Warnings and Cautions

Intended Use

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

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

Warnings

A warning indicates the possibility of injury to the user.

- This manual serves as a reference. The instructions in this manual are not intended to supersede the instructions of a medical professional.
- Read and understand the entire manual before using this device.
- Discontinue use if skin reddening or inflammation
- Do not smoke while wearing the cannula.

System Contents

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

Cautions

A caution indicates the possibility of damage to the device.

- Avoid exposure to sources of direct airflow such as
- 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 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.
- 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 your medical provider.

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KESPIRONICS

manufactured for:

User's Guide/ Response Card SIA ZudəəISUB



User's Guide



Install the battery. Slide the battery cover to open. Insert the battery with the positive end (+) toward the gray button. Slide the cover closed.





cannula into your nostrils.

Clip the device to your bed, clothes or pillow and go to sleep. If you get out of bed, keep the cannula on and take the device with you.

Problem

move.

OR

The display is flashing.

The bar on the display does not

The display reads "NO SIGNAL".

The bar on the display is flashing

Consistent invalid or incomplete

measurements with ERR being

displayed.

(not the entire display).

The display is blank.



If the device's display looks like the above display, the device is ready to be used. If the device's display does not look like the one above, refer to the troubleshooting section.



NO SIGNAL

Place the two long cannula tubes behind your ears and adjust the plastic slide so the cannula is snug under vour chin.



When you wake up, unclip the device. Disconnect the cannula by twisting and pulling firmly on the connector. Follow the instructions on the Response Card.

Troubleshooting

The battery is installed incorrectly.

The cannula is not tightly connected

The cannula is pinched/kinked.

The device's memory is full. Nine

The cannula is not secure on your

You are a restless sleeper and the nasal prongs are becoming

hours have been recorded

There is no battery installed.

The cannula is not properly

Why it Happened

The battery is low.

The battery is dead.

positioned.

OR

head.

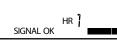
displaced.

to the main device.



Install cannula, Align cannula connector with the RUSleeping connector and twist into place.





Press and hold the gray button until the display briefly flashes (about five seconds). Breathe normally. The display should read "SIGNAL OK", and the bars on the device should be moving. If the display reads, "NO SIGNAL", refer to the troubleshooting section.

IMPORTANT:

Solution

Replace the battery.

Replace the battery.

Install the battery.

seconds to reset.

MOUTH OR NOSTRILS.

and re-check the display.

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.

Install the battery correctly. Adjust the cannula so the nasal pronas rest just inside the nostrils Make sure the cannula is firmly attached to the main device by turning the connector clockwise Replace cannula. Contact medical provider for a replacement. 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 Ensure the clear slide is against your chin to secure the cannula. Use small pieces of tape to secure the cannula to your cheekbones. DO NOT PLACE TAPE OVER THE

Response Card Please complete this Response Card and return it to your medical provider. Record the information stored on the device onto this card. Please follow the step-by-step instructions and fill in the blanks. Do not hold the button on the device down for more than 5 seconds! Doing so will erase your data from the device. Date of use: 1. The screen on the device should look like one of the two images below. Fill in the boxes in the image that matches your device. MEMORY NO SIGNAL 2. Press the button once. The screen below will be displayed. Fill in the boxes. 3. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question. Is ERR displayed? 4. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question Is ERR displayed? 5. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question. Is ERR displayed? YES 6. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question Is ERR displayed? 7. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question. Is ERR displayed? 8. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question Is ERR displayed? YES 9. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question. Is ERR displayed? 10. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question. Is ERR displayed? 11. Press the button once. The screen below will be displayed. Fill in the boxes and answer the question. Is ERR displayed? After you have filled in the boxes for all the screens, remove the battery from the device. Place the device and this response card into the traveler box and return to your medical professional according to his or her instructions. The cannula is for single patient use. It should not be returned to the medical provider.

These boxes are to be filled out by a medical provider only.	
Subject ID:	Card:
S/N Code (found on the back of the device):	
Other:	