

RESPeRATE. A breakthrough in lowering blood pressure.

What is RESPeRATE?

RESPeRATE is the first and only non-drug solution approved for the treatment of hypertension and available without a prescription. Many products on the market help monitor blood pressure, but only RESPeRATE is clinically proven to reduce it.



- ▶ clinically proven to reduce high blood pressure within 3 to 4 weeks
- ▶ not a drug and has no side effects
- ▶ pleasant and easy to use
- ▶ cleared for sale without a prescription
- ▶ guaranteed to lower your blood pressure, or your money back

How does RESPeRATE work?



High blood pressure is generally caused by your blood vessels tightening up and narrowing, causing your heart to pump harder. RESPeRATE's unique breathing exercise relaxes constricted blood vessels to reduce high blood pressure.

- ▶ When you use RESPeRATE, you put on headphones and attach a breathing sensor around your chest.
- ▶ RESPeRATE's breathing sensor automatically analyzes your individual breathing pattern and creates a personalized melody composed of two distinct inhale and exhale guiding tones.
- ▶ Simply listen to the melody through the headphones, and your body's natural tendency to follow external rhythms will enable you to easily synchronize your breathing to the tones.
- ▶ By gradually prolonging the exhalation tone to slow your breathing, RESPeRATE leads you to the therapeutic zone of less than 10 breaths per minute.
- ▶ Within a few minutes, the muscles surrounding the small blood vessels in your body relax, blood flows more freely, and your blood pressure is significantly reduced.

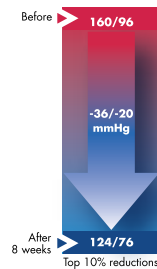
Who should use RESPeRATE?

Just 3 out of 10 people with hypertension are reaching their blood pressure goals. Whether you are already taking anti-hypertension medication or trying to lower blood pressure with diet and exercise, RESPeRATE might just be the solution you need.

What is the clinical proof?

Ten clinical trials found RESPeRATE to be safe and effective for people with high blood pressure, whether they were taking medication or not, male or female, younger or older.

One particular study, published in the American Journal of Hypertension, found that RESPeRATE delivered significant blood pressure reductions for people who had uncontrolled high blood pressure despite taking three or more medications at maximum dosage.



High Blood Pressure Reduction with RESPeRATE

Lowers high blood pressure by up to 36 points systolic and 20 points diastolic (top 10% reductions), as shown in seven separate clinical trials with average reductions of 14/8 points.

What are doctors saying?

Hypertension specialists nationwide approve of RESPeRATE as part of an overall treatment plan for lowering blood pressure, based not only on published, peer-reviewed clinical trials, but on personal experience with their own patients:



"Our clinical study concluded that RESPeRATE is easy to use, did not have any side effects and delivered a significant blood pressure reduction."

Dr. William Elliott
Rush University Medical Center
Chicago, Illinois



"My patients really like it. RESPeRATE allows patients to have more of a role in their care."

Dr. Joseph Marek
Cardiologist, Midwest Heart Specialists
Downers Grove, Illinois

It's about getting, and keeping, your blood pressure under control.

What are our customers saying?

"RESPeRATE did wonders for my blood pressure. My blood pressure dropped down to an amazing 122/74, something neither the medication nor the exercise had ever been able to do alone."

Paula Carney, Chicago, Illinois

"RESPeRATE's impact upon my life and health have been amazing. I found that the breathing exercises lowered my blood pressure almost from the start. Thanks to your product, I no longer have to fear the blood pressure cuff. I now can enjoy the security of knowing that, day after day, my blood pressure is safe and steady."

Vinton McCabe, Easton, Connecticut

"My doctor is enthusiastic over my blood pressure reading since I've started RESPeRATE, and has recommended it to several of his patients. It enabled me to be proactive about my blood pressure."

J.P., Ph.D., Pittsburgh, Pennsylvania

What is the media saying?

THE WALL STREET JOURNAL

"Mounting research shows that exercises to slow breathing can help reduce elevated blood pressure... and may be worth trying especially if you have prehypertension and are trying to avoid medication..."

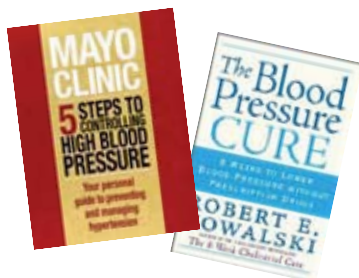
The Washington Post

"Breathing deeply and exhaling slowly can do wonders for our health, by opening up tiny blood vessels and taking pressure off the heart. But filling the lungs in a heart-healthy way is surprisingly difficult... Enter RESPeRATE..."

PARADE

"If you have high blood pressure, you now can breathe easier. RESPeRATE is the first non-drug device approved by the FDA to reduce blood pressure without the side effects of medication..."

RESPeRATE is also featured in Mayo Clinic's '5 Steps to Controlling High Blood Pressure' and 'The Blood Pressure Cure'



Frequently Asked Questions:

Q: Can I use RESPeRATE with my medications?

A: Yes, RESPeRATE can be safely added to existing high blood pressure therapies, including medications.

Q: Can I return RESPeRATE if my blood pressure is not lowered?

A: Yes. Every RESPeRATE comes with a 30 Day Satisfaction Guarantee. If you aren't totally satisfied with RESPeRATE just call within 30 days and we will refund 100% of your purchase price.

Q: Could RESPeRATE lower my blood pressure too much?

A: No. RESPeRATE doesn't reduce blood pressure for people with normal pressure levels, but rather brings it toward the optimal, healthy range for people with high blood pressure.

Q: Why can't I do the same breathing exercises without RESPeRATE?

A: Routinely practicing the type of structured breathing exercises that have been shown to reduce blood pressure is very difficult without a personalized coach such as RESPeRATE.

Q: How many people are already using RESPeRATE?

A: RESPeRATE is already in use by over 100,000 people and healthcare providers.

Buy RESPeRATE today!

To purchase RESPeRATE under our 30 Day Satisfaction Guarantee, visit www.resperate.com or call us at 1-877-988-9388.

Kit includes:

- ▶ RESPeRATE device
- ▶ Breathing sensor
- ▶ Headphones
- ▶ User Manual
- ▶ 4 AA batteries



30 DAY SATISFACTION GUARANTEE

Your complete satisfaction is our ultimate goal. If you aren't totally satisfied with RESPeRATE, just call within 30 days and we will refund 100% of your purchase price.

Please Note: RESPeRATE should only be used as a part of an overall health program for achieving goal blood pressure, as recommended by a doctor. RESPeRATE can be safely used in conjunction with medications and lifestyle modifications such as diet and exercise.

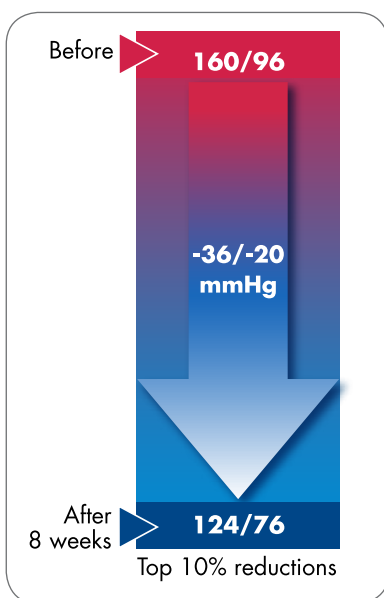
For Your Healthcare Provider

RESPeRATE is the first and only non-drug solution indicated for the treatment of hypertension and available OTC.

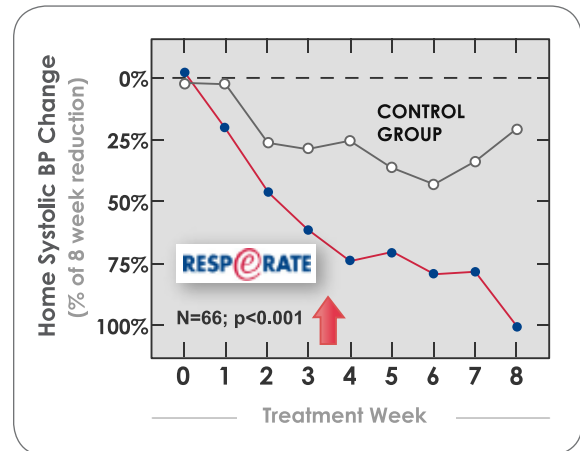
Clinical Results

Ten clinical trials, five randomized and controlled, have validated RESPeRATE's blood pressure reduction capability.

- ▶ A clinically significant, sustained reduction in blood pressure typically occurred in 3 to 4 weeks (See Graph 1).
- ▶ RESPeRATE users with uncontrolled blood pressure experienced a significant decrease in office blood pressure with average reduction of 14/8 mmHg (See Graph 2).
- ▶ Control treatment reduction (relaxation music) was 9/4 mmHg, significantly less than with RESPeRATE ($p < 0.01$ and $p < 0.002$, respectively for systolic and diastolic blood pressures).
- ▶ The results were similar across genders and medication status.



Graph 2: Lowers high blood pressure by up to 36 points systolic and 20 points diastolic (top 10% reductions), as shown in seven separate clinical trials with average reductions of 14/8 points.



Graph 1: People using RESPeRATE experienced a significant and sustained reduction in blood pressure within 3-4 weeks. The control did not show such an effect.

- ▶ The reduction in office blood pressure was directly related to the duration of slow breathing; those who used RESPeRATE more achieved better reductions.
- ▶ Larger reductions in office blood pressure occurred in older individuals and those with higher baseline blood pressures, whether taking antihypertensive medication or not.
- ▶ Home blood pressure measurements (for up to 6 months of use) and 24 hour ambulatory blood pressure monitoring have verified an all-day blood pressure reduction.
- ▶ Patients' ability to operate the RESPeRATE device without prior training and to comply with routine use were established objectively using the device's internal memory and verified by post-market surveys.

For additional clinical materials and information regarding our professional programs: Call 1-800-509-2403, visit www.resperate.com/clinician or send an email to hcp@resperate.com.

Non-Drug Blood Pressure-Lowering Device: A Clinical Overview

William Elliott, MD; Joseph Izzo, Jr. MD; Henry Black, MD

Introduction

Reduction of high blood pressure (BP) by nonpharmacological means (i.e. lifestyle modifications) is widely recommended, either as primary prevention or therapy or as adjunctive treatment with antihypertensive drugs. Several recent clinical trials have demonstrated that 8 weeks of daily at-home use of a device that slows breathing rate lowers BP¹⁻⁷.

Mechanism of Action

Inappropriately high sympathetic nervous outflow from the central nervous system is believed to be an important component in the pathophysiology of acute and chronic hypertension that stimulates increases in cardiac output and peripheral resistance. Elevated sympathetic activity is often associated with desensitization of arterial and cardiopulmonary baroreceptors, which leads to increased BP fluctuation and sustained elevations in resting pressures.

Slow breathing (<10 breaths/minute), especially with prolonged exhalation, appears to reduce sympathetic nerve traffic and thus causes arteriolar dilatation. The process is believed to be initiated by activated pulmonary mechanoreceptors, which respond to the increased tidal volume that accompanies slow breathing, and act in concert with cardiac mechanoreceptors to inhibit sympathetic outflow⁸.

Device Description

The new device (RESPeRATE®, InterCure Inc., New York, NY) consists of a control box (about the size of a paperback book) containing a microprocessor, a belt-type respiration sensor (which functions as a respiration sensor), and headphones (to provide feedback to the patient). During a session of device-guided breathing, the device analyzes the breathing rate and pattern and creates a personalized melody composed of two distinct tones – one tone for inhalation, one for exhalation. As the patient synchronizes breathing with the tones, the device gradually prolongs the exhalation tone and slows the breathing rate to <10 breaths/minute.

A record of the patient's use of the device is stored in the microprocessor for quantitation of total time of device use and adherence to the regimen.

Clinical Studies

Seven separate studies¹⁻⁷ have examined the decrease in office blood pressure for subjects who used the device for 15 minutes/day for 8 weeks, compared to "control" interventions (listening to relaxing music¹ or home BP monitoring^{4,5} or both²). Four studies were double-blind and randomized^{1,2,5,8}, one was controlled and randomized⁴, and two were open-label experiences^{3,6}.

A total of 286 individuals participated in the seven studies: 55% men; 78% drug-treated, with average age of 58 years; Body Mass Index of 28 kg/m²; and initial office BP of 150/90 mmHg (9% pre-hypertensive; 66% Stage 1; 25% Stage 2).

The decrease in office BP after 8 weeks of device-guided breathing among those with uncontrolled hypertension was 14/8 mmHg, compared to control treatment of 9/4 mmHg (p = 0.008 and p = 0.002, respectively for systolic and diastolic BPs). The difference was independent of gender and medication status. Control of BP (< 140/90 mmHg) was seen more commonly in the group that used the device: 26% vs. 4% of those with initial Stage 2 hypertension

(> 160/100 mmHg, p < 0.005); and 48% vs. 34% for those with initial Stage 1 hypertension (140-159/90-99 mmHg, p < 0.05).

The drop in office BP was directly related to the duration of slow breathing during the 8 weeks of treatment; those who used the device and achieved more than 45 minutes/week of slow breathing had the greatest lowering of office BPs. It usually takes 3-5 weeks to achieve a sustained reduction in home BP.

Larger decreases in office BPs were seen in older individuals and those with higher baseline BPs, whether taking antihypertensive medication or not. Verification of BP lowering has also been seen with home BP measurements (for up to 6 months of use⁷) and ambulatory BP monitoring³.

Usage Guidelines and Administration

The device is indicated by the US FDA for the reduction of stress and as an adjunctive therapy in hypertension that can be combined with standard antihypertensive drugs and nonpharmacologic interventions.

The clinical situations in which RESPeRATE appears particularly useful are: 1) pre-hypertensives and white-coat or labile hypertensives who might benefit from reducing stress and sympathetic activity; 2) patients with isolated systolic hypertension; and 3) resistant hypertensive patients (uncontrolled BP despite use of a diuretic and at least 2 other medications at maximum dosage).

There are no known contraindications or adverse reactions to use of the device to guide slow breathing.

Patients should be instructed to use the device routinely in 15-minute daily sessions, aiming to accumulate at least 45 minutes of slow breathing per week (as indicated by the device's display). Patients should be made aware that results, just like physical conditioning, may take a few weeks to become fully manifested and that without continued device use, any achieved benefits would likely be diminished.

Summary

Routine use of a device to guide slow breathing significantly lowers office measurements of blood pressure without adverse effects. This modality may be a useful adjunct to current antihypertensive medications and to non-pharmacologic interventions in achieving better blood pressure control.

Reprints, full indication for use and additional information can be found at www.resperate.com/MD.

References

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8. Parati et al. in *Hypertension Primer*, Lippincott, Williams, and Wilkins, 2003; Ch. A40, p117-120.