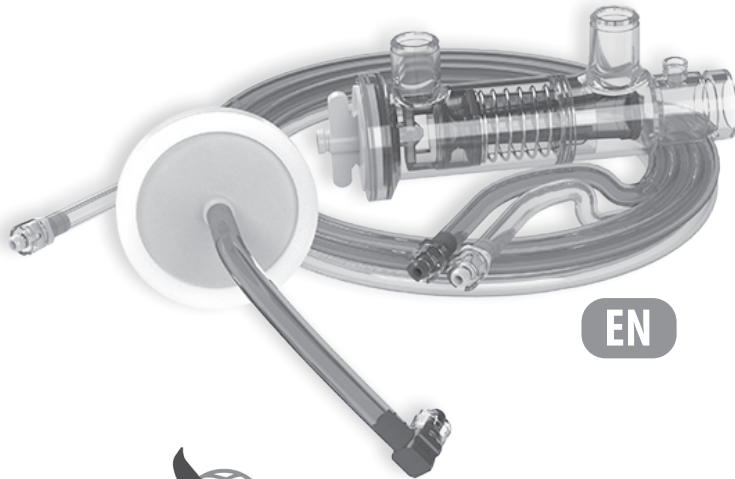




PHASITRON[®]

Breathing circuit A50606-TXP



EN



PERCUSSIONAIRE[®]
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Phasitron[®] Breathing Circuit Kit, Single Patient, Instructions for Use - English

Intended Use

The Phasitron[®] breathing circuit kit is intended to be used for continuous ventilation intended for the controlled ventilation of patients.

Patient Population

Neonates, pediatric, and adults.

Indications for Use

The Phasitron[®] breathing circuit kit is intended to be used with the TXP[™] 5 ventilator either hospital or pre-hospital use where emergency care is being provided, including intra-hospital or external hospital transport.

Absolute Contraindications

- Untreated tension pneumothorax
- Untrained or unskilled operator

Relative Contraindications

- History of pneumothorax
- Recent pneumonectomy
- Pulmonary hemorrhage
- Myocardial Infarction
- Pulmonary air leak (without functioning chest tube)
- Lack of patient cooperation
- Vomiting

Possible Adverse Reactions

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

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

Before use, read, and understand the instructions completely before setting up and using your Phasitron[®] breathing circuit kit.

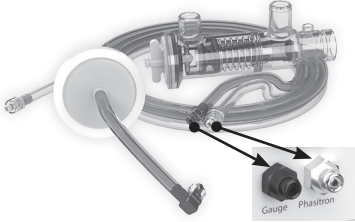
Precautions

- WARNING:** Indicates the possibility of injury to the user or operator.
- CAUTION:** Indicates the possibility of damage to the device. US Federal law restricts this device to sale by or on the order of a physician.
- CAUTION:** Do not expose to processing temperatures above 50°C/122°F.
- WARNING:** Single Patient Use

- ⚠ WARNING: Do not occlude the exhalation or entrainment ports.**
- All persons providing mechanical ventilation must be trained in the use of Percussionaire® High Frequency devices.
 - 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 ventilation.
 - Only use genuine Percussionaire® parts and accessories.
 - Never attempt to modify unit.

Phasitron® Setup

Connect breathing circuit to TXP™ 5 ventilator

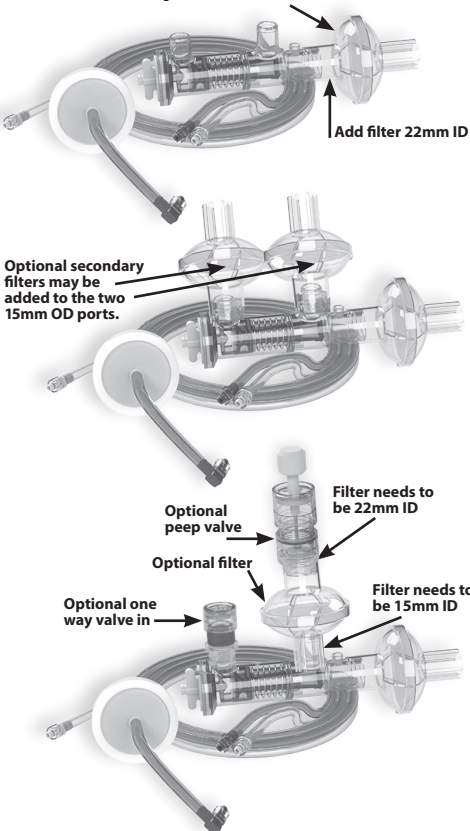


Connecting the TXP™ 5 ventilator to Phasitron®



Phasitron® valves and filtering set up Options

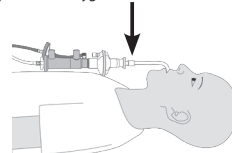
Recommended HME/HMEF bacterial/viral filter with an efficiency of >99.999% with a 2 cmH₂O or less flow resistance at 60L/min



Attach Phasitron® to patient airway using hospital approved HMEF

Always use hospital/institution protocol.

Supplemental oxygen can be added after filter.



Intubated patient with Phasitron®

Cleaning of Phasitron®

Follow hospital/institutional guidelines for cleaning, disinfection. Change Phasitron® breathing circuit kit every 7days, or prn if soiled.

Chemical Class	Active Ingredient
Bleach	5.25% Sodium hypochlorite
Alcohol	70% Isopropyl alcohol
Peroxide	3% Hydrogen peroxide
Benzyl Ammonium Chloride	N-alkyl dimethyl ethyl benzyl ammonium chloride, N-alkyl dimethyl benzyl ammonium chloride
Phenolic	Ortho-Phenylphenol, Ortho benzyl-para-chlorophenol
Quaternary Ammonium Chloride	Didecyl dimethyl ammonium chloride, Alkyl dimethyl benzyl ammonium chloride

Specifications

Percussion Frequency	0-999 pulses per minute
Pressure Range	0-150 cmH ₂ O/hPa
Run Time	Continuous
Flow	15 LPM
Red Line Filter	0.027 micron hydrophobic
Operating Range	Temp, 0° C to 49° C (32° F to 120° F) Relative humidity range 5% to 95%
Storage and Transport Range	Temp, -20° C to 60° C (-40° F to 140° F) < 93% non-condensing
Service Life	7 days
Shelf Life	2 years
Disposal	Recycle according to local laws

Limited Warranty

Percussionaire® Corporation warrants that the Phasitron® kit shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of 7 days. If the product fails to perform in accordance with the product specifications, Percussionaire® Corporation will repair or replace—at its option—the defective material or part. Percussionaire® Corporation will pay customary freight charges to and from Percussionaire® Corporation or an authorized Percussionaire® Corporation 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® Corporation 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.