NAPA™ LP-15
AIRWAY PRESSURE MONITOR

User's Manual

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1. General Information

1.1 About This Manual

This user's manual has been prepared to provide information on the correct operation of the NAPA LP-15 Airway Pressure Monitor. It contains performance specifications, installation, operation and maintenance information.

This manual is intended for trained health-care professionals. The NAPA LP-15 Airway Pressure Monitor may only be used by clinically trained operators with sufficient knowledge, training and understanding of this user's manual. The device must only be used for the purposes described.

1.2 Manufacturer Information

Manufacturer: DRW Medical, LLC
Address: 2710 Concord Rd., Aston, PA 19014 USA
Telephone: 1-800-230-6002
Website: www.drwmedical.com

1.3 Classification

This equipment is classified as protection Class II, type BF in accordance with IEC 60601-1.

2. Safety Information

2.1 Safety Warnings

Warnings are identified by the WARNING symbol shown to the left.

Warnings alert you to potential serious outcomes (death, injury, or adverse events) to the patient or user, or system damage, if the relevant safety measures are not observed.

General

- The NAPA LP-15 Airway Pressure Monitor is intended for use by clinicians with training using airway pressure monitoring devices.
- The NAPA LP-15 Airway Pressure Monitor is not a life monitor and an attendant is needed at all times to monitor the patient.
- Do not adjust alarm threshold parameters so widely as to render the alarms useless.
- Only use the NAPA LP-15 Airway Pressure Monitor with its intended patient population and application – use on other patient types or modes of respiratory support is not defined and may have unpredictable functions.
- The NAPA LP-15 Airway Pressure Monitor is not designed to measure patient respiratory cycles nor to provide alarms for high- or low-pressure excursions related to the respiratory cycle. The device measures and displays a five-second mean (average) airway pressure for the specified intended application, neonatal bubble CPAP. The device high and low alarm thresholds respond to that five-

second mean and not to changes within the respiratory cycle.

- The NAPA LP-15 Airway Pressure Monitor does not display peak or real time airway pressures, and is not intended to be used with a ventilator.

Safety and EMC

- Do not use oil or grease on the NAPA LP-15 Airway Pressure Monitor for any reason.
- Do not use the NAPA LP-15 Airway Pressure Monitor near open flames.
- The internal gas path in the NAPA LP-15 Airway Pressure Monitor has been tested against leaks to provide protection during use with enriched Oxygen CPAP treatment – follow appropriate precautions whenever sources of enriched Oxygen are used.
- Do not attempt to dismantle or to remove components since tampering with the NAPA LP-15 Airway Pressure Monitor may cause the unit to malfunction and will automatically void the warranty.
- Do not use in the presence of flammable anesthetics as this may constitute a fire or explosion hazard.
- To avoid personal injury or equipment damage, keep the power supply cable out of the way of users.
- Use the NAPA LP-15 Airway Pressure Monitor only with its original power supply (Catalog Number 51002).
- The use of portable and mobile radio frequency (RF) communications equipment can affect this and other pieces of medical equipment.
- The use of accessories, power sources and cables other than those specified by DRW Medical may result in

inaccurate readings of the device and increased emissions or decreased electromagnetic immunity of the device.

- The NAPA LP-15 Airway Pressure Monitor should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Always ensure that the NAPA LP-15 Airway Pressure Monitor, its pole mount, and the IV pole are secured near the patient to prevent unwanted movement of the system.
- The NAPA LP-15 Airway Pressure Monitor should always be used on its pole mount – improper or insecure mounting of the device can allow unwanted movement of the monitor.
- Caution: In order to minimize problems with condensation or moisture, the monitored patient connection point should be at least 25 cm (10 in.) lower than the unit.
- Do not connect the NAPA LP-15 Airway Pressure Monitor to a source of airway pressure other than CPAP/ pressure – excessive pressure can damage the unit's pressure sensor.

Accessories

- Only the accessory parts specified for the NAPA LP-15 Airway Pressure Monitor may be used with the device. The use of incompatible components can result in measurement error, degraded performance, or injury.
- Reuse of accessories specified for single patient use could pose an infection risk.

2.2 Safety Notes

NOTES are identified by the NOTE symbol shown to the left.

NOTES provide important information about the product or a specific part of the manual which should be read with particular attention:

- Position the tubing at the patient to minimize the possibility the tubing may be pulled on or interfere with the patient's position.
- Only ZERO the NAPA LP-15 pressure monitor when a pressure discrepancy exists and ensure that the monitor is disconnected from tubing and/or patient and is open to room air.
- NOTE: Be aware there is a two-minute delay prior to alarm activation following power-up.
- NOTE: The NAPA LP-15 Airway Pressure Monitor has been designed for stationary hospital use only.
- NOTE: No high priority alarm conditions are provided by the monitor because the NAPA LP-15 Airway Pressure Monitor measures pressure treatment levels which are considered medium priority, not patient vital signs such as breath rate, which are considered high priority.

3. Intended Use

3.1 Indications for Use

The NAPA™ LP-15 Airway Pressure Monitor is intended to measure and monitor mean airway pressure for neonatal patients being treated with positive pressure therapy, including neonatal

Continuous Positive Airway Pressure (CPAP) devices (e.g., Bubble CPAP)

The device provides audible and visual alarms when the airway pressure falls outside of the user selected high and low alarm limits. The device is intended to be pole mounted for stationary use in hospitals only. For professional use only.

CAUTION: Federal law (U.S.) restricts the sale of this device to, or by the order of, a physician.

3.2 Contraindications

The NAPA™ LP-15 Airway Pressure Monitor is contraindicated when the patient's airway pressures are above 35 cm H_2O.

3.3 Essential Performance

Essential Performance is performance with the absence or degradation of which, would result in an unacceptable risk, and includes the following functionalities:

- Indication of measured pressure value on display.
- Operation within specified measurement accuracy limits ± 2.5 cm H_2O or generation of either a technical alarm condition or an indication of abnormal operation.
- Generation of low and high alarm conditions or generation of a technical alarm condition.
- No unintended change of operating mode.
- Recovery from any disruption within 30 seconds without operator intervention

4. Introduction – Functional Description

4.1 Principles of Operation

The NAPA LP-15 Airway Pressure Monitor is a microprocessor-controlled, alarm and monitoring device that measures, monitors, and continuously displays a five-second mean airway pressure from 0-35.0 cm H_2O during Neonatal Continuous Positive Airway Pressure therapy (e.g., Bubble CPAP) or as an independent backup pressure monitor for devices without pressure measurement capability. The NAPA LP-15 Airway Pressure Monitor alarms when the mean airway pressure falls outside of the user-selected high- and low-pressure alarm limits, and displays mean airway pressures.

The NAPA LP-15 Airway Pressure Monitor also includes an alarm silence feature.

NOTE: The NAPA LP-15 Airway Pressure Monitor has been designed for pole-mounted hospital use only.

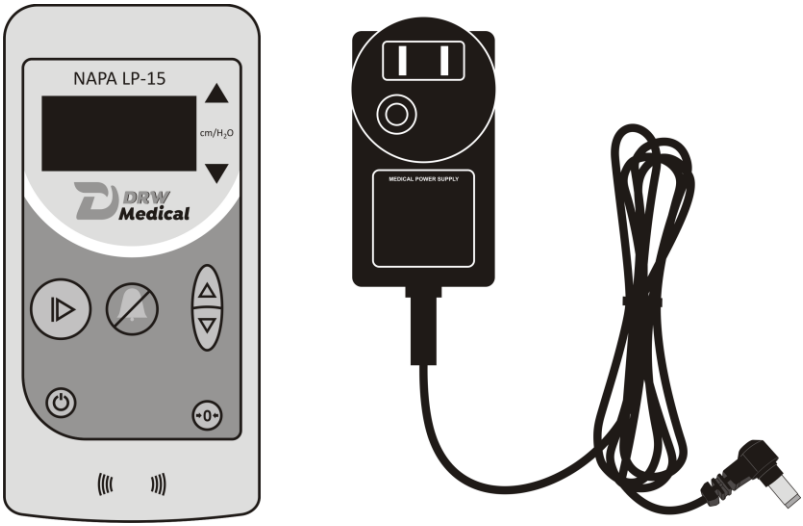


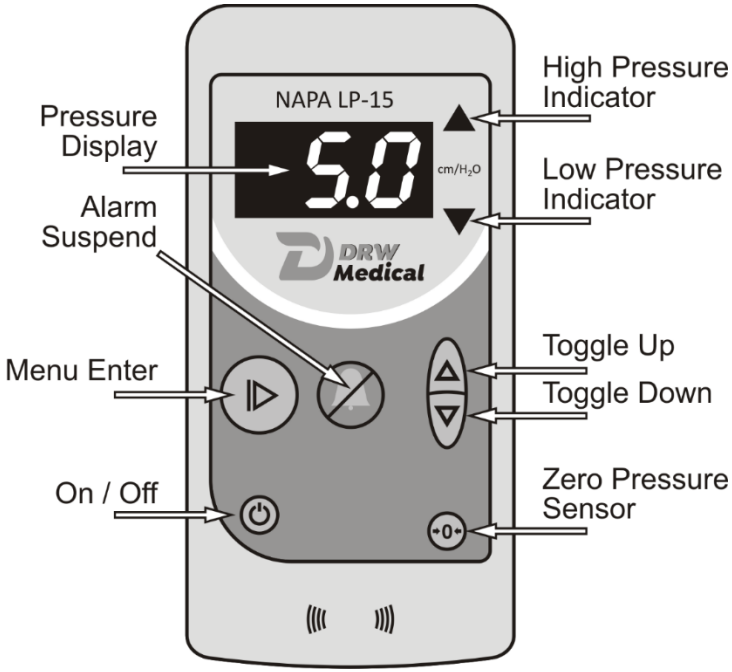
FIGURE 1

Overview of NAPA LP-15 Airway Pressure Monitor Features

- Software measures, monitors, and continuously displays a five-second mean airway pressure from 0-35.0 cm H_2O
- Measures pressures from atmosphere as 0.0.
- Manual zero pressure sensor function.
- Intuitive user interface provides adjustable audio and visual high and low airway pressure alarms which allow bracketing the desired threshold to within 0.1 cm; device alarms when the mean airway pressure falls outside of the user-selected high and low alarm limits.
- High Pressure Alarm: Provides a Medium Priority audible and visual alarm when device detects mean airway pressure 0.1 cm H_2O above preset high limit for 2 seconds and the yellow LED up arrow blinks. The high alarm settings are from 6.0 to 35.0 cm H_20.
- Low Pressure Alarm: Provides a Medium Priority audible and visual alarm when the device detects mean airway pressure 0.1 cm H_2O below preset low limits for 2 seconds. The yellow LED down arrow blinks when there is a low-pressure alarm event. Low alarm settings are from 0.1 to 28.0 cm H_20.
- Alarm Suspend button allows alarm to be silenced for two minutes.
- Alarm resets after two minutes, or automatically when the condition causing the alarm is corrected.

5. Controls, Displays, and Indicators

5.1 NAPA LP-15 Airway Pressure Monitor Front Panel



The NAPA LP-15 Airway Pressure Monitor Front Panel (*FIGURE 2*) includes the following elements:

SOFT KEYS:

- ON/OFF POWER BUTTON 
- MENU-ENTER 
  - Allows you to scroll through the three primary settings:
    - Low Alarm (L)
    - High Alarm (H)
    - Alarm Volume (A)
  - Also saves each setting prior to advancing to the next setting
- TOGGLE UP Δ
  - Scroll up to adjust values of selected setting.
- TOGGLE DOWN ∇
  - Scroll down to adjust values of selected setting.
- ALARM SUSPEND 
  - Silences the audible portion of the alarm for 2 minutes following the ALARM SUSPEND Soft Key Press
- Zero Pressure Sensor Key → 0 ←
  - A one second press and hold of this key initiates the Zero Pressure Sensor – the display flashes

"0.0" when this operation is successfully completed.

- Only ZERO the NAPA LP-15 pressure monitor when a pressure discrepancy exists and ensure that the monitor is disconnected from tubing and/or patient and is open to room air.

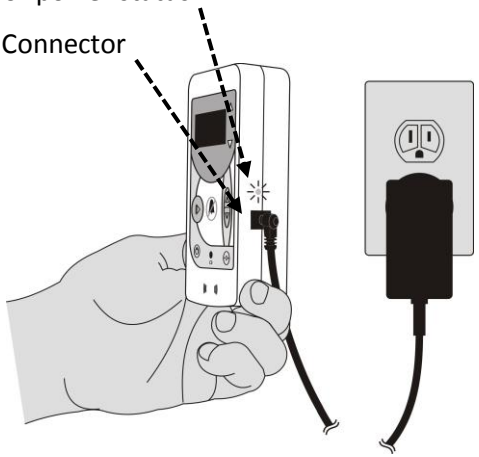
LIGHTS/INDICATORS:

- Δ HIGH PRESSURE ALARM INDICATOR: Flashes when high pressure limit is exceeded
- ∇ LOW PRESSURE ALARM SIGNAL: Flashes when low pressure limit is exceeded

5.2 NAPA LP-15 Airway Pressure Monitor Side Panel

The NAPA LP-15 Airway Pressure Monitor Side Panel (***FIGURE 3***) includes the following elements:

- LED Light for power status
- DC Power Connector



5.3 NAPA LP-15 Airway Pressure Monitor Rear Panel

The NAPA LP-15 Airway Pressure Monitor Rear Panel includes the following elements, pictured in Section 5.7, ***FIGURE 5***:

- Rear Label Location
- Mounting Screws for Pole Mount Bracket

5.4 Symbols Used on the Monitor

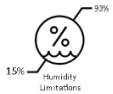
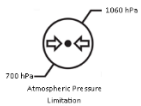
The following symbols are used on the monitor:

Symbol	Description
	On/Off Power Button
	Menu Enter Control Key
	Adjust Up Control Key (adjust value up)
	Adjust Down Control Key (adjust value down)
	Alarm Suspend Control Key
→ 0 ←	Zero Pressure Sensor Key
	LED Indicator: High Pressure Alarm
	LED Indicator: Low Pressure Alarm

5.5 Symbols Used on the Monitor Label and Packaging

The following symbols are used on the monitor label:

Symbol	Description
NAPA LP-15 Airway Pressure Monitor	Device Name
	Device Part Number
	Device Serial Number
	Refer to Instructions for Use
	Manufacturer
	Manufacturing Date
	MR Unsafe
	Attention to Proper Disposal

Symbol	Description
IP21	IP Protection; IP2x denotes mechanical ingress protection (parts >12.5mm); IPx1 denotes water ingress protection (vertical drip)
⎓ DC 5V 2A	Input of external power supply
	Type BF Applied Part, not suitable for defibrillation
	Prescription Use Only
	UDI (Universal Device Identifier) (01) DI; (11) Mfgr Date; (21) Serial Number
	Temperature Storage Limits
	Humidity Storage Limits
	Atmospheric Pressure Storage Limits
	Keep Dry
	Intertek Safety Mark

6. Setup and Operation

6.1 Connecting the NAPA LP-15 Airway Pressure Monitor to AC Mains Power

The NAPA LP-15 Airway Pressure Monitor comes with a power supply that accepts mains power and provides a 5V DC output. ***FIGURE 4*** below shows how the NAPA LP-15 Airway Pressure Monitor connects to AC (wall) power. The ON/OFF button turns monitoring on and off (when the monitor is connected to AC power.

WARNINGS

- To avoid personal injury or equipment damage, keep the power supply cable out of the way of users.
- Use the NAPA LP-15 Airway Pressure Monitor only with a DRW-approved power supply.

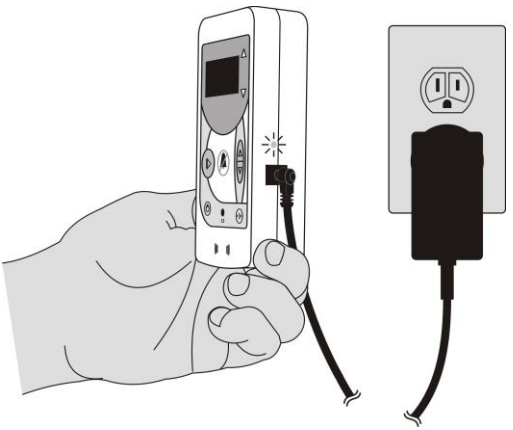


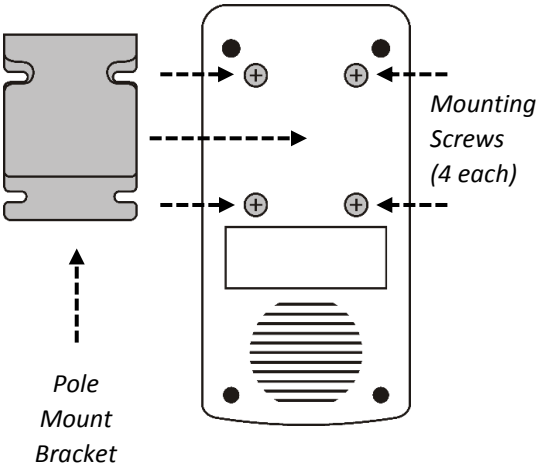
FIGURE 4

6.2 Attaching LP-15 to Pole Mount

The NAPA LP-15 Airway Pressure Monitor is designed to be used on a pole mount. The NAPA LP-15 Airway Pressure Monitor is designed to be used with a DRW pole mount bracket (AC-BR) and DRW pole mount clamp (AC-PC). See the illustrations (***FIGURES 5, 6, 7***) below for proper attachment of the pole mount bracket to the rear of the NAPA LP-15 Airway Pressure Monitor.

FIGURE 5

NAPA LP-15 Airway Pressure Monitor, rear view

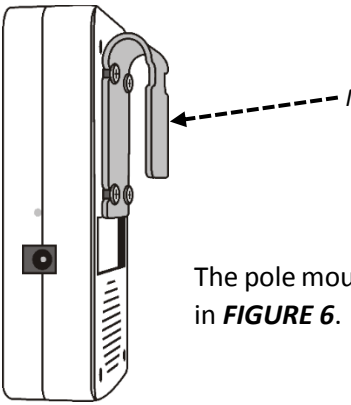


Use the four screws supplied with the unit as shown in ***FIGURE 5***.

CAUTION: Do not overtighten the screws.

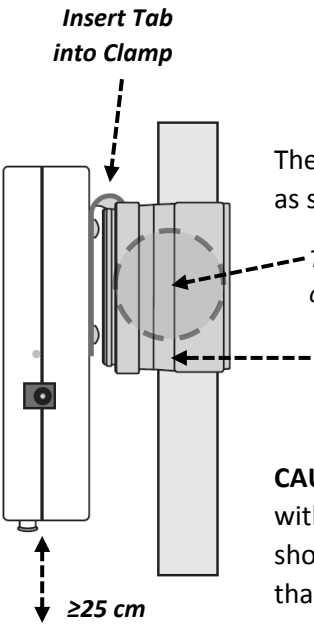
FIGURE 6

NAPA LP-15 Airway Pressure Monitor side view



The pole mount bracket includes a tab as shown in ***FIGURE 6***.

FIGURE 7



The tab is inserted into the pole mount as shown in ***FIGURE 7***.

CAUTION: In order to minimize problems with condensation, the monitored point should be at least 25 cm (10 in.) lower than the unit.

6.3 Normal Operation of the NAPA LP-15 Airway Pressure Monitor (*FIGURE 8*)

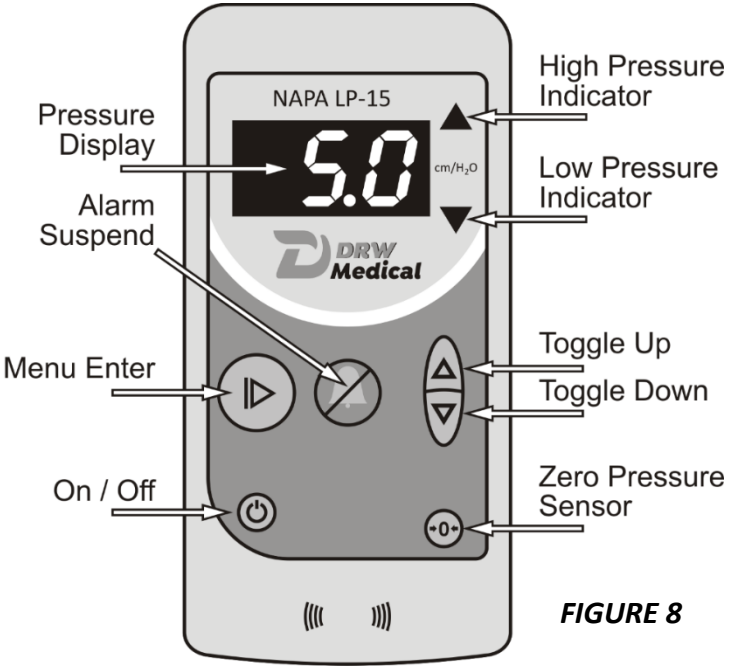
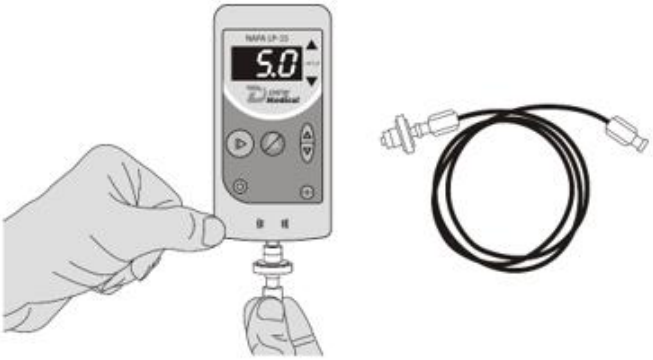


FIGURE 8

1. Press the On/Off button to turn the NAPA LP-15 Airway Pressure Monitor on.
2. To zero the NAPA LP-15 Airway Pressure Monitor, press “Zero Pressure Sensor” with the pressure tubing open to atmosphere.
3. Refer to Section 7 to set alarm limits.
4. The NAPA LP-15 Airway Pressure Monitor is now ready to attach to the patient circuit.



NOTE: Be aware there is a two-minute delay prior to alarm activation following power-up.

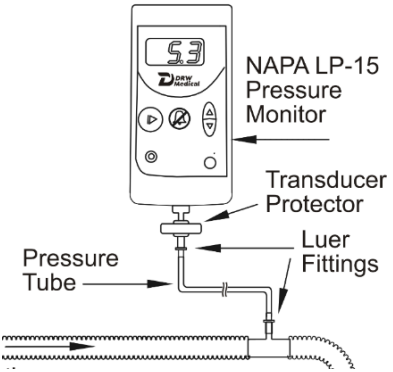
6.4 Connecting the NAPA LP-15 Airway Pressure Monitor to the Patient Circuit (*FIGURE 9*)

NOTE: The NAPA LP-15 Airway Pressure Monitor is designed for use with disposable pressure tubing that includes a transducer protector to protect the monitor from moisture and reduce the risk of contamination.

CAUTION: In order to minimize problems with condensation or moisture, the monitored patient connection point should be at least 25 cm (10 in.) lower than the unit.

FIGURE 9

1. Attach the “Transducer Protector” end of the pressure tubing to the twist connector on the bottom of the NAPA LP-15 Airway Pressure Monitor. (The NAPA LP-15 Airway Pressure Monitor is designed to be used with the AC-MT proprietary pressure tubing that includes a filter/transducer protector to protect the monitor from moisture.)
2. Locate the luer connection port in the patient’s breathing circuit.
3. Connect the other end of the pressure tubing assembly to the luer connection port in the breathing circuit.



4. The NAPA LP-15 Airway Pressure Monitor will now display mean airway pressure. (See FIGURE 10)

FIGURE 10

6.5 BCPAP System with NAPA LP-15 Airway Pressure Monitor Schematic

FIGURE 11 shows the NAPA LP-15 Airway Pressure Monitor connected to the patient circuit.

NAPA LP-15
AIRWAY PRESSURE MONITOR

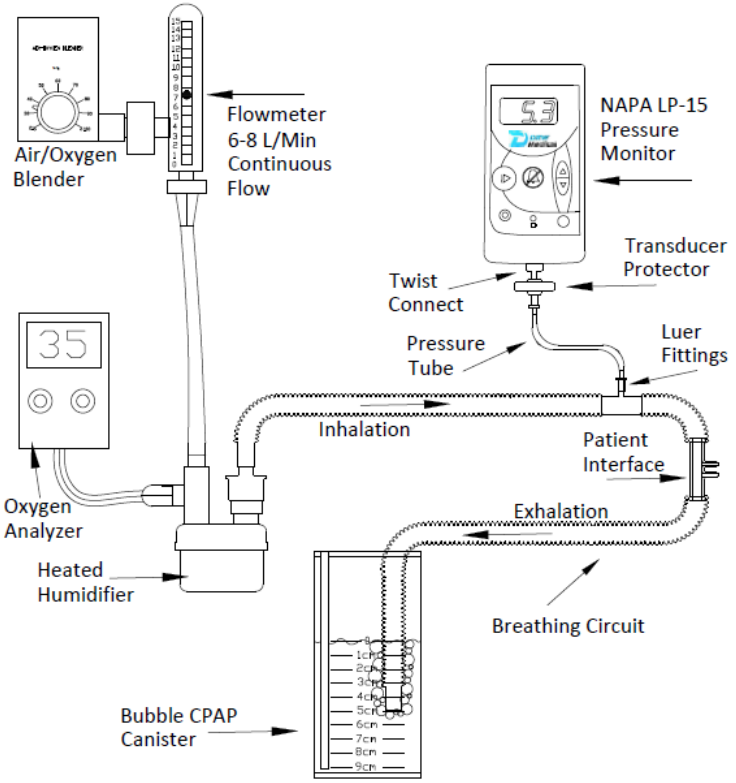


FIGURE 11

7. Alarms and Alarm Limits

7.1 NAPA LP-15 Airway Pressure Monitor Alarms Overview

The NAPA LP-15 Airway Pressure Monitor provides both visual and audible alarms when the following alarm conditions occur:

Low Pressure Alarm:

The NAPA LP-15 Airway Pressure Monitor provides a low pressure visual and audible alarm when the monitor detects pressure below the selected “low” alarm limit. The yellow LED “down” arrow indicator blinks when there is a low-pressure alarm condition.

The alarm resets automatically when the condition causing the alarm is corrected.

High Pressure Alarm:

The NAPA LP-15 Airway Pressure Monitor provides a high pressure visual and audible alarm when monitor detects pressure above the selected “high” alarm limit. The yellow LED “up” arrow blinks when there is a high-pressure alarm condition.

The alarm resets automatically when the condition causing the alarm is corrected.

7.2 Alarm Condition Types

The NAPA LP-15 Airway Pressure Monitor provides medium priority alarms as a series of 3 beeps for the low- and high-pressure alarm condition with a YELLOW flashing Indicator as described above.

NOTE: No high priority alarm conditions are provided by the monitor because the NAPA LP-15 Airway Pressure Monitor measures pressure treatment levels which are considered medium priority, not patient vital signs such as breath rate, which are considered high priority.

7.3 Alarm Delay

The NAPA LP-15 Airway Pressure Monitor measures and displays a pressure signal that has been averaged over a period of 5 seconds to reduce fluctuations in the displayed pressure value that could otherwise occur from slight variations in treatment or patient breathing. Due to the averaging, there is an effective Alarm Delay of less than five (5) seconds.

The ending of the alarm signal when an alarm condition is no longer present has a similar effective delay of less than five (5) seconds.

7.4 Alarm Limits

- **High alarm settings** are from 6.0 to 35.0 cm H_20.
- **Low alarm settings** are from 0.1 to 28.0 cm H_20.

7.5 When an Alarm is Active: Operator Actions:

- The operator's preferred position with respect to the monitor is one where the operator can both hear and see the monitor's operation, i.e., within visual range of the NAPA LP-15 Airway Pressure Monitor front panel. This position allows the operator to take actions appropriate to the monitor's displayed information.
- When an alarm becomes active, the NAPA LP-15 Airway Pressure Monitor issues 3 beeps and the "relevant" pressure alarm signal flashes. This will continue until alarm is silenced or pressures are restored/corrected.
- Press the ALARM SILENCE KEY to silence the **audible** alarm for two minutes. The **Visible** alarm signal will continue to flash while audible alarm is silenced if the alarm condition remains.
- You can change an alarm setting while an alarm is active.
- Alarms and signals will automatically stop once targeted pressures are restored to set alarm limits.

Alarms and Alarm Limits, cont'd.

7.6 Adjusting Alarm Settings *(FIGURE 12)*

Follow these steps to adjust the ALARMS settings:

1. Press and hold the MENU/ENTER key for 1 second to enter the ALARMS SET menu to adjust the alarms setting.

2. Press ENTER to scroll through the settings in the following sequence:
   - LOW > HIGH > ALARM VOLUME
   - The setting symbol L, H, or A appears on the display for the appropriate setting as shown below

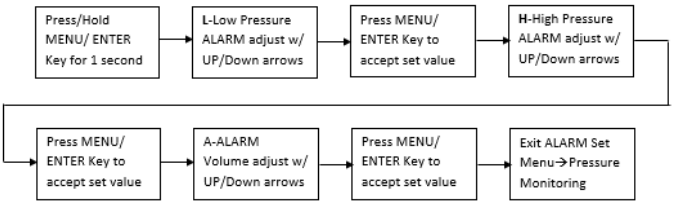


FIGURE 12

3. Press the Δ and ∇ keys to adjust the value of each setting. (You can hold down the Δ and ∇ keys to quickly scroll up or down through the selectable values.)

4. Press ENTER again to accept the adjusted setting and advance to the next setting.

5. Once all settings have been confirmed, press ENTER to exit ALARM SET mode and confirm all settings.

6. The NAPA LP-15 Airway Pressure Monitor will exit the ALARMS SET menu if there are no operator inputs for one (1) minute. In this case, the very last alarm set value will not be updated and will remain as previously set. As per Step 5, it is necessary to press the MENU/ENTER Key to accept an update to any ALARM SET value.

7.7 Alarm Suspend

The Alarm Suspend key suspends the audible portion of an alarm for two minutes following the most recent key press. The Suspend key has no effect on the visual ALARM indicator.

7.8 Alarm Settings and Power Interruption

Interruption of AC mains power should have no effect on the alarms settings. The Alarm settings are written to non-volatile memory when set.

7.9 Alarm Verification

The alarm functionality may be verified using the method shown in Section 7.2, Figure 13 titled Functional Test.

8. Performance Check

The NAPA LP-15 Airway Pressure Monitor can be checked for function and pressure accuracy as described below:

- **Zeroing the Pressure Sensor [8.1]** should be carried out routinely by all users
- It is recommended that a **Functional Test [8.2]** be periodically performed to assess the unit's function.
- **A Monitor Pressure Accuracy Check [8.3]** can be performed at any time there is a need to assess the pressure measurement accuracy.

8.1 Zeroing the Pressure Sensor (All Users)

- **Zeroing the device resets the zero point to atmosphere of the pressure sensor (the measurement when no pressure is connected).** Only ZERO the NAPA LP-15 pressure monitor when a pressure discrepancy exists and ensure that the monitor is disconnected from tubing and/or patient and is open to room air. This can be done as follows:
    - Ensure that the sensor port is not connected to pressure, i.e. is open to room air.
    - Turn the unit on using the "On/Off" button.
    - Press and hold the "Zero Pressure Sensor" button for one second.

- The monitor will confirm the Zero operation has been completed by flashing zeros on the display several times and then display a steady 0.0 display.

Only ZERO the NAPA LP-15 pressure monitor when a pressure discrepancy exists and ensure that the monitor is disconnected from tubing and/or patient and is open to room air.

8.2 Functional Test (All Users) *FIGURE 13*

The NAPA Airway Pressure Monitor functionality may be verified using the method shown in ***Figure 13***. This will confirm mean airway pressure and High and Low alarm settings.

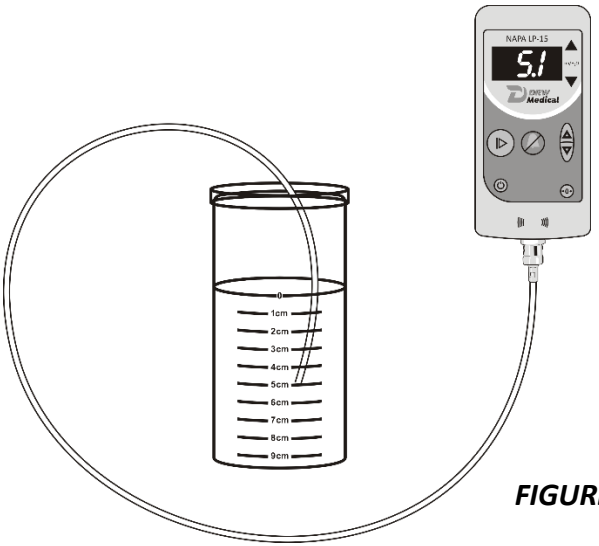


FIGURE 13

Before using the NAPA LP-15 Airway Pressure Monitor, follow these steps to verify that the monitor is functioning properly:

1. Connect AC power and turn the monitor on. The NAPA LP-15 Airway Pressure Monitor will require 2 minutes to enable alarms.
2. Once the pressure display screen reads 0.0, ensure that the unit is disconnected from the patient circuit.

3. Zero the pressure sensor by pressing the "Zero Pressure Sensor" button for one second. Once the unit has been zeroed, connect the tubing to the monitor.

4. Fill a graduated canister with water to the 0 cm/H_20 line.

5. Set the High and Low pressures at 4.0 cm/H_20 and 6.0 cm/H_2O per instructions in Section 7.6.

6. Submerse the tubing into water to the 5.0 cm/H_20 line. Pressure display should be reading 5.0 cm/H_20 (± 0.5 cmH_2O or ± 2%, whichever is greater)

7. To check the low- and high-pressure alarm settings, raise or submerse the tubing for 2 seconds to 3.5 cm/H_20 and 6.5 cm/H_20 respectively. Since both these of levels fall outside the set alarm limits, both audio and visual alarms should be observed.

8. Tubing used for testing can be removed and the device can be connected to the patient circuit. Unit is now ready for patient use.

8.3 Monitor Pressure Accuracy Check (Biomedical Engineer User) *FIGURE 14*

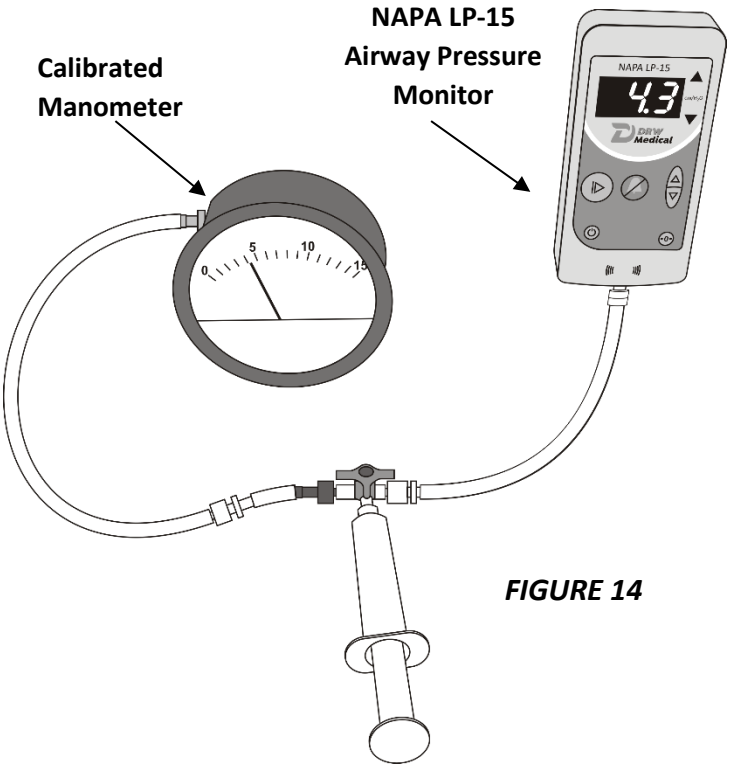


FIGURE 14

Use syringe to pressurize the system. The NAPA LP-15 Airway Pressure Monitor display and calibrated manometer should show pressures that are within ± 0.5 cmH_2O or ± 2%, whichever is greater

WARNING:

- Do not over-pressurize the system (by exceeding 35 cm/H_2O) or damage to the pressure sensor could result.

NOTES:

- Zero the pressure sensor if the monitor displays a pressure when the unit is not connected to pressure.
- If the reading on the monitor pressure display differs from the reading on a calibrated manometer (± 0.5 cmH2O or ± 2%, whichever is greater) perform a zeroing function **[Section 6.3.2]** and then perform an accuracy retest. If readings are still outside the acceptable parameters, the device must be serviced by a manufacturer-qualified technician prior to further patient use.
- If the unit does not display “0.0” after performing either an automatic or manual restart, return the unit to the manufacturer for service.

9. Maintenance

9.1 Cleaning the NAPA LP-15 Airway Pressure Monitor

1. After use, disconnect NAPA LP-15 Airway Pressure Monitor from the patient's breathing circuit.
2. Clean all exposed surfaces of the NAPA LP-15 Airway Pressure Monitor by wiping with mild detergent and clean cloth

NOTE: Under normal conditions, the NAPA LP-15 Airway Pressure Monitor does not require any special maintenance or sterilization.

Verify the NAPA LP-15 Airway Pressure Monitor for proper function after cleaning/before use:

- Allow to dry completely before using.
- Verify NAPA LP-15 Airway Pressure Monitor functions properly before returning to use.
- Should the unit be dropped, it is recommended that an immediate pressure check be performed. If the unit fails to respond properly in any way, it must be returned to the manufacturer immediately for repair.

CAUTION:

- Do not submerge the NAPA LP-15 Airway Pressure Monitor in cleaning solution.
- Do not allow liquid to penetrate the monitor.
- Do not use alcohol on the device.
- Do not autoclave.
- To avoid damage (cracking and crazing of plastic) to monitor surfaces, do not use formaldehyde or phenol-based disinfectants.
- The pressure tubing is intended for single patient use only: do not attempt to sterilize or reuse. Follow all applicable federal and local regulations for disposal or recycling of tubing material.

9.2 Troubleshooting

Problem	Possible Causes	Resolution
Unit does not turn on	Power Supply not connected	Plug monitor into power supply.
Unit does not zero	Monitor pressure other than atmospheric pressure during zero	Disconnect all tubing and re-zero to atmospheric pressure
Pressure display is giving false readings	Device zeroed while not open to atmosphere	Re-zero the device
No sound generated	Alarm suspend inadvertently pressed	Wait two minutes for alarm to resume
LED Display missing segments	Display failure	Contact manufacturer

9.3 Gain Calibration (Performed only by Manufacturer)

A factory gain calibration can be performed by the manufacturer, to ensure that the device is meeting its specified accuracy.

A factory gain calibration corrects the accuracy of pressure measurements.

- Gain calibration needs to be performed by the manufacturer's qualified technician if pressures are measuring incorrectly following a zero calibration.

NOTES:

- Should the unit fail to respond properly to a technical check of the pressure (see Section 8.3), a factory service calibration needs to be performed.

9.4 NAPA Airway Pressure Monitor DC Power Supply:

The NAPA LP-15 Airway Pressure Monitor comes with an accessory Power Supply that is used to operate the device. (***FIGURE 15***)

The NAPA LP-15 Airway Pressure Monitor Power Supply is a high-performance AC to DC external power supply designed for medical applications. It accepts mains power 120V AC and provides a 5V DC output.

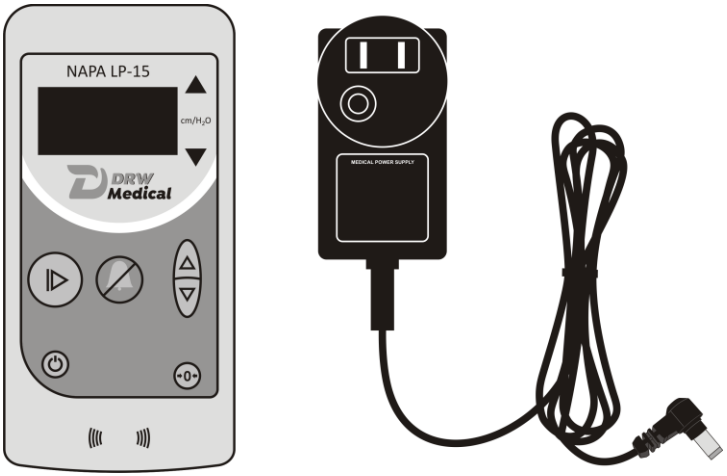


FIGURE 15

10. Item Numbers: NAPA LP-15 Airway Pressure Monitor Parts & Accessories List

REF	Item Description
LP-15	*NAPA LP-15 Airway Pressure Monitor with Power Supply
AC-PS	*Power Supply
AC-PC	**Pole Mounting Clamp
AC-BR	**Bracket
AC-MT	**Sample Line Kit
AC-UG	*NAPA LP-15 Airway Pressure Monitor User Guide
LP-15-02	2 Year Extended Warranty
NP-CATH 2.5	2.5 Fr. NP Catheter
NP CATH 3.5	3.5 Fr. NP Catheter
AC-FTST	LP-15 Functional Test Kit
AC-PSX**	Power Supply Extension Kit, 6’

* Included standard with every device

** Accessory does not come with the device, but recommended for use with the device.

11. Product Specifications

Performance Specifications

Pressure Range: 0.0 -35.0 cm H_2O
Display Resolution: 0.1 cm H_2O
Accuracy: ± 0.5 cmH2O or ± 2%, whichever is greater
High Pressure Alarm: 6.0 - 35.0 cm H_2O
Low Pressure Alarm: 0.1 - 28.0 cm H_2O

Physical/ Mechanical Specifications

Monitor Dimensions: Height: 5.0 in. (12.7 cm), Width: 2.5in. (6.4 cm), Depth: 1.24 in. (3.2cm)
Weight: 180 grams (0.4 pounds)
Display Screen: LED / 3-digit, 7 segment
Monitor Tubing Fitting: Quick-Connect and Luer
Enclosure Materials: ABS, Flame Retardant V0

Operating/Storage Ranges

Operating: +5°C to +40 °C
Storage: -25°C to +70 °C
Humidity Limits: 15 to 93% RH (non-condensing)
Ambient Pressure: 700 to 1060 hPa (-400m to 3000m Altitude)

Sound Pressure Levels

Alarm Signal Volume (50 - 80 dB(A)) at 1 m, dependent on Operator-Controlled Setting (1 – 20)

Packaging and Sterilization Characteristics:

Packaging: Packaging and simulated ship tests conform to ISTA 2A standards
Sterility: The NAPA LP-15 Airway Pressure Monitor, its components and accessories are provided non-sterile.

Equipment Classification:

Protection against electric shock:	Class II
Degree of protection against electric shock:	Type BF Applied Part
Liquid Ingress Protection: against foreign objects and moisture	IP21 Protected

Standards Compliance:

The NAPA LP-15 Airway Pressure Monitor has been tested to meet the following medical safety standards:
IEC 60601-1 Electrical Safety[1]
IEC 60601-1-2 Electromagnetic compatibility
IEC 60601-1-11 Environmental Operating/Storage and Shock and Vibration Test Levels
IEC 60601-1-8 Alarm Systems in Medical Electronics

WEEE/RoHS Recycling Directive

(Waste Electrical and Electronic Equipment and Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (WEEE/ROHS) recycling directives)

Compliant with the WEEE/RoHS recycling directives. Dispose of this device in accordance with local regulations.

12. Customer Service and Product Support

[1] See Section 13 of this manual for the EMC Declaration for this device

For Customer Service:

Please call 610-565-3843
Or email info@DRWMedical.com

For Product Support:

Please call 610-996-5308
Or email products@DRWMedical.com

Full service and repair is available from the manufacturer.

Manufacturer

DRW Medical, LLC
2710 Concord Rd.
Aston, PA 19014
USA and Canada: 1-800-230-6002
www.drwmedical.com

13. Electromagnetic Compatibility

13.1 EMC Overview

The NAPA LP-15 Airway Pressure Monitor has been tested to comply with IEC 60601-1-2:2014 (4TH EDITION) test standards for Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI).

The device needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document.

NAPA LP-15 Airway Pressure Monitor is suitable for prescription use only in the electromagnetic environments specified in the standard. Operate the monitoring system in accordance with the electromagnetic environments described.

Operation is subject to the following two conditions: (1) the device may not cause harmful interference, and (2) the device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by the manufacturer may cause harmful radio frequency interference and void your authority to operate this equipment.

WARNING:

- The use of accessories, power sources and cables other than those specified may result in inaccurate readings of the device and increased emissions or decreased electromagnetic immunity of the device.

- The NAPA LP-15 Airway Pressure Monitor should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

CAUTION:

- Observe precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- The NAPA LP-15 Airway Pressure Monitor should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Where electromagnetic devices (i.e., electrocautery) are used, patient monitoring may be interrupted due to electromagnetic interference.

13.2 EMC Declaration

Electromagnetic Emissions Guidelines and Compliance

Guidance and manufacturer's declaration - Electromagnetic emissions
The NAPA LP-15 Airway Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or user of the NAPA LP-15 Airway Pressure

Monitor should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF emissions CISPR 11	Group 1 150kHz – 30MHz	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B 30MHz – 1GHz	Class A: The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	AC Input ≤ 16 Amps	
Voltage	AC Input ≤ 16 Amps	

fluctuations/ flicker emissions IEC 61000-3-3		

Electromagnetic Immunity Guidelines and Compliance

Guidance and manufacturer's declaration - Electromagnetic immunity			
The NAPA LP-15 Airway Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601-2 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	<5% UT (>95% dip in UT)		Mains power quality should be that of a typical

interruptions and voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.		commercial or hospital environment. If the user of the NAPA LP-15 Airway Pressure Monitor requires continued operation during power interruptions, it is recommended that the NAPA LP-15 Airway Pressure Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m @ 50Hz & 60Hz	30 A/m @ 50Hz & 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to the application of the test level			

Recommended Separation Distance Calculations

Guidance and manufacturer's declaration - Electromagnetic immunity			
The NAPA LP-15 Airway Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or user of the NAPA LP-15 Airway Pressure Monitor should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 800 MHz 3 V/m 800 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 800 MHz 3 V/m 800 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$

			800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from transmitters, such as base stations for radio (cellular, cordless) telephones and land mobile radios.			

Amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NAPA LP-15 Airway Pressure Monitor is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the NAPA LP-15 Airway Pressure Monitor.
b. Over the frequency range of 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the NAPA LP-15 Airway Pressure Monitor			
The monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (Watts)	**Separation distance according to the frequency of transmitter (meters)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	.12	.12	.23

0.1	.37	.37	.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated by using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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