international BIOMEDICAL®

TXP®-2D System

Neonatal High-Frequency Percussive Ventilator

OPERATOR'S MANUAL

EN

MADE IN THE USA

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This manual was originally released and supplied in English.
For a list of available translations, contact sales@int-bio.com.

All ventilators should be operated and serviced only by trained professionals. International Biomedical'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

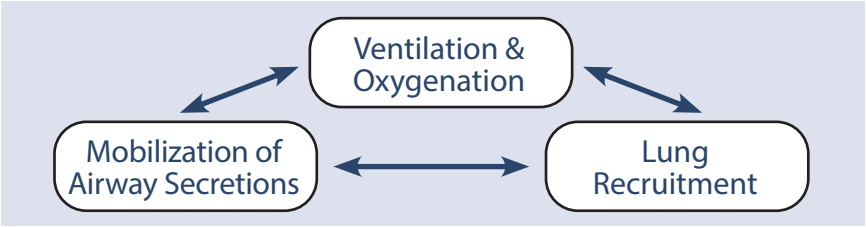
Designed specifically for transport use, the TXP®-2D is a flow-regulated and time-cycled ventilator that provides high-frequency percussive ventilation (HFPV). This HFPV system supports both diffusive and convective flow by stacking breaths in cumulative subtidal volumes, allowing for ventilation, airway clearance, and lung recruitment for most neonatal patients.

Phasitron® Breathing Circuit 731-8609

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

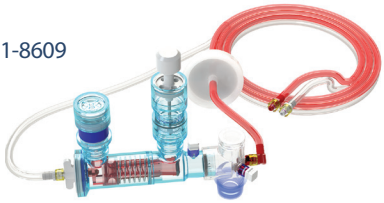


The effects of HFPV therapy occur with or without the cooperation of the patient. HFPV provides a percussive subtidal gas exchange within the respiratory bronchioles with associated alveolar recruitment, maintaining a minimal mean intrathoracic expiratory pressure increase for peripheral lung recruitment, while minimizing the potential for induced barotrauma.

Package Contents

TXP®-2D Transport face panel

Phasitron® Kit 731-8609 with 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 NxtGen, Aviator or Voyager transport incubator. The TXP®-2D ventilator is designed only for use with Sentec/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. ⚠ **WARNING:** The patient **MUST be under continuous observation by a clinician**.

Responsibility of the Clinician

- Read the User Manual before using the Device.
- **Caution:** 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 $TcPCO_2$ or $Sp0_2$ 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 731-8609 (REF A50605-D) Breathing Circuit is specifically designed for use with the TXP®-2D ventilator. Use of unopened 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.
WARNING ⚠	The patient must be under continuous observation by a clinician.
WARNING ⚠	Portable and mobile RF communications equipment can affect the performance of the TXP®-2D System. Use the TXP®-2D System according to the information contained in this adden-
WARNING ⚠	The TXP-2D® System should not be used adjacent to or stacked with other equipment, except as specified in the Instruction Manual. If adjacent or stacked use is necessary, the TXP-2D® System should be observed to verify normal operation in the configurations in which it will be used.
WARNING ⚠	Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti- theft/ electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.
WARNING ⚠	Do not operate the TXP-2D® System in a Magnetic Resonance Imaging (MRI) environment.

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 accessories designed specifically for use with the TXP®-2D. Use of unopened 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 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 read the user manual and 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.
Sale	Federal law restricts this device to sale by or on the order of a physician.

Document Symbols

	WARNING		Type BF Applied Part
	CAUTION		Single Patient Use
	Read the operator's manual before use	Rx Only	Prescription Only
CE	CE marking	REF	Catalog Number
	Manufacturer	LOT	Lot Number
	Manufacture Date	EC REP	European Representative
NON STERILE	Non-Sterile	LATEX	Not Made with Natural Rubber Latex
PHT DEHP DIBP DBP BBP	Does Not Contain the Phthalate Plasticizers DEHP, DIBP, DBP, or BBP		Disposal
UDI	Unique Device Identification		Refer to instruction manual/booklet

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 inte TM08/14/25 nded, liability for the performance of TXP®-2D shall always pass to the owner or operator. Modifications to the device are

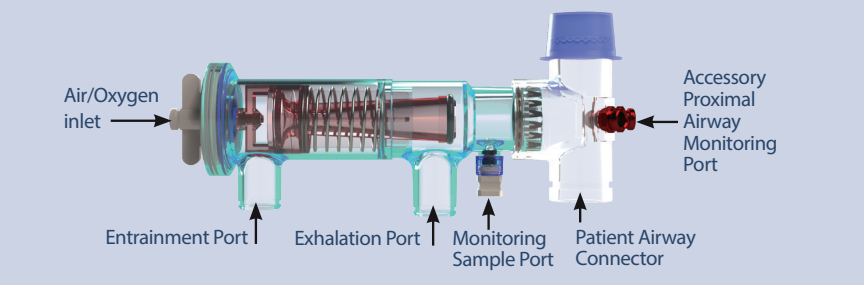
Accessories

⚠ 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.

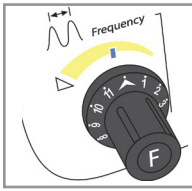
Chapter 2: System Description

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.

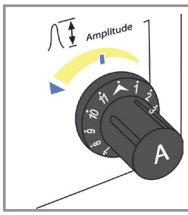
Frequency Control Knob



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

Caution: *The rate may differ at different altitudes.*

Amplitude Control Knob



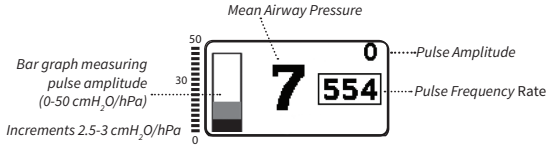
The Amplitude control knob determines the amplitude delivered to the patient during the pulse.

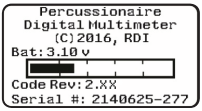
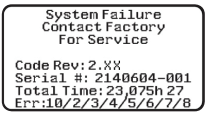
NOTE: *Amplitude is affected by lung compliance and resistance. Amplitude is attenuated by resistance and compliance to an airway pressure.*

The Digital Display (DD)

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

DD OPERATING MODES

1. **POST** (Power-On Self-Test) Percussionaire Digital Multimeter (C) 2014, RDI Bat: 3.05V Total Time: 23,075h 27 Code Rev: 2.XX Serial #: 2140604-001	When batteries are installed in a DD, 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 DD 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 DD until the POST check is complete and the screen is blank, indicating Sleep mode.*
2. **Wake Mode** 0 7 554	To wake up the DD, ensure the ventilator pressure is greater than 7.0 cmH_2O/hPa for pulsing, 2.5 cmH_2O/hPa at the Phasitron® patient delivery port for more than 1 second. DD 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. 

DD 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 DD 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 DD enters Sleep mode after 25 minutes.
5. **Sleep Mode** Blank screen, indicating DD 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 DD enters the Wake mode.
6. **Fault Mode**  	The DD 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, DD 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, DD may be used. If system failure screen recurs, contact International Biomedical® for factory service.*

Side and Rear Panel Features

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

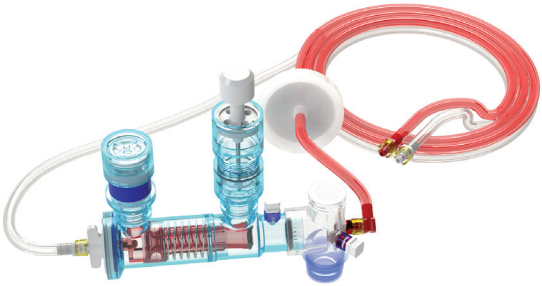
Connection for Phasitron® red tubing for the Proximal Airway Monitoring Port

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

Chapter 3: Setup

Phasitron® Kit 731-8609 (REF 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.

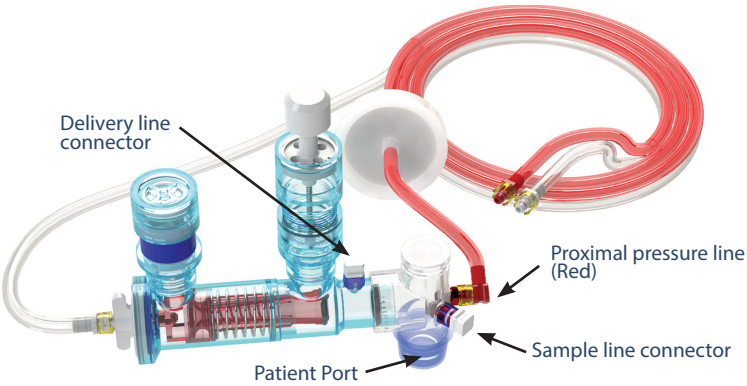


Nitric Oxide

Setup Instructions

1. Replace standard Phasitron® swivel tee with N.O. swivel tee (if applicable).
2. Connect AeroNOx2.0™ delivery line.
3. Connect AeroNOx2.0™ sample line.
4. Connect red proximal airway port from TXP®-2D unit to proximal airway monitoring port.
5. Set desired TXP®-2D settings.
6. Set desired AeroNOx2.0™ 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; refer to your Hospital/Institutions guidelines.***

Control	Neonate < 5Kg
Operating Pressure (psig)	40-42 (psig)
Amplitude	15-25 cmH_2O
PEEP Pulse Frequency Rate (cycles)	8-15 cmH_2O 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

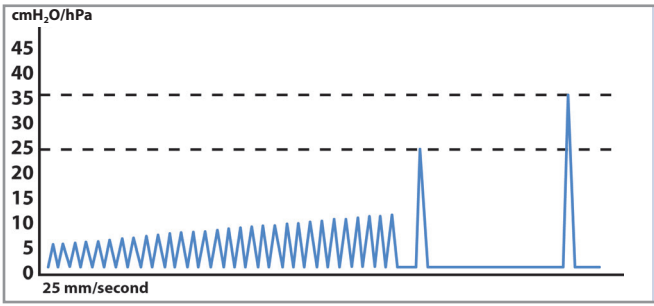
CAUTION ⚠	If the high-frequency rate is changed, the actual PIP may also change. Recheck and adjust amplitude after any high-frequency rate change.

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

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

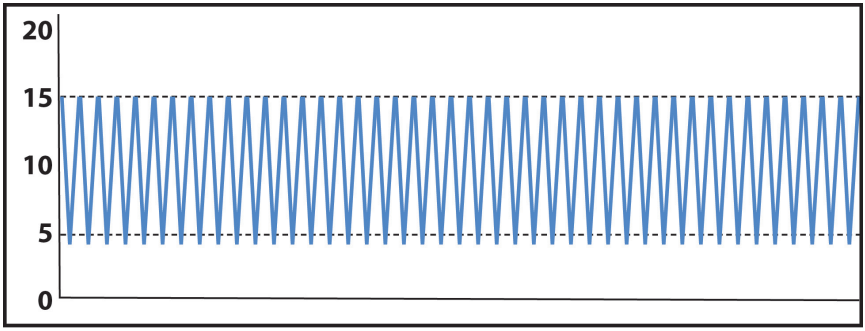
- SpO_2
- Blood Pressure and Perfusion
- Chest Wiggle
- Breath Sounds
- Ventilator Settings
- Phasitron and ETT positioning
- Blood gas ~ 20 minutes after starting therapy, after an adjustment, and then every 30 to 60 minutes

Ventilation

Control over arterial PCO_2 is achieved by manipulating delivered volumes.

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.
Adjust the attached 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	Increase FiO2
b) PEEP/MAP	Increase in 2 cmH_2O increments
c) Frequency	Increase in 60 pulses per minute increments
d) Amplitude	Increase in 2 cmH_2O increments
INCREASE VENTILATION: ↓ $PaCO_2$	
a) Amplitude	Increase in 2cmH_2O increments
b) Frequency	Decrease in 60 PPM increments
c) PEEP	Decrease in 2cmH_2O increments
DECREASE VENTILATION: ↑ $PaCO_2$	
a) Amplitude	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 89°F) Humidity 5%-95% Elevation 0-9842ft
	Storage and Transport Range	Temperature 10°C to 25°C (50°F to 77°F) Relative Humidity <93% non-condensing
Phasitron®	Operating Range	Frequency: 0-999 pulses per minute Pressure: 0-150 cm H_2O/hPa

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.

To ensure optimal performance and extend the service life of your unit, it is essential to conduct an annual functional check. By maintaining the units in a clean and moisture-free condition, a four-year interval between mandatory overhauls can be expected. For all maintenance and servicing needs, the unit must be processed through an International Biomedical authorized service center. To initiate this process, you can obtain a return material authorization number (RMA) by contacting International Biomedical Customer Service at (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.

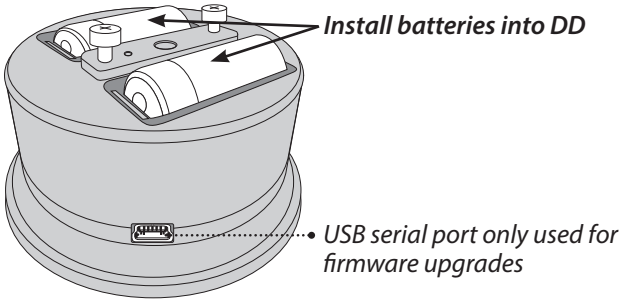
Phasitron® Kit 731-8609 (REF A50605-D) Breathing Circuit

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 Display (DD)

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



Side view of DD

It is recommended to change DD batteries every 6 months.

Changing DD Batteries

1.	Press on the DD's bezel and twist counterclockwise approximately 20 degrees.
2.	Gently pull on the DD 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 until screen turns off.
5.	Install the DD back into the housing and twist clockwise until the stop is felt.
6.	See POST mode instructions to verify display operation.

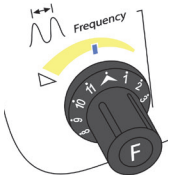
NOTE: *The DD has a USB port that is used for firmware download only. It is not enabled during normal operation.*

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 International Biomedical® Part #888-0301. 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 International Biomedical® 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 greater than 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 display indicating a lower than expected pressure.	The display 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. 
DD has no display	No signal to DD	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®.
	DD not activated	The Phasitron® patient port must see a pressure of 2.5 cmH_2O for more than one second to enter wake mode.
	DD display does not stay on.	Confirm the Phasitron® is connected to the patient, test lung, or occluded for more than 5 seconds to activate DD.
	DD not functional	Check power connection and reconnect
DD 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 DD software	Send the DD 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

Please complete the below steps in the following order. If your product is marked as "Fail" for any of the below line items, contact the customer service department, orders@int-bio.com.

1.	Connect Percussionaire® breathing circuit and A50605-D to TXP-2D.
2.	Connect neonatal test lung patient connection.
3.	Open **PEEP valve** to full counterclockwise position, "Open" position.
4.	Rotate TXP-2D **Frequency** control knob to full clockwise position.
5.	Rotate **Amplitude** control knob full counterclockwise.
6.	Observe a frequency of 185-250 bpm.
7.	Observe a Mean Pressure (MAP) between 20 and 40 cmH_2O.
8.	Rotate **PEEP valve** from "Open" to "Closed" position-observing an increase in Mean pressure. **Change of less than 5 cmH_20 = Fail.**
9.	**Rotate PEEP valve** from "Closed" to "Open" position-observing a decrease in Mean pressure. **Change of less than 5 cmH_20 = Fail.**
10.	Rotate **Amplitude** control knob clockwise.
11.	Observe a gentle decrease in amplitude until "off" at the full clockwise position.
12.	Rotate **Amplitude** control knob to full counterclockwise position.
13.	Rotate **Frequency** control knob slowly to full counterclockwise position.
14.	Observe a smooth increase in frequency.
15.	Observe a frequency of >600bpm.
16.	Observe a Mean Pressure (MAP) between 20 and 40 cmH_2O.
17.	Rotate Frequency control knob to full clockwise position.
18.	Rotate **Amplitude** control knob to the full "off" clockwise position.
19.	Pre-Use Check 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	Temperature 18°C to 26°C (64°F to 79°F)
Storage and Transport Range	Temperature -30°C to 60°C (-22°F to 140°F) Up to 75% Relative Humidity
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:	4 years
Essential Performance:	• Frequency not to go below 60 cycles per minute. • Minimum amplitude pressure not to exceed 7cmH2O.

Digital Display (DD) Specifications

Pressure Resolution	±1 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)

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 731-8609, 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 Display.
[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 added
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 731-8609, 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 Display.
[3]Inspiratory and Expiratory flow measured from peak to trough.

Manufacturer's Declaration - Electromagnetism

The following tables contain the manufacturer's declarations for the TXP-2D® System electromagnetic susceptibility, electromagnetic emissions, electromagnetic immunity, recommended separation distances between TXP-2D® System and portable and mobile RF communications equipment, and a list of compliant cables.

Environment of Use: The device is intended for use in institutional/hospital environments. The TXP-2D® System does not connect to hospital/institutional mains or network and is solely pneumatic and battery operated.

⚠ WARNING: Portable and mobile RF communications equipment can affect the performance of the TXP-2D® System. Use the TXP-2D® System according to the information contained in this addendum and the Instruction Manual.

⚠ WARNING: The TXP-2D® System should not be used adjacent to or stacked with other equipment, except as specified in the Instruction Manual. If adjacent or stacked use is necessary, the TXP-2D® System should be observed to verify normal operation in the configurations in which it will be used.

⚠ WARNING: Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti- theft/ electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

Electromagnetic Susceptibility

The TXP-2D® System complies with the requirements of IEC 60601-1-2 (EMC Collateral Standard), which includes E-field susceptibility and ESD requirements. However, even though the device is compliant at the levels of immunity specified in the standard, certain transmitting devices (cellular phones, walkie talkies, cordless phones, paging transmitters, etc.) emit radio frequencies that could interrupt operation if located in a range too close to the TXP-2D® System. It is difficult to determine when the field strength of these devices becomes excessive. Practitioners should be aware that radio frequency emissions are additive, and that the TXP-2D® System must be located a sufficient distance from transmitting devices to avoid interruption. Consult with your institution's biomedical engineering department in case of interrupted operation, and before relocating any life support equipment.

⚠ WARNING: Do not operate the TXP-2D® System in a Magnetic Resonance Imaging (MRI) environment.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The TXP-2D System uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any inteference in nearby electronic equipment.
RF Emissions CISPR 11	Group A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment. This device complies with 47 CRF 15 Federal Communications Commission Rules (FCC) for radio frequencies devices. (1) the TXP-2D® does not cause harmful interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Sentec can void the user authority to operate the device.

Electromagnetic Immunity

Immunity Test	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact + 2, 4, 8 and 15 kV air	The TXP-2D® System uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any inteference in nearby electronic equipment.
Power Frequency (50-60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Proximity

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz Pulse Modulation	27 V/m	The TXP-2D® System is suitable for the electromagnetic environment of typical hospital settings.
	450 MHz: 28 V/m @ FM Modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz, 9 V/m @ 217 Hz Pulse Modulation	9 V/m	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse Modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation	28 V/m	
	2450 MHz: 28 V/m @ 217 Hz Phase Modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse Modulation	9 V/m	

Compliance & Disposal

Standards

This device is designed to conform to the following standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for safety
- IEC 60601-1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304: Medical device software — Software life cycle processes
- IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for safety and essential performance - Collateral Standard: Usability
- IEC 62366-1: Medical devices — Part 1: Application of usability engineering to medical devices
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing (Biocompatibility)
- ISO 18562-1 Biocompatibility Evaluation of Breathing gas Pathways in Healthcare Applications - Part 1 Evaluation and Testing within a Risk Management Process
- ISO 14971: Application of Risk Management for Medical Devices

WEEE Disposal:

European consumers are obliged by law to dispose of Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2012/19/EU.

1. All electrical and electronic waste must be stored, collected, treated, recycled, and disposed of separately from other waste.
2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country.
3. The batteries of the Digital Display are not rechargeable. Dispose of the old batteries in accordance with local, state, federal, and international laws.

Limited Warranty

Unless otherwise specified, International Biomedical warrants all products of its manufacture at the time of shipment to be free from defects of material and workmanship for a period of twelve months from the date of shipment when owned by the original purchaser. Any product which is believed to be defective, if returned within twelve months after date of shipment by the Company with freight prepaid and found by the Company's inspection to be defective within the terms of this warranty, will be repaired or replaced free of charge and shipped, freight prepaid, to any point in the United States. If inspection by the Company of any such product does not disclose any defect within the terms of this warranty, the Company's regular charges for repairs or replacement and freight shall apply. All consumable and disposable products are guaranteed to be free from defects upon shipment only. The warranty period for batteries is limited to 90 days from date of shipment. This warranty specifically excludes and replaces all other express and implied warranties. The Company shall have no liability under any warranty in any amount greater than the Company receives for the sale of the product involved.

Limited Warranty

The use and manner of use of the Company's products shall be the responsibility of the purchaser and the purchaser covenants and agrees to indemnify and save harmless the Company in respect to any loss and damage that may arise through the use by the purchaser, or others, of any of the Company's products. This warranty is rendered void and International Biomedical cannot be held liable for conditions resultant therefrom if:

1. Damage to the unit is incurred as a result of mishandling.

2. The customer fails to maintain the unit in a proper manner.

3. The customer uses any parts, accessories, or fittings not specified or sold by International Biomedical.

4. Sale or Service is performed by a non-certified service / dealer agency or any other unauthorized agency.

All shipping claims must be made within 30 days from date of shipment from International Biomedical, otherwise factory will not be liable for claims of missing items. Any item ordered in error and returned to the factory for credit, will be subject to a minimum restocking charge of 15%. Requests for returning items must be made within 30 days of factory shipment date. International Biomedical will accept no returned goods without a Returned Material Authorization number (RMA) obtained from Customer Service Department.

international BIOMEDICAL®

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