

Thank you very much for agreeing to participate in the Ontario Sleep Health Study

By participating in this study, you are playing a key role in helping us better understand the impact of our genes on our sleep and biological rhythms and the impact of disrupted sleep and biological rhythms on the health and well-being of Canadians. You will also have an opportunity to learn a bit about your own sleep and circadian rhythms.

PLEASE DO NOT DISCARD OR DAMAGE THE WHITE ENVELOPE WHICH CONTAINS ALL THE STUDY EQUIPMENT AND PAPERS. You will use this envelope to send everything back to us once you complete the study.

1. Upon opening the inner white envelope, check to contain that all of the following are present:

- Table of Contents with 9-page instruction package
- 1 Actiwatch
- 1 ApneaLink device with attached nose tube, finger sensor, and black elastic belt
- 2 copies of the consent form
- 1-page sleep and work diary
- 4 AAA batteries (2 sets of 2 batteries)

Also, **make sure that there is a postage-paid label** on the outside of the white envelope.

If anything is missing, please contact the study centre at 416-480-5143 or ontariosleephealthstudy@sunnybrook.ca. Also, please note that 2 of the AAA batteries enclosed are extras. You do not need to use them during your study participation, unless there is a problem during your 1 night of ApneaLink recording.

2. Read and sign both copies of the consent form. Keep 1 copy. You will return the other copy to us. If you have any questions about this, please call or email the study centre at the phone number/email address above.

3. Once you have read and signed the consent form and had any questions answered, put on the Actiwatch. This watch will be worn for 10 days. **It is very important that you put the Actiwatch on right away.** The on-board memory will run out in 14 days, and if there is a delay in starting the recording, we will not be able to get a full 10 days of recording. Please read about the Actiwatch on pages 2-3 of this package.

4. **Tonight**, use the ApneaLink according to the instructions on pages 4-8 of this booklet. **Tomorrow** (after 1 night of ApneaLink recording), set the ApneaLink device aside until the end of the 10-day Actiwatch recording period.

5. **Daily for the next 10 days**, complete the sleep and work diary on paper.

6. **Immediately after waking up on one morning of your study participation**, complete the online questionnaire assessing memory and concentration. You will have been provided a link by e-mail. Let us know if you have not received the link.

7. **At any point over the next 10 days**, complete the online sleep questionnaire. You will have been provided a link by e-mail. Let us know if you have not. If possible, try and complete the questionnaire at one sitting. **Please note that the sleep questionnaire and the sleep & work diary are NOT the same thing.**

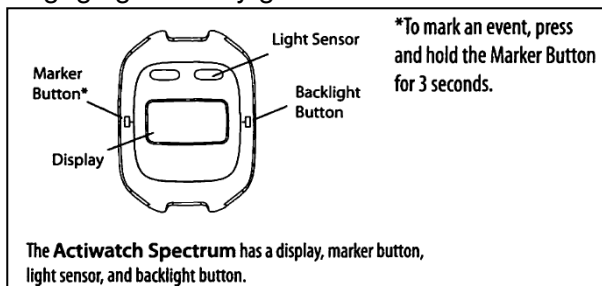
8. **11 days from now**, at the end of the Actiwatch recording period, mail the equipment and forms back to us using the postage-paid pre-addressed white envelope, according to the Mail-Back Instructions (page 9).

9. **3-4 weeks after we have received the equipment**, we will mail you a thank-you gift card. In addition, we will mail you a report summarizing the results of your Actiwatch and ApneaLink recordings.

Ontario Sleep Health Study Actiwatch Instructions

1. WHAT IS THE ACTIWATCH?

The Actiwatch is a medical device that records motion and light. It provides information about your general activity, sleep schedule, naps and wake episodes, and information about your sleep quantity and quality. It is not a GPS tracking device, it does not record heart rate, and it does not provide information about the specific activity you are engaging in at any given time.



2. WHAT DO I DO WITH THE ACTIWATCH?

As soon as you receive the Actiwatch in the mail, place it on your non-dominant wrist and secure it snugly. If you are right handed, put it on your left wrist. If you are left-handed, put it on your right wrist. Once you put it on, keep it on 24 hours a day for 10 full days, even when you are sleeping. **Do not change your daily routines - we want to measure the way you usually sleep.**

It is very important that you put the watch on right away. The on-board memory will run out in 14 days, and if there is a delay in starting the recording, we will not be able to get a full 10 days of recording.



Please press and hold the marker button (left of the watch face) for 3 seconds when:

1. You are about to fall asleep.

2. You wake up with no more intention to sleep.

} Applies to both long sleep periods and naps

NOTE: If you wake up in the middle of the night, you do NOT need to press the marker button.

The Actiwatch is water resistant. You can wear it when you shower. However, if you go swimming or take a bath, please take off the Actiwatch beforehand. You can put it back on once you are no longer swimming/bathing.

If you must remove the Actiwatch for any reason, please record the date and time you take the Actiwatch off and put it back on the provided sleep diary.

Please try to take care of the Actiwatch as the device and the data it is collecting are very valuable to us. Please do not plug the Actiwatch into any electrical or computer cords.

3. WHAT IF THE ACTIWATCH GETS DIRTY?

The Actiwatch may be cleaned with a soft cloth moistened in detergent and water to remove dirt and stains. Do not use abrasives or alcohol as they may damage the device.

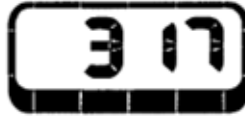
4. WHAT DO I DO AT THE END OF THE RECORDING PERIOD?

After you have worn the Actiwatch for 10 full days or 14 days after you receive the Actiwatch (whichever comes first), please remove the Actiwatch and mail it back to Sunnybrook, along with the ApneaLink, consent form, and sleep and work diary, using the postage-paid white envelope.

WHAT IS THE MEANING OF THE ACTIWATCH DISPLAY?



Shows the time of day in 12-hour format.



When you press the backlight button and hold it for 3 seconds, the date is shown in MM-DD format. This sample shows March 17th in MM-DD format.



(circling clockwise)

The circling black border indicates that data collection has begun. Although not shown here, the time or date appears in the center.



(flashing)

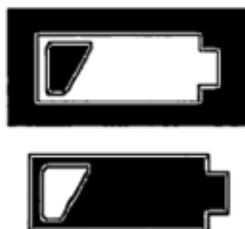
Indicates that the device is not fastened properly on your wrist. It might be too loose or too tight. Refasten the device to your wrist until the flashing stops.

(Backlight turns on.)

Indicates that the backlight button has been pressed. The backlight automatically turns off after 5 seconds.

(A pattern appears on the display and the backlight turns on briefly.)

Indicates that you have successfully marked an event by pressing the Marker Button for 3+ seconds.



When these symbols appear, the Actiwatch battery is running low. Contact the study centre at 416-480-5143 or ontariosleephealthstudy@sunnybrook.ca, and we will provide instructions for what to do.



(or blank screen)

Indicates that the on-board memory is full and that the device is in sleep mode. Remove the Actiwatch and mail it back according to the enclosed instructions.

Ontario Sleep Health Study ApneaLink Instructions

APNEALINK INSTRUCTIONS

The ApneaLink is a medical device that records your breathing and blood oxygen levels during the night. Please read these instructions carefully. Before you put on the device, please watch the instructional video which can be found in the “For Participants” section of the Ontario Sleep Health Study website at <http://sunnybrook.ca/research/content/?page=sri-proj-ontario-sleep-health-study-participate>.

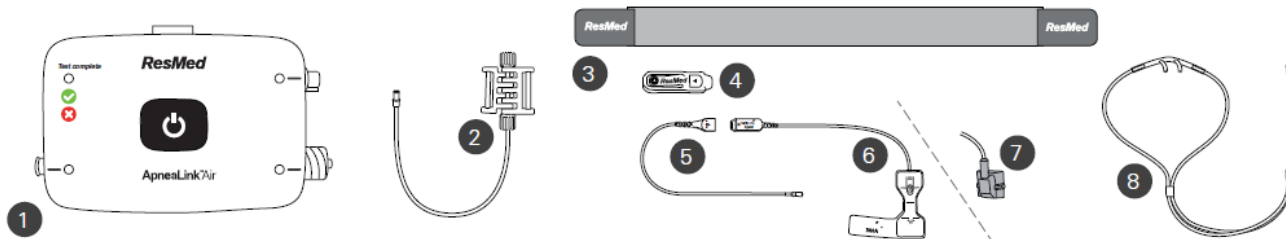
Please note:

- 1) **Don't** turn on the device until you are ready to test.
- 2) **Do** go through your regular evening and bedtime routines to ensure you get a normal night's sleep.
- 3) **Do** use the ApneaLink on the first night after you receive this package.
- 4) **Do** wear the ApneaLink over pajamas or nightshirts to avoid any discomfort from the belt.

1. Examine the contents of the package

The package should contain the ApneaLink device with sensors attached. The contents should include:

- A. The ApneaLink Air recorder (1), a dark blue effort sensor (2), and a grey belt clip (4) attached to a black elastic Velcro belt (3)
- B. A finger oxygen sensor (7) connected to grey belt clip (4)
- C. A new clear plastic nose tube (8)
- D. 4 AAA batteries (2 sets of 2 batteries)

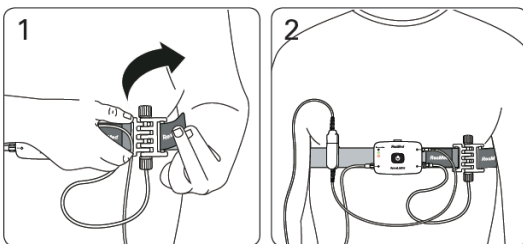


Contact us at ontariosleephealthstudy@sunnybrook.ca or 416-480-5143 if anything is missing.

2. Open the back of the ApneaLink Air recorder and put 2 AAA batteries inside. The + charge of the battery on the top should face to the right, and the + charge of the battery on the bottom should face to the left.

3. Wrap black elastic belt around chest

Stand in front of a mirror. With the ApneaLink device in front, slip the belt over your head. If the belt doesn't slip over your head and shoulders, loosen the Velcro on the left side. Position the black elastic belt around your chest and over sleepwear, as shown. Re-fasten Velcro so that the belt is snug but not uncomfortable over your chest.



Please note:

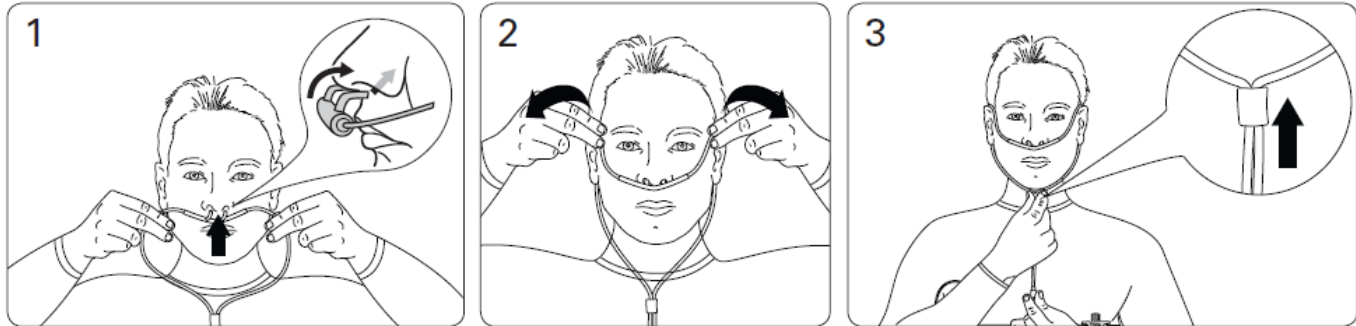
- 1) The elastic belt should not be twisted.
- 2) The belt is secure enough if the recorder and effort sensor stay in place while you are standing.
- 3) The belt should be positioned right below the armpits. **For women, the belt should be worn above the breasts.**

4. Apply clear plastic nose tube

- A. With prongs pointing towards your face, insert nose tube with one prong in each nostril, as shown. Ensure that the ends point towards your face in a slightly downward direction (figure 1 below).
- B. Wrap clear plastic tubing so that it goes behind your ears and down your neck. **Do not** wrap the tubing around the back of your head (figure 2).
- C. Adjust slider so that the loop fits securely and comfortably under your chin (figure 3).

Please note:

- 1) If the prongs don't stay in your nose, you can use medical tape or Band-aids on your cheeks to hold them in place.

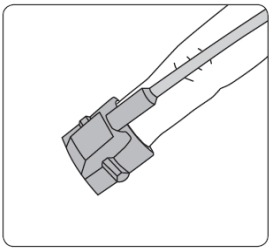


5. Apply finger sensor

Slip the finger sensor over the index finger (i.e. the finger next to your thumb) of your non-dominant hand. If this finger is uncomfortable for you, you may change it to any other finger or to your other hand.

Please note:

- 1) When on, there is a red light on the inside of the finger sensor. This is normal and does not indicate a problem.



6. Turn the device on and go to sleep

Just before you lie down to sleep, press and hold the large power button in the middle of the ApneaLink device for about 3 seconds. After 3 seconds, you will notice that the power button has turned to green. As soon as you see the power button turn to green, take your finger off the power button. You should slowly see the other 3 lights turn to green (this can take up to 20 seconds).

If any of the lights are red instead of green, the ApneaLink device is not getting a good signal from that particular sensor. The light on the left is for the nose plug, the light on the top right is for the finger sensor, and the light on the bottom right is for the effort sensor. Adjust the sensor and/or the connection to the ApneaLink until the light becomes green. If the red light continues, set the ApneaLink device aside and call 416-480-5143 or email ontariosleephealthstudy@sunnybrook.ca. You will get further instructions from the study coordinator in the morning.

Please note:

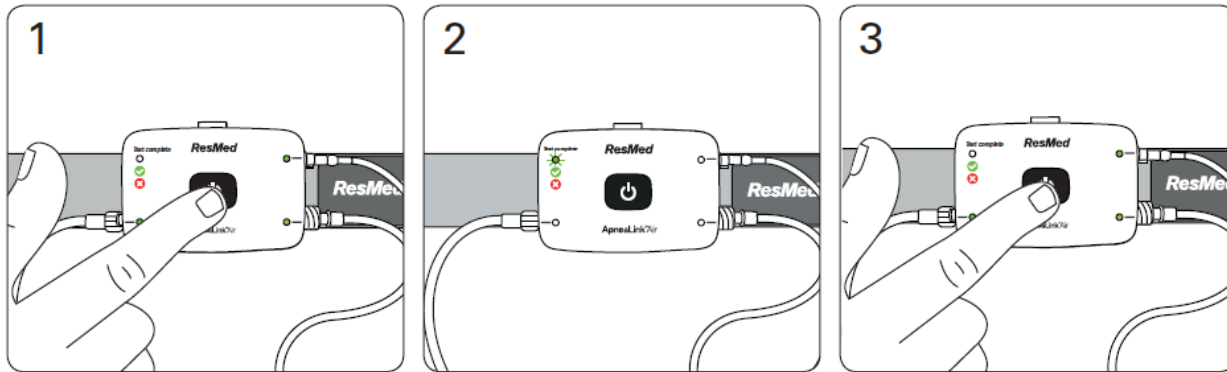
- 1) If you wake up during the night, **do not** turn the device off unless you **do not** plan to go back to sleep.
- 2) **If you have to use the restroom during the night**, please remove the finger sensor **ONLY**. Put the sensor back on when you return to bed. The three green lights should be on when you go back to bed.

7. Check that the test is completed and turn off the ApneaLink device

- A) When you wake up in the morning, press and hold the power button for three seconds (figure 1).
- B) Make sure that the test complete indicator light (top left) is green (figure 2). This means that the test completed properly. If the test indicator light is red, replace the batteries and redo the test that night.
- C) Press and hold the power button for three more seconds to turn off the device (figure 3).

Please note:

Once you have turned off the ApneaLink device, **do not** disconnect anything. **Do not** attempt to clean the unit. Set the device aside until the end of the 10-day Actiwatch recording period.



8. What to do with used batteries after you turn off the ApneaLink device

Once you have completed the ApneaLink test and turned off the device, you can either (a) leave the used batteries inside the device, (b) take out the used batteries and recycle them, OR (c) take out the used batteries, label them as “used”, and send them back to us to be recycled. **Please do not send back used batteries without labelling them as “used.”**

Please send back any unused batteries at the end of your 10-day Actiwatch recording.

9. At the end of the 10-day Actiwatch recording period

Once you have completed your 1 night of ApneaLink recording and 10 days of Actiwatch recording, put all Apnealink and Actiwatch equipment, your consent form, unused batteries, and completed sleep and work diary into the envelope pre-paid and pre-addressed to Sunnybrook Health Sciences Centre. Mail back to the study centre using this envelope.

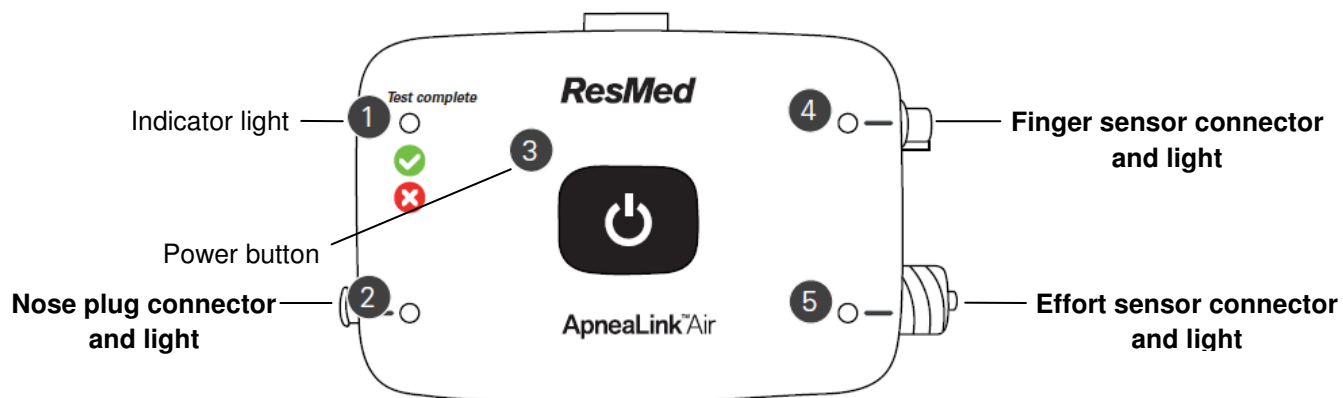
10. After your participation

Once we receive the ApneaLink and Actiwatch back from you, we will mail you a gift card as a thank you for your participation. We will also mail you a report summarizing the results of your ApneaLink recording.

Ontario Sleep Health Study ApneaLink Troubleshooting Page

1. Before I start testing, what should I do if one of the cords is not plugged into the ApneaLink device?

If a cord is detached, plug it back into the ApneaLink device. The finger sensor plugs into the top right of the device. The effort sensor on the elastic belt plugs into the bottom right of the device. The nose tube plugs into the bottom left of the device. Refer to the ApneaLink diagram below.



2. What should I do if one or two lights are red when I start the testing?

If any of the lights are red instead of green, the ApneaLink device is not getting a good signal from that particular sensor. Adjust the sensor and/or the connection to the ApneaLink until the light becomes green.

If this does not fix the problem, replace the batteries using the enclosed extra AAA batteries. If the green light still does not turn on, take off all the equipment and call the study office at 416-480-5143 or email ontariosleephealthstudy@sunnybrook.ca. The study coordinator will provide instructions in the morning for what you should do.

3. What should I do if all the lights (including the test complete indicator light) are red and blinking when I try to start the testing?

The device is faulty and cannot be used. Please contact us right away (416-480-5143 or ontariosleephealthstudy@sunnybrook.ca), and we will provide instructions for what to do.

4. What can I do if the black elastic belt won't stay in place?

Undo the Velcro on the left side of the belt and readjust until it fits more securely.

5. The nose tube and/or the finger sensor will not stay in place. What can I do?

You may add Band-aids or medical tape to keep the nose tube/finger sensor in place.

6. What can I do if the finger sensor becomes uncomfortable during the night?

You may change to any other finger or simply switch hands.

7. Do I turn off the device if I happen to wake up during the night?

No. Do not turn off the device unless you are sure that you will not be going back to sleep.

8. What do I do with the equipment if I need to use the restroom or wash my hands during the night?

Please remove only the finger sensor and put it back on as soon as you are finished. When you return to bed, check that everything is still in the right place - especially the tube under your nose and the finger sensor. Also, check that the three lights for the three sensors are still green.

9. One or more of the sensor lights is red and blinking when I wake up in the morning. What should I do?

If the effort sensor light is red and blinking, it means that the effort sensor became disconnected during the night. Test a second night with the included extra AAA batteries.

If the finger sensor light and/or the nose plug sensor light is red and blinking, check to see if the test completed by pressing the power button for three seconds. If the test complete indicator light is green, the test was successful. If the test complete indicator light is red, test a second night with the included extra AAA batteries.

10. After I wake up and press the power button to see if the test completed, the test indicator light is red. What should I do?

It means that the device did not collect enough data during the night. Replace the batteries and redo the test that night.

11. After I wake up and press the power button to see if the test completed, the test indicator light does not turn on. What should I do?

It means that the batteries ran out during the night. Replace the batteries and redo the test that night.

Instructions for Returning the Equipment and Forms

Do not discard the inner white envelope that the study equipment and papers arrived in. You will use this postage-paid envelope addressed to Sunnybrook to send the equipment and papers back to us.

When you are ready to mail the equipment back to us:

1. Place all of the following items in the white envelope:
 - Table of Contents with 9-page instruction package
 - 1 Actiwatch
 - 1 ApneaLink device with the attached nose tube, finger sensor, and black elastic belt
 - 1 signed copy of the consent form (keep the other one for your records)
 - 1-page sleep and work diary
 - 2 extra AAA batteries (if not used)

2. Peel off the covering of the adhesive strip on the back of the envelope and press firmly across the strip so that the envelope is sealed shut. If you think that the envelope is not sealed well enough, you may also seal the envelope with masking tape, Scotch tape, or duct tape.

3. Place the envelope in any Canada Post mailbox or drop it off at any Canada Post office.

4. Call or email the study coordinator at 416-480-5143 or ontariosleephealthstudy@sunnybrook.ca to let us know that you have mailed back the equipment.

5. 3-4 weeks after we have received the equipment, we will mail you a thank-you gift card. We will also mail you a report summarizing the results of your Actiwatch and ApneaLink recordings.