

## Introduction

This business case provides information on the cost effectiveness and clinical use of the dopplex® Ability. It outlines the cost savings that can be made and summarises relevant clinical studies as part of evidence based medicine. This should help a clinician in their request for purchasing a product.

## Background

### The Ankle Brachial Index

For several decades, the ankle brachial index (ABI) has been, and indeed remains, the cornerstone of non-invasive assessment of the arterial status of the lower limb. Its uses are threefold:

- Firstly, as a pivotal, first line diagnostic tool which allows both the identification and quantification of Peripheral Arterial Disease (PAD).
- Secondly, as a means of assessment of lower limb ulceration aetiology and to identify those for whom compression therapy is suitable.
- Thirdly, as a tool for cardiovascular risk assessment; a substantial evidence base has demonstrated a relationship of ABI to adverse cardiovascular events. As a result, both national and international guidelines currently recommend stringent cardiovascular risk reduction strategies for those with  $ABI \leq 0.9$ .



### The Problem Associated With ABI

The ABI has however, been hindered by issues relating to its practicality and the required operator skill for its measurement using the traditional hand held Doppler. The need to rest patients prior to Doppler ABI measurement results in a total procedure time which is often in excess of 30 minutes; this has been repeatedly shown to constitute a major barrier to its use. Furthermore, studies have questioned the accuracy of ABI when undertaken in non-specialist settings such as primary care.

### The Solution

The dopplex Ability addresses such issues via the automatic measurement of limb systolic pressures and calculation of bilateral ABIs. It has revolutionised the ABI process via a significantly reduced test time of just 3 minutes, whilst also negating the need for operator skill as minimal training is required for its use. Its portability makes it amenable for use in all settings including secondary care, primary care clinics, and also the home environment.

## Clinical Applications of the dopplex Ability

### Peripheral Arterial Disease Diagnosis

Within the primary care setting, many patients who are suspected of having intermittent claudication or peripheral arterial disease (PAD) are referred to secondary care vascular clinics based on patient history and clinical examination only. An audit by Poots et al. (2011) of 451 consecutive patients referred to a vascular clinic, revealed that 41% of referrals were deemed inappropriate as subsequent Doppler assessment revealed normal ABIs and normal triphasic Doppler signals. It appears that generic health professionals, particularly those from the primary care environment, often lack confidence and experience in Doppler ABI measurement; indeed, a recent study by Davies et al. (2014a) found that the ABI is infrequently and often incorrectly used in this setting.

The dopplex Ability overcomes the well documented barriers to ABI measurement such as lack of time and inadequate skill and knowledge to undertake the procedure. It provides fast, cost-effective and accurate ABI measurement that can be utilised to confirm or refute a suspected PAD diagnosis, thereby reducing such inappropriate secondary care referrals.

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### Wound Care

Wound care represents a significant burden to the NHS and is estimated to account for around 5% of the NHS budget (Welsh Wound Innovation Centre, 2014). The National Prescribing Centre found that wound related primary care prescribing costs accounts for about 2% of the total prescribing budget (National Prescribing Centre 2009).

The treatment of ulceration of the lower limb accounts for a large proportion of this wound care with an annual cost to the NHS of £168-198 million (2005-2006 costing). Approximately 1-2% of the general population will develop a leg ulcer at some point in their lives (Briggs and Closs, 2006). Furthermore, the burden of leg ulcers is expected to rise as a result of an ageing population and the growing epidemic of diabetes and obesity, which coupled with chronic venous insufficiency, will reduce quality of life and further increase health care costs.

In order to minimise both patient suffering and the financial burden of leg ulceration, it is paramount that treatment is firmly evidence based. Current guidelines universally advocate that patients presenting with a leg ulcer should undergo bilateral ABI measurement at first presentation by trained staff (Wounds UK, 2013; SIGN, 2010; RCN, 2006; NVDV, 2005; RAO, 2004; NZGG, 1999; VEINES, 1999). This enables determination of lower limb wound aetiology and provides a means of identifying patients who require further vascular investigation and/or intervention.

Compression therapy forms the foundation of current venous leg ulcer treatment with a recent Cochrane Review (2012) demonstrating its clinical effectiveness in increasing healing rates.

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However, prior to its instigation, arterial insufficiency, as indicated by an  $ABI \leq 0.8$  (a contraindication to compression) must be ruled out. Guidelines also recommend repeat ABI measurement in the event of ulcer deterioration, lack of healing at 12 weeks duration, ulcer recurrence, ulcer size or when pain suddenly increases, foot colour or temperature change occurs.

Despite these guidelines, studies have demonstrated that patients with leg ulcers frequently have not undergone vascular assessment of the limb via ABI measurement (Drew et al., 2007), and many venous leg ulcers have not been subject to the appropriate compression therapy.

The fast and accurate ABI measurement provided by the dopplex Ability makes a comprehensive and timely vascular assessment feasible for all patients with lower limb wounds. This would contribute to ensuring that all patients receive evidence based care that adheres to current wound guidelines. This, in turn, would result in improved healing rates, improved patient outcomes, and reduced health care costs.

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## **Cardiovascular Disease Risk Assessment**

Both the recently published Cardiovascular Disease Outcomes Strategy (Department of Health, 2013) and NICE Peripheral Arterial Disease Guideline (NICE, 2012) highlight the fact that PAD (as defined by  $ABI \leq 0.9$ ) is a very powerful marker of cardiovascular risk and preventable cardiovascular events (ABI collaboration, 2008):

- People with PAD (symptomatic or not) have a 4 fold increased risk of dying from cardiovascular disease that can be significantly reduced by modifying their risk factors.
- Subsequently NICE recommend the same strategy of cardiovascular risk modification for persons with PAD as for those with Coronary Artery Disease.
- "Failure to diagnose PAD is a missed opportunity to address cardiovascular risk factors and reduce cardiovascular death and morbidity" (DH, 2013, pg 39).

Cardiovascular risk is usually assessed and quantified using scoring systems such as the Framingham Risk Score, or the more recently developed SCORE and QRISK algorithms. However, studies have demonstrated that nearly 25% of cardiovascular deaths occur in individuals believed to possess low cardiovascular risk by traditional risk stratification models (Grondal and Lindholt, 2009). Such individuals can be identified via ABI measurement as data from several studies have demonstrated that abnormal ABI is highly prevalent among individuals not considered to be high risk according to cardiovascular risk algorithms (Dhangana et al., 2011)

Both the Department of Health and NICE recommend the prompt diagnosis and management of PAD to prevent secondary cardiovascular events, improve quality of life and prevent amputation.

The fast and easy ABI measurement provided by the dopplex Ability facilitates screening for subclinical cardiovascular disease by making its incorporation into routine patient consultations feasible.

## Financial Justification

### Reduction of inappropriate secondary care referrals

Audit data shows that General Practices refer, on average, 1 patient per week to a vascular surgeon for assessment for suspected PAD or intermittent claudication. 41% (or 21) of these referrals have been shown to be inappropriate as subsequent assessment reveals normal ABIs and Doppler signals (Poots, 2011).

The current cost of a vascular surgery outpatient appointment (first attendance) is £156 (Payment by Results Tariff, Department of Health, 2014). Use of the Ability, which can be incorporated into routine General Practice consultations, could therefore result in a cost saving of approximately £3,276 per year by reducing such inappropriate referrals (21 x £156).

Some GPs choose to refer directly to the vascular laboratory for diagnostic tests such as Duplex ultrasound scanning, at a cost of £221 per scan (Department of Health, 2014). Again, a reduction of inappropriate referrals, via prior screening of the patient with the Ability, could equate to a cost saving of approximately £4,641 per year (21 x £221).

### Early Diagnosis of PAD

NICE estimates that avoidance of leg amputation via early diagnosis and management of PAD could lead to cost savings of around £32k per person in the first year of care (NICE, 2012), with benefit to patients of 4.576 Quality Adjusted Life Years (QALYs).

### Wound Care

Nurse time is an important component of health care related costs. A wound audit carried out in 2005 suggested that nurse time accounted for 33-41% of the total wound care cost (Drew et al., 2007). The Dopplex Ability can reduce this in 2 ways:

The time taken to measure the ABI is considerably reduced. Assuming that the test was undertaken by a band 5 qualified nurse, the reduction in the total test time of 3 minutes (Ability) versus 30 minutes (Doppler) could equate to a cost saving of approximately £8.10 per ABI measurement procedure (based on the cost of employing band 5 nurse = £18 per hour).

The dopplex Ability also makes it possible for ABI measurements to be undertaken by healthcare support workers, which would further decrease ABI measurement associated costs (making a total cost saving of £8.50 per ABI measurement procedure based on the cost of employing a band 2 nurse = £10 per hour).

(See table opposite for cost calculations)

The dopplex Ability makes vascular assessment for all patients with a lower limb wound more amenable. This, in turn, could lead to improved guideline adherence and improved healing rates. This would lead to decreased nurse time as a result of fewer dressing changes and wound reassessments.

<b>Costs relating to ABI measurement times:</b>	
30 minutes of a band 5 nurse time to undertake a Doppler (band 5 paid approx £18 per hr).	<b>= £9.00</b> approx
3 minutes of a band 5 nurse time to undertake an Ability ABI	<b>= £0.90</b>
3 minutes of a band 2 nurse to undertake an Ability ABI (band 2 nurse paid approx £10 per hr).	<b>= £0.50</b>
If a band 5 nurse uses the Ability rather than a Doppler, this saves: £9.00 - £0.90	<b>= £8.10</b> per ABI measurement
If a band 2 nurse uses the Ability rather than a band 5 nurse using a Doppler, this saves £9.00 - £0.50	<b>= £8.50</b> per ABI measurement

*Note: These costs include 28% overheads. Source: RCN 2015*

## Cardiovascular Risk Assessment

A recent Dutch study utilised a Markov model to evaluate the life time cost effectiveness of selective PAD screening and consequent preventive treatment compared to no screening and no preventive treatment. They concluded that targeted ABI screening and consequent prevention of cardiovascular events using low dose aspirin or clopidogrel in the identified PAD patients is a cost effective strategy resulting in a net saving of €1,504 (£1,253) per patient with 15.66 QALYs gained (Vaidya et al., 2014).

## Clinical patient pathways

Demand for hospital services is rising everywhere in the UK and referrals need to be as appropriate and effective as possible (Evans et al., 2011).

The dopplex Ability can be incorporated into clinical care pathways to reduce inappropriate referrals and lead to prioritisation of clinical services. Tadej (2013) (Tissue Viability and Research Nurse Specialist) proposed a diagnostic pathway for screening patients with risk factors for PAD, which involves health care support workers utilising the dopplex Ability to undertake ABI measurement with qualified clinicians subsequently reviewing results..



## Clinically Proven

### A superior diagnostic modality

A well recognised limitation of the ABI concerns the fact that it becomes inaccurate or non-diagnostic in the presence of arterial calcification (which is associated with advancing age, hypertension, diabetes mellitus and chronic kidney disease). The dopplex Ability provides a print-out of pulse volume recordings for each leg which provides a second line of investigation that not only highlight when this has occurred, but also provide qualitative information with regard to the arterial status of the limb. Use of pulse volume recordings is recommended by both the European Society of Cardiology (Tendera et al., 2011) and the American College of Cardiology/American Heart Association (Anderson et al., 2013) as a second level assessment tool for patients with suspected PAD.

### Clinical Studies

#### **Recent clinical studies have demonstrated the clinical effectiveness and accuracy of the dopplex Ability in a wide range of patient groups:**

Lewis et al. (2014) compared dopplex Ability ABI to Duplex ultrasound scanning for the purpose of PAD diagnosis for 390 limbs (27% diabetic). They concluded that the Ability had excellent correlation with Duplex with a reported accuracy of 88%. ABIs measured ranged from 0.29 – 1.57 indicating good performance at the extremes of the ABI spectrum.

Davies et al. (2014b) compared the dopplex Ability ABI to Doppler ABI in a cardiovascular risk screening study (796 limbs); the Ability was 94% accurate in diagnosing PAD according to the Doppler results. The authors also noted that for 8 cases, although the ABIs were within the normal (0.91 – 1.29) or high (>1.3) range (according to the both the Ability and Doppler), the pulse volume waveforms were abnormal hence suggesting arterial disease. In these cases, arterial calcification had caused artefactually high occlusion pressures which subsequently resulted in inaccurate ABIs. The abnormal PVRs resulted in one such patient being referred to a vascular surgeon where moderate to severe PAD was confirmed, and the patient thereafter underwent successful angioplasty.

## Abbreviations

DH: Department of Health

NICE: National Institute of Clinical Excellence

NVDV: Nederlandse Vereniging voor Dermatologie en Venerologie

NZGG: New Zealand Guidelines Group

RCN: Royal College of Nursing

RNAO: Registered Nurses Association of Ontario

SIGN: Scottish Intercollegiate Guidelines Network

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