
# Respiratory Pressure Meter Operating Manual

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

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## Introduction

The respiratory pressure meter is a hand-held instrument designed for rapid assessment of inspiratory and expiratory muscle strength. The unit can measure the maximum inspiratory and expiratory mouth pressures, MIP and MEP, and the Sniff Nasal Inspiratory Pressure, SNIP. The result of each measurement is presented in units of $cmH_2O$ gauge pressure on the liquid crystal display screen.

The unit is easy to operate, battery powered and is supplied with all the necessary attachments required for immediate use.

The functionality of the unit may be greatly increased when connected to a PC running PUMA software. This application has many advanced features including:

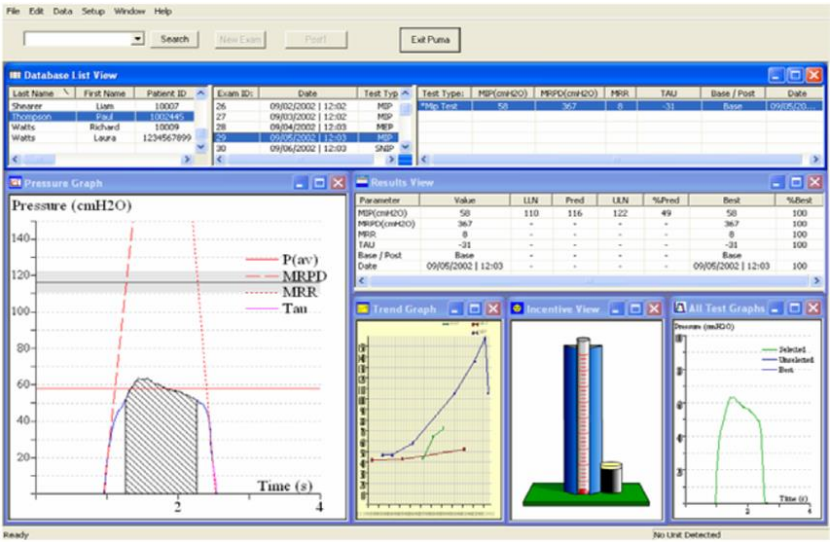
- Real time display of pressure/time curves
- Overlay of successive curves
- Predicted values
- Patient database
- Incentive display
- Maneuver quality check
- Maneuver variability measurement

## Package Contents

The respiratory pressure meter is supplied with the following items:

1. MicroRPM
2. Inspiratory pressure valve, filter and mouthpiece (Order #MIP50)
3. Expiratory pressure valve, filter and mouthpiece (Order #MEP50)
4. 9 volt battery
5. Calibration screwdriver
6. Nasal probe sample pack (Cat. No. NPROBE01 x-small; NPROBE02 small; NPROBE03 medium and NPROBE04 large)
7. Nasal probe adapter (Cat. No. ASS1091)

## PUMA PC Software




The functionality of the portable MicroRPM is greatly increased when connected to the PUMA PC Software, via an RS232 cable to the Serial Port on the side of the unit.

PUMA PC Software is available as a free download from by contacting Micro Direct customer service at 800-588-3381 or email support@mdspiro.com.

The PUMA PC Software is unique, user friendly multi windows platform for the performance, storage and analysis of the respiratory muscle strength measurement of PImax or MIP (Maximum Inspiratory Pressure), PEmax or MEP (Maximum Expiratory Pressure) and SNIP (Sniff Nasal Inspiratory Pressure). In addition, PUMA PC Software offers the user features such as live graphical displays, predicted values, printing formats, incentives, trends, post medication or exercise comparisons and additional fatigue indicators.

Note: The Respiratory Pressure Meter should only be connected to a computer that is manufactured in accordance with EN 60601-1.

Note: Keep the PC out of reach of the patient at all times.

## Contraindications

- Pathological conditions resulting in relatively large pressure swings in the abdomen or thorax.
- Aneurisms
- Uncontrolled hypertension
- Urinary incontinence

## Warnings and Cautions

The following terms are used as follows in this manual

**Caution**: Possibility of injury or serious damage

**Warning**: Conditions or practices that could result in personal injury

**Please Note**: Important information for avoiding damage to the instrument or facilitating operation of the instrument.

**Note:** The device should be used by qualified personnel trained in lung function testing.

| | |
|---|---|
|  | **CAUTION**: Read the manual before use. |
| **CAUTION**: For batteries, do not attempt to charge, connect improperly, or dispose of in fire as there is possibility of leakage or explosion. Follow manufacturer's recommendation for proper disposal. | |

**WARNING**: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anesthetic mixtures or in oxygen rich environments.

**CAUTION**: Bacterial filters are single patient use. If used on more than one patient, there is a risk of cross-infection. Repeated use may increase air resistance and lead to an incorrect measurement.

**PLEASE NOTE**: The product and the battery you have purchased should not be disposed of as unsorted waste. Please utilize your local recycling facility for the disposal of this product.

**PLEASE NOTE**: Degree of protection against Ingress of Water is IPX0.

**CAUTION**: When you connect the Respiratory Pressure Meter to other equipment, always make sure that the whole combination complies with the international safety standard IEC 60601-1 for medical electrical systems. During measurements, connect the Respiratory Pressure Meter only to computers that comply with IEC/EN 60601-1 / ANSI/AAMI ES60601-1:2005.

## Indications for Use

The MicroRPM (Respiratory Pressure Meter) is a handheld diagnostic instrument designed for rapid assessment of inspiratory and expiratory muscle strength. The unit can measure the maximum inspiratory and expiratory mouth pressures, MIP and MEP, and the Sniff Nasal Inspiratory

Pressure, SNIP. The system is intended for use with adults and pediatric patients over the age of 3 years in hospitals, physician offices, laboratories and occupational health testing environments.

## Operation – mouth pressures (PImax/MIP + PEmax/MEP)

Insert the battery into the battery compartment at the rear of the MicroRPM.

Fit the required pressure valve assembly (MIP50 (pink) for PImax (MIP) or MEP50 (blue) for PEmax (MEP)) into the MicroRPM as shown below.

## PImax (MIP) Test

Slide the MicroRPM switch from the “off” position to the MIP/MEP position, while applying no pressure to the mouthpiece. Rotating segments will be displayed while the unit performs an auto-zero function.

When the MicroRPM is ready a ‘beep’ will be heard and ‘0’ displayed.

To perform the test, instruct the subject to insert the mouthpiece into the mouth, ensuring the flange is positioned over the gums and inside the lips, while the ‘bite blocks’ are between the teeth.

The subject should then exhale to RV (Residual Volume), lungs empty, then perform a ‘Mueller’ maneuver, a forced inhalation against the MicroRPM with as much effort as possible for as long as possible (minimum of 2 seconds).

The display will report the result, the maximum average inspiratory pressure sustained over a 1 second period of the test, in centimeters of water (cmH20). Ideally, the subject should repeat this test three times to establish the best value.

## PEmax (MEP) Test

Slide the MicroRPM switch from ‘Off’ to ‘MIP/MEP’, while applying no pressure to the mouthpiece. Rotating segments will be displayed while the unit performs an auto-zero function.

When the MicroRPM is ready a ‘beep’ will be heard and ‘0’ displayed.

To perform the test, instruct the subject to insert the mouthpiece into the mouth, ensuring the flange is positioned

over the gums and inside the lips, while the ‘bite blocks’ are between the teeth.

The subject should then inhale to TLC (Total Lung Capacity), lungs full, then perform a ‘Valsalva’ maneuver, a forced exhalation against the MicroRPM with as much effort as possible for as long as possible (minimum 2 seconds).

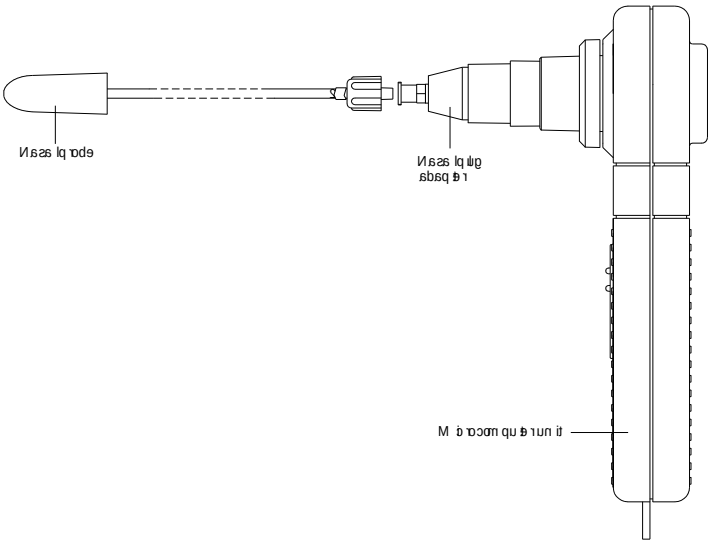
The display will report the result, the maximum average expiratory pressure sustained over a 1 second period of the test, in cmH2O. Ideally, the subject should repeat this test three times to establish a best value.

To repeat either the PImax or PEmax tests, the MicroRPM must first be returned to the ‘Off’ position.

## Operation – SNIP (Sniff Nasal Inspiratory Pressure)

Insert the battery into the rear of the MicroRPM.

Fit the nasal probe adapter into the MicroRPM and then attach the correct size nasal probe, as shown below.



The correct size (1-4) can be determined by fitting a nasal probe to the unit then firmly inserting the nasal probe into a nostril. Instruct the subject to block the open nostril with a finger and then to attempt a sniff. The correct nasal probe has been selected once there is not leakage around the nasal probe.

## SNIP Test

Slide the MicroRPM switch from ‘Off’ to ‘SNIP’, while applying no pressure to the nasal probe. Rotating segments will be displayed while the unit performs an auto-zero function.

When the MicroRPM is ready a ‘beep’ will be heard and ‘0’ displayed.

To perform the test, instruct the subject to insert the chosen nasal probe firmly into a nostril, while ensuring the other nostril remains open throughout the test.

The subject should then breathe normally and at the end of a normal tidal expiration, FRC (Functional Residual Capacity), be instructed to perform a short, sharp voluntary sniffing maneuver with as much effort as possible.

The display will report the result, the peak inspiratory nasal pressure, in cmH2O.

On subsequent tests, the MicroRPM will continue to display the highest SNIP value, overwriting previous values. Ideally, the subject should repeat this test 10-15 times to determine the highest value.

## Switching Off

The MicroRPM is switched off by sliding the switch back to the ‘Off’ position.

## Battery

The battery level is automatically checked when the unit is switched on.

When the battery is low, ‘bAt’ will be displayed before the auto-zero procedure. The MicroRPM may be used when this occurs, but the battery should be replaced as soon as possible.

When the battery is completely exhausted, the unit will beep twice and turn itself off immediately.

## Battery Replacement

Locate the sliding cover situated on the rear of the unit, toward the bottom of the device.

Place your thumb over the round thumb indent, press gently and slide the cover to the right to remove it from the unit.

Lift the old battery out and holding the battery terminal by the plastic body, pull it off the old battery.

Plug the new battery into the battery terminal, taking care that the correct polarity is observed.

Push the battery back into the battery holder and replace the battery cover onto the guides. Slide the battery cover to the left until it is fully in place.

**Note**: Please remove the battery if the meter is likely to be unused for some time.

**CAUTION**: Do not open the battery cover when the device is turned on.

**CAUTION**: The operator should not touch the contacts of the battery and the patient at the same time.

**Please Note**: Dispose of the waste battery in accordance with your local waste battery regulations.

## Cleaning Instructions

Disinfection of contaminated parts is only effective after careful preliminary cleaning. Please follow the manufacturer's instructions for the solution you are using.

The device must not be wiped with any aqueous solutions and must not be exposed to solvents e.g. alcohol, chloride solutions, as there are electronic components inside that will be permanently damaged.

**CAUTION:** Switch off the device before cleaning.

## External Surfaces of the Spirometer

**CAUTION:** Do not attempt to wash or immerse the Respiratory Pressure Meter in water or cleaning fluid, as there are electronic components inside that will be permanently damaged.

The external surfaces of the pressure meter and the inspiratory and expiratory valves may be wiped with a disinfectant wipe such as a Protex wipe (order #48-70) or a damp cloth that has been immersed in a cold disinfectant. This should be performed after every patient.

## Cleaning accessories

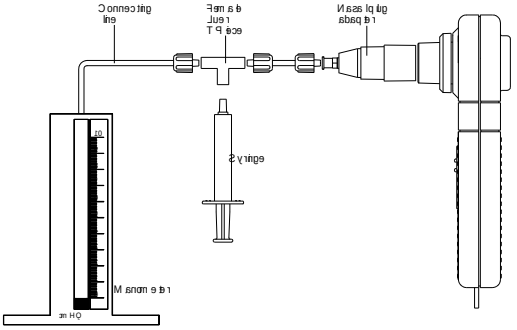
The MicroRPM unit is protected from contamination by the Bacterial Filter (MIP50 or MEP50) during mouth pressures measurements and are disposable.

**Important note:** Used mouthpieces and Nasal Probes, must be disposed of immediately after each use. If there are changes on the material surfaces (cracks, brittleness) the respective parts must be disposed of.

## Calibration

The calibration is factory set and should remain stable indefinitely.

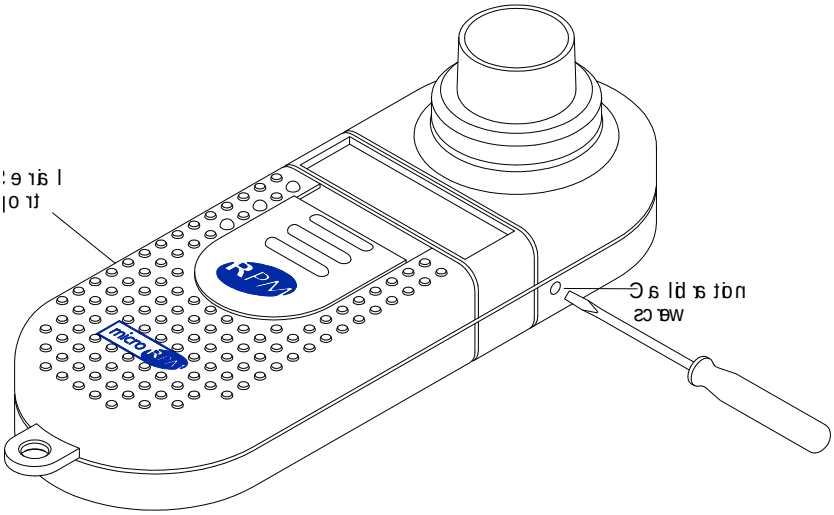
The calibration may be checked and altered, by connecting the device via the pressure calibration kit (#ASS1234) to a water manometer, as shown below:



Slide the MicroRPM switch from ‘Off’ to SNIP position while applying no pressure to the unit.

Gently fill the syringe until negative pressure of between 200 and 300 cmH2O is read on the water manometer. Check that the reading on the MicroRPM is within 3% of the manometer reading.

**Please Note**: The calibration may only be adjusted in a positive direction as the MicroRPM measures the highest peak value. Therefore, if the reading was greater than the water manometer, the calibration screw must be turned anti-clockwise a few turns before calibration is attempted.



To calibrate the MicroRPM, connect the water manometer as before, filling the syringe to obtain the required negative pressure. To change the calibration, slowly turn the calibration screw in a clockwise direction until the same value is displayed on the MicroRPM.

## Servicing

If your unit requires service or repair, please see page 23 for contact details.

A full service manual including circuit diagrams and parts list is available on request.

## Product Lifetime

The MicroRPM is designed for a product lifetime of five years.

## Trouble Shooting Information

Should you encounter problems operating your MicroRPM unit, please consult the table below:

| Problem | Possible Cause | Solution |
|---|---|---|
| Unit will not turn on | Battery is exhausted | Replace the battery |
| | Slide switch connection | Return unit for servicing |
| Display shows reading before test has been performed | Internal tubing to pressure sensor kinked | Return unit for servicing |

## Safety Designation per IEC 60601-1

| | |
|---|---|
| **Type of protection against electrical shock** | Internally powered equipment |
| **Degree of protection against electrical shock** | Type B applied part |
| **Power Equipment** | Battery |
| **Battery Life** | 2000 tests |
| **Degree of Electrical connection between equipment and patient** | Equipment designed as non-electrical connection to the patient |
| **Degree of mobility** | Transportable |
| **Mode of operation** | Continuous |
| **Classifications according to IEC 60601-1** | |
| **Respiratory Pressure Meter** | Applied part, type B |

**WARNING:** No modification of this equipment is allowed.

**WARNING:** Do not connect devices that are not specified as part of the system

**Note:** When you connect other equipment to the unit, always make sure that the whole combination complies with the international safety standard IEC 60101-1 for medical electrical systems. During measurements, connect the MicroRPM only to computers that comply with IEC/EN 60601-1 / ANSI/AAMI ES60601-1:2005.

**WARNING:** The user must not touch any conductive parts and the patient at the same time.

## Electromagnetic Compatibility (EMC) to IEC 60601-1-2

**WARNING**: Use of portable phones or other radio frequency (RF) emitting equipment near the system (< 30 cm) may cause unexpected or adverse operation.

The MicroRPM has been tested to IEC 60601-1-2:2014, regarding the ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure that the MicroRPM is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the MicroRPM.

Despite the testing of the MicroRPM that has been undertaken, normal operation of the MicroRPM can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment. Keep a distance of about 2 meters from possible error sources when using the device.

As the MicroRPM is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the MicroRPM is configured and installed /put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

Changes or modifications to the MicroRPM may results in increased emissions or decreased immunity of the MicroRPM in relation to EMC performance.

The MicroRPM should be used only with the accessories (RS232 cables) supplied (which are referenced in the accessories section of this manual). None of the MicroRPM cables should be extended in length by the user.

If any cables are extended by the user or non-approved accessories are used, this may result in an increased level of emissions or decreased level of immunity, in relation to the MicroRPM's EMC. None of the MicroRPM accessories should be used with other devices, as this may result in an increased level of emissions or decreased level of immunity, in relation to the other devices' EMC.

The MicroRPM has a minimum basic performance – The respiratory pressure readings on the product must remain within a tolerance of +/- 3%, and the unit firmware must not cease responding. Warning: In the vent the product is operated in the presence of significant electromagnetic fields (particularly in the frequency range 40-60MHz) while in the PC connected mode, ensure the results on the unit and PC are the same. If the results differ, then relocating the product away from sources of interference should resolve any issue.

List of EMC important cables. Do not exchange by other types.

| Part Number | Description |
|---|---|
| ASS3803 | Interface Cable for PUMA Software |

The MicroRPM has an essential performance – The respiratory pressure readings on the product must remain within a tolerance of +/- 3% and the unit firmware must not cease responding.

**Note**: In the event the product is operated in the presence of significant Electromagnetic Fields (particularly in the frequency range 40-60 MHz), while in the PC connected mode, ensure the results on the unit and PC are the same. If the results differ, relocate the product away from sources of interference should resolve any issue.

**WARNING**: The MicroRPM should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the MicroRPM and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

**Guidance and Manufacturer's Declaration – Electromagnetic Emissions**

The MicroRPM is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroRPM should assure that it is used in such an environment

| Emission Test | Compliance | Electromagnetic Environment - Guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The MicroRPM 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 electronic equipment |
| RF emissions CISPR 11 | Group B | The MicroRPM is suitable for use in all establishments, including residential establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC61000-3-2 | Not Applicable | |
| Voltage fluctuations / flicker emissions IEC61000-3-3 | Not Applicable | |

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The MicroRPM is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroRPM should assure that it is used in such a environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC61000-4-2 | Contact: +/- 8 kV Air: +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV | Contact: +/- 8 kV<br><br>Air: +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV | 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 IEC61000-4-4 | +/- 2 kV 100 kHz repetition frequency for power supply lines | Not Applicable | Mains power quality should be that of a typical commercial or hospital environment |
| Surge IEC61000-4-5 | +/- 0,5 kV, +/- 1 kV, +/- 2 kV | Not Applicable | Mains power quality should be that of a typical commercial or hospital environment |

| | | | |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11 | 0% $U_T$; 0,5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º<br><br>0% $U_T$; 1 cycle and 70% $U_T$; 25/30 cycles Single phase: at 0º and 0% $U_T$; 250/300 Cycle | Not Applicable | Mains power quality should be that of a typical commercial or hospital environment. If the user of the MicroRPM requires continued operation during power mains interruptions, it is recommended that the MicroRPM be powered from an uninterruptible power supply or a battery |
| Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8 | 30 A/m<br>50 & 60 Hz | 30 A/m<br>50 & 60 Hz | If incorrect operation occurs, it may be necessary to position the MicroRPM further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low. |
| NOTE $U^T$ is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity<br>The MicroRPM is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroRPM should assure that it is used in such an environment. | | |
|---|---|---|
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** |
| Conducted RF IEC61000-4-6 | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands<br>Between 0,15 MHz and 80 MHz<br>80% MHz at 1 KHz | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands<br>Between 0,15 MHz and 80 MHz<br>80% MHz at 1 KHz |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.7 GHz | 3 V/m<br>80 MHz to 2.7 GHz |
| IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 | 28 V/m<br>450 MHz, 50% PM at 18 Hz<br>810 MHz, 50% PM at 18 Hz<br>870 MHz, 50% PM at 18 Hz<br>930 MHz, 50% PM at 18 Hz<br>1720 MHz, 50% PM at 217 Hz<br>1845 MHz, 50% PM at 217 Hz<br>1970 MHz, 50% PM at 217 Hz<br>2450 MHz, 50% PM at 217 Hz<br><br>27 V/m<br>385 MHz, 50% PM at 18 Hz<br><br>9 V/M<br>710 MHz, 50% PM at 217 Hz<br>745 MHz, 50% PM at 217 Hz<br>780 MHz, 50% PM at 217 Hz<br>5240 MHz, 50% PM at 217 Hz<br>5500 MHz, 50% PM at 217 Hz<br>5785 MHz, 50% PM at 217 Hz | 28 V/m<br>450 MHz, 50% PM at 18 Hz<br>810 MHz, 50% PM at 18 Hz<br>870 MHz, 50% PM at 18 Hz<br>930 MHz, 50% PM at 18 Hz<br>1720 MHz, 50% PM at 217 Hz<br>1845 MHz, 50% PM at 217 Hz<br>1970 MHz, 50% PM at 217 Hz<br>2450 MHz, 50% PM at 217 Hz<br><br>27 V/m<br>385 MHz, 50% PM at 18 Hz<br><br>9 V/M<br>710 MHz, 50% PM at 217 Hz<br>745 MHz, 50% PM at 217 Hz<br>780 MHz, 50% PM at 217 Hz<br>5240 MHz, 50% PM at 217 Hz<br>5500 MHz, 50% PM at 217 Hz<br>5785 MHz, 50% PM at 217 Hz |

## Symbols

| | |
|---|---|
|  | Type B device |
|  | In accordance with Directive 93/42/EEC |
|  | Disposal in compliance with your local waste management facility |
|  | Consult the instructions for use |
|  | Manufacturer |
|  | Date of Manufacture |
|  | Serial Number |
| Rx only | Federal U.S. law restricts this device to sale by or on the order of a physician. |
|  | Batch Code |
|  | Reference Number |
|  | Single Patient Use |

## Specifications

| | |
|---|---|
| Measurements | Maximum Expiratory Pressure (MEP)<br>Maximum Inspiratory Pressure (MIP)<br>Sniff Nasal Inspiratory Pressure (SNIP) |
| With Puma™ | Maximum Rate of Pressure Development (MRPD)<br>Maximum Rate of Relaxation (MRR) |
| Operating Pressure | +/- 300 cmH2O (+/- 5 PSID) |
| Burst Pressure | +/- 700 CmH2O (+/- 20 PSID) |
| Accuracy | +/- 3% |
| Resolution | 1 cmH2O |
| Power Supply | Single Alkaline 9V battery |
| Dimensions | ~6.5” x 2.5” x 1” |
| Weight (Unit with battery) | ~ 6 ounces |
| Weight (in carry case) | ~1 pound 10 ounces |
| Operating Temperature | 32 – 104 $^{0}$F |
| Operating Humidity | 30% - 90% RH |
| Storage & Transport Temperature | -4 – 158 $^{0}$F |
| Storage & Transport Humidity | 10% - 90% RH |

## Consumables / Supporting Products

| Cat. No. | Description |
|---|---|
| MEP50 | Expiratory Valve, Filter and Rubber Flanged Mouthpiece (50 per box) |
| MIP50 | Inspiratory Valve, Filter and Rubber Flanged Mouthpiece (50per box) |
| NPROBE01 | Extra small nasal probes (10 per box) |
| NPROBE02 | Small nasal probes (10 per box) |
| NPROBE03 | Medium nasal probes (10 per box) |
| NPROBE04 | Large nasal probes (10 per box) |
| ASS1091 | Nasal probe adapter |
| ASS1234 | Pressure Calibration Kit |
| 48-70 | Protex Disinfectant Wipe |
| ASS3803 | Interface Cable for PUMA Software |

For further information or to place an order for disposables/supporting products, please contact us at: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