LifePulse® HFV

Advanced High-Frequency Jet Ventilation Technology for Infants

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# Table of Contents

## PROLOGUE
- Warnings and Cautions ...................... 5
- Indications for Use ...................... 10
- Intended User ............................ 11
- Use Environment ....................... 11
- Servicing Guidelines ................... 11
- Disclaimers .............................. 12

## Chapter 1: OVERVIEW
- Monitor Section ......................... 13
- Alarms Section ......................... 14
- Alarm Terminology ..................... 15
- Controls Section ....................... 16
- Humidifier Section ..................... 17
- Patient Circuit ......................... 17
- Rear Panel .............................. 18
- Patient Box .............................. 19
- LifePort Adapter ....................... 20
- Use with Conventional Ventilators ......... 21

## Chapter 2: SETUP AND TESTS
- Initial Installation and Setup ............ 23
- Installing a Circuit ..................... 24
- System Test ............................. 26
- Operational Test ....................... 28

## Chapter 3: STARTING HFJV ON A PATIENT
- Connecting a Patient to the LifePulse .......... 31
- HFJV Pressure Monitoring ............... 32
- 7 Steps to Begin HFJV .................. 33
- Adjusting Ventilator Settings ............ 36
- Adjusting Ventilator Alarms ............. 36

## Chapter 4: PATIENT MANAGEMENT
- Objectives ................................ 37
- Oxygenation ............................. 38
- Oxygenating Overexpanded Lungs .......... 40
- Oxygenation Flow Chart ................ 41
- Ventilation .............................. 42
- Ventilation Flow Chart .................. 44
- Suctioning the Patient ................... 45
- Weaning the Patient ..................... 46

## Chapter 5: VENTILATOR ALARMS
- Alarms Overview ....................... 47
- Alarms Displays and Sounds .............. 48
- Adjusting Alarm Limits .................. 49
- Servo Pressure .......................... 50
- Mean Airway Pressure ................... 52
- Loss of PIP .............................. 54
- Cannot Meet PIP ....................... 55
- High PIP ................................ 56
- Vent Inop During Test ................... 57
- Vent Inop While Operating ............... 58
- Check Vent .............................. 59
- Low Gas Pressure ....................... 60
- Battery Alarms ......................... 61
- Check Circuit ............................ 62
- High Temp - Water ...................... 63
- Low Temp - Water ...................... 64
- High Temp - Gas ....................... 65
- Low Temp - Gas ....................... 66
- High or Low Level - Water .............. 67

## Chapter 6: HUMIDIFICATION
- Humidifier Overview .................... 69
- Patient Circuit Overview ............... 70
- Starting the Humidifier ................. 71
- Stopping the Humidifier ................. 71
- Water Level Sensing .................... 72
- Gas Flow through Humidifier ............ 73
- Gas Flow through Patient Box .......... 74
- Understanding Gas Temperature ........ 75
- Understanding Water Temperature ..... 76
- Temperature Controls ................... 76
- Identifying Proper Humidification ....... 77
- Changing the Circuit .................... 78

## Chapter 7: BATTERY
- Charging the Battery .................... 81
- Running on Battery ..................... 82
- Battery Maintenance ..................... 83

## Chapter 8: CLEANING AND STORAGE ........ 85

### Appendix A
- Owner Responsibility for Maintenance ........ 87
- Warranty ............................... 88

### Appendix B
- Ventilator Alarms and Reactions .......... 89
- Humidifier Alarms and Reactions .......... 90

### Appendix C
- Ordering Information .................... 91

### Appendix D
- Device Specifications .................. 93

### Appendix E
- International Symbols Table ............ 101

### Appendix F
- Electromagnetic Declarations and Tables ... 105
Warnings and Cautions

Anyone using or involved with the use of the LifePulse High Frequency Ventilator (HFV) should study and observe the Warnings and Cautions listed here.

**WARNINGS** indicate that there is a possibility of direct 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.

**CAUTIONS** indicate that there is a possibility of damage to the instrument, other property, or indirectly to other individuals.

**NOTES** provide additional information intended to avoid inconveniences during operation.

The following Warnings and Cautions are organized by their relevancy to set-up, operation, or maintenance of the LifePulse.

**Set-Up of LifePulse**

**WARNING:** Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

**WARNING:** This device is to be operated only by a properly trained individual in accordance with the User Manual. Refer to the User Manual for applicable Warnings and Cautions related to the use of this device.

**WARNING:** Do not use the LifePulse in the presence of flammable gases or anesthetics. There is a risk of explosion. This Warning applies to hyperbaric chambers due to their oxygen-rich environment.

**WARNING:** The ventilator may be prone to malfunction if it has been transported, stored, or operated outside its recommended environmental ranges.

**WARNING:** This equipment may cause interference with radio communications and other devices in the vicinity if not installed and used in accordance with the User Manual. 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 to 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.

**WARNING:** Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by Bunnell Incorporated as replacement parts, may result in increased emissions or decreased immunity of the LifePulse HFV.

**WARNING:** The LifePulse HFJV should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the LifePulse HFJV should be observed to verify normal operation in the configuration in which it will be used.

**WARNING:** Do not modify the LifePulse, Patient Box, or Patient Circuit (the ventilator system) without authorization from Bunnell Incorporated.

**WARNING:** Only use the hospital grade power cord supplied by Bunnell that locks onto the power cord inlet receptacle on the back of the LifePulse. Don’t substitute any other power cord.

**WARNING:** Only connect to a hospital grade power outlet with a protective earth ground.

**WARNING:** To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.

**WARNING:** Only use medical grade oxygen and air that is dry and free of dust and oil. The gas supply pressure must be 30 – 60 psi (205.85 - 413.70 kPa).

**WARNING:** Do not operate the ventilator system or components if they have suffered physical damage or do not appear to be operating properly.

**WARNING:** Always use an air/oxygen blender to supply the mixed gas source to the LifePulse.

**WARNING:** Do not connect 100% oxygen directly to the “Mixed Gas Input” on the rear panel of the LifePulse, unless you intend to only deliver 100% oxygen.

**WARNING:** Plug the ventilator into an electrical wall outlet at all times to maintain proper battery charge. Charging must only occur in a properly ventilated room. The user must ensure the battery is in good condition and has sufficient capacity prior to every patient use.

**CAUTION:** The capacity of the battery must be checked regularly and the battery replaced if necessary. Avoid deep discharges, as they lead to premature degradation of the battery.
**WARNING:** Improper replacement of the battery by non-Bunnell authorized service personnel could result in an unacceptable risk (e.g., excessive temperature, fire, or explosion).

**WARNING:** If the battery charge indicator stays red with the LifePulse plugged into an electrical wall outlet, the battery needs to be checked by Bunnell-authorized service personnel. The ventilator and humidifier will function normally when plugged in but the battery will not provide adequate power, if needed.

**WARNING:** The LifePulse battery is low and needs to be charged when the battery fuel gauge is blinking red. Plug the LifePulse into an electrical wall outlet.

**WARNING:** When the battery fuel gauge is blinking red with the BATTERY DEPLETED alarm lit and a high priority alarm active the battery charge is too low to continue running the LifePulse and it will soon go to Standby mode.

**WARNING:** The discharge rate of the battery changes with the ventilator and humidifier settings as well as with the age of the battery. This can shorten the overall time the ventilator will operate on battery power before the battery depletes and the ventilator stops operating.

**WARNING:** Use only a LifePort adapter with a standard endotracheal tube and the Bunnell Patient Circuit when operating the LifePulse Ventilator.

**WARNING:** Do not connect any additional tubing or pressure monitors between the pressure monitoring tube of the LifePort adapter and the Patient Box. Doing so will degrade the LifePulse’s ability to measure airway pressures accurately and may result in inappropriate pressures or volumes being delivered to the patient.

**WARNING:** Use ONLY sterile water for inhalation, USP, in the LifePulse humidifier cartridge of the Patient Circuit. The use of deionized water or saline solutions may cause a malfunction of the water level sensors in the humidifier cartridge, resulting in the cartridge overfilling and the delivery of a bolus of water to the patient.

**WARNING:** Latch the water inlet tube on the humidifier cartridge of the Patient Circuit into the water pump housing prior to connecting to the water supply. Failure to do so may result in cartridge overfill and delivery of water to the patient by gravity feed.

**WARNING:** Clamp the water supply tube prior to opening the water pump door to prevent cartridge overfill and delivery of water to the patient by gravity feed. The water supply should be positioned at or below the level of the humidifier cartridge as an added precaution.

**WARNING:** Do not pre-fill the humidifier cartridge of the Patient Circuit prior to starting the LifePulse. Doing so may result in the cartridge overfilling and the delivery of a bolus of water to the patient. The cartridge will fill automatically once the LifePulse begins operating.

**WARNING:** The LifePulse should pass two tests to ensure proper operation. Run the System Test and an Operational Test using a test lung before starting the LifePulse on a patient. If the LifePulse displays a monitored PEEP different from 0 ±1 cm H$_2$O during the Operational Test, the Patient Box may be out of calibration and should be replaced.

**WARNING:** Never initiate a test while the LifePulse ventilator is connected to a patient. Doing so may result in inappropriate pressures or volumes being delivered to the patient, resulting in volutrauma.

**WARNING:** Remove the test lung following the successful completion of the System and Operational Tests. Place the LifePulse in Standby mode before connecting it to the patient. Failure to do so may result in inappropriate pressures or volumes being delivered to the patient, resulting in volutrauma.

**CAUTION:** Always keep an extra Patient Box, Patient Circuit, and LifePort adapters near the patient’s bedside. When operating lifesaving equipment, it is recommended to have back-up equipment available for rapid intervention by properly trained medical professionals.

**WARNING:** Do not drop the Patient Box. Always handle the Patient Box with care; it is a precision device. If the Patient Box is dropped, it must be tested by running the System and Operational Tests using a test lung to verify normal function prior to using it on a patient.

**WARNING:** Always use a conventional ventilator in tandem with the LifePulse. The conventional ventilator is essential for providing gas for the patient’s spontaneous breathing, PEEP, and periodic sigh breaths.

**CAUTION:** Do not use pens, pencils, fingernails, or other pointed objects to push the buttons on the LifePulse front panel. Doing so may result in damage to the buttons and may cause them to fail.
**Operation of LifePulse**

**WARNING:** In case of malfunction of any of the built-in monitoring or LifePulse functions, the operator must still assume full responsibility for proper ventilation and patient safety in all situations.

**WARNING:** Do not use in conjunction with magnetic resonance imaging (MRI); patient injury may result.

**WARNING:** Exposure to known sources of EMI with medical devices such as diathermy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors could affect the function of the LifePulse HFV. Use of the LifePulse around such sources should be avoided if possible until effects are known. If unexplained changes in LifePulse performance are observed, it may be necessary to take mitigation measures, such as re-orienting, relocating the LifePulse, or shielding its location. If necessary, discontinue use of the interfering device or the LifePulse. Note that the presence of RFID devices may not be obvious.

**WARNING:** Do not position the LifePulse so that it is difficult to access the electrical power cord in case it needs to be disconnected from the electrical wall outlet, if necessary (e.g., isolated from the main power supply).

**WARNING:** Do not block the air intake vents. Air is drawn in through the air intake vents to cool the ventilator’s components. Blocking the air intake may result in overheating and possible malfunction.

**WARNING:** Do not block the dump valve exhaust port on the back of the LifePulse. Doing so may interfere with the internal pressure being safely released during certain alarm conditions, which could increase the risk of volutrauma.

**CAUTION:** Do not position the LifePulse so that it is difficult to access the electrical power cord in case it needs to be disconnected from the electrical wall outlet, if necessary (e.g., isolated from the main power supply).

**WARNING:** A properly trained medical professional must be in attendance at all times when the LifePulse is connected to a patient in order to monitor the patient and detect alarms or other indications of a problem.

**WARNING:** Do not ignore audible and visual alarms. Alarms indicate changing conditions and should never go unheeded.

**WARNING:** Alarms from different medical devices can sound similar. Identify and respond to LifePulse alarms based on the alarm priority lamp, the alarm indicator message, and the audible alarm tone and rhythms.

**WARNING:** There are no airway pressure alarms active while the LifePulse is in the Standby mode.

**WARNING:** A negative monitored PEEP may indicate the airway pressure transducer is out of calibration or faulty.

**WARNING:** A significant discrepancy (>4 cm H2O) between the delivered PEEP and the monitored PEEP may indicate a potential problem and should always be evaluated by a qualified trained individual.

**WARNING:** Place the LifePulse in Standby mode if there is any concern about the ventilator functionality or safety. Support the patient using the tandem conventional ventilator or other available ventilation options.

**WARNING:** Place the LifePulse in 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 volutrauma.

**WARNING:** Troubleshoot alarms only in accordance with the guidelines in the User Manual. Troubleshooting must only be performed by properly trained individuals who have a thorough understanding of the LifePulse ventilator and its operation. Always attempt to correct the cause of the alarm before pressing the ENTER button.

**WARNING:** Patient connections must only be made in the Standby mode. Do not connect the LifePulse Patient Circuit to the LifePort adapter on the patient’s ET tube while the LifePulse is running. Failure to comply risks high pressures and volumes being delivered to the patient, which may result in volutrauma.

**WARNING:** Inspect the Pressure Monitoring Tube of the LifePort adapter for condensation as condensates may interfere with safe and effective ventilator functionality. To mitigate condensates in the Pressure Monitoring Tube, check the LifePort adapter’s orientation to ensure the Pressure Monitoring Tube is pointed upward. It may also be necessary to reduce the humidifier temperature (cartridge/water) to minimize condensation. Replace the LifePort adapter if necessary.

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

**WARNING:** Press the ENTER button to resume ventilation if a LOSS OF PIP alarm has occurred with the Ready indicator off. The Patient Box will be cycling but no gas (breaths) will be delivered to the patient until the LOSS OF PIP alarm is cleared by pressing the ENTER button. Always troubleshoot the potential causes of an alarm following the guidelines in the User Manual.
WARNING: Do not initiate ventilation with kinks or obstructions present in the Patient Circuit or LifePort pressure monitoring tube. Doing so may result in alarms or delays in ventilator support. Pressures may be generated that are too high or too low for the patient’s needs.

WARNING: Do not leave the patient’s bedside while the LifePulse water pump is running during initial start-up or 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 stops pumping.

WARNING: The LifePulse will not detect extubation of a patient during start-up (i.e., from the time the ENTER button is pushed until the Ready indicator is illuminated). During start-up the ventilator may appear to be functioning normally despite extubation and will generate no audible or visual alarms. A properly trained individual must verify the patient is being ventilated following start-up.

WARNING: There will be no LOSS OF PIP alarm for the first 15 seconds after the ENTER button is pushed. A properly trained person must observe the LifePulse reach the set PIP and the Ready indicator illuminate before leaving the patient’s bedside.

WARNING: Do not press the ENTER button during a LOSS OF PIP alarm with the Ready indicator illuminated if the patient is stable and the Servo has locked at or near an established operating value. Doing so will temporarily silence the audible alarm and unlock the LifePulse Servo. Always troubleshoot the potential causes of an alarm following the guidelines in the User Manual prior to pressing the ENTER button.

WARNING: Always troubleshoot a change in Servo that is greater than 1.0 psi (6.89 kPa) from the previously established baseline, especially if the LifePulse control settings have not been changed. Servo changes this large or larger usually represent a mechanical problem and may pose a risk of volutrauma.

WARNING: The patient is not being ventilated by the LifePulse during VENT INOP Alarms 01 & 05-09, which place the LifePulse in Standby mode.

WARNING: The patient is not being ventilated by the LifePulse during VENT INOP Alarm 10, which places the LifePulse into Standby mode. Always troubleshoot the potential causes of an alarm following the guidelines in the User Manual prior to pressing the ENTER button. Pressing the ENTER button will re-initiate ventilation immediately.

WARNING: Do not manually adjust alarm limits around MAP and Servo to the point that they become irrelevant (i.e., are effectively off). Doing so will negate critical alarms and expose the patient to potentially unsafe conditions that may result in injury.

WARNING: Do not operate the LifePulse Servo to the point that they become irrelevant (i.e., are effectively off). Doing so will limit the LifePulse’s ability to alert clinicians to alarm conditions and expose the patient to potentially unsafe conditions that may result in injury.

WARNING: The conventional ventilator rate should not exceed 10 breaths per minute when running in tandem with the LifePulse ventilator. Doing so could result in excessive Mean Airway Pressure or minute volume being delivered to the patient. The recommended conventional ventilator rate is 0 - 5 breaths per minute.

NOTE: PIP, MAP, and PEEP are reported as approximate tracheal pressures and are measured inside the LifePort adapter. They may not accurately reflect alveolar pressures and, in fact, may be higher or lower than alveolar pressures.

WARNING: Always evaluate inadvertent PEEP (LifePulse monitored PEEP greater than CV set PEEP). The patient’s lung volume should be assessed when inadvertent PEEP is present. Inadvertent PEEP reduces delta pressure, which may result in under-ventilation (hypercarbia).

WARNING: Place the LifePulse ventilator in Standby mode prior to suctioning to avoid fluctuations in the monitored pressures that may result in alarm conditions or possible injury to the patient.

WARNING: The LifePulse must be in Ready mode prior to suctioning if suctioning while the LifePulse is running. Failure to do so may result in inappropriate pressure or volumes being delivered to the patient.

WARNING: Always evaluate inadvertent PEEP (LifePulse monitored PEEP greater than CV set PEEP). The patient’s lung volume should be assessed when inadvertent PEEP is present. Inadvertent PEEP reduces delta pressure, which may result in under-ventilation (hypercarbia).

WARNING: Do not press the PUSH TO LOAD button on the Patient Box while the LifePulse is running on a patient. Doing so could result in the patient being exposed to inappropriately high pressure or large volume delivery.

WARNING: Do not tip the humidifier cartridge while removing it from the cartridge housing if the Patient Circuit is connected to the patient’s ET tube via the LifePort adapter. Doing so may result in water spilling into the Patient Circuit and a bolus of water being delivered to the patient.

WARNING: Do not open the water pump door while the pump is pumping. Doing so may result in a pinch hazard to the operator.
**WARNING:** Removal of the humidifier cartridge from the cartridge housing while the LifePulse is running exposes the heater plate and cartridge heater cup, which may be in excess of 60°C.

**WARNING:** Always attempt to minimize excessive condensation (rainout) in the Patient Circuit between the ventilator and the Patient Box. Failure to do so may result in water interfering with the monitored pressure signal at the LifePort adapter resulting in fluctuations in the delivered PIP.

**WARNING:** Do not under-humidify gas being delivered to the patient. Adjust the cartridge temperature so that condensation is always present in the green delivery tube between the Patient Box and the LifePort adapter.

**WARNING:** External temperature of the heated portion of the patient circuit may exceed 50°C. Contact with the patient’s skin should be avoided.

**WARNING:** Pushing the PAUSE button on the Humidifier shuts off the heating elements that provide for gas warming and humidification. A properly trained individual must not leave the patient’s bedside with the Humidifier in the Pause mode.

**WARNING:** Raising or lowering the Gas temperature setting may raise or lower the patient’s temperature. The normal setting of 40°C is designed to keep the patient from losing heat through respiration. It should not be changed under normal operating circumstances.

**WARNING:** Do not move the LifePulse while it is running on a patient. Doing so may result in water entering the Patient Circuit and creating a risk of water delivery to the patient. Monitor the water level closely under these circumstances.

**WARNING:** Running the LifePulse while the ventilator or patient is in motion or while high-flow or large tidal volume conditions exist may result in water entering the Patient Circuit and creating a risk of aspiration. Please monitor the water level closely.

**WARNING:** Periodically check the gas filter/water trap. If water is visible, drain the water by opening the valve. Failure to do so may result in a ventilator malfunction.

### Maintenance/Cleaning of LifePulse

**CAUTION:** The LifePulse ventilator system must receive inspections and service at regular intervals. Preventive maintenance should be performed every 2000 hours or at least once a year. Overhauls should be performed every 6000 hours of use. All service and maintenance must be performed by Bunnell authorized service personnel.

**WARNING:** Clean and disinfect the LifePulse and Patient Box prior to patient applications to avoid the risk of infection. Refer to the cleaning instructions in the User Manual.

**WARNING:** Do not store LifePulse with the pinch tube of the circuit loaded in the pinch valve jaws of the Patient Box.

**WARNING:** Disconnect the battery before disassembly of the ventilator.

**WARNING:** Do not remove the LifePulse cover due to possible shock hazard. The ventilator should only be serviced by Bunnell authorized service personnel.

**WARNING:** Severe electrical shock to the user or service personnel may be delivered by the battery and/or battery charger if direct contact is made with their electrical connections.

**CAUTION:** If the battery case is damaged (e.g., from dropping or impact during servicing or shipping) the battery must be replaced. Otherwise, it may leak battery acid and cause the LifePulse to malfunction.

**CAUTION:** Always plug the LifePulse power cord into an electrical wall outlet during storage between uses. This action will help avoid deep discharges of the battery which cause degradation and decrease battery life.

**WARNING:** The Patient Circuit and/or Patient Box should be removed to release any pressurized gas before servicing the ventilator.

**CAUTION:** Batteries that are improperly disposed of may cause harm to the environment.

**CAUTION:** The LifePulse, Patient Box, and Patient Circuit contain components made of hazardous materials that need to be disposed of appropriately. Improper disposal may cause harm to the environment.

**CAUTION:** Do not sterilize the LifePulse ventilator or Patient Box. The internal components are not compatible with sterilization techniques.

**WARNING:** Do not reuse or sterilize Patient Circuits or LifePort adapters. Failure to discard the Patient Circuit after one use or seven days may result in leaks, improper temperature, and water level control.

**WARNING:** The use of non-recommended solvents or cleaners can damage the enclosure(s) or user interface and damage equipment causing the LifePulse to malfunction. Refer to the cleaning instructions in the User Manual.

**CAUTION:** Do not ship the LifePulse ventilator or Patient Box in any packaging other than a factory authorized carton or case. Doing so may result in damage to the ventilator and will void the warranty.
Indications for Use

The Bunnell LifePulse High Frequency Ventilator (HFV) 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 gestational age from 24 to 41 weeks.

The Bunnell LifePulse 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.

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)).

Adverse Side Effects

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

1. Pulmonary air leaks
   - pneumothorax
   - pneumopericardium
   - pneumoperitoneum
   - pneumomediastinum
   - pulmonary interstitial emphysema

2. Intraventricular hemorrhage

3. Necrotizing tracheobronchitis

4. Bronchopulmonary dysplasia
**Intended User**

The LifePulse should be used only by those who

- are professional health care providers,
- have received training in the use of the LifePulse system, and
- have knowledge of pulmonary physiology and mechanical ventilation

**Use Environment**

The LifePulse should be used only

- in hospital critical care units (e.g., NICU, PICU)
- during transport of a patient within hospitals or health care facilities

**Servicing Guidelines**

**Regular Service:** The LifePulse must be serviced at regular intervals by Bunnell Incorporated authorized service personnel who have received specialized training.

**Complete Service Records:** All service performed on the LifePulse must be recorded in a service log in accordance with hospital procedures and local and national regulations.

**Service Contract:** We strongly recommend, for optimal care and performance, that all service on the LifePulse be performed as part of a service contract with Bunnell Incorporated.
**Disclaimers**

**Improper Use Environment:** Bunnell Incorporated has no responsibility for the safe operation of the LifePulse if the Intended Use and User requirements specified in this document are not followed.

**Nonprofessional Servicing:** Bunnell Incorporated has no responsibility for the safe operation of the LifePulse if service or repairs are performed by persons other than Bunnell Incorporated authorized service personnel.

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

- Operation not in accordance with the user instructions
- Faulty maintenance not in accordance with the authorized maintenance instructions
- Repair by anyone other than Bunnell authorized service personnel
- Modification of the equipment or accessories
- 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.
Chapter 1: OVERVIEW

Monitor Section

The displays in the Monitor section approximate the pressures at the tip of the endotracheal tube and the internal servo or drive pressure of the LifePulse.

The LifePulse’s pressure monitoring system is active in both Standby and Ready modes. The pressures are updated in the Monitor displays every 10 seconds in Standby mode and every 2 seconds in Ready mode.

The LifePulse monitors the following:

1. **PIP**
   Peak Inspiratory Pressure, the average maximum airway pressure measured for each HFJV breath

2. **Servo**
   Internal drive pressure of the LifePulse; indicates how much gas flow must be produced to meet the set PIP, Rate, and I-Time requested by the operator for a particular patient

3. **ΔP**
   PIP minus PEEP; proportional to tidal volume; as ΔP increases, tidal volume increases and vice versa.

4. **MAP**
   Mean Airway Pressure, an average of all pressures applied to the airway. MAP includes pressures produced by HFJV, conventional ventilation, or spontaneous breathing.

5. **PEEP**
   Positive End-Expiratory Pressure, the average minimum airway pressure

SERVO

Servo is an indication of how much gas flow the LifePulse must generate to meet the requested settings. It is regulated by the microprocessor and is outside the control of the operator. Bigger patients, or those with more compliant lungs, will require higher Servo. Infants with smaller and/or less compliant lungs will require lower Servo.

Changes in Servo above or below the established operating level for particular settings alert clinicians that the LifePulse’s performance has changed or that the patient’s condition (e.g., lung compliance, airway resistance, or lung volume) may be improving or worsening.
Alarms Section

The LifePulse alarm system alerts the operator, both audibly and visually, to changes in the ventilator or the patient. The alarm statements are not visible until they are lit.

The Alarms section has 6 key features:

1. **UPPER and LOWER LIMIT buttons**
   - adjust the limits for the Servo and Mean Airway Pressure (MAP) alarms

2. **READY indicator**
   - when lit, indicates that all internal alarms have been automatically set

3. **Alarm Priority Lamp**
   - a visual alert for an alarm and its priority, based on color and flashing sequence

4. **AUDIO PAUSED button**
   - silences audible alarms for 60 seconds

5. **ALARMS indicators**
   - display various potentially hazardous conditions

6. **Battery Fuel Gauge**
   - indicates the charge capacity of the battery

7. **SYSTEM TEST button**
   - self-tests the LifePulse’s components

Alarm indicators include the following:

- LOSS OF PIP
- CANNOT MEET PIP
- HIGH PIP
- BATTERY DEPLETED
- LOW GAS PRESS(URE)
- CHECK VENT
- VENT INOP

**MORE ON ALARMS**

See Ventilator Alarms Chapter for a detailed description of each alarm, how to interpret and troubleshoot alarms, and how to adjust MAP and Servo alarm limits.

**WARNING:** Do not ignore audible and visual alarms. Alarms indicate changing conditions and should never go unheeded.
Alarms Terminology

High Priority
Alarm Priority Lamp – flashing red
Alarm Sound – 2 bursts of 5 beeps every 5 seconds
- LOSS OF PIP
- HIGH PIP
- VENT INOP w/ Codes (01-10)
- HIGH LEVEL
- CHECK CIRCUIT LEVEL
- BATTERY DEPLETED
- Power Up (no alarm indicator)
- VENT INOP (no code) - Vent stopped or reset via Watchdog circuit
- Vent reset via software or backup vent alarm detected (no alarm indicator)

Medium Priority
Alarm Priority Lamp – flashing yellow
Alarm Sound – 3 beeps every 5 seconds
- LOW GAS PRESSURE
- CANNOT MEET PIP
- CHECK VENT (w/ Codes) 111, 222, 333
- MAP UPPER or LOWER LIMIT
- SERVO UPPER or LOWER LIMIT
- CHECK CIRCUIT TEMP
- LOW LEVEL
- LOW TEMP - WATER
- HIGH TEMP - WATER
- LOW TEMP - GAS
- HIGH TEMP - GAS
- BATTERY LOW (Fuel Gauge Blinks Red)
- CHECK VENT (No Code) - Humidifier stopped or reset via Watchdog circuit, failure to detect the purge, or valve status feedback errors
- Backup humidifier alarm detected (no alarm indicator)

Low Priority
Alarm Priority Lamp – solid yellow
Alarm Sound – 1 beep every 18 seconds
- STANDBY
- PAUSE
- BATTERY (running on battery)
- Battery missing, malfunction, or cannot accept a charge (no alarm indicator)

Power Down
Alarm Sound – 1 beep every 0.5 seconds
Controls Section

The Controls section contains the parameters you will adjust when managing a patient during HFJV with the LifePulse. The Controls section has 7 key features:

1. **PIP**
   - displays the set PIP in cm H2O that the LifePulse will deliver to the patient

2. **Rate**
   - displays the set Rate in breaths per minute (bpm) that the LifePulse will deliver to the patient

3. **I-Time**
   - displays the inspiratory time in seconds that will be delivered each breath.

4. **I:E Ratio**
   - displays the ratio of inspiratory time to expiratory time at the current LifePulse settings

5. **STANDBY Button**
   - pauses HFJV

6. **ENTER Button**
   - begins HFJV at the set PIP, Rate, and I-Time

7. **Adjustment Buttons**
   - increase or decrease PIP, Rate, and I-Time settings; each parameter has its own adjustment buttons

MORE ON CONTROLS

See Patient Management Chapter for a detailed description of when and how to adjust settings.
Humidifier Section

The Humidifier section contains the components required to heat and humidify the gas that is delivered to the patient by the LifePulse. The Humidifier section has 10 key features:

1. **PAUSE Button**
   places the humidifier into Standby mode and silences humidifier alarms

2. **Temp Display**
   displays the current gas temperature, but toggles between the gas temperature and the set temperatures of both gas and water

3. **Adjustment Buttons**
   increase or decrease the gas and water temperature settings

4. **GAS Temperature Button**
   when pressed, displays the temperature setting of the gas that is delivered to the patient

5. **WATER Temperature Button**
   displays the temperature setting of the water that humidifies the gas in the cartridge

6. **Humidifier Alarms**
   display various Gas and Water alarms

7. **Battery Charge Indicator**
   indicates if battery is charging.

8. **Water Pump**
   transfers water from a water supply to the humidifier cartridge

9. **WhisperJet Connection**
   receives the cable connector from the WhisperJet Patient Box

10. **Cartridge Receptacle**
    contains the humidifier cartridge of the Patient Circuit

Patient Circuit

The LifePulse humidifier uses a disposable cartridge-and-tubing set called the Patient Circuit.

The Patient Circuit heats and humidifies the gas that is delivered from the LifePulse to the Patient Box where it is broken up into breaths that are pushed through the jet nozzle in the LifePort adapter into the patient’s endotracheal tube.

A complete description of the Patient Circuit is in the Humidifier Chapter.
Rear Panel

The Rear Panel has the following components:

1. **Air Intake**
   pulls air into the LifePulse to cool electronic components
   
   **WARNING:** Do not block the air intake. Air is drawn in through the air intake vents to cool the ventilator’s components. Blocking the air intake may result in overheating and possible malfunction.

2. **Ventilator Power**
   main power switch for turning the LifePulse on and off

3. **Alarm Volume**
   adjusts the volume of the audible alarm

4. **Oxygen Sample Switch**
   turns on and off the flow of oxygen to the oxygen sample port

5. **Gas Filter/Water Trap**
   collects particulates, humidity, and water that may have inadvertently entered the gas supply

6. **Mixed Gas Input**
   receives the high-pressure oxygen hose from an air/oxygen blender

7. **Dump Valve & Pressure Relief Valve Exhaust Port**
   exhausts gas away from the patient in alarm conditions
   
   **WARNING:** Do not block the dump valve exhaust port on the back of the LifePulse. Doing so may interfere with the internal pressure being safely released during certain alarm conditions, which could increase the risk of volutrauma.

8. **Oxygen Sample Port**
   allows an oxygen sensor to be attached to the LifePulse for FiO₂ measurements (O₂ Sensor Flow Diverter)

9. **Potential Equalization Conductor**
   accessible stud provided for easily checking the leakage current and ground continuity of the device; these checks are performed periodically by the biomedical engineering staff as part of their routine safety evaluations (ISO60601-1 3rd Edition Clause 8.6.7.)

10. **Circuit Breaker**
    interrupts and resets the power to the LifePulse to protect it

11. **Electrical Plug Inlet**
    receives the main power cord connector for the electrical plug

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**CHECK GAS FILTER/WATER TRAP**

Gas filter/water trap should be checked periodically for water accumulation. Drain the water as necessary.

**WARNING:** Periodically check the gas filter/water trap. If water is visible, drain the water by opening the valve. Failure to do so may result in a ventilator malfunction.
Chapter 1: OVERVIEW

The Patient Box makes and measures the high-frequency breaths. It attaches to the front panel of the LifePulse and is placed near the patient during operation.

The Patient Box has 5 key features:

1. **PUSH TO LOAD Button**
   pressed to allow insertion of the pinch tube portion of the Patient Circuit into the jaws of the pinch valve

2. **Pressure Monitoring Port**
   receives a pressure pulse from the patient through the LifePort’s pressure monitoring tube and sends the signal to a pressure transducer

3. **Cable Connector**
   connects the Patient Box to the LifePulse

4. **Pinch Valve**
   pinches and releases the circuit pinch tube to create HFJV breaths

5. **Purge Port**
   receives a continuous flow of gas through the circuit purge tubing; the gas flow is used to maintain the patency of the LifePort pressure monitoring tube

### Patient Box Storage

A patient box storage area is located behind the handle on top of the LifePulse. This area is intended to hold the patient box when not in use.

Do not place open fluids in the patient box storage area.

**WARNING:** Do not drop the Patient Box. Always handle the Patient Box with care; it is a precision device. If the Patient Box is dropped, it must be tested by running the System and Operational Tests using a test lung to verify normal function prior to using it on a patient.

**WARNING:** Do not place open containers of liquid on top of or above the LifePulse ventilator. Liquids getting into the ventilator can cause equipment malfunction with a risk of patient injury.
The LifePulse is designed to be used with the LifePort adapter distributed by Bunnell Incorporated. This adapter allows the CV and the LifePulse to be simultaneously connected to a patient. The LifePort has three main features:

1. **15 mm Connector**
   - provides the standard connection to the CV circuit

2. **Jet Port**
   - connection for the Patient Circuit that delivers the high-frequency breaths provided by the LifePulse

3. **Pressure Monitoring Tube**
   - connects to the Patient Box in order to measure and the airway pressures

Replace the standard 15 mm endotracheal (ET) tube adapter with the Bunnell LifePort adapter appropriate for the patient’s ET tube.

**WARNING:** Inspect the Pressure Monitoring Tube of the LifePort adapter for condensation as condensates may interfere with safe and effective ventilator functionality. To mitigate condensates in the Pressure Monitoring Tube, check the LifePort adapter’s orientation to ensure the Pressure Monitoring Tube is pointed upward. It may also be necessary to reduce the humidifier temperature (cartridge/water) to minimize condensation. Replace the LifePort adapter if necessary.
LIFEPULSE COMPONENTS
- LifePulse Ventilator
- WhisperJet Patient Box
- Patient Circuit
- LifePort Adapter
- LifePulse Pole Stand
- Bunnell Locking Power Cord

ADDITIONAL COMPONENTS
- Conventional Ventilator
- Air/Oxygen Blender
- Water Transfer Tube
- Water Supply (Bag or Bottle)
- \( \text{O}_2 \) Sensor Flow Diverter for \( \text{O}_2 \) analyzer

Use with Conventional Ventilators

The LifePulse is used in conjunction with a conventional ventilator (CV). The CV has four functions:
- provides fresh gas for the patient’s spontaneous breathing
- regulates positive end expiratory pressure (PEEP)
- provides supplementary intermittent mandatory ventilation (IMV) when needed
- generates alarms for changes in airway pressure

The purpose of the PEEP from the CV is to maintain the inflation of alveoli for adequate functional residual capacity. CV PEEP is the primary control for MAP.

The purpose of the supplementary IMV from the CV is to provide sigh breaths sufficient to recruit atelectatic alveoli.
Chapter 2: SETUP AND TESTS

Initial Installation and Setup

A. Activities to be Performed Upon Receipt of a LifePulse

1. Remove the ventilator from its shipping carton. Save the carton for return shipping, as needed.
2. Visually inspect the ventilator to make sure there is no damage as a result of shipping.
3. Contact Bunnell Incorporated to report the receipt of the ventilator and set up in-service training. Training is provided at the hospital by a Bunnell Clinical Specialist and training materials are available online for easy access.
4. Set up the ventilator, install a Patient Circuit, and perform the tests as described in this chapter.
5. Complete and sign the warranty registration form and return it to:
   
   Bunnell Incorporated  
   436 Lawndale Drive  
   Salt Lake City, UT 84115  
   Phone: 800-800-4358  
   International: 1-801-467-0800  
   Fax: 801-467-0867  
   E-mail: info@bunl.com  

B. Setup of the LifePulse

1. Attach an air/oxygen supply from either a low flow blender (0-30 L/min) or the low flow output (2-100 L/min) of a standard blender to the Mixed Gas Input connector on the rear panel.
2. Attach the power cord provided by Bunnell to the inlet receptacle on the rear panel, lock it in place, and plug the LifePulse into a hospital grade electrical outlet.
3. Verify that the battery charge indicator is green (blinking or solid).
4. Attach the Patient Box to its connector on the front panel.
Installing a Circuit

A Patient Circuit must be installed in order to use the LifePulse. Follow these steps to install the Patient Circuit:

1. Open cartridge door and insert humidifier cartridge into receptacle.
2. Open water pump door by lifting up. Secure the water inlet tube inside the water pump and snap the pump door closed.
3. Attach the green gas inlet tube to the green-coded Gas Out port on the LifePulse.

WARNING: Do not pre-fill the humidifier cartridge of the Patient Circuit prior to starting the LifePulse. Doing so may result in the cartridge overfilling and the delivery of a bolus of water to the patient. The cartridge will fill automatically once the LifePulse begins operating.

(Continued on next page)
**WARNING:** Use ONLY sterile water for inhalation, USP, in the LifePulse humidifier cartridge of the Patient Circuit. The use of deionized water or saline solutions may cause a malfunction of the water level sensors in the humidifier cartridge, resulting in the cartridge overfilling and the delivery of a bolus of water to the patient.

**WARNING:** Never initiate a test while the LifePulse ventilator is connected to a patient. Doing so may result in inappropriate pressures or volumes being delivered to the patient, resulting in volutrauma.

4. Attach the purge tube to the yellow-coded Purge port on the LifePulse and to the yellow-coded port on the Patient Box.

5. Press PUSH TO LOAD on top of the Patient Box and gently stretch the pinch tube into the jaws of the pinch valve.

6. Connect the clear pressure monitoring tube from a LifePort adapter to its port on the Patient Box.

7. Insert the green delivery tube into the Jet port on the LifePort adapter.

8. Attach the water transfer tube to the water inlet tube and spike the water supply. The water supply should be at or below the level of the humidifier cartridge.

9. Unclamp the water transfer tube.

The circuit is now installed and ready for testing.
Chapter 2: SETUP AND TESTS

**WARNING:** Never initiate a test while the LifePulse ventilator is connected to a patient. Doing so may result in inappropriate pressures or volumes being delivered to the patient, resulting in volutrauma.

**WARNING:** The LifePulse should pass two tests to ensure proper operation. Run the System Test and an Operational Test using a test lung before starting the LifePulse on a patient. If the LifePulse displays a monitored PEEP different from 0 ±1 cm H$_2$O during the Operational Test, the Patient Box may be out of calibration and should be replaced.

### System Test

Note: Some steps may already have been completed.

1. Plug in the LifePulse to a hospital grade electrical outlet.

2. Attach an air/oxygen supply from either a low flow blender (0-30 L/min) or the low flow output (2-100 L/min) of a standard blender to the Mixed Gas Input connector on the rear panel.

3. Turn the Ventilator Power switch on the rear panel to the ON position and verify that the LEDs and displays in the Humidifier section light up. The LifePulse activates into Standby mode with an audible alarm sounding. The alarm lamp on top of the LifePulse will flash red. This alarm may be cleared by pushing AUDIO PAUSED. The STANDBY button will illuminate, the alarm lamp will turn yellow, and an audible alarm will sound every 18 seconds.

4. Attach a LifePort adapter to an ET tube and test lung. Do not attach the conventional ventilator. Leave the 15 mm connector of the LifePort open to room air.

5. Insert the green delivery tube of the Patient Circuit into the Jet port on the side of the LifePort adapter.
6. Connect the clear pressure monitoring tube of the LifePort adapter to its port on the Patient Box.

7. Press SYSTEM TEST button in the alarm section of the LifePulse.

An automatic test begins which determines the integrity of all the ventilator’s electronics and valves. The displays will count from 0 to 9 to assure no LEDs are burned out. An internal test is performed during the count.

Note: The humidifier LEDs and displays do not light up during the System Test.

If necessary, the system test may be stopped immediately by pressing STANDBY.

8. Make sure all the ventilator LEDs and displays on the front panel are lit, and listen to make sure the audible indicators are activated. Note: The humidifier LEDs and displays do not light up during the System Test.

If no problems are detected by the LifePulse, the default settings will be displayed in the Controls section, all zeros will appear in the Monitor section, and the audible and visual alarms will activate. The alarm indicator lamp will be flashing red.

If problems are detected, refer to Alarms Chapter to troubleshoot Vent Inop alarms that occur during the System Test.

9. Silence the audible and visual alarms by pressing AUDIO PAUSED button to the right of the Alarms section.

This action resets the audible and visual alarms.
Chapter 2: SETUP AND TESTS

Operational Test

The Operational Test will ensure that the LifePulse is able to ventilate at the set parameters and that the Patient Box is functioning properly.

To perform the test, follow these steps (Note: Some steps may already have been completed):

1. Attach a LifePort adapter to an ET tube and test lung. Do not attach the conventional ventilator. Leave the 15 mm connector of the LifePort open to room air.

2. Connect the LifePort adapter to the Patient Circuit and Patient Box as described above in the System Test.

3. Press ENTER to activate the default control settings.

4. Make sure the monitored PIP is able to reach the set PIP, the READY light illuminates, and the PEEP displays 0.0.

(Continued on next page)
5. Verify that the Ready indicator illuminates.

6. Make sure the PEEP displays 0.0 ±1.0 cm H\textsubscript{2}O.

   If the PEEP displays a value greater than 1.0 cm H\textsubscript{2}O or less than -1.0 cm H\textsubscript{2}O, call the Bunnell Hotline before proceeding or change the Patient Box and run both tests again.

   While the LifePulse is running on the test lung, switch the circuit breaker on the rear panel to the OFF position (see Rear Panel section in Overview chapter). This will force the LifePulse to switch to battery power. The battery indicator light will illuminate “BATTERY” in the Alarms section and the low level alarm will be activated. Cancel the audible alarm by pressing the Audio Paused button.

7. If the Battery Fuel Gauge displays one flashing red bar with a medium priority alarm, or the ventilator stops operating, the LifePulse’s battery should be further evaluated by calling the Bunnell Hotline before it is used on a patient.

   Switch the circuit breaker on the rear panel to the ON position. This will switch the LifePulse back to the wall power outlet. The Battery indicator light will turn off in the Alarms section.

8. Press STANDBY after a successful Operational Test.

9. Remove the test lung set-up (LifePort adapter, ET tube, and test lung) and store it for future use.

   The LifePulse system is now ready for patient use.

   Note: The LifePulse should be plugged in to an electrical outlet at all times to maintain battery charge. Be sure to remove the pinch tubing from the pinch valve in the patient box when storing with a circuit installed.

If a test fails, call the Bunnell Hotline

800-800-4358 (HFJV)
1-801-467-0800 (International)

**WARNING:** Remove the test lung following the successful completion of the System and Operational Tests. Place the LifePulse in Standby mode before connecting it to the patient. Failure to do so may result in inappropriate pressures or volumes being delivered to the patient, resulting in volutrauma.
Chapter 3: STARTING HFJV ON A PATIENT

Connecting a Patient to the LifePulse

The following steps describe how to connect a patient to the LifePulse in preparation for start-up:

1. Secure the caps on the new LifePort adapter. Use a LifePort adapter that is either the same size or one size bigger than the endotracheal (ET) tube.

2. With the LifePulse still in Standby mode after the successful completion of the System and Operational tests, replace the standard ET tube adapter with the LifePort adapter.

3. Reconnect the patient to the CV by connecting the conventional circuit to the 15-mm connector of the LifePort.

4. Once the patient has been stabilized on the CV—and with the LifePulse still in Standby mode—connect the pressure monitoring tube of the LifePort adapter to the Patient Box.

5. Connect the Patient Circuit to the Jet port on the side of the LifePort adapter.

**WARNING:** Patient connections must only be made in the Standby mode. Do not connect the LifePulse Patient Circuit to the LifePort adapter on the patient’s ET tube while the LifePulse is running. Failure to comply risks high pressures and volumes being delivered to the patient, which may result in volutrauma.
Chapter 3: STARTING HFJV ON A PATIENT

HFJV Pressure Monitoring

The LifePulse, in its Standby mode, will begin to monitor the pressures being delivered by the CV or other high frequency ventilator once the pressure monitoring tube of the LifePort adapter has been connected to the Patient Box. It will take about 90 seconds for the accurate measurements of the PIP, PEEP, and MAP to be displayed in the Monitor section. The monitored values will be updated every 10 seconds.

Note: The pressures displayed on the LifePulse may be different from the pressures displayed on the CV--remember that the CV displays pressures measured proximally while the LifePulse displays approximations of distal pressures.

When HFJV is started on a patient, accurate pressure monitoring allows the LifePulse to provide the patient with appropriate ventilation and to protect the patient in the event of an alarm condition after the Ready indicator illuminates. The LifePulse monitors the following:

1. **PIP**
   - Peak Inspiratory Pressure, the average maximum airway pressure measured for each HFJV breath.

2. **SERVO**
   - The internal drive pressure of the LifePulse; indicates how much gas flow must be produced to meet the set PIP, Rate, and I-Time requested by the operator for a particular patient. Servo tends to be higher for larger patients and lower for smaller patients.
   - Servo is a good indicator of changes in the patient or ventilators. See the information box to the left.

3. **∆P**
   - PIP minus PEEP; ∆P is roughly proportional to tidal volume. As ∆P increases, tidal volume increases and vice versa.

4. **MAP**
   - Mean Airway Pressure, an average of pressures measured from the total pressure waveform. It includes pressures produced by HFJV, conventional ventilation, and spontaneous breathing.

5. **PEEP**
   - Positive End-Expiratory Pressure, the average minimum airway pressure.

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**WARNING:** Do not connect any additional tubing or pressure monitors between the pressure monitoring tube of the LifePort adapter and the Patient Box. Doing so will degrade the LifePulse’s ability to measure airway pressures accurately and may result in inappropriate pressures or volumes being delivered to the patient.

**WARNING:** A properly trained medical professional must be in attendance at all times when the LifePulse is connected to a patient in order to monitor the patient and detect alarms or other indications of a problem.

**WARNING:** There are no airway pressure alarms active while the LifePulse is in the Standby mode.

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**SERVO - Increases may indicate**
- Improved compliance and/or resistance
- Moisture interference in the LifePort
- Air leaks (pulmonary and/or tubing)
- Disconnected or kinked tubes

**SERVO - Decreases may indicate**
- Worsening compliance and/or resistance
- Patient needs suctioning
- Tension pneumothorax
- ET tube obstruction
- Right mainstem intubation

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**WARNING:** There are no airway pressure alarms active while the LifePulse is in the Standby mode.
Chapter 3: STARTING HFJV ON A PATIENT

7 Steps to Begin HFJV

Initiation of HFJV involves seven steps:

1. Select a starting HFJV PIP that matches the measured CV PIP. Input your chosen value by using the + or - button next to the PIP display in the Controls section.

2. Use the default HFJV Rate of 420 bpm; alternatively, for larger patients or patients prone to or exhibiting gas trapping, lower the Rate in increments of 60 bpm (to 360, 300, 240 bpm) to avoid hyperinflation.

   Lower Rates create longer expiratory times, which may be necessary to alleviate gas trapping.

3. After selecting the starting values, press ENTER.

   As the LifePulse begins to operate, note that the monitored values return to zero and new average values are displayed based on the new Control settings.

   The LifePulse's microprocessor will begin increasing the Servo to whatever value will produce the set PIP for the set I-Time at the set Rate on a given patient.

   Although it will typically take a short time for the actual PIP to reach the set PIP, the displayed PIP will equilibrate slower because of the averaging characteristics of the display (10-second average updated every 2 seconds). Thus, it may take longer—typically within a minute—for the monitored PIP to reach the set value.

   The READY indicator will illuminate when the monitored PIP is stable around the set PIP (+2.0 to -1.5 cm H2O) for 20 seconds, indicating that the LifePulse is providing ventilation at the settings requested and automatically set alarm conditions have been established.

   Also, the water pump will begin to pump water into the humidifier cartridge. The pump will stop automatically once the water has reached the correct level.

WARNING: Do not leave the patient's bedside while the LifePulse water pump is running during initial start-up or 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 stops pumping.

WARNING: Do not initiate ventilation with kinks or obstructions present in the Patient Circuit or LifePort pressure monitoring tube. Doing so may result in alarms or delays in ventilator support. Pressures may be generated that are too high or too low for the patient’s needs.
The LifePulse may pause every time the CV delivers a breath. The interruptions in the HFJV pulses are caused by the delivery of conventional breaths at PIP higher than the set PIP on the LifePulse.

Except in cases of extremely poor lung compliance, it is usually best to allow the HFJV pulses to continue uninterrupted by lowering the CV PIP.

4. If desired, lower the CV PIP to just below the threshold of interruptions; you may need to lower it even more when treating infants with pulmonary air leaks.

5. Lower the CV Rate to CPAP for pulmonary air leaks and chronic lung disease, or 1 to 5 bpm for temporary alveolar recruitment.

Generally, the more pulmonary air leaks are a concern, the lower you will set the background CV Rate, PIP, and I-Time on the CV. PEEP is a better way to control oxygenation in patients with air leaks. The more atelectasis is a concern, the higher you will set the background CV Rate, PIP, PEEP, and I-Time.

Background CV Rates are used only as a temporary recruitment maneuver to reverse atelectasis while PEEP is optimized. A CV Rate of 5 bpm can be used temporarily for more aggressive recruitment. Once optimal PEEP is established, the Rate can be reduced to 0-2 bpm.

If atelectasis and air leaks are of equal concern after PEEP has been optimized, start with the lowest number of CV breaths possible and modest CV PIP and I-Time settings.

WARNING: Do not press the PUSH TO LOAD button on the Patient Box while the LifePulse is running on a patient. Doing so could result in the patient being exposed to inappropriately high pressures or large volume delivery (volutrauma).

### Summary of Starting HFJV on a Patient

1. Connect LifePulse to patient
2. Monitor CV or HFOV pressures
3. Choose starting LifePulse (HFJV) settings
4. Press ENTER to initiate HFJV
5. Decrease CV rate to 0-5 bpm
6. Adjust PEEP to match monitored MAP and stabilize $\text{SaO}_2$
7. Check blood gas in 30-45 minutes to evaluate settings

WARNING: There will be no LOSS OF PIP alarm for the first 15 seconds after the ENTER button is pushed. A properly trained person must observe the LifePulse reach the set PIP and the Ready indicator illuminate before leaving the patient’s bedside.

WARNING: The LifePulse will not detect extubation of a patient during start-up (i.e., from the time the ENTER button is pushed until the Ready indicator is illuminated). During start-up the ventilator may appear to be functioning normally despite extubation and will generate no audible or visual alarms. A properly trained individual must verify the patient is being ventilated following start-up.
You may find that, once high-frequency jet ventilation is initiated, the monitored PEEP is different than the set PEEP. This difference is common because the LifePulse measures PEEP with different hardware and software than the CV.

The CV PEEP is the primary control of MAP during HFJV. The PEEP may need to be increased to match the MAP monitored from the CV prior to start-up.

6. Adjust the CV PEEP to maintain appropriate SaO$_2$. Remember that average values are displayed, so give the LifePulse 20 seconds between adjustments to display the monitored PEEP value.

It is important to reevaluate or optimize PEEP periodically based on the patient’s FiO$_2$ requirements and SaO$_2$. PEEP should be optimized to obtain the best SaO$_2$ at the lowest FiO$_2$ level.

Be aware of significant changes in Servo and Mean Airway Pressure (MAP) that may occur when manipulating the CV settings. For example, a pressure change of 2 cm H$_2$O in the PEEP setting will cause a change of about 2 cm H$_2$O in the MAP.

7. If changing PEEP produces a MAP or Servo alarm, press ENTER to incorporate the change and establish new limits. Alternatively, the MAP or Servo alarm limits may be adjusted manually.

Wait 30-45 minutes to get a blood gas and evaluate HFJV effectiveness.
Adjusting Ventilator Settings

To adjust settings in the Controls section,

1. Press the + or - button next to the setting you want to change (PIP, Rate, or I-Time).

2. Continue to press the + or - button until the desired value is displayed.

In Ready mode, the display and the ENTER button will continue to flash until ENTER is pressed. The displays will not flash in Standby mode.

3. Press ENTER to activate the change.

Adjusting Ventilator Alarms

To adjust Servo and MAP alarm settings while in Ready mode (no alarm limits are set until Ready indicator is lit):

1. Press the desired UPPER or LOWER LIMIT button next to the MAP or Servo display.

The current set value for the selected limit will be displayed.

2. Press the + or - button to change the limit to the desired value.

3. Press the UPPER or LOWER LIMIT button to activate the change and return the display to the monitored value.

If the button is not pressed, the change will still be activated and the display will return to the monitored value automatically after 10 seconds.

WARNING: Do not use pens, pencils, fingernails, or other pointed objects to push the buttons on the LifePulse front panel. Doing so may result in damage to the buttons and may cause them to fail.
Chapter 4: PATIENT MANAGEMENT

**Objectives**

Managing patients on high-frequency jet ventilation is similar to managing patients on a CV.

The main difference with the LifePulse is you will be using less pressure and much smaller tidal volumes to meet your clinical objectives.

**Oxygenation** - The CV settings will be adjusted most often when oxygenation of the patient is your primary concern.

**Ventilation** - The LifePulse settings will be adjusted most often when ventilation (CO₂ removal) and/or the consequences of using high airway pressures (e.g., pulmonary air leaks) are your greatest concern.

The following pages will discuss patient management in more detail.
Oxygenation

The main choices for improving oxygenation require increasing Mean Airway Pressure (MAP) by elevating one or more of the following:

- CV PEEP
- CV Rate
- CV PIP
- CV I-Time

Exception: If the patient on conventional ventilation has grossly overexpanded lungs, the lungs will need to deflate considerably before any improvements in oxygenation will result. Refer to the next section of this chapter for more information about addressing overexpanded lungs.

Here are the choices for improving oxygenation due to atelectasis:

1. Increase CV PEEP

   Changes to PEEP are made with the CV because the LifePulse has no PEEP control. However, the PEEP adjustment will be displayed on the LifePulse in the Monitor section.

   Always optimize PEEP before increasing CV Rate, PIP, or I-Time. Adequate PEEP levels are essential for avoiding derecruitment between conventional breaths. CV Rate, PIP, and I-Time can be reduced or eliminated once optimal PEEP is achieved.

2. Increase the background CV Rate

   Avoid providing more than 5 bpm with the background CV Rate. If you feel you need more CV breaths to oxygenate, it may be an indication that PEEP is too low. CV breaths are to be considered a temporary recruitment maneuver while you recruit lung volume or optimize PEEP.

**WARNING:** The conventional ventilator rate should not exceed 10 breaths per minute when running in tandem with the LifePulse ventilator. Doing so could result in excessive Mean Airway Pressure or minute volume being delivered to the patient. The recommended conventional ventilator rate is 0 - 5 breaths per minute.
3. Increase CV PIP

3. Increase CV PIP delivered with the background conventional breaths to achieve a moderate chest rise.

The CV PIP should not be raised if it is already at a level adequate to reach the critical opening pressure of atelectatic alveoli, as determined by breath sounds, chest rise, X-ray, and other resources.

Also, remember to keep the CV PIP below the HFJV PIP to avoid interrupting the high-frequency breaths.

4. Increase CV I-Time, in combination with adequate levels of PEEP and CV PIP, to reverse atelectasis.

Consider carefully the combined effect of PIP and I-Time increases. Increasing the CV I-Time when the CV PIP is set at a high level increases the risk of lung injury.

Raising HFJV PIP and Rate would be secondary considerations. If you increase the HFJV Rate, be sure to watch the HFV-monitored PEEP level. Inadvertent PEEP may develop as the I:E ratio is shortened.

Raising HFJV I-Time has occasionally been shown to be effective in improving oxygenation.

**WARNING:** Always evaluate inadvertent PEEP (LifePulse monitored PEEP greater than CV set PEEP). The patient's lung volume should be assessed when inadvertent PEEP is present. Inadvertent PEEP reduces delta pressure, which may result in under-ventilation (hypercarbia).

**WARNING:** A significant discrepancy (>4 cm H$_2$O) between the delivered PEEP and the monitored PEEP may indicate a potential problem and should always be evaluated by a qualified trained individual.
Oxygenating Overexpanded Lungs

There is one major exception to the standard oxygenation strategies. This exception arises when the patient on conventional ventilation has grossly overexpanded lungs.

If you observe overexpansion on X-ray, you will need to allow the lungs to deflate considerably before any improvements in oxygenation will result.

To accomplish this deflation, make sure that the HFJV Rate is set low enough to allow adequate exhalation time. Lowering the HFJV Rate increases expiratory time and reduces the risk of gas trapping. Also, set the CV Rate near zero once you have started the LifePulse.

In most cases, DO NOT DECREASE PEEP. Overexpanded lungs are usually a result of gas trapping, not excessive PEEP. Decreasing CV support (Rate, PIP, and I-Time) is usually a more effective strategy. PEEP must be maintained, or even increased, when the CV Rate is very low to support MAP and maintain oxygenation.

However, beware that even if the patient initially responds well to this strategy, poor oxygenation may result sometime later due to atelectasis if the MAP is not adequate. You may then need to provide 3-5 CV breaths as a temporary recruitment strategy to reverse atelectasis while PEEP is optimized.
**Oxygenation Flow Chart**

- **Underinflation or Atelectasis?**
  - Yes: To raise MAP & PaO₂ try the following in order:
    1. increase CV PEEP
    2. increase CV Rate (3-5 bpm)
    3. increase CV PIP
    4. increase CV I-time
    5. increase FiO₂
  - No: PaCO₂ too High?
    - Yes: PaCO₂ too Low?
      - Yes: Go to Ventilation Flow Chart
      - No: PaO₂ too High?
        - Yes: Decrease FiO₂ until < 0.40 then decrease CV PEEP
        - No: PaO₂ too Low?
          - Yes: Go to Ventilation Flow Chart
          - No: Maintain Current Settings
  - No: PaCO₂ too Low?
    - Yes: PaCO₂ too High?
      - Yes: To decrease gas trapping & raise PaO₂ try the following in order:
        1. decrease CV Rate
        2. decrease HFJV Rate* (60 bpm at a time)
        3. decrease HFJV PIP**
        4. decrease CV PEEP***
        5. increase FiO₂
      - No: PaO₂ too Low?
        - Yes: Go to Ventilation Flow Chart
        - No: Maintain Current Settings

---

* Decreasing HFJV Rate decreases minute ventilation. It may also lower PaCO₂ by increasing exhalation time.
** Decreasing HFJV PIP decreases Δ pressure (amplitude) and minute ventilation; PaCO₂ may increase.
*** Decreasing CV PEEP increases Δ pressure (amplitude) and decreases MAP; PaCO₂ and PaO₂ may decrease.
Ventilation

Managing the patient's PaCO$_2$ is accomplished by adjusting the LifePulse's settings.

Studies have shown that ventilation (CO$_2$ elimination) during high-frequency jet ventilation is proportional to the tidal volume squared (V$_T^2$). Tidal volume on the LifePulse is roughly proportional to delta P (∆P), the arithmetic difference between PIP and PEEP. Thus, small changes in PIP or PEEP can produce significant changes in a patient's PaCO$_2$.

The main choices for improving ventilation require increasing minute ventilation by changing one or more of the following:

- HFJV PIP
- HFJV I-Time
- PEEP
- HFJV Rate

1. Increase HFJV PIP

Increase HFJV PIP by 1 to 2 cm H$_2$O at a time if the patient's PaO$_2$ is acceptable but PaCO$_2$ is too high.

If the patient's PaO$_2$ is low and PaCO$_2$ is high, increasing PIP may correct both problems at once since raising the HFJV PIP increases the MAP.

If PEEP has been increased to improve oxygenation, you may need to increase the HFJV PIP by an equal amount in order to keep ∆P the same and maintain tidal volume and adequate ventilation.

2. Increase HFJV I-Time

Increase HFJV I-Time by .004 to .006 seconds at a time if the patient's pathophysiology involves longer inspiratory time constants.

You may need to lower the HFJV Rate in increments of 60 bpm to maintain an adequate I:E ratio (1:5) for effective exhalation.
3. Decrease PEEP

Be careful not to compromise oxygenation when you lower PEEP.

4. Increase HFJV Rate

Increasing HFJV Rate is much less effective than increasing delta P (ΔP) for reducing PaCO₂.

Raising the CV Rate or PIP seldom improves ventilation, but it might be helpful in some cases as long as HFJV is not interrupted. Again, this strategy is only effective when the lungs are not overinflated.

The main choices for raising PaCO₂ involve doing the opposite of the above suggestions for lowering PaCO₂.

Decreasing the HFJV PIP is the most effective way to increase PaCO₂. However, the concomitant drop in MAP may cause PaO₂ to fall. Be prepared to raise PEEP in such cases to maintain adequate MAP.

Reducing the HFJV Rate will also increase PaCO₂, but it may have the opposite effect if hyperinflation is present; it may lower PaCO₂ by lengthening the exhalation time.

Do not hesitate to use the minimum HFJV Rate of 240 bpm when indicated for hyperinflation. The LifePulse can provide adequate ventilation over its entire range of HFJV Rates. With the HFJV I-Time at .020 seconds, the HFJV Rate of 240 bpm produces an I:E Ratio of 1:12.

If monitored MAP falls when the HFJV Rate is lowered, you may need to raise PEEP to maintain adequate oxygenation.
Chapter 4: PATIENT MANAGEMENT

Ventilation Flow Chart

Hypocarbia
PaCO₂ too Low?

Yes

To raise PaCO₂ try the following in order:
1. decrease HFJV PIP
2. decrease HFJV Rate
3. decrease HFJV I-time
4. increase CV PEEP

Yes

PaCO₂ too High?

No

PaO₂ too Low?

Yes

Go to Oxygenation Flow Chart

Yes

Decrease FiO₂ until < 0.40 then decrease CV PEEP

Yes

PaO₂ too High?

No

Maintain Current Settings

PaCO₂ too Low?

Yes

To lower PaCO₂ try the following in order:
1. increase HFJV PIP
2. increase HFJV I-time
3. increase HFJV Rate*
4. decrease CV PEEP**

Yes

PaO₂ too Low?

No

PaO₂ too High?

No

* Increasing HFJV Rate increases minute ventilation. However, if lungs are hyperinflated, decreasing HFJV Rate can lower PaCO₂ by increasing exhalation time.

** Decreasing CV PEEP increases Δ pressure (amplitude) and lowers PaCO₂, but it will also lower MAP, which may lower PaO₂.
Suctioning the Patient

High-frequency jet ventilation may mobilize and help remove secretions. Be prepared to suction the patient’s airway soon after starting the LifePulse on a patient.

Suctioning may need to be performed more frequently in the first 4 to 6 hours after starting HFJV. Suctioning frequency may then decrease.

You can suction using a closed suction catheter during HFJV.

1. Suction according to your normal protocol.
2. If necessary, provide a few manual CV breaths after suctioning to reestablish lost lung volume and improve oxygenation.
3. Make sure the READY light is illuminated before leaving the bedside.
4. Call the Bunnell Hotline at 800-800-4358 if you have questions about suctioning.

**WARNING:** Place the LifePulse ventilator in Standby mode prior to suctioning to avoid fluctuations in the monitored pressures that may result in alarm conditions or possible injury to the patient.

**WARNING:** The LifePulse must be in Ready mode prior to suctioning if suctioning while the LifePulse is running. Failure to do so may result in inappropriate pressure or volumes being delivered to the patient.
Chapter 4: PATIENT MANAGEMENT

Weaning the Patient

Weaning from the LifePulse will need to be performed as the patient improves. The goal in most cases will be to wean the patient off the LifePulse to non-invasive ventilation (NIV).

General guidelines for weaning:

- Decrease minute ventilation slowly by lowering PIP on the LifePulse and the CV.
- Lower FiO₂ as often as possible to the lowest value that still provides adequate oxygenation to the patient. Remember to adjust both blenders so the settings remain equal on the CV and the LifePulse.
- Adjust PEEP as necessary to maintain a MAP sufficient to achieve adequate oxygenation. Don’t wean PEEP until FiO₂ <0.40.
- Continue decreasing PIP as blood gases allow, weaning slowly (1-2 cm H₂O of PIP), unless hyperventilation is occurring, in which case PIP should be weaned faster.
- Wean HFJV Rate as tolerated to encourage spontaneous breathing by the patient.
- When the patient is stable and receiving “extubatable” settings as determined by a physician, extubate to an NIV level near the level of the last recorded MAP.

Wean SLOWLY!

- Lower HFJV PIP
- Lower FiO₂
- Maintain Optimal MAP
- Adjust PEEP if Necessary
- Extubate to NIV
Chapter 5: VENTILATOR ALARMS

Alarms Overview

The LifePulse’s alarm system alerts the operator, both audibly and visually, to changes in the ventilator or the patient. The alarm statements are not visible until they are lit.

The Alarms area has three key features:

1. Upper and lower alarm limits for Servo and Mean Airway Pressure (MAP)
2. Alarm indicators for various potentially hazardous conditions
3. AUDIO PAUSED button

Both the upper and lower alarm limits for Servo and MAP are set automatically and can be adjusted manually. They are set when the Ready indicator illuminates, which occurs after the monitored PIP has stabilized within a 3.5 cm H$_2$O ($+2.0$ to $-1.5$ cm H$_2$O) window of the set PIP for at least 20 seconds. Servo increases to bring the monitored PIP up to the set PIP after ENTER has been pressed.

Servo increases after the ENTER button has been pressed to bring the monitored PIP up to the set PIP. Servo limits vary according to the size of the patient; wider limits are set for larger patients and tighter limits for smaller patients.

**READY INDICATOR ON**

1. Monitored PIP $+2.0$ to $-1.5$ cm H$_2$O of set PIP for 20 Seconds.
2. Servo alarm limits vary according to size of patient.
3. MAP alarms are set

**WARNING:** Troubleshoot alarms only in accordance with the guidelines in the User Manual. Troubleshooting must only be performed by properly trained individuals who have a thorough understanding of the LifePulse ventilator and its operation. Always attempt to correct the cause of the alarm before pressing the ENTER button.

**WARNING:** Place the LifePulse in Standby mode if there is any concern about the ventilator functionality or safety. Support the patient using the tandem conventional ventilator or other available ventilation options.

**WARNING:** Alarms from different medical devices can sound similar. Identify and respond to LifePulse alarms based on the alarm priority lamp, the alarm indicator message, and the audible alarm tone and rhythms.
Chapter 5: VENTILATOR ALARMS

Alarm Displays and Sounds

Ventilator alarms will be identified by an illuminated indicator in the Alarms section, a yellow or red alarm priority lamp on top of the LifePulse, and a specific audible alarm.

Each alarm indicator will be accompanied by a specific display and sound:

- High Priority Alarms - 2 bursts of 5 beeps every 5 seconds and a flashing red light
- Medium Priority Alarms - 3 longer beeps every 5 seconds and a flashing yellow light
- Low Priority Alarms - 1 beep every 18 seconds and a solid yellow light

The Servo and MAP alarms are displayed as a blinking UPPER or LOWER LIMIT button, depending upon which alarm occurs.

Call the Bunnell Hotline at 800-800-4358 (Int'l: 1-801-467-0800) if an alarm occurs with no alarm indicator in the Alarms section.

Note: There are six alarms that can be reset by pressing the AUDIO PAUSED button:

- Power Up
- Check Vent - No Codes (some exceptions)
- Vent Inop - No Codes
- Battery - Running on Battery
- Battery missing, malfunction, or cannot take a charge (no alarm indicator)
- Power Down

Note: See Alarms Terminology Section for more information regarding alarm displays and descriptions.
Adjusting Alarm Limits

The upper and lower limits of the MAP and Servo alarms are set automatically but can be adjusted manually.

Press the UPPER or LOWER LIMIT buttons any time after the Ready indicator illuminates to see where the limits have been set.

If the Ready indicator is not lit, the limits have not been set and the Servo and MAP displays will not change when you press one of the limit buttons.

Do the following to adjust Servo and MAP alarm limits once the Ready indicator is lit:

1. Press the desired UPPER or LOWER LIMIT button next to the MAP or Servo display; the current set value for the selected limit will be displayed.
2. Press the + or - button to change the limit to the desired value.
3. Press the selected limit button again to activate the change and return the display to the monitored value.

If the button is not pressed again, the change will still be activated and the display will return to the monitored value after 10 seconds.

WARNING: Do not manually adjust alarm limits around MAP and Servo to the point that they become irrelevant (i.e., are effectively off). Doing so will negate critical alarms and expose the patient to potentially unsafe conditions that may result in injury.

WARNING: Do not manually adjust alarm volume to the point that the audible alarm cannot be recognized (is effectively off). Doing so will limit the LifePulse’s ability to alert clinicians to alarm conditions and expose the patient to potentially unsafe conditions that may result in injury.
Chapter 5: VENTILATOR ALARMS

SERVO

The Servo alarms alert the user to changes in the internal drive pressure or flow rate required to deliver breaths at the set PIP, Rate, and I-Time.

The UPPER LIMIT button will blink when a high Servo condition is reached; the LOWER LIMIT button will blink when a low Servo condition is met.

The alarm limits are set automatically as follows:

<table>
<thead>
<tr>
<th>Servo</th>
<th>Alarm Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>±0.2</td>
</tr>
<tr>
<td>1-5</td>
<td>±20%</td>
</tr>
<tr>
<td>&gt;5</td>
<td>±1.0</td>
</tr>
</tbody>
</table>

High Servo

Checks:

1. Examine the patient for spontaneous breathing, crying, coughing, hiccups, seizures, bronchospasm, or the need for suctioning. Calm, medicate, sedate, or suction the patient.

2. Inspect the LifePort adapter and connections for any leaks or cracks. If the adapter’s integrity is in question, replace it with a new one.

3. Inspect the Patient Circuit for leaks, poor connections, or occlusions. Correct these conditions if present.

4. Inspect the Patient Circuit between the humidifier and Patient Box for signs of over-humidification (droplets of water). If necessary, lower the Water temperature setting to reduce condensation (see Humidification Chapter).

   Note: Keep Gas temperature at 40°C.

5. Evaluate the Patient Box for abnormal functioning (odd sounds or visible problems with pinch valve operation). Change the Patient Box if necessary.

6. Examine the patient for re-expansion of the lung due to evacuation of an air leak, such as pneumothorax or bronchopleural fistula, or for improved lung volume following recruitment.

**WARNING:** Always troubleshoot a change in Servo that is greater than 1.0 psi (6.89 kPa) from the previously established baseline, especially if the LifePulse control settings have not been changed. Servo changes this large or larger usually represent a mechanical problem and may pose a risk of volutrauma.

**WARNING:** Place the LifePulse in Standby mode before unkinking any portion of the Patient Circuit. This action prevents the patient from being exposed to inappropriately high pressure or large volume delivery (volutrauma).
Low Servo

Checks:

1. Inspect the endotracheal tube for improper positioning, plugging, or occlusion. Correct these conditions if present.
2. Examine the patient for signs of airway obstruction.
3. Inspect the exhalation limb of the conventional breathing circuit for kinks.
4. Examine the patient for a tension pneumothorax or atelectasis.
5. Evaluate the Patient Box for abnormal functioning (odd sounds or visible problems with pinch valve operation). Change the Patient Box if necessary.
Chapter 5: VENTILATOR ALARMS

Mean Airway Pressure

The MAP alarms alert the user to changes in the patient, CV settings, or the CV or HFV circuit sufficient to cause an increase or decrease in measured MAP.

An LED in the UPPER LIMIT button will blink when a high MAP condition is met; an LED in the LOWER LIMIT button will blink when a low MAP condition is met.

The upper alarm limit is set automatically by adding 1.5 cm H$_2$O to the MAP measured at the moment the Ready indicator illuminates.

High MAP

Checks:

1. Inspect the CV for changes in settings (e.g., PEEP) or performance.

2. Inspect the exhalation limb of the conventional breathing circuit and remove any kinks or water.

3. Inspect the pressure monitoring tube of the LifePort adapter for excess condensation or plugging. If necessary, reduce the Water temperature setting to reduce condensation.

Note: Keep Gas temperature at 40°C.

4. Inspect the endotracheal tube or airway for obstruction.

5. Check the Patient Box pinch valve to verify it is closing completely.
Mean Airway Pressure

The lower alarm limit is set automatically by subtracting 1.5 cm H₂O from the MAP measured at the moment the Ready indicator illuminates.

Low MAP

Checks:

1. Inspect the CV for changes in settings (e.g., PEEP) or performance.
2. Inspect the pressure monitoring tube of the LifePort adapter for excess condensation or plugging. If necessary, reduce the Water temperature setting to reduce condensation.

Note: Keep Gas temperature at 40°C.
3. Inspect the endotracheal tube for proper positioning.
4. Inspect the Patient Circuit and humidifier cartridge for leaks, poor connections, or kinks.
Chapter 5: VENTILATOR ALARMS

LOSS OF PIP

The LOSS OF PIP alarm is activated by one or more of the following conditions:

- The monitored PIP has dropped below 25% of the set PIP
- The monitored PIP is less than 3 cm H₂O
- Monitored value for ∆P is ≤ 2 cm H₂O

Checks:

1. Examine the patient for spontaneous breathing, crying, coughing, hiccups, seizures, bronchospasm, or the need for suctioning. Calm, medicate, sedate, or suction the patient.

2. Over-humidification of the Patient Circuit may be causing water droplets to interfere with pressure monitoring. Check the LifePort adapter’s orientation to make sure the pressure monitoring tube is pointed upward. Adjust the humidifier temperature settings (i.e., lower the Water temperature in 1-degree increments) to minimize excess condensation.

Note: Keep Gas temperature set at 40°C; lower Water temperature as needed to control humidity and condensation.

3. Inspect the Patient Circuit and humidifier cartridge for leaks or poor connections.

4. Check the pinch valve for possible malfunctions resulting in low PIP. If necessary, replace the Patient Box while the LifePulse is in the Standby mode.

Note: If a LOSS OF PIP alarm occurs in the non-Ready condition, the servo control valves are turned off to decrease Servo and protect the patient. The alarm activates if the PIP is <3 cm H₂O or ∆P is ≤ 2 cm H₂O 15 seconds after ENTER is pressed. No other alarms are active in the non-Ready condition. Pressing ENTER will clear the alarm and allow the LifePulse another attempt to reach the set PIP.

WARNING: Place the LifePulse in 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 volutrauma.

WARNING: There will be no LOSS OF PIP alarm for the first 15 seconds after the ENTER button is pushed. A properly trained person must observe the LifePulse reach the set PIP and the Ready indicator illuminate before leaving the patient's bedside.

WARNING: Press the ENTER button to resume ventilation if a LOSS OF PIP alarm has occurred with the Ready indicator off. The Patient Box will be cycling but no gas (breaths) will be delivered to the patient until the LOSS OF PIP alarm is cleared by pressing the ENTER button.

WARNING: Do not press the ENTER button during a LOSS OF PIP alarm with the Ready indicator illuminated if the patient is clinically appropriate and the Servo has locked at or near an established operating value. Doing so will temporarily silence the audible alarm and unlock the LifePulse Servo. Always troubleshoot the potential causes of an alarm following the guidelines in the User's Manual prior to pressing the ENTER button.

WARNING: Place the LifePulse in 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 volutrauma.

WARNING: Place the LifePulse in Standby mode before unkinking any portion of the Patient Circuit. This action prevents the patient from being exposed to inappropriately high pressure or large volume delivery (volutrauma).
Chapter 5: VENTILATOR ALARMS

CANNOT MEET PIP

The CANNOT MEET PIP alarm occurs when one of the following conditions is met:

- The monitored PIP has not stabilized within +2.0 and -1.5 cm H$_2$O of the set PIP for 20 seconds within three minutes of pressing ENTER.
- The monitored PIP has not stabilized within +2.0 and -1.5 cm H$_2$O of the set PIP for 20 seconds before the Servo has risen to its maximum output of 20.

Checks:

1. Examine the patient for spontaneous breathing, crying, coughing, hiccups, seizures, bronchospasm, or the need for suctioning. Calm, medicate, sedate, or suction the patient.

2. Make sure the Servo hasn’t reached the maximum output of 20 before reaching the set PIP. The patient may be too large to be ventilated by the LifePulse at the current settings.

3. Over-humidification of the Patient Circuit may be causing water droplets to interfere with pressure monitoring. Check the LifePort adapter’s orientation to make sure the pressure monitoring tube is pointed upward. Adjust humidifier temperature settings (i.e., lower the Water temperature in 1-degree increments) to minimize excess condensation.

Note: Keep Gas temperature set at 40°C; lower Water temperature as needed to control humidity and condensation.

4. Inspect the patient circuit and humidifier cartridge for leaks or poor connections.

5. Check the pinch valve for possible malfunction resulting in fluctuating pressures. Replace the Patient Box while the LifePulse is in the Standby mode.
Chapter 5: VENTILATOR ALARMS

HIGH PIP

The HIGH PIP alarm will occur when any of the following conditions occur:

- The monitored airway pressure has exceeded the set PIP by 5 cm H\textsubscript{2}O continuously for 1 second
- The monitored PIP for all breaths delivered in the last 30 seconds has exceeded the set PIP by 10 cm H\textsubscript{2}O
- The monitored PIP for all breathes delivered in the last 0.75 seconds has exceeded the set PIP by 30 cm H\textsubscript{2}O
- The monitored PIP is >65 cm H\textsubscript{2}O

Checks:

1. Is excessive pressure being delivered by the CV due to failure or an occluded exhalation limb of CV circuit?
2. Inspect the endotracheal tube for improper positioning, kinking, or occlusion.
3. Inspect the pressure monitoring tube of the LifePort adapter for excess condensation or kinking. Check the adapter’s orientation to make sure the pressure monitoring tube is pointed upward. Replace the LifePort adapter if necessary.
4. Check the pinch valve for possible malfunction resulting in high PIP. If necessary, replace the Patient Box while the LifePulse is in the Standby mode.
5. If the alarm persists, it could be a stuck Servo control valve. If necessary, change out the LifePulse ventilator.

WARNING: Patient connections must only be made in the Standby mode. Do not connect the LifePulse Patient Circuit to the LifePort adapter on the patient’s ET tube while the LifePulse is running. Failure to comply risks high pressures and volumes being delivered to the patient, which may result in volutrauma.
VENT INOP During Test

During System Test: Codes 02, 03, 04

If any of these codes appear during the System Test, record the code number and call the Bunnell Hotline. Turn the Ventilator Power switch off and back on to clear the failed test so you can retry the System Test again after troubleshooting with a Bunnell clinical specialist.

**Code 02** is related to the purge system. Causes can be:

- a lack of purge gas supply from the LifePulse
- a failure of the purge valve or pressure transducer in the Patient Box
- a Patient Circuit being disconnected from the LifePort adapter on the test lung
- a Patient Box being disconnected from the front panel of the LifePulse

**Code 03** is related to the servo system. The 03 code will appear if:

- any of the valves do not open or are sluggish during the System Test
- the servo pressure transducer does not recognize (respond to) the opening of the servo control valves
- the dump valve is open
- the green gas inlet tube of the Patient Circuit is not connected to the Gas Out port

Sometimes running the LifePulse on a test lung for 5 minutes will correct this alarm condition by cycling the servo control valves.

**Code 04** is related to watchdog circuit failure. The watchdog circuit checks the microprocessor and software in the LifePulse.
**Chapter 5: VENTILATOR ALARMS**

**VENT INOP While Operating**

**During Operation: Codes 01 and 05-10**

Codes 01 and 05-09 are all related to microprocessor or electronic problems. These codes place the LifePulse in Standby mode.

1. Support the patient on CV
2. Turn off the Ventilator Power switch to reset the LifePulse’s microprocessor
3. Run the System and Operational Tests on a test lung before restarting on a patient

**Code 10** indicates a significant rise in Servo, which can be caused by a dramatic change in ventilator settings, such as changing the Rate from 420 to 240 bpm.

1. Check for mechanical problems such as tubing disconnects or kinks
2. Correct any disconnects or kinks before pressing ENTER to restart the LifePulse

**VENT INOP NO CODE**

There is one VENT INOP alarm that does not generate a code. It is associated with the Watchdog circuit resetting the ventilator’s microprocessor. This condition is quite rare. Typically, the LifePulse continues to run normally following a reset.

There is also a backup ventilator alarm that can be generated if the primary alarm system fails. There is no alarm indicator for this condition, only a high priority alarm.

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**WARNING:** The patient is not being ventilated by the LifePulse during VENT INOP Alarms 01 & 05-09, which place the LifePulse in Standby mode.

**WARNING:** The patient is not being ventilated by the LifePulse during VENT INOP Alarm 10, which places the LifePulse into Standby mode. Always troubleshoot the potential causes of an alarm following the guidelines in the User’s Manual prior to pressing the ENTER button.

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**VENT INOP CODES**

01 – A/D converter failure
05 – RAM failure
06 – ROM failure
07 – NMI failure to execute
08 – IRQ failure to execute
09 – Both IRQ and NMI failure to execute
10 – Significant rise in Servo
Chapter 5: VENTILATOR ALARMS

CHECK VENT

The CHECK VENT alarm indicates a problem (feedback error) with one of the valves in the LifePulse or Patient Box, or electronic failures in the Humidifier section. The following are possible causes:

- The purge gas supply is missing or the purge tube is disconnected or kinked.
- The pressure monitoring tube is disconnected or kinked at the Patient Box pressure monitoring tube connector.
- A problem exists with the purge valve or pinch valve in the Patient Box, or the servo valves in the LifePulse.

Checks:

1. Make sure the purge tubing is connected and not kinked at both the Purge port on the LifePulse’s front panel and the From Purge port on the Patient Box.
2. Make sure the pressure monitoring tube is connected to the Patient Box and not kinked.
3. Make sure the purge gas supply is present at the LifePulse front panel by disconnecting the purge tube. If gas is present, reconnect the purge tube.
4. Replace the Patient Box to determine if there is a purge valve failure or a problem with the pinch valve causing the alarm.
5. If the purge gas supply is absent or if the alarm continues after changing the Patient Box, change out the LifePulse.
6. The Humidifier codes can only be cleared by turning off and back on the Ventilator Power switch to reset the Humidifier. The patient will need to be supported during this process. Once the LifePulse powers up, enter the patient’s settings and press ENTER to restart the LifePulse.
7. Replace the LifePulse if the alarm cannot be cleared.

Codes displayed in the temperature display on the humidifier

111 - RAM Failure
222 - ROM Failure
333 - A/D Converter Failure
**LOW GAS PRESSURE**

The LOW GAS PRESS alarm indicates that the pressure of the gas supply to the LifePulse is below 30 psi (205.85 kPa) or the gas supply pressure switch is faulty.

**Checks:**

1. Make sure a gas supply is connected to the blender and that the low flow output from the blender is connected to the Mixed Gas Input on the back of the LifePulse.

2. Make sure the gas supply pressure is greater than 30 psi (205.85 kPa). If the supply pressure is less than this level, check the high pressure supply hoses for leaks. Change the gas source, blender, or high pressure hoses as needed.

3. If the alarm persists, there may be a problem with the gas supply pressure switch in the LifePulse, in which case you will have to switch to another LifePulse ventilator.

**WARNING:** Only use medical grade oxygen and air that is dry and free of dust and oil. The gas supply pressure must be 30 – 60 psi (205.85 - 413.70 kPa).
Chapter 5: VENTILATOR ALARMS

Battery Alarms

The battery alarms are progressive as the capacity of the battery decreases.

If the LifePulse is running on battery,

- the BATTERY alarm indicator will be lit
- the battery charge indicator lamp will be off
- there will be a low priority alarm, which can be cleared by pressing AUDIO PAUSED
- the green bars on the battery fuel gauge will indicate the battery’s remaining capacity

If the LifePulse is plugged in and the battery has malfunctioned, is missing, or will not take a charge,

- the battery charge indicator lamp will be red continuously
- there will be a low priority alarm
- the battery fuel gauge bars will not be lit

If the battery's capacity is low,

- the BATTERY alarm indicator will be lit
- there will be a medium priority alarm
- the battery fuel gauge bars will be depleted down to a single flashing red bar

Plug the power cord into an electrical wall outlet to re-establish the electrical power supply.

If the battery's capacity is critically low and unable to support the LifePulse's continued functioning,

- the BATTERY DEPLETED alarm indicator will be lit
- there will be a high priority alarm

Immediate action must be taken to keep the LifePulse from being forced into Standby mode.

Checks:

1. Verify that the LifePulse’s power cord is connected securely at the back panel and at the electrical wall outlet. If it is, try plugging the power cord into a different outlet.

2. If the battery has failed, switch out the LifePulse so the battery can be checked and serviced.

3. If the hospital’s electrical power supply has failed, switch out the LifePulse with one that has a fully charged battery. Otherwise, support the patient with manual ventilation or other forms of ventilatory support.

WARNING: If the battery charge indicator stays red with the LifePulse plugged into an electrical wall outlet, the battery needs to be checked by Bunnell-authorized service personnel. The ventilator and humidifier will function normally when plugged in but the battery will not provide adequate power, if needed.

WARNING: The LifePulse battery is low and needs to be charged when the battery fuel gauge is blinking red. Plug the LifePulse into an electrical wall outlet.

WARNING: When the battery fuel gauge is blinking red with the Battery Depleted alarm lit and a high priority alarm active the battery charge is too low to continue running the LifePulse and it will go to Standby mode in a minute or two.

The battery’s capacity can be extended by placing the Humidifier in Pause mode.
**CHECK CIRCUIT**

**CHECK CIRCUIT** alarms will appear on the right side of the Humidifier section.

**CHECK CIRCUIT - TEMP** alarms indicate that the cartridge door is not properly latched or that an electrical fault is present in the humidifier cartridge or Patient Circuit.

**CHECK CIRCUIT - LEVEL** alarms indicate that the humidifier cartridge did not fill to the normal operating level in 86 seconds.

### CHECK CIRCUIT - TEMP

**Checks:**

1. Inspect the humidifier cartridge door to make sure it is latched properly.

2. Open the cartridge door, leave the cartridge in place, and check the spring-loaded contact pins by pressing them inward with a pencil eraser. Make sure they spring in and out and that all the pins are at about the same level ±1-2 mm. Try pulling stuck pins back out to the level of the other pins. Close the cartridge door, press PAUSE again, and see if the alarm has cleared.

3. If the alarm persists, press STANDBY and replace the Patient Breathing Circuit. Press ENTER to resume normal operation. If the alarm does not go away, it is likely that the humidifier module has failed internally and the LifePulse will need to be changed out.

### CHECK CIRCUIT - LEVEL

**Checks:**

1. If the alarm occurs within the first 2 minutes after pressing ENTER, check the water supply to see if it is empty or disconnected. Also, inspect the water supply tubing coming from the water supply to see if it is clamped off or disconnected.

2. Repeat steps 2 and 3 above.
Chapter 5: VENTILATOR ALARMS

HIGH TEMP - WATER

The HIGH TEMP - WATER alarm will occur if one of the following conditions is met:

- The temperature measured in the humidifier cartridge has exceeded the Water temperature setting by more than 3°C and has remained high for 10 minutes
- The measured temperature is ≥45°C, which is the upper allowable limit

Checks:

1. Place the humidifier in Pause mode. Open the cartridge door and check the spring-loaded contact pins with a pen or pencil. Make sure they spring in and out and that all the pins are at about the same level ±1-2 mm. Try pulling stuck pins back out to the level of the other pins. Close the cartridge door, press PAUSE again, and see if the alarm has cleared.

2. If the alarm persists, press STANDBY and replace the Patient Breathing Circuit. Press ENTER to resume normal operation. If the alarm does not go away, it is likely that the humidifier module has failed internally and the LifePulse will need to be changed out.
Chapter 5: VENTILATOR ALARMS

LOW TEMP - WATER

The LOW TEMP - WATER alarm will occur when the following condition is met:

- The temperature measured in the humidifier cartridge has dropped below the Water temperature setting by 3°C and remained there more than 30 minutes

Checks:

1. Place the humidifier in Pause mode. Open the cartridge door and check the spring-loaded contact pins using a pen or pencil. Make sure they spring in and out and that all the pins are at about the same level ±1-2 mm. Try pulling stuck pins back out to the level of the other pins. Close the cartridge door, press PAUSE, and see if the alarm has cleared.

2. If the alarm persists, press STANDBY and replace the Patient Breathing Circuit. Press ENTER to resume normal operation. If the alarm does not go away, it is likely that the humidifier module has failed internally and the LifePulse will need to be changed out.
Chapter 5: VENTILATOR ALARMS

HIGH TEMP - GAS

The HIGH TEMP - GAS alarm occurs when one of the following conditions is met:

- The temperature in the patient circuit, as measured proximal to the Patient Box, has exceeded the Gas temperature setting by more than 3°C and remained there for more than 1 minute
- The measured temperature is ≥45°C, which is the upper allowable limit

Checks:

1. Place the humidifier in Pause mode. Open the cartridge door and check the spring loaded contact pins using a pen or pencil. Make sure they spring in and out and that all the pins are at about the same level ±1-2 mm. Try pulling stuck pins back out to the level of the other pins. Close the cartridge door, press the PAUSE button, and see if the alarm has cleared.

2. If the alarm persists, press STANDBY and replace the Patient Breathing Circuit. Press ENTER to resume normal operation. If alarm does not go away, it is likely that the humidifier module has failed internally and the LifePulse will need to be changed out.
Chapter 5: VENTILATOR ALARMS

LOW TEMP - GAS

The LOW TEMP - GAS alarm will occur when the following condition is met:

- The temperature in the patient circuit, as measured proximal to the Patient Box, has dropped below the Gas temperature setting by more than 3°C and has remained there for more than 3 minutes

Checks:

1. Place the humidifier in Pause mode. Open the cartridge door and check the spring loaded contact pins using a pen or pencil. Make sure they spring in and out and that all the pins are at about the same level ±1-2 mm. Try pulling stuck pins back out to the level of the other pins. Close the cartridge door, press PAUSE, and see if the alarm has cleared.

2. If the alarm persists, press STANDBY and replace the Patient Breathing Circuit. Press ENTER to resume normal operation. If the alarm does not go away, it is likely that the humidifier module has failed internally and the LifePulse will need to be changed out.
Chapter 5: VENTILATOR ALARMS

## HIGH or LOW LEVEL - WATER

The High Level alarm indicates that the water in the humidifier cartridge has reached the high water level sensor. The Low Level alarm indicates the water in the humidifier cartridge has not reached the low water level sensing pin.

### HIGH LEVEL - WATER

Checks:

1. Make sure sterile H₂O, not saline, was used to fill the humidifier cartridge.
2. Make sure the water inlet tube is installed properly in the water pump housing.
3. Was the humidifier manually filled to the high level sensor?
4. Was the water supply clamp opened prior to securing the water inlet tube inside the water pump housing, so that the humidifier cartridge over-filled by gravity?
5. Open the cartridge door, leave the cartridge in place, and check the spring-loaded contact pins by pressing them inward with a pencil eraser. Make sure they spring in and out and that all the pins are at about the same level ±1-2 mm. Try pulling stuck pins back out to the level of the other pins. Close the cartridge door, press PAUSE, and see if the alarm has cleared.
6. Press STANDBY, support the patient with the conventional ventilator, and replace the Patient Circuit.
7. Press ENTER to resume normal operation. If the alarm does not go away, it is likely that the humidifier module has failed internally and the LifePulse will need to be changed out.

### LOW LEVEL - WATER

Checks:

1. Inspect the water supply tubing from the water supply to see if it is clamped off or disconnected. Unclamp or reconnect the water supply tubing.
2. Inspect the water supply to see if it is empty. Replace the water supply if necessary.
3. Make sure that sterile H₂O, not saline, was used to fill the humidifier cartridge.
4. Follow 5-6 above.

NOTE: If the circuit fails and has been in use for less than seven days, call Bunnell Incorporated for a Return Authorization number and return the circuit for a possible credit.
Chapter 6: HUMIDIFICATION

Humidifier Overview

The Humidifier section resides in the lower half of the LifePulse and consists of controls, alarms, a PAUSE button, a receptacle for the humidifier cartridge, and a water pump.

The Humidifier section is responsible for heating and humidifying the gas provided to the patient. It requires very little adjustment and will self regulate the water level, water temperature, and gas temperature.

The Humidifier alarms will alert you to potential problems with the Patient Circuit.
Chapter 6: HUMIDIFICATION

Patient Circuit Overview

The LifePulse's Humidifier section uses a disposable cartridge-and-tubing set called the Patient Circuit. This item is often referred to as “the cartridge,” “the circuit,” or “the humidifier cartridge/circuit”; all are terms that refer to all or part of the Patient Circuit. It is pre-assembled and contains the heating wire, thermistors, and connections needed for operation.

The Patient Circuit includes the following components:

1. **Cartridge**
   contains the water used to humidify the gas delivered to the patient

2. **Gas Inlet Tube**
   transports blended gas to the cartridge

3. **Cartridge Thermistor**
   measures the temperature of the humidified gas before it exits the cartridge in order to maintain the desired water temperature

4. **Purge Tube**
   delivers a low flow of dry gas to the Patient Box; the gas will periodically purge the LifePort pressure monitoring tube

5. **Patient Circuit Tube**
   the primary conduit for transferring heated, humidified gas from the LifePulse to the patient

6. **Heating Wire**
   heats the gas being delivered to the patient to maintain the desired temperature

7. **Circuit Thermistor**
   measures the temperature of the gas before the gas passes through the Patient Box in order to maintain the desired gas temperature

8. **Pinch Tubing**
   periodically compressed and released by the Patient Box pinch valve to create high frequency breaths

9. **Circuit Leur Connector**
   inserts by friction fit into the Jet port of the LifePort adapter

10. **Water Inlet Tube**
    transfers sterile USP inhalation water from a supply bag to the cartridge

WARNING: External temperature of the heated portion of the patient circuit may exceed 50°C. Contact with the patient’s skin should be avoided.

WARNING: Do not reuse or sterilize Patient Circuits or LifePort adapters. Failure to discard the Patient Circuit after one use or seven days may result in leaks, improper temperature, and water level control.
Starting the Humidifier

The humidifier starts when ENTER is pressed to begin HFJV:

• The water pump starts filling the humidifier cartridge with water.
• Water in the cartridge is heated by the hot plate behind the cartridge.
• The circuit heater wire in the patient circuit tube begins heating the gas.
• The water pump stops when the water in the cartridge contacts the second water level sensing pin (normal operating level).

Stopping the Humidifier

The humidifier will stop operating whenever STANDBY is pressed. The humidifier will resume operation when ENTER is pressed.

The humidifier will also stop operating when the PAUSE button in the Humidifier section is pressed. The stoppage will be indicated by the following conditions:

• flashing blue light in the corner of the PAUSE button
• solid yellow alarm priority lamp
• single-beep alarm every 18 seconds as a reminder that the humidifier is not operating

Pressing PAUSE again will bring the humidifier back into operation.

WARNING: Do not pre-fill the humidifier cartridge of the Patient Circuit prior to starting the LifePulse. Doing so may result in the cartridge overfilling and the delivery of a bolus of water to the patient. The cartridge will fill automatically once the LifePulse begins operating.

WARNING: Do not open the water pump door while the pump is pumping. Doing so may result in a pinch hazard to the operator.

WARNING: Always attempt to minimize condensation/rainout in the Patient Circuit between the ventilator and the Patient Box. Failure to do so may result in water interfering with the monitored pressure signal at the LifePort adapter resulting in fluctuations in the delivered PIP.

WARNING: Do not under-humidify gas being delivered to the patient. Adjust the cartridge temperature so that condensation is always present in the green delivery tube between the Patient Box and the LifePort adapter.

WARNING: Pushing the PAUSE button on the humidifier shuts off the heating elements that provide for gas warming and humidification. A properly trained person must not leave the patient’s bedside with the Humidifier in the PAUSE mode.
Water Level Sensing

Whenever installing a new Patient Circuit, watch the cartridge fill with water until the pump stops to ensure that the pump does not overfill the cartridge.

The pump stops when the water reaches the second water level sensing pin inside the cartridge.

The cartridge has a third sensing pin to detect high water and prevent overfill into the circuit. The water pump stops automatically if the water level reaches the third pin. A HIGH WATER LEVEL alarm will be generated and the water pump is disabled. If the pump does not turn off at the third sensing pin, press PAUSE to turn off the humidifier while you troubleshoot the problem.

If any of the water level sensing pins are defective, the water level can’t be sensed properly. A default maximum fill time of 86 seconds is programmed to turn the pump off in time to prevent overfill.
Gas Flow through Humidifier

The gas flows through the LifePulse humidifier and circuit to the patient as follows:

1. The gas enters the cartridge through the green gas inlet tube.
2. The gas flows down into the water and then back up through a Venturi mechanism, which atomizes some of the heated water.
3. The gas flows over the heated reservoir of water and past a series of baffles which filter out water droplets.
4. The humidified gas passes over the cartridge thermistor. The LifePulse’s microprocessor uses the measured temperature to regulate the amount of heat delivered to the cartridge through the metal heating plate.
5. The black heater panel heats the water based on feedback control from the cartridge thermistor.
6. Heated and humidified gas leaves the cartridge and enters the circuit tubing with blue and white wires inside.

(continued on next page)
Chapter 6: HUMIDIFICATION

Gas Flow through Patient Box

7. The heated and humidified gas flows into the pinch tubing portion of the circuit where the pinch valve creates the high-frequency breaths.

8. The gas begins to cool as it leaves the pinch valve and condensation occurs as a result.
Understanding Gas Temperature

The actual gas temperature is measured in the patient circuit tube just before the Patient Box and is displayed in the Temp window in the Humidifier section.

Upon starting HFJV, the temperature in the circuit will approach the default set value of 40°C; it may overshoot slightly before settling in right at or near 40°C.

There is a drop in gas temperature of 3°C from the circuit thermistor to the patient. The default setting for the Gas temperature is 40°C to compensate for this temperature drop. If the set gas temperature is 40°C, the actual temperature of the gas as it enters the patient will be approximately 37°C (i.e., body temperature).

The lungs are very effective heat exchangers. Therefore, unless there is a reason for wanting to raise or lower the patient’s core temperature, do not adjust the set gas temperature to any value other than 40°C.

**WARNING:** Raising or lowering the Gas temperature setting may raise or lower the patient’s temperature. 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.
Understanding Water Temperature

The water temperature controls the humidity level of the gas delivered to the patient. Lowering the set water temperature is the best way to reduce excess condensation in the circuit. See the next page for information about identifying proper humidification levels.

Upon starting HFJV, the water temperature will default to a set value of 38°C. The set water temperature can be seen by pressing WATER in the Humidifier section.

Temperature Controls

The temperature in the cartridge (water) and the circuit tubing (gas) are set and controlled independently. Pressing the WATER or GAS button in the Humidifier section will display the set value of the respective temperature.

The gas temperature should be kept at its default setting of 40°C.

Change the water temperature to provide appropriate levels of humidification if over- or under-humidification occurs. See the next page for information about identifying proper humidification levels. To change the water temperature,

1. Press WATER to display the set value.

2. Adjust the temperature up or down by using the + or - adjustment button.

The displayed value is the new set temperature. The ENTER button does not have to be pressed to activate the new set temperature value.

See Identifying Proper Humidification for information about appropriate humidification levels.
Chapter 6: HUMIDIFICATION

Identifying Proper Humidification

**Proper humidification** of the gas in the circuit will appear as a fine mist in the green delivery tube between the Patient Box and the LifePort adapter. It will look similar to the mist you would see when breathing on a mirror or against a car window on a cold winter day. This condensation is an indication that the gas has reached 100% relative humidity.

**Over-humidification** appears as a collection of water droplets pooling in the clear portion of the circuit tubing between the Humidifier and the Patient Box. Water in this portion of the circuit can cause pressure instability and LOSS OF PIP alarms. This condition can be alleviated by lowering the set water temperature in small increments, as needed.

**Under-humidification** will be indicated by the green delivery tube between the Patient Box and the LifePort being dry. This can be corrected by raising the set water temperature in 0.5°C increments at 30-minute intervals until condensation is present.
Removing the Old Circuit

A circuit change should be done with the LifePulse in Standby mode and the patient supported by the CV. The procedure is best performed with two people. Both people can complete their tasks simultaneously.

1. Press STANDBY on the LifePulse and increase CV settings to the minimum level required to support the patient.

2. Disconnect the used circuit from the Jet port on the side of the LifePort adapter and cap the Jet port.

3. Remove the pinch tube from the jaws of the pinch valve on the Patient Box.

4. Disconnect the purge tube from both the Patient Box and the Purge port on the LifePulse.

5. Disconnect the green gas inlet tube from the Gas Out port on the LifePulse.

6. Clamp off the water transfer tube connecting the water supply to the water inlet tube.

7. Disconnect the water transfer tube from the water inlet tube.

8. Remove the water inlet tube from the water pump.

9. Open the cartridge door and remove the cartridge. Discard the used Patient Circuit.

You are now ready to install the new circuit.

WARNING: Clamp the water supply tube prior to opening the water pump door to prevent cartridge overfill and delivery of water to the patient by gravity feed. The water supply should be positioned at or below the level of the humidifier cartridge as an added precaution.

WARNING: Do not tip the humidifier cartridge while removing it from the cartridge housing if the LifePulse is running. Doing so might result in water spilling into the Patient Circuit and a bolus of water being delivered to the patient.
Installing the New Circuit

Once the used circuit has been removed from the bedside and discarded, the new circuit may be installed.

1. Slide the new humidifier cartridge into the cartridge door and close the door.

2. Secure the water inlet tube into the water pump and snap the pump housing closed.

**WARNING:** Clamp the water supply tube prior to opening the water pump door to prevent cartridge overfill and delivery of water to the patient by gravity feed. The water supply should be positioned at or below the level of the humidifier cartridge as an added precaution.

3. Attach the green gas inlet tube to the Gas Out port on the LifePulse.

4. Attach the purge tube to the purge ports on both the LifePulse and the Patient Box.

5. Insert the pinch tubing into the jaws of the pinch valve on the Patient Box.

6. Uncap the Jet port on the LifePort adapter and insert the green delivery tube into the Jet port.

7. Reattach the water transfer tube to the water inlet tube and spike the water supply. The water supply should be at or below the level of the humidifier cartridge.

8. Unclamp the water transfer tube.
Completing the Circuit Change

To complete a circuit change,

1. Resume HFJV by pressing ENTER and lowering the CV settings to their original values.

2. Verify that the water pump stops when water fills the cartridge to normal operating level (approximately 2/3).

3. Verify that in 20-30 minutes humidity (condensation) appears in the green delivery tube of the circuit between the Patient Box and the LifePort adapter.

On rare occasions, a defective cartridge might not fill, might over fill, or might not heat properly. The Patient Circuit will then need to be replaced.

**WARNING:** Do not leave the patient’s bedside while the LifePulse water pump is running during initial start-up or 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 stops pumping.

**WARNING:** Do not open the water pump door while the pump is pumping. Doing so may result in a pinch hazard to the operator.

**WARNING:** Removal of the humidifier cartridge from the cartridge housing while the LifePulse is running exposes the heater plate and cartridge heater cup, which may be in excess of 60ºC.

**WARNING:** Do not move the LifePulse while it is running on a patient. Doing so may result in water entering the Patient Circuit and creating a risk of water delivery to the patient. Monitor the water level closely under these circumstances.

**WARNING:** Operating while the LifePulse or patient is in motion or while in high-flow or large tidal volume conditions may result in water entering the Patient Circuit and creating a risk of aspiration. Please monitor the water level closely.
Chapter 7: BATTERY

The LifePulse Model 204 contains a lead-acid battery for continued operation during power outages, after accidental disconnects, and while moving a patient within the hospital setting, if necessary.

Charging the Battery

The battery automatically charges when the LifePulse is plugged into an electrical wall outlet with the Circuit Breaker switch on the rear panel in the ON (I) position. Note: The Ventilator Power switch does not have to be in the ON (I) position for the battery to charge.

The battery will be fully charged in no more than twelve (12) hours. This charging time is based on the time needed to reach a full charge following a full discharge. The charging time may be significantly longer than 12 hours if the battery has been discharged several times in succession without being fully recharged or if the battery has been left uncharged for a significant amount of time. It is best to leave the LifePulse plugged in at all times to make sure the battery is fully charged.

While the battery is charging, the charge indicator lamp below the water pump indicates the charge status. When the LifePulse is first plugged in, the charger circuit checks the battery’s condition, the charge indicator lamp will blink green to indicate charging, turn solid green to indicate fully charged, turn solid red to indicate a bad battery, or alternately blink green and red to indicate a severe discharge. The severe discharge condition can take up to 30 minutes to resolve itself.

If the battery is missing or cannot take a charge, the charge indicator lamp will turn solid red and the battery fuel gauge will be off. This low priority alarm can be cleared by pressing AUDIO PAUSED. Once a charging battery is fully charged, the charge indicator lamp and the battery fuel gauge will turn from blinking green to solid green. The charger circuit continues to apply a small, “trickle” current to the battery to maintain the charge level.
Running on Battery

The LifePulse will automatically switch to battery power if the main electrical power is lost for any reason. (Note: The LifePulse cannot be powered up on battery power alone.)

The Battery indicator will light up in the Alarms section of the front panel if the LifePulse is running on battery. The charge indicator lamp below the water pump will turn off, and the low priority audible and visual alarm will be activated. This alarm can be cleared by pressing AUDIO PAUSED.

The actual battery run time available once the battery is fully charged depends on a number of variables including the battery age, condition, and the ambient temperature. The absolute condition of the battery cannot be determined by the charger circuit. Therefore, even though the green lamp is on continuously, the run time of old or defective batteries may be less than the operating times specified.

As the battery capacity drops the battery fuel gauge will decrease (turn off) one bar at a time. There are five green bars and the last green bar turns red and starts flashing when the capacity is very low. The alarm priority changes to medium at this time (yellow flashing alarm priority lamp and three beeps every 5 seconds).

It is important to note that the fuel gauge reflects the battery voltage not the rate of discharge in time. The voltage will decrease differently depending on the LifePulse settings, battery age, and usage history.

The LifePulse must be plugged into an electrical power supply once the BATTERY Low alarm is generated; or, the LifePulse must be switched out with one that has a fully charged battery.

Placing the LifePulse humidifier into Pause mode can extend the battery run time up to three minutes before Standby mode will occur.

WARNING: The discharge rate of the battery changes with the ventilator and humidifier settings as well as with the age of the battery. This can shorten the overall time the ventilator will operate on battery power before the battery depletes and the ventilator stops operating.

WARNING: If the battery charge indicator stays red with the LifePulse plugged into an electrical wall outlet, the battery needs to be checked by Bunnell-authorized service personnel. The ventilator and humidifier will function normally when plugged in but the battery will not provide adequate power, if needed.
The final battery alarm is **BATTERY DEPLETED**. This high priority alarm is the final alert before the battery fails and the LifePulse is forced into Standby mode. To avoid being forced into Standby mode the LifePulse must either be immediately plugged into an electrical wall outlet or be switched out with one that has a fully charged battery.

If the LifePulse is forced into Standby mode, support the patient and immediately plug the LifePulse power cord into an electrical wall outlet. Once power is restored, press ENTER to re-establish ventilation.

### Battery Maintenance

The battery should always be fully charged, and if possible, never deeply discharged. No damage to the battery will result from leaving the LifePulse plugged into an electrical wall outlet indefinitely. If the LifePulse cannot be plugged into an electrical wall outlet indefinitely, at a minimum it should be plugged in at least once every month for 12 hours. The battery may be damaged as a result of long-term storage without being charged and should be replaced over time and with extensive use.

To evaluate the battery's capacity/condition, set up the LifePulse so it can be run on a test lung with the humidifier operational (refer to Setup and Tests Chapter). Make sure the LifePulse has been plugged in to an electrical wall outlet for at least 12 hours and the Battery Charge Indicator is lit solid green (battery fully charged) before beginning this evaluation.

Turn ON the main power switch on the rear panel. The Battery Fuel Gauge should display five green bars when the battery is fully charged. Once the LifePulse is running on default settings, switch the circuit breaker on the rear panel to the OFF position. This will force the LifePulse to switch to battery power. Let the LifePulse run on battery for 15 minutes, then note how many Fuel Gauge bars are lit.

The battery has adequate capacity if one or more green bars are lit at the end of 15 minutes. If the last bar turns red and flashes with a Medium Priority alarm, or the LifePulse stops operating, the battery capacity/function should be evaluated by a Bunnell authorized service personnel before the next patient application. **The battery's capacity should be evaluated once a month.**

Switch the circuit breaker on the rear panel to the ON position. This will switch power to the LifePulse back to the wall outlet. The LifePulse may now be powered off by turning the main power switch to the OFF position. Be sure to leave the LifePulse plugged into the wall outlet for at least 12 hours after the battery capacity has been evaluated to allow the battery to fully recharge.

The LifePulse will still function normally as long as it is plugged into electrical power.
Physically damaged batteries may leak and damage the ventilator and/or other equipment. Damaged batteries should be replaced immediately by Bunnell authorized service personnel.

Batteries should last approximately three years under normal operating conditions with proper care. The battery should be replaced every 3 years.

The battery should only be replaced by Bunnell-authorized service personnel and should only be replaced with the specific battery supplied by Bunnell Incorporated.

These batteries contain lead and should be recycled. Follow local or regional standards for proper disposal.
Chapter 8: CLEANING AND STORAGE

**WARNING:** Clean and disinfect the LifePulse and Patient Box prior to patient applications to avoid the risk of infection. Refer to cleaning instructions in the User’s Manual.

**WARNING:** The use of non-recommended solvents or cleaners can damage the enclosure(s) or user interface and damage equipment causing the LifePulse to malfunction. Refer to the cleaning instructions in the User’s Manual.

**WARNING:** Do not reuse or sterilize Patient Circuits or LifePort adapters. Failure to discard the Patient Circuit after one use or seven days may result in leaks, improper temperature and water level control.

**WARNING:** Plug the ventilator into an electrical wall outlet at all times to maintain proper battery charge. Charging must only occur in a properly ventilated room. The user must ensure the battery is in good condition and has sufficient capacity prior to every patient use.

**WARNING:** Do not store LifePulse with the pinch tube of the circuit loaded in the pinch valve jaws of the Patient Box.

**WARNING:** The LifePulse, Patient Box, and Patient Circuit contain components made of hazardous materials that need to be disposed of appropriately. Improper disposal may cause harm to the environment.

**CAUTION:** Do not sterilize the LifePulse ventilator or Patient Box. The internal components are not compatible with sterilization techniques.

The exterior surfaces of the LifePulse and Patient Box may be cleaned with a mild soap and water solution or hospital grade disinfectants. Care should be taken not to saturate the device surfaces or spray cleaning products directly on surfaces.

The disposable Patient Circuit and LifePort adapters are for single patient use only and must be discarded after use. Do not sterilize and reuse the Patient Circuits.

During storage, plug the LifePulse into an electrical wall outlet in a properly ventilated room in order to maintain proper battery charge.

Ensure the battery is in good condition and has sufficient capacity prior to every patient use.

Do not store the LifePulse with the pinch tube of the circuit loaded in the pinch valve jaws of the Patient Box. Doing so may result in the pinch tube sticking to itself and could create a LOSS OF PIP alarm on start-up or a spontaneous but brief delivery of an excess volume of gas to the patient when the pinch tube becomes unstuck.

**WARNING:** The LifePulse, Patient Box, and Patient Circuit contain components made of hazardous materials that need to be disposed of appropriately. Improper disposal may cause harm to the environment.
Appendix A

Owner Responsibility for Maintenance

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

The LifePulse High Frequency Ventilator and Patient Box(es) should be returned to the factory every 2,000 hours or every year, whichever comes first, to be checked, re-calibrated, maintained, and have 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.

The Life Pulse should be overhauled every 6,000 hours of use. The battery should be replaced every 3 years.

Equipment that 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 Bunnell authorized service personnel have verified that the equipment is functioning according to specifications 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

- Operation not in accordance with the user instructions,
- Faulty maintenance not in accordance with the authorized maintenance instructions,
- Repair by anyone other than Bunnell service personnel,
- Modification of the equipment or accessories, or 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.
Appendix A

Warranty

The Bunnell Incorporated LifePulse 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. Buyer’s 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) has 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 Buyer’s 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.
## Ventilator Alarms and Reactions

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Visual?</th>
<th>Delay</th>
<th>Audible?</th>
<th>Delay</th>
<th>Other Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Servo</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Servo control valves timing not allowed to increase</td>
</tr>
<tr>
<td>Lower Servo</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Servo control valves timing not allowed to decrease</td>
</tr>
<tr>
<td>Upper MAP</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Servo control valves timing not allowed to increase</td>
</tr>
<tr>
<td>Lower MAP</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Yes</td>
<td>20 sec.</td>
<td>Servo control valves timing not allowed to decrease</td>
</tr>
<tr>
<td>Loss of PIP, Ready condition</td>
<td>Yes</td>
<td>1 sec.</td>
<td>Yes</td>
<td>1 sec.</td>
<td>Servo valve timing held constant; if monitored Servo increases control valves are closed</td>
</tr>
<tr>
<td>Loss of PIP, Non-Ready condition</td>
<td>Yes</td>
<td>15 sec.</td>
<td>Yes</td>
<td>15 sec.</td>
<td>Servo control valves are closed and dump valve is opened</td>
</tr>
<tr>
<td>Cannot Meet PIP</td>
<td>Yes</td>
<td>3 min.</td>
<td>Yes</td>
<td>3 min.</td>
<td>None</td>
</tr>
<tr>
<td>High PIP</td>
<td>Yes</td>
<td>1 sec.</td>
<td>Yes</td>
<td>1 sec.</td>
<td>Pinch and/or servo valves are closed and servo is vented to atmosphere</td>
</tr>
<tr>
<td>Vent Inop</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Code #s appear in I-Time display and ventilator is placed in Standby mode</td>
</tr>
<tr>
<td>Check Vent, Pinch Value Status error</td>
<td>Yes</td>
<td>3 sec.</td>
<td>Yes</td>
<td>3 sec.</td>
<td>None</td>
</tr>
<tr>
<td>Check Vent, all others</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Code #s for the Humidifier appear in the Temperature display and Humidifier is placed in Standby mode</td>
</tr>
<tr>
<td>Battery</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>None</td>
</tr>
<tr>
<td>Battery Low</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>None</td>
</tr>
<tr>
<td>Battery Depleted</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Ventilator is placed in Standby mode imminently</td>
</tr>
<tr>
<td>Standby mode</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Standby button is lit</td>
</tr>
</tbody>
</table>
# Humidifier Alarms and Reactions

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Visual?</th>
<th>Delay</th>
<th>Audible?</th>
<th>Delay</th>
<th>Other Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Temp Water</td>
<td>Yes</td>
<td>10 min.</td>
<td>Yes</td>
<td>10 min.</td>
<td>Heater plate is turned off</td>
</tr>
<tr>
<td>Low Temp Water</td>
<td>Yes</td>
<td>30 min.</td>
<td>Yes</td>
<td>30 min.</td>
<td>None</td>
</tr>
<tr>
<td>High Temp Gas</td>
<td>Yes</td>
<td>1 min.</td>
<td>Yes</td>
<td>1 min.</td>
<td>Heater wire is turned off</td>
</tr>
<tr>
<td>Low Temp Gas</td>
<td>Yes</td>
<td>3 min.</td>
<td>Yes</td>
<td>3 min.</td>
<td>None</td>
</tr>
<tr>
<td>High Level</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Water pump is turned off</td>
</tr>
<tr>
<td>Low Level</td>
<td>Yes</td>
<td>2 min.</td>
<td>Yes</td>
<td>2 min.</td>
<td>None</td>
</tr>
<tr>
<td>Check Circuit</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>Pause mode</td>
<td>Yes</td>
<td>0 sec.</td>
<td>Yes</td>
<td>0 sec.</td>
<td>LED on Pause button is turned on</td>
</tr>
</tbody>
</table>
Ordering Information

Bunnell Incorporated
436 Lawndale Drive
Salt Lake City, Utah 84115

Phone: 800-800-4358
International: 1-801-467-0800
Fax: 801-467-0867
E-mail orders@bunl.com

Visit the Bunnell Incorporated website at www.bunl.com
for a complete list of available products.
Device Specifications

LifePulse High Frequency Ventilator Model 204

Description of Controls

- **POWER**: Turns ventilator on or off; does not affect battery charger circuit
- **ENTER**: Initiates ventilation using selected settings; resets MAP and Servo alarm limits
- **STANDBY**: Ceases ventilation and places humidifier in Pause
- **SYSTEM TEST**: Initiates self test routine
- **AUDIO PAUSED**: Silences audible alarm for 60 seconds

Description of Ventilator Controls

- **PIP**: Selects new PIP setting
- **Rate**: Selects new Rate and changes I:E RATIO setting
- **I-Time**: Selects new I-Time and changes I:E RATIO setting
- **MAP LIMITS**: Displays and/or adjusts MAP alarm limits
- **SERVO LIMITS**: Displays and/or adjusts SERVO alarm limits
- **Increment (+) / Decrement (-)**: Adjusts the control settings

Parameters Set and Their Ranges

- **PIP**: 8 to 50 cm H₂O, 1 cm H₂O increments
- **Rate**: 240 to 660 bpm, 10 bpm increments
- **I-Time**: 0.020 to 0.034 sec, 0.002 sec increments
- **MAP LIMITS**: 0.0 to 40.0 cm H₂O, 0.1 cm H₂O increments
- **SERVO LIMITS**: 0.0 to 25.0 psi (0.0 to 172.4 kPa), 0.1 psi (0.689 kPa) increments
- **SERVO**: ≤20 psi (137.9 kPa)

Default Settings

- **PIP**: 20 cm H₂O
- **Rate**: 420 bpm
- **I-Time**: 0.020 seconds
- **Mode**: Standby

Parameters Measured and Displayed and Their Ranges

- **PIP**: 0.0 to 92.3 cm H₂O, 0.1 cm H₂O resolution
- **PEEP**: -9.9 to 92 cm H₂O, 0.1 cm H₂O resolution (PEEP <20), 1 cm H₂O (PEEP ≥ 20)
- **Δ P**: 0.0 to 92.3 cm H₂O, 0.1 cm H₂O resolution
- **MAP**: 0.0 to 92.3 cm H₂O, 0.1 cm H₂O resolution
- **SERVO**: 0.0 to 40.0 psi (0.0 to 275.8 kPa), 0.1 psi (0.689 kPa) resolution
- **I:E RATIO**: 1:1.6 to 1:12, displays VENT INOP codes
Audible and Visual Indicators and Alarms

READY
PIP stable within +2.0 and -1.5 cm H$_2$O of set value for 20 seconds

LOW GAS PRESSURE
Mixed gas inlet supply pressure <30 psi (205.85 kPa)

LOSS OF PIP
15 seconds after ENTER is pressed, the airway pressure is <3 cm H$_2$O, or PIP - PEEP ($\Delta$P) is ≤2 cm H$_2$O, or the airway pressure drops to <25% of the set PIP in the Ready condition.

HIGH PIP
Instantaneous airway pressure > set PIP + 5 cm H$_2$O, or >65 cm H$_2$O for 1 second, or PIP > set PIP + 10 cm H$_2$O for every breath cycle delivered for 30 seconds, or PIP > set PIP + 30 cm H$_2$O for every breath cycle delivered for 0.75 second

CANNOT MEET PIP
Does not achieve Ready status or the Servo reaches 20 within 3 minutes of pressing the ENTER button

VENT INOP (without a code)
Ventilator reset or stopped via the watchdog circuit

VENT INOP (with a code)
01 A/D converter failure
02 During System Test, failure of the airway pressure system
03 During System Test, failure of servo pressure system
04 During System Test, failure of ventilator microprocessor watchdog circuit
05 RAM failure
06 ROM failure
07 NMI failure to execute
08 IRQ failure to execute
09 Both NMI and IRQ fail to execute
10 Rapid increase in Servo (>3.4 psi; 23.44 kPa)

CHECK VENT
Valve status feedback error
Pinch valve status feedback error
Failure to detect purge

UPPER/LOWER MAP LIMIT
MAP at onset of Ready condition ±1.5 cm H$_2$O or adjustable manual setting

UPPER/LOWER SERVO LIMIT
Servo at onset of Ready condition ±1 if Servo >5, 20% if Servo between 1 and 5, and 0.2 if Servo <1, or adjustable manual setting

BATTERY
Operating from battery, AC power is interrupted

BATTERY LOW
Battery’s useful capacity low during operation

BATTERY DEPLETED
Battery’s useful charge expended

Audible and Visual Alarm Only
Backup ventilator alarm detected
Ventilator reset via the software

Audible Alarm Only
Loss of power to the ventilator
Alarm logic circuit malfunction

BATTERY FUEL GAUGE
Shows approximate level of charge remaining on the battery
BATTERY CHARGING/FAILURE Indicates battery fails to charge, charging, or fully charged when connected to AC power

STANDBY Ventilator is in the Standby mode

ENTER Ventilator is in the Operating mode

SYSTEM TEST Ventilator is in the Self Test mode

System Sensitivity and Accuracy

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway pressure sensitivity</td>
<td>0.1 cm H₂O</td>
</tr>
<tr>
<td>Airway pressure accuracy</td>
<td>±2.0 cm H₂O</td>
</tr>
<tr>
<td>Servo pressure sensitivity</td>
<td>0.04 psi (0.276 kPa)</td>
</tr>
<tr>
<td>Servo pressure accuracy</td>
<td>±1.0 psi (6.895 kPa)</td>
</tr>
</tbody>
</table>

Response Times

- Patient airway pressure sampling rate: 0.5 kHz
- Time to display pressures within specified accuracies after a step change:
  - Standby: 80 seconds, updated every 10 seconds
  - Running, not Ready condition: 10 seconds, updated every 2 seconds
  - Running, Ready condition: 20 seconds, updated every 2 seconds
  - Time until PIP is stable: <3 minutes
  - Time required for compliance chamber to vent from 20 psi to ambient: <1.0 second

Miscellaneous

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas supply requirements</td>
<td>30 to 60 psi (206.85 – 413.7 kPa)</td>
</tr>
<tr>
<td></td>
<td>&gt;0.5 SCFM (14 slpm)</td>
</tr>
<tr>
<td>Oxygen Sample Port Flow</td>
<td>1.5 ±0.5 slpm</td>
</tr>
<tr>
<td>Power requirements</td>
<td>100-240 VAC, 50-60 Hz, 2A</td>
</tr>
<tr>
<td>Battery Operating Time</td>
<td>&gt;10 minutes</td>
</tr>
<tr>
<td>Battery Recharge Time</td>
<td>&lt;12 hours</td>
</tr>
<tr>
<td>Battery Qualification Time</td>
<td>&lt;30 minutes</td>
</tr>
<tr>
<td>Hour Meter</td>
<td>0-99,999 Hours, Non-resettable</td>
</tr>
<tr>
<td>High, Medium, and Low Auditory Alarm</td>
<td>45 – 85 dBA Sound Pressure Range</td>
</tr>
</tbody>
</table>
Appendix D

Dimensions

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Front height</td>
<td>13.1 in (33.3 cm)</td>
</tr>
<tr>
<td>Length</td>
<td>16.3 in (41.4 cm)</td>
</tr>
<tr>
<td>Width</td>
<td>12.3 in (31.2 cm)</td>
</tr>
<tr>
<td>Weight (with power cord)</td>
<td>26.9 lbs (12.2 kg)</td>
</tr>
</tbody>
</table>

Humidifier

Description of Controls

- **PAUSE**  
  Ceases/initiates humidification system
- **GAS**  
  Displays gas set temperature
- **WATER**  
  Displays water set temperature
- **Increment (+) / Decrement (-)**  
  Adjusts the Water or Gas temperature settings

Parameters Set, Measured, and/or Displayed

- **Gas temperature setting**  
  32.0 to 42.0°C, 0.1°C increments
- **Gas temperature measured**  
  20.0 to 50.0°C, 0.1°C resolution
- **Water temperature setting**  
  32.0 to 42.0°C, 0.1°C increments
- **Water temperature measured**  
  20.0 to 50.0°C, 0.1°C resolution

Default Settings

- **Gas Temperature**  
  40.0°C
- **Water Temperature**  
  38.0°C

Audible and Visual Indicators and Alarms

- **CHECK CIRCUIT - LEVEL**  
  Water level not detected within 86 seconds after exiting Pause mode
- **CHECK CIRCUIT - TEMP**  
  Gas or water temperature sensor determined to be out of range or cartridge door is open
- **HIGH LEVEL**  
  High water level detected
- **LOW LEVEL**  
  Low water detected for 2 minutes
- **HIGH TEMP - WATER**  
  More than 3°C above set point or >45°C for 10 minutes
- **LOW TEMP - WATER**  
  More than 3°C below set point for 30 minutes
Appendix D

HIGH TEMP - GAS  More than 3°C above set point or >45°C for 1 minute
LOW TEMP - GAS  More than 3°C below set point for 3 minutes
CHECK VENT (without a code)  Humidifier reset or stopped via the watchdog circuit
CHECK VENT (with a code)  111 RAM failure
                          222 ROM failure
                          333 A/D converter failure
Audible and Visual Alarm Only Backup humidifier alarm detected
PAUSE  Humidifier in Pause mode

Sensitivity and Accuracy
Temperature sensitivity  ~0.1°C
Temperature accuracy    ±2.0°C

Servo Response Times
Gas temperature  3 minutes
Water temperature 30 minutes
Pump Rate  0.7 mL/second

Patient Circuit

Humidifier Cartridge
H2O reservoir volume  50 mL
Compressible volume  20 mL
Total internal volume 70 mL

Patient Circuit
Gas Inlet Tube  10 ±0.25 inches (25.4 ±0.63 cm)
Water Inlet Tube 12 ±0.25 inches (30.5 ±0.63 cm)
Patient Circuit Tube 74 ±1.5 inches (188 ±3.8 cm)
Patient Box Model 314

Dimensions

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width</td>
<td>3.3 inches (8.4 cm)</td>
</tr>
<tr>
<td>Height</td>
<td>3.3 inches (8.4 cm)</td>
</tr>
<tr>
<td>Length</td>
<td>4.4 inches (11.2 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>1.8 lbs (0.81 kg)</td>
</tr>
</tbody>
</table>

Output

<table>
<thead>
<tr>
<th>Voltage</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 V</td>
<td>100 cm H₂O</td>
</tr>
<tr>
<td>10.0 V</td>
<td>0 cm H₂O</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>10 mV / 0.1 cm H₂O</td>
</tr>
</tbody>
</table>

Miscellaneous

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sound Pressure Level</td>
<td>&lt;45 dBA</td>
</tr>
<tr>
<td>External Temperature</td>
<td>&lt;44°C</td>
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</table>

Environmental Conditions

Transportation and Storage

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Temperature</td>
<td>-10 to 50°C</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>10 to 80% (non-condensing)</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>500 to 1060 hPa</td>
</tr>
</tbody>
</table>

Operating

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Temperature</td>
<td>10 to 40°C</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>10 to 75% (non-condensing)</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>700 to 1060 hPa</td>
</tr>
</tbody>
</table>
Classifications/Applied Parts

- FDA Class III type medical equipment.
- Class I Electrical Equipment per ISO 60601-1.
- Fulfills the requirements of IEC 60601-1:2005 Ed: 3. Conforms to AAMI ES60601-1, IEC STDS 60601-1-6 & 60601-1-8, Certified to CSA 22.2 NO. 60601-1.
- Type BF Applied Parts. The Patient Box and the gas delivery tube of the Patient Circuit may come in contact with the patient and are therefore considered applied parts.
- Degree of protection against ingress per IEC 60529: IP21 rating on the LifePulse Ventilator and IP24 on the Patient Box.
- The LifePulse HFV System is categorized as an external communicating device with tissue/bone/dentin contact for prolonged periods per ISO 10993.
# International Symbols Table

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Publication</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>ISO 7000-1641</td>
<td>Operating Instructions</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5041</td>
<td>Caution – Hot Surface</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5333</td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>ISO 7000-1364</td>
<td>Variability, Rotational Adjustment</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5019</td>
<td>Protective Earth (Ground)</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5021</td>
<td>Equipotentiality</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5032</td>
<td>Alternating Current</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5031</td>
<td>Direct Current</td>
</tr>
<tr>
<td><strong>IP24</strong></td>
<td>IEC 60529</td>
<td>Protection of Patient Box Enclosure</td>
</tr>
<tr>
<td><strong>IP21</strong></td>
<td>IEC 60529</td>
<td>Protection of Ventilator Enclosure</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>BS EN 980:2008, 5.12</td>
<td>Manufacturer</td>
</tr>
<tr>
<td><strong>SN</strong></td>
<td>ISO 7000-2498</td>
<td>Serial Number</td>
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<tr>
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<tr>
<td><img src="image" alt="Symbol" /></td>
<td>ISO 7010-P001</td>
<td>General Prohibition</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Dustbin with ISO 7000-1135 (in accordance with DIN EN 61249)</td>
<td>General Recycling, Do not Dispose Improperly Contains Lead (Pb)</td>
</tr>
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<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5448</td>
<td>Electrical Input/output</td>
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<td><img src="image" alt="Symbol" /></td>
<td>In accordance with ISO 1219-1</td>
<td>Pneumatic Output</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>ISO 7000-0247</td>
<td>Battery Charging Condition</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5576</td>
<td>Bell Cancel (AUDIO PAUSED)</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5265</td>
<td>&quot;OFF&quot; for part of equipment (STANDBY)</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5264</td>
<td>&quot;ON&quot; for part of equipment (ENTER)</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5111B</td>
<td>Pause; Interruption (PAUSE)</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>IEC 60417-5659</td>
<td>Start, Test Run (SYSTEM TEST)</td>
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<tr>
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<td>Adjustable Upper Limit (UPPER LIMIT)</td>
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<td><img src="image2" alt="Symbol" /></td>
<td>IEC 60417-5651</td>
<td>Adjustable Lower Limit (LOWER LIMIT)</td>
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<td><img src="image3" alt="Symbol" /></td>
<td>ISO 7000-0536</td>
<td>Water; Fluid (WATER)</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>ISO 7000-0537</td>
<td>Air (GAS)</td>
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<td>ISO 7000-0034</td>
<td>Temperature</td>
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<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>IEC 60417-5007</td>
<td>“ON” (power)</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>IEC 60417-5008</td>
<td>“OFF” (power)</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>ISO 7010-W001</td>
<td>General Warning Sign</td>
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<td><img src="image9" alt="Symbol" /></td>
<td>Complies with ISO EN 7010 and Safety signs and signals regulations 1996</td>
<td>Pinch Point</td>
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<td>ISO 7000-0434A</td>
<td>Caution</td>
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<td><img src="image11" alt="Symbol" /></td>
<td>ISO 7000-0794</td>
<td>Input</td>
</tr>
<tr>
<td><img src="image12" alt="Symbol" /></td>
<td>ASTM F2503-13</td>
<td>MR Unsafe</td>
</tr>
</tbody>
</table>
Electromagnetic Declarations and Tables

General information on electromagnetic compatibility (EMC) according to the international EMC standard IEC 600601-1-2:2001:

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables below.

Portable and mobile RF communications equipment can affect medical electrical equipment.

**WARNING:** Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by Bunnell Incorporated as replacement parts, may result in increased emissions or decreased immunity of the LifePulse HFV.

**WARNING:** The LifePulse HFV should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the LifePulse HFV should be observed to verify normal operation in the configuration in which it will be used.

**WARNING:** Exposure to known sources of EMI with medical devices such as diathermy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors could affect the function of the LifePulse HFV. Use of the LifePulse around such sources should be avoided if possible until effects are known. If unexplained changes in LifePulse performance are observed, it may be necessary to take mitigation measures, such as re-orienting, relocating the LifePulse, or shielding its location. If necessary, discontinue use of the interfering device or the LifePulse. Note that the presence of RFID devices may not be obvious.

**Essential Performance**

The essential performance consists of controlled, monitored, and humidified patient ventilation at the LifePort connector at user-defined settings within the alarm limits or generation of an alarm condition:

- Airway pressure
- Water and gas temperature
- Water level

Additionally, alarms will be generated in the following situations:

- Cessation of electrical power
- Battery near depletion
- Minimum gas supply pressure
- Humidifier not running during ventilation
EN 60601-1-2:2007 – Table 1 (emissions for all Medical Equipment)

The LifePulse High Frequency Ventilator (HFV) is intended for use in the electromagnetic environment specified below. The customer or the user should assure that the LifePulse HFV is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The LifePulse HFV uses RF energy only for its internal functions. Therefore RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class A</td>
<td>The LifePulse HFV is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is headed:</td>
</tr>
<tr>
<td>Harmonic Emissions EN 61000-3-2</td>
<td>Class A</td>
<td>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the LifePulse HFV or shielding the location.</td>
</tr>
<tr>
<td>Flicker EN 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
EN60601-1-2:2007 – Table 2 (immunity for all Medical Equipment)

The LifePulse HFV is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePulse HFV should assure that the product is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8kV air</td>
<td>±2, 4, 6 kV contact ±2, 4, 8kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>±0.5, 1, 2 kV line(s) to earth</td>
<td>Mains power quality should be of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variation on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles &lt;5% UT (&gt;95% dip in UT) for 5s</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles &lt;5% UT (&gt;95% dip in UT) for 5s</td>
<td>Mains power quality should be of a typical commercial or hospital environment. If the user of the LifePulse HFV requires continued operation during mains power interruptions, it is recommended that the LifePulse HFV be powered from an uninterruptible power supply or a battery.NOTE: UT is the a.c. main voltage prior to application of the test level.</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
The LifePulse HFV is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePulse HFV should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz outside ISM bands</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the LifePulse HFV, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:</td>
</tr>
<tr>
<td></td>
<td>10 Vrms 150 kHz to 80 MHz in ISM bands</td>
<td>10 V</td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>10 V/m 80 MHz to 2.5 GHz</td>
<td>10 V/m</td>
<td></td>
</tr>
</tbody>
</table>

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).\

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifePulse HFV is used exceeds the applicable compliance level above, the LifePulse HFV should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the product.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.
EN 60601-1-2:2007 – Table 5 (for Life Supporting Medical Equipment)

The LifePulse HFV is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifePulse HFV can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifePulse HFV as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz outside ISM bands</td>
</tr>
<tr>
<td></td>
<td>( d = \left[\frac{3.5}{3}\right]\sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1.0</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 1:** The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

**NOTE 1:** An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency.

**NOTE 1:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption reflection from structures, objects and people.