

Dear Doctor,

We are pleased to provide you with the information you requested about RESPeRATE to Lower Blood Pressure, the first and only medical device indicated for the adjunctive treatment of hypertension. We are also pleased to inform you that following the latest US-based clinical study RESPeRATE's market clearance has been extended to over-the-counter distribution.

Enclosed please find a Clinical Information brochure, journal article reprints and a few RESPeRATE Patient Education brochures that you can pass on to your interested patients.

For the most updated information, please visit our website at [www.high-blood-pressure-help.com](http://www.high-blood-pressure-help.com) where you will find the latest results of our clinical studies, biographies of members of our world-renowned Scientific Advisory Board, video testimonials from physicians, and a product demonstration. You may also order additional RESPeRATE Patient Educational brochures for your office on the site.

Key facts from clinical studies:

- Results of 6 clinical studies have been published in peer-reviewed journals, including the *American Journal of Hypertension*.
- RESPeRATE delivers an average 14/9 mmHg sustained blood pressure reduction within 8 weeks of proper use (just 15 minutes a day, 3-4 times per week).
- RESPeRATE has no side effects, no drug interactions and patients report that it is pleasant to use.
- Our Scientific Advisory Board includes many of the world's leading hypertension experts, including past presidents of the American, European and International Societies of Hypertension.

In short, RESPeRATE offers an additional non-drug option to further lower patients' high blood pressure with no side effects. Should your patient inquire, RESPeRATE sells for \$299 and has a money back guarantee - If your patients' blood pressure does not go down within 8 weeks of proper use, we will refund their money.

Sincerely,

*Ariela Alter*

Ariela Alter, F.D.C.

Director of Clinical Affairs  
InterCure, Ltd.

The First Non-Drug Medical Device  
Indicated for the Adjunctive  
Treatment of Hypertension ...  
With No Side Effects

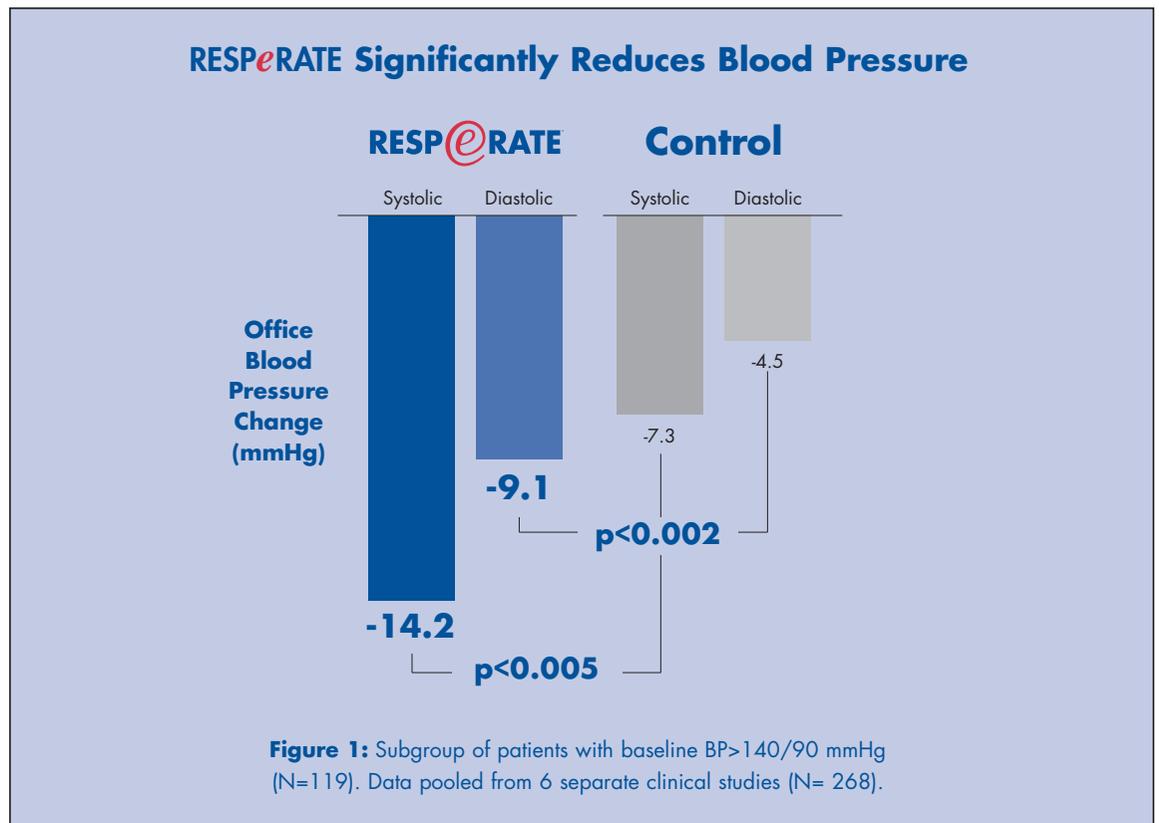
**RESP@RATE**<sup>™</sup>  
**TO LOWER  
BLOOD PRESSURE**



Pharmacological interventions and lifestyle modifications do not always get patients to goal blood pressure. Adverse reactions to medication and poor compliance further frustrate both patient and physician.

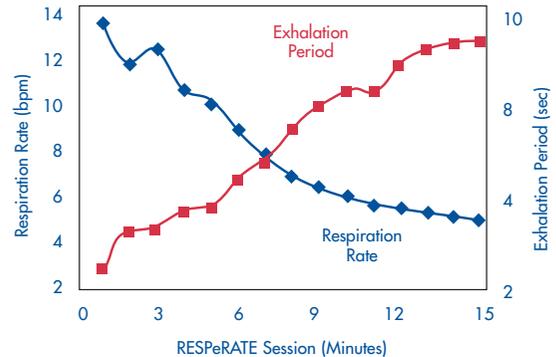
**RESP@RATE offers an additional non-drug option to further lower patients' blood pressure with no side effects.**

- ▶ First and only medical device indicated for the adjunctive treatment of hypertension
- ▶ 14/9 mmHg average sustained blood pressure reductions within 8 weeks
- ▶ No side effects, no drug interactions
- ▶ Results of 6 clinical studies published in peer-reviewed medical journals<sup>1-5</sup>



## How RESPeRATE Works:

RESPeRATE's patented interactive technology safely and effectively guides patients through unique breathing exercises that have been clinically proven to reduce blood pressure. RESPeRATE enables patients to effortlessly slow their breathing rate from the normal range of 14 to 18 breaths per minute to the "therapeutic pattern" of under 10 breaths per minute with prolonged exhalation. These breathing exercises are difficult to perform properly without continuous individualized coaching. RESPeRATE provides this individualized coaching, in the comfort of the patient's home. After each RESPeRATE session, respiration returns to normal, but the beneficial effects on blood pressure accumulate.



**Figure 2:** RESPeRATE interactively guides patients to slow breathing while lengthening exhalation period in an optimized way

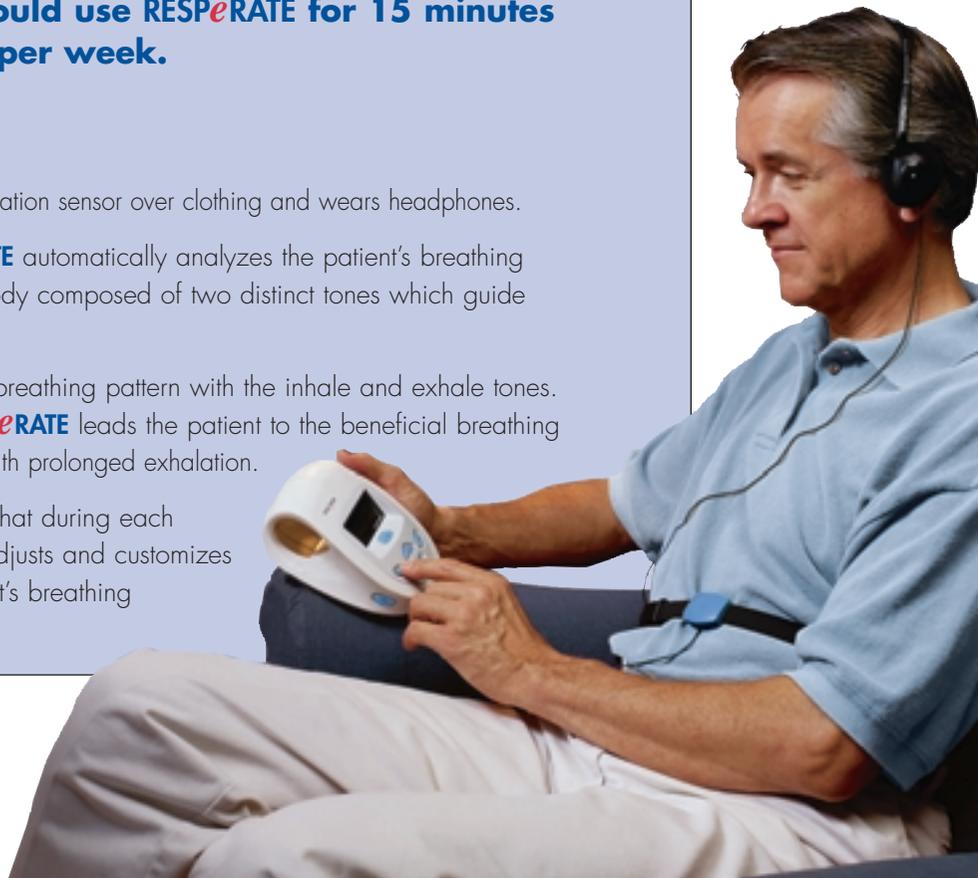
## Why RESPeRATE Works:

RESPeRATE's unique therapeutic breathing exercises reduce the body's sympathetic neural activity and relax the muscles surrounding small blood vessels, allowing blood to flow more freely. In addition, RESPeRATE has been shown to enhance baroreflex sensitivity following the exercise.<sup>6</sup> RESPeRATE's patented method of interactively synchronizing the inhale-exhale tones with the constantly changing breathing pattern is key to maximizing the effectiveness of the therapy as it allows patients to "effortlessly" reach the therapeutic breathing pattern.

**For best results, the patient should use RESPeRATE for 15 minutes per session, at least 3-4 times per week.**

### The RESPeRATE Experience

- ▶ Patient places the elastic belt with the respiration sensor over clothing and wears headphones.
- ▶ During each exercise session, RESPeRATE automatically analyzes the patient's breathing pattern and creates a personalized melody composed of two distinct tones which guide the patient to inhale and exhale.
- ▶ Patient listens and synchronizes his/her breathing pattern with the inhale and exhale tones. By prolonging the exhalation tone, RESPeRATE leads the patient to the beneficial breathing pattern of under 10 breaths per minute, with prolonged exhalation.
- ▶ RESPeRATE is *interactive*, which means that during each session it constantly and automatically adjusts and customizes the melody to optimally guide the patient's breathing according to his/her individual needs.



## Clinical Summary

- ▶ Six separate clinical studies performed in 12 outpatient and family clinics in the US, Italy and Israel: four double-blinded, randomized, controlled<sup>1-2,5</sup>; one non-randomized controlled<sup>4</sup>; one open design<sup>3</sup>
- ▶ Sustained blood pressure reductions achieved within the first 8 weeks of 15-minute daily treatment
- ▶ No side effects
- ▶ Greater reductions for older patients and patients with higher baseline blood pressure
- ▶ Consistent results measured at the clinic, at home and with 24-hour ambulatory blood pressure monitoring
- ▶ Dose-response relationship between the accumulated amount of **RESPeRATE** slow breathing exercise and the resulting blood pressure reduction: 45 minutes of **RESPeRATE** slow breathing exercises per week delivered clinically significant reductions; additional minutes of slow breathing resulted in larger reductions.
- ▶ Patients' ability to operate the **RESPeRATE** device without prior training and to comply with routine use were established objectively and quantitatively using the device's internal memory.

**Table 2:** Pooled results of clinical studies\*

Population	RESPeRATE		Control*		P-value
	BP reduction (mmHg)	N	BP reduction (mmHg)	N	
Any Baseline BP	<b>12.1/6.1</b>	141	7.9/3.4	127	<b>0.02/0.007</b>
Baseline >140/90	<b>14.2/9.1</b>	63	7.3/4.5	56	<b>0.005/0.002</b>

\* Control group: Relaxation treatment by alternative device (Walkman with relaxing music)<sup>1-2</sup>, placebo intervention by home blood pressure monitor<sup>4,5</sup> and both<sup>2</sup>

**Table 1:** Pooled characteristics of patient population on enrollment\*

Number of patients	268	
% Males	60%	
Age (years):	57±11	
Patients' Age	<40	25%
	40-60	38%
	>60	37%
% Medicated	77%	
# of meds	1 med	38%
	2 meds	38%
	>3 meds	24%
Systolic BP (mmHg)	150±14	
Diastolic BP (mmHg)	90±9	

\* After excluding 21 dropouts and 46 patients who did not use the device as directed

## References

- [1] - Schein M, Gavish B, Herz M et al. "Treating hypertension with a device that slows and regularizes breathing: a randomized double-blind controlled study." J Human Hyperten 2001; 15(4): 271 - 278.
- [2] - Grossman E, Grossman A, Schein MH, Zimlichman R, Gavish B "Breathing-control lowers blood pressure." J Human Hyperten 2001; 15(4): 263 - 269.
- [3] - Rosenthal T, Alter A, Peleg E, Gavish B. "Device-guided breathing exercises reduce blood pressure and ambulatory and home measurement." Am J Hyperten 2001; 14(1): 74 - 76.
- [4] - Giannattasio C, Failla M, Meles E, Gentile G, Grappiolo A and Mancia G "Efficacy of self treatment of hypertension at home with device-guided breathing." Am J Hyperten 2002; 15(4) Part 2: 186A.
- [5] - Elliott W, Izzo J, Rosing D, Snyder C, White W, Alter A, Gavish B, and Black H "Blood pressure reduction by device-guided breathing shows a dose-response relationship." Am J Hyperten 2002; 15(4) Part 2: 186A.
- [6] - Parati G, Glavina F, Ongaro G, Maronati A, Gavish B, Castiglioni P, Di Rienzo M, Mancia G. " Acute effects of device-guided breathing on cardiovascular parameters and baroreflex sensitivity in normal subjects." Am J Hyperten 2002; 15(4) Part 2: 182A.

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 medication and lifestyle modifications such as diet and exercise.

For more information visit [www.high-blood-pressure-help.com](http://www.high-blood-pressure-help.com) or call 1-888-779-7177