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Chapter 1: Introduction

This chapter provides an overview of the device.

Intended Use

The TXP®-2D is a continuous ventilator intended for use in the controlled ventilation of patients at the site of trauma, during transport, or within a medical facility.

Patient Population

Neonates

TXP®-2D

Designed specifically for transport use, the TXP®-2D is a flow-regulated and time-cycled ventilator that provides high-frequency percussive ventilation (HFPV). This HFPV system supports both diffusive and convective flow by stacking breaths in cumulative subtidal volumes, allowing for ventilation, airway clearance, and lung recruitment for most neonatal patients.
HFPV is delivered using the Phasitron breathing circuit to provide respiratory assistance. The Phasitron® delivers pulsatile flow of subtidal, mini pulses of air into the lungs at rates from 200-700 times each minute. During the delivery of the percussive pulses of air, a continued wedge pressure is maintained to stabilize the pulmonary airways while a percussive high-velocity flow is delivered to the airways to enhance cyclical intrapulmonary exchange of respiratory gases.

**NOTE:** *The Phasitron® breathing circuit is part of the system and can not be used independently or with any other manufacturer's products.*

**Effects of HFPV**

The effects of HFPV therapy occur with or without the cooperation of the patient. HFPV provides a percussive subtidal gas exchange within the respiratory bronchioles with associated alveolar recruitment, maintaining a minimal mean intrathoracic expiratory pressure increase for peripheral lung recruitment, while minimizing the potential for induced barotrauma.
The TXP®-2D is indicated for neonatal transport ventilation. The transport ventilator comes with multiple mounting options for a custom fit on the International Biomedical Aviator or Voyager transport incubator. The TXP®-2D ventilator is designed only for use with Percussionaire® recommended configurations of the Phasitron® breathing circuit kit.

### Indications for Use

The TXP®-2D is indicated for neonatal transport ventilation. The transport ventilator comes with multiple mounting options for a custom fit on the International Biomedical Aviator or Voyager transport incubator. The TXP®-2D ventilator is designed only for use with Percussionaire® recommended configurations of the Phasitron® breathing circuit kit.

### Package Contents

- TXP®-2D Transport face panel
- Phasitron® Kit A50605-D with included Nitric Oxide and PEEP Valve

### Indications for Use

The TXP®-2D is indicated for neonatal transport ventilation. The transport ventilator comes with multiple mounting options for a custom fit on the International Biomedical Aviator or Voyager transport incubator. The TXP®-2D ventilator is designed only for use with Percussionaire® recommended configurations of the Phasitron® breathing circuit kit.

### Contraindications for Use

- **Absolute Contraindications**
  - Untreated tension pneumothorax
  - Untrained or unskilled operator

- **Relative Contraindications**
  - History of pneumothorax
  - Pulmonary air leak
  - Recent pneumonectomy
  - Pulmonary hemorrhage
  - Myocardial infarction
  - Vomiting

### Possible Adverse Reactions

- Decreased cardiac output
- Increased intracranial pressure
- Contamination
- Pneumothorax
- Increased air trapping
- Hyperoxygenation
- Pulmonary air leak
- Pulmonary hemorrhage
- Hyperventilation
- Gastric distension

### Clinical Limitations/Restrictions

Use of the TXP®-2D Transport Ventilator® is limited to individuals who have received proper training. The patient MUST be under continuous observation by a clinician.

### Responsibility of the Clinician

- Read the User Manual before using the Device.
- Federal law restricts this device to sale by or on the order of a physician.
### Warnings

**NOTE:** A WARNING icon indicates a risk of injury to patient or operator. A CAUTION icon indicates a risk of equipment damage.

**NOTE:** Individuals attempting to operate the TXP®-2D Ventilator must understand Warnings and Cautions contained in User Manual to prevent bodily injury or equipment failure.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The operator of the TXP®-2D is responsible for reading and understanding the manual before use.</td>
<td></td>
</tr>
<tr>
<td>Failure to comply could cause injury or death to the patient</td>
<td></td>
</tr>
<tr>
<td>Inherent to all positive-pressure ventilators, improved compliance and increased intra-thoracic pressures may cause a decrease in venous return, which in turn may result in decreased cardiac output and may increase the risk for intraventricular hemorrhage for neonates.</td>
<td></td>
</tr>
<tr>
<td>A pre-use check procedure must be followed before ventilation of a new patient commences. If during the functional evaluation and start-up procedure any abnormal function is noted with the TXP®-2D ventilator, do not start with patient ventilation.</td>
<td></td>
</tr>
<tr>
<td>Proper care needs to be taken during set-up operation to ensure all lines running to or from Phasitron® breathing circuit are not crimped or perforated. Failure to conform could cause malfunction of pressure limit controls.</td>
<td></td>
</tr>
<tr>
<td>During TXP®-2D ventilation it is important to maintain an unobstructed and unrestricted airway. Only proximal airway pressure is monitored; in the event of an obstructed or restricted airway, alarming may not occur. Proper suctioning procedures should be followed to maintain a patent airway. Regular patient assessment, along with continuous monitoring of TcPO₂, TcPCO₂, SpO₂ is required.</td>
<td></td>
</tr>
<tr>
<td>If TXP®-2D High-Frequency Transport Ventilator is used on a patient with an indwelling airway (i.e. endotracheal or tracheostomy tube), a clinician must be present so that a one-to-one relationship exists.</td>
<td></td>
</tr>
<tr>
<td>Prior to placing a patient on the TXP®-2D ventilator, a clinical assessment should be completed to determine if alternative ventilation equipment is needed.</td>
<td></td>
</tr>
<tr>
<td>For ventilator-dependent patients, it is necessary to have alternative ventilation equipment, such as a manual resuscitator, or a back-up ventilator available.</td>
<td></td>
</tr>
<tr>
<td>The prescription and other device settings should only be changed on the order of the supervising physician.</td>
<td></td>
</tr>
</tbody>
</table>
**WARNING**

The Phasitron® kit A50605-D is specifically designed for use with the TXP®-2D ventilator. Use of non-Percussionaire® breathing circuits will immediately invalidate the warranty and could result in injury to patients.

**WARNING**

Proper support and orientation of patient circuit must be made to avoid inadvertent disconnection.

**WARNING**

Administration of oxygen to a patient may be harmful. The prescribed oxygen concentration delivered by the blending system should be verified with an oxygen analyzer.

**WARNING**

Maintenance procedures must be complied with. Failure may result in injury to the patient.

---

**Cautions**

**NOTE:** It is the user’s responsibility to follow the instructions given in this manual. Keep the operating instructions near the device to ensure correct operation. If the safety instructions are not followed, the patient may be endangered.

---

**Accessories**

Only use Percussionaire® accessories designed specifically for use with the TXP®-2D. Use of non-Percussionaire® breathing circuits will immediately invalidate the warranty and may cause equipment damage.

**Assembly**

Deviation from manufacturer’s suggested assembly could cause the TXP®-2D to malfunction. Any questions regarding the assembly should be made to International Biomedical.

**Modifications**

Never attempt to modify the TXP®-2D ventilator, as this may cause equipment damage.

**Qualified Service Personnel**

Only authorized service personnel may open the TXP®-2D ventilator for any device servicing or repair.

**User Manual**

Follow the instructions in the User Manual when using the TXP®-2D ventilator.

**Cleaning**

Do not use any steam cleaning methods to clean the device or Phasitron® breathing circuit. Always follow hospital/institutional protocols for cleaning and disinfection.

**Maintenance**

The TXP®-2D ventilator must not be opened by anyone other than authorized service personnel. Maintain and service the device according to the recommendations provided in this manual. Only use Percussionaire® accessories explicitly designed for use with the TXP®-2D ventilator.

**Malfunctions**

If the TXP®-2D ventilator malfunctions, it should not be utilized any further. Report any malfunctions immediately.

**Read and Understand Manual**

All persons providing HFPV must be trained in the use of the TXP®-2D ventilator.

**Safety**

Do not place objects on top of the device. Do not cover the device during use.
**Document Symbols**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>WARNING</td>
</tr>
<tr>
<td>⚠️</td>
<td>CAUTION</td>
</tr>
<tr>
<td>Ⓚ</td>
<td>Read the manual before use</td>
</tr>
<tr>
<td>Ⓚ</td>
<td>CE marking</td>
</tr>
<tr>
<td>🗂️</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🗂️</td>
<td>Manufacture Date</td>
</tr>
<tr>
<td>🗂️</td>
<td>Non-Sterile</td>
</tr>
<tr>
<td>🗂️</td>
<td>Does Not Contain the Phthalate Plasticizers DEHP, DIBP, DBP, or BBP</td>
</tr>
<tr>
<td>⚠️</td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td>⚠️</td>
<td>Single Patient Use</td>
</tr>
<tr>
<td>📖</td>
<td>Prescription Only</td>
</tr>
<tr>
<td>📖</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>📖</td>
<td>Lot Number</td>
</tr>
<tr>
<td>🏴‍☠️</td>
<td>European Representative</td>
</tr>
<tr>
<td>🏴‍☠️</td>
<td>Not Made with Natural Rubber Latex</td>
</tr>
<tr>
<td>🗑️</td>
<td>Disposal</td>
</tr>
</tbody>
</table>

**Liability**

The manufacturer does not assume liability for any damage that occurs owing to non-compliance with this User Manual. The terms of warranty and liability contained in the manufacturer’s terms and conditions of sale and delivery are not extended by the following provisions. If the device is not used as intended, liability for the performance of TXP®-2D shall always pass to the owner or operator. Modifications to the device are prohibited.

### Accessibility

⚠️ **WARNING** Use TXP®-2D only with accessories, replacement parts, and breathing circuits which are approved by the manufacturer. Use of unapproved parts, or parts that are not within the specifications, may jeopardize the proper function of TXP®-2D, degrade ventilation performance, and compromise the safety of the patient and/or user. The operator is responsible for ensuring that TXP®-2D is only operated with accessories approved for it.

#### The use of non-approved accessories

- Jeopardise the safety of the patient and/or user
- Have a negative impact on the proper functioning of TXP®-2D
- Reduce performance
- Lead to non-compliance with legal regulations.
Chapter 2: System Description

The TXP®-2D transport ventilator provides High-Frequency Percussive Ventilation (HFPV) as the patient breathes through the Phasitron®. The Phasitron® uses a unique, sliding venturi to protect the lung from overpressure. By automatically adjusting to the resistance of the lung, the Phasitron® precisely and instantaneously delivers the amount of air required by the alveolar space.

The high-frequency percussions delivered by the Phasitron® stack up to produce pulsatile airflow down the center of the airway – through the physiological dead space – delivering ventilation of oxygenated air. These pulsatile counter-current pulses ramify throughout the airways and alveolar ducts, augmenting diffusive ventilation in the gas exchange regions of the lungs, allowing improved ventilation, FRC, CO₂ removal, airway clearance, and lung recruitment.

Frequency Control Knob

The Frequency knob controls the frequency rate from approximately 200-700 pulses (inflations) per minute.

NOTE: The rate may differ at different altitudes.

Amplitude Control Knob

The Amplitude control knob determines the amplitude delivered to the patient during the pulse.

NOTE: Amplitude is affected by lung compliance and resistance. Amplitude is attenuated by resistance and compliance to an airway pressure.
The Digital Multimeter (DM)

The Digital Multimeter (DM) has six different operating modes: POST, Wake, Active, Report, Sleep, and Fault.

DM OPERATING MODES

1. **POST** (Power-On Self-Test)

   When batteries are installed in a DM, software displays the revision, battery voltage, and serial number for 15 seconds. Power-On Self-Test (POST) is started. If any errors are detected in the POST, the DM enters the Fault Mode. The POST checks require that the measurement port be left disconnected and exposed to the atmosphere for the entire duration.

   **NOTE:** Do not install DM until the POST check is complete and the screen is blank, indicating Sleep mode.

2. **Wake Mode**

   To wake up the DM, ensure the ventilator pressure is greater than 2.5 cmH₂O/hPa at the Phasitron® patient delivery port for more than 1 second. DM remains on for the first 15 seconds, showing bar-graph timer. If usage is stopped within 12 seconds, the current session continues counting from 16 seconds, which turns into Active Mode.

3. **Active Mode**

   Display metrics: Pulse Frequency Rate, Pulse Amplitude Pressure, Mean Airway Pressure, Pulse Amplitude Bar Graph. Pulse amplitude reading is displayed at the top right and is calculated at the instantaneous moment of peak and trough amplitude pressure. Mean Airway Pressure (MAP), averages pulse amplitude over 5 seconds. At 100 samples per second, this is an average of 500 measurements. Mechanical PEEP adjusted at the Phasitron® can be observed on the bar graph, allowing the clinician to dial the desired amount. As PEEP is added, it is displayed as a solid black area at the base of the bar graph. Each bar in the bar graph, represents approximately 2.5-3 cmH₂O pressure.

   Pulsating grey color represents AIP. Solid black shows PEEP, only when adding PEEP with PEEP valve.
### DM OPERATING MODES

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td><strong>Report Mode</strong></td>
</tr>
<tr>
<td>A.</td>
<td>The Total Usage Time (A) is displayed for two seconds, followed by the System Information page (B) for 2 seconds, alternating. This continues for 5 minutes or until usage resumes and the DM enters <strong>Active Mode</strong>. During the 5-minute period, a horizontal bar graph indicates the time. After 5 minutes of no usage, the system information page is no longer displayed and the time display flashes (2 seconds on, 2 seconds off) (C) for an additional 25 minutes. The DM enters <strong>Sleep</strong> mode after 25 minutes.</td>
</tr>
<tr>
<td>B.</td>
<td><strong>System Information Page</strong></td>
</tr>
<tr>
<td>C.</td>
<td><strong>Blank Screen</strong> indicating DM Sleep mode</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Sleep Mode</strong></td>
</tr>
<tr>
<td></td>
<td>The LCD is off, but the microcontroller continues to sample and calculate the pressure at the measuring port 5 times a second. Over any 3-second period, if the pressure is greater than 2.5 cmH₂O/hPa at the Phasitron® patient delivery port for more than 1 second, the DM enters the <strong>Wake mode</strong>.</td>
</tr>
<tr>
<td>6.</td>
<td><strong>Fault Mode</strong></td>
</tr>
<tr>
<td></td>
<td>The DM displays an error message on the LCD stating, “Contact Factory for Service” and stays in this mode until both batteries are removed. The displayed information includes the software revision, DM serial number, the Total Usage Time, and an error code for the exclusive use of the factory.</td>
</tr>
</tbody>
</table>

**NOTE:** If system failure screen is displayed, remove batteries for 30 seconds. Replace batteries (note that positive terminals face same direction), and wait 30 seconds. If POST check runs correctly, DM may be used. If system failure screen recurs, contact Percussionaire® Corporation for factory service.
Side and Rear Panel Features

Ventilator Switch
The switch located on the transporter selects between conventional and high-frequency ventilation modes.

Connection for Phasitron®
clear tubing for the Phasitron® breathing circuit gas supply

Connection for Phasitron®
red tubing for the Proximal Airway Monitoring Port

TXP®-2D

Blended gas knob
Chapter 3: Setup

Phasitron® Kit A50605-D Breathing Circuit

The patented Phasitron® uses a unique sliding venturi mechanism to protect the lung from overpressure. By automatically adjusting to the resistance of the lung, the Phasitron® precisely and safely delivers the optimal amount and pressure of air required by the alveolar space.

Nitric Oxide

Setup Instructions
1. Replace standard Phasitron® swivel tee with N.O. swivel tee (if applicable).
2. Connect AeroNOx™ injection port to Phasitron® N.O. injection port.
3. Connect AeroNOx™ monitoring port to Phasitron® monitoring port.
4. Connect red proximal airway port from TXP®-2D unit to proximal airway monitoring port.
5. Set desired TXP®-2D settings.
6. Set desired AeroNOx™ settings.
7. Attach to patient.
8. Adjust all settings as necessary.

NOTE: If patient is breathing spontaneously, a change in N.O. PPM may be noted.
Chapter 4: Settings

Initial Settings Guidelines

NOTE: These are merely suggested guidelines based on clinical consensus.

<table>
<thead>
<tr>
<th>Control</th>
<th>Neonate &lt; 5Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Pressure (psig)</td>
<td>40-42 (psig)</td>
</tr>
<tr>
<td>Amplitude</td>
<td>15-25 cmH₂O</td>
</tr>
<tr>
<td>PEEP</td>
<td>8-15 cmH₂O</td>
</tr>
<tr>
<td>Pulse Frequency Rate (cycles)</td>
<td>500 (400-800)</td>
</tr>
</tbody>
</table>

NOTE: As Pulse Frequency is increased, the Pressure Amplitude weakens. Decreasing PF rate to (380-420) creates the greatest Pressure Amplitude when more power is required for ventilation.

| FiO₂ (%)                            | Per NICU protocol with emphasis towards lowest FiO₂ |

CAUTION: If the high-frequency rate is changed, the actual PIP may also change. Recheck and adjust PIP after any high-frequency rate change.

Chapter 5: Therapy Modes and Features

NOTE: Individuals attempting to operate the TXP®-2D ventilator must understand Warnings and Cautions contained in TXP®-2D User Manual to prevent bodily injury or equipment failure.

Clinical Application

Because of the TXP®-2D controller’s programmability and the Phasitron® combination inhalation/exhalation valve, the TXP®-2D can provide for control of oxygenation (diffusion) and CO₂ washout (convection).

Parameter Changes

Adjustments to the TXP®-2D ventilator to correct blood gas are based on a few simple principles and working knowledge of pressure-limited ventilation and traditional high-frequency ventilation.
Chapter 6: High-Frequency Percussive Ventilation (HFPV) Protocol

NOTE: These are merely suggested guidelines based on clinical consensus.

1. Establish patient airway (i.e.: mask, endotracheal tube, nasal cannula).
2. Turn Ventilator Switch (shown in Chapter 2: Side and Rear Panel Features) to "High Frequency."
3. Connect multi-colored harness to Phasitron® and TXP*-2D unit.
4. Rotate FREQUENCY control knob full counterclockwise.
5. Observe multimeter pressure.
6. Connect Phasitron® to patient interface.
7. PIP and frequency should be adjusted to clinician judgment based upon physiological and monitored assessments.

Patient Monitoring

Therapists should evaluate how their patients tolerate the treatment. Auscultation and observation of the mechanical vibrations of the chest and abdomen are primary indicators of effective treatment. During TXP*-2D ventilation, it is important to maintain an unobstructed and unrestricted airway. Only proximal airway pressure is monitored. Proper suctioning procedures should be followed to maintain a patent airway. Regular patient assessment along with continuous monitoring of TcPO₂, TcPCO₂, SpO₂, and end tidal CO₂, are needed to ensure that blood gases are at the proper level.

- SpO₂
- Blood Pressure and Perfusion
- Chest Wiggle
- Breath Sounds
- Ventilator Settings
- Phasitron and ETT positioning
- Blood gas ~ 20 minutes after starting therapy, after an adjustment, and then every 30 to 60 minutes

Ventilation

Control over arterial PCO₂ is achieved by manipulating delivered volumes.

- HF = VCO₂ + (VT)² x f

To increase ventilation and decrease PCO₂:
Increase amplitude in 2-3 cmH₂O increments. Amplitude is directly related to tidal volume delivery.
Decrease oscillatory frequency. This will increase inspiratory time, therefore increase tidal volume.
Oxygenation

Control over arterial PO₂ is achieved by manipulating FiO₂ or increasing the Mean Airway Pressure. The following will increase FiO₂ and/or mean airway pressure, thereby increasing arterial PO₂. The choice of which parameter to adjust is up to clinical discretion.

<table>
<thead>
<tr>
<th><strong>Increase FiO₂</strong></th>
<th>This is accomplished if the unit is connected to a blended air/O₂ system and an accessory intensive care breathing circuit is used. If the TXP®-2D is connected to an oxygen source, FiO₂ of approximately 60% can be expected.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Increase amplitude</strong></td>
<td>This will increase mean airway pressure, which will increase PO₂.</td>
</tr>
<tr>
<td><strong>Increase frequency</strong></td>
<td>This will increase mean airway pressure, which will increase PO₂.</td>
</tr>
<tr>
<td><strong>Attach accessory PEEP valve to expiratory limb.</strong></td>
<td>This will increase FRC, which in turn will increase mean airway pressure.</td>
</tr>
</tbody>
</table>

In the face of a difficult clinical scenario with worsening ventilation and/or oxygenation, a complete assessment of the patient is necessary to find the cause for ventilation/perfusion (V/Q) inequality. Common V/Q problems are associated with acute or chronic respiratory injuries.

**NOTE:**
*Any increase in MAP will increase PO₂*

\[
MAP = \frac{1}{2} (PIP - EEP) + \left( \frac{It}{TCT} + EEP \right) 
\]
*Any increase in amplitude, PEEP, or rate will increase MAP.*

**NOTE:**
*Amplitude and rate are interconnected; changing one parameter will affect the other.*
**INCREASE OXYGENATION: ↑ PaO₂**

a) FiO₂  
Wean to < 60% before reducing PEEP/MAP

b) PEEP/MAP  
Increase in 2 cmH₂O increments

c) Frequency  
Increase in 60 pulses per minute increments

d) Pulsatile Flowrate (PIP)  
Increase in 2 cmH₂O increments

**INCREASE VENTILATION: ↓ PaCO₂**

a) Pulsatile Flowrate (PIP)  
Increase in 2 cmH₂O increments

b) Frequency  
Decrease in 60 PPM increments

c) PEEP  
Decrease in 2 cmH₂O increments

**DECREASE VENTILATION: ↑ PaCO₂**

a) Pulsatile Flowrate (PIP)  
Decrease in 2 cmH₂O increments

b) PEEP  
Increase in 2 cmH₂O increments

c) Frequency  
Increase in 60 PPM increments

**NOTE:** *These are merely suggested guidelines based on clinical consensus.*

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>STRATEGY</th>
</tr>
</thead>
</table>
| RDS/Diffuse Alveolar Disease | a. MAP: 1-2 cmH₂O > conventional  
b. Frequency: 500 PPM  
c. Amplitude: Slight chest wiggle |
| Pulmonary Hypoplasia | a. MAP: 1-2 cmH₂O above conventional.  
Advance 1 cmH₂O until oxygenation improves.  
b. Frequency: 500 PPM  
c. Amplitude: Slight chest wiggle |
| Meconium Aspiration (with air trapping) | a. MAP: equal to conventional  
b. Frequency: 350-500 PPM  
c. Amplitude: Good chest wiggle |
| Meconium Aspiration (diffusely hazy) | a. MAP: 2-4 cmH₂O > conventional  
b. Frequency: 350-500 PPM  
c. Amplitude: Good chest wiggle |
| Severe Air Leak (PIE) | a. MAP: 1 cmH₂O < conventional  
b. Frequency: 500 PPM  
c. Amplitude: Slight chest wiggle/Minimal chest wall movement |
| Gross Air Leak (Pneumothorax) | a. MAP: equal to or 1 cmH₂O > conventional  
b. Frequency: 500 PPM  
c. Amplitude: Slight chest wiggle |
| Persistent Pulmonary Hypertension of the Newborn (PPHN) | a. MAP: equal to or 1 cm < conventional  
b. Frequency: 350-500 PPM  
c. Amplitude: Good chest wiggle |
Chapter 7: Environmental Conditions Protocol

Operating, Storage, and Transport

| TXP®-2D | Operating Range | Temperature 5°C to 32°C (41°F to 90°F)  
|         |                 | Humidity 5% - 95%  
|         |                 | Elevation 0-9842 ft  
| Storage and Transport Range | Temperature 10°C to 25°C (50°F to 77°F)  
| Phasitron® | Operating Range | Frequency: 0-999 pulses per minute  
|           |                 | Pressure: 0-150 cmH₂O/hPa  
| Digital Multimeter (DM) | Storage and Transport Range | Temp -20°C to 60°C (-4°F to 140°F)  
|               |                 | Humidity < 93% non-condensing  

Chapter 8: Cleaning and Maintenance Protocol

The TXP®-2D should be checked by International Biomedical authorized technician anytime clinical efficacy is not as expected.

A pre-use check should be performed before each patient use.

Annually, each unit should have a preventive maintenance check (PM) performed to insure proper function. Units returned for maintenance and service must be handled by a Percussionaire®-authorized service center. A return material authorization number (RMA) can be obtained by contacting: International Biomedical (512) 873-0033.

TXP®-2D Controller

Do not spray any cleaning solution on to the TXP®-2D controller.  
Do not immerse or allow liquids to access the controller.  
Clean the controller according to hospital/institutional protocol. Always clean between patients and when visibly soiled. Clean the controller with a clean, lint-free cloth or paper towel moistened with the cleaner. Use only approved cleaners.

Phasitron® Kit A50605-D

The Phasitron® breathing circuit is a single-patient, single-use breathing circuit kit, used only for patient transport. After patient transport is complete, discard Phasitron® breathing circuit according to hospital protocol. Do NOT reuse.

NOTE: The Phasitron® kit is for single patient use only.
It is recommended to change DM batteries every 6 months.

### Changing DM Batteries

1. Press on the DM’s bezel and twist counterclockwise approximately 20 degrees.
2. Gently pull on the DM to remove it from the housing.
3. Remove the two old batteries.
4. Install two new batteries. Note that the positive terminals face the same direction. Wait 30 seconds until screen turns off.
5. Install the DM back into the housing and twist clockwise until the stop is felt.
6. See POST mode instructions to verify display operation.

**NOTE:** The DM has a USB port that is used for firmware download only. It is not enabled during normal operation.

**WARNING** ⚠️ The cell used in this device may present a risk of fire or chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F), or incinerate. Replace cell with type recognized CR123A only, or Percussionaire® Part #PRT-B13350. Use of another cell may present a risk of fire or explosion. Dispose of in accordance with appropriate regulations.
## Troubleshooting

⚠️ **WARNING:** If there are any unexplained changes in the performance of the device, if the device makes unusual sounds or is damaged in any way, discontinue use. Begin troubleshooting process and contact distributor or an authorized Percussionaire® service center.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Percussion</strong></td>
<td>No air or gas supply to the TXP®-2D</td>
<td>Confirm gas supply can deliver 50 psig pressure at 15 LPM flow rate. Connect to a different gas source to confirm pressure and capacity.</td>
</tr>
<tr>
<td></td>
<td>TXP®-2D has air or gas supply, but no percussion.</td>
<td>Make sure the AMPLITUDE knob is turned fully counterclockwise, and the Phasitron® red and clear tubing is connected.</td>
</tr>
<tr>
<td></td>
<td>Internal percussion valve failed.</td>
<td>Send device to an authorized service center for repair.</td>
</tr>
<tr>
<td><strong>Low Amplitude</strong></td>
<td>Low air or gas supply pressure/flow capacity</td>
<td>Confirm gas supply connection can deliver 50 psig pressure at 15 LPM flow rate. Connect to a different gas source to confirm pressure and capacity.</td>
</tr>
<tr>
<td></td>
<td>Gas supply air leak</td>
<td>Listen for air leaks. Visually inspect both the gas supply connections and the Phasitron® to TXP®-2D connections. Inspect for damaged O-rings at the tubing connectors.</td>
</tr>
<tr>
<td></td>
<td>Correct amplitude, but the multimeter indicating a lower than expected pressure.</td>
<td>The multimeter displays the pulse amplitude pressure in the small upper-right part of the display. The numbers near the center of the display indicate Mean Airway Pressure. This is a lower number than the pulse amplitude pressure. Check with a test lung.</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Corrective Action</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Frequency does not change</td>
<td>The <strong>FREQUENCY</strong> knob is loose on control shaft.</td>
<td>The <strong>FREQUENCY</strong> knob must be turned fully counterclockwise to the stop. Remove the <strong>FREQUENCY</strong> knob with a 3/32” hex key wrench and rotate the valve shaft for a frequency of 200 ppm. Reinstall the knob and confirm the frequency is about 200 ppm at the full clockwise position.</td>
</tr>
<tr>
<td>DM has no display</td>
<td>No signal to DM</td>
<td>The Phasitron® must be connected to the clear and red tubing. Silver and red connectors on the TXP® 5 face panel must be connected to the Phasitron®.</td>
</tr>
<tr>
<td>DM not activated</td>
<td></td>
<td>The Phasitron® patient port must see a pressure of 2.5 cmH₂O for more than one second to enter wake mode.</td>
</tr>
<tr>
<td>DM display does not stay on</td>
<td></td>
<td>Confirm the Phasitron® is connected to the patient, test lung, or occluded for more than 5 seconds to activate DM.</td>
</tr>
<tr>
<td>DM not functional</td>
<td></td>
<td>Check power connection and reconnect</td>
</tr>
<tr>
<td>DM has wrong display</td>
<td>Power-On Self-Test® and calibration were unable to start correctly.</td>
<td>Turn off device and unplug power. Wait 5 seconds and reconnect power.</td>
</tr>
<tr>
<td></td>
<td>Failed DM software</td>
<td>Send the DM to an authorized service center for repairs.</td>
</tr>
<tr>
<td>Device performance changes</td>
<td>Electrical interference</td>
<td>Move TXP®-2D away from any potential sources of electromagnetic interference (EMI) including MRI equipment, medical imaging systems, security systems, appliances, wireless communications equipment (such as cellular phones), computers, and televisions.</td>
</tr>
</tbody>
</table>

![Diagram of FREQUENCY knob](image-url)
Chapter 9: Pre-Use Check

1. Rotate the FREQUENCY knob to full clockwise position.

2. Rotate the AMPLITUDE knob to full clockwise position.

3. Connect the Phasitron® to the TXP®-2D red and silver bulkhead fittings.

4. Close the Phasitron® patient port, with or without filter, ensuring a tight seal.

5. Rotate the AMPLITUDE knob to full counterclockwise position.

6. Observe frequency on right side of display less than 250 pulses per minute.

7. Observe Mean Airway Pressure on display greater than 15 cmH₂O. Open the Phasitron® patient port; the disconnect alarm must sound. Re-close port to stop alarm and continue.

8. Rotate the FREQUENCY knob to the left, full counterclockwise position.

9. Observe an increase in pulse frequency to a rate greater than 600 pulses per minute.

10. Observe Mean Airway Pressure on display greater than 15 cmH₂O.

11. Rotate the FREQUENCY knob to arrow up 12:00 position.

12. Rotate the AMPLITUDE knob slowly clockwise. Observe a decrease in amplitude until “off” at the full clockwise position.

13. Pre-use check is complete.
## TXP®-2D Controller

### Settings

<table>
<thead>
<tr>
<th>Pulse/Interval Ratio</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate:</td>
<td>I:E</td>
</tr>
<tr>
<td>450+</td>
<td>1:1</td>
</tr>
<tr>
<td>350-450</td>
<td>1:1.5</td>
</tr>
<tr>
<td>250-350</td>
<td>1:2</td>
</tr>
</tbody>
</table>

### Pulse Frequency

- 200-700 cycles/minute
- Displays 1 cycle increments

### Operating Conditions

<table>
<thead>
<tr>
<th>Operating Range</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp., 5°C to 32°C</td>
<td>(41°F to 90°F)</td>
</tr>
<tr>
<td>Humidity 5%-95%</td>
<td></td>
</tr>
<tr>
<td>Elevation 0-9842 ft</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage and Transport Range</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp., 10°C to 25°C</td>
<td>(50°F-77°F)</td>
</tr>
<tr>
<td>Humidity &lt; 93% non-condensing</td>
<td></td>
</tr>
</tbody>
</table>

### Run Time

- Continuous

### Gas Source/Consumption

<table>
<thead>
<tr>
<th>Cylinder</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-60 PSI</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flow</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-15 LPM</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E cylinder consumption</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1800 psi x .28 @ 25 LPM = 20 minutes</td>
<td></td>
</tr>
</tbody>
</table>

### Filters

- Red line filter: Monitoring line Hydrophobic filter

### Dimensions/Weights

<table>
<thead>
<tr>
<th>Dimensions (WxHxD)</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voyager</td>
<td>(vertical mount) version 15.9 cm H x 11.4 cm W x 10.2 cm D</td>
</tr>
<tr>
<td>Aviator</td>
<td>(horizontal mount) version 11.4 cm H x 15.9 cm W x 10.2 cm D</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4 lb</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service Life:</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 years</td>
<td></td>
</tr>
</tbody>
</table>
## Digital Multimeter (DM) Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td>73 mm (2.87 inch) diameter</td>
</tr>
<tr>
<td><strong>Mass</strong></td>
<td>165 g (0.36 lb)</td>
</tr>
<tr>
<td><strong>Storage and Transport Range</strong></td>
<td>Temp -20°C to 60°C (-4°F to 140°F), Humidity &lt; 93% non-condensing</td>
</tr>
<tr>
<td><strong>Operating Range</strong></td>
<td>Temp -20°C to 60°C (-4°F to 140°F), Humidity &lt; 93% non-condensing</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>128 x 64-pixel FSTN chip-on-glass LCD with reflector</td>
</tr>
<tr>
<td><strong>Fault Detection</strong></td>
<td>Independent Hardware and Software “Watchdogs”</td>
</tr>
<tr>
<td><strong>Serial Port</strong></td>
<td>USB (Firmware Upgrade)</td>
</tr>
<tr>
<td><strong>Rate Range</strong></td>
<td>50 - 999 pulses per minute</td>
</tr>
<tr>
<td><strong>Display output</strong></td>
<td>Mean Airway Pressure, Pulse Amplitude, Pulse Frequency</td>
</tr>
<tr>
<td><strong>Pressure Resolution</strong></td>
<td>1-150 cmH₂O/hPa</td>
</tr>
<tr>
<td><strong>Pressure Accuracy</strong></td>
<td>Greater of ±0.5% of reading or 1 cmH₂O/hPa</td>
</tr>
<tr>
<td><strong>Battery Type</strong></td>
<td>CR123A 3.0V (2)</td>
</tr>
<tr>
<td><strong>Battery Duration</strong></td>
<td>3,250 Operational hours at 35°C (95°F)</td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>3.5 Years at 35°C (95°F)</td>
</tr>
</tbody>
</table>
## Measured Performance

<table>
<thead>
<tr>
<th>TXP®-2D Frequency</th>
<th>R=125, C=3 ml/cmH₂O</th>
<th>Inspiratory Flow</th>
<th>Expiratory Flow</th>
<th>O₂ SAT -with Blender set @100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>500</td>
<td>MAP Amplitude</td>
<td>30 cmH₂O, 72 cmH₂O</td>
<td>16 LPM</td>
<td>13 LPM</td>
</tr>
<tr>
<td>700</td>
<td>MAP Amplitude</td>
<td>30 cmH₂O, 62 cmH₂O</td>
<td>12.23 LPM</td>
<td>12 LPM</td>
</tr>
</tbody>
</table>

Sampled from Phasitron® breathing circuit PN A50605-D, inline with ASL 5000, Neonatal RDS.

1. Resistance on ASL 5000 set at a resistance settings of 125 to simulate a 2.5et tube, while compliance set at 3 ml/cmH₂O.
2. Frequency recorded from TXP®-2D Multimeter.
3. Inspiratory and Expiratory flow measured from peak to trough.

## FiO₂ Measurements

<table>
<thead>
<tr>
<th>TXP®-2D Frequency</th>
<th>R=125, C=3 ml/cmH₂O</th>
<th>Inspiratory Flow</th>
<th>Expiratory Flow</th>
<th>Blender set @100% with 10 LPM O₂ added</th>
</tr>
</thead>
<tbody>
<tr>
<td>500</td>
<td>MAP Amplitude</td>
<td>31 cmH₂O, 75 cmH₂O</td>
<td>15 LPM</td>
<td>14.5 LPM</td>
</tr>
<tr>
<td>700</td>
<td>MAP Amplitude</td>
<td>31 cmH₂O, 65 cmH₂O</td>
<td>11.9 LPM</td>
<td>10.33 LPM</td>
</tr>
</tbody>
</table>

Sampled from Phasitron® breathing circuit PN A50605-D, inline with ASL 5000, Neonatal RDS.

1. Resistance on ASL 5000 set at a resistance settings of 125 to simulate a 2.5et tube, while compliance set at 3 ml/cmH₂O.
2. Frequency recorded from TXP®-2D Multimeter.
3. Inspiratory and Expiratory flow measured from peak to trough.

## Limited Warranty

Percussionaire® warrants that the TXP®-2D shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one year from the date of first use (proof of delivery will be required). If the product fails to perform in accordance with the product specifications, Percussionaire® will repair or replace – at its option – the defective material or part. Percussionaire® will pay customary freight charges to and from Percussionaire® or an authorized Percussionaire® service center. This warranty does not cover damage caused by non-approved cleaning or sterilization, accident, misuse, abuse, alteration, and other defects not related to material or workmanship. Percussionaire® disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product.