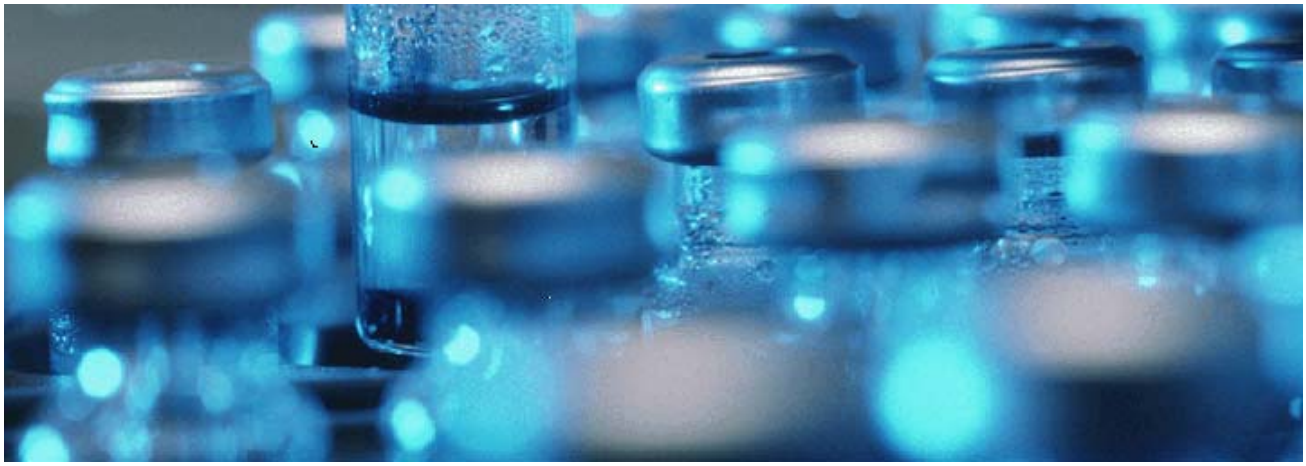
NHS
Technology Adoption Centre

BRIEFING PACK



WatchBP Office ABI®

Microlife Health Management Ltd

Prepared by:
NHS Technology Adoption Centre
Suite 3E
1 Portland Street
Manchester
M1 3BE

Telephone: 0161 200 1620

www.ntac.nhs.uk

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1 EXECUTIVE SUMMARY

Microlife reports that the WatchBP Office ABI® has the potential for net financial savings of £351,656,000 across England in relation to early diagnosis of atrial fibrillation (AF), peripheral artery disease (PAD) and hypertension.

Screening with WatchBP Office ABI® has the potential to reduce the current number of appointments associated with ankle brachial measurements and echocardiogram (ECG) to confirm AF, whilst ensuring appropriate referrals are made to GPs and hospitals for those patients with suspected presence of one or more cardiovascular diseases.

Atrial fibrillation is the most common cardiac arrhythmia, affecting between 1-2% of the general UK population and is related to 20% of all strokes. Reported prevalence of AF is underestimated and currently shows a 5% increase annually, leading to 46,000 new diagnoses in the UK. It is expected that the number of AF patients will be increased by 40% in the coming two decades because of the demographic and lifestyle changes[1]. Many of the cardiovascular diseases screened for are asymptomatic which suggests that current numbers of people with atrial fibrillation and hypertension are most likely to be underestimated[2].

The WatchBP Office ABI® is an automated oscillometric BHS (A/A) and ESH validated blood pressure monitor designed for clinical use. The device is equipped with innovative cardiovascular screening tools which are able to detect atrial fibrillation, simultaneous blood pressure measurement of both arms (as recommended by NICE guidelines) and ankle-brachial index performance for identification of peripheral arterial disease.

It is proposed that this product could be linked in with existing cardiovascular screening, such as NHS Health Check Programme[3], to assess and monitor patients' blood pressure and potential diagnosis of atrial fibrillation in all patients aged 40 years and over. Microlife suggest that, as a result of this, the effects of hypertension, peripheral artery disease and atrial fibrillation (stroke, heart attack) will be minimised as more patients will be diagnosed before the onset of cardiac events and can be treated earlier through lifestyle changes and medication.

Findings from a 12 month pilot study at North East Lincolnshire Care Trust Plus demonstrated at least one patient diagnosed with atrial fibrillation and over 5 patients diagnosed with hypertension in primary care.

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[2] Camm, AJ (2010) Guidelines for the management of atrial fibrillation: the Taskforce for the management of Atrial Fibrillation of the European Society of Cardiology. Europace. Vol 12.pp1360-420.
[3] Department of Health (2009) Putting Prevention First: NHS Health Check: Vascular Risk Assessment and Management. London. HMSO.

2 INTRODUCTION

The NHS Technology Adoption Centre (NTAC) has been commissioned by the Department of Health to formulate this Briefing Pack, which is a summary of the information provided to the Department of Health by Microlife. The technology has been identified by the Innovative Technology Adoption Procurement Programme (iTAPP) as being significant to the NHS Quality, Innovation, Productivity and Prevention (QIPP) agenda and its benefits have been explored at a local, regional or national level in consideration of the benefit of a wider health economy. It is recognised that technology is an enabler of the step-change innovation needed to make the necessary and significant impact and improvements in healthcare service delivery.

This technology Briefing Pack is designed to provide comprehensive information and data required to demonstrate how WatchBP Office ABI® can be introduced into local healthcare services to yield real, significant and sustainable benefits to its patients and the healthcare system.

As part of this work, NTAC has consulted with North East Lincolnshire Care Trust Plus and feedback from this Trust is included in Section 10.

3 THE TECHNOLOGY AND PRODUCT

Microlife Health Management Ltd supplies the WatchBP Office ABI®, CE marked as a Class IIa medical device. Contact details are as follows:

Microlife Health Management Ltd
St Johns Innovation Centre
Cowley Road
Cambridge
CB4 0WS
Tel. 01223 422444

www.microlife.com

The WatchBP Office ABI® is an automated oscillometric BHS (A/A) and ESH validated blood pressure monitor designed for clinical use[4,5]. The device is equipped with innovative cardiovascular screening tools including an implemented AF detection system, simultaneous BP measurement of both arms and ankle-brachial index performance. This product is available through NHS Supply Chain.

[4] Saladini, F; Benetti, E; Masieron, S; Palatini, P (2002) Accuracy of Microlife WatchBP Office ABI monitor assessed according to the 2002 European Society of Hypertension protocaol and the British Hypertension Society protocol. Blood Pressure Monitor. Vol 16. Pp258-61.

[5] Stergiou, GS; Tzamouranis, D; Protogerou, A; Nasothimiou, E; Kapralos, C (2008) Validation of the Microlife WatchBP Office professional device for office blood pressure measurement according to the International protocol. Blood Pressure Monitoring. Vol 13. Pp299-303.

4 THE PATIENT GROUP

This product is aimed at primary prevention of cardiovascular disease ie. those people who have not previously been diagnosed with hypertension, peripheral arterial disease or atrial fibrillation. The technology would offer additional diagnostic technology to screen patients between the ages of 40-74 years for these conditions.

The NHS Health Checks aim to identify patients who are at high risk of developing cardiovascular disease such as diabetic patients, those who smoke and those with identifiable risk factors. NICE (2011) guidance recommends ambulatory blood pressure monitoring to confirm the diagnosis of hypertension. This technology would offer an additional diagnostic tool, to enable these high risk groups to receive diagnosis of hypertension, peripheral arterial disease and atrial fibrillation allowing them to join the appropriate treatment pathway earlier than may currently be the case.

It should be noted that NICE (2011) acknowledge that automated devices may not measure blood pressure accurately, if there is a pulse irregularity (eg. Due to AF), it is recommended to palpate the radial or brachial pulse before measuring blood pressure. If the pulse irregularity is present, NICE (2011) recommends that the blood pressure be measured manually using direct auscultation over the brachial artery.

Microlife report that screening all people above the age of 55 years will lead to the diagnosis of:

- 134,000 patients with asymptomatic AF
- 1,150,000 patients with major asymptomatic PAD
- 1,150,000 patients with minor PAD
- 23,200 patients with subclavian stenosis
- 4,600,000 patients with hypertension

Should improved and earlier diagnosis be followed up by earlier treatment and improved lifestyle adaptions, it is believed that the percentage of major cardiovascular events will decrease significantly, leading to major cost reductions to the NHS.

5 THE EVIDENCE

Microlife report the estimated expected total annual mortality to be reduced by 15,264 patients in England, based on those patients who would be prevented from dying from myocardial infarction and stroke. Screening with the WatchBP Office ABI® would, in the short-term, potentially lead to multiple referrals to GPs and secondary care because of suspected/diagnosed cardiovascular conditions. This will result in more patients being treated who require follow up visits, although it may also reduce unnecessary visits, ankle brachial measurements and unnecessary ECGs required for diagnosis and confirmation of AF.

33% of patients with AF have no symptoms and are not aware of its presence, remaining undiagnosed. If these patients could be diagnosed and treated at an early stage, the risk of stroke can be reduced by 68%[2]. Potential target adopting sites have been identified by Microlife as acute care in hospitals, community care, GP practices, primary care and pharmacies.

The WatchBP Office ABI®'s accuracy has been investigated in two scientific studies[5, 6]. Although not directly compared, the WatchBP Office ABI® shows a higher rate of accuracy for the detection of AF than GPs or nurses using a 12-lead ECG system. Kollias et al[7] reported that this product was recommended as being a suitable tool for performing ankle brachial measurements when tested against Doppler and produced more reproducible inter-arm differences than obtained with conventional BP measurement[8] which suggests the product has the potential to improve management and treatment for those who have AF, PAD or hypertension.

Microlife suggest that this product has the potential to reduce mortality rates for the 12,670 fatalities associated with the 101,000 people who suffer myocardial infarctions each year and a third of more than 45,000 patients fatally affected by stroke each year. Further information is available through accessing www.bhf.org.uk/heart-healthy/statistics/morbidity and www.stroke.org.

6 RELEVANCE TO NHS IMPROVEMENT AREAS

THE TECHNOLOGY ALIGNS WITH THE FOLLOWING DOMAINS WITHIN THE NHS OUTCOMES FRAMEWORK[9]:

The WatchBP Office ABI aligns with the NHS Outcomes Frameworks in the following areas:

- Domain 1 Preventing people from dying prematurely
- Improvement area 1.1 Under 75 mortality rate from cardiovascular disease
- Domain 2 Enhancing quality of life for people with long-term conditions
- Improvement area 2.1 Proportion of people feeling supported to manage their condition.

7 THE BENEFITS

CLINICAL BENEFITS

WatchBP Office ABI® has a positive impact on the following key areas:

- Supports risk assessment for cardiovascular events
- Prevention of serious consequences from PAD such as leg amputation
- Identifying opportunities for earlier treatment
- Reduced mortality rates

[6] Wiesel, J; Fitzig, L; Herschman, V; Messineo, FC (2009) Detection of atrial fibrillation using a modified microlife blood pressure monitor. American Journal of Hypertension. Vol 22. Pp848-52.

[7] Kollias, A; Xilomenos, A; Protogerou, A; Dimakakos, E; Stergiou, GS (2011) Automated determination of the ankle-brachial index using an oscillometric blood pressure monitor: validation vs. Doppler measurement and cardiovascular risk factor profile. Hypertens Res. Vol 34. Pp825-30.

[8] Lohmann, FW; Eckert, S; Verdberk, WJ (2011) Interarm differences in blood pressure should be determined by measuring both arms simultaneously with an automatic oscillometric device. Blood Pressure Monitoring. Vol 16. Pp37-42.

[9] http://healthandcare.dh.gov.uk/files/2011/01/outcomesglance.pdf - NHS Outcomes Framework

8 FINANCIAL CASE

Microlife Health Management Ltd has provided the financial information contained in this Pack.

Stroke

Each year more than 110,000 people in England will suffer from a stroke,[10] and of these 300,000 will live with moderate to severe disability as a result of stroke, incurring an annual cost of approximately £15,000 per patient[10].

Of these strokes, one in five are attributed to AF - approximately 25,000 patients. Treatment of AF reduces the risk of stroke by 68%[2]. Potential annual saving due to AF related stroke prevention for the population over 55 years is estimated at **£315,000,000.**

PAD

Savings for PAD are based on the assumption that there are 18 million people above the age of 55 years who would be selected for screening (UK Survey, 2003). It is expected that 8% (1.44million people) will have major asymptomatic PAD. At least one third of those screened (500,000) will have occlusion of a major artery[11]. We expect that 80% of these subjects are newly diagnosed due to absence of symptoms. This means that the screening would lead to 1.15 million people with newly diagnosed major PAD with 400,000 having occlusion of a major artery. From these 1.15M patients, it is expected that 175,000 (15.2%)[11] will develop claudication related to an annual mortality rate of approximately 5% (8750 patients), related to stroke and 7% (12,250 patients) related to MI[12], which is 8750 (£131,000,000), and 12250 (£311,000,000) subjects, total related costs being £441,000,000. It is suggested that, for these patients adequate treatment can prevent the need for antiplatelet therapy for patients with PAD demonstrated a 23% related relative risk reduction in the rates of nonfatal MI, nonfatal stroke, or vascular death. This would lead to a reduction in the cost for stroke and MI by (0.23 X £441,000,000), equating to £101,000,000. In addition, 8% (1.44million patients) are expected to have minor PAD with 5 % (5112 patients) leading to an annual morbidity rate due to stroke and MI. In total the annual cost saving related to PAD is estimated at **(£160m + £81.4m + £47.75m) £289,150,000 for the UK, £242,886,000 for England**.

Summary of financial benefits in England

Based on assumption of screening every person over the age of 55 years in England.
Savings related to:

Stroke reduction (25,000 patients) due to AF treatment	£315,000,000
Savings resulting from diagnosis and treatment of PAD	£242,886,000
Total Savings for reducing cardiovascular events	**£557,886,000**

(Analysis continues overleaf)

[10] Department of Health (2007) National Stroke Strategy. London. HMSO.

[11] Fowkes, FG (2009) Peripheral Vascular Disease. www.hcna.bham.ac.uk/documents/09 HCNA3 D2.pdf

[12] Stansby, G; Mister, R; Fowkes, G. (2011) High Risk of peripheral arterial disease in the United Kingdom: 2-year results of a prospective registry. Angiology. Vol 62. Pp111-8.

Costs for:	
Screening – nurse consultancy costs	£151,200,000
600 patients screened over 40 weeks/year (15,120,000patients)	
Cost for equipment £1140 X 25,200 nurses	£28,728,000
Cost for administration	
(£1000 per nurse/year X 30,000 practices)	£25,200,000
Treatment	£1,102,000
Total Costs	**£206,230,000**
Net Financial savings of	**£351,656,000**

It is expected that both the clinical and financial benefits will be visible after one year of screening but the benefits will be more evident following three consecutive years' of screening. There is potentially a significant financial investment associated with setting up new screening programmes e.g. staff, premises, resources but this would be heavily reduced by incorporating this technology as an additional diagnostic tool into the existing NHS Health Check Programme. There is also the financial benefit of NHS Health Check Programmes already has money going into PCT budgets.

9 STAKEHOLDER GROUP

The staff groups who may be engaged prior to adoption of the WatchBP Office ABI® would be clinicians (GPs, Practice Nurses, NHS Health Checks practitioners etc.), management, procurement and staff focus groups in relation to wound care and cardiology as well as podiatry services and NHS Health Check Programme providers.

10 ADOPTION CONSIDERATIONS

The following are considerations of the adoption of WatchBP Office ABI®:

- Adoption may require a significant change to clinical practice
- Higher short term costs drive medium or long term benefits
- Using this technology as an additional diagnostic tool in an existing screening programme may be viewed as unnecessary and there may be potential resistance from commissioners.
- Some people may not respond to their invitation for screening and may need to be motivated or visited at home. This will require additional resources and planning
- Current guidance (NICE) does not recommend using devices to confirm diagnosis for suspected AF.
- Some trusts prioritise their screening arrangements in line with local public health strategies to attempt to reduce their levels of cardiac related mortality. With this in mind, there will need to be a clear business case that clearly identifies and details what changes to clinical practice and screening procedures are to be introduced to be able to realise the benefits of this product.

11 FEEDBACK FROM NHS SITES

The technology deployment is currently in its infancy and is not used widely within the UK, although other countries have been using the product both clinically and for research purposes for some time. There are currently plans to actively recruit patients for trials at trusts in the North West and this follows a large pilot study undertaken in North East Lincolnshire where the product has been implemented within both primary and secondary care.

North East Lincolnshire Care Trust Plus started using Microlife WatchBP Office ABI® in early 2011. The Trust had previously identified a clinical need for Health Care Assistants to be able to perform accurate blood pressure monitoring within primary care. They found the product via the internet and made contact with Microlife in Scandanavia and then the UK. Following several days of discussions with GPs and clinical staff, the Trust was able to acquire sufficient supplies of the product directly from Scandinavia within 24 hours. Use of the product has increased from the GP Practices initially, through to Community Matrons, District Nurses, Practice Nurses, School Nurses, Community Practitioners and Health Trainers within primary care and acute settings such as the Stroke Unit and the A&E Department. Data has been collected over the 12 month pilot study period, which has shown the clinical impact of the technology has shown an increase in numbers of patients diagnosed with atrial fibrillation and hypertension in primary care.

Both staff and patients provided positive feedback about the technology. There has been changes to clinical practice in adopting this technology, which has improved over the duration of the pilot study. Several care pathways have been amended, improved and validated to incorporate this technology. Auditing has taken place throughout the Trust in the areas who have piloted this product.

Individual services, such as the Stroke Unit, have purchased and negotiated their own supply of this product directly from the company, and GPs will need to fund the continuation of this technology. Microlife provided initial training on the usage of the product and the technology has inspired the Trust to develop and disseminate further ongoing training to staff on Atrial Fibrillation and related issues.

NTAC can provide advice and guidance to implementation sites on project planning, objective setting, reporting and data collection and developing a business plan and a communication plan. NTAC have developed a Generic Adoption Process (GAP), which offers a stepped approach to successful adoption, with all of the necessary tools and resources available. To access this, *www.ntac.nhs.uk*

Potential benefits, challenges, tools, support available can be disseminated through launch events prior to implementation. NTAC are also able to host a dedicated web based forum to facilitate an online shared learning environment.

12 ACKNOWLEDGEMENTS

NTAC would like to thank Phillipa Hobson (NHS Health Check Programme Coordinator, North East Lincolnshire Care Trust Plus) for her clinical input.

13 NTAC SUPPORT

NTAC have developed a Generic Adoption Process (GAP), which offers a stepped approach to successful adoption, with all of the necessary tools and resources available. For access, visit the NTAC website - *www.ntac.nhs.uk* which may be of help if you wish to adopt this technology.