PERCUSSIONAIRE®

Impulsator®
User Manual

Home Care
TRUE-IPV® Therapy Device

EN

Dear Customer,
Congratulations on the purchase of your Impulsator®! Your new TRUE-IPV® therapy device is portable, self-contained and easy to use. It allows you the freedom to go where you want to go while complying with the treatment plan prescribed by your doctor. To make sure you receive maximum benefit from TRUE-IPV® therapy and to ensure your safety, please read the enclosed Impulsator® User Manual. It contains important SAFETY and TECHNICAL DATA that should be kept handy for easy reference.
Your safety and satisfaction are important to us!
For assistance setting up or using the Impulsator®, or to report unexpected operation or events, please contact Percussionaire® or your local distributor. With proper care, the Impulsator® will reward you with long, trouble-free service life.
Thank you for placing your trust with us!
Sincerely,
Percussionaire® Corporation

1st Edition
First Printing July 2020

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, is 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.

Table of Contents

Chapter 1: Introduction

This chapter provides an overview of the Impulsator® device and TRUE-IPV® therapy.

Intrapulmonary Percussive Ventilation (IPV®)

Designed specifically for non-continuous home and institutional use, the Impulsator® is a pressure-limited, flow-interrupted, and time-cycled ventilator which delivers TRUE-IPV® therapy, a modality of mechanical ventilation, "Intrapulmonary Percussive Ventilation." The Impulsator delivers high-frequency percussive pulses approximately 60-400 cycles per minute. These high-frequency percussive pulses ramify throughout the airways and alveolar ducts, augmenting diffusive ventilation in the gas exchange regions of the lungs, allowing airway clearance and lung recruitment.

The Impulsator® system also supplies a dense aerosol mist that is delivered into the lungs during therapeutic percussion, serving to reduce the adhesive and cohesive forces of retained airway secretions.

Impulsator® Control Functions

i:e RATIO

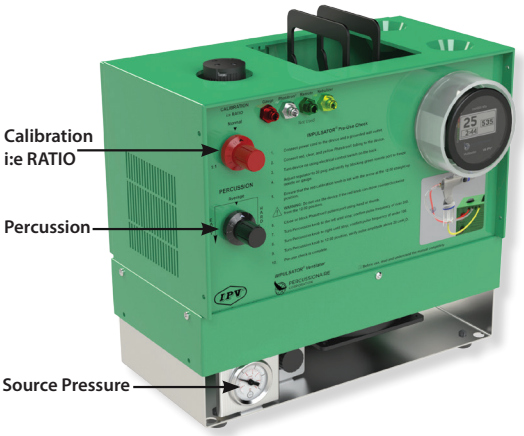
Used to adjust i/e percussion ratios. Kept in 12:00 position for patient use.

Percussion

Determines frequency of delivered breaths.

Source Pressure

Determines amplitude of percussive subtidal breath deliveries.

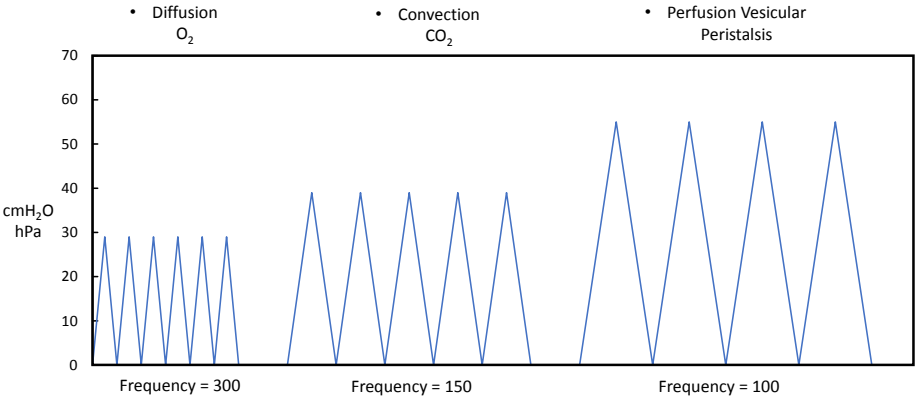



On/Off Switch


Power Plug

The Impulsator® home care device provides intrapulmonary percussive ventilation either invasively, through an artificial airway, or non-invasively, by mouthpiece or mask.

Three Components of TRUE-IPV®



f=300 Percussive Mechanical Mixing Diffusion	f=150 Percussive Convective Ventilation with Diffusion	f=100 Percussive Perfusion Vesicular Peristalsis

Effects of TRUE-IPV®

The effects of TRUE-IPV® therapy occur with or without the cooperation of the patient.

TRUE-IPV® 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 stabilization. This allows for mechanical ventilation to provide for peripheral lung recruitment while minimizing the potential for induced barotrauma.

Chapter 2: Intended Use

Indications for Use

The Impulsator® is indicated for mobilization of secretions and raising of endobronchial secretions, bronchodilation, reducing mucosal edema, and the resolution of diffuse patchy atelectasis.

Patient Population

The Impulsator® ventilator is for use on patient populations from pediatric through adult.

Absolute Contraindications

• Untreated tension pneumothorax	• Untrained or unskilled operator

Relative Contraindications

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

Possible Adverse Reactions

• Decreased cardiac output	• Increased intracranial pressure
• Pneumothorax	• Increased air trapping
• Hyper-oxygenation	• Pulmonary air leak
• Pulmonary hemorrhage	• Hyperventilation
• Gastric distension	

Physiological Benefits of TRUE-IPV®

• Recruitment of atelectatic lung	• Mechanical bronchodilation
• Improved FRC	• May Improve breathing pattern
• Decreased work of breathing	• Increased secretion mobilization

Clinical Limitations/Restrictions

Use of the Impulsator® is limited to patients, caregivers, respiratory therapists/clinicians who have received proper training and who have read and understand this manual.

⚠ **WARNING:** When used on a patient with an artificial airway (i.e., endotracheal or tracheostomy tube), a clinician must be present so that a one-to-one relationship exists. These devices enhance secretion clearance. Patients must be assessed pre- and post-treatment for a reduced vital capacity/FRC or the need for assistance in clearing airway secretions.

⚠ **WARNING:** Because pulmonary alveoli cannot be ventilated when their transmitting airways are obstructed, suction should be performed as necessary.

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

Document Symbols

⚠	**WARNING**		**Type BF Applied Part**
⚠	**CAUTION**		**Single Patient Use**
	Read the manual before use	℞ Only	**Prescription Only**
	Manufacturer	REF	**Catalog Number**
	Manufacture Date	LOT	**Lot Number**
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**

Chapter 3: Setup

Impulsator® Controller

Place the Impulsator® controller on the table or floor, in a place with good unrestricted airflow. Make sure the controller is away from curtains, sheets, bedspreads, or anything that might block the vents and airflow.

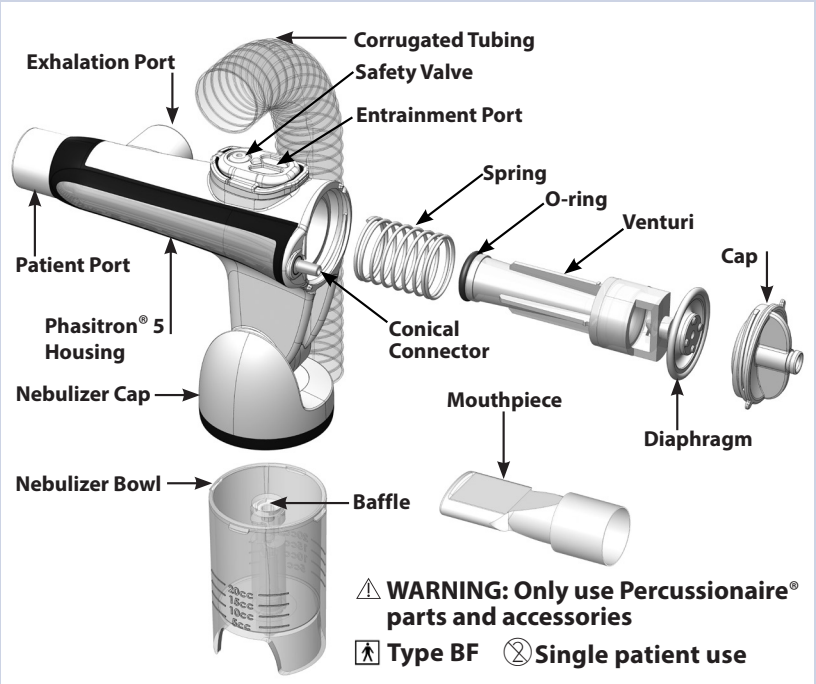
Plug the female end of the power cord into the back of the controller. Plug the male end of the power cord into a wall outlet.

Phasitron®5 Breathing Circuit Setup

The patented Phasitron®5 uses a unique venturi as a "clutch" mechanism to protect the lung from over pressure. By automatically adjusting to the resistance of the lung, the Phasitron®5 precisely and safely delivers the optimal amount and pressure of air required by the alveolar space. When lung resistance is low, as in a compliant lung, all the pulsed air from the Impulsator® enters the mouth of the venturi. Each air pulse draws up to four times as much additional air into the venturi tube. This low-pressure entrained air automatically fills the available space in the lung. The Phasitron®5 continuously and instantaneously adjusts to keep a gentle and safe air pressure, even in a compromised lung.

NOTE: *TRUE-IPV® therapy can only be achieved using the Phasitron®5.*

Phasitron®5 Diagram

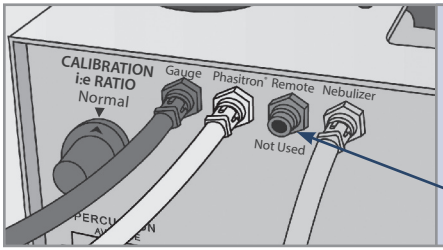


Configurations

Phasitron®5 kit can be used with or without a mouthpiece or standard mask (as shown below). Connection sizes: 15mm ID or 22mm OD.

Phasitron®5 without mouthpiece or mask	Phasitron®5 with mouthpiece (included)	Phasitron®5 with face mask (sold separately)

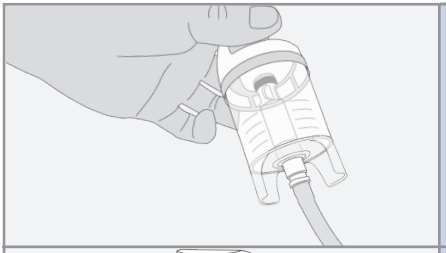
Connecting to the Impulsator®



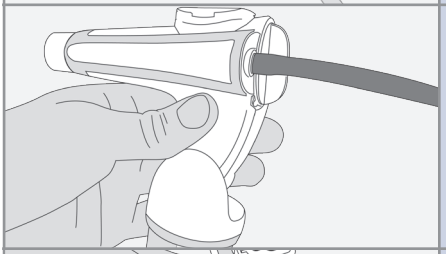
Connect red, clear, and yellow tubing connectors to the Impulsator® Model F00012 controller device.

⚠ **WARNING:** Green REMOTE connector is a vent; do not obstruct.

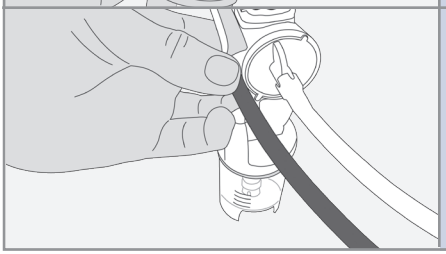
Connecting the Tubing Harness to the Phasitron®5



Connect yellow tubing quick-connect fitting to nebulizer bowl.

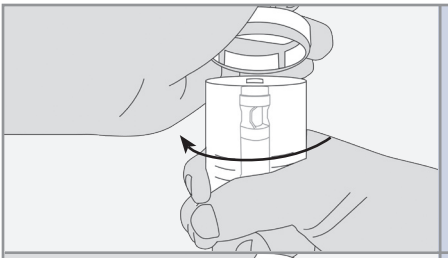


Press red tubing onto conical connector at rear of Phasitron® 5 body.

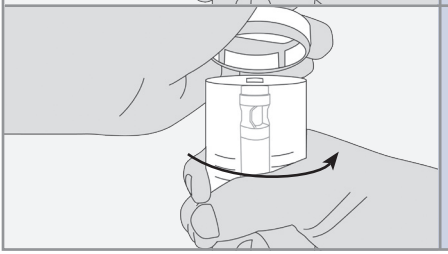


Connect the clear tubing quick-connect fitting to the cap at the rear of the Phasitron® 5 body.

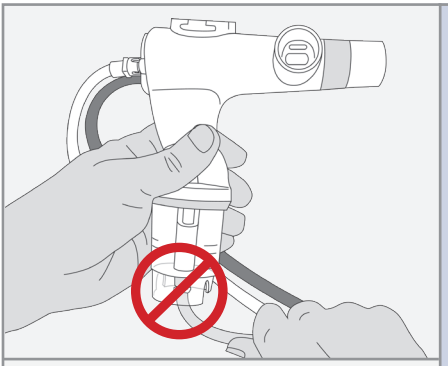
Adding Saline, Sterile Water, or Medication



Twist clockwise to open nebulizer bowl. Add prescribed amount.



Reverse to close.

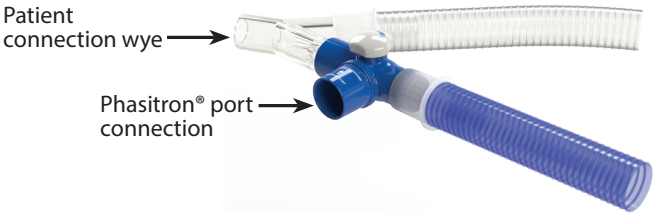


⚠ **CAUTION:** Ensure yellow nebulizer tubing is not bent. This may cause undue stress on connector.

⚠ **CAUTION:** Do not bend nebulizer bowl while holding the tubing. This may cause undue stress on the red line conical connector.

TRUE-IPV® In-Line Valve Setup

⚠ **WARNING:** In-line valve setup and use are for physicians, respiratory clinicians/therapists only.



Pediatric to Adult
Recommended to install as close to the patient wye as allowable

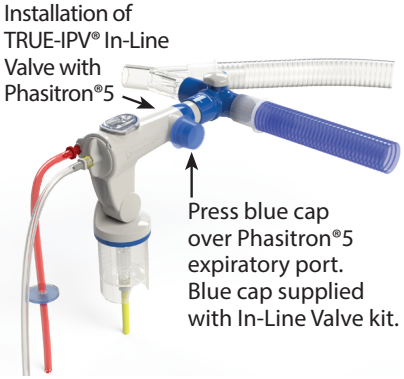
Insert TRUE-IPV® In-Line Valve into inspiratory limb of ventilator circuit.

⚠ **WARNING:** Ensure Pressure Relief valve is closed.

⚠ **WARNING:** Allow ventilator to cycle with valve in place.

⚠ **WARNING:** Ensure TRUE-IPV® In-Line Valve is inserted into inspiratory side of ventilator circuit.

Adding Phasitron® 5 to In-Line Valve



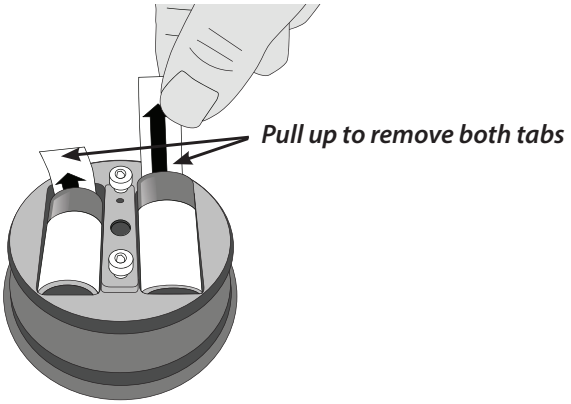
Install provided blue cap (color may vary) onto the Phasitron®5 expiratory port. Port must be occluded for proper use and treatment. The cap is provided with TRUE-IPV® In-Line Valve kit.

Fill nebulizer with 15 to 20 cc normal saline or prescribed medication. Aerosol consumption approximately .75 cc per minute.

⚠ **WARNING:** Blue cap must be removed when giving a direct treatment, either by mouth, mask, or directly connected to endotracheal tube.

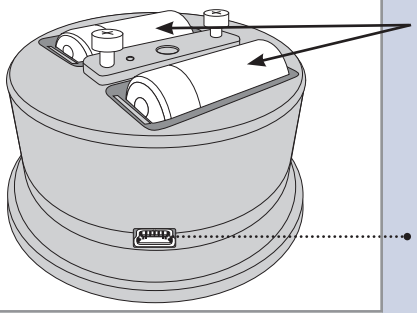
Percussionaire® Digital Multimeter (PDM) Setup

NOTE: *To access battery pull tabs, turn the PDM counterclockwise and remove from Impulsator® device.*



NOTE: *To ensure correct atmospheric pressure calibration at start up, remove batteries, wait 30 seconds and reinstall. Allow 15 seconds for power-on self-test. When screen goes blank, the multimeter can be installed into the device.*

Side view of PDM



NOTE: *The PDM has a USB serial port that is used for manufacturing, calibration and firmware upload. It is not enabled during normal operation.*

Changing PDM Batteries

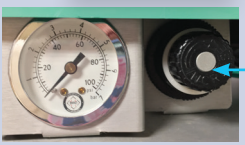
1.	Press on the PDM's bezel and twist counterclockwise approximately 20 degrees.
2.	Gently pull on the multimeter to remove it from the housing.
3.	Remove the two old batteries.
4.	Install two new batteries. Note that the positive terminals face the same direction. Wait 30 seconds until screen turns off.
5.	Install the PDM back into the housing and twist clockwise until the stop is felt.
6.	See instructions on Power-On Self-Test (POST) Mode section, to verify display operation.

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

A Low Battery indicator is displayed when battery capacity is nearing depletion.

Chapter 4: Controller Functions

Knob, Switch, Gauge

Knob, Switch, Gauge	Function
	The red **CALIBRATION** knob is kept in the 12:00 position (straight up).
	The **PERCUSSION** control knob adjusts frequency of pulses at a fixed i:e ratio. Controls the rate of high-frequency amplitudes delivered. Ranges from 100 to above 300 cycles per minute. Affects mean airway pressure.
	The Operational Pressure knob controls the peak operating pressure of the entire unit. The optimal pressure is between 30 psig (2.07 bar, 207 kPa) and 40 psig (3.4 bar, 345 kPa).
	The Source Pressure gauge shows the operating pressure of the entire unit.
	The Percussionaire® Digital Multimeter (PDM) has six different operating modes: POST, Wake, Active, Report, Sleep, and Fault. See Percussionaire® Digital Multimeter (PDM) section for detailed information on each mode.
 	The device uses an inner white felt filter and an outer gray/black foam filter. The filters must be in place at all times when the device is operating. ⚠ **CAUTION:** The foam inlet filters are required to protect the ventilator from dirt and dust. Wash both filters periodically. Replace every six months, or when damaged, for proper operation.

Percussionaire® Digital Multimeter (PDM)

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

Power-On Self-Test (POST) Mode

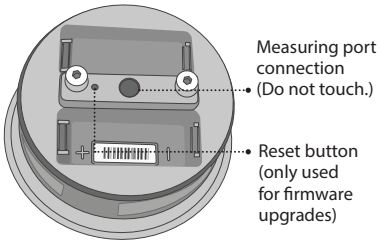
When batteries are installed in a system, the Percussionaire® Digital Multimeter (PDM) software displays the software revision, battery voltage, total usage time and serial number for 15 seconds. This Start-Up mode allows the software to perform additional tests on the hardware that are part of the Power-On Self-Test. If any errors are detected in POST, the PDM enters the Fault mode (see Fault Mode section).

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

System Information Display

```
Percussionaire
Digital Multimeter
(C) 2014, RDI
Bat: 3.05V
Total Time: 23,075h 27
Code Rev: 2.XX
Serial #: 2140604-001
```

Rear view of PDM



Wake Mode

To wake up the PDM, ensure the ventilator pressure is greater than 2 cmH_2O/hPa at the Phasitron® 5 patient delivery port for more than 1 second, with patient port blocked.

The PDM remains on for the first 15 seconds, showing the Bar-Graph timer.
If usage is stopped within 12 seconds, the PDM enters Report mode. After 15 seconds, the current session continues counting from 16 seconds, which turns into Active mode.

The PDM display screen in Wake mode

NOTE: *Display numbers are for reference only.*

Model: Home IPV
Device: Impulsator®
Display Metrics: Pulse Frequency Rate, Pulse Amplitude Pressure

Active Mode

Home IPV: Impulsator® Display

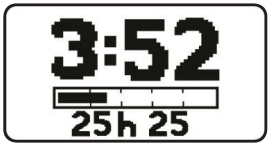
At 16 seconds, the PDM enters Active mode. The timer bar will change to a numeric display, showing the current usage Session Timer. Above the timer reading is the pulse amplitude display. This is calculated from the pressure measurements at the moment of instantaneous peak and trough amplitude, averaged over 5 seconds. The Active mode display also shows the currently measured percussion rate/pulse frequency.

The PDM displays the usage Session Timer in minutes and seconds. The Session Timer is the total time of the current usage. The Session Timer can display a maximum of 59 minutes and 59 seconds. If usage has been stopped for more than 5 minutes, the Session Timer will reset and start over.

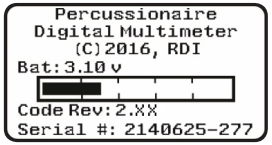
NOTE: *To display the most recent usage duration time, see Report mode.*

Report Mode

A.



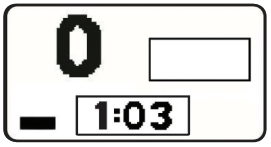
B.



C.

The Session Timer and the Total Usage Timer **(A)** are displayed for 2 seconds, followed by the System Information page **(B)** for 2 seconds, alternating. The alternating page display continues for 5 minutes, or until usage resumes and the PDM enters **Active** mode.

During the 5-minute period, a horizontal bar graph indicates the time by moving from left to right at a fixed rate. 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 PDM enters **Sleep** mode after 25 minutes.



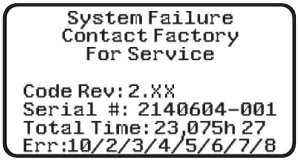
When the Impulsator® is switched off, the measurements drop to zero after a few seconds

Sleep Mode

Blank Screen – PDM Sleep Mode

In 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 or 2 hPa at the Phasitron® delivery port, for more than 1 second, the PDM enters the Wake mode.

Fault Mode



The PDM 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, PDM serial number, the total usage time and an error code for the exclusive use of the factory.

In all other modes, the software continuously monitors the hardware for errors, as well as verifying that each data sample has a valid value. If an error is detected, the software logs the error and reboots the processor. Rebooting causes it to recover from a transient error. After reboot, the processor returns to the same mode it was in before the reboot. If more than one error is detected in any 10-second period, it is considered a fatal error, and the software enters **Fault** mode.

NOTE: *Pressure faults are triggered by a continuous pressure of more than 150 cmH_2O for more than 5 seconds during Wake and Active modes.*

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 until the screen turns off. If POST check runs correctly, PDM may be used. If System Failure screen recurs, contact an authorized Percussionaire® service center.*

Fault Logging

The software keeps track of several types of hardware and data faults. All faults are logged in the microcontroller's memory and are retained even if the batteries are removed. If multiple faults happen within 10 seconds of each other, the PDM stops normal operation and enters Fault mode. In this mode, a subset of the collected fault information is displayed on the LCD. This data is intended for manufacturing and repair use only.

The user can exit the Fault mode by removing and replacing the batteries. This resumes normal operation of the PDM but does not erase the faults stored in memory or fix the problem that caused the fault.

Fault Detection

The PDM has both hardware and software fault detection. This is a dedicated hardware "watchdog" that runs on an independent clock source and can continue to operate even if the main microprocessor's clock fails or the microcontroller pauses in any way. The independent fault detection is reset each time a valid pressure reading (free of hardware and software errors) is obtained.

In addition to the hardware fault detection, the software also implements a fault detection "watchdog." This watchdog detects if a software task fails to complete within the specified time, logs an error, and resets the processor.

Chapter 5: Pre-Use Check

Regularly perform this test before using the Impulsator® TRUE-IPV® device. If the Impulsator® has been stored in conditions outside the operational conditions outlined in the Technical Specifications section of this manual, allow the unit to acclimate for 2 hours before using.

1.	Check that the Impulsator® is clean on the outside and the power cord is in good condition.
2.	Connect power cord to the device and a grounded wall outlet.
3.	Connect Phasitron® 5 and tubing to the device.
4.	Turn device on using electrical control switch on back of device.
5.	Listen for the compressor to start.
6.	Adjust regulator to 30 psig.
7.	Ensure that the red **CALIBRATION** control knob is set with the arrow at the 12:00 straight-up position (this control should not be adjusted during normal use).
8.	Close Phasitron® patient port using hand or thumb without mask or mouthpiece.
9.	Turn **PERCUSSION** control knob to the left stop; confirm pulse frequency of over 300.
10.	Turn **PERCUSSION** control knob to right stop; confirm pulse frequency of under 100.
11.	Turn **PERCUSSION** control knob to 12:00; verify pulse amplitude above 20 cmH_2O.
12.	Occlude the green port with finger and observe that the pulses stop.
13	Turn device off.

Chapter 6: General TRUE-IPV® Therapy Protocol for Adults

⚠ **WARNING:** Never run the Impulsator® without liquid in the nebulizer during your treatment. This is required for airway hydration.

1.	The patient should be in an upright comfortable armchair or lying with head and shoulders elevated by pillows.
	NOTE: *Patient's gravitational position is not a factor with TRUE-IPV®.*
2.	Connect the Phasitron® 5 kit as indicated on package insert or Phasitron®5 Breathing Circuit section.
3.	Add prescribed medications into nebulizer bowl as directed by physician, to a maximum of 20 ml. If no medications are prescribed, use normal saline or sterile water.
4.	Ensure red **CALIBRATION** knob is at the12:00 position (straight up).
5.	Turn the Impulsator® compressor switch on, rotate the Operational Pressure control regulator knob to an operating pressure of 30 psig.
6.	If needed, allow patient to observe and feel pulses on their hand before either connecting to the airway or breathing through the mouthpiece. This will help familiarize the patient with the sensations they will experience during treatment.
7.	When using a mouthpiece, the patient should be instructed to inhale and exhale through the pulses. Most patients will initially allow percussive bursts of air to leak through their nose at the expense of an observable chest movement (wiggle). Start to notice the chest movement as the patient exhales through the mouthpiece. Advise the patient to take normal spontaneous breaths through the pulses whenever they desire. The objective is to complete a treatment session of 15 to 20 minutes. Initially, cheek fatigue might result in early termination of treatment. However, this is soon eliminated as the patient gets used to the treatment. When a patient has an artificial airway, the process is similar. The patient must be observed for signs of distress. While cheek fatigue is less of a consideration, pauses or breaks may still be necessary for the patient.
8.	The patient should be instructed to keep lips and cheeks tight to avoid nasal air venting. As the patient learns to prevent air from leaking out of the lip seal around the mouthpiece, the **PERCUSSION** control knob arrow can be gradually rotated clockwise toward the 12:00 position (straight up).

9.	After the ability to prevent leaking of percussive air deliveries from the nose and mouth is learned, the entire percussion frequency band should be scanned by briefly rotating the **PERCUSSION** control knob arrow from easy to hard, back and forth (several times), returning the arrow to the 12:00 position (straight up). This will help raise secretions from the bronchial airways.
	NOTE: *Always pay attention to patient comfort.*
10.	The selected source pressure may be increased for effective endobronchial percussion by assessing chest percussion (wiggle). Nominal operating pressure is 30-40 psig.
11.	For prolonged therapy with mechanical airways, etc., additional diluents or medication may be used in the nebulizer, as prescribed by physician.
12.	When treatment is complete, the Impulsator® controller should be turned off. The Phasitron® 5 should be rinsed, cleaned, and stored in the supplied bag until the next treatment.
	NOTE: *The Phasitron® 5 is for a SINGLE patient only, to be used multiple times.*

Chapter 7: Cleaning and Disinfection

Controller

Clean the controller according to home care/institutional protocols. 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.

⚠ **CAUTION:** Do not spray any cleaning solution directly onto the device.

⚠ **CAUTION:** Do not immerse or allow liquids to access the device.

Percussionaire® Digital Multimeter (PDM)

Clean the PDM when visibly soiled or according to facility protocols. Do not spray any type of cleaner directly onto the multimeter. Percussionaire® recommends cleaning the glass with a product or chemical approved for cleaning glass only. When cleaning outer bezel, use a moist cloth with warm soapy water. Use of cleaning methods not outlined in these instructions will cause damage to the multimeter.

⚠ **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 a CR123A only, or Percussionaire® part PRT- B13350. Use of another cell may present a risk of fire or explosion.*

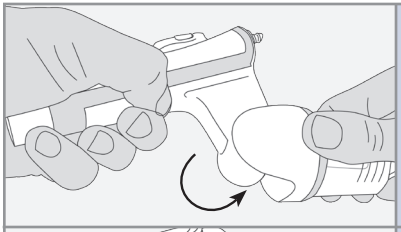
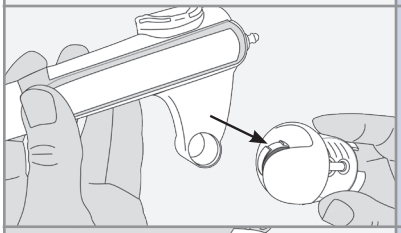
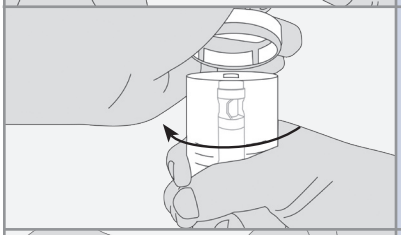
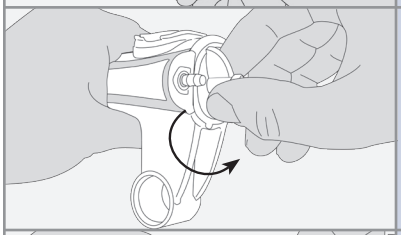
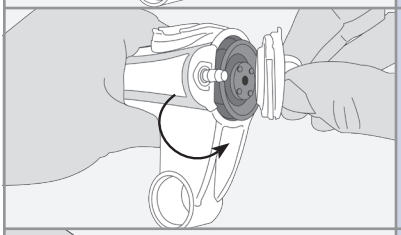
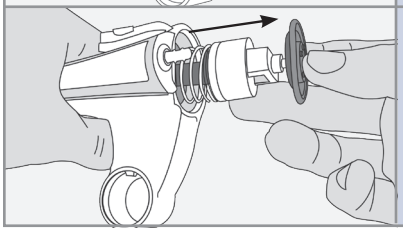
Dispose of in accordance with appropriate regulations, local, state and country.

Phasitron®5 Breathing Circuit

Clean the Phasitron® 5 according to home care/institutional protocols. It is not necessary to clean the Phasitron® 5 after each use; however, rinsing with sterile water is advised. Cleaning instructions are for single patient, multiple uses. Before starting cleaning process, wash hands thoroughly with soap and water or use an alcohol-based hand sanitizer. When disassembling the Phasitron® 5, visually inspect the exterior of all parts, including tubing, for corrosion, discoloration, pitting, and missing O-rings. Do not immerse the antibacterial filter.

Disassembly of the Phasitron® 5

Disconnect tubing from controller device and Phasitron® 5.

	1. Rotate nebulizer bowl towards rear of Phasitron®5, moving gently past the stop to release.
	2. Gently lift nebulizer cap and bowl to separate from Phasitron®5.
	3. Holding the nebulizer cap, twist the nebulizer bowl to remove bowl from cap. Discard any unused medication in accordance with physician orders.
	4. Twist white cap on the rear of Phasitron®5 to remove.
	5. Remove cap.
	6. Remove sliding venturi and spring from Phasitron®5 body.

Cleaning and Disinfecting Solutions

The Phasitron® 5 breathing circuit has been tested for biocompatibility with the following cleaning solutions:

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 chlorides 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

Cleaning Phasitron® 5

1.	Thoroughly rinse each of the disassembled parts (except for tubing harness and filter) under warm running tap water for approximately 10 seconds.
2.	Use fragrance-free liquid soap added to a clean bowl or basin with warm water. ⚠ **CAUTION:** Do NOT use "white" liquid dish soaps or antibacterial liquid dish soap as they may contain additives harmful to parts of the Phasitron® 5 kit.
3.	Hand wash all parts of the Phasitron® 5 kit and accessories in the warm soapy water. Use a pipe cleaner to clean monitoring port with warm soapy water. 
4.	Rinse all parts thoroughly using sterile water.
5.	Gently shake all parts to remove as much water as possible, then dry with a clean lint-free cloth or paper towel. Alternatively, place on a clean, lint-free cloth or paper towel and allow to air dry completely.
6.	Use a clean, damp cloth to wipe the exterior of the tubing harness with an approved alcohol-based cleaner.
7.	Inspect before reassembly for any remaining soil or damaged parts. Repeat cleaning steps if needed.
8.	Reassemble the Phasitron® 5 and place in the supplied bag until next use.
9.	Do not disinfect the Phasitron® 5 for reuse with more than one patient.

⚠ **CAUTION:** Use of cleaning methods not outlined in this User Manual may damage the Phasitron® 5 and accessories.

⚠ **WARNING:** The Phasitron® 5 breathing circuit is for a SINGLE patient, multiple uses.

Phasitron®5 Disinfection

Disinfection Solution:

Use standard household bleach (sodium hypochlorite 5.25%) for disinfection.
Mix solution of 1-part household bleach and 8-parts water.

Example: 8 ounces of bleach to 64 ounces of water, or 250 ml bleach to 2 liters of water.

Disinfection Procedure:

1.	Wear disposable gloves.
2.	Pour bleach solution into an airtight container large enough to hold 64 ounces or 2 liters.
3.	Completely immerse all the Phasitron® 5 parts, including mouth piece and mask, into bleach solution. Do not disinfect hydrophobic filter.
4.	Let soak for 30 minutes minimum. Do not exceed 1 hour.
5.	Rinse off cold-disinfection solution using sterile water or filtered water (less than or equal to 0.2-micron filter). Do not use tap water.
6.	Gently shake all parts to remove as much water as possible.
7.	Dry with a clean, lint-free cloth. Place on clean, lint-free cloth or paper towel and allow to air dry completely.
8.	Insert all parts into sealable plastic bag and store in a dry, clean location.

Dry Inside of Tubing

Dry the inside of the tubing with air from the controller device. Connect each tube, one at a time, to the yellow connector on the controller device. Turn on device and run for two minutes at a time to remove moisture. Hang tubing to air dry.

⚠ **WARNING:** Do not steam clean the controller or circuit. Injury or equipment damage could occur.

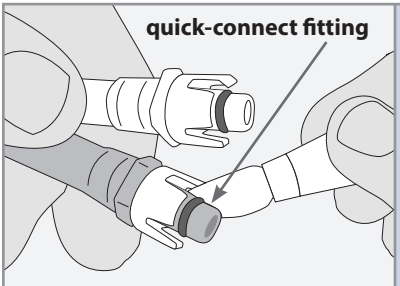
⚠ **WARNING:** Do not expose the unit to excessive moisture. Injury or equipment damage could occur.

⚠ **CAUTION:** Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.

⚠ **WARNING:** Percussionaire® makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection.

Phasitron® 5 Lubrication After Cleaning and Disinfection

Lubrication is needed only after cleaning and/or disinfection of your Phasitron®5 breathing circuit.

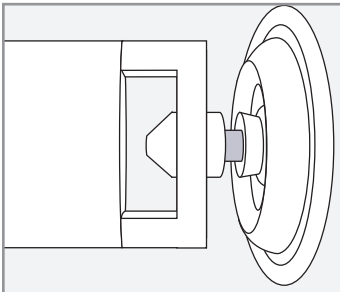


Wash hands thoroughly with soap and water or use an alcohol-based hand sanitizer before reassembly and lubrication.

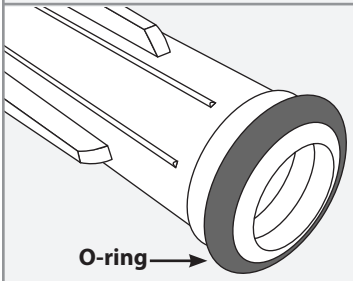
Lightly coat each quick-connect fitting O-ring with the Percussionaire® lubricant Lubetube, supplied with the Impulsator® device.

⚠ **CAUTION:** Use only Percussionaire®-approved lubricant.

Reassembly of the Phasitron® 5

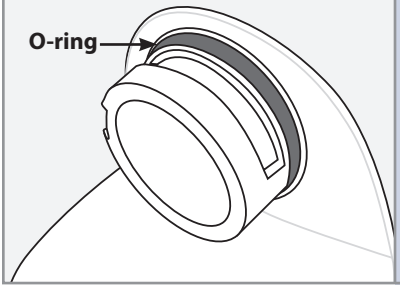


⚠ **CAUTION:** Do NOT lubricate diaphragm.



Visually inspect O-rings on sliding venturi for cracks and damage.

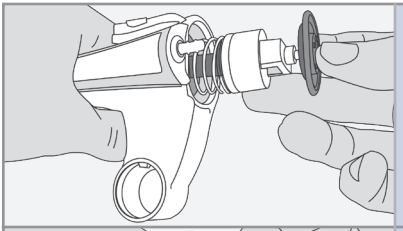
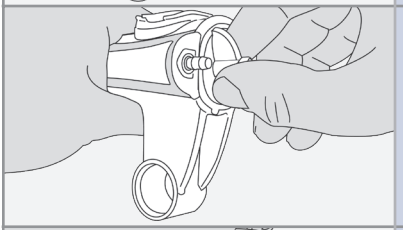
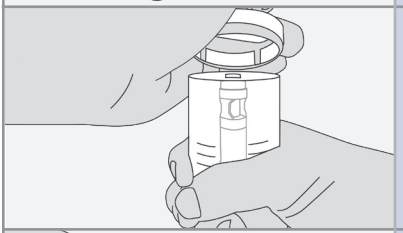
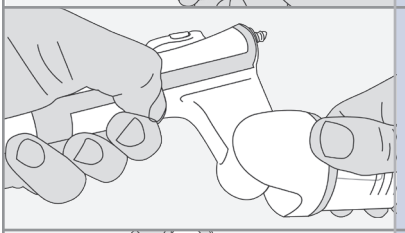
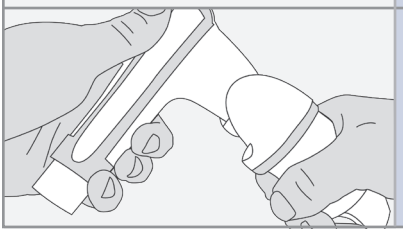
⚠ **CAUTION:** Do NOT lubricate sliding venturi O-ring.



Visually inspect O-rings on nebulizer cap for cracks and damage.

⚠ **CAUTION:** Do NOT lubricate nebulizer cap O-ring.

Reassembly of the Phasitron® 5 (continued)

	Insert venturi and spring into Phasitron® 5 body.
	Screw white cap onto rear of the Phasitron® 5 body until stop.
	Holding the ring of the nebulizer cap, insert and twist nebulizer bowl until it locks.
	Add mouthpiece, mask, and corrugated tubing to the Phasitron® 5 as needed.
	By aligning the notch, insert the nebulizer housing into the Phasitron® 5 body, then rotate to lock.

Chapter 8: Technical Specifications

Impulsator® Specifications

Size	33.02 cm W x 29.71 cm H x 20.82 cm D (13" W x 11.7" H x 8.2" D)
Mass	10.43 kg (23 lb)
Storage and Transport	Temp -40°C to 60°C (-40°F to 140°F) Humidity < 93% non-condensing
Operating Range	Temp 0°C to 49°C (32°F to 120°F) Humidity 5% - 95% Elevation 0-9842 ft.
Display/Output	Pulse Amplitude: Digital display, 0 to 150 cmH_2O Pulse Frequency: approximately 60-400 pulses per minute Session Usage Time: Digital display
Aerosol Flow	Liquid consumption of .75 cc per minute
Pulse/Interval Ratio	Average ratio 1:2.5
Power Supply	110V 60 Hz
Run Time	Intermittent for 15-to-20-minute treatments ⚠ **WARNING:** Do not exceed 20 minutes.
Aerosol Flow	Liquid consumption of .75 cc per minute
Filters	Red line filter
Accessories	Phasitron® 5 kit P5-TH
Required Maintenance	Every 3 years from date of manufacture

Percussionaire® Digital Multimeter (PDM) Specifications

Size	73 mm diameter (2.87-inch diameter)
Mass	165 g (0.36 lb)
Storage and Transport	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 (Manufacturing, firmware upgrade use only)
Thermal	-40°C to +60°C (-40°F to 140°F)
Rate Range	50-999 pulses per minute
Pressure Range	1-150 cmH_2O/hPa
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)
Shelf Life	3.5 years at 35°C (95°F)

Phasitron®5 Technical Specifications

Size	13.5 mm x 17 mm (5 ¼" x 6 ¾")
Mass	123 g (0.27 lb)
Operating Range	Temp., 0°C to 49°C (32°F to 120°F) Relative humidity range, 15% to < 90% non-condensing
Storage and Transport Range	Temp., -40°C to 60°C (-40°F to 140°F)
Rate Range	0-999 pulses per minute
Pressure Range	0-150 cmH_2O/hPa
Aerosol Flow	.75 cc per minute
Safety Valve Release	30-50 cmH_2O/hPa
Red Line Filter	1-3 micron hydrophobic
Disposal	Recycle according to local laws
Service Life	6 months or 540 uses, whichever is less
Shelf Life	2 years from date of manufacture

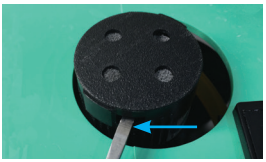
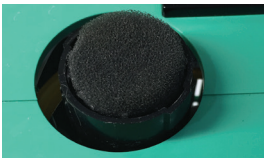
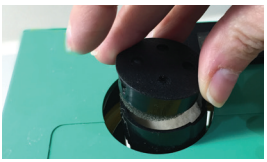
Chapter 9: Maintenance

Phasitron® 5

Use the Phasitron® Timestrip® as your guideline for replacing filters. When the Timestrip® indicates it is necessary to replace your Phasitron® P5-TH breathing circuit, also replace the Impulsator® filters. (Refer to Timestrip® section for information).

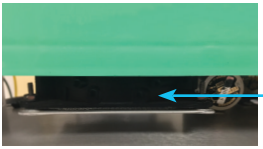
Air Intake Filter Replacement

Check, clean, and/or change filters every 6 months (more often in dusty environments).

	To replace air intake filter, remove cap by pressing small flat blade screwdriver into slot and prying up.
	Remove grey/black filter from inside top cap.
	Remove white filter with screwdriver. ⚠ **CAUTION:** Do not wash white filter.
	Filters removed
	Install white filter first; grey/black filter installs into the cap. Align and reinstall cap.

Cooling Fan Maintenance

Wipe dust off fan as often as needed.

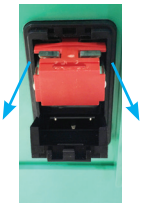


Cooling fan located near the bottom of device.

Fuse Replacement

Locate fuse holder above power cord attachment.

With a small, flat-blade screwdriver, pry the fuse panel out by twisting screwdriver in the small slot at the top.



Fuse holder will release.
Pull out the red fuse carrier.

Remove and replace with new fuses, Percussionaire® part number B12792 (BK/MDL-5 115V), or equivalent.
Two extra fuses (B12792) are supplied in the Accessory Kit (A50162).

Fuse Replacement Continued

	Replace red fuse carrier into the fuse panel by squeezing fuses together from sides and sliding fuse holder into housing.
	Replace black cover by aligning it with the housing and pushing in until it snaps into place. Make sure both sides are engaged.

Chapter 10: Troubleshooting

Problem	Examine	Repair
Impulsator® will not turn on.	Unit is not connected to an approved power source. There is a loose wire connection or grounding defect. Fuse not functioning properly.	Plug unit into an approved power source. Service required. Check Fuse.
Impulsator® has delayed start-up.	Capacitor failure Compressor failure	Service required.
Impulsator® fails to pulse.	Working pressure is not set correctly. Regulator pressure gauge malfunction	Set working pressure to achieve appropriate peak pressure. Service required.
Phasitron® 5 breathing circuit will not function.	Remove white quick connector from Phasitron® 5. Check for pulse flow while device is running.	If no flow, service required.
Nebulizer is not aerosolizing properly.	Check to see if nebulizer baffle is in place. Check yellow line for gas flow while device is running.	Replace Phasitron® 5. If no gas flow, service required.
No change when frequency control knob is rotated.	Check if unit has been damaged (dropped, fallen, etc.). Check last calibration or functional check performed.	Service required.
Multimeter not functioning properly, or display is off.	Check that red conical connector is attached to port of Phasitron® 5.	Ensure the end of the Phasitron® 5 is blocked with patient thumb or finger.

Chapter 11: Service and Repair

Percussionaire® recommends an annual Preventive Maintenance (PM) for each device. An annual PM consists of a thorough cleaning, functional evaluation, and if necessary, recalibration. A mandated service is required every 3 years from the date of manufacture and/or not later than 4 years. The service includes recalibration, functional evaluation, conformance certification, and a one-year warranty on all parts.
A device that has not received its required service, whether in use during that period or not, may be considered beyond economic repair. Service by an unauthorized individual or repair maintenance facility will cause the immediate expiration of the clinical readiness of the device. Return the device to Percussionaire® or an authorized service center for repair, required service, or annual preventive maintenance.

Disposal of Equipment

At the end of useful life of a unit, disposal should be in accordance with local, state, federal, and international laws.

Chapter 12: Limited Warranty

Percussionaire® warrants that the Impulsator® 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.

NOTE: *In the event that the operation of a Percussionaire® product is in any way adversely affected by using components other than those designed, manufactured, or approved by Percussionaire® Corporation, Percussionaire® shall not be liable under this warranty with respect to such product.*

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