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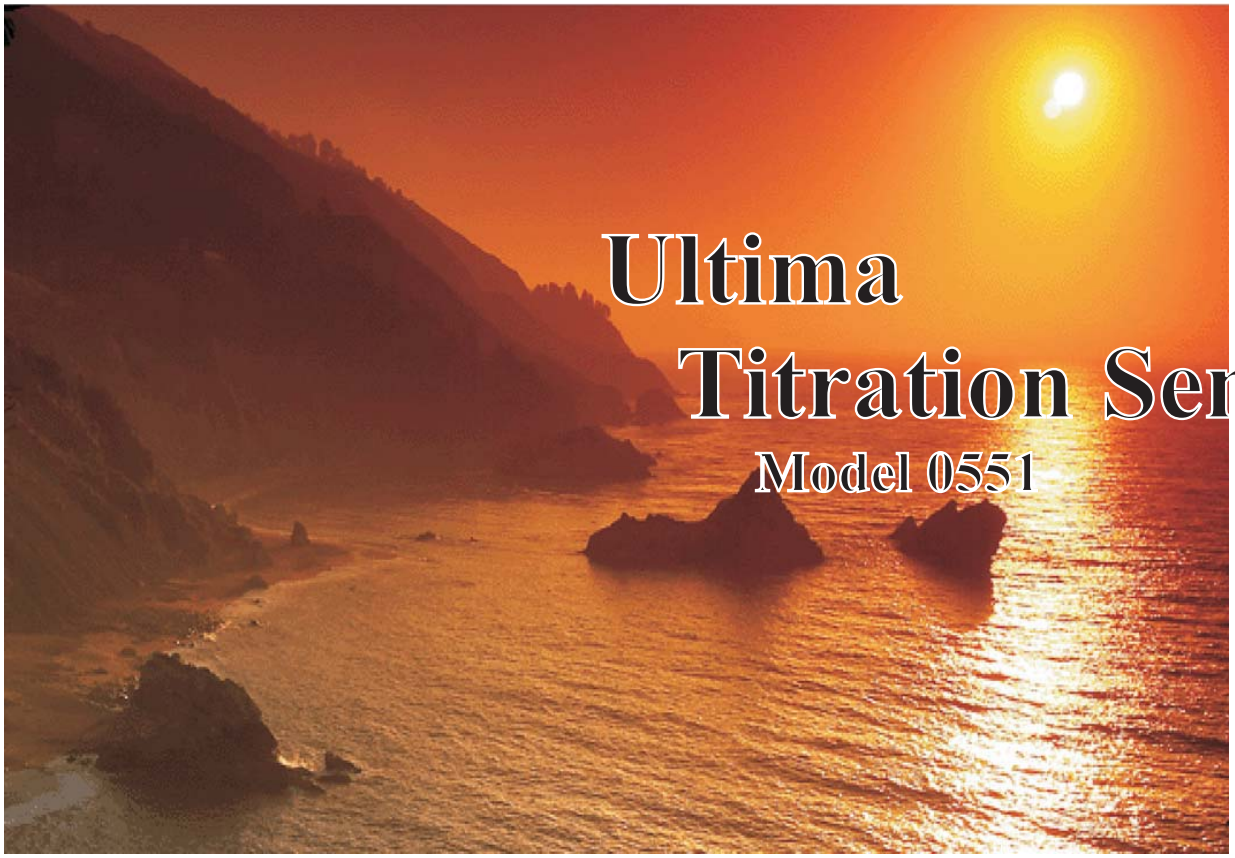

Ultima Titration Sensor

Model 0551

User Guide

BRAEBON™ is an ISO 13485 compliant company.

Legal Notices

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Table of Contents

Intended Use

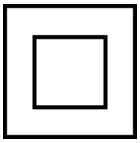
The Ultima Titration Sensor, Model 0551, is intended for use during sleep disorder studies as a qualitative measure of respiratory airflow for recording onto a data acquisition system. Respiratory pressures are converted into voltage signals. The sensor uses a battery and plugs directly into an existing patient headbox or FDA-cleared DC amplifier. A disposable nasal cannula with a 0.2 micron hydrophobic filter attaches to the patient and connects to the input of the Ultima Titration Sensor.

The target population of the Ultima Titration Sensor is all children and adult patients who are screened during sleep disorder studies. The screenings occur in a sleep laboratory or other clinical setting.

The Ultima Titration Sensor is intended to be used only by or on the order of a physician.

Safety Conventions for the Ultima Titration Sensor

These are the safety conventions used on the Ultima Titration Sensor. The table below lists the safety symbol, the name of the symbol and the meaning of the symbol.

 **Double Insulation**	A regulatory standard classification for protection against electrical shock. Class II equipment relies on double insulation rather than protective earthing.
 **B Protection**	Type B Applied Part: Non-cardiac grounded, applied part. A regulatory standard classification for protection against electrical shock for the part of the device that contacts the patient. **Note**: Type B Applied Parts are not suitable for Direct Cardiac Application.

Conventions for this User Guide

Following are document and safety conventions. Each shows the document symbol or safety symbol, the name of the symbol and the meaning of the symbol.

Warning: This symbol flags a serious warning. It is vital that you heed all warnings to prevent injury to yourself or to your patient.

Caution: This symbol flags a caution. Heed all cautions to prevent damage to your equipment.

Note: This symbol flags a note. Notes provide important information about the device.

Warnings and Cautions

Warnings

- Do NOT touch the battery contacts and the patient simultaneously as this could harm the patient.
- The Ultima Titration 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.
- Always use a new BRAEBON™ safety filter (Model 0583) with each patient on the pressure port. The BRAEBON™ safety filter is required to prevent the spread of contaminants between patients and to prevent moisture damage to the Ultima Titration 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.
- Do NOT immerse the Ultima Titration Sensor in any liquids.
- Do NOT steam autoclave or gas sterilize the Ultima Titration Sensor or damage will result.
- Only use two 1.5 V AA batteries or damage to the Ultima Titration Sensor will result.
- Do NOT mix battery types.
- Do NOT insert the batteries backwards.
- If mounting the Ultima Titration Sensor on the wall, mount the unit upside down to minimize the likelihood of bending or kinking the tubing.
- Only use BRAEBON-supplied tubing with the Ultima Titration Sensor.
- Only connect output connectors to products compliant with IEC 60601-1:1988 +A1-A2.

Battery Warning:

- Battery to be replaced by qualified personnel only.
- Remove the battery if the device is not to be used for a long period of time.
- Fire, explosion and severe burn hazard. Do not recharge, short circuit, crush, disassemble, heat above 100 °C (212 °F), incinerate or expose contents to water.

Cautions

- Use ONLY BRAEBON™ sensors and accessories.
- Always use a new BRAEBON™ safety filter (Model 0583) with each patient on the pressure port. The BRAEBON™ safety filter is required to prevent the spread of contaminants between patients and to prevent moisture damage to the Ultima Titration Sensor. Failure to use the BRAEBON™ safety filter will void the warranty.
- Do NOT set anything on top of the Ultima Titration Sensor and its accessories.
- Sterilization of the Ultima Titration Sensor is NOT required. Do NOT steam autoclave the Ultima Titration Sensor or damage will occur and void the warranty.
- Do NOT immerse the Ultima Titration Sensor in any liquids because damage will result. Advise all patients to keep the Ultima Titration Sensor away from water. Water damage will void the warranty.
- Do NOT drop the Ultima Titration Sensor.
- Use only two 1.5 V AA batteries.
- Ensure the polarity of the battery is correct when inserting, otherwise the device will not operate.
- Operate and store the Ultima Titration Sensor under the following environmental conditions:

	Operating Conditions	Storage Conditions
Temperature (in degrees Celsius)	10°C–40°C	10°C–40°C
Relative Humidity	30%–75% (Without condensation)	30%–75%

Description

The Ultima Titration Sensor is used in conjunction with a Positive Airflow Pressure (PAP) Device and a ploysomnograph (PSG) system to detect Pressure, Flow, Leak and Snore.

The Ultima Titration Sensor has three inputs for connecting non-conductive PVC tubing to a PAP device and six outputs with a DC output range of ± 1.0 volts and an AC output range of ± 1 mV. The Ultima Titration Sensor is calibrated in the factory; there is no need to recalibrate the sensor; however, you must calibrate your PSG system to properly use this sensor. The output range will vary according to the gain and baseline settings you used during recording.

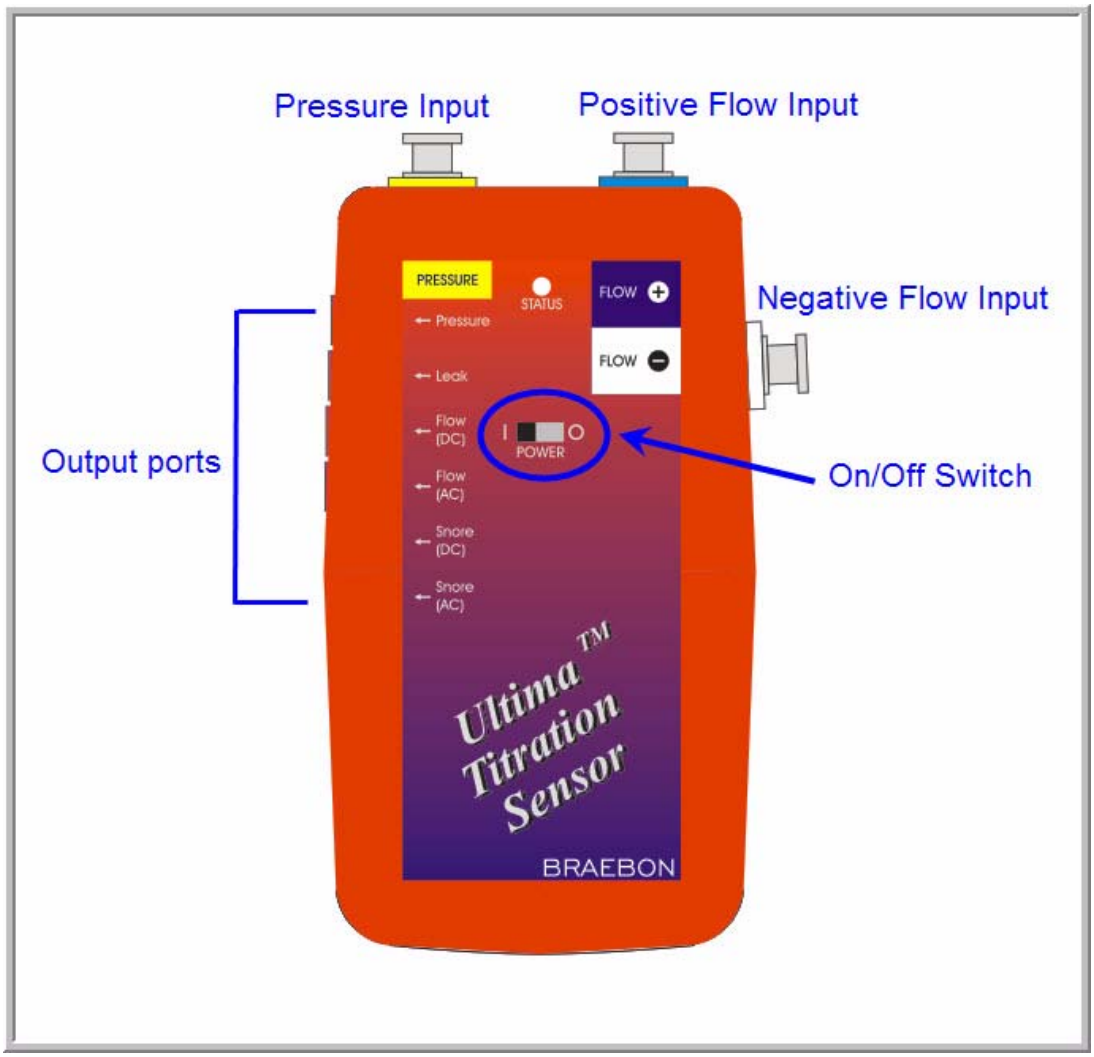


Figure 1: Ultima Titration Sensor

Table 1-1: Ultima Titration Sensor Inputs

Input	Description
Pressure	Yellow connector for the pressure port of the PAP
Flow +	Blue positive flow port from a dual output pitot tube connected to a PAP.
Flow -	White negative flow port from a dual output pitot tube connected to a PAP.

Table 1-2: Ultima Titration Sensor Outputs

Signal	Range (High, Low, Resolution)	Filters
Pressure (quantitative)	1.00 V = 20 cm H_2O -1.00 V = -20 cm H_2O ± 0.1 cm H_2O	HFF (LP) = 0.02 Hz
Leak (quantitative)	1.00 V = 150 Lpm -0.33V = -50 Lpm 15-150 Lpm = ± 10 Lpm	HFF (LP) = 0.02 Hz
Flow (DC) (quantitative)	1.00 V = 150 Lpm -1.00 V = -150 Lpm ± 10 Lpm	LFF (HP) = 0.01 Hz HFF (LP) = 16 Hz
Flow (AC) (quantitative)	1.00 mV = 150 Lpm -1.00 mV = -150 Lpm ± 10 Lpm	
Snore (DC) (qualitative)	1.0000 V -1.0000 V ± 100 µV	LFF (HP) = 10 Hz HFF (LP) = 100 Hz
Snore (AC) (qualitative)	1.000 mV -1.000 mV ± 5 µV	

Table 1-3: Displays and Indicator

LED	Status
Flashing green once every ten seconds	Unit is operating
Flashing red once every two seconds	Very low battery

Table 1-4: Controls

Control	Function
On/Off Switch	Used to turn the unit on or off.

Table 1-5: Specifications

Dimensions	5.0 x 2.8 x 0.9 inches (125 x 70 x 24 mm)
Weight	2.9 oz. with battery (82 g)
Case	Plastic (ABS)
Power	2 AA Alkaline batteries.
Battery life	50 days
Indicators	One bi-colored (red/green) status LED. Green blink every 10 seconds indicates unit operating; red blink every two seconds indicates a bad battery.
Controls	On/Off switch

Table 1-6: Contents of the Kit

Ultima Titration Sensor
3' dual channel tubing set with hydrophobic filters to connect the device to the inlet pitot, color coded blue and white
6' single channel tube with hydrophobic filters to connect the device to the pressure port on mask pressure connector, color coded yellow
2 x AA batteries
User Guide

Table 1-7: Accessories

Part #	Description
0574	45cm (18”) 1 mm dual safety pin to 1.5 mm safety pin connector cable
0353	45cm (18”) 1 mm dual safety pin to 3.5 mm male phone connector cable
0354	45cm (18”) 1 mm dual safety pin to 3.5 mm female phone connector cable
0355	45cm (18”) 1 mm dual safety pin to 2.5 mm male phone connector cable
0356	45cm (18”) 1 mm dual safety pin to 2.5 mm female phone connector cable
0357	45cm (18”) 1 mm dual safety pin to RJ11 connector cable
0358	45cm (18”) 1 mm dual safety pin to RJ10 connector cable
0552	1.8 m (6') single channel tube with hydrophobic filters to connect the device to the pressure port on mask pressure connector, color coded yellow
0553	1.8 m (6') dual channel tubing set with hydrophobic filters to connect the device to the inlet pitot, color coded blue and white

Test Signals

The unit generates a test signal across all the flow/snore channels when you turn the it on. It generates a high/low test signal for ten seconds, then a high test signal for ten seconds and finally a low test signal for ten seconds.You will see the pressure and leak signals as flatlines as they are filtered. Ensure that the airflow and snore signals are visible and appropriate (see below).

Note: The test signal will not be visible on the leak or pressure outputs because of the lo-pass filter. This does not affect the operation of the signals.

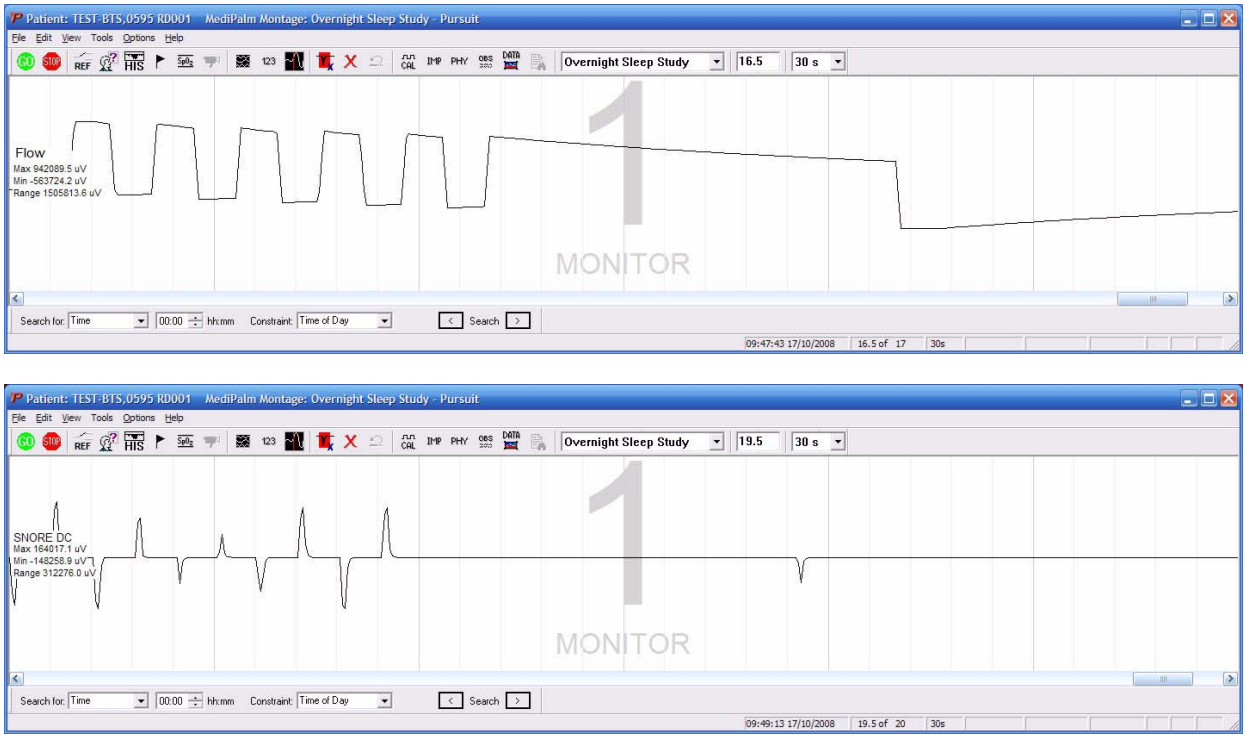


Figure 2: Airflow and Snore test signal

Calibration

Note: the unit will output negative voltages. If you are plugging into a DC system, ensure that you can output negative voltages, otherwise, the snoring and flow signals will be truncated.

To calibrate Pressure

How you calibrate the pressure is dependent upon the type of PSG system you are using.

A If you have a PSG system whereby you can enter the calibration values, type the following:

0 V = 0 cm H_2O

1 V = 20 cm H_2O

B If you have a PSG system which requires a generated signal to calibrate, connect the Ultima Titration Sensor to the PAP device (turned off) and wait two minutes for the signal to stabilize. Run the calibration procedure for your PSG for low; i.e., 0 V = 0 cm H_2O.

- Next, turn the PAP device on, set the pressure signal to 20 cm H_2O and plug the mask end of the tubing. Wait two minutes for the signal to stabilize and run the calibration procedure for your PSG for high; i.e., 1 V = 20 cm H_2O.

C If you have a semi-automatic calibration system PSG whereby you may enter the upper and lower limits from a generated signal, connect the Ultima Titration Sensor to the PAP device (turned off) and wait two minutes. The PAP device may automatically accept this as the low or you may have to enter 0 V = 0 cm H_2O.

- Turn the PAP device on, plug the mask end of the tubing and wait two minutes for the signal to stabilize. Your unit may automatically accept this signal as the upper level or you may have to enter 1 V = 20 cm H_2O.

The following table shows the relationship of the high level output to the PAP pressure.

Table 1-8: Calibration Settings, Pressure

High Level Output (V)	PAP Pressure cm H_2O
1	20.0
0.0	0
-1	-20.0

To calibrate Leak

How you calibrate Leak is dependent upon the type of PSG system you are using.

A If you have a PSG system whereby you can enter the calibration values, type the following:

0 V = 0 Lpm

1 V = 150 Lpm

B If you have a PSG system which requires a generated signal to calibrate, connect the Ultima Titration Sensor to the PAP device (turned off) and wait two minutes for the signal to stabilize. Run the calibration procedure for your PSG for low; i.e., 0 V = 0 Lpm.

- Next, turn the PAP device on, set the pressure signal to 4 cm H_20. Wait two minutes for the signal to stabilize and run the calibration procedure for your PSG for high; i.e., 1 V = 150 Lpm.

C If you have a semi-automatic calibration system PSG whereby you may enter the upper and lower limits from a generated signal, connect the Ultima Titration Sensor to the PAP device (turned off) and wait two minutes. Your unit may automatically accept this as the low or you may have to enter 0 V = 0 Lpm.

- Turn the PAP device on, set the pressure signal to 4 cm H_20 and wait two minutes for the signal to stabilize. Your unit may automatically accept this signal as the upper level or you may have to enter 1 V = 150 Lpm.

The following table shows the relationship of the high level output to the flow rate.

Table 1-9: Calibration Settings, Leak

High Level Output (V)	Flow Rate, (Lpm)
1	150
0.0	0
-0.333	-50

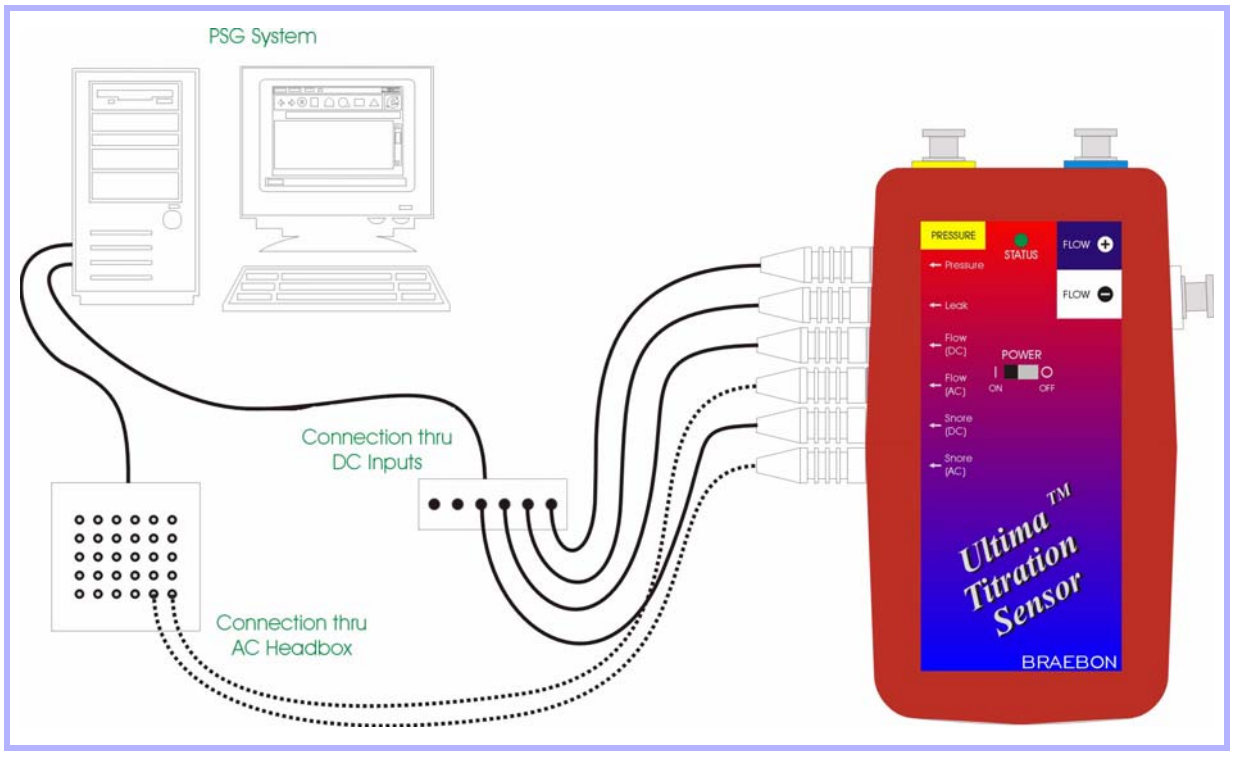
Setup

The setup of the Ultima Titration Sensor consists of the following steps:

1. Connect the Ultima Titration Sensor to the PSG.
2. Connect the Tubing to the Ultima Titration Sensor and the PAP device.
3. Connect the Tubing to the Patient.

Connect the Ultima Titration Sensor to the PSG

1. Connect the output cables to the desired Ultima Titration Sensor output jacks.
2. Connect the terminal ends of the cables to the selected polysomnograph inputs as shown. The output cables selected at the time of ordering determine either a high or low level output.



Note: dashed lines represent alternate connections.

Figure 3: Connect the Ultima Titration Sensor to the PSG

Connect the Tubing to the PAP, the Ultima Titration Sensor and the Patient

1. Attach the two 3-foot tubes to the differential pressure connector on the back of the PAP device.
2. Attach the color-coded Luer lock ends to the Ultima Titration Sensor at Flow+ and Flow-. The blue ended tube attaches to Flow+ and the White ended tube attaches to Flow-.
3. Attach the 6-foot tube to a port on the PAP mask with slip fit connection.
4. Attach the yellow Luer lock end to the yellow Pressure input on the Ultima Titration Sensor.

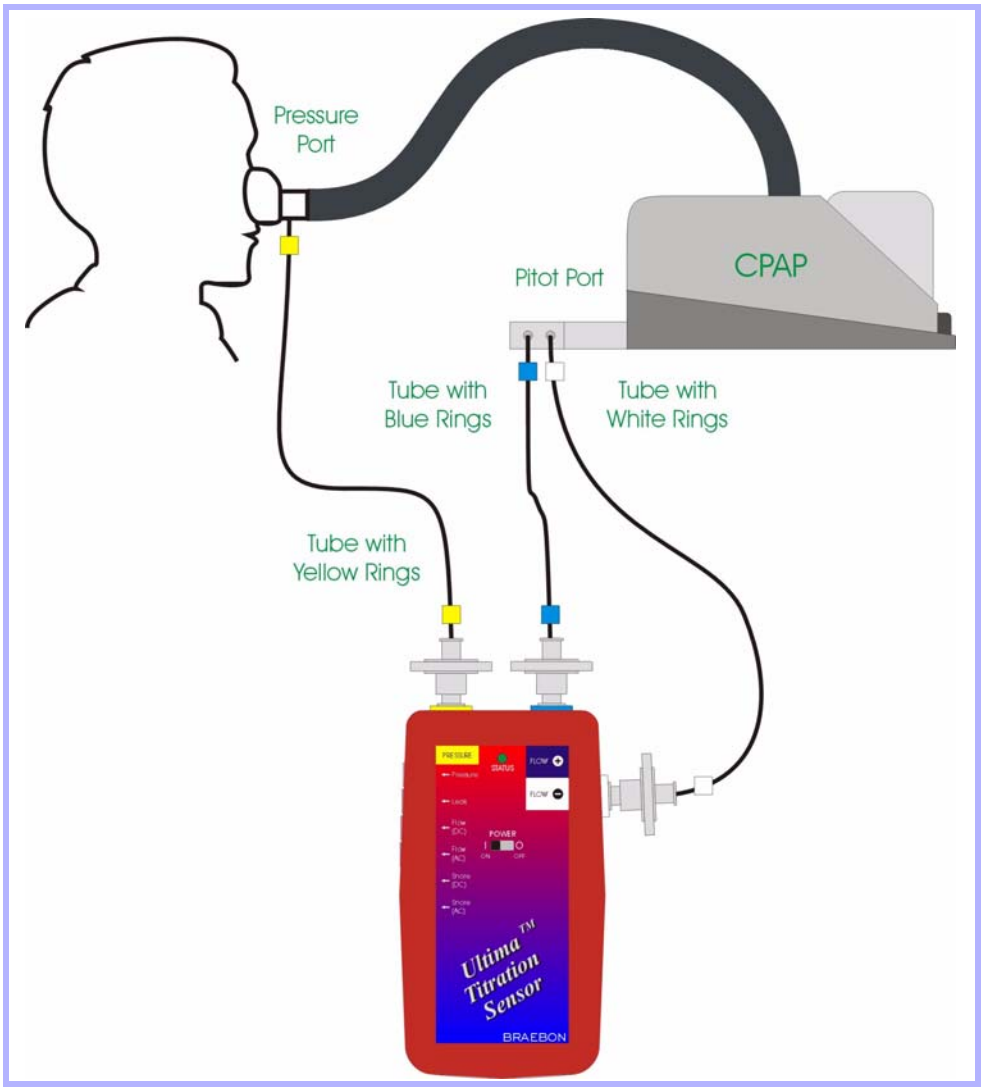


Figure 4: Tubing Connections

Maintaining the Ultima Titration Sensor

Caution: Sterilization of the Ultima Titration Sensor is NOT required. Do NOT steam autoclave the Titration Senor or damage will occur and void the warranty.

Caution: Do NOT immerse the Ultima Titration Sensor in any liquids because damage will result. Water damage will void the warranty.

The Ultima Titration Sensor is a non-sterile device that does not contact the patient. You can moisten a clean cloth with water and wipe the sensor with the damp (not wet) cloth.

Cleaning the Ultima Titration Sensor:

1. Moisten a clean cloth with water.
2. Gently, wipe the Ultima Titration Sensor with the damp cloth.
3. Ensure that the Ultima Titration Sensor is completely dry before using.

For additional information, refer to the Association for Professionals in Infection Control and Epidemiology (APIC) Guidelines for selection and use of disinfectants (*American Journal of Infection Control*. Vol. 18, No. 2, April 1990).

Pressure Tubing

The pressure tubing used with the Ultima Titration Sensor is for single-use only. Dispose of the pressure tubing after use and replace with new tubing for each patient.

Repairing the Ultima Titration Sensor

The Ultima Titration Sensor does not contain serviceable parts.r

Warning: Unauthorized opening of the Ultima Titration Sensor will void both the safety of the Ultima Titration Sensor and the terms and conditions of the Ultima Titration Sensor warranty.

Warning: Do NOT use or attempt to service damaged parts.

The Ultima Titration Sensor is only repairable by BRAEBON™– trained personnel. The opening of the Ultima Titration Sensor by unauthorized individuals will void both the safety of the Ultima Titration Sensor and the terms and conditions of the Ultima Titration Sensor warranty.

If your Ultima Titration Sensor or any of its accessories are damaged, please contact BRAEBON™ immediately at 1-888-462-4841.

Battery Disposal

Please dispose of used batteries responsibly. To locate a battery disposal sight near you, go to **www.ehso.com.**

Troubleshooting

If you have difficulty using this product, please verify the following:

Problem	Solution
No test waveforms for Airflow or Snore	• Check batteries • Check connections to PSG
No pressure signal	• Ensure tube is connected from the patient mask to the Ultima Titration Sensor as described on page 14.
No leak signal	• Ensure that both tubes are connected from the differential pressure connector to the Ultima Titration Sensor as described on page 13.
Ultima Titration Sensor was submerged in liquid	• Contact BRAEBON™ Medical Corporation at 1-888-462-4841. Please have the product model and serial number available when you call.

If you still experience trouble with the product, contact technical support by **telephone at 1-888-462-4841** or by E-mail at **support@braebon.com**. Visit our website for solutions to Frequently Asked Questions (FAQs): **www.braebon.com**.

Warranty

BRAEBON MEDICAL CORPORATION warrants to the first consumer that this Ultima Titration 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 Ultima Titration 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 Ultima Titration 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 Ultima Titration 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 Ultima Titration Sensor which were caused by abuse, misuse, tampering, neglect, incorrect battery type, or repairs or attempted repairs performed by anyone other than an authorized service person. This warranty covers the Ultima Titration Sensor Model MP8 only. Accessories and consumables have separate warranties with different coverage periods.

Warning: Unauthorized opening of the Ultima Titration Sensor will void both the safety of the Ultima Titration Sensor and the terms and conditions of the Ultima Titration Sensor warranty.

Caution: Failure to use the correct battery type as stated in this User Guide will void the warranty.

Note: Specifications subject to change without notice.

Index

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