PERCUSSIONAIRE®
CORPORATION

VDR®-4 System

Volumetric Diffusive Respirator

Operator's Manual

1st Edition
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The VDR®-4 may be covered by one or more patents.

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

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

⚠ WARNING and CAUTIONS

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 at risk.

⚠ WARNING

A WARNING indicates the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

A/C Power	If the VDR®-4 is connected to a Monitron® II Waveform Analyzer, a hospital-grade AC power plug is provided. Grounding reliability can only be guaranteed if connected to a tested, hospital-grade outlet. Any alteration to proper connection may cause harm to the patient or personnel associated with the device.
Airway Obstruction/Suctioning	Perform suctioning as necessary. Only proximal airway 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.
Alteration, Assembly	Deviation from manufacturer's suggested assembly could cause the VDR®-4 to malfunction.
Alarms	Audible alarming could indicate a potentially harmful situation and should be attended to immediately. Failure to comply could result in injury or death to the patient. See "Pre-Use Checks."
Breathing Circuits	The Phasitron® breathing circuit is specifically designed for use with the VDR®-4. Any attempt to substitute another circuit or configuration could result in injury to patients or operator and damage to equipment.
Artificial Airway	The VDR®-4 device can be used on a patient with an artificial airway. 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.
Maintenance	Equipment maintenance procedures must be complied with. Failure may result in injury to the patient or operator and could result in damage to the equipment. Proximal airway filter should be changed when large amounts of water are downstream of filter. Failure to replace the filter when necessary could result in patient injury and/or damage to the equipment.
Operational Pressure Settings	Always check the operational pressure settings on the VDR®-4 before placement of the ventilator on a new patient.
Oxygen Analyzer	Administration of excessive oxygen to a patient may be harmful. The prescribed oxygen concentration delivered by the blending system should be verified with an oxygen analyzer.

Patient Disconnect Protection	Test the operation of the VDR®-4 patient disconnect alarm when doing pre-use check and pre-setup procedure. An increase in circuit resistance can prevent proper operations of some alarms. Speaking valves, heat moisture exchangers (HMEs), and filters create additional circuit resistance and may affect the performance of alarms chosen for circuit disconnect protection.
Patient Monitoring	Prior to placing a patient on the VDR®-4 ventilator, a clinical assessment should be completed to determine the device alarm settings, alternative ventilation equipment needed, and if an alternative monitor is required. Therapists should evaluate how their patients tolerate mechanical ventilation with the VDR®-4. Auscultation and observation of the chest and abdomen can be primary indicators of effective mechanical ventilation.
Personnel Qualifications	The VDR®-4 is a restricted medical device designed for hospital use by respiratory therapists or other trained clinicians under the supervision of a physician. The operator of the VDR®-4 is responsible for reading and understanding the manual before use. All persons using the VDR®-4 ventilation device must be trained in its use.
Pre-Use Checks	Pre-use checks must be completed before any ventilation is started on a new patient. If any abnormal function is noted, do not start ventilation. Failure to comply could cause injury or death to the patient. Alarm functions must be tested prior to each use to verify the capability of the device to detect conditions that could cause injury to the patient.
Setup	Proper care needs to be taken during setup to ensure all lines running to or from the patient circuit are not crimped or perforated. Failure to conform could cause malfunction of alarms and/or pressure limit controls. Proper support and orientation of the patient circuit must be made to avoid inadvertent disconnection.
Water Traps	Water traps (if used) should be drained at intervals to prevent the possibility of injury to the patient.
Guidelines	All guidelines in this manual are only suggested; always follow hospital or institutional protocols.

⚠ CAUTIONS

A CAUTION indicates the possibility of a problem with the device associated with its use or misuse, such as a device malfunction, device failure, device damage, or other property damage.

A/C Power	If the VDR®-4 is connected to a Monitron® II Waveform Analyzer, a hospital-grade AC power plug is provided. Grounding reliability can only be guaranteed if connected to a tested, hospital-grade outlet. Any alteration to proper connection may cause damage to the equipment.
Alarms	Audible alarming could indicate a potentially harmful situation and should be attended to immediately. Failure to comply could result in harm to the patient and damage to the VDR®-4 ventilator device.
Clinician Training	All persons providing high-frequency percussive ventilation (HFPV) must be trained in the use of the VDR®-4, the functions and the settings, in addition to each of the therapeutic procedures used. All persons using the VDR®-4 must read and understand the manual before using the device.
Do NOT Cover Device	Do not place objects on top of the VDR®-4; do not cover the device during use. Failure to comply may cause harm to the patient and/or damage the VDR®-4 ventilator device.
Malfunctions	The VDR®-4 must not be opened by anyone other than Percussionaire®-authorized service personnel holding a current certification.
Maintenance	Maintain and service the VDR®-4 device according to the recommendations provided in this manual. Use only Percussionaire® accessories designed specifically for use with the VDR®-4 device. Never attempt to modify the unit. Maintenance procedures must be complied with. Failure may result in injury to the patient or operator and could result in damage to the equipment. Proximal airway filter should be changed when large amounts of water are downstream of filter. Failure to replace the filter when necessary could result in patient injury and/or damage to the equipment.
Steam	Do not steam clean the device. Only clean and disinfect as described in the Cleaning and Maintenance Protocol section of this manual (refer to Chapter 9).

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

Table of Contents

Chapter 1: Introduction

This chapter provides an overview of the VDR®-4 device and High-Frequency Percussive Ventilation (HFPV).

Volumetric Diffusive Respirator (VDR®)

Designed specifically for hospital use, the Volumetric Diffusive Respirator unit (VDR®-4) is a flow-regulated and time-cycled ventilator which provides high-frequency percussive ventilation (HFPV). The Phasitron® breathing circuit delivers HFPV and interfaces with hospital humidification systems. 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 hospital patient populations, neonatal to adult. The VDR®-4 can be used to treat respiratory conditions including hypoxemia, hypercapnia, aspiration, smoke inhalation, and ARDS. This unit is paired with the Monitron® II Waveform Analyzer, which provides accurate, real-time visual waveform, pressures, and alarms, making the VDR®-4 a versatile tool for critical and intensive care respiratory ventilation.

Demand CPAP/PEEP

Reducing the work of breathing.

Inspiratory Time

Selects the time interval in which the inspiratory amplitude (set with the pulsatile flowrate) is delivered.

Pulsatile Flow

Determines the amplitude delivered to the patient during inspiratory phase.

Frequency

Controls the rate of high-frequency pulses delivered.

Manual Inspiration

Delivers a regulated source of gas through the orifice of the Phasitron® venturi.

Operation Pressure Control

Controls the peak operating pressure of the entire unit. This control at maximum output will only provide pressure slightly less than that of the institution. The optimal pressure setting is 40 psi/2.75 Bar.

Phasitron® A50094-D Breathing Circuit Kit

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.

When lung resistance is low, as in a compliant lung, all the pulsed air from the device enters the mouth of the venturi tube inside the Phasitron® and is delivered instantly to the patient. If needed, each pulse of the Phasitron® is capable of entraining up to four times as much additional air into the venturi, which is delivered directly to the patient. This low-pressure entrained air automatically fills the available space in the lung. The Phasitron® continuously and instantaneously adjusts to keep a gentle and safe air pressure, even in a compromised lung.

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.

Chapter 2: Intended Use

Indications for Use

The VDR®-4 is indicated for patients diagnosed with either respiratory failure or respiratory insufficiency requiring partial or full ventilator support in hospitals and for intra-hospital transport of these patients.

Patient Population

The VDR®-4 ventilator is for use on neonatal, pediatric, and adult patient populations.

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	• Improved breathing pattern
• Decreased work of breathing	• Increased secretion mobilization

Clinical Limitations/Restrictions

Use of the VDR®-4 ventilator device is limited to respiratory therapists/clinicians who have received proper training and have read and understand this manual.

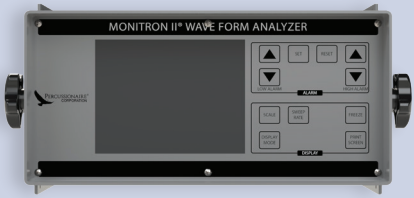
⚠ **WARNING:** As with any type of mechanical ventilation, perform suctioning as needed.

Chapter 3: System Description

Package Contents

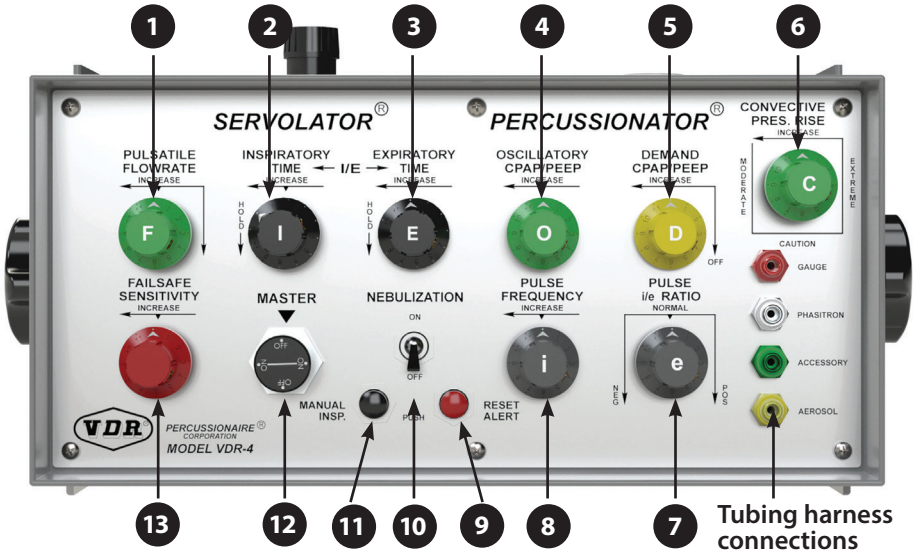
VDR®-4

Monitron® II



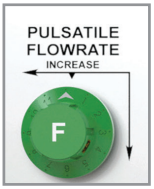
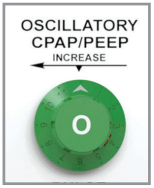
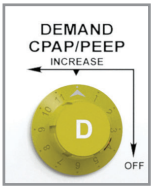
Phasitron® A50094-D

VDR®-4 Description of Controls



Tubing harness connections to the Phasitron®

Front Panel

No.	Control	Function
1.		**Pulsatile Flowrate** Determines the pulse amplitude delivered to the patient during inspiratory phase.
2.		**Inspiratory Time** Selects the time interval (adjustable from 0.5 seconds to approximately 10 seconds) in which the inspiratory amplitude (set with the pulsatile flowrate) is delivered.
3.		**Expiratory Time** Selects the time interval (adjustable from 0.5 seconds to approximately 10 seconds) that the expiratory amplitude is being delivered.
4.		**Oscillatory CPAP/PEEP** Determines the pulse amplitude delivered to the patient during the expiratory phase. The Oscillatory CPAP/PEEP is limited to approximately 20% below the high-amplitude setting, which is selected by pulsatile flow. This prevents the selection of an incompatible oscillatory CPAP/ PEEP during the adjusted expiratory interval.
5.		**Demand CPAP/PEEP** Provides for the establishment of "static PEEP" that automatically increases flow to the patient as the inspiratory demand warrants. Can be used for spontaneous weaning trial with the Master switch "OFF."

No.	Control	Function
6.		**Convective Pressure Rise** Adjusted to accelerate the pulsatile flowrate after 0.7-seconds delay and deliver a secondary, higher inspiratory amplitude during inspiratory phase.
7.		**Pulse i:e Ratio** Controls the pulse to interval (i:e) ratio of the high-frequency pulses delivered.
8.		**Pulse Frequency** Controls the rate of the high-frequency pulses delivered.
9.		**Reset Alert** Failsafe Sensitivity Alert System Reset
10.		**Nebulization** Controls the flow of gas to the aerosol circuit. Nebulizer toggle valve provides for a constant flow for nebulization and/or humidification. This is part of the fresh gas supplied to the patient.
11.		**Manual Inspiration** Delivers a regulated source of gas through the orifice of the Phasitron® venturi. The longer the button is pressed, the greater the potential for large volumes of flow delivered. ⚠ **WARNING:** The longer the Manual Inspiration button is pressed, the greater the potential for large volumes to be delivered.
12.		**Master Switch** Activates unit when placed into the "ON" position. When master valve is in "OFF" position, Manual Inspiration, Nebulization, and Demand CPAP/PEEP are still functional for weaning purposes.

No.	Control	Function
13.		**Failsafe Sensitivity** Limits a maximum sustained pressure over a defined time. If the failsafe pressure rise system is activated, a pneumatic alert is activated by a partial pressure release. A counterclockwise control knob rotation increases the sensitivity by decreasing the time required to activate the alert. A clockwise rotation decreases sensitivity by increasing the time for activation. This alert requires a manual reset by pressing the reset alert button, item 9, above.

Top Panel

VDR®-4 Top Panel with Manometer (if equipped)

VDR®-4 Top Panel with Digital Multimeter (if equipped)

No.	Control	Function
14.		**Operating Pressure Control** Controls the peak operating pressure of the entire control unit. This control at maximum output will only provide pressure slightly less than that of the institution. The optimal source gas pressure is 50 psi/3.4 bar.
15.		**Operating Pressure Gauge** A pressure regulator serves to control the 50 psi/3.4 bar sources of air and oxygen supplies, which are blended for a constant selectable FiO_2. A regulated 40 psig operational pressure is optimal.
	NOTE: *The VDR®-4 is supplied with either a Manometer or a Digital Multimeter (DM) to monitor patient proximal airway pressures.*	
16.		**Digital Multimeter (DM) if equipped** (Proximal Airway Pressure Digital Multimeter) The DM displays pulse frequency rate, mean airway pressure (MAP), average inhalation pressure (AIP), and average exhalation pressure (AEP) displayed as a dynamic number and pulse amplitude bar graph.
17.		**Manometer if equipped** (Proximal Airway Pressure Gauge) The manometer measures both pulsatile flow and oscillatory CPAP/PEEP. It can also measure the MAP.
18.		**Integrated Manometer Switch if equipped** In the "on" position, the manometer will display orificed pressure readings, collected over time, that approximate mean airway pressure. In the "off" position, an orificed breath-by-breath proximal inspiratory (AIP) and expiratory (AEP) pressure is displayed.
19.		**Blender** Allows selection of oxygen concentrations from 21% to 99+%.

NOTE: *Limitations of the cryogenic distillation process prevent the production of 100% pure medical oxygen. For technical and legal reasons, medical oxygen is listed on manufacturer's data sheets as 99+% pure. The blender can deliver oxygen concentrations between 21% and the 99+% purity of medical oxygen supplied to the VDR®-4 (see #19 above).*

Digital Multimeter (DM)

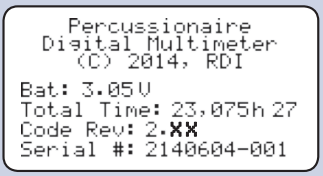
The Digital Multimeter (DM) has six different operating modes: POST, Wake, Active, Report, Sleep, and Fault.

Power-On Self-Test (POST) Mode

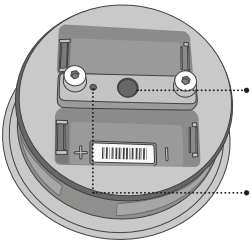
When batteries are installed in the Digital Multimeter (DM), the software displays the software revision, battery voltage, total usage time, and serial number for 15 seconds. This start-up mode allows the software to perform additional tests on the hardware that are part of the POST. If any errors are detected in the POST, the DM enters the Fault mode. The POST checks require that the measurement port be left disconnected and exposed to the atmosphere for the entire duration.

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

System Information Page



Rear view of DM



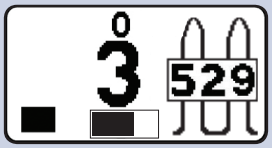
Measuring port connection
⚠ (Do not touch or insert any object into this port)

Reset button
(only used for firmware upgrades)

Wake Mode

To wake up the DM, ensure the VDR®-4 ventilator pressure is greater than 2.5 cmH_2O/hPa at the Phasitron® patient delivery port for more than 1 second.

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



NOTE: *Display numbers are for reference only.*

Active Mode

Software: 2.26
Device: VDR®-4
Display Metrics: Pulse Frequency Rate, Mean Airway Pressure, Dynamic Pressure, (AIP and AEP), Usage Timer, and Pulse Amplitude Bar Graph.

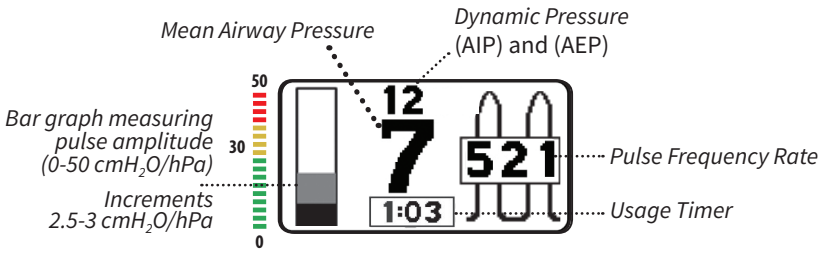
At 16 seconds, the DM enters **Active** mode. The timer bar will change to a numeric display, showing the current usage Session Timer. The display on the right shows the currently measured pulse frequency rate.

Mean Airway Pressure (MAP) averages pulse amplitude over 5 seconds. At 100 samples per second, this is an average of 500 measurements.

Average Inhalation Pressure (AIP) is the average pressure of the inspiratory phase over a set period of I time (range: 0-99 cmH_2O/hPa).

Average Exhalation Pressure (AEP) is the average pressure during the expiratory phase over a set period of E time (range: 0-99 cmH_2O/hPa).

NOTE: *DM display represents an estimate of pressure in the lung (after resistance of ET tube, etc.). 100 measurements per second at Phasitron®. Time duration of the average depends on time duration of pulsatile flow or O/CPAP.*



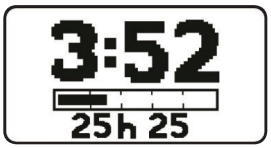
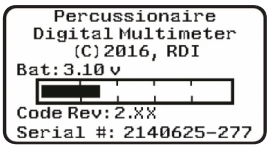
Pulsating Bar Graph

The pulsating bar graph on the left side displays pulse amplitude calculated as average peak maximum pressure sample in last 5 seconds minus minimum pressure sample in last 5 seconds. The bar graph is a visual representation better reflecting AIP and AEP values and represents an estimate of airway pressure.

The solid black at the bottom of the bar graph represents PEEP. The pulsating grey represents AIP.

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

Report Mode

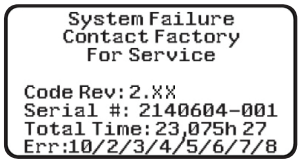
A. 	The Session Timer and the Total Usage Timer **(A)** are displayed for 2 seconds, followed by the System Information page **(B)** for 2 seconds, alternating. The alternating page display continues for 5 minutes, or until usage resumes and the DM enters **Active** mode.
B. 	During the 5-minute period, 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.
C. 	The DM enters **Sleep** mode after 25 minutes.

Sleep Mode

Blank screen, indicating DM 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/hPa at the Phasitron® patient delivery port, for more than 1 second, the DM enters the **Wake** mode.

Fault Mode



The DM displays an error message on the LCD stating, "Contact Factory for Service" and stays in **Fault** mode until both batteries are removed.

The displayed information includes the software revision, DM serial number, the Total Usage time, and an error code for the exclusive use of the factory.

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

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 allows the DM 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: *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, DM may be used. If System Failure screen recurs, contact an authorized Percussionaire® service center.*

Fault Detection

The DM 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.

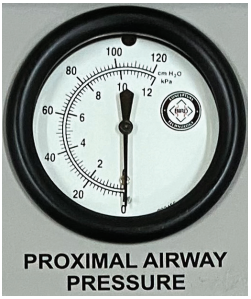
In addition to the hardware fault detection, the software also implements a fault detection "watchdog." This "watchdog" detects if a software task fails to complete within the specified time, logs an error, and resets the processor.

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 DM 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 DM but does not erase the faults stored in memory or fix the problem that caused the fault.

Manometer (Proximal Airway Pressure Gauge)



Airway pressure manometer with range from 0 to 120 cmH_2O is installed in the top panel of the VDR®-4. The manometer reads a selected mode of proximal airway pressure.

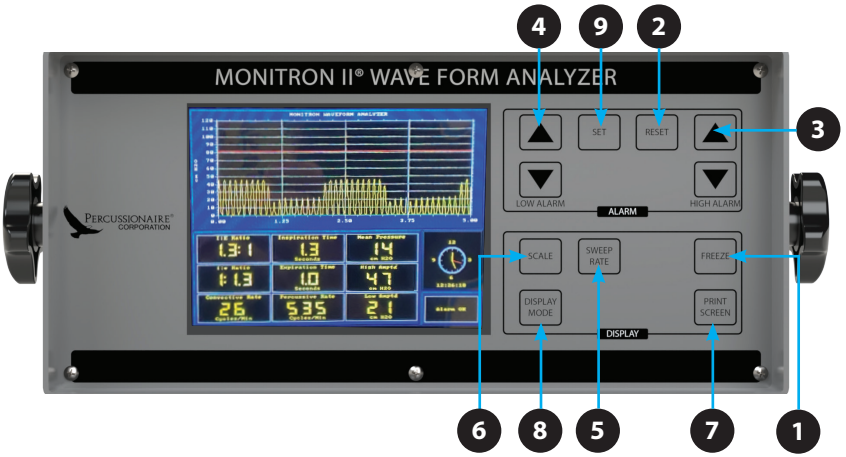
A switch labeled **Integrated Manometer** selects the mode of display.

When the integrated manometer switch is in the "off" mode, the signal is dampened to represent AIP and AEP, as present in the airway.

When the Integrated Manometer switch is in the "on" mode, the manometer is calibrated to display mean airway pressure (MAP).

NOTE: *The basic conventional internal monitoring of Proximal Airway Pressure is presented on the Manometer. If, during patient programming, an integrated mean proximal airway pressure is desired on the Manometer, select "Integrated Manometer ON."*

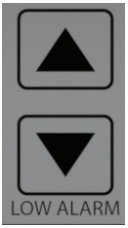
Monitron® II Waveform Analyzer Description of Controls



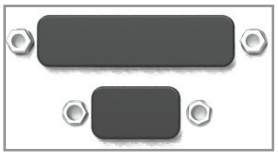
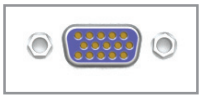
NOTE: *Waveform and numbers for display only*

Front Panel

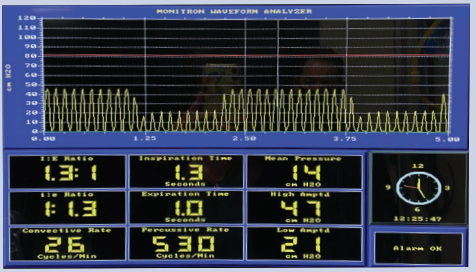
No.	Control	Function
1.		**Freeze On/Off Switch** The **Freeze** switch is a push button located on the front panel. The normal position of the freeze mode is "OFF." With the freeze mode "ON," information that is displayed on the LCD will be frozen for observation. The freeze mode will last for 30 seconds, and then it returns to the normal display mode.
2.		**Alarm Reset** The **Reset** switch is a push-button momentary switch used to clear a low-level alarm after the alarm has been corrected.
3.		**High Alarm Adjust** The **High Alarm** is adjusted by pressing the buttons on the front panel to move the "red" high alarm limit up and down. The up and down arrows are pushed repeatedly until the desired high alarm limit is achieved.

No.	Control	Function
4.		**Low Alarm Adjust** The **Low Alarm** is adjusted by pressing the buttons to move the "green" low alarm limit line up and down. The up and down arrows are pushed repeatedly until the desired low alarm limit is achieved.
5.		**Sweep Rate** **Sweep Rate** determines the rate that new data is displayed on the LCD. The sweep speeds available are 1, 2, 5, and 8 seconds per screen.
6.		**Scale** The vertical **Scale** button allows the user to select sensitivity settings of 30, 60 and 120 cmH_2O. No negative signals are displayed.
7.		**Print Screen** The **Print Screen** function is not supported at this time.
8.		**Display Mode** The **Display Mode** button re-scales the proportion of the displayed graph to the numeric indicators.
9.		**Set Button** The **Set** button will automatically position the "High" alarm to 20% above PIP. The "Low" alarm will be set at 4 cmH_2O.

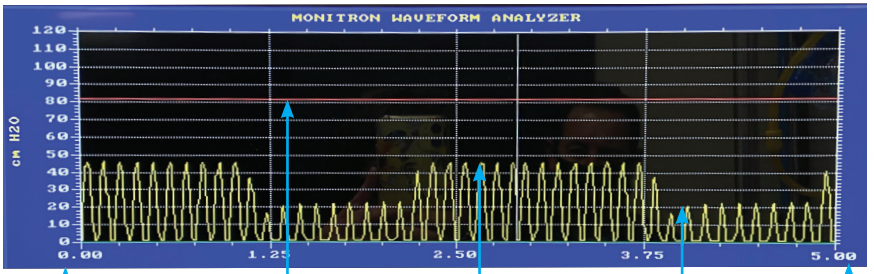
Rear Panel

Control	Function
	**Power Switch** The **Power Switch** has two positions, "ON" and "OFF."
	**Signal Output** The Monitron® II is fitted with a 25-pin "D" connector and a 9-pin connector on the back panel. Both of these connectors are non-functional and should be covered when not in use.
	**VGA monitor connector**

Visual Outputs



Waveform Display



Amplitude scale:
with 3 selectable options
0-30 cmH_2O, 0-60 cmH_2O,
0-120 cmH_2O

High alarm setting

High Amplitude

Low Amplitude

Time scale with four
selectable options of
1, 2, 5, and 8 seconds.

Monitoring Parameters

Control	Function
	Ratio between I time and E time
	The ratio between pulse and interval for the high frequency
	"Convective " rate from the I time and E time in cycles per minute
	Inspiration time or T-high in seconds
	Expiration time or T-low in seconds
	High-frequency rate in cycles per minute
	Mean airway pressure in cmH_2O
	High Amplitude in cmH_2O
	Low Amplitude in cmH_2O

Control	Function
	Clock
	Alarm status

Low Alarm Level
Low Alarm will display as a green line on the LCD at the set pressure level.

High Alarm Level
High Alarm will display as a red line on the LCD at the set pressure level.

The Proximal Airway Pressure (pulse amplitude) signal is collected from the red tubing connection on the Phasitron Tee. Data will be displayed on the LCD moving from left to right.

Audible Outputs

Whenever an alarm condition exists, the circuitry will trigger an audible alarm of at least 65 db and approximately 2800 Hz.

Blended Gas/Air Connection

Current Air/Gas Connectors Available:			
DISS	USA	NIST	European
AFNOR	French	UNIFOR	Italian
DIN	German	AGA	Scandinavian
BS	British		

Chapter 4: Alarms

Failsafe Sensitivity

The Failsafe alarm is an obstruction alert intended to protect the patient from a high-pressure situation. This alert should be considered as the highest level of alert that requires immediate and urgent attention because ventilation of the patient is significantly reduced.

This alert is activated in situations such as an obstructed airway or an obstructed tube where initially, the patient may receive zero or a low pressure. When the obstruction is cleared, the alert protects the patient from any overpressure from a sudden release of flow.

When the alert is activated, the VDR®-4 reduces flow to deliver minimal ventilation while an audible alert sounds. The red, **FAILSAFE SENSITIVITY** control may be used to adjust the time delay before the alert is activated. This control is normally set with the arrow in the straight-up position, allowing a delay of about 2 seconds.

This alert requires a manual reset by pressing the red **RESET ALERT** button. If the condition has not been resolved, the alert will reactivate within 2 seconds (this alert cannot be silenced and requires immediate attention).

NOTE: *This alert is activated by flow restriction causing excessive back pressure. This alert may be tested by causing a 100% obstruction; in this condition the flow restriction will cause a pressure over 100 cmH_2O.*

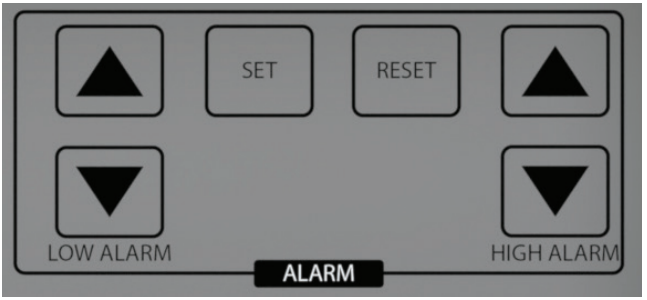
Disconnect Alarm

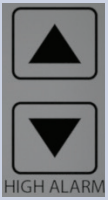
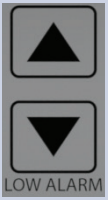
A battery-operated Low-Pressure Alarm is installed as an independent disconnect alarm. The waveform monitor (Monitron II) provides audible alarms for high and low amplitude. When set appropriately, the low alarm can be used as a disconnect alarm since it requires a manual reset when the condition is restored.

⚠ **WARNING:** Audible alarming could indicate a potentially harmful situation and should be attended to immediately. Failure to comply could result in harm to the patient and damage to the VDR®-4 ventilator device.

Modifying Alarm Parameters

NOTE: *RESET High and Low alarms after any change in programming.*



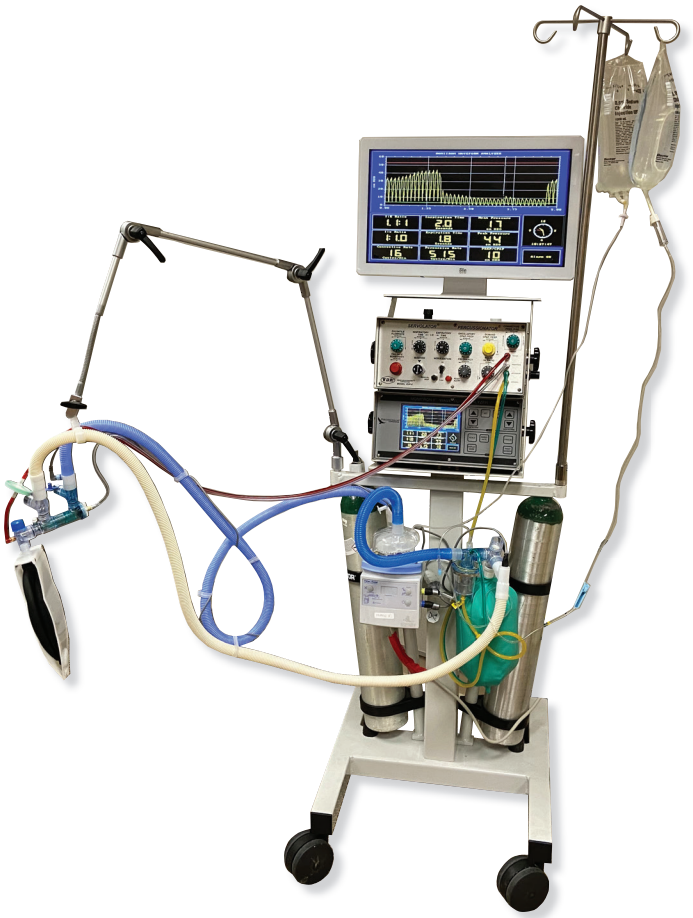
High Alarm Adjust 	The **High Alarm** is adjusted by pressing the arrow buttons on the front panel to move the "red" high alarm up and down. The up and down arrows are pushed repeatedly until the desired high alarm is achieved. This alarm will reset automatically once the high amplitude condition is resolved.
Low Alarm Adjust 	The **Low Alarm** is adjusted by pressing the arrow buttons to move the "green" low alarm up and down. The up and down arrows are pushed repeatedly until the desired low alarm is achieved. This alarm requires a manual reset and does not automatically reset if the condition resolves.
Set Alarm 	The **SET** button will automatically position the "high" alarm to 20% above inspiratory amplitude. The "low" alarm will be set at 4 cmH_2O.
Reset Alarm 	The **RESET** button is used to clear a low-level alarm after the fault has been corrected. **NOTE:** *This device is not equipped with a 2-minute silence reset option.*

Alarm Activity

1.	High-Amplitude Pressure Alarm Event – visual and audible indicators
2.	Low-Amplitude Pressure Alarm Event – visual and audible indicators
3.	Patient-Disconnect Alarm Event – audible indicator
4.	Blender Gas Supply – audible indicator

Alarm Summary Table

High-Amplitude Pressure Alarm Event	**Visible:** When amplitude exceeds set level, high alarm will display as a red line on the LCD at the appropriate pressure level. There will also be a red **WARNING** in the lower right corner of the LCD with "High Pressure" text displayed. **Audible:** The alarm tone sound will be at least 65 decibles at approximately 2800 Hz.
Low-Amplitude Pressure Alarm Event	**Visible:** When amplitude falls below set level, low alarm will display as a green line on the LCD at the appropriate pressure level. There will also be a blue **WARNING** light in the lower right corner with the text "Low Pressure" displayed. This alarm requires manual resetting. **Audible:** The alarm tone sound will be at least 65 decibles at approximately 2800 Hz. **Visible:** Silence any event by pressing the reset button.
Alarm Silence	**Audible:** The alarm tone will reactivate immediately if the condition has not been resolved (this is not a 2-minute silence).
Disconnect Event	**Visible:** When the patient is disconnected from the VDR®-4 breathing circuit, an appropriately set low-pressure alarm will sound. This may be both the alarm on the waveform with visual and audible indicators and the battery-operated alarm with an audible indicator. **Audible:** An alarm tone will sound.



Typical VDR®-4 Configuration

Roll Stand and VDR®-4 Assembly

The VDR®-4 is mounted on a standard ventilator stand and is set up for two e-cylinders to be mounted to provide for transportation of the patient while receiving mechanical ventilation with the VDR®-4.

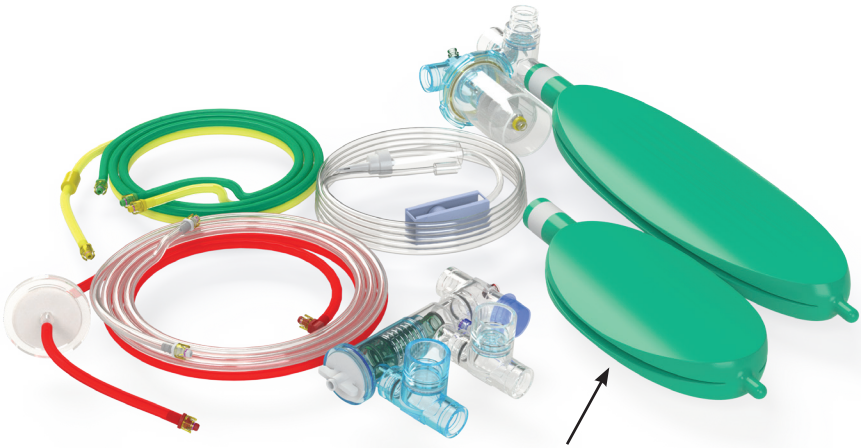
Blended Gas/Air Connection

The VDR®-4 mechanical ventilator comes with a standard O_2 and air hose configuration for the ventilator to be plugged into hospital gas sources for O_2 and air.

AC Power Connection

The Monitron® II waveform has a universal standard IEC ac connection.

Phasitron® A50094-D Breathing Circuit

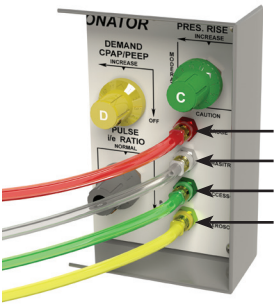


NOTE: *0.5 L bag supplied for neonatal patients only. This is not a test lung.*

NOTE: *A heated wire circuit is required.*

Connecting to the VDR®-4

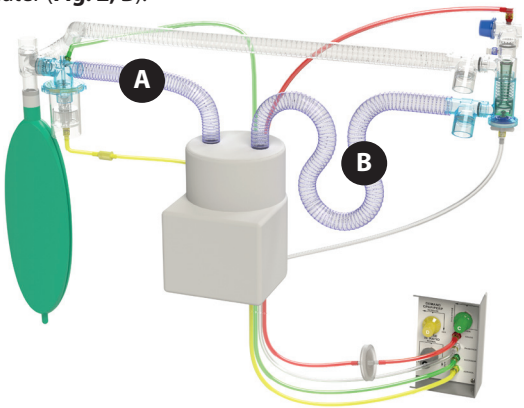
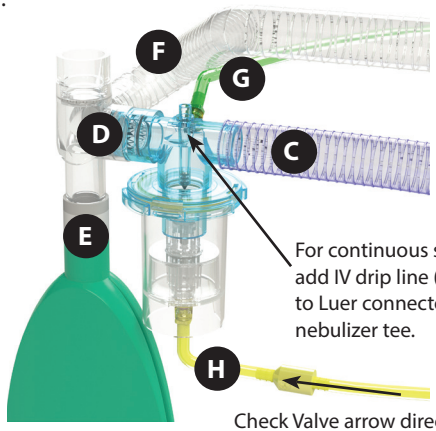
1.	Place heater chamber onto heater. Insert nebulizer into mounting hook, normally installed near heater.
2.	Connect red, clear, yellow, and green connectors to the VDR®-4 front panel (**Fig. 1**).

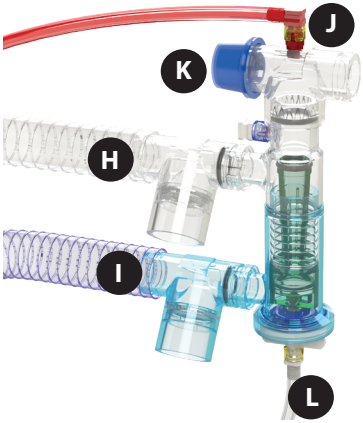


Tubing Connections

- Red to Gauge
- Clear to Phasitron®
- Green to Access
- Yellow to Aerosol

Fig. 1

3.	Connect nebulizer to heater chamber using unheated, fresh gas, blue corrugated tubing (see **Fig. 2, A** and **Fig. 3, C**). Connect blue heated-wire tubing to heater (**Fig. 2, B**).  **Fig. 2**
4.	Insert 4-way manifold 22 mm port into nebulizer with flapper gate placed upright (**Fig. 3, D**).  **Fig. 3**
5.	Install 3 L anesthesia bag 15 mm onto manifold (**Fig. 3, E**). Optional 0.5 L bag is included for NICU patients if preferred by hospital protocol.
6.	Connect white, expiratory, corrugated heated-wire limb to side of manifold (**Fig. 3, F**).
7.	Connect green tubing quick-connect fitting to nebulizer top tee at 45 degrees (**Fig. 3, G**).
8.	Connect yellow tubing quick-connect fitting to bottom of nebulizer bowl (**Fig. 3, H**).

9.	Remove wye from heated-wire circuit and attach white corrugated tubing to the clear expiration port valve on the Phasitron® (**Fig. 4, H**).  **Fig. 4**
10.	Connect blue corrugated heated-wire tubing to blue Phasitron® entrainment port (**Fig. 4, I**).
11.	Connect red tubing quick-connect fitting to middle tee connected to Phasitron® (**Fig. 4, J**).
12.	Install blue cap onto one end of Phasitron® tee (**Fig. 4, K**).
13.	Connect clear tubing quick-connect fitting onto Phasitron® cap (**Fig. 4, L**).

Adding Sterile Inhalation Water

Add sterile water bags to both conventional circuit humidifier and Phasitron® kit nebulizer for two continuous sources of sterile water.

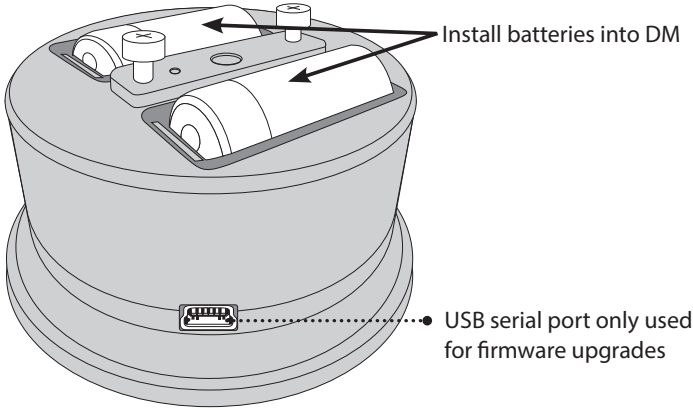
It is suggested for optimal humidification delivery to set heater at 40°C and maintain patency of blue heated-wire tubing (**Fig. 2**, B) by draining at regular intervals.

⚠ **WARNING:** This setup will deliver 30-36 ml H_2O at 26°C; running either the nebulizer or the heater dry may result in adverse conditions.

Digital Multimeter (DM) Setup

To ensure correct atmospheric pressure calibration at startup, remove batteries, wait 30 seconds, and reinstall. Allow 15 seconds for Power-On Self-Test. When screen goes blank, the DM can be installed into the VDR®-4.

Side view of DM



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

Changing DM Batteries

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

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

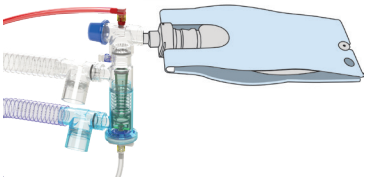
NOTE: *The DM has a USB serial port that is used for manufacturing, calibration, and firmware upload. It is not enabled during normal operation.*

Chapter 6: Pre-Use Check

Blender Pre-Use Check

Check blender with FiO_2 analyzer at 21% and 100% FiO_2 per department policy with O_2 analyzer before initializing mechanical ventilation.

Pre-Use Check

1.	Connect hospital air supply hose to VDR®-4. Listen for blender alarm, then disconnect air hose.
2.	Connect hospital oxygen supply hose to VDR®-4 and disconnect air hose. Listen for blender alarm.
3.	Connect hospital air supply hose to VDR®-4.
4.	Turn Monitron® II "ON."
5.	Connect Phasitron® patient port to a test lung (such as Vadi 210 or equivalent). 
6.	Perform all tests using your standard heater/humidification setup, set up according to your hospital protocol.
7.	Turn operating pressure knob until it reaches a static 42 psig.
8.	Turn VDR®-4 "ON."
9.	Turn off **OSCILLATORY PEEP/CPAP, DEMAND CPAP**, and **CONVECTIVE PRES. RISE** (full clockwise).
10.	Set the **PULSATILE FLOWRATE** control to AIP of 30 cmH_2O as read on DM or manometer.
11.	Set pulse frequency to 500. • Set **PULSE i/e RATIO** with arrow at the 12:00 position (straight up) for a 1:1 i/e ratio.

12.	Set inspiratory time and expiratory time to: • 2.0 seconds to get a convective rate of ~15 (adult/large peds) • 1.5 seconds to get a convective rate of ~20 (small peds) • 1.0 second to get a convective rate of ~30 (neonatal)
13.	Set oscillatory CPAP/PEEP to AEP of 5 cmH_2O as read on DM or manometer.
14.	Check Monitron® II for appropriate rise and fall on waveform.
15.	Verify pulse frequency will go greater than 700 and less than 200.
16.	Return pulse frequency to 500.
17.	Manually compress test lung and hold as tightly as possible. • Verify pulsatile flowrate will achieve AIP of 50 cmH_2O. • Verify oscillatory CPAP will reach a minimum AEP of 18 cmH_2O. (Release hold on test lung).
18.	Return pulsatile flowrate to an AIP of 30 cmH_2O and **OSCILLATORY CPAP** control to an AEP of 5 cmH_2O.
19.	Verify a gradient of 8-10 cmH_2O when convective pressure rise is applied.
	NOTE: *Convective pressure rise will begin after approximately 0.7 seconds have passed from the start of the inspiration cycle.*
20.	Increase convective pressure rise until failsafe alarm sounds. Observe that ventilation continues at lower settings. Turn convective pressure rise off and then press red button to reset.
21.	Lower high-amplitude pressure alarm below set pulsatile flowrate to trigger the high-pressure alarm. Press reset on Monitron® to clear audible alarm.
22.	Trigger low-amplitude pressure alarm by disconnecting test cap. Press reset on Monitron® II to clear audible alarm.
23.	Turn off VDR®-4 and Monitron® II. Silence alarm on Monitron® II by pressing any button.
24.	Switch nebulizer on and listen for gas flow, then switch off.
25.	Pre-use check is complete.

Alarm Check

Routine alarm checks should be performed before use with each new patient. If the alarms do not function as described in this manual, contact your distributor.

Settings

To check alarms, set the VDR®-4 to the following settings:

1.	Operating pressure 40 psig
2.	FiO_2 60%
3.	Attach the VDR®-4 failsafe circuit to test lung (Part #PRT-B13603 or equivalent).
4.	Inspiratory time at 2 seconds
5.	Expiratory time at 2 seconds
6.	Inspiratory Amplitude at 40 cmH_2O
7.	Demand CPAP/PEEP "OFF"
8.	Oscillatory CPAP/PEEP at 10 cmH_2O of Expiratory Amplitude
9.	Convective Pressure Rise "OFF"
10.	Pulse Frequency at 500 bpm
11.	**MASTER** switch "ON"
12.	Nebulization "OFF"
13.	Failsafe sensitivity at 12:00
14.	Pulse i/e ratio to arrow straight up for a 1:1 ratio.

Monitron® II Waveform Analyzer Alarm System:

1.	With VDR®-4 functioning, adjust red line with **HIGH ALARM** selection arrow to 50 cmH_2O.
2.	Adjust green line with **LOW ALARM** selection arrow to 8 cmH_2O.
3.	During inspiratory phase, squeeze the test lung so that a pressure of > 50 cmH_2O registers on the screen. The alarm should sound and will not reset until the cause of the pressure rise is corrected, and screen is clear.
4.	Remove test lung.
5.	After approximately 5 seconds, the low-pressure alarm will sound and will not reset until the problem is solved, and alarm **RESET** button is pushed.
6.	If alarms function as they should, alarm checks are complete.

Chapter 7: PATIENT MANAGEMENT

Therapeutic Objectives

Managing patients on high-frequency percussive ventilation is similar to managing patients on a CMV.

Oxygenation - adjustments will be made to increase mean airway pressure if oxygenation is the primary concern.

Ventilation - adjustments that increase minute volume will be made when CO_2 elimination is the primary concern.

Ventilation - The VDR®-4 settings will be adjusted most often when ventilation (CO_2 removal) and/or the consequences of using high airway pressures (e.g., pulmonary air leaks) are the greatest concern.

Chapter 8: Clinical Guidelines

Color-Coded Control Knobs

Specific meanings:	
Green	Green knobs are for the selection of **Inspiratory** and **Expiratory Flowrates.**
Yellow	The yellow knob is for **Demand CPAP/PEEP**. Demand CPAP/PEEP is used for a spontaneously breathing patient with high inspiratory or respiratory rate demand or, with the VDR®-4 master switch in the "off" position, it effectively places the patient in a CPAP weaning trial.
Grey	Grey knobs are for pulse **Frequency** (high-frequency) and **i/e ratio** control with resultant frequency selections.
Black	Black knobs are for general **Inspiratory** and **Expiratory Time** (convective) I/E phasing intervals.

Default Settings

Default	Determine initial settings based upon ADULT, PEDIATRIC, or NEONATAL guidelines listed below.
Nebulizer	Nebulizer gas flow into the yellow interfacing tubing is provided by an ON/OFF switch. Turn on when ventilating a patient.

Prepare for Patient Airway Connection

1.	Rotate **MASTER** switch to "OFF."
2.	Set up both the nebulizer/humidifier and switch to "ON."
3.	Use patient's SPO_2 or PaO_2 to determine FiO_2 selection.
4.	Rotate upper **MASTER** switch to "ON" (if equipped with a manometer), remove the cap from the patient port, and attach the Phasitron to the patient. **NOTE:** Once the patient is attached, you may need to readjust control settings.

Adjusting Settings

Wait for recruitment or effect of updated control setting changes. It is important to allow time for the changes to take effect. After a period of ventilatory stabilization, check SPO_2 or blood-gas determinations to determine oxygenation.

Determine Period of Oscillatory Equilibrium	The black **Inspiratory Time** control knob determines the period of oscillatory equilibrium, providing for intrapulmonary mechanical gas mixing time. Increasing I time will increase both MAP and minute volume.
Inspiratory Amplitude	The green **Pulsatile Flowrate** control knob should be used to adjust CO_2 within appropriate ranges. Increasing amplitude during I time will increase MAP and minute volume.
Increase Inspiratory Amplitude	The green **Convective Pressure Rise** control knob arrow should be gradually rotated counterclockwise to increase inspiratory amplitude until recruitment is obtained. Convective Pressure Rise will increase minute volume faster than **Amplitude**.
Check for Airway Obstruction	Airway obstruction may cause an increase in inspiratory amplitude (without the clinician making an adjustment). When doing routine ventilator checks, if it is found that the inspiratory amplitude has increased, always consider an obstruction, which may require suctioning.

Adult Patient Starting Guidelines

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

Operating Pressure (psi)	40-42
Pulsatile Flowrate cmH_2O	AIP 28-32 (Max 40-46) Alternately, adjust pulsatile flowrate to match mean airway pressure (MAP) on current ventilator.
Convective Rate (bpm)	15
I time (seconds)	2.0
E time (seconds)	2.0
Oscillatory CPAP/PEEP (cmH_2O)	AEP 10-12 (max 14-18)
NOTE: *When Demand CPAP/PEEP is on, it combines both Demand CPAP and Oscillatory CPAP for total PEEP.*	
Demand CPAP/PEEP (cmH_2O)	0 (5-8 when needed)
Convective Pressure Rise (CPR)	Gradient of 3-5 to start with, maximum of 8-10 between CPR and pulsatile flow
Pulse Frequency Rate (cycles)	500 (400-700) adjust in increments of 50 cycles
FiO_2 (%)	Per Dr. orders

1.	Set up the Monitron® II. • Monitron®: "ON" • Scale: 0-60 • Sweep: 0.00 - 5.00
2.	Select **FiO_2** per Dr. order.
3.	Rotate all control knobs until their arrows are at the 12:00 center, up ↑position (except yellow **DEMAND CPAP/PEEP** control knob). Rotate yellow **DEMAND CPAP/PEEP** control knob full clockwise (OFF).
4.	Rotate black **INSPIRATORY TIME** control knob arrow to the 12:00 center, up ↑position for about a 2-second inspiratory interval.
5.	Rotate black **EXPIRATORY TIME** control knob arrow to the 12:00 center, up ↑position for about a 2-second expiratory interval.
6.	Rotate green **OSCILLATORY CPAP/PEEP** control knob counterclockwise with arrow pointing to 9:00. Rotate green **PULSATILE FLOW** control knob arrow to 12:00 center, up ↑position.
7.	Rotate **MASTER** switch to "ON." Reset Monitron® alarm.
8.	Observe a 2-step increase in Oscillatory PIP on the Monitron® screen.
9.	• First stage is the oscillatory baseline created by an oscillatory demand CPAP selection of between 5-10 cmH_2O. • Second stage is created by percussive flowrate selection of about 25-35 cmH_2O.

NOTE: *Do not use more than 4 cmH_2O of demand CPAP/PEEP during oscillatory CPAP programming. Non-oscillatory, demand CPAP/PEEP is to reduce the work of breathing.*
NOTE: *If demand CPAP is selected with a programmed oscillatory demand CPAP, it will program an accumulative increase.*

Adult Patient Blood Gas Manipulation

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

Decrease CO_2 only	Increase Oxygenation with $PaCO_2$ in Range	Increase PaO_2 and Lower $PaCO_2$
a. ↑Pulsatile flow by 2 cmH_2O up to maximum AIP 40-46 cmH_2O b. ↓Pulse Frequency by 50-100 bpm to a minimum of 400 c. Lengthen I time to 3.0 seconds and shorten E time to 1 second. d. Turn on convective pressure rise. Gradient between convective pressure rise and pulsatile flow = (3-10). If all of the above have not achieved desired CO_2 level, creating a mild to moderate cuff leak per auscultation can be used depending on your infection control/ VAP guidelines.	a. ↑FIO_2 if at low levels b. ↑Oscillatory CPAP/PEEP by 2 cmH_2O max (16-20) c. If maximum Oscillatory CPAP/PEEP is reached: • ↑Pulse Frequency by 50-100 ppm to a maximum of 700 • May cause some increase in CO_2 d. ↑Time at P High • ↑IT by 0.5-1.0 seconds up to 3.5 seconds max e. Turn on convective pressure rise. Gradient between convective pressure rise and pulsatile flow = (3-10) ⇨ **BE PATIENT**-it can take up to 2-4 hours for recruitment to take place.	a. ↑Pulsatile flow by 2 cmH_2O up to maximum AIP 40-46 cmH_2O b. ↑Increase Oscillatory CPAP/PEEP by 2, but keep the gap between pulsatile flow and Oscillatory CPAP/ PEEP the same with adjustment. If the gap is decreased, then CO_2 removal may not be as effective.

Pediatric Starting Guidelines

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

	Pediatrics <10 kg	Pediatrics 10-20 kg	Pediatrics >20 kg
Operating Pressure (psi)	40	40	40
Pulse Frequency Rate (cycles per minute)	500	500	500
Convective Rate (bpm)	30	20	15
I time (seconds)	1.0	1.5	2.0
E time (seconds)	1.0	1.5	2.0
Oscillatory PEEP (AEP)	6-8	6-10	8-10
Pulsatile Flow (AIP)	24-28	24-28	28-32
Demand PEEP	off	off	off
Convective Pressure Rise	off	off	off

For basic CO_2 manipulation:
Increase pulsatile flow in 2-4 cmH_2O increments up to 40-44 cmH_2O in pediatrics.

For basic oxygenation improvement:
Increase PEEP in 2 cmH_2O increments up to 14-16 cmH_2O.

Increase FiO_2 appropriately.

Neonatal Starting Guidelines

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

Operating Pressure (psi)	40
Pulse Frequency Rate (cycles per minute)	600
Convective Rate (bpm)	30
I time (seconds)	1.0
E time (seconds)	1.0
Oscillatory PEEP (AEP)	4-8
Pulsatile Flow (AIP)	15-20
Demand PEEP	off
Convective Pressure Rise	N/A

For basic CO_2 manipulation:
Increase pulsatile flow in 2-4 cmH_2O increments up to 28-34 cmH_2O.

For basic oxygenation improvement:
Increase PEEP in 2 cmH_2O increments up to 8-12 cmH_2O.

Increase FiO_2 appropriately.

Neonatal Patient VDR®-4 Strategies

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

PRDS	Meconium Asp. / PPHN	Lung Protective Strategies & Reduce PIE/Air Leak
a. HFV Rate 600 cycles per minute b. Peep 8 to 10 cmH_2O to narrow ΔP 6 to 10 cmH_2O c. Pulsatile flow for slight chest wiggle (1) d. Convective Rate 30 BPM e. I:E 1:1 Insp. Time 1 second **Weaning goals:** a. Peep 6 to 7 cmH_2O with ΔP 4 to 8 cmH_2O b. Pulsatile Flow < P-high of 16 PIP. Convective Rate slowly by 5 increments down to 15 BPM d. Insp. Time 0.7 to 1 sec. with I:E 1:2 to 1:3	a. HFV Rate 450 to 500 b. Peep 6 to 8 cmH_2O to narrow ΔP 6 to 10 cmH_2O c. Demand CPAP 2 cmH_2O to reach PEEP total. d. Pulsatile flow for good chest wiggle (2) e. Convective Rate 30 BPM f. I:E 1:1 Insp. Time 1 second **Weaning goals:** a. Peep 6 to 7 cmH_2O with ΔP 6 to 8 cmH_2O b. Pulsatile Flow < P-high of 16 PIP. c. Convective Rate slowly by 5 increments down to 10 BPM d. Insp. Time 1 second with I:E > 1:1	a. HFV Rate 500 to 600. Target 600 rate when possible. b. Peep 7 to 9 cmH_2O to narrow ΔP 6 to 8 cmH_2O c. Pulsatile flow for slight chest wiggle (1) d. Convective Rate 25 BPM e. I:E 1: 2 or greater. Insp. Time 0.7 seconds **Weaning goals:** a. Peep 6 to 7 cmH_2O with ΔP 4 to 6 cm H_2O b. Pulsatile Flow < P-high of 16 PIP. c. Convective Rate slowly by 5 increments down to 15 BPM d. Extubate from HFV and don't go back to Conventional.

Neonatal Patient Blood Gas Manipulation

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

Increase PaO_2 and Lower $PaCO_2$	**Increase Oxygenation with $PaCO_2$ in Range**	**Decrease CO_2 only**
a. ↑ Pulsatile Flow by 2-4 cmH_2O up to max (AIP 28-34 cmH_2O) b. ↑ Increase Oscillatory CPAP/PEEP by 2, but keep the gap between P high and P low the same by increasing pulsatile flow. (Max. AEP 12 cmH_2O) If the gap is decreased, then CO_2 removal may not be as effective.	a. ↑ FIO2 if at low levels b. ↑ Oscillatory CPAP/PEEP by 2 cmH_2O (Max AEP 12cmH20) c. If maximum Oscillatory CPAP/PEEP is reached: • ↑ Pulse Frequency by 50 pulses per minute to a maximum 800 • May cause some increase in CO_2 d. ↑ Time at P High • ↑ IT° by 0.1-0.2 seconds up to 1.5 seconds max ⇨BE PATIENT-it can take up to 2-4 hours for recruitment to take place	a. ↑ Pulsatile flow by 2 cmH_2O up to max (AEP 28-34 cmH_2O) b. ↓ Pulse Frequency by 50 pulses per minute to a minimum of 400. **Raise CO_2 with Low PIP** a. ↓ Convective Rate by 5 bpm (minimum 15/min) (↑ Exp. Time) b. ↓ Time at P high • ↓ IT by 0.1 to 0.2 seconds down to minimum 0.7 seconds c. ↑ Pulse Frequency in increments of 50 pulses per minute to a maximum 800

Wean

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

1.	Gradually reduce FiO_2 to under 30%.
2.	Gradually reduce green **CONVECTIVE PRESSURE RISE** to "OFF" (clockwise).
3.	Gradually reduce green **PULSATILE FLOWRATE**.
4.	Watch inspiratory amplitude reduction rate during weaning to maintain acceptable blood gases.
5.	Observe chest for appropriate chest rise.
6.	Discontinue percussive ventilation; rotate **MASTER** switch to "OFF."
7.	Immediately adjust yellow **DEMAND CPAP/PEEP** to prevent sternal retraction and/or notable increased work of spontaneous respiration in most patient populations.
8.	Do NOT reduce demand CPAP below 5 cmH_2O of expiratory amplitude until ready to extubate.
9.	Use non-invasive mask or nasal prongs for non-invasive ventilation after extubation, if desired.
10.	If blood gases indicate weaning too rapidly, turn **MASTER** switch back "ON" and reverse the order of weaning.

Chapter 9: Cleaning and Disinfection

Controller

NOTE: *All single-patient use components and Phasitron® are not intended for cleaning, sterilization, or re-use. Replace single-patient use components regularly, following your healthcare institution's protocol.*
Before cleaning any part of the VDR®-4, disconnect external power sources.

1.	Do not spray any cleaning solution directly onto the controller.
2.	Do not submerge or allow liquids to enter the controller.
3.	Clean the controller according to hospital/institutional protocols. Always clean between patients and when visibly soiled.
4.	Clean the controller with a clean, lint-free cloth or paper towel moistened with the 70% isopropyl alcohol solution.
5.	Use only institution/hospital approved disinfectants and cleaners.

Monitron® II

The waveform unit should be wiped down between patient uses with an institutional-approved disinfectant for cleaning glass or 70% isopropyl alcohol.

Do not spray disinfectant directly onto the waveform unit. Spray the solution onto a cloth and then use the cloth to wipe down the unit.

LCD Screen

1.	Before cleaning, make sure the monitor is turned off.
2.	Take care not to damage or scratch the LCD screen with fingernails, rings, or jewelry.
3.	Remove dust with a dry, lint-free, non-abrasive, soft cotton cloth.
4.	Remove fingerprints or grease using a lint-free, non-abrasive, soft cotton cloth that is lightly moistened with plain water (including water mixed with soap or a mild detergent) or 70% isopropyl alcohol. Dry with a lint-free, non-abrasive, soft cotton cloth. ⚠ **CAUTION:** Do not spray any liquid directly onto the LCD screen.
5.	Clean using hospital/institutional-approved products specifically for LCD monitors.

Digital Multimeter (DM) or Manometer

Clean the DM/Manometer when visibly soiled using 70% isopropyl alcohol or according to facility protocols. Do not spray any type of cleaner directly onto the DM or Manometer.

⚠ **CAUTION:** Use of cleaning methods not outlined in these instructions may cause damage to the multimeter.

Stand Assembly

1.	The stand assembly may be cleaned with most mild, non-abrasive solutions commonly used in the hospital environment (e.g., diluted bleach, ammonia, or alcohol solutions).
2.	The surface finish will be permanently damaged by strong chemicals and solvents such as acetone or trichloroethylene.
3.	Steel wool or other abrasive material should never be used.
4.	Damage caused by using unapproved substances or processes will not be warrantied. We recommend testing any cleaning solution on a small, non-visible area of the mounting assembly to verify compatibility.
5.	Never submerge or allow liquids to enter the mounting assembly. Wipe any cleaning agents off the mounting assembly immediately using a water-dampened cloth. Dry the assembly thoroughly after cleaning.

⚠ **WARNING:** Percussionaire® makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital's infection control officer or epidemiologist. To clean or sterilize mounted devices or accessory equipment, refer to the specific instructions delivered with those products.

Phasitron® Breathing Circuit Kit

Cleaning and Disinfecting Solutions

The Phasitron® breathing circuit has been tested for biocompatibility with the following cleaning and disinfecting 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

⚠ **WARNING:** Follow hospital/institutional guidelines for storage between treatments.

⚠ **WARNING:** Always follow institutional/hospital protocols for cleaning and disinfection.

Phasitron® Cleaning

Follow hospital/institutional guidelines for cleaning and disinfection. It is recommended to change the Phasitron® Breathing Circuit kit not to exceed 7 days.

NOTE: *The Phasitron® breathing circuit is not intended for cleaning, sterilization, or re-use. Replace single-patient use components regularly, following your healthcare institution's protocol.*

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

⚠ **CAUTION:** Failure to follow the manufacturer's cleaning instructions could cause equipment damage.

Chapter 10: Troubleshooting

VDR®-4

Problem	Check	Solution
Frequencies of percussions do not change as frequency control knob is rotated.	Check if unit has been abused, fallen, etc. Check last calibration or functional check performed. Check for contamination of hospital gas service.	Unit must be sent to authorized service center. Contact your distributor.
Proximal manometer not functioning properly, or needle is not zeroed.	Check to see that red proximal airway tubing is connected to bulkhead fitting and/or to proximal port on Phasitron®.	Reconnect harness to proper connection (see Chapter 3: System Description).
	Repeated use may cause the needle on manometer to read at a higher or lower pressure when in the off position.	Carefully remove gauge cover with a small flathead screwdriver and zero manometer. (Unit must be in the off position.)

Monitron® II Waveform Analyzer

Problem	Check	Action
With waveform "ON," no readings appear on the LCD screen.	Check to see if unit is connected to an approved power source. Check to see if power switch (back panel) is in the "ON" position. Check that the red pneumatic input from waveform is connected and unobstructed (no kinks or tight bends).	If problem is not resolved after completing all the checks, contact your distributor.
Pulse frequency is not displayed.	Check to see if unit is connected to an approved power source. Check to see if power switch is in the "ON" position. Check to see if the blue pneumatic input tube is connected and unobstructed.	If problem is not resolved after completing all the checks, contact your distributor.
Phase rate is not displayed.	Check to see if the unit is connected to an approved power source. Check to see if power switch is in the "ON" position. Check to see if yellow pneumatic line to waveform is connected properly and unobstructed.	If problem is not resolved after completing all the checks, contact your distributor.
Expiratory baseline is + or – from desired reference pressure.	Refer to authorized service center.	Contact your distributor.
Alarm sounds and will not reset.	Check high and low alarm settings to verify parameters.	If problem is not resolved, contact your distributor

Digital Multimeter (DM)

Problem	Check	Action
Service error screen	Batteries	Remove batteries and wait 30 seconds. Replace batteries and watch the screen until the text disappears before putting DM back into the device.
Not turning on	Red sample line is connected, no blockage in the sample line, and the Phasitron is occluded or connected to an airway or test lung.	DM reads pressure from the patient to wake up. If there is no signal because the Phasitron is not connected or the red sampling tube is blocked, there will be no reading.
Only information is Mean Airway Pressure, frequency, and the moving bar on left (AIP and AEP show zero).	DM is still acquiring data.	Observe bar graph on left of DM and the waveform while listening to VDR® and observing patient chest movement to confirm VDR® is running; wait for DM to acquire data.
There are only two pressure numbers: Mean Airway Pressure and a number above that changes.	Is the bar graph moving, and does the top number change dynamically and match the bar graph?	DM is installed with ver 2.66 software with dynamic pressure reading; observe to see AIP and AEP numbers as they pause.
AIP and AEP information is "flipped."	Observe that the bar graph on the left of the DM is moving up and down and that the waveform is also displaying movement.	DM is installed with ver 2.33 software, and the patient is spontaneously breathing or had some spontaneous breaths that did not match the DM algorithm.

Phasitron® A50094-D Breathing Circuit Kit

Problem	Check	Action
No percussion	Improper assembly	Refer to assembly instructions.
	No airflow from the clear tubing	Check device connections.
Nebulizer does not aerosolize.	Loose nebulizer baffle	Inspect and re-seat baffle on stem.
	No airflow in the yellow tubing	Check device connections.
	Orifice clogged inside unit	Confirm direction of check valve in yellow tubing.
Phasitron® air leak	Improper assembly	Refer to assembly instructions.

Chapter 11: Service and Repair

Preventive Maintenance

Percussionaire® recommends an annual Preventive Maintenance (PM) for each device. This consists of a thorough cleaning, functional evaluation, and, if necessary, recalibration. This must be done by a Percussionaire® factory-trained service technician. Please contact the Percussionaire® Service Department for scheduling and pricing of our biomedical training classes.

Device	Maintenance and Service
VDR®-4 Controller	Factory-trained service technician performs an annual PM consisting of a thorough cleaning, functional evaluation, and recalibration (if necessary).
Stand	Periodically inspect all fasteners associated with the mounting assembly. Tighten or adjust as necessary for optimal operation and safety.
Phasitron®	The Phasitron® is a single-patient breathing circuit. Follow the cleaning instructions as given in this manual. Replace Phasitron® every 7 days.

Service

A mandated service is required every 3 years from the date of manufacture and/or not later than 4 years. A full service consists of an installation of a new front bezel which replaces all elastomeric seals, harnesses, check valves, and cartridges. All components are inspected, and device is factory calibrated with a new certificate of conformance, including a new one-year warranty. If replacement parts other than those specified in the full service are required, the cost of the parts will be quoted.

Device service kits are newly manufactured and will be warrantied from the time of installation for 12 months.

A device which has not received a mandated full service for a period of 10 years, whether in use during that period or not, will not be serviced.

Repair

To repair a Percussionaire® VDR®-4, contact Percussionaire® Service Department or the distributor.

Disposal of Equipment

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

Shipping and Packaging

To ship the VDR®-4 to a factory service center, contact: 800-850-7205 or (208) 263-2549 and request a Return Authorization (RA) number.

The VDR®-4 must be cleaned, air-dried, placed in a plastic bag, and placed in a sturdy box with packaging material thoroughly surrounding and protecting the unit. Packing material must protect the device from damage during shipment. A packaging slip must accompany device with information to include RA number, name, and address of sender. The box must be securely closed with the RA number clearly visible on the outside of the packaging.

Chapter 12: Limited Warranty

Percussionaire® warrants that the VDR®-4 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.

Chapter 13: Technical Specifications

VDR®-4

Phasitron® Kit	A50094-D
Liquid Consumption	1 cc per minute
Percussion Frequency	50-900 pulses per minute
Pulse/Interval Ratio	Adjustable
Operating Range	Temp., 0°C to 49°C (32°F to 120°F)
Storage and Transport Range	Temp., -20°C to 60°C (-4°F to 140°F) Humidity < 93% non-condensing
Run Time	Continuous
Alarm condition High Airway Pressure Limit	Audible indicator (pneumatic pressure failsafe) with automatic pressure relief
Electronic High/Low-Pressure Alarm	Visual and audible indicators
Disconnect Alarm	Audible indicator
Blender Gas Supply Alert	Audible indicator
Wall Gas	50-80 psi air and O_2
Flow	25 LPM per gas source-sustained
Dimensions (W x H xD)	40.64 cm x 33 cm x 25.4 cm (16" x 13" x 10”)
Weight	8.98 kg (19.8 lb)
Maintenance Required	Every 3 years

Monitron® II Waveform Analyzer

Operating Range	Temp., 0°C to 49°C (32°F to 120°F)
Storage and Transport Range	Temp., -20°C to 60°C (-4°F to 140°F) Humidity < 93% non-condensing Vibration: ½ g at 10 Hz , Shock: 2 g 10 sec.
Proximal Airway Pressure	Maximum allowable: -100 cmH_2O to +200 cmH_2O
Display Range	0-35 cmH_2O at 30 cm scale 0-70 cmH_2O at 60 cm scale 0-150 cmH_2O at 120 cm scale
Alarms	Audible Alarm 65 db
Power Input	100-240 VAC, 50/60 Hz, 1 A
Fuse Rating	Electrical (2) 1 A/250 VAC
Cordset	U.S.: Cordset provided International: Distributor will provide cordset with harmonized marking
Batteries	Internal rechargeable batteries provide power to alarm in the event of AC power failure. In the event of battery failure or malfunction, batteries can only be replaced by a Percussionaire®-authorized service center.
Dimensions	W x H x D 33 cm x 20.3 cm x 23.4 cm (13" x 8" x 9.2")
Weight	4.5 kg (9.8 lb)

Phasitron® A50094-D

Rate Range	0-999 pulses per minute
Pressure Range	0-150 cmH_2O/hPa
Aerosol Flow	1 cc per minute
Safety Valve Release	30-50 cmH_2O/hPa
Red Line Filter	1 micron hydrophobic
Operating Range	Temp., 0°C to 49°C (32°F to 120°F)
Storage and Transport Range	Temp., -40°C to 60°C (-40°F to 120°F) – relative humidity up to 90% non-condensing
Service Life	7 days
Shelf Life	2 years
Disposal	Recycle according to local laws.

Digital Multimeter (DM)

Size	73 mm (2.87 inch) diameter
Mass	165 g (0.36 lb)
Operating Range	Temperature -20°C to 60°C (-4°F to 140°F), Humidity <93% non-condensing
Storage and Transport Range	Temperature -20°C to 60°C (-4°F to 140°F) Humidity < 93% non-condensing
Display	128 x 64-pixel FSTN chip-on-glass LCD with reflector
Fault Detection	Independent hardware and software watchdogs
Serial Port	USB (firmware upgrade)
Rate Range	50-999 pulses per minute
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)

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