. **WARNING:** If either the mean airway pressure (MAP), positive end-expiratory pressure (PEEP), or arterial carbon dioxide tension (PaCO₂) are found to be increasing the user should:
   a. check the patient breathing circuit for damage or disconnection.
   b. check the position of the tracheal tube in the airway.
   c. check the tracheal tube for signs of adequate humidification.
   d. check the patient for signs of airway obstruction.
   e. check the patency of the pressure monitoring tube of the LifePort adapter.

19. **PRECAUTION:** Failure to perform periodic preventive maintenance on the Patient Box according to the schedule described in Section XI may cause excessive wear on the circuit pinch tubing. Monitor the integrity of the pinch tubing and replace the circuit if a leak is detected.

20. **WARNING:** Raising or lowering the CIRCUIT TEMP setting may raise or lower the temperature of the patient. The normal setting of 40 °C is designed to keep the patient from losing any heat through respiration. It should not be changed under normal operating circumstances. High or low inspired gas temperatures may result from CIRCUIT TEMP changes.

21. **WARNING:** PIP, MAP, and PEEP are reported as tracheal pressures and are measured inside the tracheal tube adapter when using a LifePort adapter. They may not accurately reflect alveolar pressures, and, in fact, may be lower than alveolar pressures.

22. **WARNING:** There is a possibility of under-display of PIP and over-display of PEEP.

23. **WARNING:** There is a possibility of inadvertent increases in PEEP resulting from changes in lung compliance and/or pulmonary air leak.

24. **WARNING:** Failure to place the Life Pulse ventilator in the Standby mode prior to succioning the patient may result in airway pressures other than the selected peak inspiratory pressure (PIP).

25. **WARNING:** The Life Pulse must be in the READY condition prior to succioning if succioning while the Life Pulse is running. Failure to do so may result in airway pressures other than the selected peak inspiratory pressure.
26. **WARNING:** Direct application of suction to tracheal mucosa may cause significant airway damage.

27. **WARNING:** The application of excessive oxygen to a patient may have harmful effects. Consult a physician on proper fractional concentration of inspired oxygen (FiO₂). Monitor oxygen concentrations with an oxygen analyzer, and obtain serial blood gas determinations to assure acceptable levels of partial pressure of oxygen in the arterial blood.

28. **WARNING:** If the green portion of the circuit between the Patient Box and the LifePort adapter is kinked during a clinical application, place the Life Pulse in STANDBY before unkinking the tube. This action prevents the patient from being exposed to inappropriately large volume delivery and possible barotrauma.

29. **WARNING:** Place Life Pulse into the STANDBY mode prior to troubleshooting if the Patient Box pinch valve stops operating while on a patient. This action prevents the patient from being exposed to inappropriately large volume delivery and possible barotrauma.

30. **WARNING:** Do not press the “Push to Load” button while the Life Pulse is running on a patient. This action would result in the patient from being exposed to inappropriately large volume delivery and possible barotrauma.

31. **WARNING:** Use while the Life Pulse or patient is in motion or use in high-flow or large tidal volume conditions may result in water entering the patient breathing circuit and creating a risk of aspiration. Please monitor the water level closely.

C. **WARNINGS, PRECAUTIONS, and Other Notes on the Life Pulse Ventilator:**

1. **DANGER:** Explosion hazard. Do not use in the presence of flammable anesthetics.

2. **WARNING:** Operate unit only in accordance with manufacturers operating manual. Do not remove the cover due to possible shock hazard. Refer all servicing questions to the Bunnell Hotline at 1-800-800-4358.

D. **WARNINGS, PRECAUTIONS, and Other Notes on the Patient Box:**

1. **WARNING:** Do not connect any additional tubing or pressure monitors between the Patient Box and the pressure monitoring tube of the LifePort adapter.

2. **NOTE:** Disconnecting the purge tube will cause a VENTILATOR FAULT" alarm.
### E. WARNING and Informational Symbols

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<th>Publication</th>
<th>Description</th>
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IV. GENERAL INFORMATION

A. System Overview

The Bunnell Life Pulse High-Frequency Ventilator (HFV) is a microprocessor-controlled infant ventilating system capable of delivering and monitoring between 240 and 660 humidified high-frequency "breaths" per minute. All hardware elements in the system, from the initial gas input connection to the special tracheal tube or the LifePort adapter, have been specifically designed to convey information back to the controlling software elements. Together, these elements form a fully integrated, self-regulating unit which maximizes both machine efficiency and patient safety. Figure 1 illustrates the main components of the ventilator.

1. Feedback Control

Figure 1 and Figure 2 illustrate the feedback control pathways used to control peak pressure and gas temperature. The operator sets the peak pressure, rate, and valve on-time desired and the Life Pulse manipulates the valves that regulate breath size and timing to meet those settings. This design allows exquisite control of the gas delivered to the patient.

Servo control of the temperature of the gas, both in the humidifier cartridge and patient breathing circuit, ensures that the gas entering the lungs is completely humidified and always near body temperature even when ventilator changes are made.

2. The Patient Box

The Patient Box contains the pressure transducer (sensor) and the pinch valve. The pressure transducer must be as close to the tracheal tube as possible in order to measure the pressure accurately. Any long tube of gas will dampen pressure signals, especially at high frequencies. Having the pinch valve as close to the patient as possible allows very crisp inspirations. The more crisp the inhalation, the deeper it will penetrate towards the alveoli.

3. Monitoring Pressure in the Tracheal Tube

The Life Pulse is designed to be used with the LifePort adapter distributed by Bunnell and a standard endotracheal tube. The LifePort Adapter enables high-frequency breaths to be injected into the center of the tracheal tube. The pressure generated is then measured just before the breaths exit the adapter and enter the tracheal tube.

The LifePort adapter is designed to approximate the pressure reading at the distal tip of the endotracheal tube. Since the pressure drop in tracheal tubes during mechanical ventilation can be substantial, approximations of pressure at the distal tip of tracheal tube should be the most sensitive indicator of the peak and mean pressures actually experienced by the patient.
4. Use with Conventional Infant Ventilators

The Life Pulse is designed to be used in conjunction with conventional infant ventilators. The function of the conventional ventilator is to provide fresh gas for the spontaneously breathing patient, to control PEEP (Positive End Expiratory Pressure), and in some cases to provide a supplementary low rate IMV (Intermittent Mandatory Ventilation).

Figure 1: Life Pulse Ventilator Block Diagram of Principal Control Elements
Figure 2: Humidifier Feedback Control
**B. Subsystems and Panel Areas**

The Life Pulse High-Frequency Ventilator System is composed of seven distinct subsystems and panel areas. A basic understanding of the appearance, operation, and safety features of these subsystems, as well as their interaction with conventional ventilators, will greatly enhance the operator's ability to make effective use of the Life Pulse.

For 1 through 6 below, refer to Figure 3.

1. **Monitor**
   The upper left portion of the front panel displays patient and machine pressure parameters, and lights ON and OFF LEDs in synchrony with the opening and closing of the pinch valve.

2. **Alarms**
   The upper right portion of the front panel indicates ventilator alarm conditions.

3. **Controls**
   The middle portion of the front panel provides the operator with the ability to set the peak inspiratory pressure, rate, and inspiratory time (ON-time).

4. **Humidifier Monitor, Alarms, and Controls**
   The upper left portion of the humidifier panel monitors the temperature of the gas flowing through the disposable cartridge/circuit. The operator may manipulate the cartridge/circuit temperature settings here, and any alarm conditions related to humidification are displayed in the upper right portion of the humidifier panel.

5. **Patient Box**
   This small external box is designed for positioning near the patient. It houses the pinch valve, purge valve and pressure transducer, and connects onto the disposable cartridge/circuit.

6. **Disposable Cartridge/Circuit**
   This disposable patient breathing circuit includes the unique humidifier cartridge and attaches to the LifePort adapter.
7. Rear Panel

**Model 203 (Figure 4)**
The rear panel contains the mixed gas input connection, the hour meter, the circuit breaker, the alarm volume control, the Patient Box connector, the analog output, the dump valve port, and the oxygen sensor port (available on HFV Serial No. 2414 and higher).

**Model 203A (Figure 5)**
The rear panel contains the mixed gas input connection, the hour meter, the circuit breaker, the alarm volume control, the Patient Box connector, the dump valve port, and the Protective Earth Terminal (ground stud).
Figure 4: Life Pulse Ventilator Rear Panel (Model 203)

Figure 5: Life Pulse Ventilator Rear Panel (Model 203A)

NOTE: Not available on HFV Serial No. 2414 and higher.
C. Theory of Gas Exchange during High-Frequency Ventilation

Many adverse side effects associated with the use of mechanical ventilation are associated with the amount of positive pressure used. Any method of reducing the positive pressure delivered to the lungs should reduce the incidence of these side effects.

One way of reducing pressure during mechanical ventilation is to reduce the size of the delivered breath or tidal volume. High-frequency ventilation offers this opportunity.

Gas exchange during high-frequency ventilation takes place by combinations of two basic mechanisms: convection and diffusion. Both mechanisms are facilitated by other phenomena during high-frequency ventilation.

1. Convection

During conventional ventilation, inspired gas reaches the alveoli in bulk flow because the volume of the breath (tidal volume) exceeds the volume of the airways leading to the alveoli (dead space volume). During high-frequency ventilation, tidal volumes are much smaller. However, some alveoli do receive fresh gas in bulk flow even though the tidal volume may be less than the dead space volume for the whole lung because those alveoli are closer to the trachea than other alveoli. Although relatively few in number, their contribution to overall gas exchange can be considerable during high-frequency ventilation, strictly because of the high frequency with which they are ventilated.

2. Facilitated Convection - Pendelluft

Pendelluft is the name for the bulk flow that takes place between alveoli. This phenomenon occurs because of differences in time constants, the products of local resistance and compliance. Areas with different time constants fill and empty at different rates. When airway pressures rise and fall during high-frequency ventilation, connecting pathways may experience flow in and out of their local network of alveoli which is out of phase with the flow in and out of their common pathway depending on their time constants. Bulk flow may then be created between local networks at the same level of the lungs, and the sum of the flows to the various lung regions will exceed the flow in their common pathway, the trachea.

3. Diffusion

Molecular diffusion takes place continuously in the lungs wherever a concentration gradient exists. While convection is the dominant mechanism of gas exchange wherever bulk flow exists, diffusion becomes dominant when and where bulk flow stops.

The rate at which gas molecules exhibit a net movement in the direction of reduced concentration is proportional to the size of the concentration gradient and the cross-sectional area over which that gradient exists:

\[ Q = D_{\text{mol}} A \frac{dF}{dx} \]

where \( Q \) = net gas flow rate,

\( D_{\text{mol}} \) = diffusivity of the gas (a property which is proportional to the molecular weights of the gases involved),

\( A \) = the cross sectional area across which the concentration exists, and
\[
\frac{dF}{dx} = \text{the concentration gradient (normally measured in partial pressures differences per cm downstream)}.
\]

During conventional ventilation, bulk flow stops at the respiratory bronchioles and/or within the alveoli. During high-frequency ventilation, flow may stop well before the alveoli are reached. However, factors such as pendelluft and flow-streaming may advance bulk flow into the alveoli during high-frequency ventilation as well.

4. **Flow Streaming and Taylor Dispersion**

Taylor Dispersion is the gas transport mechanism that combines diffusion with flow streaming. In laminar flow, which is characteristic of inhaled gas in all airways with the possible exception of the trachea, the velocity of the gas in the center of the airways is greater than that found at the walls. A parabolic shaped velocity profile results that greatly enlarges the surface area for diffusion.

During exhalation, the bifurcations of the airways cause acceleration of the gas since the cross-sectional area of the airways is reduced as two smaller airways exhaust their gas into one slightly larger airway. This acceleration and the mixing action of the two streams cause turbulence and a blunt velocity profile.

Haselton and Scherer ("Bronchial bifurcations and respiratory mass transport," Science, 208:69, 1980) have shown that the net effect of the parabolic flow profiles that exist on inspiration, and the blunt flow profiles that exist on expiration, result in a net movement of gas down the center of straight tubes during high-frequency ventilation. In tubes with regular bifurcations, as in the lungs, the inspired flow distal to bifurcations tends to hug the inner wall.

After several bifurcations and several in and out cycles, the inspired gas tends to flow down the center of the airway as the expired gas tends to flow out along the outer walls of the airways. One effect of this flow streaming is the elongation of convective fresh gas flow towards the alveoli.

As the flow of inhaled gas slips by the flow of exhaled gas in the lungs, an opportunity for gas exchange to take place by diffusion is produced. This diffusion can be quite significant due to the relatively large cross sectional area available for diffusion. To the extent that this phenomenon occurs in the airways, effective gas exchange is retarded; the fresh gas mixes more readily with the expired gas. To the extent that flow-streaming takes gas into the respiratory bronchioles and alveoli, effective gas exchange is enhanced.

Chang (see reference below) has hypothesized that the net effect of these mechanisms is that gas transfer is proportional to the tidal volume squared and the frequency of ventilation to the first power:

\[
V = k V_T^2 f
\]

where \(V\) = the transfer of gas by dispersion,
\(k\) = a constant,
\(V_T\) = tidal volume, and
\(f\) = frequency.

General references that discuss the above mechanisms of gas exchange during high-frequency ventilation include:


V. DESCRIPTION OF THE COMPONENTS OF THE LIFE PULSE SYSTEM

The following section describes the controls, displays, and pneumatic and patient connections of the Life Pulse High-Frequency Ventilator.

A. Description of the Ventilator Monitoring Displays

The ventilator monitoring displays (Figure 6) located in the upper left corner of the front panel provide the operator with continuous patient and ventilator performance data. The four patient pressure parameters, PIP, ΔP, PEEP, and MAP, display pressures sampled in the patient's trachea during each ventilator cycle. Two ventilator performance indicators, SERVO PRESS and the pinch valve ON/OFF light provide feedback concerning the operation of the Life Pulse itself.

![Ventilator Monitor Displays]

Figure 6: Ventilator Monitor Displays

1. Tracheal Tube Pressures

Distal airway pressures are approximated by measurements near the distal tip of the LifePort adapter. These pressures are measured by the transducer located in the Patient Box then displayed in cm H₂O in the ventilator monitor displays.

NOTE: The analog equivalent of these pressure measurements may be sent to an analog strip chart recorder via the ANALOG OUTPUT connection on the rear panel (Model 203 only).

a. PIP

The PIP (peak inspiratory pressure) window displays the average PIP. During startup (i.e., before the READY light illuminates), a PIP sample is taken with every inhalation cycle and is averaged with all other samples taken over the most recent ten-second period. After regular operation begins, samples are averaged over the most recent twenty-second period.

b. ΔP (Delta P)

The value displayed in the ΔP (pressure difference) window represents the difference between the PIP value and the PEEP value (PIP minus PEEP = ΔP).
c. **PEEP**

The PEEP (positive end-expiratory pressure) window displays the average lowest pressure measured during the exhalation cycle. During startup, a PEEP sample is taken for every exhalation cycle and is averaged with all other samples taken over the most recent ten-second period. After regular operation begins, samples are averaged over the most recent twenty-second period.

d. **MAP**

The MAP (mean airway pressure) window displays the mean or average pressure measured over the entire ventilator cycle. During startup, a sample is taken and is averaged with all other samples taken over the most recent ten-second period. After regular operation begins, samples are averaged over the most recent twenty-second period.

2. **Ventilator Performance Indicators**

a. **SERVO PRESS**

Unlike conventional ventilators which require an operator to manually adjust dials until the desired peak inspiratory pressure (PIP) is achieved, the Life Pulse Ventilator requires only that a desired PIP setting be entered. The microprocessor then automatically "servo" regulates internal pressure until the desired PIP is achieved at the distal tip of the tracheal tube.

This internal machine pressure is called "Servo pressure." Its value can range from 0 to 20 psi (0 to 137.9 kPa) and is displayed in the SERVO PRESS window. During the start-up period, samples of Servo pressure are averaged over the most recent ten-second period. After regular operation begins, samples are averaged over the most recent twenty-second period.

The SERVO PRESS display indicates the amount of pressure the machine must generate internally in order to achieve the PIP appearing in the NOW display. If the PIP sensed or approximated at the distal tip of the tracheal tube deviates from the desired PIP, the machine automatically generates more or less internal pressure in an attempt to compensate for the change. The SERVO PRESS display keeps the operator informed. This display is a vital key to HFV management because it serves as a clinical indicator of such things as changes in the compliance or resistance of the patient's lungs, as well as loss of lung volume due to tension pneumothorax.

b. **Pinch Valve ON/OFF Lights**

The pinch valve ON/OFF lights are simple indicators of what the ventilator is currently telling the pinch valve to do. An illuminated ON light means the valve is signaled to open for an inhale cycle. An illuminated OFF light means it is signaled to close for an exhale cycle. During operation, the light will alternate rapidly back and forth between the ON and OFF positions.
B. Ventilator Alarm Displays

The Ventilator Alarm Displays (Figure 7), located in the upper right corner of the front panel, contain three areas:

1. The UPPER and LOWER ALARM LIMIT controls for MAP and SERVO PRESS;
2. An alarm RESET button, READY light, and SILENCE button; and
3. An alarm indicator message area which contains a series of backlit alarm messages.

![Figure 7: Ventilator Alarm Displays](image)

A detailed description of each alarm and the procedures for setting alarms is contained in Section VI.

NOTE: An alarm condition is defined as any change in the patient's condition or the machine's operation that may constitute a hazard to the patient.

C. Ventilator Control Displays

The ventilator display and control area (Figure 8) of the Life Pulse contains three sections:

- the NOW displays,
- the NEW displays and setting controls, and
- the operating mode selection buttons

![Figure 8: Ventilator Control Displays](image)
1. **NOW Displays**

The NOW display area is composed of a row of four windows that display the current PIP, RATE, JET VALUE ON-Time settings and ON/OFF Ratio. This area is blank during the Standby mode unless a VENTILATOR FAULT exists. In that case, a number representing a fault code for troubleshooting is displayed in the ON/OFF window.

a. **PIP**

Displays the PIP (peak inspiratory pressure) setting in cm H₂O which the ventilator is currently attempting to deliver to the patient. The actual PIP being delivered is displayed in the PIP display in the Ventilator Monitor Display section.

b. **RATE**

Displays the rate at which the ventilator is currently operating in breaths per minute.

c. **JET VALVE ON-TIME**

Displays the time in seconds that the Jet valve is allowed to remain open for each breath. This time is analogous to the inspiratory time setting on conventional ventilators.

d. **JET VALVE ON/OFF TIME**

Displays the ratio of the current JET VALVE ON-TIME to the time the pinch valve is closed during each breath. This ratio is similar to the I:E ratio display found on many conventional ventilators. If a VENTILATOR FAULT occurs, a code number representing the type of fault detected will be displayed in the Standby mode.

2. **NEW Displays and Controls**

The NEW displays and controls area is composed of three sets of windows and increment/decrement buttons which allow the operator to change and display the PIP, RATE or JET VALVE ON-TIME settings before they are "entered" and become the NOW settings.

a. **PIP**

Before the ENTER button is pressed, the NEW PIP selected by the operator will be displayed. After the ENTER button is pressed, the NOW PIP display will read the same as the NEW PIP display.

b. **PIP increment/decrement buttons**

These buttons are used to select NEW PIP levels between 8 and 50 cm H₂O.

c. **RATE**

Before the ENTER button is pressed, the NEW RATE selected by the operator will be displayed. After the ENTER button is pressed, the NOW RATE display will read the same as the NEW RATE display.
d. **RATE increment/decrement buttons**

These buttons are used to select NEW RATES between 240 and 660 breaths per minute.

e. **JET VALVE ON-TIME**

Before the ENTER button is pressed, the NEW JET VALVE ON-TIME selected by the operator will be displayed. After the ENTER button is pressed, the NOW JET VALVE ON-TIME display will read the same as the NEW JET VALVE ON-TIME display.

f. **JET VALVE ON-TIME increment/decrement buttons**

These buttons are used to select NEW JET VALVE ON-TIME. The range of JET VALVE ON-TIME is between 0.020 and 0.034 sec.

3. **OPERATING Mode Selection Buttons**

The Mode buttons area contains three push buttons labeled ENTER, STANDBY, and TEST which control the three modes available to the operator.

a. **ENTER**

Pushing the ENTER button causes the desired settings in the NEW display windows to become current operating settings in the NOW display windows. Pushing ENTER also switches the machine into the RUN mode from the Standby mode.

b. **STANDBY**

Pushing the STANDBY button places the machine in the Standby mode, indicated by lights in the corner of the STANDBY and WAIT buttons, and a 5-second audible alarm every 30 seconds. This mode is useful when the operator wishes to interrupt high-frequency ventilation temporarily, or when he wishes to monitor conventional ventilation prior to, or separate from, high-frequency ventilation. For proper monitoring of conventional ventilation, a minimum rate of six breaths per minute should be maintained.

NEW settings can still be increased or decreased while in Standby mode. Changes will go into effect and the normal operating mode will be resumed when the ENTER button is pushed.

Standby is the mode automatically assumed by the machine on power up.

c. **TEST**

The Test mode can only be entered from the Standby mode. Pushing the TEST button while in the Standby mode will illuminate the light in the corner of the TEST button, and cause the routine Test sequence to begin. This automatic test allows the machine to check its mechanical and electrical systems to insure that they are in good operating condition.

**WARNING:** The Test should not be performed with a patient attached to the Life Pulse.
A detailed discussion of the Test mode is contained in Section VII.E, which discusses initial setup and test of the Life Pulse.

d. ON/OFF Button

The ON/OFF button is located midway down the left side of the front panel. Push the button once: the machine powers up and the green "ON" light illuminates. Push it again: the machine shuts OFF and the light goes out.

D. Humidifier Displays, Controls, and Alarms

The humidifier (Figure 9) regulates the humidification and temperature of the gas as it travels through the disposable humidifier cartridge/patient breathing circuit. It is composed of a display window, a set of six humidifier controls, an alarm system with its own SILENCE button, a water pump, a cartridge receptacle, and the pneumatic connections.

1. Humidifier Displays and Controls

a. WAIT

The WAIT button allows the operator to shut off the humidifier's heater and water pump. This function is useful when changing the disposable humidifier cartridge/patient breathing circuit.

Pushing the WAIT button once shuts off the heater and pump, indicated by a flashing light in the corner of the button and a 5-second audible alarm every 30 seconds. Pushing it a second time turns the displays back on and causes the light to go out.

The humidifier will enter the Wait mode automatically whenever the STANDBY button is pushed or during a LOSS OF PIP alarm in the Non-READY mode. The automatic Wait mode is indicated by a solid light in the corner of the WAIT button. As long as the Wait mode is in effect, whether manually or automatically entered, TEMPERATURE displays will be blank. Temperature set points may still be adjusted by pressing the SET button.

b. TEMPERATURE

The TEMPERATURE window displays in degrees Centigrade (C) any one of three temperatures.

(1) CIRCUIT temperature - The desired temperature for the patient breathing circuit.

(2) CARTRIDGE temperature - The desired temperature for the gas as it exits the humidifier cartridge.

(3) CIRCUIT TEMP - The actual temperature of the gas in the patient breathing circuit. This value is measured just before the gas passes into the pinch valve at the Patient Box.
c. **INCREASE/DECREASE BUTTONS**

The circuit and cartridge temperature settings can be changed using the pair of arrow shaped INCREASE and DECREASE buttons to the left of the SET button. The range of possible temperatures is from 32-42°C.

d. **SET**

The SET button allows the operator to select which temperature setting or measurement will be displayed in the TEMPERATURE window: CIRCUIT, CARTRIDGE, or CIRCUIT TEMP. Indicator lights indicate which of the three temperatures is currently being displayed.

These temperatures display in a fixed sequence with each push of the SET button. The sequence runs CIRCUIT, CARTRIDGE, CIRCUIT TEMP, then back to CIRCUIT.

The normal operating display for the TEMPERATURE window is CIRCUIT TEMP. After fifteen seconds of displaying either the CIRCUIT or CARTRIDGE temperature settings, the window automatically reverts to the CIRCUIT TEMP reading.

e. **CIRCUIT**

The CIRCUIT light indicates that the desired temperature of the gas in the patient breathing circuit is being displayed in the TEMPERATURE display.

f. **CARTRIDGE**

The CARTRIDGE light indicates that the desired temperature of the gas as it exits the humidifier cartridge is being displayed in the TEMPERATURE display.
The CIRCUIT TEMP light indicates that the actual temperature of the gas in the patient breathing circuit, just proximal to the Patient Box, is being displayed in the TEMPERATURE display.

2. Humidifier Alarms

The humidifier alarm system is composed of an alarm SILENCE button and a series of back lit alarm indicator messages.

The function of the humidifier alarms is to warn the operator when temperature or water levels become too high or too low, when an electrical problem exists in the cartridge/circuit, or when the humidifier is in the Wait mode. A detailed discussion of the humidifier alarms is contained in Section VI.

3. Water Pump

The water pump is used to transfer water from a non-pressurized source (bag or bottle) to the pressurized humidifier cartridge. The pump is regulated by the high and low water level sensor pins in the cartridge. When the water level is low, sensors activate the pump. When the water reaches the proper level, a sensor signals the pump to shut-off.

4. Cartridge Receptacle

A cartridge receptacle holds the humidifier cartridge during operation. When the receptacle lid is latched into place, all electrical connections are made automatically. A thermistor regulated heater plate inside the receptacle warms the water in the cartridge.

E. Front Panel Pneumatic Connectors

The front panel contains two barbed pneumatic connectors. Each connector is a different size to eliminate the possibility of incorrect connection.

1. GAS OUT

Located to the left of the humidifier (Figure 9), the GAS OUT is the main gas supply outlet to the humidifier cartridge/patient breathing circuit. The green gas inlet tube on the humidifier cartridge is attached to this connector.

2. PURGE

Located to the right of the humidifier (Figure 9), the PURGE is the port that provides the gas supply for the purge valve, which is located on the Patient Box. Gas from this tube is used to clear moisture from the pressure monitoring tube of the LifePort adapter. One end of the small, clear, tube of the patient breathing circuit is attached here.

F. Patient Box

The Patient Box is a satellite component. It has been designed for placement near the patient's head in order to provide accurate monitoring of pressure waveforms in the patient's trachea and ensure the delivery of crisp jets of gas to the patient. The Patient Box Model 312 (Figure 10
and Figure 11) houses the pinch valve, purge valve, and a pressure transducer. The Patient Box is linked to the ventilator by an electrical cable connected to the rear panel.

1. **Pinch Valve**

   The function of the pinch valve is to break the flow of pressurized gas coming from the ventilator into small bursts. This function is accomplished by the rapid pinch and release action of the valve jaws on the pinch tubing segment of the patient breathing circuit.

2. **PUSH TO LOAD** (pinch valve release button)

   The PUSH TO LOAD button is used to open the jaws of the pinch valve so the pinch tube of the patient breathing circuit may be placed into the pinch valve.

---

**Figure 10: Patient Box Model 312 Top View**

**Figure 11: Patient Box Model 312 Side View**
3. **FROM PURGE** (Purge Valve)

The function of the purge valve is to maintain the patency of the pressure monitoring tube of the LifePort adapter. This is done by allowing pressurized dry gas from the ventilator to flow into the pressure monitoring tube every fifteen seconds, once per second for 11 seconds after the ENTER button is pressed, and once per second whenever the pressure waveform becomes distinctive of partial occlusion with airway secretions or condensation.

There are two connectors are found on opposite ends of the Patient Box (Model 312). The smaller Purge connector is on the cable end and the Pressure Monitoring Tube connector is on the end opposite the cable.

4. **TO Hi-Lo PRESSURE MONITORING LUMEN** (Pressure Transducer)

This label appears on the original Patient Box. The label on the New Patient Box reads “To Pressure Monitoring Tube.” The function of the pressure transducer is to measure the pressure in the patient's trachea via the pressure monitoring tube, and to electrically relay this information back to the ventilator via the electrical cable. The ventilator's microprocessor receives this information and is programmed to ignore pressures added by periodic purge valve releases.

5. **Patient Box Connector**

This connector is used to connect the Patient Box to the ventilator via a mating connector located on the rear panel of the ventilator.

G. **Humidifier Cartridge/Patient Breathing Circuit**

The function of the disposable humidifier cartridge/patient breathing circuit is to provide a conduit for the humidification, warming, and temperature monitoring of the pressurized gas leaving the ventilator. It is a closed system and is not open to contamination during operation.

This cartridge/circuit is composed of two elements: the humidifier cartridge and the patient breathing circuit. These elements have been assembled as one continuous disposable unit.

1. **Humidifier Cartridge**

The humidifier cartridge (Figure 12) portion of the cartridge/circuit is the site where gas is both heated and humidified before it is delivered to the patient. The humidifier cartridge contains:

   a. Green gas inlet tube: the green gas inlet tube is connected to the GAS OUT connector on the left side of the front panel. This tube is the conduit through which gas flows from the ventilator into the cartridge.
Figure 12: Humidifier Cartridge
b. Water inlet tube with valve: this tube, which is placed in the water pump, is used to transfer water via the pump to fill the humidifier cartridge.

c. Heater plate: an anodized aluminum heating plate is used to heat the water to the cartridge temperature selected by the operator.

d. Water level sensors: three water level sensors are used by the microprocessor to monitor the level of water in the humidifier cartridge. When the water level drops below the minimum allowable level for 10 seconds, the water pump is activated and the cartridge is refilled. If the water level cannot be maintained within acceptable levels, the HIGH or LOW WATER LEVEL alarm is activated.

e. Cartridge thermistor: a thermistor located at the connection of the patient breathing circuit to the cartridge is used to ensure that the gas is heated to the cartridge temperature selected by the operator.

**WARNING:** Care should be taken not to tip the cartridge during removal, as water could spill directly into the patient breathing circuit. Too much water in the patient breathing circuit may endanger the patient.

2. **Patient Breathing Circuit**

   The patient breathing circuit (Figure 13) is the tubing that delivers gas from the humidifier cartridge to the LifePort adapter. The patient breathing circuit consists of:

   a. **Heated patient breathing circuit:** this clear tube runs from the humidifier cartridge to the pinch tube that is placed in the pinch valve.

   b. **Pinch tube:** a 3" segment of pinch tubing is attached near the end of the heated patient breathing circuit for placement between the jaws of the pinch valve.

   c. **Gas delivery tube:** a 13" length of green tubing is attached to the pinch tube. It is used to connect the patient breathing circuit to the Jet port on the LifePort adapter.

   d. **Circuit thermistor:** this thermistor is used to measure the temperature of the gas in the breathing circuit just before it reaches the pinch valve. The thermistor is covered with a piece of Mylar tape.
Figure 13: Patient Breathing Circuit
e. **Heating wire**: an insulated wire is used to maintain the temperature of the gas at the level selected by the operator. It runs the length of the patient breathing circuit from the cartridge almost to the pinch valve.

f. **Purge tube**: a small diameter tube that is connected to the clear patient circuit tube and connects to the PURGE connector at the ventilator and to the PURGE VALVE connector at the Patient Box.

3. **GUARANTEE**

The Life Pulse HFV Patient Circuit is guaranteed for seven days of use. If the circuit fails prior to seven days of use Bunnell will replace it at no charge. The faulty circuit must be returned to Bunnell before the replacement circuit can be issued.

H. **LifePort Adapter**

The Life Pulse High-Frequency Ventilator is designed to work with the LifePort adapter distributed by Bunnell (See Figure 14) and a standard endotracheal tube. These products provide a disposable conduit from the Patient Box to the patient's lungs. The LifePort adapters come in internal diameter sizes of 2.5, 3.5, and 4.5 mm.

1. **LifePort Adapter**:  
   a. **15 mm Connection**
      
      The 15 mm main lumen, or the largest opening, serves as the connection point for either a conventional neonatal ventilator circuit or the circuitry through which CPAP may be provided.
   
   b. **Jet Port**
      
      The side port on the LifePort adapter is the Jet port. The green delivery tube from the Life Pulse patient breathing circuit is attached here.
   
   c. **Pressure Monitoring Tube**
      
      The long, clear tube is used to monitor pressures at the distal tip of the LifePort adapter. Pressures monitored using the LifePort approximate pressure from the distal tip of the endotracheal tube. This tube is connected to the PRESSURE MONITORING LUMEN connector on the Patient Box.
Figure 14: LifePort Adapter

1. Rear Panel

The rear panel (Figure 4 and Figure 5) is the location of a number of miscellaneous controls and connections including the MIXED GAS INPUT connection, the ANALOG OUTPUT (Model 203 only), the "dump" valve outlet labeled with the words DO NOT BLOCK, the three amp circuit breaker, the hour meter, the ALARM VOLUME control, the PATIENT BOX connector, the OXYGEN SENSOR port (Model 203 only, not available on HFV Serial No. 2414 and higher), and the protective earth terminal (Model 203A only).

1. MIXED GAS INPUT

The MIXED GAS INPUT fitting is a standard DISS O₂ fitting which connects the ventilator to a low flow blender (0-30 L/min.) or to the low flow output (2-100 L/min.) of a standard air/oxygen blender. A 30 – 60 psi (206.85 – 413.7 kPa) supply source is required for operation. Gas is normally supplied from an external blender to provide a mechanism for varying the FiO₂.

2. ANALOG OUTPUT (Model 203 only)

The ANALOG OUTPUT is a 20-volt peak-to-peak, phone jack output, capable of delivering pressure waveform information to an external strip chart recorder.

3. DUMP VALVE

The "dump valve" is a safety valve through which internal pressure in the ventilator can be released. This is done through an outlet port labeled DO NOT BLOCK. Care should be taken to see that this port does not become blocked.

4. CIRCUIT BREAKER

The three-amp circuit breaker cuts off power to the unit in the event of excessive current flow.

Model 203
The Circuit Breaker is located next to the “3 AMPS” label and can be reset by toggling the switch.
Model 203A
The Circuit Breaker has a “3” labeled on it and can be reset by pushing the plunger.

5. **HOUR METER**

The hour meter provides a cumulative display of the total number of hours the machine has been powered. Hour tracking stops whenever the machine is turned off.

6. **ALARM VOLUME**

The ALARM VOLUME knob allows the operator to adjust the volume of the system's audible alarm.

7. **PATIENT BOX**

The PATIENT BOX connector is used to connect the Patient Box to the ventilator via a mating connector located on the Patient Box.

8. **OXYGEN SENSOR (Model 203 only)**

The OXYGEN SENSOR port is provided for connection to an oxygen analyzer. Gas can be sampled in this manner at a low gas flow rate of approximately 0.1 liters per minute (not available on HFV Serial No. 2414 and higher).

9. **PROTECTIVE EARTH TERMINAL (Model 203A only)**

The protective earth terminal (ground stud) connects the exposed conductive parts of the ventilator to the protective earth conductor for electrical safety checks.
VI. VENTILATOR ALARMS:

The Life Pulse High-Frequency Ventilator contains a complete airway pressure monitoring and alarm system to inform the operator of changes in the status of the patient and to alert the operator to potentially dangerous situations. The distal tip ET tube pressures are approximated by the LifePort adapter using a pressure transducer located in the Patient Box. The ventilator alarms (Figure 15) are displayed in the upper right hand corner of the Life Pulse.

![Figure 15: Ventilator Alarm System](image)

A. Automatically Set Alarms:

Unlike most conventional ventilators, the Life Pulse has been programmed to automatically establish high and low alarm limits around SERVO PRESSURE, MAP, and PIP, and to automatically check for other alarm conditions.

1. SERVO PRESS:
   a. **Definition**: The SERVO PRESS alarm alerts the user to changes in the internal driving pressure required to deliver breaths at the set NOW PIP, RATE, and JET VALVE ON-TIME.

   b. **Method of automatically setting limits**: Once the ENTER button is pushed, the microprocessor changes the values for SERVO PRESS until the monitored PIP matches the NOW PIP. The moment the READY light is on, the present value of SERVO PRESS is used to set alarm limits as follows:

<table>
<thead>
<tr>
<th>Servo Press</th>
<th>Alarm Window</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 psi (6.9 kPa)</td>
<td>± 0.2 psi (1.4 kPa)</td>
</tr>
<tr>
<td>1 - 5 psi (6.9 - 34.5 kPa)</td>
<td>± 20%</td>
</tr>
<tr>
<td>&gt; 5 psi (34.5 kPa)</td>
<td>± 1 psi (6.9 kPa)</td>
</tr>
</tbody>
</table>

   **NOTE**: There are no alarm limits in effect unless the READY light is ON.
c. **Method of Manually Setting Limits:**

(1) Changing the UPPER LIMIT (READY light must be lit)

(a) Determine the current upper limit by pressing the UPPER LIMIT button. The current UPPER LIMIT will appear in the SERVO PRESS display.

(b) To raise the UPPER LIMIT, simultaneously push the UPPER LIMIT button and the increase button until the value in the SERVO PRESS display reaches the desired UPPER LIMIT.

(c) To lower the UPPER LIMIT, simultaneously push the UPPER LIMIT button and the decrease button until the value in the SERVO PRESS display reaches the desired UPPER LIMIT.

(2) Changing the LOWER LIMIT (READY light must be lit)

(a) Determine the current lower limit by pressing the LOWER LIMIT button. The current LOWER LIMIT will appear in the SERVO PRESS display.

(b) To raise the LOWER LIMIT, simultaneously push the LOWER LIMIT button and the increase button until the value in the SERVO PRESS display reaches the desired LOWER LIMIT.

(c) To lower the LOWER LIMIT, simultaneously push the LOWER LIMIT button and the decrease button until the value in the SERVO PRESS display reaches the desired LOWER LIMIT.

d. **Methods of Indicating SERVO PRESS Alarms:**

(1) High SERVO PRESS alarm

(a) The four red lights in the corners of the UPPER LIMIT button will be lit until the alarm condition is corrected.

(b) An audible alarm will sound.

(2) Low SERVO PRESS alarm

(a) The four red lights in the corners of the LOWER LIMIT button will be lit until the alarm condition is corrected.

(b) An audible alarm will sound.
e. **Conditions which may cause SERVO PRESS alarms:**

(1) Changes in the impedance of the patient's respiratory system due to:
   
   (a) Changes in airway resistance.

   (b) Obstructions in the tracheal tube or the patient's airway.

   (c) Changes in lung compliance.

   (d) Air leaks such as pneumothorax, pneumopericardium, etc.

(2) Leaks in the cartridge/circuit due to damage or misconnection.

f. **Responses of the Life Pulse to a SERVO PRESS alarm:**

(1) High SERVO PRESS alarms

   (a) The Servo pressure is locked to prevent any further increases.

   (b) Ventilation of the patient is continued.

(2) Low SERVO PRESS alarms

   (a) The Servo pressure is locked to prevent any further decreases.

   (b) Ventilation of the patient is continued.

g. **Suggested Operator's response to a SERVO PRESS alarm:**

(1) High SERVO PRESS alarms

   (a) Inspect the breathing circuit for leaks, poor connections, or occlusions.

       If YES: Place the Life Pulse in Standby mode.

       Replace circuit if tubing is damaged.

       Check tubing connections.

       Un-kink tube, and Press the Enter button to re-establish ventilation.

       If NO: See (b).

   (b) Examine the patient for an increase in an evacuated air leak, such as pneumothorax or bronchopleural fistula.

       If YES: Provide appropriate medical attention.

       Push RESET to re-establish settings.

       If NO: See (c).
(c) Examine the patient for signs of improved atelectasis and newly-expanded alveoli.

If YES: Provide appropriate medical attention.

Push RESET to re-establish settings.

If NO: Call the Bunnell Hotline.

(2) Low SERVO PRESS alarms

(a) Inspect the tracheal tube for position, plugging, or occlusion.

If YES: Re-position tube.

Clear tube (suctioning).

Un-kink tube and press RESET button to re-establish alarm limit.

If NO: See (b).

(b) Examine the patient for tension pneumothorax and/or atelectasis.

If YES: Provide appropriate medical attention.

Push RESET to re-establish alarm limits.

If NO: See (c).

(c) Examine the patient for signs of airway obstruction.

If YES: Provide appropriate medical attention (suctioning, bronchoscopy, etc.).

If NO: See (d).

(d) Inspect the exhalation limb of the conventional breathing circuit for kinks.

If YES: Replace damaged tubing.

Un-kink tube.

If NO: Call the Bunnell Hotline.

2. MAP:

a. **Definition:** The MAP alarm alerts the user to changes in the mean airway pressure as measured or approximated at the distal tip of the tracheal tube.

b. **Method of automatically setting limits:** Once the ENTER button is pushed, the microprocessor will monitor the values for MAP until the READY light comes on. The
moment the ready light is switched on, the microprocessor will store the current values for MAP and automatically set alarm limits around MAP. These limits are set as follows:

High Limit = stored value + 1.5 cm H₂O

Low Limit = stored value - 1.5 cm H₂O

**NOTE:** There are no alarm limits in effect until the READY light is ON.

c. **Method of manually setting limits:**

(1) Changing the UPPER LIMIT

(a) Determine the current UPPER LIMIT by pressing the UPPER LIMIT button. The current UPPER LIMIT will appear in the MAP display.

(b) To increase the UPPER LIMIT, simultaneously push the UPPER LIMIT button and the increase button until the value in the MAP display reaches the desired UPPER LIMIT.

(c) To decrease the UPPER LIMIT, simultaneously push the UPPER LIMIT button and the decrease button until the value in the MAP display reaches the desired UPPER LIMIT.

(2) Changing the LOWER LIMIT

(a) Determine the current lower limit by pressing the LOWER LIMIT button. The current LOWER LIMIT will appear in the MAP display.

(b) To increase the LOWER LIMIT, simultaneously push the LOWER LIMIT button and the increase button until the value in the MAP display reaches the desired LOWER LIMIT.

(c) To decrease the LOWER LIMIT, simultaneously push the LOWER LIMIT button and the decrease button until the value in the MAP display reaches the desired LOWER LIMIT.

d. **Methods of indicating MAP alarms:**

(1) High MAP alarm

(a) The four red lights in the corners of the UPPER LIMIT button will be lit until the alarm condition is corrected.

(b) An audible alarm will be sounded.

(2) Low MAP alarm

(a) The four red lights in the corners of the LOWER LIMIT button will be lit until the alarm condition is corrected.

(b) An audible alarm will be sounded.
e. **Conditions which may cause MAP alarms:**

   (1) Changes in the *conventional* ventilator's settings or performance.
   (2) Leaks in the cartridge/circuit due to damage or misconnection.
   (3) Obstruction in the expiratory limb of the conventional circuit.
   (4) Improper position or obstruction of E.T. tube.

f. **Responses of the Life Pulse to a MAP alarm:**

   (1) High MAP alarms
       (a) The Servo pressure is locked to prevent any further increases.
       (b) Ventilation of the patient is continued.
   (2) Low MAP alarms
       (a) The Servo pressure is locked to prevent any further decreases.
       (b) Ventilation of the patient is continued.

g. **Suggested operator's response to a MAP alarm:**

   (1) High MAP alarms
       (a) Check pressure monitoring tube of the LifePort adapter for excess condensation or obstructions.
           
           If YES: Flush monitoring tube with 2-3 ml dry air via syringe.
           When necessary, reduce humidifier cartridge temperature to reduce water condensation.
           Keep circuit temperature at 40° C.
           
           If NO: See (b).
       (b) Inspect the exhalation limb of the conventional breathing circuit for kinks.
           If YES: Replace damaged tubing.
           Un-kink the tubing.
           
           If NO: See (c).
       (c) Inspect the tracheal tube for obstructions.
           If YES: Clear tube. Change tube if necessary.
           If NO: See (d).
(d) Inspect conventional ventilator for changes in settings or performance.
   If YES: Correct settings of conventional ventilator.
            Push RESET to re-establish settings.
   If NO: Call the Bunnell Hotline.

(2) Low MAP alarms

(a) Check pressure monitoring tube of the LifePort adapter for excess condensation or plugging.
   If YES: Flush monitoring tube with 2-3 ml dry air via syringe.
            When necessary, reduce humidifier cartridge temperature to reduce water condensation.
            Keep circuit temperature at 40°C.
   If NO: See (b).

(b) Inspect the breathing circuit and humidifier cartridge for leaks, poor connections, or kinks.
   If YES: Replace damaged circuit.
            Repair poor tubing connections.

   **WARNING:** If the Life Pulse circuit is kinked, place Life Pulse in Standby before un-kinking tube.
   If NO: See (c).

(c) Inspect the tracheal tube for positioning and/or excess leakage.
   If YES: Re-position tube so bevel at distal end opens toward left side.
            Change tube if necessary.
   If NO: See (d).

(d) Inspect conventional ventilator for changes in settings or performance.
   If YES: Correct settings of conventional ventilator.
            Push RESET to re-establish settings.
   If NO: See (c).
(e) Check gas supply to Life Pulse for pressures less than 30 psi (206.85 kPa). (Low gas pressure will cause LOW GAS PRESS alarm.)

If YES: Provide supply pressure greater than 30 psi (206.85 kPa).

If NO: Call the Bunnell Hotline.

3. HIGH PIP:

a. Definition: The HIGH PIP alarm indicates that

(1) the monitored airway pressure has exceeded the NOW PIP setting by at least 5 cm H$_2$O continuously for at least 1 second;

(2) monitored PIPs for all breaths delivered by the Life Pulse in the last 30 seconds have exceeded the NOW PIP by at least 10 cm H$_2$O, or;

(3) the monitored PIP for each breath during a 0.75 sec period exceeds the PIP set point by 30 cm H$_2$O.

b. Method of automatically setting limits: Once the ENTER button is pushed, the microprocessor will monitor the values for PIP until the READY light comes on. The moment the READY light is switched on, the microprocessor will store the current average values for PIP and automatically set alarm limits around PIP. The HIGH PIP limits established are NOW PIP + 5, 10, 30 cm H$_2$O. (See Definition)

c. Method of manually setting limits: The HIGH PIP alarm is controlled by the Life Pulse's microprocessor, and there is no method of manually adjusting the limits for this alarm.

d. Methods of indicating HIGH PIP alarms:

(1) "HIGH PIP" appears as a back-lit message in the lower portion of the upper right corner of the Life Pulse. (See Figure 15)

(2) An audible alarm will sound.

e. Conditions which may cause HIGH PIP alarms:

(1) Failure of the conventional ventilator.

(2) Failure of the pinch valve located in the Patient Box.

(3) Failure of the purge valve, also located in the Patient Box.

(4) Obstruction of the main lumen of the tracheal tube.

(5) Obstruction of any part of the exhalation tubing of the conventional breathing circuit.

f. Responses of the Life Pulse to HIGH PIP:

(1) The Life Pulse will truncate or shorten the inspiratory cycle.
(2) If the over-pressure condition exists for more than 2 seconds, the HIGH PIP visual alarm and the audible alarm will be activated.

(3) The pinch valve will be closed and the Servo pressure will be released through the DUMP VALVE, located in the rear of the Life Pulse. The Servo pressure will be at a lower level than that which existed prior to the High PIP alarm condition.

g. **Suggested operator's response to a HIGH PIP alarm:**

(1) Inspect the tracheal tube for positioning, plugging, or occlusion.
   - If YES: Re-position tracheal tube.
     - Clear tube by suctioning.
     - Un-kink tube.
   - If NO: See (2).

(2) Check pressure monitoring tube of the LifePort adapter for excess condensation or plugging.
   - If YES: Flush monitoring lumen with 2-3 ml dry air via syringe.
     - If necessary, reduce humidifier cartridge temperature to reduce water condensation.
     - Keep circuit temperature at 40° C.
   - If NO: See (3).

(3) Inspect expiratory line from conventional ventilator for obstruction or occlusion.
   - If YES: Clear obstruction.
     - Un-kink tubing.
     - Replace circuit if necessary.
   - If NO: See (4).

(4) Exchange the Patient Box with an alternate Patient Box to check for malfunction. Place ventilator in Standby mode.
   - If YES: Call an authorized service representative.
   - If NO: Call the Bunnell Hotline.

4. **LOSS OF PIP:**

   a. **Definition:** The LOSS OF PIP alarm may be activated by one or more of the following conditions. (See following "Method of automatically setting limits"): 
The monitored PIP has dropped below 25% of the NOW PIP.

The monitored PIP is less than 3 cm H₂O.

Monitored values for PIP and PEEP are within 2 cm H₂O of each other.

b. **Method of automatically setting limits:** The first limit of the monitored PIP has dropped below 25% of the NOW PIP setting becomes activated at the instant the READY light is lit. The last two LOSS OF PIP limits defined above are established seconds after the ENTER button has been pushed.

**WARNING:** There will be no LOSS OF PIP alarm for the first 15 seconds after the ENTER button is pushed or until the READY light becomes lit.

c. **Method of manually setting limits:** The LOSS OF PIP alarm is controlled by the Life Pulse's microprocessor, and there is no method of manually adjusting the limits for this alarm.

d. **Methods of indicating LOSS OF PIP alarms:**

1. "LOSS OF PIP" appears as a back lit message in the lower portion of the upper right corner of the Life Pulse. (See Figure 15)

2. An audible alarm will sound.

**WARNING:** Pressing the ENTER button during the LOSS OF PIP alarm will temporarily silence the audible alarm and cause the Life Pulse to restart efforts to ventilate the patient under new alarm parameters. The risk in such a procedure is that it allows an operator to restart ventilation without first correcting the alarm condition.

e. **Conditions which may cause LOSS OF PIP alarms:**

1. The monitoring, circuit, and/or tracheal tube(s) of the LifePort adapter may be disconnected.

2. Other connections in the humidifier cartridge or patient circuit may be disconnected.

3. The gas supply to the Life Pulse may have failed, in which case the LOW GAS PRESS alarm should be activated.

4. Water or mucus may be plugging the pressure monitoring tube of the LifePort adapter.

5. The conventional ventilator may be malfunctioning causing a drastic fall or rise in PEEP.

6. The Life Pulse may have failed.

7. Malfunction or failure of Patient Box.

8. Patient is fighting the Life Pulse.
f. **Responses of the Life Pulse to LOSS OF PIP:**

(1) If the READY light is on, besides activating the alarm, the Life Pulse locks the Servo pressure at the level present when the current LOSS OF PIP alarm occurred. The Life Pulse continues to attempt to ventilate the patient. If the actual Servo pressure increases from the locked Servo pressure by the following amount, the Life Pulse will close the flow control valves:

<table>
<thead>
<tr>
<th>Locked Servo</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \leq 5 \text{ psi (34.5 kPa)} )</td>
<td>0.5 psi (3.45 kPa)</td>
</tr>
<tr>
<td>&gt; 5 psi (34.5 kPa)</td>
<td>1.0 psi (6.9 kPa)</td>
</tr>
</tbody>
</table>

**WARNING:** Do not press the ENTER button during a LOSS OF PIP alarm if the patient is clinically appropriate and the Servo pressure has locked at or near the established operating value. Doing so will temporarily silence the audible alarm and unlock the Servo pressure. This action may shut off the Servo valves and will result in high-frequency breaths of decreased volume to be delivered to the patient.

(2) The Servo pressure valves are shut and the dump valve is opened when a LOSS OF PIP alarm occurs while the Ready light is off. This response protects the patient when the Life Pulse circuit is disconnected or kinked, then reconnected or un-kinked during start-up.

**WARNING:** If a LOSS OF PIP alarm has occurred with the READY light off, it will be necessary to press the ENTER button to resume ventilation.

g. **Suggested operator's response to a LOSS OF PIP alarm:**

(1) Inspect the breathing circuit and humidifier cartridge for leaks, poor connections, or occlusions.

If YES: Replace damaged cartridge and tubing.

Secure tubing connection.

If NO: See (2).

(2) Check pressure monitoring tube of the LifePort adapter for excess condensation or plugging.

If YES: Flush monitoring lumen with 2-3 ml dry air via syringe.

When necessary, reduce humidifier cartridge temperature to reduce water condensation.

Keep circuit temperature at 40° C.

If NO: See (3).

(3) Inspect the conventional ventilator for changes in settings or performance.
If YES: Correct settings of the conventional ventilator.

Push RESET to re-establish alarm limits.

If NO: See (4).

(4) Check gas supply to Life Pulse for pressures less than 30 (206.85 kPa). (Low gas pressure should also cause a LOW GAS PRESS alarm.)

If YES: Provide gas supply pressure greater than 30 psi (206.85 kPa).

If NO: See (5).

(5) See if patient is agitated or fighting Life Pulse.

If YES: Try to calm patient or consider sedation.

If NO: See (6).

(6) Check Patient Box for malfunction (stopped cycling or inability to maintain pressures).

If YES: Switch out Patient Box and check on test lung.

If NO: Call the Bunnell Hotline.

5. CANNOT MEET PIP:

a. Definition:

(1) The Life Pulse has failed to deliver peak pressures within +2.0 and -1.5 cm H₂O of the NOW PIP setting while the Servo pressure has risen up to 20 psi (137.9 kPa) or greater.

(2) The monitored PIP has not stabilized within +2.0 and -1.5 cm H₂O of the NOW PIP (established the "READY" condition) within 3 minutes of the ENTER or RESET button being pushed.

b. Method of automatically setting limits:

(1) If the Servo pressure is 20 psi (137.9 kPa), a lower limit for the monitored PIP is set at the NOW PIP setting - 1.5 cm H₂O.

(2) The other limits are defined by the READY condition which must be reached within 3 minutes of the ENTER or RESET button being pushed.

c. Method of manually setting limits: The CANNOT MEET PIP alarm is controlled by the Life Pulse's microprocessor, and there is no method of manually adjusting the limits for this alarm.

d. Methods of indicating CANNOT MEET PIP alarms:

(1) The CANNOT MEET PIP appears as a back lit message in the lower portion of the upper right corner of the Life Pulse. (See Figure 15)
(2) An audible alarm will sound.

e. **Conditions which may cause CANNOT MEET PIP alarms:**

(1) A leak in the humidifier cartridge/patient breathing circuit.

(2) The humidifier cartridge/patient breathing circuit is not properly connected to the LifePort adapter.

(3) The LifePort adapter is damaged or defective (e.g., there is too much restriction to the high-frequency pulses).

(4) The patient is too large to be ventilated by present Life Pulse settings.

(5) The patient is fighting the Life Pulse.

(6) The pinch valve may not be opening enough, necessitating high Servo pressures to meet the desired settings.

(7) Over-humidification of Life Pulse circuit is causing water droplets to interfere with pressure monitoring at the LifePort adapter.

f. **Response of the Life Pulse to CANNOT MEET PIP:** The Life Pulse continues to ventilate the patient while alarming.

g. **Suggested operator's response to CANNOT MEET PIP:**

(1) Inspect the breathing circuit and humidifier cartridge for leaks, poor connections, or occlusions.

   If YES: Replace damaged tubing.
   Repair tubing connections.

   **WARNING:** If a kink is in Life Pulse circuit, place Life Pulse in Standby mode before un-kinking tube.

   If NO: See (2).

(2) Inspect the tracheal tube for positioning, plugging, occlusion, or excess leaks.

   If YES: Reposition tracheal tube.
   Clear tube by suctioning.
   Un-kink tube.

   **WARNING:** If a kink is in Life Pulse circuit, place Life Pulse in Standby mode before un-kinking tube.

   If NO: See (3).

(3) Check for malfunctioning of the pinch valve by replacing the Patient Box while the Life Pulse is in the Standby mode.
If YES: Call an authorized service representative.

If NO: See (4).

(4) Verify patient is of appropriate size. The Life Pulse may not be able to ventilate larger patients. It has been proven capable of ventilating patients weighing up to 3.66 kg, and will require higher Servo pressures for larger patients.

If YES: Call Bunnell Hotline to discuss possible solutions.

If NO: See (5).

(5) Patient fighting the Life Pulse.

If YES: Try to calm patient or consider sedation.

If NO: See (6).

(6) Life Pulse circuit between the humidifier and patient box contains water droplets or puddles of water.

If YES: Decrease cartridge temperature in 0.5°C increments until circuit is mostly dry.

If NO: Call the Bunnell Hotline.

6. LOW GAS PRESS:

a. **Definition:** The LOW GAS PRESS alarm indicates that the pressure of the gas supply to the Life Pulse is below 30 psi (206.85 kPa).

b. **Method of automatically setting limits:** The limit established is 30 psi (206.85 kPa).

c. **Method of manually setting limits:** The LOW GAS PRESS alarm is controlled by the Life Pulse, and there is no method of manually adjusting the limits for this alarm.

d. **Methods of indicating LOW GAS PRESS alarms:**

   (1) "LOW GAS PRESS" appears as a backlit message in the lower portion of the upper right corner of the Life Pulse. (See Figure 15)

   (2) An audible alarm will sound.

e. **Conditions which may cause LOW GAS PRESS alarms:**

   (1) The gas supply is disconnected or is empty.

   (2) The blender failed.

   (3) Gas supply pressure switch failed.

f. **Response of the Life Pulse to LOW GAS PRESS:** Continues to attempt to ventilate the patient.
g. **Suggested operator's response to a LOW GAS PRESS alarm:**

(1) Gas supply disconnected.

   If YES: Connect gas supply.
   
   If NO: See (2).

(2) Check gas supply for pressures less than 30 psi (206.85 kPa) and/or supply lines for leaks.

   If YES: Supply pressures greater than 30 psi (206.85 kPa).
   
   Repair or replace damaged gas supply hose.
   
   If NO: See (3).

(3) Check air/oxygen blender for leaks or malfunction.

   If YES: Replace the blender.
   
   If NO: Call the Bunnell Hotline.

7. **VENTILATOR FAULT:**

a. **Definition:** The VENTILATOR FAULT alarm indicates a possible problem with the Life Pulse electronics or valves.

b. **Method of automatically setting limits:** The functions of several components and electronic circuits are continuously monitored by the microprocessor. If a malfunction is detected, the VENTILATOR FAULT alarm is activated.

c. **Method of manually setting limits:** The VENTILATOR FAULT alarm is controlled by the Life Pulse's microprocessor, and there are no methods of manually adjusting the limits for this alarm.

d. **Methods of indicating VENTILATOR FAULT alarms:**

   (1) "VENTILATOR FAULT" appears as a backlit message in the lower portion of the upper right corner of the Life Pulse. (See Figure 15)

   (2) An audible alarm will sound.

   (3) A numerical code may be displayed in the JET VALVE ON/OFF TIME window to indicate what type of failure has occurred.

e. **Conditions which may cause VENTILATOR FAULT alarms:**

   (1) Purge tube is disconnected at the ventilator's front panel or the Patient Box.

   (2) Disconnected pressure monitoring tube.

   (3) A purge or Servo pressure valve failure.
(4) Failure of any of the electronic circuitry related to computer memory, pressure monitoring, or control of the purge or Servo pressure valves.

f. **Responses of the Life Pulse to a VENTILATOR FAULT:**

(1) Disconnected purge tube, failed purge valve, or failed pressure transducer will cause visual and audible alarms, but the Life Pulse will continue to operate. These failures in the TEST mode will cause failure code "02" to be displayed in the ON/OFF window. A pressure transducer failure will also cause either a "LOSS OF PIP" or "HIGH PIP" alarm.

(2) Servo pressure valve or transducer failures will cause visual and audible alarms, and the Life Pulse will automatically revert to the Standby mode if the Servo pressure begins to rise rapidly. In this case, failure code "10" will be displayed in the ON/OFF window. A minor failure, such as a servo valve stuck shut or a Servo pressure transducer failure, will allow the Life Pulse to continue operating. These failures in the TEST mode will cause failure code "03" to be displayed in the ON/OFF window.

(3) Electronic circuitry and/or computer memory failures will cause visual and audible alarms, and the Life Pulse will automatically revert to the Standby mode with failure code "01", "04", "05", "06", "07", "08", or "09" displayed in the ON/OFF window.

g. **Suggested operator's response to a VENTILATOR FAULT alarm:**

(1) Inspect the purge tube for poor connections at front panel PURGE and Patient Box FROM PURGE connectors.

   If YES: Connect purge tube.

   If NO: See (2).

(2) Inspect the pressure monitoring tube for poor connection at the Patient Box PRESSURE MONITORING LUMEN connector.

   If YES: Connect pressure monitoring tube.

   If NO: See (3).

(3) Replace the Patient Box to determine if the purge valve or some other component in the Patient Box is the cause of the alarm.

   If YES: Call authorized service representative.

   If NO: See (4).

(4) Look for code numbers 01 - 09 in ON/OFF ratio window.

   If YES: Turn off power to Life Pulse to reset it, then power-up Life Pulse and use a test lung to run the TEST procedure by pressing TEST button. If Life Pulse passes TEST, restart on patient and call the Bunnell Hotline.

   If NO: Discontinue use of Life Pulse and call the Bunnell Hotline.
WARNING: The patient is not being ventilated by the Life Pulse during VENT FAULT alarms that place the Life Pulse into Standby mode.

8. JET VALVE FAULT:

a. **Definition:** The JET VALVE FAULT alarm indicates that the pinch valve is out of synchrony with the ventilator.

b. **Method of automatically setting limits:** The function of the pinch valve is continuously monitored by the microprocessor. If a malfunction is detected, the JET VALVE FAULT alarm is activated.

c. **Method of manually setting limits:** There is no method of manually adjusting the limits for this alarm.

d. **Methods of indicating JET VALVE FAULT alarms:**

   (1) "JET VALVE FAULT" appears as a back-lit message in the lower portion of the upper right corner of the Life Pulse. (See Figure 15)

   (2) An audible alarm will sound.

e. **Conditions which may cause JET VALVE FAULT alarms:**

   (1) Failure of the pinch valve assembly.

   (2) Failure of an internal electronic or feedback circuit.

f. **Response of the Life Pulse to JET VALVE FAULT:** The Life Pulse will continue to operate although the pinch valve may not cycle.

g. **Suggested Operator's response to a JET VALVE FAULT alarm:**

   Replace the Patient Box to determine if the pinch valve or some other component in the Patient Box is the cause of the alarm.

   If YES: Call authorized service representative.

   If NO: Call the Bunnell Hotline.

9. Loss of Electrical Power:

a. **Definition:** The Life Pulse will react predictably to any disruption in electrical power with at least an audible alarm as described below.

b. **Method of automatically setting limits:** The Life Pulse will react to any loss of power below approximately 105 volts AC.

c. **Method of manually setting limits:** not applicable.
d. **Methods of indicating loss of electrical power:**

(1) Complete loss of power will trigger an audible alarm with all lights on the front panel being turned off and the Servo pressure dumped to atmosphere.

(2) Momentary power loss of up to 1-minute duration will also result in an audible alarm, a blank front panel, and the Servo pressure being dumped, but the Life Pulse will re-start its operation upon regaining power. The audible alarm will remain on until silenced after the re-start.

(3) Power losses of greater than 1 minute duration that are subsequently restored will result in the Life Pulse assuming the Standby mode with its start-up settings of PIP = 20, RATE = 420, and ON TIME = 0.020, and the audible alarm sounding.

e. **Conditions which may cause loss of power alarms:**

(1) Pulling the power cord plug from the wall outlet.

(2) General power outages.

(3) Pressing the power switch while the Life Pulse is operating.

(4) "Brownouts", electrical storms, and other disruptions of various duration that may be passed through the hospital's electrical outlets.

(5) Failure of the Life Pulse's internal power supply.

f. **Response of the Life Pulse to loss of electrical power:**

(1) All valves are placed in their "safe" state (e.g., the pinch valve is shut and the dump valve is opened to exhaust Servo pressure).

(2) An audible alarm is sounded.

(3) The Life Pulse operating conditions just prior to the loss of power are maintained in computer memory up to 1 minute.

(4) If the duration of the power loss is less than 1 minute, the Life Pulse re-initiates operation at the previously current settings.

(5) If the duration of the power loss is more than 1 minute, the Life Pulse initiates its start-up routine and enters the **Standby mode upon re-establishment of power** with its start-up settings of PIP = 20, RATE = 420, and ON TIME = 0.020, and the audible alarm sounding.

g. **Suggested Operator's Response to a loss of electrical power:**

(1) Manually ventilate the patient as needed.

(2) Re-establish power if the plug has been pulled or the power switch has been inadvertently pushed.

(3) Press the SILENCE button to turn off the audible alarm.
Be ready to readjust the Life Pulse settings to previous current settings, and to push the ENTER button when power is restored if necessary.

NOTE: An Uninterruptible Power Supply (UPS) is available from Bunnell Incorporated. The UPS ensures operation of the Life Pulse during losses of electrical power.

B. Other Indicators and Controls:

1. SILENCE button:

Pushing the SILENCE button during an audible alarm provides silence for 60 seconds. If the alarm condition has not been corrected after 60 seconds, the alarm will resume. If the condition is corrected before the 60 seconds is up, the alarm will not resume.

The red light in the corner of the SILENCE button lights up whenever the silence function is in effect. Pushing the SILENCE button a second time before 60 seconds has elapsed terminates the SILENCE function causing the red light to go out.

Visual and audible alarms stop automatically when the alarm-triggering conditions are corrected.

2. READY:

The READY light indicates that the machine has stabilized following Startup or RESET, has calculated the necessary alarm limits, and is ready for automatic operation. The operator should carefully observe the patient and ventilator until the READY light comes on. It requires approximately 90 seconds.

Conditions may arise when the machine takes longer than 90 seconds to stabilize. For example, airway pressures may be fluctuating irregularly due to patient breathing, etc. If the READY light is not lit, the alarm limits above and below MAP and SERVO PRESS will not be set. In addition, LOSS OF PIP will not occur unless the PIP and PEEP are within 2 cm H₂O of each other, or unless PIP is less than 3 cm H₂O.

If the average monitored PIP does not get up to within + 2.0 and - 1.5 cm H₂O of the NOW PIP 3 minutes after the ENTER or RESET button is pushed, the CANNOT MEET PIP alarm will result. This alarm will be canceled if this condition is subsequently met.

3. RESET button:

Pushing the RESET button causes the machine to recalculate the automatic upper and lower alarm limits around the SERVO PRESS, PIP and MAP parameters. It should be used whenever changes are made in the conventional ventilator settings (PEEP or IMV rate), and manual adjustments are not required.

When the RESET button is pushed, the READY light goes off and the alarm indicators become inactive. The Life Pulse takes approximately 30 seconds to re-characterize the normal pressure waveform and re-calculate the alarm limits. When this is accomplished, the READY light illuminates and all alarms become activated.

Pushing the RESET button a second time before the READY light comes on extends the recalculation period at least an additional 20 seconds.
C. Humidifier Alarm System:

The humidifier alarm system (Figure 16) is composed of an alarm SILENCE button for temporary silencing of audible humidifier alarms, and a series of alarm-indicator messages. The function of this alarm system is to warn the operator when temperature or water levels are too high or low, when an electrical problem exists in the cartridge/circuit, or when the humidifier has been placed in the WAIT mode.

![Figure 16: Humidifier Alarm System](image-url)

1. SILENCE Button:

   a. Pushing the SILENCE button silences the audible humidifier alarm for 60 seconds. If the alarm conditions are not corrected within 60 seconds, the alarm will resume.

   b. New alarm conditions occurring during the 60-second SILENCE period will not reactivate the audible alarm until the 60 seconds elapse.

   c. A red LED in the corner of the SILENCE button will be lit during the 60-second silence period. Pushing the button a second time cancels the silencing effect and causes the LED to go out.

   **WARNING:** Pushing the WAIT button shuts off all heating elements, which provide for gas warming and humidification.

2. CIRCUIT HIGH TEMP:

   a. **Definition:** The CIRCUIT HIGH TEMP alarm (Figure 17) indicates that the temperature measured proximal to the Patient Box in the patient breathing circuit has exceeded:

      (1) The chosen setting by more than 3° C and remained there for more than 1 minute.

      (2) 45° C, which is the upper allowable limit.

   b. **Method of automatically setting limits:** The alarm limits are set at:

      (1) 45° C, the absolute upper limit.

      (2) The SET circuit temperature + 3° C.

   c. **Method of manually setting limits:** There is no method of manually adjusting the limits for this alarm.
d. Methods of indicating CIRCUIT HIGH TEMP alarms:

   (1) The CIRCUIT HIGH TEMP alarm is visually indicated by the words "HIGH" and "TEMP" and the CIRCUIT LED being lit.

   (2) An audible alarm will sound.

e. Conditions which may cause CIRCUIT HIGH TEMP alarms:

   (1) An incorrect or incomplete electrical connection between the humidifier cartridge and the spring-loaded contact pins in the cartridge receptacle.

   (2) A malfunctioning humidifier cartridge/circuit.

   (3) Failure in the circuit temperature servo feedback system.

f. Response of the Life Pulse Humidifier to CIRCUIT HIGH TEMP: Electrical current to the circuit heater wire is shut off.

g. Suggested Operator's response to a CIRCUIT HIGH TEMP alarm:

   (1) Open the cartridge receptacle and inspect the spring-loaded contact pins and back of cartridge for damage.

      If YES: Correct the conditions or call the Bunnell Hotline.

      If NO: See (2).

   (2) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press ENTER button and resume normal operation without the alarm.

      NOTE: It may take the circuit heater several minutes to overheat again after circuit replacement if there is a problem in the Life Pulse Humidifier electronics.

      If YES: Resume normal operation.

      Observe the monitored CIRCUIT TEMP carefully over the next 20 minutes to be certain that the humidifier is working properly.

      If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.
3. CIRCUIT LOW TEMP:

a. **Definition:** The CIRCUIT LOW TEMP alarm (Figure 18) indicates the temperature in the patient breathing circuit, as measured proximal to the Patient Box, has dropped below the chosen setting by more than 3°C and remained there for more than 3 minutes.

b. **Method of automatically setting limits:** The alarm limit is set at 3°C below the SET circuit temperature.

c. **Method of manually setting limits:** There is no method of manually adjusting the limits for this alarm.

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![Figure 18: Circuit Low Temp](image)

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d. **Methods of indicating CIRCUIT LOW TEMP alarms:**

(1) The CIRCUIT LOW TEMP alarm is visually indicated by the words "LOW" and "TEMP", and the CIRCUIT LED being lit.

(2) An audible alarm will sound.

e. **Conditions which may cause CIRCUIT LOW TEMP alarms:**

(1) An incorrect or incomplete electrical connection between the humidifier cartridge and the spring-loaded contact pins in the cartridge receptacle.

(2) A malfunctioning humidifier cartridge/circuit.

(3) Failure in the circuit temperature servo feedback system.

f. **Response of the Life Pulse Humidifier to CIRCUIT LOW TEMP:** The circuit heater wire attempts to increase the circuit temperature.

g. **Suggested Operator's response to CIRCUIT LOW TEMP:**

(1) Open the cartridge receptacle and inspect the spring-loaded contact pins and back of cartridge for damage.

   If YES: Correct the conditions or call the Bunnell Hotline.

   If NO: See (2).

(2) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press ENTER button and resume normal operation without the alarm.

   **NOTE:** It will take the circuit heater a few minutes to heat up after circuit replacement if there are no problems in the Life Pulse Humidifier electronics. The CIRCUIT TEMP display should indicate a steady
rise in temperature after the Life Pulse is re-started if it is operating properly.

If YES: Resume normal operation.

Observe the monitored CIRCUIT TEMP carefully over the next 20 minutes to be certain that the humidifier is working properly.

If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.

4. CARTRIDGE HIGH TEMP:

a. Definition: The CARTRIDGE HIGH TEMP alarm (Figure 19) indicates that the temperature in the humidifier cartridge, as measured at the outlet to the patient breathing circuit, has exceeded:

   (1) The chosen setting by more than 3°C and has remained there for more than 10 minutes.

   (2) 45°C, which is the upper allowable limit.

b. Method of automatically setting limits: The alarm limits are set at:

   (1) 45°C, the absolute upper limit.

   (2) The SET cartridge temperature + 3°C.

c. Method of manually setting limits: There is no method of manually adjusting the limits for this alarm.

   ![CARTRIDGE HIGH TEMP Figure 19](image)

   Figure 19: Cartridge High Temp

d. Methods of indicating CARTRIDGE HIGH TEMP alarms:

   (1) The CARTRIDGE HIGH TEMP alarm is visually indicated by the words "HIGH" and "TEMP" and the CARTRIDGE LED being lit.

   (2) An audible alarm will sound.

e. Conditions which may cause CARTRIDGE HIGH TEMP alarms:

   (1) An incorrect or incomplete electrical connection between the humidifier cartridge and the spring-loaded contact pins in the cartridge receptacle.

   (2) A malfunctioning humidifier cartridge/circuit.
Failure in the cartridge temperature servo feedback system.

f. **Response of the Life Pulse Humidifier to CARTRIDGE HIGH TEMP:** The cartridge heater is shut off.

g. **Suggested Operator's response to a CARTRIDGE HIGH TEMP alarm:**

(1) Open the cartridge receptacle and inspect the spring-loaded contact pins and back of cartridge for damage.

   If YES: Correct the conditions or call the Bunnell Hotline.

   If NO: See (2).

(2) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press ENTER button and resume normal operation without the alarm.

   **NOTE:** It may take the cartridge heater several minutes to overheat again after cartridge replacement if there is a problem in the Life Pulse Humidifier electronics.

   If YES: Resume normal operation.

   Carefully observe the amount of condensation in the green portion of the Life Pulse circuit between the patient box and the LifePort adapter over the next 20 minutes to be certain that the humidifier is working properly.

   If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.

5. **CARTRIDGE LOW TEMP:**

   a. **Definition:** The CARTRIDGE LOW TEMP alarm (Figure 20) indicates that the temperature in the humidifier cartridge, as measured at the outlet to the patient breathing circuit, has dropped below the set temperature by more than 3°C and remained there for more than 30 minutes.

   b. **Method of automatically setting limits:** The alarm limits are set at the SET cartridge temperature minus 3°C.

   c. **Method of manually setting limits:** There is no method of manually adjusting the limits for this alarm.

![Figure 20: Cartridge Low Temp](image)
d. **Methods of indicating CARTRIDGE LOW TEMP alarms:**

(1) The CARTRIDGE LOW TEMP alarm is visually indicated by the words "LOW" and "TEMP", and the CARTRIDGE LED being lit.

(2) An audible alarm will sound.

e. **Conditions which may cause CARTRIDGE LOW TEMP alarms:**

(1) An incorrect or incomplete connection between the humidifier cartridge and the spring-loaded contact pins in the cartridge receptacle.

(2) Failure of the humidifier cartridge.

(3) Failure of the humidifier cartridge heater.

(4) Failure in the servo feedback system.

f. **Response of the Life Pulse humidifier to CARTRIDGE LOW TEMP:** The cartridge heater attempts to raise the cartridge temperature.

g. **Suggested Operator's response to a CARTRIDGE LOW TEMP alarm:**

(1) Open the cartridge receptacle and inspect the spring-loaded contact pins and back of cartridge for damage.

   If YES: Correct the conditions or call the Bunnell Hotline.

   If NO: See (2).

(2) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press ENTER button and resume normal operation without the alarm.

   If YES: Resume normal operation.

   Carefully observe the amount of condensation in the green portion of the Life Pulse circuit tubing over the next 20 minutes to be certain that the humidifier is working properly.

   If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.

6. **LEVEL HIGH:**

a. **Definition:** The LEVEL HIGH alarm (Figure 21) indicates that the water in the humidifier cartridge has reached the highest water level sensor.

b. **Method of automatically setting limits:** If the water level in the cartridge reaches the highest water level sensor, the LEVEL HIGH alarm is activated. Thus, the alarm limit is determined by the location of the water level sensor in the humidifier cartridge.

c. **Method of manually setting limits:** There is no method of manually adjusting the limits for this alarm.
d. **Methods of indicating LEVEL HIGH alarms:**

(1) The LEVEL HIGH alarm is visually indicated by the words "LEVEL" and "HIGH" being lit.

(2) An audible alarm will sound.

e. **Conditions which may cause LEVEL HIGH alarms:**

(1) Water inlet tube not latched in pump housing.

(2) The use of any solution other than sterile H₂O in the humidifier cartridge.

(3) An incorrect or incomplete electrical connection between the humidifier cartridge and the spring-loaded contact pins in the cartridge receptacle.

(4) Failure of the level-sensing pins in the humidifier cartridge.

(5) Failure in the feedback system controlling the water pump.

**WARNING:** The water inlet tube of the humidifier cartridge/circuit must be latched into the pump housing to prevent cartridge overfill and delivery of water to the patient by gravity feed.

**WARNING:** The water supply should be positioned at or below the level of the humidifier cartridge to decrease the potential of overfilling the cartridge by gravity feed.

f. **Response of the Life Pulse Humidifier to LEVEL HIGH:** The water pump is shut off.

g. **Suggested Operator's response to a LEVEL HIGH alarm:**

(1) Check water inlet tube to see if it is out of the pump housing.

   If YES: Install water inlet tube in pump housing and latch pump door securely.

   If NO: See (2)

(2) Check for a substance other than sterile H₂O in the humidifier cartridge (e.g., saline, soap, etc.).

   If YES: If a solution other than sterile H₂O has been used, the cartridge should be replaced.

   If NO: See (3).
(3) Check the cartridge receptacle for conditions that may contribute to a faulty connection between the Life Pulse Humidifier electronics and the cartridge, such as contact of spring-loaded pins with the back of the cartridge.

If YES: Correct the conditions or call the Bunnell Hotline.
If NO: See (4).

(4) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press the ENTER button and resume normal operation without the alarm.

If YES: Resume normal operation.
If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.

7. **LEVEL LOW:**

a. **Definition:** The LEVEL LOW alarm (Figure 22) indicates the water in the humidifier cartridge has not reached the lowest water level sensor.

b. **Method of automatically setting limits:** If the water level in the cartridge fails to reach the lowest water level sensor, the LEVEL LOW alarm is activated. Thus, the alarm limit is determined by the location of the water level sensor in the humidifier cartridge.

c. **Method of manually setting limits:** There is no method of manually adjusting the limits for this alarm.

![Figure 22: Water Level Low](image)

d. **Methods of indicating LEVEL LOW alarms:**

(1) The LEVEL LOW alarm is visually indicated by the words "LEVEL" and "LOW" being lit.

(2) An audible alarm will sound.

e. **Conditions which may cause LEVEL LOW alarms:**

(1) The water transfer tube from the water supply is clamped off or disconnected.

(2) The water supply is empty.

(3) The use of any solution other than sterile H₂O in the humidifier cartridge.

(4) An incorrect or incomplete electrical connection between the humidifier cartridge and the spring-loaded contact pins in the cartridge receptacle.
(5) Failure of the level-sensing pins in the humidifier cartridge.

(6) Failure in the feedback system controlling the water pump.

(7) Failure of the water pump assembly.

f. Responses of the Life Pulse Humidifier to LEVEL LOW:

(1) The water pump is activated for the maximum allowable time.

(2) If the LEVEL LOW condition is not corrected within 2 minutes, the heaters are shut down.

g. Suggested Operator's response to a LEVEL LOW alarm:

(1) Determine if the cartridge is less than \(\frac{2}{3}\) full but not empty.

   If YES: Press the WAIT button twice to re-start the water pump.

   If NO: See (2).

(2) Check to see if the water transfer tube from the water supply is clamped off or disconnected, or the water supply is empty.

   If YES: Unclamp or connect the water transfer tube, replace water supply with a bag or bottle of sterile water.

   If NO: See (3).

(3) Check for a substance other than sterile H\(_2\)O in the humidifier cartridge (e.g., saline, soap, etc.).

   If YES: If a solution other than sterile H\(_2\)O has been used, the cartridge should be replaced and the proper solution used.

   If NO: See (4).

(4) Check the cartridge receptacle for conditions that may contribute to a faulty connection between the Life Pulse Humidifier electronics and the cartridge, such as contact of spring-loaded contact pins with the back of the cartridge.

   If YES: Correct the conditions or call the Bunnell Hotline.

   If NO: See (5).

(5) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press the ENTER button and resume normal operation without the alarm.

   If YES: Resume normal operation.

   If NO: See (6).
(6) Check to see if the water pump is stuck by pressing the WAIT button, clamp water transfer tube, open the pump door and press WAIT again.

If YES: If the pump turns on, reinstall the water inlet tube, latch door, unclamp water transfer tube, and continue normal operation.

If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.

NOTE: If the water pump has failed, the cartridge may be filled manually. Remove the water inlet tube from the water pump, hold the water supply higher than the cartridge, and allow gravity to fill the cartridge to the middle water level sensing pin. Reinstall the water inlet tube into the water pump. You will be alerted by a LEVEL LOW alarm that the cartridge requires more water.

8. CIRCUIT FAULT:

a. Definition: The CIRCUIT FAULT alarm (Figure 23) indicates an electrical fault is present in either the humidifier, the pump, the humidifier cartridge or patient breathing circuit.

b. Method of automatically setting limits: Not applicable.

c. Method of manually setting limits: There is no method of manually adjusting the limits for this alarm.

![Figure 23: Circuit Fault](image)

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d. Methods of indicating CIRCUIT FAULT alarms:

(1) The CIRCUIT FAULT alarm is visually indicated by the words "CIRCUIT FAULT" being lit with all other humidifier displays blank.

(2) A constant audible alarm will be sounded.

e. Conditions which may cause CIRCUIT FAULT alarms:

(1) If the low-water level sensor does not detect the presence of water within 86 seconds after the ENTER button is pushed.

(2) The cartridge door is not properly closed.

(3) Failure of either the humidifier or patient breathing circuit thermistors.

(4) The humidifier pump has failed or is stuck.
f. **Responses of the Life Pulse Humidifier to CIRCUIT FAULT:**

(1) The water pump is turned off.

(2) Both the humidifier cartridge and patient breathing circuit heaters are turned off.

g. **Suggested Operator's response to a CIRCUIT FAULT alarm:**

(1) If the alarm occurs within the first 2 minutes after the ENTER button was pushed, check the water supply to see if it is empty or disconnected.

   If YES: Re-connect or replace with a bag or bottle of sterile water.
   
   If NO: See (2).

(2) If the alarm occurs within the first 2 minutes after the ENTER button was pushed, check the water transfer tube to see if it is disconnected or clamped off.

   If YES: Unclamp or connect the water transfer tube.
   
   Press the WAIT button on and off to re-start the water pump.

   If NO: See (3).

(3) Check the cartridge receptacle for conditions (such as the door being open) that may contribute to a faulty electrical connection between the humidifier electronics and the cartridge. Check the spring-loaded pin contacts with the back of the cartridge.

   If YES: Correct the conditions or call the Bunnell Hotline.
   
   If NO: See (4).

(4) Press the STANDBY button and replace the humidifier cartridge/patient breathing circuit. Press the ENTER button and resume normal operation without the alarm.

   If YES: Resume normal operation.
   
   If NO: Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.

9. **Loss of Electrical Power:**

   a. **Definition:** The Life Pulse Humidifier will react predictably to any disruptions in electrical power as described below

   b. **Method of automatically setting limits:** not applicable.

   c. **Method of manually setting limits:** not applicable.

   d. **Methods of indicating loss of electrical power:**

      (1) Complete loss of power will result in all lights on the front panel being turned off.
(2) Momentary power losses of up to 1-minute duration will also result in a blank front panel, but the humidifier will re-start its operation upon regaining power.

(3) Power losses of greater than 1-minute duration that are subsequently restored will result in the humidifier assuming the WAIT mode with its start-up settings of 38°C for the cartridge (40°C for Life Pulse ventilators with serial numbers 2169 and below) and 40°C for the circuit temperatures.

(4) Some momentary power disruptions will cause the humidifier to cease functioning with "3"s in the temperature display.

e. **Conditions which may cause loss of power alarms:**

   (1) Pulling the power cord plug from the wall outlet.

   (2) General power outages.

   (3) Pressing the power switch while the Life Pulse is operating.

   (4) "Brownouts", electrical storms, and other disruptions of various duration that may be passed through the hospital's electrical outlets.

   (5) Failure of the Life Pulse's internal power supply system.

f. **Responses of the Humidifier to loss of electrical power:**

   (1) All heaters and the pump are turned off.

   (2) If the duration of the power loss is less than 1 minute, the Humidifier re-initiates operation at the cartridge and circuit temperatures that were present prior to the power loss.

   (3) If the duration of the power loss is more than 1 minute, the Humidifier initiates its start-up routine and enters the WAIT mode upon re-establishment of power with its start-up settings of 38°C for the cartridge and 40°C for the circuit temperatures.

g. **Suggested Operator's Response to a loss of electrical power:**

   (1) Re-establish power if the plug has been pulled, or the power switch has been inadvertently pushed.

   (2) Be ready to readjust the Humidifier temperature settings to previously current settings when power is restored if necessary.

   (3) If the Humidifier is displaying "3"s, remove the Life Pulse from the patient and turn the power to the Life Pulse OFF, then back ON to see if that action corrects the problem.

     If YES: Resume normal operation after adjusting the SET temperatures to previously current settings.

     If NO: Call the Bunnell Hotline.
D. Summary of Life Pulse Reactions to Ventilator and Humidifier Alarms:

Table 2 and Table 3 summarize the ventilator and humidifier alarms and the response of the Life Pulse to these alarms.
<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Definition of Alarm</th>
<th>Audible?</th>
<th>Delay</th>
<th>Visual?</th>
<th>Delay</th>
<th>Other Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW GAS PRESS</td>
<td>Gas supply &lt; 30 psi (206.85 kPa)</td>
<td>yes</td>
<td>0 sec</td>
<td>yes</td>
<td>0 sec</td>
<td>None.</td>
</tr>
<tr>
<td>HIGH PIP</td>
<td>Airway pressure &gt; NOW PIP + 5 cm H₂O for 1 sec; or PIP &gt; NOW PIP + 10 cm H₂O for each breath 30 seconds; or PIP for each breath during 0.75 sec is 30 cm H₂O &gt; NOW PIP.</td>
<td>yes</td>
<td>3 sec</td>
<td>yes</td>
<td>1 sec</td>
<td>Pinch and Servo pressure valves are closed. Servo pressure is vented.</td>
</tr>
<tr>
<td>LOSS OF PIP</td>
<td>PIP drops below 25% of NOW PIP after READY light is on; or PIP &lt; PEEP + 2 cm H₂O; or PIP &lt; 3 cm H₂O.</td>
<td>yes</td>
<td>2 sec</td>
<td>yes</td>
<td>1 sec</td>
<td>Servo pressure locks to maintain PIP, if monitored servo pressure increases, the control valve are closed.</td>
</tr>
<tr>
<td>VENTILATOR FAULT</td>
<td>Disconnected purge tube, purge valve failure or pressure transducer failure.</td>
<td>yes</td>
<td>2 sec</td>
<td>yes</td>
<td>2 sec</td>
<td>Fails TEST with code 02 in ON/OFF display, otherwise keeps running with visual and audible alarms.</td>
</tr>
<tr>
<td></td>
<td>Servo pressure valve or servo transducer failure.</td>
<td>yes</td>
<td>0 sec</td>
<td>yes</td>
<td>0 sec</td>
<td>May fail TEST with code 03 in ON/OFF display, may keep running with visual and audible alarms, or may revert to Standby mode with failure code 10 in ON/OFF display.</td>
</tr>
<tr>
<td></td>
<td>Electronic circuitry failure.</td>
<td>yes</td>
<td>0 sec</td>
<td>yes</td>
<td>0 sec</td>
<td>May fail TEST with code 04 in ON/OFF display, or may revert to Standby mode with failure 01, 05, 06, 07, 08, or 09 in ON/OFF display.</td>
</tr>
<tr>
<td>Alarm Name</td>
<td>Definition of Alarm</td>
<td>Audible?</td>
<td>Delay</td>
<td>Visual?</td>
<td>Delay</td>
<td>Other Reactions</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>----------</td>
<td>-------</td>
<td>---------</td>
<td>-------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>CANNOT MEET PIP</td>
<td>PIP &lt; NOW PIP - 1.5 and NOW PIP +2.0 cm H₂O when Servo pressure = 20 psi (137.9 kPa) or 3 min after ENTER or RESET.</td>
<td>yes</td>
<td>3 min</td>
<td>yes</td>
<td>3 min</td>
<td>None</td>
</tr>
<tr>
<td>JET VALVE FAULT</td>
<td>The pinch valve signal is out of synch with the ventilator.</td>
<td>Yes</td>
<td>3 sec</td>
<td>yes</td>
<td>3 sec</td>
<td>None.</td>
</tr>
<tr>
<td>UPPER SERVO PRESS</td>
<td>Servo pressure &gt; SERVO PRESS UPPER alarm limit.</td>
<td>yes</td>
<td>20 sec</td>
<td>yes</td>
<td>20 sec</td>
<td>Servo pressure not allowed to go higher than Upper limit.</td>
</tr>
<tr>
<td>LOWER SERVO PRESS</td>
<td>Servo pressure &lt; SERVO PRESS LOWER alarm limit.</td>
<td>yes</td>
<td>20 sec</td>
<td>yes</td>
<td>20 sec</td>
<td>Servo pressure not allowed to go lower than Lower limit.</td>
</tr>
<tr>
<td>UPPER MAP</td>
<td>MAP &gt; MAP UPPER alarm limit.</td>
<td>yes</td>
<td>20 sec</td>
<td>yes</td>
<td>20 sec</td>
<td>Servo pressure valve timing held constant.</td>
</tr>
<tr>
<td>LOWER MAP</td>
<td>MAP &lt; MAP LOWER alarm limit.</td>
<td>yes</td>
<td>20 sec</td>
<td>yes</td>
<td>20 sec</td>
<td>Servo pressure valve timing held constant.</td>
</tr>
<tr>
<td>STANDBY</td>
<td>Life Pulse enters Standby mode either automatically at start-up or manually during operation.</td>
<td>yes</td>
<td>beeps 5 sec every 30 sec</td>
<td>no</td>
<td>N/A</td>
<td>LED on STANDBY button is illuminated.</td>
</tr>
<tr>
<td>POWER LOSS</td>
<td>Electrical power to the Life Pulse has been disrupted.</td>
<td>yes</td>
<td>0 sec</td>
<td>no</td>
<td>N/A</td>
<td>Servo pressure is dumped, and front panel is blanked.</td>
</tr>
<tr>
<td>MOMENTARY POWER LOSS</td>
<td>Electrical power to the Life Pulse has been disrupted for less than one minute.</td>
<td>yes</td>
<td>0 sec</td>
<td>no</td>
<td>N/A</td>
<td>Servo pressure is dumped. Front panel is blanked then briefly displays &quot;8&quot;s. Ventilation resumes at current settings upon restoration of power.</td>
</tr>
</tbody>
</table>
### Table 3: Humidifier Alarms and Reactions

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Definition of Alarm</th>
<th>Audible?</th>
<th>Delay</th>
<th>Visual?</th>
<th>Delay</th>
<th>Other Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartridge TEMP HIGH</td>
<td>Cartridge temp &gt; CARTRIDGE SET TEMP + 3°C.</td>
<td>yes</td>
<td>10 min</td>
<td>yes</td>
<td>10 min</td>
<td>Heater plate off.</td>
</tr>
<tr>
<td>Cartridge TEMP LOW</td>
<td>Cartridge temp &lt; CARTRIDGE SET TEMP - 3°C.</td>
<td>yes</td>
<td>30 min</td>
<td>yes</td>
<td>30 min</td>
<td>Heater plate attempts to increase cartridge temperature.</td>
</tr>
<tr>
<td>Circuit TEMP HIGH</td>
<td>Circuit temp &gt; CIRCUIT SET TEMP + 3°C.</td>
<td>yes</td>
<td>1 min</td>
<td>yes</td>
<td>1 min</td>
<td>Heater wire off.</td>
</tr>
<tr>
<td>Circuit TEMP LOW</td>
<td>Circuit temp &gt; CIRCUIT SET TEMP - 3°C.</td>
<td>yes</td>
<td>3 min</td>
<td>yes</td>
<td>3 min</td>
<td>Heater wire attempts to increase circuit temperature.</td>
</tr>
<tr>
<td>HIGH LEVEL</td>
<td>Water level &gt; high sensor</td>
<td>yes</td>
<td>0 sec</td>
<td>yes</td>
<td>0 sec</td>
<td>Pump off.</td>
</tr>
<tr>
<td>LOW LEVEL</td>
<td>Water level &lt; low sensor</td>
<td>yes</td>
<td>2 min</td>
<td>yes</td>
<td>2 min</td>
<td>None.</td>
</tr>
<tr>
<td>CIRCUIT FAULT</td>
<td>Open / shorted thermistor or the Pump runs &gt; 86 sec in filling.</td>
<td>yes</td>
<td>0 sec</td>
<td>yes</td>
<td>0 sec</td>
<td>Heater plate, heater wire, and water pump are turned off.</td>
</tr>
<tr>
<td>WAIT</td>
<td>Standby mode.</td>
<td>yes</td>
<td>30 sec</td>
<td>no</td>
<td>0 sec</td>
<td>WAIT button flashes.</td>
</tr>
</tbody>
</table>
VII. INSTALLATION, SET-UP, AND TEST

A. Activities to Be Performed Upon Receipt:

Upon receipt of your Life Pulse High-Frequency Ventilator the following should be performed:

1. Visually inspect your Life Pulse to ensure that it was not physically damaged in shipment.

2. Set-up the Life Pulse and initiate the TEST as described below.

3. Notify Bunnell Incorporated when you have received your Life Pulse High-Frequency Ventilator and schedule your in-service training program.

4. Complete warranty registration form should be signed and give it to the in-service trainer or mail to:

   Bunnell Incorporated  
   436 Lawndale Drive  
   Salt Lake City, Utah 84115

B. Set-Up

1. Remove the Life Pulse from its shipping carton.

   **PRECAUTION:** Save the shipping carton for use when your Life Pulse is returned to Bunnell for service. Shipping a Life Pulse Ventilator in other than a factory carton may result in voiding of the warranty.

2. Attach the Patient Box to the Patient Box connector on the rear panel of the Life Pulse.

3. Attach the air/oxygen supply from the low flow output (2-100 L/min.) of a standard blender or from a low flow blender (0-30 L/min.) to the MIXED GAS INPUT connector that is also located on the rear panel of the Life Pulse.

4. Plug into a hospital-grade electrical outlet.

C. Installation of the Disposable Humidifier Cartridge / Patient Breathing Circuit

1. Remove the clean humidifier cartridge/patient breathing circuit from its protective package. Use appropriate aseptic technique when handling the open ends of the circuit's tubing to prevent contamination.

2. Undo the latch, lift the lid, open the door on the cartridge receptacle, and insert the humidifier cartridge so that all tubing faces outward, and the green gas inlet tube is in the upper left hand corner. (See Figure 24.)
Figure 24: Life Pulse Ventilator Front View
3. Close the door and latch securely. Be sure that the two locator pins on the PC board are aligned with their respective openings in the connector block.

4. Attach the green gas inlet tube to the GAS OUT connector on the front panel of the Life Pulse.

5. Attach the proximal end of the small purge tube to the PURGE connector on the front panel of the Life Pulse.

6. Install the clear water inlet tube with the check valve into the water pump on the front of the humidifier.
   a. Open the pump door.
   b. Place the opaque water inlet tube into the pump housing.
   c. Close and latch the pump door securely.

7. Connect a 1-3 liter water supply bag or bottle of sterile H₂O to the check valve on the water inlet tube using a water transfer tube with a Luer tip.

   **WARNING:** Use ONLY sterile water for inhalation, USP, in the Life Pulse humidifier. The use of deionized water or salt solutions may cause the water level sensors in the humidifier cartridge to malfunction.

   **WARNING:** The water inlet tube of the humidifier cartridge/circuit must be latched into the pump housing to prevent cartridge overfill and delivery of water to the patient by gravity feed.

   **WARNING:** The water supply should be positioned at or below the level of the humidifier cartridge to decrease the potential of overfilling the cartridge by gravity feed.

8. Insert the pinch tube from the patient breathing circuit into the pinch valve located in the Patient Box. Follow the gas delivery direction decals on the Patient Box. Press down on the button labeled PUSH TO LOAD and pull the tube into the jaws of the pinch valve. Figure 11 (Chapter V) shows the pinch tubing correctly installed in the pinch valve.

9. Attach the end of the small purge tube to the connector labeled FROM PURGE on the Patient Box.

10. The Life Pulse humidifier cartridge/circuit is intended for single-patient use and should be discarded after one use or after 7 days of continuous use.

    **WARNING:** Failure to discard cartridge/circuit after use may result in leaks and/or improper temperature and water level control.

11. When replacement of the humidifier cartridge/circuit is required, place the Life Pulse in Standby, disconnect the circuit from the LifePort adapter, and reverse the steps listed above. Recommended replacement is at least once every 7 days.
D. Connection to the LifePort Adapter

1. Replace the standard ET tube connector with a LifePort adapter.
   a. Use the same or a half-size larger LifePort adapter on the ET tube (e.g., use a 3.5 LifePort adapter on a 3.0 and 3.5 ET tube.)

2. Connect the female luer connector of the clear pressure monitoring tube to the barbed connector labeled "PRESSURE MONITORING LUMEN" on the Patient Box.

3. Connect the green patient end of the Life Pulse circuit to the Jet port on the LifePort adapter.
   **PRECAUTION:** It is recommended that an extra Patient Box, humidifier cartridge/circuit, and LifePort adapter be kept near the bedside of a patient receiving treatment from the Life Pulse. These items are the Life Pulse components most vulnerable to being dropped, damaged, and/or replaced.

E. Perform the Test

1. Power up the Life Pulse by pressing the ON/OFF switch, which is located on the front panel. The Life Pulse will react as follows:
   a. The audible alarm will sound until the operator presses the SILENCE button.
   b. Display windows will show 8's for 2 seconds. (Exception: PEEP will show -18.8)
   c. The displays will then blank and the Life Pulse will enter the Standby mode. The light on the STANDBY button will be lit.
   d. The Life Pulse displays will contain the default operating settings (i.e., PIP = 20, RATE = 420, and ON TIME = 0.020), and the monitored values will be 0.

2. Attach patient end of endotracheal tube to a test lung. The 15 mm connector on the LifePort adapter should be left open to the room.

3. Press the TEST button which is located next to the STANDBY button.
   During the TEST, the Life Pulse's microprocessor runs a series of tests to ensure that all the major components of the ventilator are responding. **The Life Pulse TEST should be run before each use.**
   a. All displays and lights will blank with the exception of:
      (1) SILENCE button light.
      (2) TEST button light.
      (3) Decimal points in the numeric displays.
   b. All alarm messages will light up and the numeric displays will count consecutively from 0 to 9.
      (Exception: PEEP starts at 0.0 then goes to -1.1 - -4.4, then to 55 - 99).
c. All alarms will remain lit and all numeric displays will go blank.

d. The code 04 will flash in the JET VALVE ON-OFF TIME window briefly.

e. The Life Pulse will return to the Standby mode.

f. The audible alarm will sound. It may be silenced by pressing the SILENCE button.

g. If the Life Pulse's microprocessor detects a failure during any part of the TEST, it will lock the Life Pulse at the point in the TEST where the failure occurred. (See Section IX, TROUBLESHOOTING GUIDE).

h. If the Life Pulse passes the TEST, it reloads the default Control settings and turns on the audible alarm. Press the SILENCE button to quiet the alarm.

i. Following a successful Test, it is also advisable to run an operational test. While still attached to the Test lung, press the ENTER button. Allow the Life Pulse to cycle up and stabilize pressure on the default valves (PIP 20, Rate 420, On-Time 0.02). The Life Pulse should be able to maintain consistent pressure, establish the READY Condition that indicates the alarms have been activated, and have a monitored PEEP of 0 ± 1 cm H₂O when no PEEP is being applied from the conventional ventilator. If the Life Pulse passes both the Test procedure and the operational test, it is ready for patient use. Place the Life Pulse in to **Standby mode**.

j. Remove the pressure monitoring tube of the LifePort adapter from the Patient Box and disconnect the Life Pulse circuit. Save the Test lung and the LifePort adapter and standard endotracheal tube for future tests.

**WARNING:** Following a successfully completed TEST of the Life Pulse, remove the LifePort adapter and endotracheal tube with test lung from the Life Pulse and the Patient Box.
VIII. OPERATION

Prior to using the Life Pulse High-Frequency Ventilator in a clinical setting, the operator should read and comprehend all sections of this manual, especially Section II, Indications for Use, Contraindications, and Adverse Side Effects, Section III, Warnings and Precautions, and Section VII, Installation, Setup, and Test.

A. Setting Up the Life Pulse for Clinical Use

Complete details on setting up are provided in Section VII.

1. Connect the output of a low flow air/oxygen blender (0-30 L/min.) or the output from the low flow port (2-100 L/min.) of a standard blender to the MIXED GAS INPUT connector on the rear of the unit. The Life Pulse must have a minimum of 30 psi (206.85 kPa) input pressure to operate properly.

2. Plug the Life Pulse into a hospital grade electrical outlet.

3. Press the ON/OFF switch on the front panel.

4. Install a new humidifier cartridge/patient breathing circuit as per the instructions in its package and those of Section VII of this manual.

5. Connect a source of sterile water to the water inlet tube of the humidifier cartridge. Unclamp the water transfer tubing.

   **WARNING:** The water inlet tube of the humidifier cartridge/circuit must be latched into the pump housing to prevent cartridge overfill and delivery of water to the patient by gravity feed.

   **WARNING:** The water supply should be positioned at or below the level of the humidifier cartridge to decrease the potential of overfilling the cartridge by gravity feed.

6. Connect the pressure monitoring tube of the LifePort adapter to the Patient Box and connect the green patient end of the Life Pulse circuit to the Jet port on the LifePort adapter.

7. Attach the LifePort adapter and standard endotracheal tube to a Test lung.

8. Press the TEST button and verify that the Life Pulse successfully passes its Tests by coming back to the Standby mode with the audible alarm sounding. Press the SILENCE button to quiet the alarm.

9. Following a successful Test, it is also advisable to run an operational test. While still attached to the Test lung, press the ENTER button. Allow the Life Pulse to cycle up and stabilize pressure on the default valves (PIP 20, Rate 420, On-Time 0.02). The Life Pulse should be able to maintain consistent pressure, establish the READY Condition that indicates the alarms have been activated, and have a monitored PEEP of $0 \pm 1 \text{ cm H}_2\text{O}$ when no PEEP is being applied from the conventional ventilator. If the Life Pulse passes both the Test procedure and the operational test, it is ready for patient use. Place the Life Pulse in to Standby mode.
10. Remove the pressure monitoring tube of the LifePort adapter from the Patient Box and disconnect the Life Pulse circuit. Save the Test lung and the LifePort adapter and standard endotracheal tube for future tests.

**NOTE:** The attachment of the pressure monitoring tube of the LifePort adapter to the Patient Box is necessary for the Life Pulse Ventilator to pass the pressure transducer test. Failure to have the pressure monitoring tube attached to the PRESSURE MONITORING LUMEN connector on the Patient Box during the Test may result in a VENTILATOR FAULT 02.

**WARNING:** Following a successfully completed Test of the Life Pulse, remove the LifePort adapter and standard endotracheal tube with test lung from the Life Pulse and the Patient Box. Failure to do so may result in unsafe conditions that can endanger the patient. The Life Pulse must monitor the pressure in the patient's tracheal tube during use.

**WARNING:** All patient connections to the Life Pulse circuit must only be made while the Life Pulse is in the Standby mode. Failure to comply may result in a high volume of gas being delivered at pressure to the patient, which may result in severe patient injury.

B. Preparation of the Patient for Ventilation by the Life Pulse High-Frequency Ventilator

1. Establish the proper airway

   The patient must be intubated with an endotracheal tube and a LifePort adapter must be attached to the standard endotracheal tube.

2. Continue conventional mechanical ventilation

   The Life Pulse is designed to be used with a conventional ventilator at all times. The conventional ventilator is essential for the purposes of providing gas for entrainment by the jet pulses and the patient's spontaneous breathing, PEEP, and periodic normally-sized breaths (background IMV). The following elements are specified:

   a. A continuous or demand flow system capable of delivering a mean gas flow of 5 - 10 lpm.

   b. Means of adjusting the fraction of inhaled oxygen from .21 to 1.00.

   c. Means of humidifying and heating the gas to 100% relative humidity at 37° C.

   d. Means of providing conventional breaths at rates from 0 to 20 breaths/minute with inspiratory times from 0.3 to 0.5 seconds and peak inspiratory pressures from 10 to 60 cm H₂O.

   e. Means of providing positive end-expiratory pressure (PEEP) from 0 to 20 cm H₂O.

   These specifications all lie well within the range of all contemporary conventional infant ventilators. These ventilators are typically classified as pressure limited, time cycled, constant flow generators for treatment of infants.
Examples of conventional ventilators used with the Life Pulse include:

- VIP Bird or VIP Gold
- Bear Cub or BP2001
- Bourns BP200
- Babylog
- Infrasonics Infant Star
- Sechrist I.V.-100 and I.V.-100B
- Marquet SERVO-i
- Seimens 300

- Bird Products Corporation
- Bear Life Systems, Inc.
- Bear Life Systems, Inc.
- Dräger Critical Care
- Infrasonics, Incorporated
- Sechrist Industries, Inc.
- Marquet, Inc.
- Seimens Medical Systems

3. **Monitor the pressures being delivered by the conventional ventilator using the Life Pulse.**

The Life Pulse monitors the pressures in the patient's airway by using a pressure transducer located in the Patient Box. It is recommended that the Life Pulse be connected to the patient and the PIP, PEEP and MAP values produced by the conventional ventilator be monitored using the pressure monitoring capability of the Life Pulse. To do this the operator must:

a. Attach the green patient end of the patient breathing circuit to the Jet port on the LifePort adapter.

b. Attach the clear pressure monitoring tube of the LifePort adapter to the PRESSURE MONITORING LUMEN connector on the Patient Box.

c. **Keep the Life Pulse in its Standby mode.**

d. Monitor the values for PIP, PEEP and MAP displayed in the upper left corner of the Life Pulse until they are stable.

**WARNING:** Do not connect any additional tubing or pressure monitors between the pressure monitoring tube of the LifePort adapter and the pressure monitoring port on the Patient Box. Doing so will destroy the Life Pulse's ability to measure airway pressures accurately and may lead to dangerously high pressures being applied to the patient.

4. **Monitor the patient.**

The patient should be monitored routinely by experienced personnel who have been properly trained in the use of the Life Pulse.

This monitoring, at a minimum, should include:

a. Continuous transcutaneous or equivalent monitoring of arterial CO₂ and O₂.
b. Continuous monitoring of arterial blood pressure.
c. Recording of the Life Pulse Ventilator settings.
d. Recording of the monitored pressures on the Life Pulse.
e. Periodic arterial blood gases.
f. Periodic chest x-rays.
g. Other monitoring as clinically indicated, or required by the hospital's ventilatory protocols.
C. How to Begin High-Frequency Ventilation

All infants treated with the Life Pulse must first be connected to a conventional time cycled, constant flow, pressure limited infant ventilator and continuous blood gas monitors (transcutaneous and/or pulse oximetry). They must also have a LifePort adapter connected to a standard endotracheal tube. The following steps may then be taken (See also Start Up flow chart):

**WARNING:** All patient connections to the Life Pulse circuit must only be made while the Life Pulse is in the Standby mode. Failure to comply may result in a high volume of gas being delivered at pressure to the patient, which may result in severe patient injury.

1. Monitor the PIP, PEEP, and MAP being delivered by the conventional ventilator to the distal tip of the tracheal tube using the Life Pulse in its Standby mode. (Wait at least 90 seconds for the averaging of the PIP and PEEP samples to reach stability.)

2. Note the before high-frequency ventilation blood gas monitor values and/or draw an arterial blood gas sample.

3. Adjust the NEW PIP of the Life Pulse to be equal to 90% - 100% of the average PIP delivered by the conventional ventilator and displayed in the upper left corner of the Life Pulse.

   **NOTE:** A 10% drop in Life Pulse PIP may yield a 20-25% drop in Mean Airway Pressure (MAP). If RDS is your primary concern, you may need to maintain or increase MAP (raise PEEP). If pulmonary air leaks are your primary concern, you may need to decrease MAP (lower PIP). In either case, delta P will be decreased and PaCO₂ may rise.

4. Adjust the NEW RATE of the Life Pulse to an intermediate frequency of between 360 to 480 bpm (420 bpm is recommended). Use lower rates for larger patients or patients with hyperinflated lungs.

5. Adjust the NEW ON TIME of the Life Pulse to 0.020 seconds, its lowest available value.

6. Press ENTER on the Life Pulse to convert the NEW settings to NOW settings. The PIP will quickly rise breath by breath towards the set NOW PIP. However, the Life Pulse may pause (i.e., its breaths will be interrupted) every time a breath is delivered by the conventional ventilator.

   **WARNING:** Using pens, pencils, fingernails, or other pointed objects to push the buttons on the front panel will damage the buttons and may cause them to fail.

7. If you detect interruptions of the Life Pulse breaths, slowly reduce the peak pressure delivered by the conventional ventilator until the high-frequency pulses are no longer interrupted. The interruptions will cease when the conventional ventilator peak pressure is less than the Life Pulse NOW PIP. The JET VALVE ON/OFF lights at the top of the Life Pulse front panel may be used as a guide.

8. Lower the rate of the conventional ventilator to between 0 and 5 bpm. (Use 0 to 2 bpm if air leak is the patient's primary problem. Use 3 to 5 bpm if atelectasis is the main problem.)
The monitored PIP will initially overshoot, then undershoot the set PIP value, then it will settle in at the NOW PIP, all within three minutes.

The READY light will illuminate when the displayed PIP value reaches and stays within +2.0 and -1.5 cm H₂O of the NOW PIP for twenty seconds.

9. Adjust the PEEP setting on the conventional ventilator to obtain the desired PEEP. Maintaining the PEEP monitored by the Life Pulse before the ENTER button was pushed, or at levels consistent with conventional ventilator therapy, is recommended.

10. Note blood gas monitor values and/or draw arterial blood gas samples to determine if and what ventilator adjustments may now be necessary. (See Start Up, Hypercapnia, and Hypoxemia Flow Charts and Suggestions for Treatment.)

**WARNING:** Before leaving the Life Pulse, during initial start-up and following a circuit change, a properly trained person must observe the cartridge fill with sterile water for inhalation, USP, to the second water level sensing pin and the pump stop pumping.

**D. Clinical Strategies**

The first goal in the initial stages of high-frequency ventilation will be to bring the PaCO₂ into an acceptable range (usually between 45 and 60 mm Hg). This goal can most often be accomplished by the manipulation of PIP alone: higher PIP's produce greater minute ventilation and consequently lower PaCO₂'s.

A relatively high PaCO₂ may be tolerated when pulmonary air leaks are of major concern so that the minimum PIP possible is used in order to facilitate the healing of air leaks.

In cases where oxygenation is the primary problem, PEEP can be used to increase MAP rather than raising PIP. This approach helps to avoid hyperventilation and low PaCO₂’s.

Once PaCO₂ is stabilized at an acceptable value, further treatment depends on the other therapeutic goals. The following flow charts have been constructed as guides. The suggested ventilator manipulations are designed to be implemented one at a time, in the order presented, until improvement in the patient's PaO₂ is realized.

**NOTE:** Sufficient time for accommodation and stabilization by the patient's cardiovascular system (i.e., 10 to 15 minutes) must be allowed between ventilator manipulations in order for the effect of ventilator changes to be realized. **Users should avoid making too many changes too quickly!**
Start Up

Install LifePort adapter

Monitor pressures at distal tip of tracheal tube using the Life Pulse

Ventilator Settings

<table>
<thead>
<tr>
<th>Life Pulse</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate: 420 bpm</td>
<td>Rate: 0 to 5 bpm</td>
</tr>
<tr>
<td>PIP: 0.9 - 1 x CMV PIP*</td>
<td>PIP: decrease until Life Pulse interruptions disappear</td>
</tr>
<tr>
<td>On-Time: 0.02 sec</td>
<td>Inspiration Time: 0.3 - 0.4 sec</td>
</tr>
</tbody>
</table>

PaCO<sub>2</sub> too high?

PaCO<sub>2</sub> too low?

decrease HFV PIP

PaO<sub>2</sub> too low?

Increase MAP**

PaO<sub>2</sub> too high?

Go to Weaning chart

Maintain support

Try the following one at a time in order to increase minute ventilation:

- increase HFV PIP
- increase HFV Rate***
- decrease PEEP

* If patient has persistent pulmonary hypertension, set HFV PIP = CMV PIP
** Refer to Hypoxemia chart
*** If lungs are hyperinflated, decrease HFV rate
Hypercapnia

PaCO₂ is too high
PaO₂ is acceptable

Try the following one at a time to increase HFV minute ventilation

- Increase HFV PIP
- Decrease PEEP
- Increase HFV rate *
- Increase HFV On-Time

Pa CO₂ too low?

Yes
- Decrease HFV PIP

No

Pa O₂ too low?

Yes
- Go to Hypoxemia chart

No

Pa O₂ too high?

Yes
- Go to weaning chart

No

Maintain support

* If lungs are hyperinflated, decrease HFV Rate to increase exhalation time.
Hypoxemia

\[ \text{PaCO}_2 \text{ is acceptable, PaO}_2 \text{ is too low} \]

1. Atelectasis?
   - Yes
     - Try the following one at a time in order to recruit and stabilize collapsed alveoli:
       - Increase PEEP
       - Increase CMV rate to 3 - 5 bpm
       - Increase CMV PIP
     - PaO\(_2\) too low?
       - Yes
         - Try the following one at a time in order to reduce alveolar recruitment:
           - Decrease CMV rate to 0 bpm
           - Decrease CMV PIP
           - Maintain PEEP
         - PaO\(_2\) stable?
           - Yes
           - No
   - No
     - PaO\(_2\) too low?
       - Yes
         - Try the following one at a time in order to increase mean airway pressure:
           - Increase PEEP
           - Increase CMV rate (3 - 5 bpm)
           - Increase CMV PIP
           - Increase HFV rate
           - Increase HFV PIP
         - PaO\(_2\) too low?
           - Yes
             - No
   - PaO\(_2\) stable?
     - Yes
     - No

2. X-ray: massive alveolar over-distension or severe air leak?
   - Yes
     - Try the following one at a time in order to decrease mean airway pressure:
       - Decrease CMV rate to 0
       - Decrease HFV rate
       - Decrease HFV On-Time to 0.02 sec
       - Decrease HFV PIP
       - Decrease PEEP
     - PaCO\(_2\) too high?
       - Yes
         - Try the following one at a time in order to increase minute ventilation:
           - Increase HFV PIP
           - Decrease PEEP
           - Increase HFV Rate
           - Increase HFV On-Time
         - PaO\(_2\) too low?
           - Yes
   - No
     - PaO\(_2\) too low?
       - Yes
       - Go to weaning chart
       - No
       - Maintain support

Hypoxemia
Managing Hypoxemia

When managing hypoxemia, the first question to ask is "What is causing the hypoxemia?" A chest x-ray and clinical observations should give sufficient information to answer this question. Depending on the answer, the patient should be treated by one of three paths illustrated on the previous page. (VIII-8)

Are there signs of atelectasis or under inflation? If so, follow path number (1) to improve oxygenation in the presence of atelectasis. First recruit alveoli by using sigh (IMV) breaths and/or longer IMV I-times (0.4 - 0.6 sec). Then maintain the expanded alveoli with higher PEEP.

If the chest film looks fairly normal, perhaps there is simply a need for higher mean airway pressure. Follow the recommendations in path number (2) to increase mean airway pressure and improve oxygenation.

The most difficult patients to manage are those with significant over-distension or air leaks (pneumothorax or PIE). To improve oxygenation in these patients, first decrease the level of support to improve pulmonary blood flow or resolve the air leaks. Path number (3) identifies the options that decrease mean airway pressures. The difficult part of following this path is that oxygenation may get worse before it gets better.
E. More on Conventional Ventilator Settings

The Life Pulse Jet Ventilator has been clinically tested with a variety of conventional infant ventilators that utilize a continuous flow past the patient’s tracheal tube, and an exhalation/PEEP valve on the downstream limb of the breathing circuit. These two features must be part of any conventional infant ventilator used with the Life Pulse.

The fraction of inhaled oxygen and the heated humidification of this gas must be independently controlled to match that supplied by the Life Pulse.

1. Peak Inspiratory Pressure

If the peak pressure for conventional breaths is set above the PIP in the NOW display on the Life Pulse, the Life Pulse will pause during conventional breaths.

It is recommended that the peak pressure for conventional breaths be set slightly lower than the PIP in the NOW display of the Life Pulse so that the Life Pulse will continue to cycle when the IMV breaths are given. The high-frequency breaths will "stack" upon the conventional breaths. The Life Pulse will slowly reduce its Servo pressure in response to high-frequency breaths that exceed the NOW PIP. However, the goal of the Servo pressure adjustment is to keep the mean high frequency PIP at the NOW setting.

After start up the PIP on the conventional ventilator and the PIP on the Life Pulse are not adjusted in a fixed relationship. The LifePulse PIP is adjusted to control PaCO₂ (ventilation) and the conventional PIP is adjusted to provide an adequate “sigh” breath.

2. Rate

The Life Pulse may be used in conjunction with low rate conventional ventilation. Many patients have responded well to the delivery of 1 to 10 normally sized breaths per minute. Higher conventional ventilator rates may only increase mean airway pressure while minimizing the beneficial effects of the high-frequency ventilator.

3. Inspiratory Time

Any customary inspiratory time for the conventional breaths may be used up to a maximum of 2 seconds.

**NOTE:** If the inspiratory time of the conventional breath is greater than 1 second and the PIP of the conventional breath is greater than the PIP of the Life Pulse by more than 5 cm H₂O, the Life Pulse will sound a HIGH PIP alarm.

4. PEEP

PEEP is provided by the conventional ventilator and monitored by the Life Pulse. Initial PEEP should be adjusted to its pre high frequency setting by manipulation of the conventional ventilator's PEEP adjustment knob.

The monitored PEEP reported by the Life Pulse is the mean lowest pressure measured during ventilation of the patient. Some conventional ventilators introduce a low-pressure artifact just before initiation of their conventional breath. The Life Pulse will report that low artifact as PEEP when it is in the Standby mode. During high-frequency ventilation, the
lowest pressure measured during the high-frequency breaths will be averaged to report the monitored PEEP.

On occasion, inadvertent PEEP may be of concern. In this situation, the following steps may be taken to reduce PEEP beyond what may be immediately available through manipulation of the conventional ventilator PEEP control knob.

a. Lower Life Pulse ON-TIME (0.020 sec = minimum).

b. Lower Life Pulse RATE (240 bpm = minimum).

c. Reduce the gas flow rate of the conventional ventilator.

d. Reduce the resistance to gas flow in the exhalation limb of the conventional circuit. (e.g., eliminate unnecessary tubing, etc.)

5. Flow Rate

The rate of the continuous gas flow past the patient's tracheal tube may be adjusted to facilitate setting the desired PEEP level, to provide more or less gas for entrainment by the jet pulses of the Life Pulse, and/or to provide more gas for the infant's spontaneous breathing. A flow rate of 6 - 10 lpm is typical.

6. CPAP

The Life Pulse may also be used with the conventional ventilator in the CPAP Mode. An initial flow of 10 lpm is suggested.

F. Suctioning the Patient While on the Life Pulse High-Frequency Ventilator

The following suctioning technique is recommended for use while the patient is on the Life Pulse.

**Suctioning in Standby mode**

**WARNING:** Failure to place the Life Pulse ventilator in the Standby mode prior to suctioning the patient may result in airway pressures other than the selected peak inspiratory pressure (PIP).

1. Place the Life Pulse in Standby.

2. Provide adequate ventilatory support.

3. Suction the patient using the hospital's normal suctioning procedure.

4. When suctioning is completed, restart the Life Pulse by pressing the ENTER button.

5. Make sure the monitored pressures are stable and the READY light is on before leaving the patient’s bedside.

**WARNING:** Direct application of suction to tracheal mucosa may cause significant airway damage.
G. Maintaining Proper Humidification

The two key elements to proper humidification of patients on the Life Pulse are delivery of gas at body temperature and condensation. If the gas arrives at the patient at body temperature with condensation, one knows that 100% relative humidity has been reached. Without condensation, one cannot know what % relative humidity exists without additional instrumentation.

The Life Pulse is designed to keep the temperature of the gas just proximal to the pinch valve at 40°C. Measurements have shown that there is a 3°C temperature drop from that point to the patient under almost all conditions.

The TEMPERATURE display shows the current temperature measured by the thermistor located just proximal to the pinch valve (i.e., the CIRCUIT TEMP). Whenever this temperature is near 40°C, the patient is receiving gas near body temperature.

Clinicians at the bedside must monitor the green patient end of the Life Pulse circuit for condensation. The green tubing should be coated with condensation or mist (tiny droplets of moisture "marching" through the fog on the wall of the green tubing in synchrony with the Jet pulses). However, if droplets are large and over abundant, they can cause pressure monitoring problems.

Condensation is increased and decreased in direct relationship with the cartridge temperature. The cartridge acts as a teakettle on a hot-plate. The higher one sets the CARTRIDGE TEMP, the more humidity or water vapor one produces.

The Life Pulse starts with the CARTRIDGE TEMP set at 38°C (40°C for Life Pulse ventilators with serial numbers 2169 and below). This setting is almost always high enough to produce adequate condensation. If it is too high, it may be reduced to 36 or 37°C in order to reduce condensation and rainout that is interfering with proper pressure monitoring. If there is inadequate condensation, the CARTRIDGE TEMP may be increased to 39 or 40°C (higher for Life Pulse ventilators with serial numbers 2169 and below).

Ideally, there should be a fine mist or fog in the clear portion of the patient circuit between the humidifier and the patient box with only a few droplets present. If many droplets are present and pulsing toward the Patient Box, slowly reduce the cartridge temperature in 0.5°C steps until droplets are minimal but mist or fog remains. Allow 15 - 20 minutes between changes to realize overall effect of this servo-controlled system.

Caution: DO NOT UNDER-HUMIDIFY.

Pressing the SET button twice lights the CARTRIDGE LED light directly above the button. Pressing the up and down buttons just to the left of the SET button will then adjust the CARTRIDGE TEMP setting up and down respectively. Whatever temperature is displayed when the CARTRIDGE LED is lit is the temperature that the cartridge heater will use to adjust its heat input to produce the condensation that is observed in the patient circuit.

WARNING: Raising or lowering the CIRCUIT TEMP setting may raise or lower the temperature of the patient. The normal setting of 40°C is designed to keep the patient from losing any heat through respiration. It should not be changed under normal operating circumstances.
H. **Weaning the Patient from the Life Pulse**

General guidelines for weaning the patient from the Life Pulse have been developed through years of clinical experience: (See Flow Chart and Suggestions for Weaning.)

1. Keep the RATE on the Life Pulse steady and begin to reduce the Life Pulse PIP. Weaning the Life Pulse PIP should be done slowly and in increments of 1 to 2 cm H₂O at a time.

2. Continue to reduce the PIP on the Life Pulse, keeping the RATE on the Life Pulse steady. Reduce the PIP on the conventional ventilator to avoid interruption of the Jet pulses. In most cases, when the PIP has been reduced into the teens, you may begin to increase slowly conventional ventilator support while continuing to decrease Life Pulse support. Interrupting the Jet pulses with conventional breaths may now be desirable.

3. Generally, it may be appropriate to consider a trial of conventional ventilation alone once the Life Pulse PIP is less than 16 cm H₂O and the FiO₂ is less than 30%. At this low level of support, it is possible to wean patients directly to Nasal CPAP. In either case, place the Life Pulse into the Standby mode.

4. Observe the patient to ensure a positive response to the conventional ventilation trial or CPAP. You may need to increase slightly conventional ventilator support soon after the Life Pulse is placed in Standby. Begin weaning the patient from conventional ventilation if he responds positively to the trial. If the patient responds poorly to the trial, re-ENTER the Life Pulse at the same or higher settings and repeat the steps described above.
Weaning to CMV

- PaO\(_2\) is too high or acceptable
- PaCO\(_2\) is too low or acceptable

No

- PaO\(_2\) is too high?
  - Yes
    - Try the following
      - decrease FiO\(_2\)
      - decrease HFV PIP
      - decrease CMV PIP
      - decrease PEEP
  - PaCO\(_2\) too low?
    - Yes
      - Try the following
        - decrease HFV PIP
        - decrease CMV PIP
        - decrease HFV rate
    - No
      - PaO\(_2\) too low?
        - Yes
          - increase PEEP
          - increase CMV Rate
          - increase CMV PIP
          - CMV PIP may interrupt HFV Breaths
          - PaCO\(_2\) too high?
            - Yes
              - increase CMV Rate
            - No
              - HFV PIP < 15?
                - Yes
                  - Increase CMV support as needed to manage patient
                - No
                  - decrease HFV PIP
              - No
                - decrease HFV PIP

Weaning to IMV

- If CMV PIP has to be increased to control PaO\(_2\) or PaCO\(_2\), return patient to HFV at previous setting.
## IX. TROUBLESHOOTING GUIDE

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>POSSIBLE CAUSE</th>
<th>CORRECTIVE ACTION</th>
<th>REFERENCE</th>
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</thead>
<tbody>
<tr>
<td><strong>TEST FAILURES</strong>:</td>
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<td></td>
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</tr>
<tr>
<td>&quot;02&quot; in ON/OFF display; VENTILATOR FAULT visual alarm.</td>
<td>Purge tube is kinked or disconnected.</td>
<td>Unkink or reconnect tubing at PURGE outlet on the front panel or at FROM PURGE inlet on Patient Box.</td>
<td>VI.A.7 Pg. VI-15</td>
</tr>
<tr>
<td></td>
<td>LifePort adapter and/or pressure monitoring line are not connected</td>
<td>Attach pressuring monitoring line of LifePort adapter to patient box.</td>
<td></td>
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<tr>
<td></td>
<td>Patient Box problem.</td>
<td>Call the Bunnell Hotline to determine if the Patient Box needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Electronic problem.</td>
<td>If unable to pass TEST, call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>&quot;03&quot; in ON/OFF display; VENTILATOR FAULT visual alarm.</td>
<td>One or more of the Servo pressure control valves is compromised.</td>
<td>If unable to pass TEST, call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.7 Pg. VI-15</td>
</tr>
<tr>
<td>&quot;04&quot; in ON/OFF display; VENTILATOR FAULT visual alarm.</td>
<td>Electronics problem.</td>
<td>If unable to pass TEST, call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.7 Pg. VI-15</td>
</tr>
<tr>
<td>All displays are blank; with LOW GAS PRESS visual alarm.</td>
<td>No gas supply connected.</td>
<td>Connect high pressure output of air-oxygen blender. Press STANDBY to exit test mode.</td>
<td>VI.A.6 Pg. VI-14</td>
</tr>
<tr>
<td></td>
<td>Gas at less than 30 psi (206.85 kPa) is being supplied.</td>
<td>Check for leaks in high pressure hoses, fittings and connectors or loss of gas pressure form source. Press STANDBY to exit test mode.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gas supply pressure switch has problem.</td>
<td>Call the Bunnell Hotline.</td>
<td></td>
</tr>
<tr>
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<tr>
<td><strong>Operational Conditions Where Life Pulse Continues Running:</strong></td>
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<td></td>
</tr>
<tr>
<td>Life Pulse momentarily stops running, dumps the SERVO pressure, flashes &quot;8&quot; in all the displays, then resumes running with an audible alarm.</td>
<td>The electrical supply for the Life Pulse was momentarily disrupted.</td>
<td>Press the SILENCE and ENTER buttons and resume operation.</td>
<td>VI.A.9 Pg. VI-17</td>
</tr>
<tr>
<td><strong>VENTILATOR FAULT</strong> alarm. Other alarms may also appear.</td>
<td>Purge tube has been disconnected at the front panel, at the Patient Box, or internally.</td>
<td>Reconnect Purge tube. If alarm persists, call the Bunnell Hotline to determine if tubing has been disconnected internally.</td>
<td>VI.A.7 Pg. VI-15</td>
</tr>
<tr>
<td><strong>LOSS OF PIP.</strong> Other alarms may also appear.</td>
<td>Pressure monitoring tube of the LifePort adapter is disconnected, kinked, or obstructed.</td>
<td>Unkink or re-connect pressure-monitoring tube (PMT) to the Pressure Monitoring port on the Patient Box. Flush PMT with 2-3 ml of air to clear line. Check patient circuit for excess condensation. Adjust cartridge temperature as needed. Press ENTER button to resume ventilation if Servo pressure has dropped to or near 0.</td>
<td>VI.A.4 Pg. VI-9</td>
</tr>
<tr>
<td>Humidifier cartridge/ circuit leaking, kinked, or improperly installed</td>
<td></td>
<td>Inspect cartridge/circuit for leaks, kinks or poor connections and correct condition.</td>
<td></td>
</tr>
<tr>
<td>Pinch Valve stopped cycling</td>
<td></td>
<td>Place Life Pulse in STANDBY mode, increase CV support, and call Bunnell Hotline.</td>
<td></td>
</tr>
<tr>
<td>The pressure transducer in the Patient Box is malfunctioning.</td>
<td></td>
<td>Call the Bunnell Hotline to determine if the Patient Box needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>Life Pulse in READY mode with HIGH SERVO PRESS alarm and 25.0 in SERVO PRESS display.</td>
<td>Servo pressure transducer has failed in maximum signal output state.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.1 Pg. VI-1</td>
</tr>
<tr>
<td>SYMPTOMS</td>
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<tr>
<td>Unusually high Servo Pressure.</td>
<td>A gas leak exists somewhere in the humidifier.</td>
<td>If leak is found, change humidifier cartridge/circuit. Call the Bunnell Hotline if a leak is NOT found.</td>
<td>VI.A.1 Pg. VI-1</td>
</tr>
<tr>
<td>SERVO PRESS = 0.0 when READY light comes on.</td>
<td>Servo pressure transducer problem: no output.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.1 Pg. VI-1</td>
</tr>
<tr>
<td>LOW GAS PRESS alarm in the presence of adequate supply.</td>
<td>Problem with the gas supply pressure switch.</td>
<td>Call the Bunnell Hotline.</td>
<td>VI.A.6 Pg. VI-14</td>
</tr>
<tr>
<td>LOSS OF PIP, LOW MAP, and LOW SERVO PRESS alarms. No LOW GAS PRESS alarm in the absence of adequate supply.</td>
<td>Loss of gas supply and problem with the gas supply pressure switch.</td>
<td>Call the Bunnell Hotline to determine best method of repairing gas supply or connection.</td>
<td>VI.A.6 Pg. VI-14</td>
</tr>
<tr>
<td>Life Pulse operating without gas delivery: No output from GAS OUT port.</td>
<td>LOSS OF PIP alarm occurred in Non-READY mode.</td>
<td>Press the ENTER button to clear LOSS OF PIP and resume ventilation.</td>
<td>VI.A.4 Pg. VI-9</td>
</tr>
<tr>
<td>Dump valve is obstructed (stuck open)</td>
<td></td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>Servo pressure valves are not opening.</td>
<td></td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>Internal tubing has become disconnected.</td>
<td></td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>V.E.1 Pg. V-8</td>
</tr>
<tr>
<td>No output from Patient Box.</td>
<td>Pinch valve problem - Pinch valve may be stuck.</td>
<td>Place Life Pulse in Standby, increase CV support and call the Bunnell Hotline to determine if the Patient Box needs to be replaced.</td>
<td>V.F.1 Pg. V-9</td>
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<tr>
<td>SYMPTOMS</td>
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<tr>
<td>Operational Conditions Where Life Pulse Continues Running:</td>
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<tr>
<td>No output from humidifier circuit.</td>
<td>Humidifier cartridge is blocked off.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>V.G</td>
</tr>
<tr>
<td>Immediate CANNOT MEET PIP alarm upon start-up.</td>
<td>SERVO pressure transducer stuck in full output state.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.5</td>
</tr>
<tr>
<td>Excessive PEEP.</td>
<td>Inadequate time for exhalation.</td>
<td>Increase exhalation time by decreasing HFV RATE and/or ON-TIME. Decreased minute volume may then be compensated for by increasing PIP.</td>
<td>VIII.E.4</td>
</tr>
<tr>
<td>Water in the pressure monitoring tube.</td>
<td></td>
<td>Flush the pressure monitoring tube of the LifePort adapter with 2-3 ml dry gas via syringe. Reconnect to Patient Box as soon as possible. Consider succioning the patient and reducing the humidifier cartridge temperature.</td>
<td>VI.A.2</td>
</tr>
<tr>
<td>Partial obstruction of exhalation limb of conventional circuit.</td>
<td></td>
<td>Eliminate obstructions in the exhalation limb of the conventional ventilator's patient circuit.</td>
<td>VIII.E.4</td>
</tr>
<tr>
<td>Pressure transducer is out of calibration.</td>
<td></td>
<td>Test by pressing STANDBY button and disconnecting Life Pulse from patient. Connect a test lung, press ENTER button and allow pressures to stabilize. Once Ready light comes on if anything except 0.0 appears in the PEEP display, the Patient Box may be out of calibration. Call Bunnell the Hotline.</td>
<td></td>
</tr>
</tbody>
</table>

IX-4
<table>
<thead>
<tr>
<th>SYMPTOMS</th>
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<tr>
<td>Operational Conditions Where Life Pulse Continues Running</td>
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<tr>
<td>Loud Patient Box pinch valve.</td>
<td>Valve is out of alignment or needs service.</td>
<td>Call the Bunnell Hotline to determine if the Patient Box needs to be replaced.</td>
<td>V.F.1 Pg. V-9</td>
</tr>
<tr>
<td>Inadequate control of PIP. Monitored pressures are unstable.</td>
<td>Water in pressure monitoring tube.</td>
<td>Flush pressure-monitoring tube of the LifePort adapter with 2-3 ml dry gas from a syringe.</td>
<td>VI.A.2 Pg. VI-4</td>
</tr>
<tr>
<td>Patient needs to be suctioned.</td>
<td></td>
<td>Lower humidifier cartridge temperature a degree or two so that excess condensation decreases.</td>
<td>VIII.G Pg. VIII-12</td>
</tr>
<tr>
<td>Spontaneous breathing or increased chest tube activity.</td>
<td></td>
<td><strong>NOTE:</strong> it may take 20 minutes or so before excess condensation evaporates. Suctioning of the patient's tracheal tube may also help alleviate fluctuating PIP. <strong>CAUTION: Do not eliminate all condensation. It is important to keep the gas delivery near 100% relative humidity at 37°C in order not to damage tracheal mucosa.</strong></td>
<td>VI.A.4 Pg. VI-9</td>
</tr>
<tr>
<td>Problem with Servo pressure control valve(s).</td>
<td></td>
<td>Support the patient with the conventional ventilator and attach the Life Pulse to a test lung. Press TEST button. If test stops with &quot;03&quot; in the ON/OFF display, problem with the Servo pressure control valves is confirmed. Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.1 Pg. VI-1</td>
</tr>
<tr>
<td>SERVO pressure does not dump when Life Pulse enters Standby mode; HIGH PIP visual alarm.</td>
<td>Dump valve is not opening or is obstructed.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>V.I.3 Pg. V-15</td>
</tr>
<tr>
<td>SYMPTOMS</td>
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<tr>
<td>Operational Conditions Where Life Pulse Continues Running:</td>
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</tr>
<tr>
<td>SERVO pressure will not rise with LOSS OF PIP and CANNOT MEET PIP alarms.</td>
<td>LOSS OF PIP alarm occurred in Non-READY mode.</td>
<td>Press the ENTER button to clear LOSS OF PIP and resume ventilation.</td>
<td>VI.A.4 Pg. VI-9</td>
</tr>
<tr>
<td>Dump valve will not close.</td>
<td></td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>V.I.3 Pg. V-15</td>
</tr>
<tr>
<td>CIRCUIT FAULT alarm occurs within 2 minutes after coming out of the Standby mode.</td>
<td>Water inlet tube not installed in pump housing.</td>
<td>Check and correct any and all of the listed possible causes of water supply problem.</td>
<td>VI.C.8 Pg. VI-29</td>
</tr>
<tr>
<td>Water transfer tube clamp or stopcock is shut.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water supply is not connected or is empty.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excess condensation near tracheal tube.</td>
<td>Humidifier cartridge temperature too high.</td>
<td>Reduce humidifier cartridge temperature a degree or two. Consider suctioning patient or flushing pressure monitor tube if pressure displays are erratic. <strong>NOTE</strong>: Water in the humidifier cartridge cools slowly. Patience and follow-up are necessary to find the optimal cartridge temperature setting. <strong>CAUTION</strong>: Overreaction to excessive condensation may cause under-humidification with subsequent damage to tracheal mucosa.</td>
<td>VIII.G Pg. VIII-12</td>
</tr>
<tr>
<td>SYMPTOMS</td>
<td>POSSIBLE CAUSE</td>
<td>CORRECTIVE ACTION</td>
<td>REFERENCE</td>
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<tr>
<td><strong>Humidifier Operational Conditions Where Life Pulse Continues Running:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIRCUIT TEMP LOW alarm.</td>
<td>Humidifier cartridge problem.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.C.3 Pg. VI-22</td>
</tr>
<tr>
<td></td>
<td>Problem with power to the circuit heater.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>CIRCUIT TEMP HIGH alarm.</td>
<td>Humidifier cartridge problem.</td>
<td>Call the Bunnell Hotline before replacing the humidifier cartridge.</td>
<td>VI.C.2 Pg. VI-20</td>
</tr>
<tr>
<td></td>
<td>Problem with control of circuit heater.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>CARTRIDGE TEMP LOW alarm.</td>
<td>Humidifier cartridge problem.</td>
<td>Call the Bunnell Hotline before replacing the humidifier cartridge.</td>
<td>VI.C.5 Pg. VI-24</td>
</tr>
<tr>
<td>CARTRIDGE TEMP HIGH alarm.</td>
<td>Problem with power to the cartridge heater.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.C.4 Pg. VI-23</td>
</tr>
<tr>
<td></td>
<td>Humidifier cartridge problem.</td>
<td>Call the Bunnell Hotline before replacing the humidifier cartridge.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem with control of cartridge heater.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>Water pump fails to turn on with no alarms.</td>
<td>Humidifier cartridge problem.</td>
<td>Call the Bunnell Hotline before replacing the humidifier cartridge.</td>
<td>V.D.3 Pg. V-8</td>
</tr>
<tr>
<td>CIRCUIT FAULT alarm appears immediately at start-up.</td>
<td>Humidifier door has not been closed, door or latch problem.</td>
<td>Close humidifier door. If necessary, call the Bunnell Hotline to determine if the door or latch needs to be replaced.</td>
<td>VI.C.8 Pg. VI-29</td>
</tr>
<tr>
<td>SYMPTOMS</td>
<td>POSSIBLE CAUSE</td>
<td>CORRECTIVE ACTION</td>
<td>REFERENCE SECTION</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Humidifier Operational Conditions where Life Pulse continues Running:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water pump fails to turn on with CIRCUIT FAULT alarm appearing</td>
<td>Water pump problem.</td>
<td>Push WAIT button. Clamp the water transfer tube. Open pump door and push WAIT</td>
<td>VI.C.8</td>
</tr>
<tr>
<td>2 minutes after initiation of startup or with the LEVEL LOW alarm</td>
<td></td>
<td>again. If the pump turns on, re-install water inlet tube in pump housing, latch</td>
<td>Pg. VI-29</td>
</tr>
<tr>
<td>after the Life Pulse has been running for some time.</td>
<td></td>
<td>door securely, un-clamp water transfer tube, and press WAIT to re-start pump.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If the pump does not turn on when latch is open, turn power off and back on. If</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>problem persists, call the Bunnell Hotline to determine if the Life Pulse needs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>to be replaced.</td>
<td></td>
</tr>
<tr>
<td>LOW LEVEL alarm.</td>
<td>Water supply has been</td>
<td>Replace water supply.</td>
<td>VI.C.7</td>
</tr>
<tr>
<td></td>
<td>depleted.</td>
<td></td>
<td>Pg. VI-27</td>
</tr>
<tr>
<td></td>
<td>Water pump problem.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMS</td>
<td>POSSIBLE CAUSE</td>
<td>CORRECTIVE ACTION</td>
<td>REFERENCE SECTION</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Humidifier Operational Conditions where the Life Pulse stops Running:</td>
<td>HIGH LEVEL alarm.</td>
<td>Place Life Pulse in STANDBY mode and support patient. Remove cartridge/circuit and dump out excess water through green gas inlet tube. Re-install circuit making sure to install water inlet tube in pump housing, latching pump door securely. After making all appropriate connections restart Life Pulse by pressing ENTER button.</td>
<td>VI.C.6</td>
</tr>
<tr>
<td></td>
<td>Water inlet tube not latched in pump housing</td>
<td></td>
<td>Pg. VI-25</td>
</tr>
<tr>
<td></td>
<td>Humidifier cartridge problem.</td>
<td>Call Bunnell Hotline before replacing humidifier cartridge.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem with control of water pump.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Humidifier stays in WAIT mode with blank displays.</td>
<td>Press WAIT button to release manual WAIT.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Humidifier in manual WAIT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem with control signal from the ventilator.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.C.9</td>
</tr>
<tr>
<td></td>
<td>Humidifier does not enter WAIT mode when the STANDBY button is pressed. Displays remain lit and heater remains active.</td>
<td></td>
<td>Pg. VI-30</td>
</tr>
<tr>
<td></td>
<td>Problem with control signal from the ventilator.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.C.9</td>
</tr>
<tr>
<td></td>
<td>Humidifier stops operating with blank displays.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>Pg. VI-30</td>
</tr>
<tr>
<td></td>
<td>Internal power supply problem.</td>
<td>Turn power off and then back on. If &quot;3&quot;s clear, the humidifier has reset and should function normally. If &quot;3&quot;s do not clear, call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.C.9</td>
</tr>
<tr>
<td></td>
<td>Problem with power to the humidifier.</td>
<td></td>
<td>Pg. VI-30</td>
</tr>
</tbody>
</table>

IX-9
<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>POSSIBLE CAUSE</th>
<th>CORRECTIVE ACTION</th>
<th>REFERENCE SECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operational Conditions Where The Life Pulse STOPS Running:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life Pulse stops operating with audible alarm and a blank front panel.</td>
<td>Electrical plug has been pulled from the wall.</td>
<td>Plug the Life Pulse into the wall outlet.</td>
<td>VI.A.9 Pg. VI-17</td>
</tr>
<tr>
<td></td>
<td>The hospital has lost its electrical power.</td>
<td>Manually ventilate the patient as needed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem with the internal power supply of the Life Pulse.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>Life Pulse Patient Box stops with Loss of PIP or Vent Fault 10 alarms</td>
<td>Pinch valve problem.</td>
<td>Place Life Pulse into STANDBY mode. Check for kinked or disconnected tubes. Evaluate patient for changes. Try to re-start Life Pulse by pressing the Enter button. If alarms reoccur, switch out the Patient Box and try again.</td>
<td></td>
</tr>
<tr>
<td>Life Pulse reverts to STANDBY mode with audible alarm.</td>
<td>Hospital electrical power loss of more than one-minute duration.</td>
<td>Press ENTER and SILENCE buttons. If control section displays default settings, review patient flow chart and reset proper PIP, RATE, and ON-TIME. Press ENTER again.</td>
<td>VI.A.9 Pg. VI-17</td>
</tr>
<tr>
<td>Life Pulse stops operating with HIGH PIP, HIGH MAP, and possibly LOW SERVO PRESS alarms.</td>
<td>The exhalation limb of the conventional circuit is obstructed.</td>
<td>Clear the exhalation circuit of kinks or obstructions.</td>
<td>VI.A.3 Pg. VI-8</td>
</tr>
<tr>
<td></td>
<td>The pressure monitoring tube of the LifePort adaptor is kinked or obstructed.</td>
<td>Un-kink or clear the pressure monitoring tube.</td>
<td></td>
</tr>
<tr>
<td>SYMPTOMS</td>
<td>POSSIBLE CAUSE</td>
<td>CORRECTIVE ACTION</td>
<td>REFERENCE SECTION</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Operational Conditions where the Life Pulse stops Running:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life Pulse stops operating with JET VALVE FAULT and LOSS OF PIP alarms.</td>
<td>The pressure transducer in the Patient Box is malfunctioning.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>VI.A.8</td>
</tr>
<tr>
<td></td>
<td>Pinch valve problem.</td>
<td>Call the Bunnell Hotline to determine if the Patient Box needs to be replaced.</td>
<td>Pg. VI-17</td>
</tr>
<tr>
<td>Life Pulse stops operating with VENTILATOR FAULT and other alarms.</td>
<td>Electrical irregularity has disrupted the microprocessor functions.</td>
<td>Turn power to Life Pulse off to reset it and then turn power back ON. If Life Pulse passes the self-test, and operational test, restart on patient and call the Bunnell Hotline.</td>
<td>VI.A.7</td>
</tr>
<tr>
<td></td>
<td>Problem with the internal power supply of the Life Pulse.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td>Pg. VI-15</td>
</tr>
<tr>
<td></td>
<td>Other electronic circuitry problem.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Power to the Patient Box has been disrupted.</td>
<td>Check Patient Box connections. Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The SERVO pressure valves will not open.</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse needs to be replaced.</td>
<td></td>
</tr>
<tr>
<td>VENTILATOR FAULT alarm and has automatically assumed the standby mode &quot;10&quot; displayed in the ON/OFF window.</td>
<td>SERVO pressure has risen suddenly because of a radical change in operating parameter.</td>
<td>Press the SILENCE button, check patient and circuit for obvious problems. Correct any problems then press the ENTER button to resume operation.</td>
<td>VI.A.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pg. VI-15</td>
</tr>
<tr>
<td>SYMPTOMS</td>
<td>POSSIBLE CAUSE</td>
<td>CORRECTIVE ACTION</td>
<td>REFERENCE SECTION</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------------</td>
<td>--------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>One or more of the SERVO</td>
<td>Call the Bunnell Hotline to determine if the Life</td>
<td>Call the Bunnell Hotline to determine if the Life Pulse</td>
<td>VI.A.3</td>
</tr>
<tr>
<td>pressure control valves</td>
<td>Pulse needs to be replaced.</td>
<td>Pulse needs to be replaced.</td>
<td>Pg. VI-8</td>
</tr>
<tr>
<td>is stuck open.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VENTILATOR FAULT and</td>
<td>Purge valve has stuck open.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIGH PIP alarms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
X. CLEANING AND STERILIZATION

A. Cleaning

The exterior surfaces of the Life Pulse High-Frequency Ventilator may be cleaned with a mild soap and water solution.

CAUTION: The use of solvents including acetone may result in damage to the unit.

B. Sterilization

CAUTION: Do not sterilize the Life Pulse ventilator. The internal electronic components of the Life Pulse may not be compatible with sterilization techniques.

The disposable humidifier cartridge/patient breathing circuit, and the LifePort adapters, which are used with the Life Pulse, are for single patient use only and must be discarded after use. Do not sterilize and re-use humidifier cartridge/patient breathing circuits.

CAUTION: Failure to discard cartridge/circuits after use may result in leaks and/or improper temperature and water level control.
XI. MAINTENANCE

All maintenance of the Life Pulse High-Frequency Ventilator must be performed by Bunnell trained service personnel. With the exception of the TEST described in Section VII, there is no routine maintenance that may be performed at the hospital unless a technician from the hospital has attended a Bunnell Service Seminar, and even then only with factory supervision.

**Bunnell Incorporated recommends the Life Pulse High-Frequency Ventilator and Patient Box(es) be returned to a factory authorized service center for routine maintenance every 12 months or 2000 hours of operation, whichever comes first.**

As with any calibrated equipment, consistent and accurate performance is dependent on a regular maintenance schedule.

A Service contract for preventive maintenance and service beyond the warranty period is available through Bunnell Incorporated. Call 801-467-0800 for more information.

The HFV Service Manual is available (see Section XII) which contains the theory of operation, system description, maintenance, troubleshooting guide, schematics and drawings, and spare parts list which will assist appropriately trained individuals in the repair and service of Bunnell equipment.
XII. ORDERING INFORMATION

A. Life Pulse High-Frequency Ventilator

The following may be ordered directly from:

Bunnell Incorporated
436 Lawndale Drive
Salt Lake City, Utah 84115

Phone: 800-800-4358
Fax: 801-467-0867

Catalog Number

203  Life Pulse High-Frequency Ventilator, Patient Box, and Operator's Manual
603  Equipment Cart
704  30-Minute Uninterruptible Power Supply (Hospital Grade)
911  HFV Balloon Test Lung
915  Humidifier Test Cartridge
992  HFV Service Manual
999  HFV In-Service Manual

The following parts are included with the Life Pulse High-Frequency Ventilator and may be ordered as extra components:

Catalog Number

312  Patient Box
991  Life Pulse Operator's Manual
B. Disposable Supplies for Use with Life Pulse High-Frequency Ventilator

The following disposable are approved for use with the Life Pulse High-Frequency Ventilator.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>937</td>
<td>HFV Patient Circuit Kit (includes 2 circuit and 4 LifePort adapters)</td>
</tr>
<tr>
<td>9025</td>
<td>LifePort 2.5 mm I.D., Pkg. of 10</td>
</tr>
<tr>
<td>9035</td>
<td>LifePort 3.5 mm I.D., Pkg. of 10</td>
</tr>
<tr>
<td>9045</td>
<td>LifePort 4.5 mm I.D., Pkg. of 10</td>
</tr>
<tr>
<td>9055</td>
<td>LifePort 5.5 mm I.D., Pkg. of 10</td>
</tr>
</tbody>
</table>
### XIII. GLOSSARY OF ABBREVIATED TERMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>atm</td>
<td>atmosphere (zero gauge pressure)</td>
</tr>
<tr>
<td>bpm</td>
<td>breaths per minute</td>
</tr>
<tr>
<td>cm</td>
<td>centimeters</td>
</tr>
<tr>
<td>cm H₂O</td>
<td>centimeters of water pressure</td>
</tr>
<tr>
<td>CPAP</td>
<td>continuous positive airway pressure</td>
</tr>
<tr>
<td>E.T.</td>
<td>endotracheal tube</td>
</tr>
<tr>
<td>F₁O₂</td>
<td>fraction of inspired oxygen</td>
</tr>
<tr>
<td>HFV</td>
<td>high-frequency ventilator or ventilation</td>
</tr>
<tr>
<td>ID</td>
<td>internal diameter</td>
</tr>
<tr>
<td>I:E</td>
<td>inspiratory time to expiratory time ratio</td>
</tr>
<tr>
<td>IMV</td>
<td>intermittent mandatory ventilation</td>
</tr>
<tr>
<td>kPa</td>
<td>kiloPascals</td>
</tr>
<tr>
<td>LED</td>
<td>light emitting diode (small, usually round lamp)</td>
</tr>
<tr>
<td>lpm</td>
<td>liters per minute</td>
</tr>
<tr>
<td>MAP</td>
<td>mean airway pressure</td>
</tr>
<tr>
<td>ml/min</td>
<td>milliliters per minute</td>
</tr>
<tr>
<td>mm</td>
<td>millimeters</td>
</tr>
<tr>
<td>mm Hg</td>
<td>millimeters of mercury pressure</td>
</tr>
<tr>
<td>PaCO₂</td>
<td>arterial partial pressure of carbon dioxide</td>
</tr>
<tr>
<td>PaO₂</td>
<td>arterial partial pressure of oxygen</td>
</tr>
<tr>
<td>PEEP</td>
<td>positive end-expiratory pressure</td>
</tr>
<tr>
<td>PIP</td>
<td>peak inspiratory pressure</td>
</tr>
<tr>
<td>PRESS</td>
<td>pressure</td>
</tr>
<tr>
<td>psi</td>
<td>pounds per square inch (pressure)</td>
</tr>
<tr>
<td>TEMP</td>
<td>temperature</td>
</tr>
<tr>
<td>Tᵢ</td>
<td>inspiratory time</td>
</tr>
</tbody>
</table>
XIV. SPECIFICATIONS

A. Life Pulse High-Frequency Ventilator

1. Description of Controls

<table>
<thead>
<tr>
<th>Control</th>
<th>Function Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTER</td>
<td>Initiates ventilation using NEW settings</td>
</tr>
<tr>
<td>STANDBY</td>
<td>Places ventilator in Standby mode</td>
</tr>
<tr>
<td>TEST</td>
<td>Initiates TEST function</td>
</tr>
<tr>
<td>RESET</td>
<td>Resets MAP and SERVO PRESSure alarm limits</td>
</tr>
<tr>
<td>SILENCE</td>
<td>Silences audible alarm for 60 seconds</td>
</tr>
</tbody>
</table>

The controls listed below use increment/decrement switches.

- **PIP**: Selects new PIP setting
- **RATE**: Selects new RATE setting
- **ON JET VALVE TIME**: Selects new JET VALVE TIME on and on/off settings
- **MAP LIMITS**: Displays and/or adjusts MAP alarm limits
- **SERVO PRESSURE LIMITS**: Displays and/or adjusts SERVO PRESSure alarm limits

2. Parameters Set and Their Ranges

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIP</td>
<td>8.0 to 50 cm H2O</td>
</tr>
<tr>
<td>RATE</td>
<td>240 to 660 bpm</td>
</tr>
<tr>
<td>JET VALVE ON TIME</td>
<td>0.020 to 0.034 sec</td>
</tr>
<tr>
<td>Maximum SERVO PRESSURE</td>
<td>20 psi (137.9 kPa)</td>
</tr>
</tbody>
</table>

3. Parameters Measured and Displayed and Their Ranges

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIP</td>
<td>0.0 to 92.3 cm H2O</td>
</tr>
<tr>
<td>PEEP</td>
<td>-9.9 to 92.3 cm H2O</td>
</tr>
<tr>
<td>Δ P</td>
<td>0.0 to 92.3 cm H2O</td>
</tr>
<tr>
<td>MAP LIMITS</td>
<td>0.0 to 40 cm H2O</td>
</tr>
<tr>
<td>SERVO PRESSURE LIMITS</td>
<td>0.0 to 25 psi (0.0 to 172.4 kPa)</td>
</tr>
<tr>
<td>ON/OFF</td>
<td>1:1.6 to 1:12</td>
</tr>
</tbody>
</table>

4. Audible and Visual Alarms

- **LOW GAS PRESSURE**: automatically set
- **LOSS OF PIP**: automatically set
- **HIGH PIP**: automatically set
- **CANNOT MEET PIP**: automatically set
- **JET VALVE FAULT**: automatically set
- **VENTILATOR FAULT**: automatically set
- **UPPER/LOWER MAP LIMITS**: automatically set and adjustable
- **UPPER/LOWER SERVO PRESS LIMITS**: automatically set and adjustable
- **Power Disconnect**: automatically set
- **Standby**: automatically set
5. Sensitivity and Accuracy

Airway pressure sensitivity 0.1 cm H₂O
Airway pressure accuracy ± 0.5 cm H₂O
Servo Pressure sensitivity 0.04 psi (0.276 kPa)
Servo Pressure accuracy ± 1.0 psi (6.895 kPa)

HFV/PB system airway pressure accuracy ± 1.5 cm H₂O

6. Response Times

Patient airway pressure sampling rate 500 Hz

Time to display pressures within specified accuracies after a step change:

Standby 80 sec
Running 20 sec

Typical servo response time until PIP is stable to within 2.0 cm H₂O of setting 60-90 sec

7. Miscellaneous

Recorder Output
-10V = 0.0 cm H₂O
+10V = 100 cm H₂O

Gas supply requirements 30 to 60 psi (206.85 – 413.7 kPa)
Power requirements 120 VAC, 60 Hz (U.S.)
1.1Amps

Size
Front height: 14.0 in
Rear height: 9.25 in
Length: 19.25 in
Width: 14.5 in
Weight 48 lbs

B. Humidifier

1. Description of Controls

WAIT Places humidifier in Standby mode
SET Permits selection cartridge or circuit temperature display
SILENCE Silences audible alarm for 60 seconds.
INCREMENT/DECREMENT Adjust the cartridge or circuit temperature settings.

2. Parameters Set, Measured, and/or Displayed

Circuit temperature setting 32.0 to 42.0°C
Cartridge temperature setting 32.0 to 42.0°C
Circuit temperature measured 20.0 to 50.0°C
3. **Audible and Visual Alarms**

CIRCUIT FAULT automatically set
HIGH/LOW Water LEVEL automatically set
HIGH/LOW Cartridge TEMP automatically set
HIGH/LOW Circuit TEMP automatically set
WAIT automatically set

4. **Sensitivity and Accuracy**

Temperature sensitivity \(\sim 0.1 \, ^\circ C\)
Temperature accuracy \(\pm 0.5 \, ^\circ C\)

5. **Servo Response Times**

Circuit temperature 3 min
Cartridge temperature 30 min

6. **Pump Rate**

\(> 0.6 \text{ ml/sec}\)

C. **Humidifier Cartridge/Patient Breathing Circuit**

1. **Humidifier Cartridge**

\(\text{H}_2\text{O} \text{ reservoir volume} \quad 50 \text{ ml}\)
Compressible Volume 20 ml
Total internal volume 70 ml

2. **Patient Breathing Circuit**

Gas Inlet Tube 10 ± 0.25 inches
Water Inlet Tube 12 ± 0.25 inches
Gas Delivery Tubing 74 ± 1.5 inches

D. **Patient Box Model 312**

1. **Dimension**

Width 3.25 inches
Height 3.30 inches
Length 4.38 inches
Weight 1.8 lbs.

2. **Output**

\(-10\text{V} = 100 \pm 1.0 \text{ cm H}_2\text{O}\)
\(+10\text{V} = 0 \pm 1.0 \text{ cm H}_2\text{O}\)
Sensitivity = 20 mv / 0.1 cm H\(_2\)O

E. **Transportation and Storage Conditions**

Ambient Temperature: -10 to 50 °C
Relative Humidity: 10 to 80 % (non-condensing)
Atmospheric Pressure: 500 to 1060 hPa
F. Operating Conditions

Ambient Temperature: 10 to 40 ºC
Relative Humidity: 10 to 75 % (non-condensing)
Atmospheric Pressure: 700 to 1060 hPa

G. Applicable Classifications

1. Complies with IEC 60601-1 with Amendments 1 & 2, C22.2 No 601.1-M90 and UL Std No 2601-1.
2. Type BF Applied Parts.
3. Class I equipment.
4. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
5. IPX0 rating on the Life Pulse Ventilator, IPX4 on the Patient Box (degree of protection against ingress of water).
6. All information required under Clause 6.1
XV. LIMITED WARRANTY AND LIMITATION OF REMEDIES

The Bunnell Incorporated Life Pulse High-Frequency Ventilator is warranted to be free from defects in materials and workmanship and to meet published specifications under normal use for a period of one (1) year from the date of in-service. The foregoing is in lieu of any other warranty, expressed or implied, including without limitation any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of Bunnell Incorporated. Repair of this equipment shall be done by a Bunnell certified technician. Buyers exclusive remedy and Bunnell Incorporated's sole obligation shall be to replace, repair or issue credit, at the discretion of Bunnell Incorporated, for the parts that become defective or fail to meet published specifications during the warranty period, provided that, Bunnell Incorporated will not be liable under this warranty unless:

A. Bunnell Incorporated is notified promptly in writing by buyer upon discovery of defects or failure to meet specifications.

B. The defective part is returned to Bunnell Incorporated, transportation prepaid by buyer;

C. The defective unit or part is received by Bunnell Incorporated for adjustment no later than one (1) week following the last day of the warranty period; and

D. Bunnell Incorporated's examination of the returned unit discloses, to Bunnell Incorporated's satisfaction, that the defect(s) or failure(s) have not been caused by misuse, neglect, improper installation or operation, unauthorized repair or alteration, operator error or accident.

Any authorization of buyer by Bunnell Incorporated for repair of Buyers unit or part by Buyer must be in writing to prevent voiding warranty.

Products or parts replaced under the terms of this warranty are warranted only through the terms of the original warranty.

THIS WARRANTY DOES NOT COVER NORMAL MAINTENANCE SUCH AS CLEANING, ADJUSTMENT OR LUBRICATION, AND UPDATING OF EQUIPMENT OR PARTS. THIS WARRANTY SHALL BE VOID AND SHALL NOT APPLY IF THE EQUIPMENT IS USED WITH ACCESSORIES OR PARTS NOT MANUFACTURED BY BUNNELL INCORPORATED OR AUTHORIZED FOR USE IN WRITING BY BUNNELL INCORPORATED, OR IF THE EQUIPMENT IS NOT MAINTAINED IN ACCORDANCE WITH A PRESCRIBED SCHEDULE OF MAINTENANCE.