General Commissioning Policy

Treatment	**Resperate® (InterCure Ltd)**
For the treatment of	**Hypertension**
Background	This commissioning policy is needed because there is insufficient cost effectiveness evidence regarding this device, for its use to be commissioned, despite it being listed on the NHS drug tariff since February 2012, thus allowing prescribing on prescription.
Commissioning position	NHS Hull Clinical Commissioning Group (CCG) does not commission the use of the Resperate® device for the treatment of hypertension owing to inadequate evidence of long term benefit over other relaxation techniques. As such, clinicians should not routinely prescribe or recommend this product to patients either as monotherapy or an adjunct to pharmacological management because there is limited clinical evidence of effectiveness.
Effective from	Oct 2014 (replaces previous version dated Sept 2012)
Summary of evidence / rationale	A significant proportion of patients with hypertension do not achieve target blood pressure (BP) reductions on medication. This is thought to be due in the majority to a combination of poor compliance and resistant hypertension. It has been proposed that slowing the breathing rate may reduce BP, via an effect on the reflex control of the cardiovascular system via adaptation of pulmonary stretch receptors and the baroreflex response. Resperate® (InterCure Ltd) is a device that slows breathing rates, currently being marketed as a non-pharmacological treatment to lower BP on the basis of a number of published clinical trials. Users of the device listen to a melody through headphones that guides them to reduce their breathing rate, aiming for <10 breaths per minute. In essence, Resperate® is a biofeedback device, which makes it similar to yoga, meditation, and music, in that all of these approaches have been shown to reduce BP. A theme common to each of these non-pharmacologic therapies is that the sympathetic nervous system is reduced. A systematic review and meta-analysis (Ref 1) yielded a total of eight randomised controlled trials (RCTs) of >4 weeks' duration (maximum 9 weeks) comparing Resperate® to a placebo device in adults, with a >80% follow-up within both arms (total n=494). Seven trials attempted to control for the Resperate device using music or a standard BP monitoring unit, and one trial used standard care alone as the control. The following main results are reported: • Use of the Resperate® device reduced systolic BP by

Notes
1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policy Statements are agreed by the Planning and Commissioning Committee on behalf of NHS Hull Clinical Commissioning Group.

	3.67mmHg (95% CI −5.99 to −1.39; P=0.002) and diastolic BP by 2.51mmHg (−4.15 to −0.87; P=0.003). • A sensitivity analysis that excluded the 3 trials performed by the manufacturer (n=100) revealed no statistically significant effect of using the device on BP. • No overall effect was seen on heart rate or quality of life using the device. • The methodological quality of the studies was variable with a high risk of bias. The review concludes that despite the overall BP lowering effect seen, the results should be interpreted with caution due to small study sizes, variability in study quality, the cost of the device, and potential conflicts of interest from the trial sponsors and the manufacturers. To summarise, the data on the efficacy of Resperate® is contradictory and it is not mentioned in NICE guidance or any other national hypertension guidelines. The British Hypertension Society has issued a statement (Ref 2) on this device, as it has received a number of enquiries on its use since it became listed on the NHS Drug Tariff (cost of £132). The opinion of the BHS is that such small effects on BP over very short durations of time do not provide sufficient evidence for this equipment to be recommended.
Date	June 2017
Review Date	June 2018
Contact for this policy	Karen Billany, Head of Acute Care, NHS Hull Clinical Commissioning Group. Karen.billany@nhs.net

References:

1. Mahtani KR, Nunan D, Heneghan CJ. Device-guided breathing exercises in the control of human blood pressure: systematic review and meta-analysis. Journal of Hypertension 2012; 30(5):852-860 http://www.ncbi.nlm.nih.gov/pubmed/22495126
2. Meta-analysis of the RESPeRATE device for lowering BP and related statement from the British Hypertension Society. (April 2012) http://www.bhsoc.org/pdfs/Statement%20on%20RESPeRATE%20April%2012.pdf