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Australia and New Zealand Horizon Scanning Network

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# **National Horizon Scanning Unit**

## **Horizon scanning prioritising summary**

**Volume 5, Number 2:**

**RESPeRATE™ : Self guided breathing  
device for the treatment of hypertension in  
the home.**

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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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# PRIORITISING SUMMARY

**REGISTER ID:** 000093

**NAME OF TECHNOLOGY:** RESPeRATE™

**PURPOSE AND TARGET GROUP:** SELF GUIDED BREATHING DEVICE FOR TREATMENT OF HYPERTENSION IN THE HOME

**STAGE OF DEVELOPMENT (IN AUSTRALIA AND/OR AUSTRALIA):**

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

**AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL**

- |  |   |
|--|---|
| <input type="checkbox"/> Yes           | ARTG number                             |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

**INTERNATIONAL UTILISATION:**

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Israel	✓		
Italy	✓		
Finland	✓		

**IMPACT SUMMARY:**

InterCure Ltd provides RESPeRATE™ with the aim of treating hypertension. The device is not yet available in Australia but has received approval for over-the-counter use in the United States and Korea.

**BACKGROUND**

RESPeRATE™ is a battery operated biofeedback device designed to automatically analyse the user's breathing rate and pattern. It then interactively guides the user through a therapeutic breathing exercise to reduce the number of breaths per minute. The reduction in number of breaths per minute produces a significant reduction in blood pressure.

The device is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions. RESPeRATE™ consists of a belt-type respiration movement sensor that is mounted on the upper abdomen or chest and attached to a computerised control unit and headphones (Figure 1).

The device guides the user to slow breathing with a relatively prolonged expiration by monitoring breathing patterns, averaging them over the last four breaths, synthesizing musical patterns with “inspiration” and “expiration” sounds, and synchronizing inhaling and exhaling with musical sounds. The inspiration and expiration times are stored automatically once every minute of use together with the date, hour and other performance variables (Meles et al 2004).



Figure 1 RESPeRATE device (printed with permission Intercure Ltd, Source [www.intercure.com](http://www.intercure.com))

### CLINICAL NEED AND BURDEN OF DISEASE

Hypertension is a major risk factor for coronary heart disease, stroke, peripheral vascular disease and renal failure, accounting for 5.4% of all Disability-Adjusted Life Years in Australia (Mathers et al 1999). The term ‘hypertension’ refers to people with high blood pressure and/or receiving treatment for high blood pressure, defined as systolic blood pressure  $\geq 160$  mmHg and/or diastolic blood pressure  $\geq 95$ mmHg (Mathers et al. 1999). Studies suggest that the risk of cardiovascular disease increases as the level of blood pressure increases (Mathers et al. 1999). When high blood pressure is controlled by medication the risk of cardiovascular disease is reduced, although not to the levels of non-affected people.

In 1995, around 2.2 million adult Australians (17% of men and 15% of women over 18 years of age) had high blood pressure and/or were receiving treatment for the condition. The proportion of men and women with high blood pressure increases with age. In 1999, among people aged 65–69 years, approximately 41% of men and women had high blood pressure and/or were on treatment for the condition (AIHW 1999).

Conditions that may be associated with hypertension, along with the associated deaths, Years of Life Lost due to mortality (YLL), Years of Life Lost due to disability (YLD) and Disability-Adjusted Life-Years (DALYs) are listed in Table 1.

Table 1. The attributable burden of hypertension by condition, Australia, 1996

Condition	Attributable deaths	Attributable YLL	Attributable YLD	Attributable DALYs	Attributable DALYs as a proportion of total DALYs
Ischaemic heart disease	7,948	64,217	7,706	71,923	2.9
Stroke	4,327	31,714	12,016	43,730	1.7
Hypertensive heart disease	1,643	11,310	1,731	13,041	0.5
Nephritis and nephrosis	263	1,826	3,820	5,646	0.2
Peripheral arterial disease	188	1,456	273	1,730	0.1
<b>Total</b>	<b>14,369</b>	<b>110,524</b>	<b>25,547</b>	<b>136,070</b>	<b>5.4</b>

source: Mathers et al. 1999

## **DIFFUSION**

It was not possible to gauge the level of diffusion in the United States from the sources examined. However, as the device is approved for over-the-counter use it may be an alternative or adjunct for patients receiving medication.

## **COMPARATORS**

Clinical testing in an Over The Counter (OTC) setting has shown that RESPeRATE™ can be properly used without the direction of a physician (FDA 2004). RESPeRATE™ is substantially equivalent to InterCure's previously approved Respi-Low biofeedback device (FDA approval number K000495) for use in stress reduction and adjunctive treatment to reduce blood pressure (FDA 2004). The Respi-Low device shares the same indications for use as RESPeRATE™ except for the OTC setting.

The conventional approaches to treating and/or reducing hypertension are the use of medications, changing diet and increasing exercise.

## **COST IMPACT**

An estimation of health system costs associated with specific cardiovascular diseases and risk factors in 1993–94 reports that hypertension is the second most expensive condition to treat and costs approximately \$831 million in Australia in 1993 –1994 (Mathers and Penn 1999). This total cost includes the cost of detecting and treating high blood pressure (essential hypertension), as well as the cost of treating hypertensive heart and renal disease (which accounts for \$15.9 million of the total \$831 million). Effective, patient-managed, non-pharmacologic treatment for hypertension may reduce costs associated with treating the condition.

The cost of the device is US \$299.00.

## **EFFECTIVENESS AND SAFETY ISSUES**

RESPeRATE™ has been tested in seven clinical trials ([http://www.resperate.com/resperate/consumers\\_clinical.asp](http://www.resperate.com/resperate/consumers_clinical.asp) Accessed 05.05.2004). It was not possible, however, to source full publications for each of these trials.

One of the published studies described a randomised, double-blind controlled trial involving 65 hypertensive patients, who were either unmedicated or receiving antihypertensive drug therapy (Schein et al. 2001). The study (level II evidence) compared systolic blood pressure, diastolic blood pressure and mean arterial pressure in patients using RESPeRATE™ (n=32), as compared to a Walkman (n=29), during a period of 2 months. Medication was unchanged 2 months prior to and during the study. There was a reduction from baseline in systolic blood pressure, diastolic blood pressure and mean arterial pressure by 15.2, 10.0 and 11.7 mmHg in the RESPeRATE™ group as compared to 11.3, 5.6 and 7.5 mmHg (p=0.14, p=0.008, p=0.03) in the group with the Walkman.

In a non-randomised controlled trial (level III-2 evidence) with 79 mild hypertensive patients, office and home blood pressure measurements were compared in 48 patients using RESPeRATE™ daily (treatment group) with 31 patients in the control group who received no intervention (Meles et al 2004). Results are likely to be affected by selection bias as nearly all of the patients in the RESPeRATE™ group (42) were medicated, compared to half of the patients (21) in the control group. In the treatment group, both office diastolic blood pressure and home systolic blood pressure and diastolic blood pressure were reduced by  $3.6 \pm 12.0$ ,  $5.4 \pm 7.5$ ,  $3.2 \pm 4.4$

mmHg respectively ( $p < 0.05$ ,  $p < 0.001$ ,  $p < 0.001$ ). There were lower readings in the control group for office and home systolic blood pressure and diastolic blood pressure but these were not significantly different from baseline. The differences between treatment and control groups were significant for office diastolic blood pressure and for both home systolic blood pressure and diastolic blood pressure: treatment group values of  $-3.6 \pm 12.0$ ,  $-5.4 \pm 7.5$ ,  $-2 \pm 4.4$  mmHg respectively compared to  $+0.9 \pm 7.0$ ,  $-1.9 \pm 5.8$ ,  $-1.0 \pm 5.2$  mmHg in the control group ( $p < 0.05$ ,  $p < 0.02$ ,  $p < 0.04$ ).

In both the treatment and control groups there was an initial reduction in outcome measures (placebo effect). However, after 2 weeks, the control group reached a plateau, whereas outcome measures in the treatment group continued to fall and reached a plateau after 6 weeks. The patients used RESPeRATE™ for 74% of the 56 daily sessions required. No adverse events were observed or reported.

Two further case series studies (level IV evidence) report that the device produced significant reductions in both office and home blood pressure in patients; the first in 17 patients with resistance to drug therapy and the second study included 13 patients (6 medicated and 7 unmedicated) who used RESPeRATE™ (Viskoper et al 2003 and Rosenthal et al 2001). Both studies used RESPeRATE™ for 8 weeks, for 15 minutes daily.

#### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

#### **CONCLUSION:**

There is good quality and quantity of evidence available on the effectiveness of RESPeRATE. The high prevalence of hypertension in the population gives the potential of high uptake of this non-invasive self-management device. However, it is unlikely to have significant clinical or policy impact on the public health system. However the use of Stan S21® will not have a significant impact on the public health system.

#### **HEALTHPACT ACTION:**

Therefore it is recommended that this technology be archived.

#### **SOURCES OF FURTHER INFORMATION:**

Australian Institute of Health and Welfare (AIHW) 1999. Heart, stroke and vascular diseases, Australian facts. AIHW cat. no. CVD7. Canberra: AIHW and the Heart Foundation of Australia (Cardiovascular Disease Series no. 10).

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Mathers C, Vos T, Stevenson C 1999. The burden of disease and injury in Australia. AIHWcat. no. PHE 17. Canberra: AIHW.

Grossman, E., Grossman, A. et al (2001). 'Breathing-control lowers blood pressure', *J Hum Hypertens*, 15 (4), 263-269.

Meles, E., Giannattasio, C. et al (2004). 'Nonpharmacologic treatment of hypertension by respiratory exercise in the home setting', *Am J Hypertens*, 17 (4), 370-374.

Rosenthal, T., Alter, A. et al (2001). 'Device-guided breathing exercises reduce blood pressure: ambulatory and home measurements', *Am J Hypertens*, 14 (1), 74-76.

Schein, M. H., Gavish, B. et al (2001). 'Treating hypertension with a device that slows and regularises breathing: a randomised, double-blind controlled study', *J Hum Hypertens*, 15 (4), 271-278.

United States Food and Drug Administration 2004 [Internet] Available from: <http://www.fda.gov/cdrh/pdf2/k020399.pdf> [Accessed May 18, 2004].

Viskoper, R., Shapira, I. et al (2003). 'Nonpharmacologic treatment of resistant hypertensives by device-guided slow breathing exercises', *Am J Hypertens*, 16 (6), 484-487.

**SEARCH CRITERIA TO BE USED:**

Blood Pressure

Blood Pressure Monitoring, Ambulatory

Breathing Exercises

Hypertension/ therapy

Hypertension/ physiopathology/ therapy