PERCUSSIONAIRE®

TXP®-2D System

Neonatal High-Frequency Percussive Ventilator

OPERATOR'S MANUAL

EN

MADE IN THE USA

1st Edition
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The devices and products contained in this manual may be covered by one or more patents.

This manual was originally released and supplied in English.
For a list of available translations, contact customerservice@percussionaire.com.

All ventilators should be operated and serviced only by trained professionals. Percussionaire® Corporation's sole responsibility with respect to its ventilators, accessories, components, and software, and their use, are as stated in the warranty provided in the manuals. The information set forth herein is believed to be accurate; it is not a substitute for the exercise of professional judgment.

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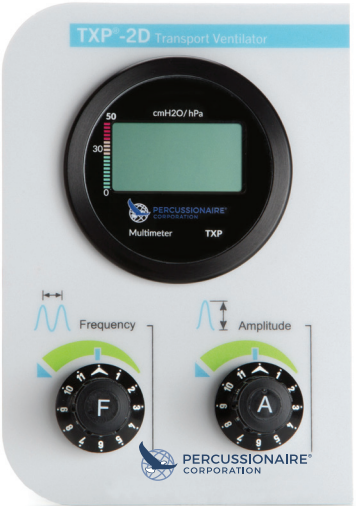
Chapter 1: Introduction

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.

Phasitron® Breathing Circuit A50605-D

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.*

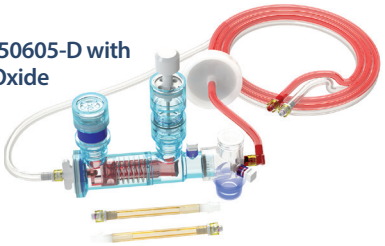
Effects of HFPV

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.

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.*

WARNING ⚠	The operator of the TXP®-2D is responsible for reading and understanding the manual before use.
WARNING ⚠	Failure to comply could cause injury or death to the patient
WARNING ⚠	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.
WARNING ⚠	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.
WARNING ⚠	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.
WARNING ⚠	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 $TcPO_2$, $TcPCO_2$, $Sp0_2$ is required.
WARNING ⚠	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.
WARNING ⚠	Prior to placing a patient on the TXP®-2D ventilator, a clinical assessment should be completed to determine if alternative ventilation equipment is needed.
WARNING ⚠	For ventilator-dependent patients, it is necessary to have alternative ventilation equipment, such as a manual resuscitator, or a back-up ventilator available.
WARNING ⚠	The prescription and other device settings should only be changed on the order of the supervising physician.

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

	WARNING		Type BF Applied Part
	CAUTION		Single Patient Use
	Read the manual before use		Prescription Only
	CE marking		Catalog Number
	Manufacturer		Lot Number
	Manufacture Date		European Representative
	Non-Sterile		Not Made with Natural Rubber Latex
	Does Not Contain the Phthalate Plasticizers DEHP, DIBP, DBP, or BBP		Disposal

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.

Accessories

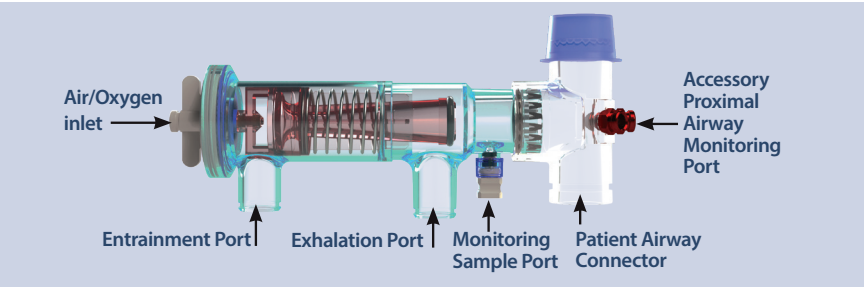
⚠ **WARNING** Use TXP®-2D only with accessories, replacement parts, and breathing circuits which are approved by the manufacturer. Use of unapproved parts, or parts that are not within the specifications, may jeopardize the proper function of TXP®-2D, degrade ventilation performance, and compromise the 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.

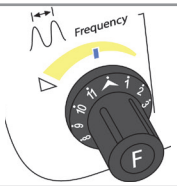
Chapter 2: System Description

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, CO_2 removal, airway clearance, and lung recruitment.

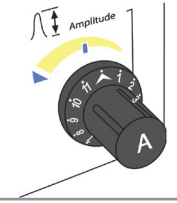
Frequency Control Knob



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.

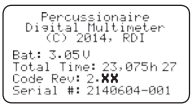
NOTE: *Amplitude is affected by lung compliance and resistance. Amplitude is attenuated by resistance and compliance to an airway pressure.*

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.*

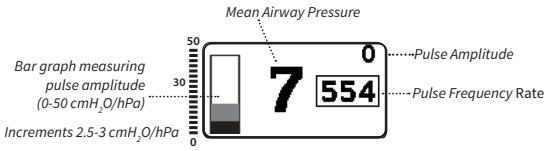
2. **Wake Mode**

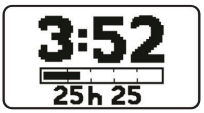
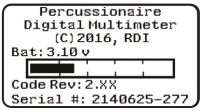
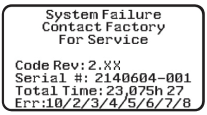
To wake up the DM, ensure the ventilator pressure is greater than 2.5 cmH_2O/hPa at the Phasitron® patient delivery port for more than 1 second. DM remains on for the first 15 seconds, showing bar-graph timer. If usage is stopped within 12 seconds, the current session continues counting from 16 seconds, which turns into Active Mode.

3. **Active Mode**

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

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 cmH_2O pressure.



DM OPERATING MODES	
4. **Report Mode** A.  B.  C.  	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 **Active Mode**. 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 **Sleep** mode after 25 minutes.
5. **Sleep Mode** Blank screen, indicating DM Sleep mode 	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 cmH_2O/hPa at the Phasitron® patient delivery port for more than 1 second, the DM enters the Wake mode.
6. **Fault Mode**  	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.

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

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

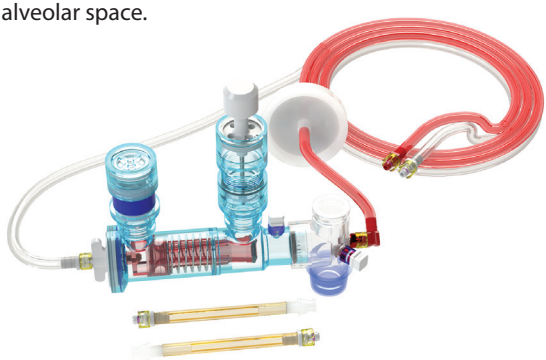
Connection for Phasitron® red tubing for the Proximal Airway Monitoring Port

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

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.

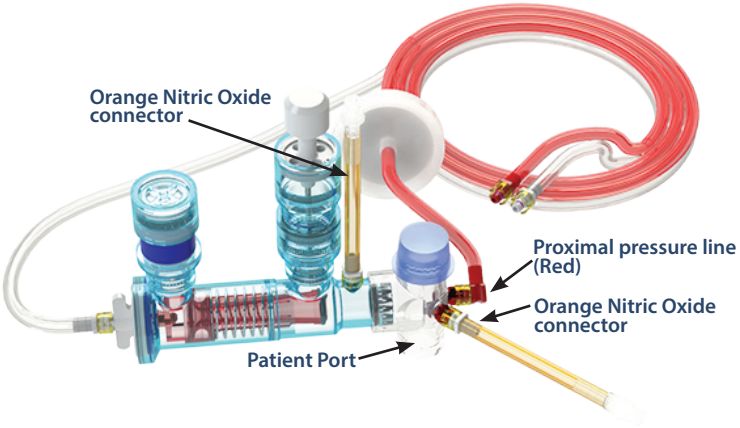


Nitric Oxide

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.***

Control	Neonate < 5Kg
Operating Pressure (psig)	40-42 (psig)
Amplitude	15-25 cmH_2O
PEEP	8-15 cmH_2O
Pulse Frequency Rate (cycles)	500 (400-800)
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.*	
FiO_2 (%)	Per NICU protocol with emphasis towards lowest FiO_2

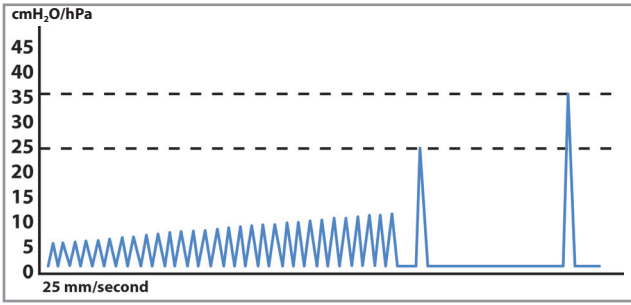
CAUTION ⚠	If the high-frequency rate is changed, the actual PIP may also change. Recheck and adjust PIP after any high-frequency rate change.

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 CO_2 washout (convection).



NOTE: *As pulsatile frequencies are decreased, the i/e ratio automatically becomes increasingly positive.*

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 $TcPO_2$, $TcPCO_2$, SpO_2, and end tidal CO_2, are needed to ensure that blood gases are at the proper level.

- SpO_2
- 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

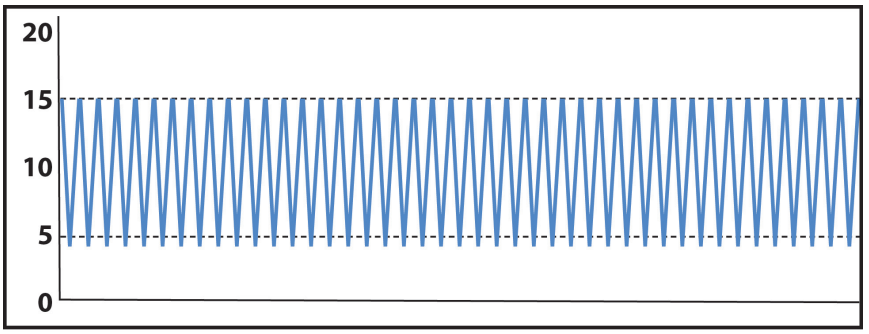
Ventilation

Control over arterial PCO_2 is achieved by manipulating delivered volumes.

- $HF = VCO_2 + (VT)_2 \times f$

To increase ventilation and decrease PCO_2:
Increase amplitude in 2-3 cmH_2O increments. Amplitude is directly related to tidal volume delivery.
Decrease oscillatory frequency. This will increase inspiratory time, therefore increase tidal volume.

FLOW



Oxygenation

Control over arterial PO_2 is achieved by manipulating FiO_2 or increasing the Mean Airway Pressure. The following will increase FiO_2 and/or mean airway pressure, thereby increasing arterial PO_2. The choice of which parameter to adjust is up to clinical discretion.

Increase FiO_2	This is accomplished if the unit is connected to a blended air/O_2 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.
Increase amplitude	This will increase mean airway pressure, which will increase PO_2.
Increase frequency	This will increase mean airway pressure, which will increase PO_2.
Attach accessory PEEP valve to expiratory limb.	This will increase FRC, which in turn will increase mean airway pressure.

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 PO_2
MAP = ½ (PIP-EEP) + (It/TCT + EEP)
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: ↑ PaO_2	
a) FiO_2	Wean to < 60% before reducing PEEP/MAP
b) PEEP/MAP	Increase in 2 cmH_2O increments
c) Frequency	Increase in 60 pulses per minute increments
d) Pulsatile Flowrate (PIP)	Increase in 2 cmH_2O increments
INCREASE VENTILATION: ↓ $PaCO_2$	
a) Pulsatile Flowrate (PIP)	Increase in 2cmH_2O increments
b) Frequency	Decrease in 60 PPM increments
c) PEEP	Decrease in 2cmH_2O increments
DECREASE VENTILATION: ↑ $PaCO_2$	
a) Pulsatile Flowrate (PIP)	Decrease in 2cmH_2O increments
b) PEEP	Increase in 2cmH_2O increments
c) Frequency	Increase in 60 PPM increments

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

TXP®-2D TREATMENT STRATEGIES	
CONDITION	**STRATEGY**
RDS/Diffuse Alveolar Disease	a. MAP: 1-2 cmH_2O > conventional b. Frequency: 500 PPM c. Amplitude: Slight chest wiggle
Pulmonary Hypoplasia	a. MAP 1-2 cmH_2O above conventional. Advance 1 cmH_2O 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 cmH_2O > conventional b. Frequency: 350-500 PPM c. Amplitude: Good chest wiggle
Severe Air Leak (PIE)	a. MAP 1 cmH_2O < conventional b. Frequency: 500 PPM c. Amplitude: Slight chest wiggle/ Minimal chest wall movement
Gross Air Leak (Pneumothorax)	a. MAP equal to or 1 cmH_2O > 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) Humidity < 93% non-condensing
Phasitron®	**Operating Range**	Frequency: 0-999 pulses per minute Pressure: 0-150 cmH_2O/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.

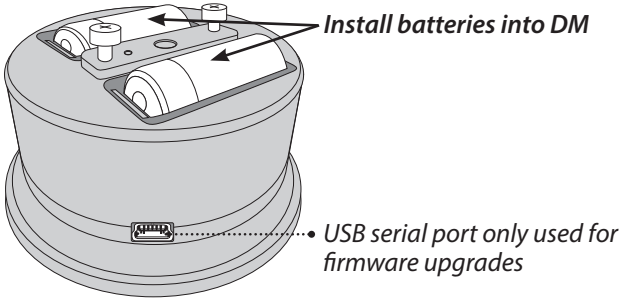
Phasitron® Kit A50605-D

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.*

Digital Multimeter (DM)

A **Low Battery** indicator is displayed when battery capacity is estimated to be low.



Side view of DM

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.

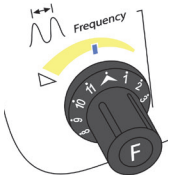
NOTE: *The DM has a USB port that is used for firmware download only. It is not enabled during normal operation.*

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

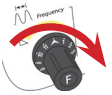
⚠ **WARNING:** *If there are any unexplained changes in the performance of the device, if the device makes unusual sounds or is damaged in any way, discontinue use. Begin troubleshooting process and contact distributor or an authorized Percussionaire® service center.*

Problem	Possible Cause	Corrective Action
No Percussion	No air or gas supply to the TXP®-2D	Confirm gas supply can deliver 50 psig pressure at 15 LPM flow rate. Connect to a different gas source to confirm pressure and capacity.
	TXP®-2D has air or gas supply, but no percussion.	Make sure the **AMPLITUDE** knob is turned fully counterclockwise, and the Phasitron® red and clear tubing is connected.
	Internal percussion valve failed.	Send device to an authorized service center for repair.
Low Amplitude	Low air or gas supply pressure/flow capacity	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.
	Gas supply air leak	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.
	Correct amplitude, but the multimeter indicating a lower than expected pressure.	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.

Problem	Possible Cause	Corrective Action
Frequency does not change	The **FREQUENCY** knob is loose on control shaft.	The **FREQUENCY** knob must be turned fully counterclockwise to the stop. Remove the **FREQUENCY** 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. 
DM has no display	No signal to DM	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®.
	DM not activated	The Phasitron® patient port must see a pressure of 2.5 cmH_2O for more than one second to enter wake mode.
	DM display does not stay on.	Confirm the Phasitron® is connected to the patient, test lung, or occluded for more than 5 seconds to activate DM.
	DM not functional	Check power connection and reconnect
DM has wrong display	Power-On Self-Test and calibration were unable to start correctly.	Turn off device and unplug power. Wait 5 seconds and reconnect power.
	Failed DM software	Send the DM to an authorized service center for repairs.
Device performance changes	Electrical interference	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.

Chapter 9: Pre-Use Check

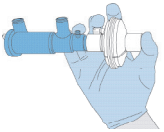
1. Rotate the **FREQUENCY** knob to full clockwise position.



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 cmH_2O. 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 cmH_2O.

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.

Chapter 10: Technical Specifications

TXP®-2D Controller

Settings	**Specifications**
Pulse/Interval Ratio	**Rate:** **I:E** 450+ 1:1 350-450 1:1.5 250-350 1:2
Pulse Frequency	200-700 cycles/minute Displays 1 cycle increments
Operating Conditions	**Specifications**
Operating Range	Temp., 5°C to 32°C (41°F to 90°F) Humidity 5%-95% Elevation 0-9842 ft
Storage and Transport Range	Temp., 10°C to 25°C (50°F-77°F) Humidity < 93% non-condensing
Run Time	Continuous
Gas Source/Consumption	**Specifications**
Cylinder	50-60 PSI
Flow	10-15 LPM
E cylinder consumption	1800 psi x .28 @ 25 LPM = 20 minutes
Filters	**Description**
Red line filter	Monitoring line Hydrophobic filter
Dimensions/Weights	**Specifications**
Dimensions (WxHxD)	**Voyager** (vertical mount) version 15.9 cm H x 11.4 cm W x 10.2 cm D **Aviator** (horizontal mount) version 11.4 cm H x 15.9 cm W x 10.2 cm D
Weight	2.4 lb
Service Life:	3 years

Digital Multimeter (DM) Specifications

Size	73 mm (2.87 inch) diameter
Mass	165 g (0.36 lb)
Storage and Transport Range	Temp -20°C to 60°C (-4°F to 140°F) Humidity < 93% non-condensing
Operating Range	Temp -20°C to 60°C (-4°F to 140°F), Humidity < 93% non-condensing
Display	128 x 64-pixel FSTN chip-on-glass LCD with reflector
Fault Detection	Independent Hardware and Software "Watchdogs"
Serial Port	USB (Firmware Upgrade)
Rate Range	50 - 999 pulses per minute
Display output	Mean Airway Pressure, Pulse Amplitude, Pulse Frequency
Pressure Resolution	1-150 cmH_2O/hPa
Pressure Accuracy	Greater of ±0.5% of reading or 1 cmH_2O/hPa
Battery Type	CR123A 3.0V (2)
Battery Duration	3,250 Operational hours at 35°C (95°F)
Shelf Life	3.5 Years at 35°C (95°F)

Measured Performance

TXP®-2D Frequency		R=125, C=3 ml/cmH_2O	Inspiratory Flow	Expiratory Flow	O_2 SAT -with Blender set @100%
500	MAP	30 cmH_2O	16 LPM	13 LPM	76%
	Amplitude	72 cmH_2O			
700	MAP	30 cmH_2O	12.23 LPM	12 LPM	77%
	Amplitude	62 cmH_2O			

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/cmH_2O.

[2]Frequency recorded from TXP®-2D Multimeter.

[3]Inspiratory and Expiratory flow measured from peak to trough.

FiO_2 Measurements

TXP®-2D Frequency		R=125, C=3 ml/cmH_2O	Inspiratory Flow	Expiratory Flow	Blender set @100% with 10 LPM O_2 addec
500	MAP	31 cmH_2O	15 LPM	14.5 LPM	93.50%
	Amplitude	75 cmH_2O			
700	MAP	31 cmH_2O	11.9 LPM	10.33 LPM	94%
	Amplitude	65 cmH_2O			

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/cmH_2O.

[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.

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