

## Warranty

BRAEBON MEDICAL CORPORATION warrants to the first consumer that this *Ultima* Airflow Pressure Sensor™ (the “Sensor”), when shipped in its original container, will be free from defective workmanship, performance and materials and agrees that it will, at its option, either repair the defect or replace the defective Sensor or part thereof at no charge to the purchaser for parts or labor for a time period of one year from the date of purchase. The warranty described herein shall be the sole and exclusive warranty granted by BRAEBON MEDICAL CORPORATION and shall be the sole and exclusive remedy available to the purchaser. Use of the Sensor constitutes total and complete acceptance of this warranty. Correction of defects, in the manner and for the time period described herein, shall constitute complete fulfillment of all liabilities and responsibilities of BRAEBON MEDICAL CORPORATION to the purchaser with respect to the Sensor and shall constitute full satisfaction of all claims, whether based on contract, negligence, strict liability or otherwise. In no event shall BRAEBON MEDICAL CORPORATION be liable, or in any way responsible, for any loss of revenues or damage, direct, incidental, or consequential, including property damage, loss of profit, or personal injury resulting from the use or misuse of, or the inability to use this product. Nor shall BRAEBON MEDICAL CORPORATION be liable, or in any way responsible, for any damages or defects in the Sensor which were caused by abuse, misuse, tampering, neglect, incorrect battery type, or repairs or attempted repairs performed by anyone other than an authorized servicer.

## Attention:

**Failure to use the AAA alkaline batteries as stated in this User Guide will void the warranty. Failure to use the BRAEBON hydrophobic filter (part # 0583) will void the warranty. Specifications subject to change without notice.**

In the US:

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# *Ultima* Airflow Pressure Sensor™ Kit Model 0580 User Guide

## A Braebon Medical Corporation Product

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## Intended Use

The *Ultima* Airflow Pressure Sensor™ is intended for use during sleep disorder studies as a measure of respiratory airflow for recording onto a data acquisition system. Respiratory pressures are converted into voltage signals compatible with a variety of data acquisition systems. The sensor is battery-powered, using a disposable nasal cannula with a 0.2-micron hydrophobic filter that attaches to the patient and connects into the input of the *Ultima* Airflow Pressure Sensor.

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## Introduction

Thank you for purchasing The *Ultima* Airflow Pressure Sensor™ by BRAEBON MEDICAL CORPORATION. We chose the name *Ultima* because we believe that our sensor is the ultimate airflow pressure sensor available. The *Ultima* Airflow Pressure Sensor uses state-of-the-art-miniaturized technology to detect and reproduce waveforms associated with respiratory airflow. The differential pressure system uses either the custom BRAEBON cannula (part # 0589) or a standard O<sub>2</sub> cannula. The pressure sensor essentially functions as an uncalibrated pneumotachograph. The sensor detects and amplifies pressure swings from the cannula using a stable pressure transducer capable of detecting differential pressures in the ±20 cm H<sub>2</sub>O range. The corresponding voltage is then output for data acquisition.

## Features

- **Airflow & Snoring Output**  
Raw airflow pressure with superimposed snoring signal
- **Airflow Output**  
Filtered airflow pressure with no snoring signal
- **Snoring Output**  
Snoring signal from upper airway pressure vibrations
- **Exclusive BRAEBON Nasal + Oral Cannulas**  
Provides the benefit of oral airflow pressure capability
- **State-of-the-Art Hydrophobic (Safety) Filters on all BRAEBON Cannulas**  
Filtered cannulas prevent both patient cross-contamination from airborne disease and prevent moisture damage to pressure transducer components
- **Uses AAA alkaline Batteries**  
Standard AAA alkaline batteries are both inexpensive and easy to locate
- **Ergonomic Design**  
Few cables, simple labeling, plug & play design
- **Auto-off**  
After 10 hours of continuous use
- **One Year Unlimited Use Warranty**  
Backed by BRAEBON's no-hassle free-replacement warranty and toll-free phone support

## Airflow Pressure Sensor Kit (0580) Contents

- One Ultima Airflow Pressure Sensor (part #0581)
- Two 1.5 mm safety pin cables (part #0592)
- Two adult single-use nasal + oral cannulas (part #0589)
- Three adult micro single-use nasal cannulas (part #0582s)
- Two AAA alkaline batteries (installed when shipped from factory)
- One User Guide
- One Year Unlimited Use Warranty
- Toll-free telephone technical support

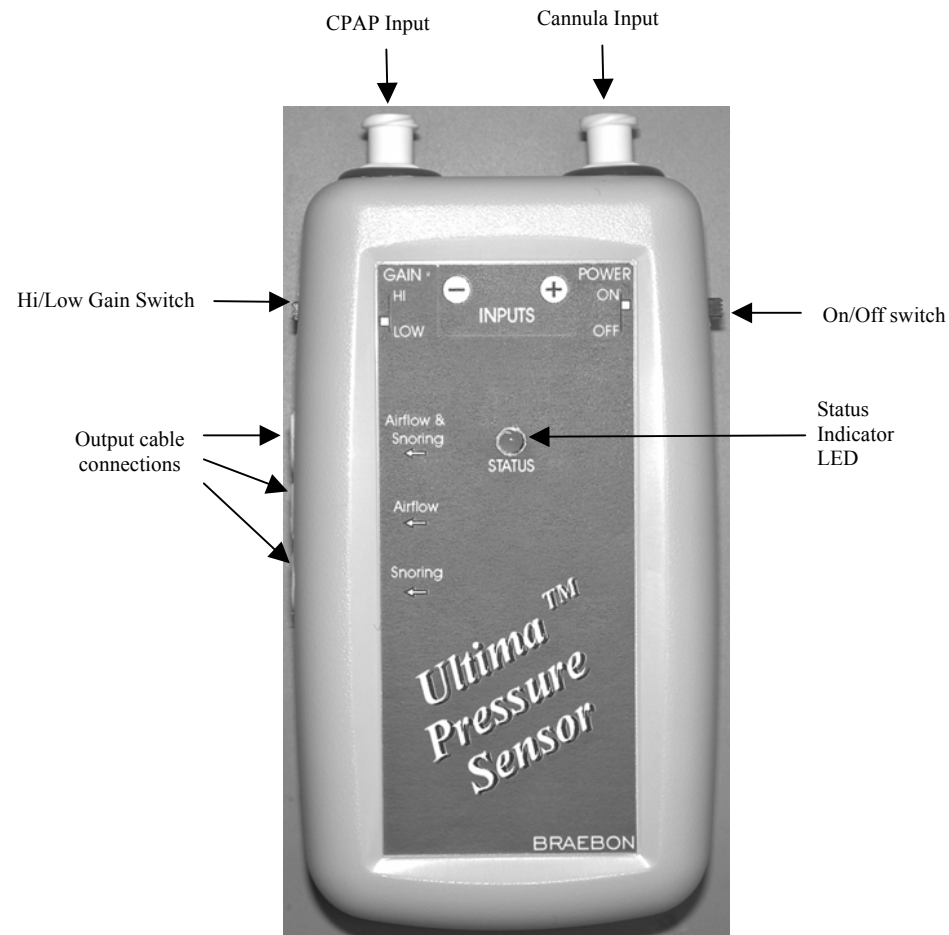


Figure 1. Actual size of *Ultima* Airflow Pressure Sensor™ Model 0581.

## Product Specifications

### Sensor Technology

One Differential Pressure Transducer  
(with overload protection circuitry)

### Input Ports

Positive Input Port (+) for Cannula Connection  
Negative Input Port (-) for CPAP Connection

### Input Types

Male Luer

### Output Types

Airflow & Snoring (raw or unfiltered)  
Airflow (filters our snoring)  
Snoring (filters out airflow)

### Maximum Output Range (Typical Output Range)

Model 0581 Hi Gain:  $\pm 5$  volts ( $\pm 200$  mV)  
Model 0581 Low Gain:  $\pm 500$  mV ( $\pm 10$  mV)

### Size (L x W x H)

3.90 x 2.20 x 0.92 inches  
(99 x 56 x 23 millimeters)

### Weight in grams

85

### Battery Type

AAA alkaline

### Estimated Battery Life (Estimated # of 8-hour nights)

480 hours (60)

### Input Pressure Range

Model 0581 Hi Gain:  $\pm 20$  cm H<sub>2</sub>O  $\cong$   $\pm 5.0$  volts  
Model 0581 Low Gain:  $\pm 20$  cm H<sub>2</sub>O  $\cong$   $\pm 100$  mV

### Nasal + Oral cannula

✓

### Auto-Off (after 10 hours run-time)

✓

### One-year Unlimited Use Warranty

“If it fails within one year from date of purchase we’ll replace it – no questions asked!”

## Troubleshooting

When turned on and functioning properly, the LED will immediately blink green then red followed by a two-second pause. If the batteries have sufficient power, the LED will then continue to blink green once every 10 seconds for the next 10 hours or until manually turned off. If the batteries are low, the LED will blink red once every two seconds indicating that you need to change the batteries with new AAA alkaline batteries (see page ten). If the LED does not blink, turn the unit off wait 10 seconds and turn the unit on again. Replace the batteries if the LED still fails to blink. If the problem persists contact technical support and have your model number, serial number and a pen and paper available. The batteries will last approximately 60 nights (8-hour recordings).

After changing the batteries, if you are still experiencing difficulty, please verify the following:

1. The airflow pressure sensor is properly attached to both the patient and the headbox.
2. Correct sensitivity and filter settings.
3. All amplifier and recorder connections are functional.
4. A sharp spike every 10 seconds indicates new batteries are needed. Refer to Battery Replacement on page 10.

If you still experience trouble with the product, contact our technical support department at 1-888-462-4841. Please have the model number and serial number available when you call.

## Warnings and Cautions

**Warning:** The *Ultima* Airflow Pressure Sensor™ is for diagnostic use only; it is not intended as an apnea monitor, and it is not to be used in life sustaining situations. U.S. Federal law restricts this device to sale by or on the order of a physician.

**Warning:** Always use a new disposable *Ultima* Airflow Pressure Cannula (part # 0589) and a new BRAEBON safety filter (part # 0583) with each patient. The BRAEBON safety filter is required to prevent the spread of contaminants between patients and to prevent moisture damage to the pressure sensor. Failure to use the BRAEBON safety filter will void the warranty. To prevent dust contamination to the pressure sensor always keep safety filters attached to the unit and change the safety filters immediately prior to next patient use.

**Caution:** Do NOT immerse the pressure sensor (0581) in any liquids. Use only isopropyl alcohol pads to clean the pressure sensor. Do not steam autoclave or gas sterilize the pressure sensor or damage will result.

**Caution:** Use only AAA alkaline Batteries or damage to the *Ultima* Airflow Pressure Sensor will result. Product features and specifications may change without notice.

**Caution:** If mounting the pressure sensor on the wall, mount the unit upside down to minimize the likelihood of bending/kinking the cannula tubing.

## Using the *Ultima* Airflow Pressure Sensor (part #0581)

**Warning:** Always use a new disposable *Ultima* Airflow Pressure Cannula (part # 0589) and a new safety filter (part # 0583) with each patient. The safety filter is required to prevent the spread of contaminants between patients and to prevent moisture damage to the pressure sensor.

**Caution:** To prevent dust contamination to the *Ultima* Airflow Pressure Sensor (part #0581), keep safety filters attached to the unit at all times and change the safety filters immediately prior to patient use.

The *Ultima* Pressure Sensor Model #0581 has an output range of  $\pm 5$  volts @  $\pm 20$  cm H<sub>2</sub>O when the Hi/Low Gain switch is placed in Hi Gain mode, and an output range of  $\pm 100$  mV @  $\pm 20$  cm H<sub>2</sub>O when the Hi/Low Gain switch is placed in Low Gain mode.

1. Position the BRAEBON Pressure Sensor Cannula on the patient and place the cannula sensor tips into the nose and in front of the mouth as illustrated in Figure 2.
2. Once the nasal/oral prongs are comfortably placed, slide the cannula tubing over the

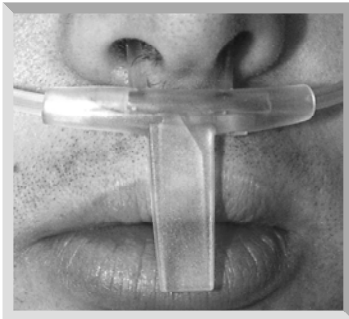


Figure 2: Positioning the Cannula

patient's ears and down the front of the chest. Slide the cinch tubing toward the neck for a comfortable fit under the chin.

3. Connect the male luer end of the hydrophobic filter to the Input on the pressure sensor (see Figure 1 and Figure 3).
4. Mount the pressure sensor on the bedside table.
5. For AC amplifier connection, set the gain switch to Low. For DC amplifier connection, set the gain switch to Hi. Plug the pressure sensor output cable (part #0592) into either the Airflow & Snoring, Airflow, or Snoring output port on the side of the unit, and connect the pair of safety pins into the headbox (jackbox). You are provided with two output cables (part #0592). The most commonly used output port is Airflow (snoring filtered out) because it offers the best view of flow limitation and UARS. Refer to Table 1 for the appropriate filter settings. See Figures 1 and 3.

## Maintaining The *Ultima* Airflow Pressure Sensor

**Warning:** Always use a new disposable *Ultima* Airflow Pressure Cannula (part # 0589) and a new safety filter (part # 0583) with each patient. The safety filter is required to prevent the spread of contaminants between patients and to prevent moisture damage to the pressure sensor.

**Caution:** To prevent dust contamination to the *Ultima* Airflow Pressure Sensor (part #0581), keep safety filters attached to the unit at all times and change the safety filters immediately prior to patient use.

The batteries are the only user-serviceable parts in the *Ultima* Airflow Pressure Sensor.

1. Use the necessary safety filters (part # 0583) with the *Ultima* Pressure Sensor Cannula (part # 0589). You may use any cannula with the pressure sensor, but you must use the safety filter (part # 0583), but continued use of the BRAEBON safety filter will indefinitely extend the pressure sensor warranty. Always replace the cannula and filter after each use.
2. For additional information, refer to the APIC guidelines for selection and use of disinfectants (American Journal of Infection Control, Vol. 18, number 2, April, 1990).

### Battery Replacement

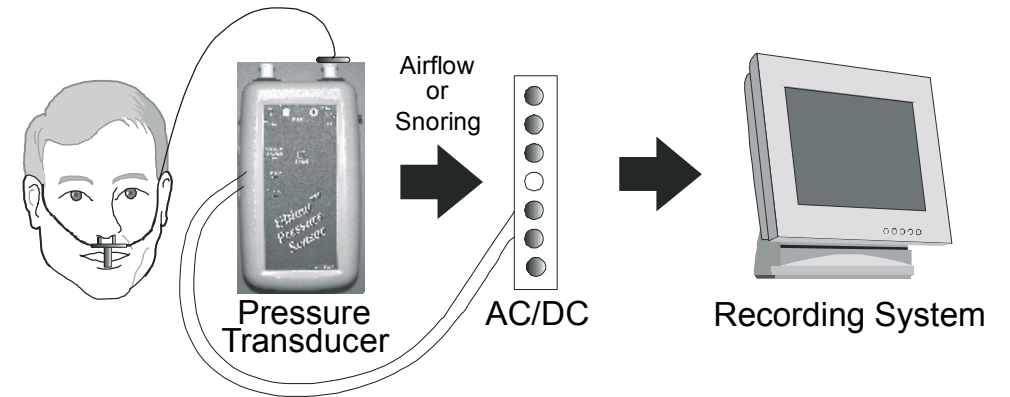
**Caution:** Use only AAA alkaline batteries or damage to The *Ultima* Airflow Pressure Sensor will result. Do not insert the batteries backwards or damage may occur to the pressure sensor. The battery will last about 60 nights (8-hour recordings) on the 0581.

1. Slide out the battery cover and remove the old batteries from the compartment.
2. Insert the new batteries. Note the polarity indicator in the battery compartment.
3. Slide the battery cover back onto the casing, ensuring the edges are sealed.

## Calibration

The Ultima Airflow Pressure Sensor™ is a qualitative device designed to measure nasal and/or oral pressure associated with human respiratory activity and functions essentially as an uncalibrated pneumotachograph. Calibration of the device for this application is not recommended.

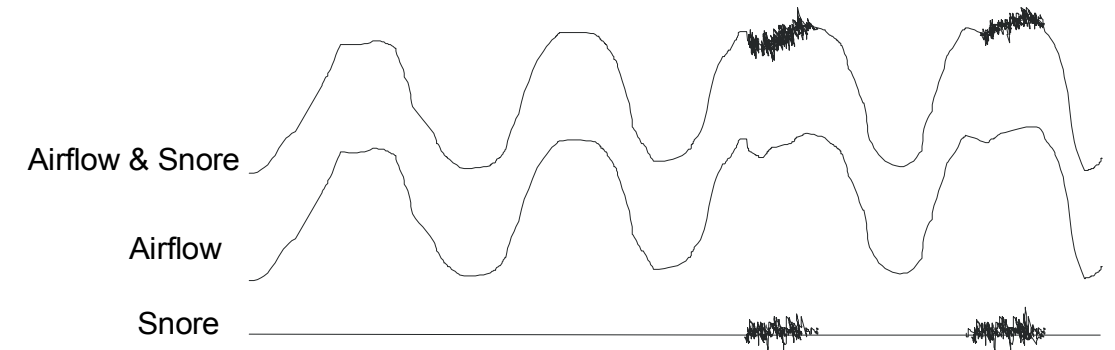
**Figure 3. AC/DC Recorder Connections – Model 0581**



**Table 1. AC/DC Recorder Connections – Model 0581**

Channel Output	Low Frequency Filter	High Frequency Filter	Gain/Sensitivity	Sampling Rate
Airflow & Snoring	0.05 Hz or lower	70 Hz or higher	20 mV/cm or 1000 x increase or decrease as necessary	100 Hz or greater
Airflow	0.05 Hz or lower	10 Hz or higher	20 mV/cm or 1000 x increase or decrease as necessary	20 Hz or greater
Snoring	10 Hz or higher	70 Hz or higher	20 mV/cm or 1000 x increase or decrease as necessary	100 Hz or greater

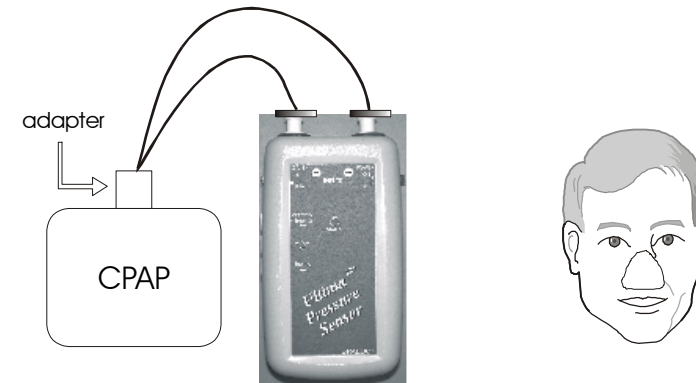
Note: Set gain switch to Low for AC connection. Set gain switch to Hi for DC connection.



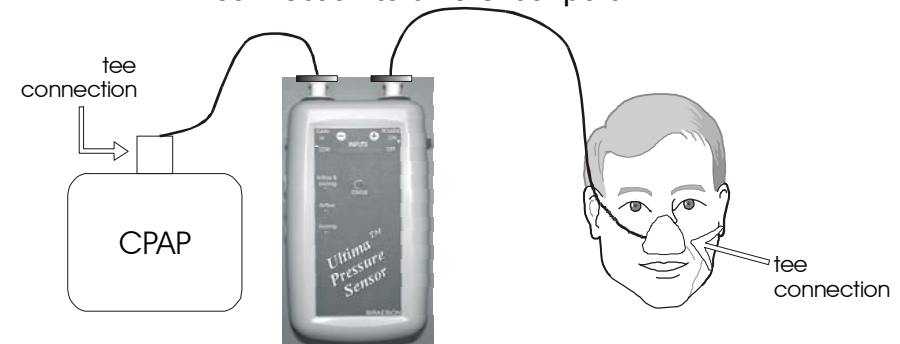
6. When turned on and functioning properly, the LED will immediately blink green then red followed by a two-second pause. If the battery has sufficient power, the LED will then continue to blink green once every 10 seconds for the next 10 hours or until manually turned off. If the battery is low, the LED will blink red once every two seconds indicating that you need to change the batteries with AAA alkaline batteries (see page ten). If the LED does not blink see the Troubleshooting section on page eleven.
7. When using the pressure transducer with CPAP, establish connections as shown in Figure 4.

If you wish to simultaneously record nasal and oral breathing on one channel you must use the BRAEBON Ultima Oral + Nasal Cannula (part #0589) connected to the input port (+). If you wish to record nasal breathing only you may use any cannula with the BRAEBON Safety Filter (part #0583) connected to the input port (+).

#### Figure 4. CPAP mask connections



**Figure 4a.** CPAP adapter connection and connection to differential port.



**Figure 4b.** CPAP mask connection and CPAP tee connection to differential port.



**Figure 4c.** CPAP mask connection.