

Ultima SmartBelt™ User Guide P/N 0560

A BRAEBON MEDICAL CORPORATION PRODUCT



Intended Use

The BRAEBON MEDICAL CORPORATION *Ultima SmartBelt™* is intended for use during sleep disorder studies as a superior qualitative measure of respiratory effort for recording onto a data acquisition system. The sensor uses state-of-the-art technology and is designed to be used overtop of clothing. The SmartBelt™ plugs directly into your existing electrode headbox.

Congratulations on your purchase of The *Ultima SmartBelt™* by BRAEBON MEDICAL CORPORATION. We chose the name *Ultima* because we are sure you will agree that our sensor is the ultimate respiratory effort sensor available today! The *Ultima SmartBelt™* uses state-of-the-art technology to measure thoracic or abdominal respiratory effort. The sensor is plugged directly into the headbox and the signal is then sent to a data acquisition system for permanent recording.

Component Names and Functions

The *Ultima SmartBelt™* Kit (part #0560) includes parts 0561, 0562, 0523, and 0525.

The *Ultima SmartBelt™* consists of four components: (1) a pair of safety lead jackpins to connect the sensor to the headbox; (2) a state-of-the-art sensor system which is affixed to belt fabric (part #0562); (3) a battery enclosure (part #0561, interface kit) containing the replaceable battery and interface circuitry; and (4) an Allen key to open the battery enclosure during battery replacement (see Figure 1).



Figure 1. The *Ultima SmartBelt™* Interface (Model 0561).

Using The *Ultima SmartBelt™*

Caution: Do not wash any component of The *Ultima SmartBelt™*.

The *Ultima SmartBelt™* ships with two SmartBelts and velstretch bands of various size (medium, large) which use a buckle connector.

1. Adjust The *Ultima SmartBelt™* to fit the patient comfortably. Place the belt snugly around either the patient's thorax or abdomen. The thoracic belt should be just below or above the nipple line and the

abdominal belt should be below the rib cage. To use the buckle connector, simply fasten one end of the belt into the other end of the belt. Ensure that the belt is neither excessively tight nor loose.

3. Connect the abdominal and thoracic SmartBelt™ sensors to the SmartBelt™ Interface. Turn on the SmartBelt™ Interface. The LED will flash green then red, followed by a two second pause and one green flash. The LED will then continue to blink green once every 10 seconds for the next 10 hours or until manually turned off.
4. The auto-off feature will turn the unit off after 10 hours of continuous use. To re-start the SmartBelt™ Interface unit, turn the unit off, wait 20 seconds and turn the unit back on. It should immediately begin the blinking sequence indicated above. Repeat if necessary. If the unit fails to re-initialize contact technical support (see Troubleshooting section below).



Figure 2. Frontal view of The *Ultima SmartBelt™*

Warranty

BRAEBON MEDICAL CORPORATION warrants to the first consumer that this *Ultima SmartBelt™* (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.

Note: Product specifications are subject to change without notice.

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Disinfection & Cleaning

Caution: *The Ultima SmartBelt™* is designed to be placed overtop of clothing. Do not wash or disinfect any component of the sensor or damage may occur.

1. If the sensor is spoiled or damaged replace the sensor with a new unit. Do not attempt to repair or clean the sensor. Doing so will damage the product and void the warranty.
2. Steam autoclaving is not recommended.
3. 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

Approximately every six months you will need to replace the battery within the battery enclosure. The LED on the SmartBelt™ Interface will blink red to indicate a new battery is needed. Simply unscrew the Allen screw located in the interface enclosure (see Figure 1) with the Allen key provided. Carefully pry the battery loose (the Allen key may be used) and replace the old battery with a Saft LS-14250 ½ AA lithium battery only.

Caution: Using a battery type other than that recommended may damage the sensor unit.

Warning:

The Ultima SmartBelt™ is for diagnostic use only and is not intended as an "apnea monitor." U.S. Federal law restricts this device to sale by or on the order of a physician.

Technical Specifications

Amplifier Settings:

- 0.01 Hz to 0.1 Hz Low Frequency Filter
- 15 to 30 Hz High Frequency Filter
- 50/60 Hz Notch Filter as required
- 7.5 mV/cm Sensitivity (increase or decrease as required)

Sensor Housing:

- 72 mm X 37 mm X 15mm (L x W x H)
- signal output ±4 - 6 mV

SmartBelt™:

- SmartBelt™ Kit Part #0560 consists of two 0562 SmartBelts, one SmartBelt™ Interface (0561), and two velstretch bands (two 3' and two 5' bands)
- SmartBelt™ Interface part #0561
- SmartBelt™ Part #0562
- 3' Velstretch Bands Part #0523
- 5' Velstretch Bands Part #0525

Troubleshooting

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

1. SmartBelt™ is properly attached to both the patient and the headbox.
2. Sensitivity, filter settings, and all amplifier and recorder connections are functional.
3. Ensure the LED is blinking green. If the LED is blinking red only replace the battery with a new Saft LS-14250 ½ AA lithium.

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