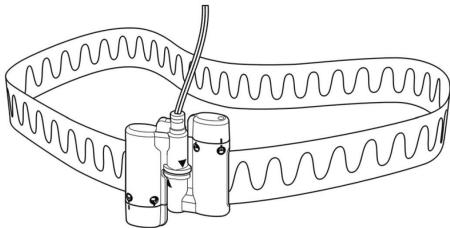




Cadwell[®] Sleepmate

Instructions for Use (IFU)

RIPmate[™] Disposable Respiratory Effort





The Single Use RIPmate™ Respiratory Inductive Plethysmograph (RIP) sensor belt is a respiratory effort sensor used in the diagnosis of sleep disordered breathing. RIPmate measures changes in inductance and converts it into a digital signal that gives both qualitative and quantitative data. This sensor is more sensitive and reliable than typical respiratory effort sensors, especially in cases of paradoxical breathing. The Single Use RIPmate belts consist of a belt roll that can be cut down in appropriate lengths for each patient and two Belt Locks for the abdomen and thoracic regions.

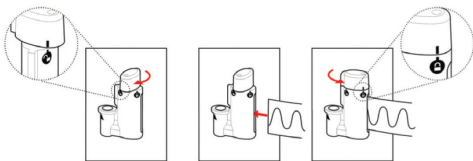
Fitting the RIPmate Single Use Belts

The RIPmate belts must be custom fit for each patient. When using the RIPmate belts, it is advised to avoid all unnecessary contact with moisture.



1. Encircle the belt around the patient's chest under the arm to approximate the circumference for the thoracic belt.
2. When cutting the belt, reduce its circumference by 10-15cm (4-6") so that it will stretch around the thorax. The belt should fit snugly to prevent slippage during the night. It is important to use sharp scissors for a clean cut. The wire should not exceed the end of the belt.
3. Secure the cut ends of the belt into the Belt Lock according to the following steps:

EN



Twist the top end of the Belt Lock clockwise to open the catch. The white mark on the top should match the open lock symbol on the catch.

Insert the cut end of the belt into the catch. Make sure to insert the end all the way to the bottom of the catch.

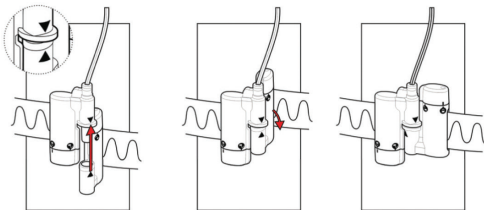
Twist the top end of the Belt Lock counter clockwise to close the catch. When the white mark on the top matches the closed lock symbol on the catch, the Belt Lock is properly closed.

4. Prepare the abdominal belt in the same manner, only this time fitting the belt around the patient's stomach at the navel.

Attaching the RIPmate Belts

The RIPmate belts are intended to be worn over the patient's night clothes.

1. Place the belt sized for abdomen around the patient's stomach at the navel.
2. Take the two components of the Belt Lock and connect them as shown below:



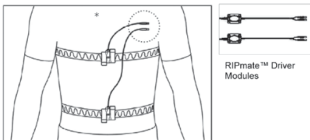
3. Place the belt sized for thorax around the patient's chest under the arm.
4. Connect the second Belt Lock as shown above.

Caution Statement:



US Federal Law restricts this device to sale by or on the order of a physician. This product is for diagnostic purposes only and is not intended to be used as an apnea monitor or in a life supporting or sustaining capacity.

5. Insert the connector from the Chest belt into the driver module labeled Thorax (* in drawing).
6. Insert the connector from the Abdomen belt into the driver module labeled Abdomen.



7. Plug the thorax module output into the appropriate bipolar input of your polygraph. The red touch proof is plugged into (+) input, and the black into (-) input.
8. Plug the thorax module output into the appropriate bipolar input of your polygraph. Note: Do not use two abdomen or two thorax modules in the same recording. This will cause interference between the two sensors, resulting in bad signals.

RIPmate™ Instructions for Use

Polygraph Settings

Sensitivity—Adjustment of the sensitivity up or down is typically required. Response is dependent upon variables such as sensor application and patient effort.

Low Frequency Filter / Time Constant—0.16 Hz (or 1 second or longer)
Shorter time constants or higher low frequency filter settings will significantly attenuate waveforms.

High Frequency Filter—15 to 35 Hz.

Battery Life

The battery life is estimated to be 3000 hours or 375 eight hour studies. The battery is activated once the sensor module is connected to the belt.

Maintenance

No special maintenance of the RIPmate™ System is required.

Warranty

Cadwell warrants the sensor to be free of defects in materials and workmanship. The sole liability of Cadwell and our Distributor(s) is limited to replacement or repair of the product at the option of Cadwell with no charge for parts or labor if any part is proven to be defective in workmanship, performance, or materials during the warranty period. Under no circumstances shall Cadwell or our Distributor(s) be liable for any loss of revenues or damage, direct, consequential, or incidental, including loss of profit, property damage, or personal injury arising from the use of, or the inability, to use this product. This warranty is intended only for the original buyer and is in lieu of all other warranties or previous agreements, expressed or implied. This warranty is rendered void if the product is used for other than its intended purpose or is subject to abuse, misuse, tampering, neglect, or unauthorized modifications. Use of this product constitutes acceptance of this warranty in total.

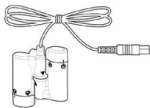
Storage

Proper storage of the RIPmate™ Belt Locks and modules between uses will increase life of the product. To protect the sensors from damage, follow these guidelines for storage:

- do not wrap the wires tightly around the Belt Lock as it may cause the wire to break.
- To save battery power, the modules MUST be disconnected for the Belt Locks when not in use.



Incorrect



Correct

Cleaning and Disposal

No part of the RIPmate™ system requires sterilization.

- The Driver Modules and locks may be wiped clean with a moist cloth of hospital grade cleaner that is not corrosive to plastic or metal, and then dried with a clean, dry cloth. Do not immerse in liquid. Care should be taken to avoid contact of the cleaning solution with the connectors and plugs.
- The belts do not require cleaning since they are to be used as single use only and disposed of properly after use.

Warnings

- Do not use damaged belts or cables.
- Do not use the device in an MRI environment.
- Do not use the device in an explosive environment, i.e. in the presence of flammable liquids or gases, such as anesthetic mixture with air or with oxygen or nitrous oxide.
- The RIPmate™ systems are only to be connected to an electrically isolated input. Do not plug cables into electrical outlets as this could result in serious electrical shock.
- The device contains a battery and must therefore be disposed of properly. Local, state or national laws may prohibit disposal of batteries in ordinary trash. Contact your local waste authority for information regarding available recycling and disposal options.
- The belts shall be worn over night clothes.
- The RIPmate™ system is non-repairable by the user and the user's service personnel. Contact Sleepmate in case of device failure.
- Portable and mobile RF communications can affect the performance of the device.
- No user serviceable parts inside. Serviced by Sleepmate and authorized parties only. Warranty void if opened.

Technical Specifications

Description	Properties
Belt	Length: Roll of 35 yards, cut to fit each patient. Material: Elastic band with wire
Cable	Length: 80" (205cm) Material: PVC jacketed; ZIP-style cord
Module	Box: ABS Cable: PVC jacketed; Zip Style cord
Power	
Battery	Non-replaceable Lithium Coin cell battery
Environmental Specifications	
Temperature	Operation: 40°F to 120°F (+5°C to +50°C) Storage: 0°F to 120°F (-20°C to +50°C)
Relative Humidity	Operation: 15-95% (non-condensing) Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressures from 7.3 psi to 29 psi
Output Specifications	
Output Signal	Maximum signal amplitude: ±5mV Frequency Range: 0.2 to 3 Hz Sensitivity: Approximately 50µV/mm



Cadwell Industries Inc.

909 N. Kellogg Street, Kennewick, WA 99336 USA
1 (800) 245-3001 U.S.A. toll-free | +1 (509) 735-6481
+1 (509) 783-6503 Fax
www.cadwell.com | info@cadwell.com

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