



User Manual

RESP*e*RATE TO LOWER BLOOD PRESSURE





Contacts

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Introduction

Congratulations! **RESPERATE TO LOWER BLOOD PRESSURE** will help you take an active step toward improved treatment of your high blood pressure.

Please note: RESPERATE should only be used as part of your overall health program for achieving goal blood pressure, as recommended by your doctor. **RESPERATE** can be safely used in conjunction with medication and lifestyle modifications such as diet and exercise.

Scientific evidence has shown that breathing exercises, when performed routinely, can lower blood pressure. These breathing exercises are difficult to perform correctly without continuous, individualized coaching. Using a patented technology, RESPeRATE provides this coaching in an extremely effective way.

INTRODUCTION

RESPERATE guides you to slow down your rate of breathing. RESPERATE will lead you to breathe at a rate of 10 breaths per minute or less. We call this "Effective Exercise".

To achieve best results, it is recommended that you use RESPeRATE for at least 45 minutes of Weekly Effective Exercise Time, preferably in 15 minute daily sessions. As with other exercises, you should expect to see notable results within approximately six to eight weeks, and maitain benefits with routine use.

What is optimal blood pressure

Optimal blood pressure is 120/80 mmHg. High blood pressure puts you at increased risk for stroke, heart attack, and other life threatening disorders.

What is **RESP***e***RATE**

 $\ensuremath{\mathsf{RESP}\ell\mathsf{RATE}}$ is the only non-drug medical device clinically proven to lower blood pressure.

How Does it Work

RESPERATE analyzes your breathing rate and pattern, then interactively guides you through breathing exercises that reduce your breathing rate, slowly and effortlessly. Your inhalation and/or exhalation rates are prolonged according to your personal need. After each exercise, your breathing returns to its normal rate and pattern; however the beneficial effect on blood pressure accumulates.

Why Does it WORK

RESPERATE's breathing exercises reduce neural sympathetic activity and relax the muscles that surround your small blood vessels. Over time, these effects allow blood to flow more easily through your blood vessels, resulting in sustained lower blood pressure.

Exploring Your New RESPERATE Device



Note: The PC communication port appears in selected models and is only needed if you are using the optional Reporting and Support System.

USING YOUR RESPERATE DEVICE

Preparing To Use RESPERATE

1. Install the batteries.

When using **RESPERATE** for the first time, install 4 AA batteries in the battery compartment in the back of the device. Position the batteries as shown inside the compartment.



2. Carefully remove the headphones and the sensor.

- The sensor cable is already connected to the **RESPERATE** device. Pull the cable with care.
- Return the sensor to its compartment at the end of each session.
- 3. Sit comfortably on a chair.

4. Put on the elastic belt.

- a) Buckle the elastic belt (over your clothing) around your upper abdomen or chest.
- b) Adjust the belt to fit snugly while you are in a sitting position. Be sure it is neither too tight nor too loose.

Notes:



Men



Women

- Men tend toward abdominal breathing, while women tend toward thoracic (chest) breathing.
- Be sure the elastic belt is positioned horizontally, not diagonally, across your upper abdomen or chest.

5. Position the respiration sensor.

Slide the sensor along the belt, to ensure it can move freely. Position the sensor in the center of the abdomen (for abdominal breathing) or on the right side of the chest (for chest breathing).

Tip: To verify if you are an abdominal or chest breather, simply place one hand on the abdomen and the other on the chest. Now inhale and watch for the hand that moves furthest – abdomen or chest.

6. Plug in and put on the headphones.

Plug headphones into the **RESPERATE** device headphone port located on the right side of device, marked with the () icon. You should hear a click when the headphones are fully inserted into the port.

Performing the Breathing Exercises - 6

USING YOUR RESPERATE DEVICE

Performing the Breathing Exercises

1. Press the (\bigcirc) ON/OFF button.

At first, **RESPERATE** displays your accumulated Weekly Effective Exercise Time.

Note: You accumulate Effective Exercise Time when you breathe slower than 10 breaths per minute. To achieve maximum benefit It is recommended that you accumulate a total of at least 45 minutes of Weekly Effective Exercise Time.

2. Breathe normally.

You do not need to breathe especially deeply or slowly at the start of the exercise. Simply allow **RESPERATE** to "recognize" your personal breathing pattern. This is called the Recognition Phase.

During the Recognition Phase, each well-analyzed breath is displayed as a vertical line. You hear short musical tones during this process. These tones indicate that the Recognition Phase is in progress.

A flashing dot on the display accompanies your breathing and appears each time you inhale.

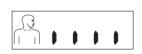
Once **RESPERATE** has recognized four stable breaths (signified by the display of four vertical

bars, as shown above), the device will display your current number of breaths per minute (e.g. 17.8 bpm). The exercise session will now begin, signified by the start of the melody.

Note: If the Recognition Phase lasts longer than two minutes, please refer to the "Troubleshooting" section of this manual, starting on page 10.







3. Breathe according to the Melody.

You will now start your Exercise Phase. Your current breathing rate will be displayed as the number of breaths per minute (bpm).

RESPERATE now composes a melody according to your individual breathing. The melody is composed of two distinct tones - one ("going up") which will coach you to inhale and the second ("going down") tone to exhale.

By gradually prolonging the exhalation tone, the melody slows down and interactively guides you towards a slower and more stable breathing pattern.

- Use the Inhale and Exhale arrows on the display as a guide for synchronizing your breathing with the melody.
- The arrows disappear after one minute of melody. At this point, close your eyes, relax and follow the melody with your breathing.

The goal of RESPeRATE is to guide you towards the slowest breathing rate that is comfortable for you. It does so by gradually slowing the guiding tones as you breathe in synchronization with the tones.

In order to maximize the benefits from RESPeRATE, it is important that you perform the breathing exercises without making an effort. This means that you should not try to hold your breath or try to overly prolong the periods of inhaling or exhaling beyond what is comfortable for you. If you ever feel that the melody is too slow for you and requires effort to stay in synch with it, simply breathe at the last pace, which was comfortable for you. Within a few breaths, RESPeRATE will automatically readjust the melody to your new breathing rate and pattern and begin again to guide you toward a slower breathing rate.

It is also recommended not to use any other breathing techniques such as breath-holding or Buteyko during the exercise as these maneuvers may require concentration and effort.



Note: In the first few sessions, your slowest comfortable breathing rate might be higher than 10 breaths per minute.

Just before the session ends, **RESPERATE** gradually decreases the volume of the melody. **RESPERATE** automatically shuts down when the end of the Exercise Session is reached. The default duration of the Exercise Session is 15 minutes. In order to change this default, please refer to "Changing the Duration of your Default Exercise Session" on page 9.

9 — Personalizing the Device

USING YOUR RESPERATE DEVICE

Personalizing the Device

Adjusting the Volume

Press the UP or DOWN button (\blacklozenge) repeatedly, until you reach the volume you prefer.

The volume (*a*) icon is displayed, along with the current volume level.

After a few seconds, **RESPERATE** automatically returns to the previous display.

Selecting the Melody

Press the MELODY SELECTION (&) button, then immediately press the Up or Down button to scroll between melodies.

The (§) icon is displayed, along with the selected melody number. For your convenience, **RESPERATE** stores your last selected melody, and uses it the next time you begin your Exercise Session (the device allows to also select the melody by repeatedly pressing MELODY SELECTION (§) button).

Viewing the Effective Exercise Time of the Current Session

The Effective Exercise Time of your current session is the number of minutes in which your breathing has been slower than 10 breaths per

minute. Press the **CURRENT EFFECTIVE EXERCISE TIME** (O) button to view the Effective Exercise Time accumulated in the current session.

• 50





Exercise Time

Press the Exercise Time (() button to view the remaining time of the session. After a few seconds, RESPeRATE automatically returns to the previous display.



RESPERATE automatically switches off at the end of the selected time for your exercise session. By default, the time is set at 15 minutes.

Changing the Duration of Your Current Exercise Session

If you would like to extend or shorten the duration of the current exercise session:

- 1. Press the EXERCISE TIME (${}^{\textcircled{O}}$) button.
- 2. Then immediately press the Up or Down button to change the exercise time.

Changing the Duration of Your Default Exercise Session

If you would like to extend or shorten the duration of the default exercise session:

- 1. Hold down the EXERCISE TIME () button until the display blinks. The () icon is displayed, along with the current Exercise Session Time Default.
- 2. Use the UP or DOWN button to change the Exercise Session Time Default.
- 3. Press the EXERCISE TIME button again, in order to save the new Exercise Session Time Default.

Errors and Troubleshooting

The display screen of the **RESPERATE** device will notify you if there are any problems with the device or if the exercises are not being performed as directed. Use the chart to understand the most common issues and tips to easily handle them.

lcon	Meaning	Action
I I	Sensor belt is too tight.	Loosen the belt. The icon disappears when the belt is properly mounted.
	Sensor belt is too loose.	Tighten the belt. The icon disappears when the belt is properly mounted.
	The elastic belt is improperly positioned. The sensor is improperly positioned.	Reposition the elastic belt, according to the instructions.
	Breathing is not synchronized with the guiding tones.	Try to syncronize your breathing with the guiding tones or select a different melody that might be easier to follow.
	You are breathing more than 30 times per minute.	Try to breathe more slowly.
1	Batteries are weak.	Replace the batteries.

Troubleshooting

Problem	Meaning	Action
The display does not light when the device is switched on.	Batteries need to be replaced.	Install new batteries.
	The +/- poles of the batteries are positioned incorrectly.	Re-install the batteries with the +/- poles positioned correctly.
Music is not playing through the headphones.	The headphones are not properly connected.	Reconnect the headphones.
	RESP <i>e</i> RATE has automatically switched off because the session is over.	Restart RESPeRATE .
The Recognition Phase takes longer than two minutes.	The sensor is improperly positioned.	Reposition the sensor.
	' Breathing is too unstable.	Relax, and breathe normally.
Static noise heard through headphones	Headphones not fully plugged into RESPERATE port.	Plug headphones fully into device.
	Electronic communication device (such as cell phone, bi-directional beeper, or other wireless communication device) is operating within 5 feet of RESPERATE .	Do not use such a communication device within 5 feet of RESP <i>e</i> RATE while conducting your exercise sessions.
Flashing dot does not respond to inhales		Reposition the sensor.
	positioned. Sensor belt has been tightened during the session	Wait 30 seconds, the sensor will automatically readjust and the flashing dot will reappear
Weekly Effective Time does not match actual use	Batteries have not been replaced in time	Replace batteries once low battery icon is displayed

USING YOUR RESPERATE DEVICE

Assessing Your Overall Performance

The **RESPERATE** device can measure your overall use of the device.

Did you meet your Weekly Effective Exercise Time goal?

The quickest way to assess your performance is to ensure that every time you turn on the device the Weekly Effective Exercise Time (momentarily displayed on the screen whenever the device is turned on) is 45 minutes or greater. When 45 or greater is indicated, it means that you are using the device as recommended and therefore are most likely to get maximum benefit from the exercises.

Don't forget: Your goal is to accumulate at least 45 minutes of Weekly Effective Exercise Time in order to see reductions in your blood pressure!

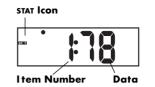
Advanced Analysis of Performance - (Statistical Report)

The "Statistical Report" function enables you to assess your performance during earlier **RESPERATE** sessions. The report displays three groups of parameters that provide data on:

- A. All Sessions,
- B. The Last 10 Sessions, and
- C. The Last Session Only.

To view this information:

1. Turn on the RESPERATE device.



2. During the Recognition Phase, press the STAT button on the left side of the RESPERATE device.

The **STAT** icon is displayed, along with the first statistical item, as shown in the figure above. Scroll through the different items using the UP or DOWN button.

Key to Statistical Report Items

A. Statistical Report of All Sessions

Item Number	Reports On
0	The accumulated duration of the Effective Exercise Time, in minutes.
1	The number of uses that have reached the Exercise Phase. (e.g. Display reads 1:78 means that 78 uses of the device have reached the Exercise Phase).
2	The number of uses not proceeding on to the Exercise Phase. (e.g. Display reads 2:07 means that 7 uses of the device did not proceed on to the Exercise Phase).
3	The average duration of the Exercise Phase, in minutes.

B. Statistical Report of the Last 10 Sessions

Item Number	Reports On
4	The average duration of the Recognition Phase, in minutes.
5	The average duration of the Exercise Phase, in minutes.
6	The average duration of the Effective Exercise Time, in minutes.
7	The percentage of breaths that were synchronized with the guiding tones.
8	The number of successful sessions.
9	The number of sessions that were unsuccessful because the Effective Exercise Time per session was less than five minutes.
10	The number of sessions that were unsuccessful because of the low quality of the respiration data.
11	The number of sessions that were unsuccessful because breaths were not synchronized with the guiding tones.

USING YOUR RESPERATE DEVICE

Item Number	Reports On
12	The duration of the Recognition Phase, in minutes.
13	The duration of the Exercise Phase, in minutes.
14	The duration of Effective Exercise Time, in minutes.
15	Your initial breathing rate, in breaths per minute (bpm).
16	Your final breathing rate, in breaths per minute (bpm).
17	Percentage of respiration data that is identified.
18	The percentage of breaths that were synchronized with the guiding tones.

C. Statistical Report of the Last Session Only

Cleaning and Maintenance

- To clean **RESPERATE**, use a soft, damp cloth. Do not wash the sensor or the **RESPERATE** device. Do not use petroleum products, thinners, or cleaning solvents!
- Store the sensor in its compartment, to protect it from dust and moisture.
- Protect your **RESPERATE** against excessive vibrations.
- Do not leave your RESPERATE in a place where temperatures are below -14°F (-10°C) or above 158°F (70°C), or in conditions of very high humidity (+85%).
- Do not attempt to make repairs of any kind on **RESPERATE**. If repairs are necessary, contact Customer Service.
- To avoid damage to the device, remove batteries from the compartment if you do not plan to use the **RESPERATE** for a period of more than two months.

Customer Support

If you are having trouble using the RESPeRATE device, call Customer Support at 1-877-988-9388 (U.S.Only) or at 972-8-9212126 (outside of U.S.)

Technical Information and Approvals

Technical Information

Model: **RESPERATE** RR-150 ; display type: LCD; power source: four alkaline batteries, 1.5v (type AA); battery life: two months, with regular use of 15 minutes per day; maximum audio output: 1.5mW RMS @ 32x2; respiration rate operational range: 2.5 - 30 BPM; operating temperature: 10°C - 40°C (50°F - 104°F); operation humidity: 30 - 75%; storage temperature: -10°C - 70°C (14°F - 158°F); storage humidity: 30 - 85%; weight: 480grams; outer dimensions: approximately 17cm(L) x 13cm(W) x 8cm(H).

Country Specific Market Clearance

United States: 510(k) number K020399, as well as K000405 Israel: Ministry of Health number 408/96 237-0000 European Union: CE marked

CE Statement

The **RESPERATE** carries a CE marking of conformity

Manufacturer Authorized Representative in Europe: MEDES Ltd. 9, Beaumont Gate P.O.Box 231 Shenley Hill, Radlett, Herts London WD78BX, UK tel/fax: +44 (0) 1923859810 email: medes@arazygroup.com

Indication for Use

Device Name: RESPERATE

Indications for Use

RESPERATE is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure together with other pharmacological and/or non-pharmacological interventions.

Over-the-counter Use

Contraindication

None known.

Precautions

Please note: **RESPERATE** should only be used as part of your overall health program for achieving goal blood pressure, as recommended by your doctor. **RESPERATE** can be safely used in conjunction with medication and lifestyle modifications such as diet and exercise.

Do not use this device without consulting your physician if you suffer or have suffered in the past from: active ischemic heart disease/unstable angina, severe congestive heart failure, chronic atrial fibrillation, stroke resulting in permanent impairment, chronic renal failure, severe asthma, chronic obstructive pulmonary disease (COPD), like chronic bronchitis and emphysema, or major organ failure.

InterCure strongly recommends that you do not modify your hypertension treatments without the advice and consent of your physician.

Do not use your **RESPERATE** when you need to be alert or to concentrate, or when using heavy equipment. Do not use **RESPERATE** while driving.

If you experience any side effects or if you feel any change in your general health or mood, immediately discontinue use of your **RESP**@RATE, and contact your physician.

Breathe naturally throughout the exercise. Excessive deep breathing may cause dizziness and/or palpitation.



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