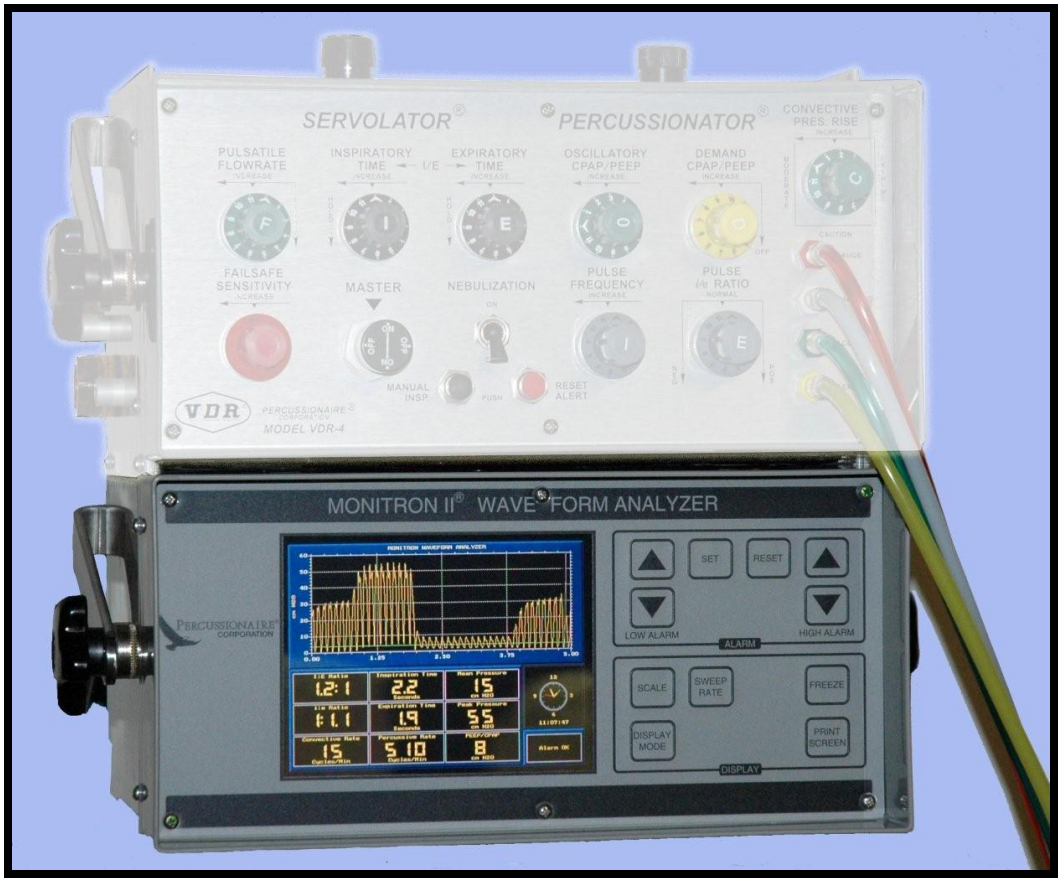
PERCUSSIONAIRE®
CORPORATION

MONITRON® II WAVEFORM ANALYZER
MODEL F00007-1
INSTRUCTIONS FOR USE



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

ONLY
QUALIFIED KNOWLEDGEABLE PERSONNEL
SHOULD INSTALL, SERVICE,
ADJUST AND MAINTAIN THIS UNIT.

TABLE OF CONTENTS

INTRODUCTION:

The waveform analyzer is built under the direction of Bird Institute of Biomedical Technology.

The waveform analyzer monitors three specific air pressure signals and converts these to a Liquid Color Display (LCD).

INSTALLATION:

See **Statement for Accessories** page 15

Waveform analyzer part # F00007-1

The waveform analyzer is packaged in a stackable plastic housing.

The pressure signals are transferred to the analyzer by the red, blue and yellow tubes, located on the top of the waveform analyzer.

To connect the analyzer the tubes from the analyzer are connected to corresponding color-coded fittings.

OPERATION:

Once the waveform analyzer has been installed and connected to an appropriate power source, the unit is ready for operation.

With the waveform analyzer on/off switch in the "on" position, the baseline should be observed for proper zero pressure reading. Refer to the "troubleshooting" section if the baseline needs to be corrected. The sensitivity should be adjusted initially to the 120cmH_2O, and the selection sweep speed should be adjusted initially to the 5 sec speed. Once baseline settings for the patient have been established, alarm parameters can be set. Low pressure alarms are normally set 10cmH_2O below PIP and high pressure alarms are normally set 10cmH_2O above PIP. Alarm settings here are only a guideline and each hospital protocol should be followed as to exact settings.

DESCRIPTION OF CONTROLS:

1. Power On/Off Switch

2. The power switch is a two-position rocker switch located on the left rear of the analyzer.

3. 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 will revert back to the normal display mode.

3. Alarm Reset

The reset switch is a push button momentary switch used to clear a low-level alarm after the alarm has been corrected. The switch is located on the front panel.

4. High Alarm Adjust

The high alarm is adjusted by pressing the momentary buttons on the front panel to move the "red" high limit alarm limit line up and down. The up and down arrows are pushed repeatedly until the desired high alarm limit is achieved.

5. Low Alarm Adjust

The low alarm is adjusted by pressing the momentary buttons on the front panel to move the "green" low limit alarm limit line up and down. The up and down arrows are pushed repeatedly until the desired low alarm limit is achieved.

6. Sweep Rate

Sweep rate is switched by a button on the front panel. The sweep speeds available shall be 1 sec/Div, 2 sec/Div, 5 sec/Div and 8 sec/Div.
Sweep speed is defined as the rate that new data is being displayed on the LCD.

7. Scale

   The vertical scale is controlled by a button on the front panel. Sensitivity settings of 30, 60 and 120cm of water may be selected. There are no negative signals displayed.

8. Print Screen

   This function is not supported at this time.

9. Display Mode

   The "display mode" button on the front panel re-scales the proportion of the displayed graph to the numeric indicators.

10. Set Button

    The "set" button on the front panel will automatically position the "High" alarm to 10 cmH_2O above PIP. The "Low" alarm will be set at 2 cmH_2O. Alarms should be manually adjusted to appropriate levels.

OUTPUTS:

Electrical 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. See **Statement for Accessories** page 14.

Visual Outputs:

1. Low Alarm Level

   Low alarm will be displayed as a green line on the LCD at the appropriate pressure level.

2. High Alarm Level

   High alarm will be displayed as a red line on the LCD at the appropriate pressure level.

3. Proximal Airway Pressure Level (Pulse Amplitude)

   The proximal pressure signal is converted into an electrical signal by using a micro switch PC16 transducer and digitized by an A/D converter and stored in an electrical memory for display later. The electronic circuitry will output data to a LCD. Data will be displayed on LCD from left to right. New data will always be to the left of the vertical white line that moves across the LCD screen.

Audible Output:

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

SPECIFICATIONS

The following is a summary of monitor specifications and tolerances.

Environmental:

Temperature range	10° to 30° Celsius
Humidity	0-95% Non-condensing
Vibration	½ g at 10 Hz
Shock	2g. 10 sec.

Proximal Airway Pressure:

Maximum allowable	-100 cm H_2O to +200 cm H_2O

Display Range:

0-35 cm	H_2O	at	30 cm scale
0-70 cm	H_2O	at	60 cm scale
0-140 cm	H_2O	at	120 cm scale

Alarms:

Audible Alarm	65 db

Fuse Rating

(2) 3AG
3 AMP/250 VAC
Series 312 fuses

Electrical

Volts 110vac/60Hz
Volts 230vac/50Hz
Watts 40-50
Convection cooling Max 40w

Cordsets

US	Cordset provided
International	Distributor will provide a cordset with harmonized marking<HAR>

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 be replaced only by a qualified service center

DIMENSIONAL ASPECTS – MONITRON® II WAVEFORM ANALYZER

WIDTH	HEIGHT	DEPTH	WEIGHT
13” / 33 cm	8” / 20.3 cm	9.2” / 23.4 cm	9.8 lb / 4.5 kg.

Adjusting the Null Point
(Baseline Adjustment)

Figure A

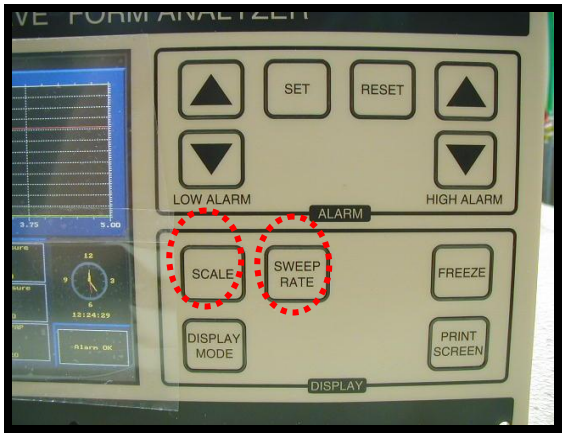
This Operation adjusts the zero point for all scales. Pressing either of the up/down arrow keys makes the adjustment. Pressing an up arrow key will move the base line upward. Pressing the down arrow key will move the base line downward.

Pressing the appropriate arrow key causes a small adjustment in the baseline and the system returns to normal operation. If further adjustment is required, then the sequence needs to be repeated. The total amount of adjustment is limited. Thus, if failure to return baseline to zero or baseline fails to respond, a recalibration is required.

Steps:

- Press small button located on back of the WFA unit located inside small hole. (Refer to figure A.)
- Press SWEEP RATE key. (Refer to “B” on next page.)
- Use arrow keys ⇑ or ⇓ to move baseline in appropriate direction.

SET CLOCK



(A) (B)

- WITH MONITRON® II "ON", LOCATE SMALL HOLE ON BACK (A)
- USING SMALL SCREWDRIVER OR PAPERCLIP, INSERT INTO HOLE, LISTEN FOR BEEP
- ON FRONT PANEL (B) PUSH "SCALE"
- USE LOW ALARM BUTTONS FOR HOURS
- USE HIGH ALARM BUTTONS FOR MINUTES
- PRESS "SCALE" WHEN FINISHED

YOUR MONITRON® II UNIT HAS BEEN FACTORY CALIBRATED AND SHOULD NOT REQUIRE OPENING.

PROBLEM	FIX
With waveform ON no readings appear on screen	Check to see if unit is connected to an approved power source.
	Check to see if power switch, located on back of waveform is in the "on" position.
	Check to see that the red pneumatic input line from Waveform is connected and unobstructed. (I.e.: no kinks or tight bends.)
	Refer to qualified service center if problem cannot be found.
Pulse frequency not functioning	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 blue pneumatic input tube is connected and unobstructed.
Phase rate not functioning	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 yellow pneumatic line to waveform is connected properly and unobstructed.
Expiratory baseline is + or – from desired reference pressure	Refer to qualified service
High/Low alarm adjust potentiometer will not function	Return to a qualified service center.
Alarm sounds and will not reset	Check high & low alarm settings to verify parameters.
	Return to qualified service center if problem is not associated with alarms.

ALARM VERIFICATION

With the VDR-4 set-up as follows, evaluate the alarm systems.

Working pressure 40 psi
FIO_2 60%
VDR-4 failsafe circuit attached to test lung (Part # B11048)
It at 2 seconds
Et at 2 seconds
PIP at 40 cm H_2O
Demand CPAP/PEEP off
Oscillatory CPAP/PEEP at 10 cm H_2O
Convective Pressure Rise off
Pulse Frequency at 500 bpm
Master Switch on
Nebulization off
Failsafe sensitivity at 12:00
Pulse i/e ratio to #7

Monitron® II Waveform Analyzer Alarm system:

With VDR-4 functioning, adjust red line with high alarm selection arrow to 50 cm H_2O. Adjust green line with low alarm selection arrow to 8 cm H_2O.

During Inspiratory phase, squeeze test lung so that a pressure of > 50 cm H_2O registers on the screen. Alarm should sound and will not reset until cause of pressure rise is corrected and screen is clear. Remove test lung, after approximately 30 seconds low pressure alarm will sound and will not reset until problem is solved and alarm reset button is pushed.

CLEANING INSTRUCTIONS

Waveform and power supply should be wiped down between patient uses with an institutional approved disinfectant.

Disinfectant solution should not be sprayed directly onto the waveform unit. The solution should be sprayed onto a cloth and then the cloth should be used to wipe down the unit.

STORAGE

The Monitron® II should be stored in a clean environment and covered when not in use. Temperature should be maintained between 0˚ to 30˚ Celsius. Humidity range is 0-95% non-condensation.

MAINTENANCE AND REPAIR FOR MONITRON II WAVEFORM

ROUTINE MAINTENANCE / PREVENTIVE INSPECTION

Routine alarm verification should be performed between each patient. If during preventive maintenance inspection and alarm verification, the waveform analyzer does not function as described, the authorized maintenance center should be contacted.

Pneumatic parts should be checked annually for cracking, kinking and/or damaged connections. Part numbers for the pneumatic harnesses are as follows:

A67001	Yellow harness connection
A67002	Blue harness connection
A67003	Red harness connection

REPAIR

Devices should be checked by an authorized maintenance center anytime clinical efficacy is not as expected.

Units sent back for maintenance and repair must be handled by a Percussionaire distributor, and must have an RGA number which is obtained by calling the Repair Department at Percussionaire Corporation: (800) 850-7205. (See next page for shipping information.)

SHIPPING REQUIREMENTS

When Monitron® II is shipped for repair or maintenance, the following shipping and packaging instructions should be followed.

1. Monitron® II should be placed in a large plastic bag to protect unit from packaging materials.

2. Monitron® II should be placed in a box at least 18” x 14” x 14”.

3. Packaging material should be placed around all sides, including top and bottom of unit, to protect from damage during transportation to the designated facility.

4. Box should be closed and sealed. Appropriate labels should be placed on the outside of the box.

5. During shipping, the Monitron® II waveform should be maintained at temperatures between 10˚ to 30˚ Celsius.

SHIPPING INFORMATION

TELEPHONE/FAX

Phone (208) 263-2549
Fax (208) 263-0577

MAILING AND SHIPPING ADDRESS

Percussionaire® Corporation
130 McGhee Rd., Ste. 109
Sandpoint, ID 83864

WEBSITE ADDRESS

www.percussionaire.com

SPECIAL INSTRUCTIONS

Interference:

Any observed artifact in Monitron® II waveform analyzer may be caused by a source of RF or ferrite interference. The cause of this interference should be removed from proximity to preserve accuracy of parameters.

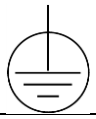
STATEMENT FOR ACCESSORIES

The Monitron® II functions or dysfunctions do not effect the performance of the host device. Each monitored device used for intensive care must possess its own monitoring means.

Accessory equipment connected to the analog and digital interfaces and or the tubing connections must be certified according to the current respective IEC standards. Furthermore, all configurations shall comply with the current system standards. Everybody who connects additional equipment to the signal input port or signal output port configures a medical system, and is, therefore, responsible that the system complies with the requirements of IEC. If in doubt, consult the technical services department or your local representative.

Accessory pneumatic equipment must protect through filters, dryers, desiccants, etc. from the egress of water into Monitron® II Waveform Analyzer.

GLOSSARY OF SYMBOLS

	**ALTERNATING CURRENT**
	**DANGEROUS VOLTAGE WITHIN THE DEVICE MAY CONSITITUTE A RISK OF ELECTRICAL SHOCK**
	**PROTECTIVE EARTH GROUND**
	**ATTENTION, CONSULT ACCOMPANYING DOCUMENTS**
	**OFF**
	ON
	**CLASS 1 TYPE BF ORDINARY EQUIPMENT NOT SUITABLE FOR USE WITH FLAMMABLE MIXTURES/ SUITABLE FOR CONTINUOUS OPERATION**
 **xxxx-xx-xx**	**YEAR OF MANUFACTURE (yyyy-mm-dd = YEAR-MONTH-DAY)**
	**AT THE END OF USEFUL LIFE OF THE MONITRON® II WAVEFORM ANALYZER AND POWER SUPPLY, DISPOSAL SHOULD BE IN ACCORDANCE WITH LOCAL, STATE, FEDERAL AND INTERNATIONAL LAWS. THE MONITRON® II WAVEFORM ANALYZER AND POWER SUPPLY MAY ALSO BE PACKAGED ACCORDING TO INSTRUCTIONS FOUND WITHIN THIS MANUAL AND SHIPPED TO AUTHORIZED MAINTENANCE CENTER FOR DISPOSAL.**

LIMITED WARRANTY

Model No:_____

Serial No:_____

Purchased By: _____
(name of purchaser or company)

Date:_____

The products of Percussionaire® Corporation are warranted, for a period of one year from date of purchase, to be free from defects in materials and workmanship and to meet the published specifications. THE FOREGOING IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, except as to title, and can be amended only in writing by a duly authorized representative of Percussionaire® Corporation. The liability under this warranty is limited solely to replacing, repairing or issuing credit, at the discretion of Percussionaire® Corporation, for the parts that become defective or fail to meet published specifications during the warranty period; provided that, Percussionaire® Corporation will not be liable under this warranty unless (I) Percussionaire® Corporation is promptly notified in writing by Buyer upon discovery of defects or failure to meet specifications; (II) the defective unit or part is returned to Percussionaire® Corporation, transportation charges prepaid by Buyer; (III) the defective unit or part is received by Percussionaire® Corporation for adjustment no later than four weeks following the last day of the warranty period; and (IV) Percussionaire® Corporation's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair or alteration or accident. Any authorization of Percussionaire® Corporation for repair or alteration by the Buyer must be in writing to prevent voiding warranty. In no event shall Percussionaire® Corporation be liable to Buyer for loss of profits, loss of use, consequential damages or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder. Percussionaire® Corporation warranties as hereinabove set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by Percussionaire® Corporation or its agents in connection with Buyer's order or the products furnished hereunder.

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

Percussionaire® Corporation recommends an annual preventive maintenance (PM) for each device. A mandated remanufacture/overhaul (OH) is required every three (3) years after the device is initiated into service or not later than four (4) years after the first date of purchase.

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www.percussionaire.com
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