



PERCUSSIONAIRE® CORPORATION

MONITRON® II WAVEFORM ANALYZER

MODEL F00007-1

A STAND-ALONE EDUCATIONAL MONITOR FOR VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®-4)



INSTRUCTIONS FOR USE

ONLY QUALIFIED PERSONNEL ARE AUTHORIZED TO INSTALL AND SERVICE THIS DEVICE.

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INTRODUCTION

The MONITRON® II WAVEFORM ANALYZER computes and displays parameters numerically and visually based off three air pressure signal inputs from a VDR®-4.

INSTALLATION

Utilize the following section to interact and install the MONITRON® II device in your facility.

CONTROLS INTERFACE

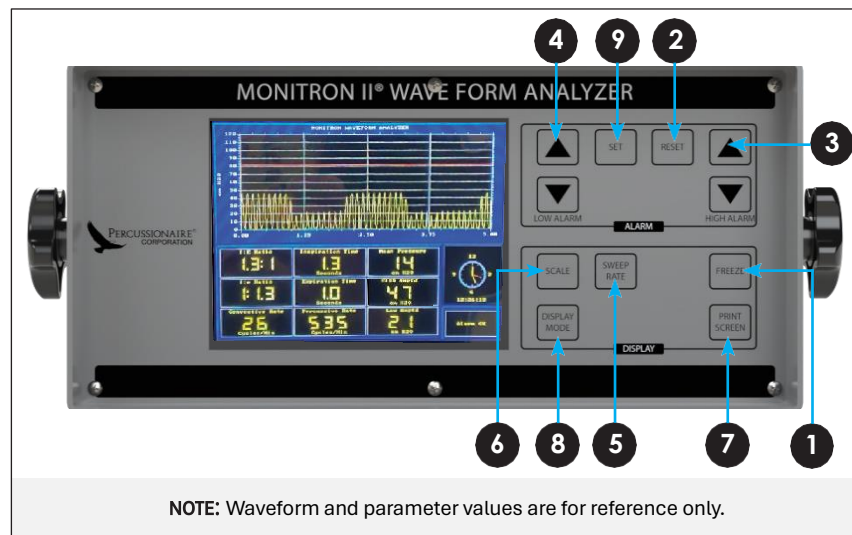


Figure 1: MONITRON® II Front Display Panel

Table 1: MONITRON® II Front Display Buttons and Descriptions




Figure 1 No.	Image of Button	Function
1		The FREEZE button is used to pause the display for observation. After 30 seconds, live monitoring will resume.
2		The RESET button is used to dismiss the device alarm. The alarm level that triggered the alarm must be adjusted before RESET will stop the alarm.
3		The HIGH ALARM arrow buttons are used to adjust the high alarm limit on the graph. The up and down arrows may be pushed repeatedly until the desired high alarm limit is achieved. <u>Note:</u> The high alarm will reset automatically once the high amplitude condition is resolved.










Figure 1 No.	Image of Button	Function
4		The LOW ALARM arrow buttons are used to adjust the low alarm limit on the graph. The up and down arrows may be pushed repeatedly until the desired low alarm limit is achieved. <u>Note:</u> The low alarm requires a manual reset by pressing the RESET button. The low alarm <i>will not</i> automatically reset if the amplitude or low alarm level changes.
5		The SWEEP RATE button is used to cycle through the available horizontal sweep rates of the displayed graph. The sweep rates available are: 1, 2, 5, and 8 seconds per sweep.
6		The SCALE button is used to cycle through the available vertical scales of the displayed graph. The vertical scales available are: 30 cmH ₂ O, 60 cmH ₂ O, and 120 cmH ₂ O.
7		The PRINT SCREEN button defaults as non-functional.
8		The DISPLAY MODE button toggles between a graph centric display and a value centric display.
9		The SET button will automatically position the “High” alarm to 20% above PIP. The “Low” alarm will be set at 4 cmH ₂ O.

Table 2: Rear Panel Controls of MONITRON® II

Item	Function
	The Power Switch is used to turn the unit “ON” and “OFF.”
	The 25-pin D-Sub and 9-pin D-Sub connectors are non-functional for external inputs. Do not remove the covers.
	The VGA connector is used to connect an external monitor. The image displayed on the external monitor will be a duplicate of the display on the MONITRON® II.

MONITORING PARAMETERS

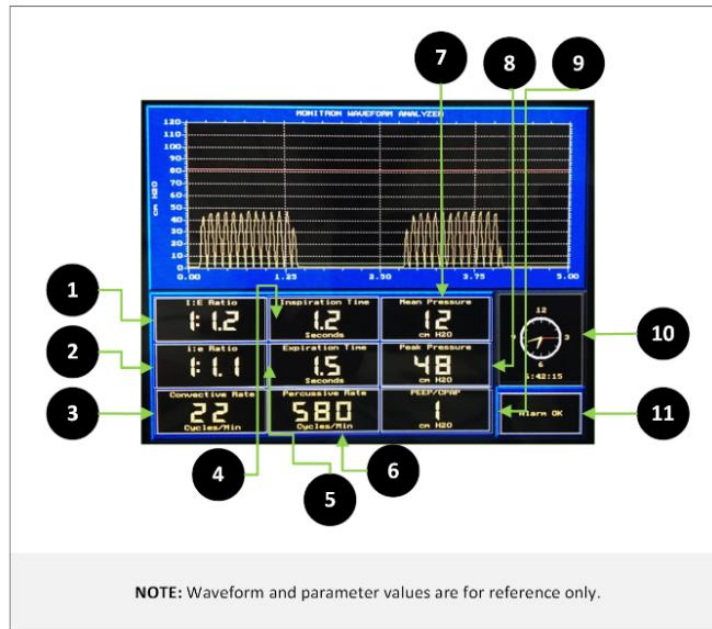

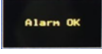


Figure 2: Display Parameters

Table 3: MONITRON® II Parameter Descriptions

Figure 2 No.	Image	Function	Units
1		Ratio between Inspiratory Cycle and Expiratory Cycle	N/A
2		Ratio of inspiratory segment to the expiratory segment	N/A
3		Number of inspiratory/expiratory cycles per minute	cycles/min
4		Length of Inspiratory Cycle	seconds
5		Length of Expiratory Cycle	seconds
6		Cyclic rate of percussions per minute (rounded to the nearest 5)	cycles/min
7		Averaged air pressure from total inspiratory time to total expiratory time	cmH ₂ O
8		Pressure measured at its highest point also known as PIP. Parameter may be titled “High Amp’d” depending on software version.	cmH ₂ O
9		Positive End Expiratory Pressure (PEEP): Pressure inside the lungs at the end of the expiratory cycle during machine ventilation Continuous Positive Airway Pressure (CPAP): Pressure is constant throughout the entire inspiratory/expiratory cycle Parameter may be titled “PEEP/CPAP” depending on software version.	cmH ₂ O

10		Clock set by customer	N/A
11		Alarm Status	N/A

VISUAL AND AUDITORY OUTPUTS

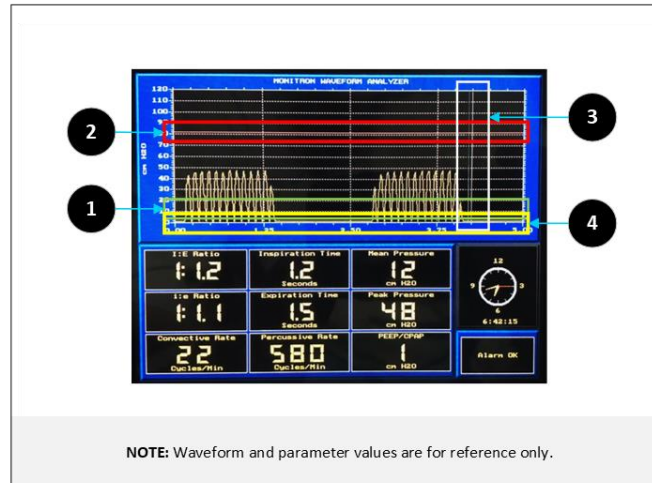


Figure 3: Visual Outputs Diagram

Table 4: MONITRON® II Visual and Auditory Output Descriptions

Figure 3 No.	Item	Description
1	Low Alarm Trigger Level	Displayed as a green line on the graph.
2	High Alarm Trigger Level	Displayed as a red line on the graph.
3	Proximal Airway Pressure	The proximal airway pressure is displayed as a sweeping graph. Data will be displayed from left to right that sweeps across the display. Negative values are not displayed.
4	Baseline	Displayed as the bottom of the yellow line on the graph.
N/A	Alarm	Whenever an alarm condition exists, an audible alarm of at least 65db and approximately 3 KHz will sound.

See the STATEMENT ON ACCESSORIES on page 9 for more information on additional accessories that may be inputted into the MONITRON®II.

SET UP

Complete the following steps to complete final set up of the MONITRON® II:

1. Install each tubing harness, located on the top of the device, into its corresponding-colored port located at the bottom of the VDR®-4 device.

2. Once the MONITRON® II and VDR®-4 devices are connected, the VDR®-4 may be stacked upon the MONITRON®II device.
3. Input the provided power cord into the power supply port on the back side of the MONITRON® II. Plug the power cord into an appropriate power source per the SPECIFICATIONS on page 10.
4. Turn on the MONITRON® II by pressing the Power Switch located on the back of the device.

Table 5 provides a starting point for operational settings explained in steps 5. through 7. Hospital and care provider protocol should be followed for exact settings.


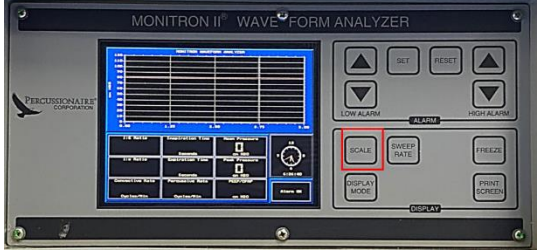

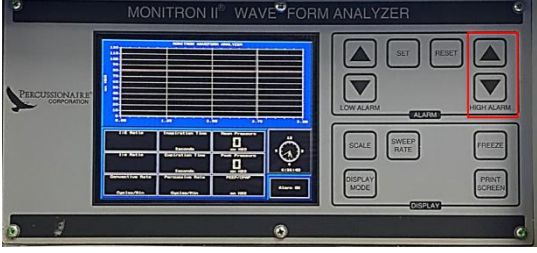
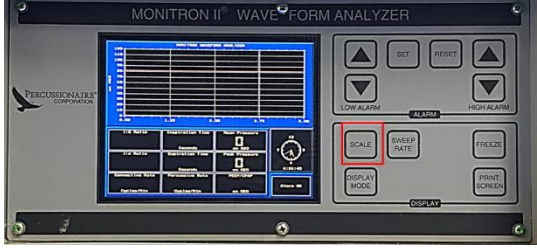
Table 5: Setting Guidelines for Device Operation

Setting	Starting Point Value
High Pressure Alarm	10 cmH ₂ O above PIP
Low Pressure Alarm	10 cmH ₂ O below PIP
Scale	120 cmH ₂ O
Sweep Rate	5 seconds per sweep

5. Set the low- and high-pressure alarms (shown in Figure 3) by using the corresponding up and down arrows on the display.
 - a. The **LOW ALARM** level can be identified as a green line on the display graph.
 - b. The **HIGH ALARM** level can be identified as a red line of the display graph.
6. Set the sweep rate to 5 seconds by pressing the **SWEEP RATE** button on the front display.
7. Ensure the display pressure scale on the y-axis is 120cmH₂O. If not 120cmH₂O, press the **SCALE** button on the front display to set the parameter.
8. Set the clock to the local time by completing the instructions listed in section **CLOCK SETTING** on page 8.
9. Allow the MONITRON® II to run for approximately 15 minutes before every use.
10. Verify the device baseline, the lowest point of the yellow amplitude line, is reading a zero-pressure.

CLOCK SETTING

Table 6: Clock Setting Procedure

Step	Description	Illustration
1.	With the MONITRON® II On, insert a paperclip into the hole and press the RESET button on the front display.	
2.	On the front panel of the device press the SCALE button.	
3.	Press the <u>low alarm</u> up and down arrows to set the <u>hour</u> .	
4.	Press the <u>high alarm</u> up and down arrows to set the <u>minutes</u> .	
5.	Press the SCALE button to set the time.	

ALARM VERIFICATION

Alarm verification should be performed between each patient by completing the following:

1. Connect a VDR®-4 failsafe circuit connected to a test lung to the VDR®-4 device.
2. Set the parameters dictated in Table 7 below:

Table 7: VDR®-4 Settings for Alarm Verification

Parameter	Setting
VDR®-4 operating pressure	40psi
FIO ₂	60%
Inspiratory Time	2 secs
Expiratory Time	2 secs
PIP	40 cm H ₂ O
Demand CPAP/PEEP	Off
Oscillatory CPAP/PEEP	10 cm H ₂ O
Convective Pressure Rise	Off
Pulse Frequency	500 cycles/min
Nebulization	Off
Master Switch	On
Failsafe sensitivity	12:00 position
Pulse i/e Ratio	7:00 position

3. On the MONITRON® II, adjust the high alarm level to 50 cm H₂O and adjust the low alarm level to 8 cm H₂O using the corresponding up and down arrows on the front display.
4. During Inspiratory phase, squeeze the test lung so that a pressure of > 50 cm H₂O registers on the screen.
5. Verify that the high-pressure alarm sounds and will not cease until the wave caused by squeezing the test lung clears the display graph.
6. Disconnect the test lung.
7. Verify that after approximately 30 seconds the low-pressure alarm sounds and will not cease until the test lung is reconnected and the **RESET** button is pushed.

STATEMENT ON ACCESSORIES

Each device may be accompanied by an additional monitoring system. Additional equipment inputted into the signal ports must comply with International Electrotechnical Commission (IEC) mandated requirements. It is recommended to contact the service center if issues occur. Percussionaire® is not responsible for any additional equipment connected to the MONITRON®II.

To maintain functional performance of the MONITRON® II, supplemental pneumatic accessories must prevent the egress of liquid into the device.

SPECIFICATIONS

Environmental:

Temperature range	10° to 30° Celsius
Humidity	0-95% non-condensing
Vibration	1/2g at 10 Hz
Shock	2g. 10 sec.

Proximal Airway Pressure:

Maximum allowable range	-100 cmH ₂ O to +200 cmH ₂ O
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Display Range:

0-30 cm H₂O	30 cmH ₂ O scale
0-60 cm H₂O	60 cmH ₂ O scale
0-120 cm H₂O	120 cmH ₂ O scale

Alarm:

Audible Alarm	65 dB
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Electrical:

Power Consumption	40 Watts
Operating Power Supply	110VAC-230VAC (50/60Hz)
Power Cord Port Type	C14
Fuse	1A 3AG
Fuse Voltage Rating	250 V
Fuse Series	Series 312

Dimensional:

Width	13"	33cm
Height	7"	17.78cm
Depth	9.2"	23.4cm
Weight	9.8lb	4.6kg

Batteries:

The internal rechargeable batteries supply power to the alarm in the event of an AC power failure. If a battery failure or malfunction occurs, batteries must be replaced by a qualified service center only.

CLEANING INSTRUCTIONS

The MONITRON® II and the power cord should be wiped down between patient uses with a hospital approved disinfectant. Apply disinfectant to a cloth before cleaning device. Do not spray disinfectant directly on the device.

STORAGE

The Monitron® II should be stored covered and in a clean environment when not in use. For storage, the temperature must be maintained between 50°F – 86°F (10°C - 30°C); the humidity range must be 0-95% non-condensing.

PREVENTATIVE MAINTENANCE

The ALARM VERIFICATION procedure included on page 9 should be performed between each patient.

Tubing harnesses should be inspected annually for cracks, kinks, and general damage. If replacements are necessary, contact a qualified service provider. The part numbers for the pneumatic harnesses are as follows:

Table 8: Replaceable Harness Part numbers

Part Number	Description
A67001	Yellow tubing harness
A67002	Blue tubing harness
A67003	Red tubing harness

REPAIR

Contact a qualified service center for repair or replacement if any issues occur or functional performance is diminished. Do not open the device to troubleshoot or repair device.

SHIPPING REQUIREMENTS


During shipping, the Monitron® II should be maintained at temperatures between 50°F – 86°F (10°C - 30°C). To properly package the device, follow the instructions below:

1. To protect the MONITRON® II from scratches and liquids, place the device in a large plastic bag and seal with tape.
2. Package the Monitron® II in a box at least 18" x 14" x 14".
3. To protect from impact, place packaging material around all sides, including the top and bottom of the device.
4. Apply labels to the box, close and then seal.

TROUBLESHOOTING GUIDE

Utilize Table 9 to troubleshoot any issues that arise with the MONITRON® II. DO NOT open the device to service or troubleshoot.

Table 9: Troubleshooting Instructions

Issue	Solution
<p>No parameters are displayed on the screen when the MONITRON® II is powered On.</p>	<ol style="list-style-type: none"> 1. Verify that the device power cord is inputted into an appropriate power source based on electrical specifications per this manual on page 10. 2. Verify the power switch located on the back of the MONITRON® II is On. <div style="text-align: center; margin: 10px 0;">  </div> 3. Verify the red tubing harness is fully inputted in the MONITRON® II and connected to the correct colored port from the VDR®-4. 4. Verify there are no kinks or tight bends along the red tubing harness. 5. Contact a qualified service center if the problem persists.
<p>Frequency parameters are not displayed.</p>	<ol style="list-style-type: none"> 1. Verify the blue tubing harness is fully inputted in the MONITRON® II and connected to the correctly colored port from the VDR®-4. 2. Verify there are no kinks or tight bends in the blue tubing harness. 3. Contact a qualified service center if the problem persists.
<p>Convective Pressure rate not functioning.</p>	<ol style="list-style-type: none"> 1. Verify the yellow tubing harness is fully inputted in the MONITRON® II and connected to the correctly colored port from the VDR®-4. 2. Verify there are no kinks or tight bends in the yellow tubing harness. 3. Contact a qualified service center if the problem persists.
<p>The baseline level is above or below the desired reference pressure.</p>	<ol style="list-style-type: none"> 1. Verify that the MONITRON® II has been running for at least 15 minutes. 2. Contact a qualified service center if the problem persists.
<p>Alarm will not stop sounding.</p>	<ol style="list-style-type: none"> 1. Verify that the high and low alarm levels are above and below the pressure value inputting into the MONITRON® II. 2. Press RESET on the display. 3. Contact a qualified service center if the problem persists.

CONTACT INFORMATION

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Lincoln, RI 02865
United States

WEBSITE

www.sentec.com

GLOSSARY

 Manufacturer	 Manufactured Date
 Catalog Number	 Serial Number
 Prescribed Use Only	 Read Manual Before Use
 Caution	 Type BF Applied Parts

LIMITED WARRANTY

The manufacturer warrants to the initial purchaser that each new MONITRON® II will be free from defects in workmanship and materials for two years from the date of first use (proof of delivery will be required). The manufacturer's sole obligation under this warranty is to, at its own choice, repair or replace any component – for which the manufacturer acknowledges the warranty coverage – with a replacement component.

WARRANTY EXCLUSIONS AND SYSTEM PERFORMANCE

Percussionaire® can neither guarantee nor verify product performance characteristics, nor accept warranty or product liability claims, if the recommended procedures are not carried out, if the product has been subject to misuse, neglect or accident, if the product has been damaged by extraneous causes, or if accessories other than those recommended by Sentec are used.

Any serious incident that has occurred in relation to the MONITRON® II has to be reported to Sentec (regulatory.percussionaire@sentec.com) and/or to the competent authority of the country where the incident occurred. If unsure whether an incident is a reportable event, contact Sentec.



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Document ID: P058-2 REV I