



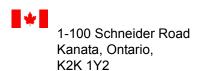


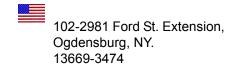
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Intended Use

The BRAEBON Medical Corporation Q-RIP™ Respiratory Effort System™ is intended for use during sleep disorder studies as a measure of respiratory effort for recording by a data acquisition system. The sensor uses respiratory inductance plethysmography (RIP) technology and plugs directly into an electrode headbox or a DC amplifier.

The target population of the Q-RIP Respiratory Effort System 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 Q-RIP Respiratory Effort System intended to be used only by or on the order of a physician.



Warnings

- The Q-RIP 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.
- Do NOT steam autoclave or gas sterilize the Q-RIP interface or belts as damage will result.



Note: Unlike piezo belts, RIP belts must be put on tightly. You can easily loosen the belt once it is on. It is more difficult to tighten the RIP belt once it is on the body.

Contents of the Q-RIP Kit, 0570

Part Number	Description	Quantity
0571	Q-RIP Interface	1
0572	Q-RIP Effort Belt, adjustable from 24" to 48"	2
0573	Q-RIP Belt to Controller Cable	2
0574	Q-RIP Controller Output Cable	3
820-0005-01	1.5 V AA battery	2
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Description

The Q-RIP System consists of two respiratory effort belts (0572) and one Q-RIP interface (0571). The two respiratory effort belts are worn by the patient around the waist and abdomen to measure respiratory effort. The belts are plugged into the Input ports on the interface using the cables provided with the belts. Three output cables plug into the Output ports on the interface and into the PSG system. These output cables send the abdominal, chest and sum signals to the PSG system.

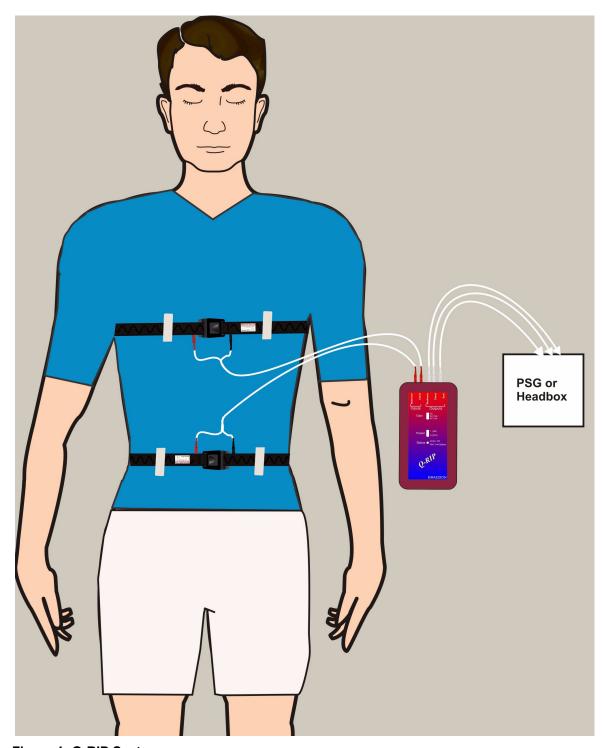


Figure 1: Q-RIP System

To fit the chest belt

- 1. Tighten the belt as much as possible; it is much easier to loosen a tight belt on the body than to tighten a loose belt.
- 2. Wrap the chest belt around the chest and snap it closed. It is not necessary to place the belt on bare skin; we recommend you place the belts over bedtime clothing.
- 3. Ensure the belt is located above or below the nipple line and loosen for a firm but comfortable fit.
- 4. Use medical tape to secure the belt to clothing to prevent shifting.
- 5. Take one of the Y-shaped cables and plug one safety pin connector into the left socket on the belt and the other safety pin connector into the right socket. It does not matter which colored pin goes into the socket.
- 6. Plug the keyhole connector into the keyhole input of the Q-RIP interface, labelled **CHEST**.

PSG or Headbox

Figure 1: Chest belt plugged into the Q-RIP interface

To fit the abdominal belt

- 1. As with the chest belt, tighten the belt as much as possible before putting it on.
- 2. Wrap the belt around the belly and snap closed. Loosen for a firm but comfortable fit.
- 3. Use medical tape to secure the belt to clothing to prevent shifting.
- 4. Take the remaining Y-shaped cable and plug one safety pin connector into the left socket located on the belt and the other safety pin connector into the right socket.
- 5. Plug the keyhole connector into the keyhole input on the Q-RIP interface labelled **ABDOMEN**.

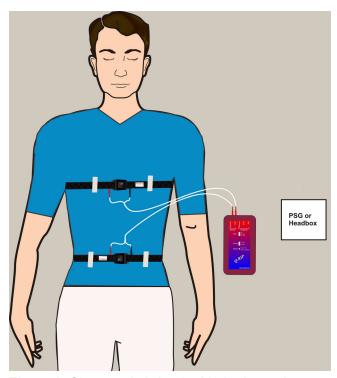


Figure 2: Chest and abdominal belt plugged into the Q-RIP interface

Output to PSG

- 1. Connect the three output cables to the three output ports on the Q-RIP.
- 2. Plug the other ends into your PSG or headbox.



Figure 3: Q-RIP interface with inputs and outputs

System Settings

Refer to your sleep system user guide for the manufacturers's recommended settings. General recording system settings:

- Low Frequency Filter: 0.1 Hz or lower (TC=1 sec. or longer)
- High Frequency Filter: 5 Hz to 15 Hz
- 50/60 Hz Notch Filter: optional
- Sensitivity/Gain 2 mV/cm or 4 000 gain (increase or decrease as needed).

Starting the Q-RIP

- 1. Set the Gain on the front of the Q-RIP Interface, refer to Table 1 on page 7 for the gain ranges.
- 2. Turn the power ON.
- 3. Wait two minutes for the signals to settle. This means that when you review the data, the signals in the first two minutes may not look correct.

Stopping the Q-RIP

1. At the end of the study, turn the Q-RIP power OFF. If you forget, the system will automatically turn off after 14 hours.

Signals

The Q-RIP collects the chest, abdominal and sum signal. The sum signal is useful as an aid for detecting paradoxical breathing. When the chest and abdominal signals are completely out of synchronization, the sum channel will tend toward flatness.

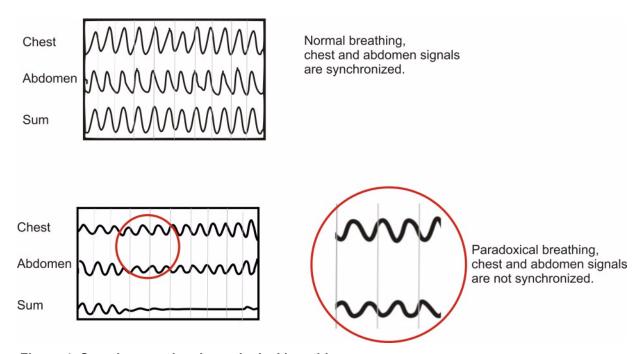


Figure 4: Sample normal and paradoxical breathing

Troubleshooting

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

Problem	Solution	
	If you have just turned the unit on, wait 2 minutes	
	Check batteries	
No signal	Check belt connections	
	Check connections to PSG	
	Check the gain setting is in the correct position	
Noisy signal	Belts not tight enough.	
Noisy signal	Check the gain setting is in the correct position	
Q-RIP was submerged in liquid	Contact BRAEBON™ Medical Corporation at 1.888.462.4841 x 214. Please iquid 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 x 214** or by E-mail at **support@braebon.com**. Visit our website for solutions to Frequently Asked Questions (FAQs): www.braebon.com/FAQ.

Maintaining the Q-RIP

The Q-RIP Respiratory Effort System is a non-sterile device. It is classified as a non-critical item because it only contacts clothing and intact skin.



Caution: Sterilization of the Q-RIP is NOT required. Do NOT steam autoclave any component of the Q-RIP System as damage will occur and void the warranty.

Caution: Do NOT immerse the Q-RIP Interface in any liquids because damage will result. Water damage will void the warranty.

Cleaning the Q-RIP Interface:

- 1. Moisten a clean cloth with water.
- 2. Gently, wipe the Q-RIP interface with the damp cloth.
- 3. Ensure that the Q-RIP interface 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).

Cleaning the Q-RIP Belts

Place RIP belts into a mesh laundry bag to prevent tangling. Machine-wash on the gentle cycle, hang to dry.

Table 1: Specifications

Dimensions	5.0 x 2.8 x 0.9 inches (125 x 70 x 24 mm)	
Weight	2.9 oz. with batteries (82 g)	
Case	Plastic (ABS)	
Power	2 x AA Alkaline batteries; 2 x NiMH or 2 x NiCD rechargeable batteries may be used. Do not mix different types of batteries; do not mix old and new batteries.	
Battery life	Up to 70 nights	
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.	
Gain Switch	Set the Gain to DC, AC High or AC Low	
DC	Set the gain for a DC amplifier	0 V - 1 V
AC High	Set the gain for Alice 5, MediPalm	± 250 mV
AC Low	Set the gain for most headboxes, PSG systems	± 5 mV

Table 2: Q-RIP Belts

Part #	Description	
0572	Q-RIP Effort Belt, medium size, adjustable from 24"-48'.	
0572L	Q-RIP Effort Belt, large size, adjustable from 48"-72".	
0572Ped Q-RIP Effort Belt, small size, adjustable from 12"-24".		

Table 3: Accessories

Part #	Description	Connector
0352	36" (90 cm) Dual 1 mm keyhole connector to 1 mm keyhole connector	
0353	18" (45 cm) Dual 1 mm (keyhole) connector to 1/8" (3.5 mm) male phone connector	
0354	18" (45 cm) Dual 1 mm (keyhole) connector to 1/8" (3.5 mm) female phone connector	
0355	18" (45 cm) Dual 1 mm (keyhole) connector to 3/32" (2.5 mm) male phone connector	
0356	18" (45 cm) Dual 1 mm (keyhole) connector to 3/32" (2.5 mm) female phone connector	
0357	18" (45 cm) Dual 1 mm (keyhole) connector to RJ11 connector	

Table 3: Accessories

Part #	Description	Connector
0358	18" (45 cm) Dual 1 mm (keyhole) connector to RJ10 connector	
0573	Q-RIP Belt to Controller Cable: 84" Dual 1 mm (keyhole) connector to two 1.5 mm touchproof connectors.	
0574	Q-RIP Controller Output Cable: 18" (45 cm) Dual 1 mm (keyhole) connector to two 1.5 mm touchproof connectors	

Table 4: Environmental Conditions

	Operating Conditions	Storage Conditions
Temperature (in degrees Celsius)	10°C-40°C	5°C-50°C
Relative Humidity	10%–85% (Non-condensing)	10%–85%

Repairing the Q-RIP

The Q-RIP does not contain serviceable parts.



Warning: Unauthorized opening of the Q-RIP will void both the safety of the Q-RIP and the terms and conditions of the Q-RIP warranty.

Do NOT use or attempt to service damaged parts.

The Q-RIP is only repairable by BRAEBON™— trained personnel. Opening of the Q-RIP interface by unauthorized individuals will void both the safety of the Q-RIP and the terms and conditions of the Q-RIP warranty.

If your Q-RIP or any of its accessories are damaged, please contact BRAEBON™ immediately at 1.888.462.4841 x 214.

Battery Disposal

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

Warranty

BRAEBON MEDICAL CORPORATION warrants to the first consumer that this Ultima Q-RIP 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 Q-RIP 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 Q-RIP 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 Q-RIP 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 Q-RIP 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 Q-RIP Model 0571 only. Accessories and consumables have separate warranties with different coverage periods.



Warning: Unauthorized opening of the Q-RIP will void both the safety of the Q-RIP and the terms and conditions of the Q-RIP warranty.



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

Notes



In Canada: 1-100 Schneider Road Kanata, Ontario, K2K 1Y2 In the US: 102-2981 Ford St. Extension, Ogdensburg, NY 13669-3474

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