RU*Sleeping*™ RTS

Provider's Guide

Table of Contents

How to Use This Guide

This guide is designed to provide information about the RUSleeping RTS device and supply material to review with patients regarding its proper use.

It is strongly recommended that the medical professional and patient thoroughly review the entire "Warnings, Cautions, and Contraindications," "Intended Use," and "Instructions for Use" sections together - including operation of the main device and the donning of the cannula.

IMPORTANT:

Read and understand this entire manual before operating this device.

Warnings, Cautions, and Contraindications

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

NOTE:

Additional warnings, cautions and notes are located throughout this manual.

Warnings

A warning indicates the possibility of injury to you or the operator of this device

This manual serves as a reference.

Read and understand the entire manual before using the device.

Discontinue use if skin reddening or inflammation appears.

Do not smoke while wearing the RUSleeping RTS cannula.

Cautions

A caution indicates the possibility of damage to the device.

Avoid exposure to sources of direct airflow such as fans during recording.

Avoid using this device in an MRI environment or in close proximity to a high EMI emission source.

Do not attempt to take the main device apart. No user-serviceable parts are inside.

Do not immerse the main device in water.

Do not use if you are wearing a nasal or full face mask for CPAP or bilevel therapy. This will affect the accuracy of the RUS score.

Do not use if you are wearing a cannula for therapy. This will affect the accuracy of the RUS score.

Cautions (continued)

If you notice any unexplained changes in the performance of this device, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact Respironics.

Contraindications

No contraindications are known for this device.

Intended Use

The RUSleeping RTS is a small monitor designed to assess nasal airflow during sleep. Apnea events are counted based on reduction of airflow.

The RUSleeping RTS device is intended for use as a screening device to determine the need for clinical evaluation and diagnosis of sleep apnea based on the patient's score.

What is RUSleeping RTS?

The RUSleeping RTS device is a multi-patient, small, lightweight, battery-operated device with a specially designed cannula for detecting apnea events.

RUSleeping RTS provides the following results to the user:

1. The rate of apnea events (AH) occurring during the sleep period
2. The total number of apnea events occurring each hour
3. Device status

RUSleeping RTS is not a diagnostic tool. Rather, it is an assessment tool for collecting and displaying information about sleep related apnea events.

Because the RUSleeping RTS can be used in the home it is a reliable, comfortable and cost-effective tool for assessing the need for further patient testing.

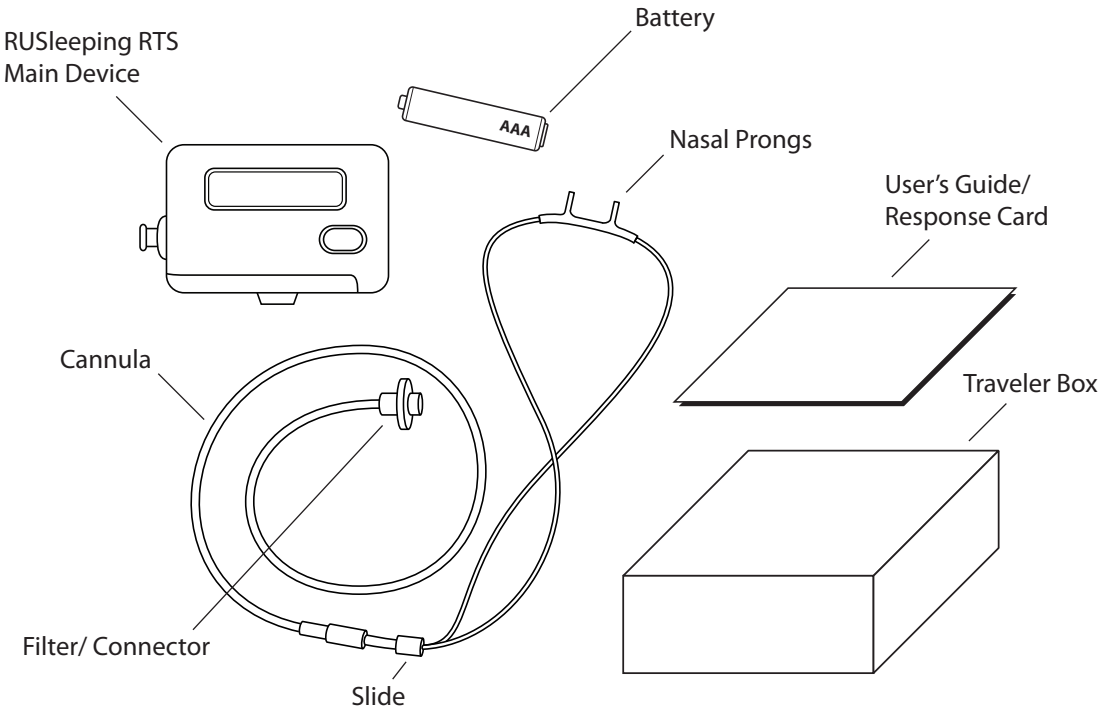
System Contents

Patient System Contents

- Traveler Box
- 1 User's Guide/ Response Card
- Cannula
- RUSleeping RTS Main Device
- Battery (AAA)

Medical Professional System Contents

- Provider's Guide
- Additional User's Guide/ Response Cards



Symbols

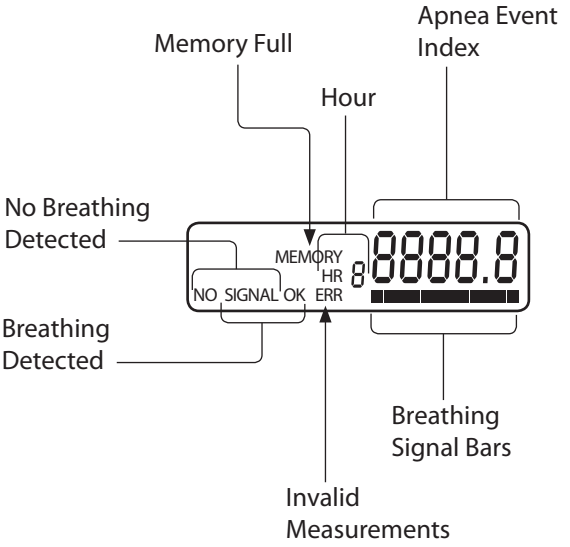
These symbols are used on the RUSleeping RTS device.

Follow instructions for use

Type BF Applied Part

Canadian/ US Certification

RUSleeping Display



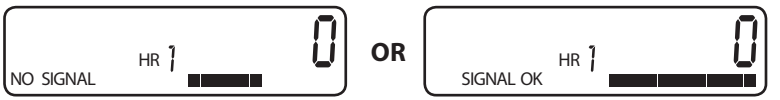
Instructions for Use

Setup

1. Remove the RUSleeping RTS device and cannula from the package.

2. The main device requires a single 1.5V AAA alkaline battery (or equivalent). To install the battery, slide the battery cover open and insert the battery with the positive end (+) toward the gray button. Slide the battery cover closed, making sure it is secure.

3. Check the display. When the battery is correctly installed the device will initiate a short startup process. The device is ready when it reads:



CAUTION:

If you install the battery and the entire display flashes, you need to replace the battery.

If nothing appears on the display the battery is dead or installed incorrectly.

NOTE:

The device will automatically save recorded data at the end of each hour. If the battery is removed while in use, previously recorded data will be recalled and displayed when the battery is replaced.

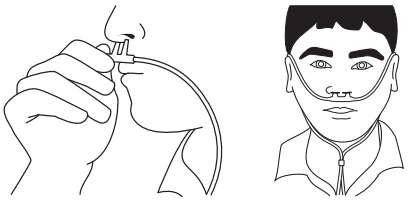
Instructions for Use

Before Sleeping

Each RUSleeping RTS device includes a new cannula. At one end are two small nasal prongs for measuring breathing. These two nasal prongs must lie inside your nostrils to accurately measure breathing.

1. Remove the cannula from it's package and move the slide away from the nasal prongs, toward the end of the double tubing.

2. Put the cannula on your face so the nasal prongs rest just inside your nostrils as shown and gently loop the cannula tubes around each ear. The cannula should lead from the device to your collarbone, around each ear and finally to your nostrils. Do not place your head inside the cannula loop.



3. Gently move the slide toward your chin until the cannula feels secure under your nose.

4. To attach the cannula to the main device, twist the connector into place . Press firmly to ensure the cannula is securely attached.

NOTE:

Each cannula is for single-use only. If the cannula is not sealed in it's own packaging, throw the cannula away. Do not use the device without a new cannula.

NOTE:

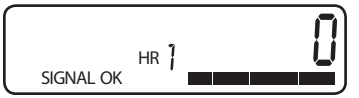
It is important the cannula tubing runs over the ears and the slide is secure and snug under the chin when the device is in use. This is the correct position for use and minimizes the chance the cannula will become displaced while sleeping.

NOTE:

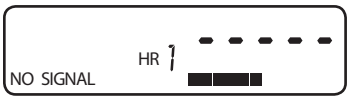
If you find the cannula becomes uncomfortable, loosen the clear slide so the nasal prongs are most comfortable in place. It is very important to recheck the display after making any adjustment.

Instructions for Use (continued)

5. Check the display. It should read, "SIGNAL OK" and the bar graph should be displayed and moving according to the breathing cycle.



6. To clear the main device's memory in preparation for the sleep session, **press and hold the gray button for five seconds** until the display briefly flashes and reads "NO SIGNAL" as shown:



7. **When you release the gray button** the display should read "SIGNAL OK" and begin recording. If not, rearrange the nasal prongs and breathe normally for three seconds. Continue adjusting until the display reads, "SIGNAL OK." You should also see the bars on the display move with your breathing.

8. Use the clip on the device to attach it to your bed, clothes, or pillow. Relax and go to sleep. Throughout the night, the device will monitor your respiration and record the results in the RUSleeping RTS device.

NOTE:

If the bar does not move with your breathing, the nasal prongs are not correctly in place. Rearrange the nasal prongs until the bar moves as you breathe in and out.

IMPORTANT:

If you should wake or need to get up in the middle of the night, leave the cannula on your face and keep the device with you. The device is portable and can accompany you as you move. Ensure the cannula remains adjusted comfortably around your ears with the nasal prongs gently resting inside your nostrils. Check to see the display reads "SIGNAL OK." The device will continue monitoring as you return to sleep.

Instructions for Use (continued)

Upon Awakening

1. Lower the slide from under your chin and take off the cannula. Unclip the device from your bed, clothes, or pillow. Remove the cannula from the main device by twisting the cannula connector and pulling firmly.

2. Write your results on the section of the User's Guide titled "Response Card." Follow the instructions on the "Response Card" and continue with Step 3 below.

3. Keep the cannula for future personal use as instructed by your medical provider.

4. Remove the battery. Discard according to local regulations.

5. Carefully package the RUSleeping RTS main device and the completed response card into the traveler box provided. Please return the device or keep it for further testing according to your medical provider's instructions.

IMPORTANT:

When you wake up, **do not press the gray button for more than 5 seconds.** Doing so will re-initialize the monitor and erase the data.

NOTE:

The battery may be used up to three nights.

Important Steps for Use

It is important to check the monitor before sleeping to ensure proper function.

The bar graph on the display should move as you breathe in and out.	If the bar graph does NOT move with your breathing, the nasal prongs of the cannula are not correctly in place. Rearrange the nasal prongs until the bar moves as you breathe in and out.
The display should read "SIGNAL OK".	If after pressing and releasing the gray button (Setup steps 7 & 8) the display reads "NO SIGNAL," rearrange the nasal prongs of the cannula and breathe normally for three seconds. Continue adjusting the nasal prongs until the display reads, "SIGNAL OK."

Troubleshooting

Problem	Why it Happened	Solution
The display is flashing.	The battery is low.	Replace the battery.
The display is blank.	The battery is dead.	Replace the battery.
	OR	
	The battery is installed incorrectly.	Install battery correctly.
	OR	
	There is no battery installed.	Install battery.
The bar on the display does not move.	The cannula is not properly positioned.	Adjust the cannula so the nasal prongs rest just inside the nostrils and re-check the display.
OR	**OR**	
The display reads "NO SIGNAL".	The cannula is not tightly connected to the main device.	Make sure the cannula is firmly attached to the main device by turning the connector in a clockwise direction.
	OR	
	The cannula is pinched/ kinked.	Replace cannula. Contact medical provider for a replacement.

Troubleshooting (continued)

Problem	Why it Happened	Solution
The bar on the display is flashing (not the entire display).	The device's memory is full - nine hours have been recorded.	If you have completed a sleep period this is normal - follow the instructions on the Response Card. If you are starting a new sleep session and you have recorded the results on the response card, press and hold the gray button for five seconds to reset the device's memory.
Consistent invalid or incomplete measurements with ERR being displayed.	The cannula is not secure on the head. **OR** The patient is a restless sleeper and the nasal prongs are becoming displaced.	Ensure the clear slide is against the chin to secure the cannula. Use small pieces of tape to secure the cannula prongs to the cheekbones. DO NOT PLACE TAPE OVER THE MOUTH OR NOSTRILS

Specifications

Environmental Conditions

Operating Temperature:	41° to 95° F (5° to 35° C)
Storage Temperature:	-4° to 140° F (-20° to 60° C)
Operating/ Storage Relative Humidity:	15 to 95% (non-condensing)

Physical

Dimensions:	
Weight:	3″ L x 2″ W x .9″ H (7.62 x 5.08 x 2.29 cm) 1.9 ounces (59 grams) without cannula

Standards Compliance

This device is designed to conform to the following standards:

IEC 60601-1 - Medical Electrical Equipment Part 1: General Requirements for Safety

IEC 60601-1-2 2nd Edition Medical Electrical Equipment Part 1-2: General Requirements for Safety. Collateral Standard: Electromechanical Combatibility - Requirements and Tests.

IEC 60601-1 Classification

Type of Protection Against Electric Shock:	Internally Powered
Degree of Protection Against Electric Shock:	Type BF Applied Part
Degree of Protection Against Ingress of Water:	IPXO Ordinary Protection
Mode of Operation:	Continuous

Electrical

Power Requirements:	1.5 VDC AAA Battery

Specifications (continued)

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1 Class B	The Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Device is suitable for use in all establishments, including domestic establishments.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.

Specifications (continued)

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 600 MHz 1 V/m 600 MHz to 2.5 GHz	RF interference may affect the device's accuracy with no safety hazard to the user. Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 600 MHz $d = 6.9\sqrt{P}$ 600 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 600 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a - Field strength fro fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures mat be necessary, such as re-orienting or relocating the Device.

b - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Specifications (continued)

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Device.

The Device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (Watts)	**Separation Distance According to Frequency of Transmitter (meters)**		
	150 kHz to 80 MHz $d = 6.9\sqrt{P}$	**80 MHz to 600 MHz** $d = 6.9\sqrt{P}$	**600 MHz to 2.5 GHz** $d = 6.9\sqrt{P}$
0.01	0.12	0.12	0.69
0.1	0.38	0.38	2.2
1	1.2	1.2	6.9
10	3.8	3.8	21.8
100	12	12	69

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter manufacturer.

Note 1: At 80 MHz and 600 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Cleaning

The RUSleeping RTS is not intended to be cleaned.

CAUTION:

Do not attempt to take the main device apart. No user-service able parts are inside.

Disinfection

Between patient use the RUSleeping RTS should be surface disinfected in accordance with established clinical practice.

Disposal

The cannula is a single patient use device intended for use by one person only. Dispose of in accordance with local regulations.

Reordering

Replacement Parts:	Part Number
RUSleeping RTS System	**1037683**
RUSleeping RTS Traveler Package	**1036123**
User's Guide/ Response Cards - 75 pk.	**1037755**
RUSleeping RTS Cannulas - 60 pk.	**P1259**

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668 - 6443
1-800-345-6443
1-724-387-4000

Limited Warranty

Respironics, Inc. warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace - at its option- the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead , or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition , any implied warranties - including any warranty of merchantability or fitness for the particular purpose - are limited to two years. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668 - 6443
1-800-345-6443
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