

dopplex® ABILITY

Automatic Ankle Brachial Index System

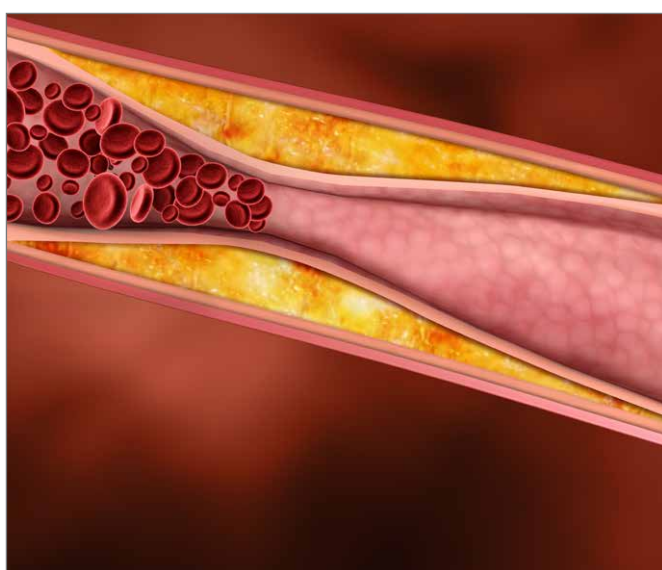
HUNTLEIGH



The Problem



Cardiovascular Disease (CVD) remains the leading cause of global death and disability and was responsible for the loss of 17 million lives in 2008. Early identification of CVD risk factors and disease is vital in securing future advances against the disease.



Cardiovascular Disease

Peripheral Arterial Disease (PAD) is a manifestation of systemic atherosclerosis that is:

- Common - affecting 20% of people aged over 60 years (NICE, 2012)
- Silent - up to two thirds of PAD patients in the community have no symptoms (ESC, 2011)
- Lethal - associated with a 3 to 6 fold increased risk of death from cardiovascular causes (NICE, 2012)

PAD is easily diagnosed and quantified by means of the Ankle Brachial Index (ABI) which is determined by dividing the blood pressure at the ankle by the blood pressure at the arm. If the ABI is ≤ 0.9 it is considered diagnostic of the disease.

It is therefore not surprising that there have been escalating calls for PAD screening which would identify those at increased risk and potentially allow alteration of the progression of disease via secondary risk factor modification. Current guidelines recommend the same strategy of cardiovascular risk management for people with PAD as for those with coronary artery disease (NICE, 2012 and ESC, 2011).

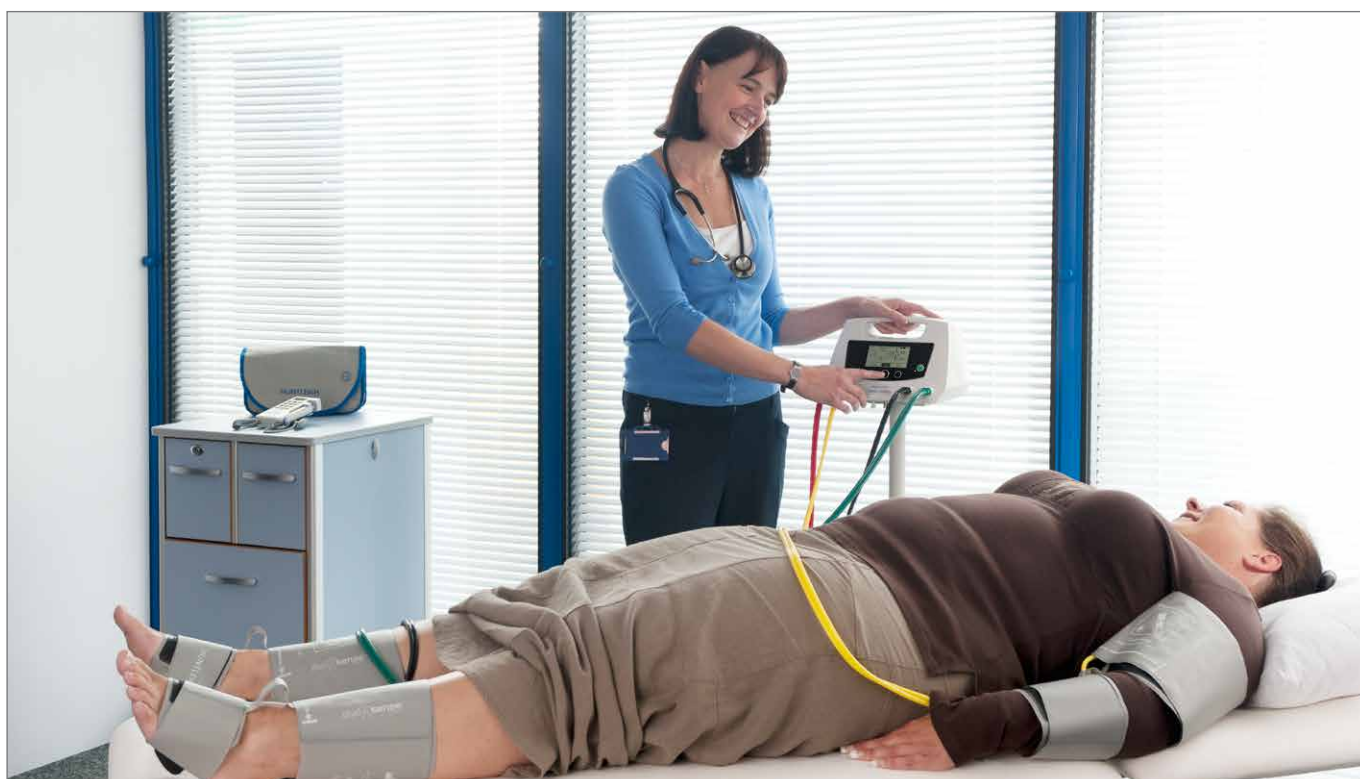


Wound Care - The ABI also has a pivotal role in lower limb wound management:

- It is a fundamental first step in determination of lower limb wound aetiology and a means of identifying patients who require further vascular investigation/intervention.
- International wound guidelines stipulate that an ABI should be undertaken prior to instigation of compression therapy. An ABI of < 0.8 is usually regarded as a contraindication to compression, unless recommended by a specialist wound practitioner, who may instigate a reduced level of compression to be implemented under careful supervision.

The **Solution**

The Dopplex Ability has revolutionised the ABI process and provides automatic, easy, fast and accurate measurements with an immediate printout of results from the integral printer or optional DR4 software package.



Dopplex Ability

Dopplex Ability requires minimal training and provides rapid bilateral ABI measurements in just 3 minutes. Its portability enables measurements to be made more efficiently in the primary care clinic, hospital or patient's home. This can lead to the prioritisation of clinical services by improving clinical pathways.

Where can Dopplex Ability be used?

Wound care – for detecting arterial disease prior to applying compression bandaging
PAD detection – symptomatic or asymptomatic
CHD screening – identifying risk factors

Cost Effective

The Dopplex Ability offers a cost effective solution for the measurement of ABI:

- Rapid measurements in 3mins (Doppler based ABI typically takes 30mins)
- No need to rest the patient
- Can be used by healthcare support staff
- Reduces inappropriate referrals

10 reasons why you need the Ability

1. Extremely easy to use and fully automatic
Minimal training required
2. No need to rest patient for 15mins
Reduces total test time
3. Rapid bi-lateral ABI measurement in 3mins
Simultaneous measurements reduces time
4. ABI can now be undertaken by healthcare support staff
Makes the measurement more cost effective
5. No need to remove patient's socks or tights
Maintains patient comfort and dignity
6. Easy to apply 4 cuff system
Improves patient experience
7. Portable and powered by mains or rechargeable battery
For home or clinical environments
8. Integral printer or PC software for documentation of results and waveforms
Instant hard copy for patient notes and reimbursement
9. Automatic classification of ABI
Reduces operator error
10. Accurate reproducible results over a wide range of ABIs
Clinically proven by recent studies

Dopplex Ability – How Does it Work ?



Our patented two chamber cuffs use duo sense™ pneumatic technology to measure systolic pressures and is based on volume plethysmography and not oscillometric techniques. One chamber is used to occlude the vessel, while the second distal chamber is used to sense the returning signals allowing four limbs to be measured simultaneously.



Ability Technology vs Oscillometric

The Ability is based on volume plethysmography technology which is superior to other automatic systems using the oscillometric method, especially in detecting low ankle pressures. When low ankle pressures are present, pulses are faint or undetectable and the oscillometric technique fails to detect systolic pressures correctly. However, the Ability does not depend upon detectable pulses being present and can therefore measure ankle pressures as low as 55mmHg and ABIs as low as 0.29 (Lewis, 2014).

Systematic reviews (Caruana, 2005 and Verberk, 2012) have shown that automatic ABI systems based on oscillometric technology have poor correlation and sensitivity when compared to Doppler ABIs. It is questionable whether they are suited for applications in wound care and PAD screening.

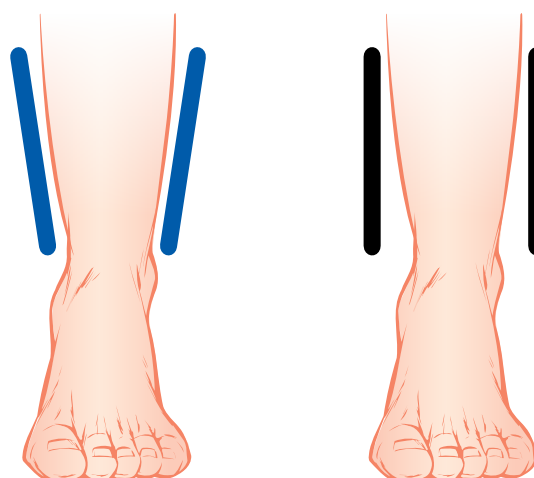
Simultaneous Arm Pressures

The Dopplex Ability is also superior to other ABI automated systems as it measures the blood pressures in both arms before utilising the higher pressure to calculate the ABI. This complies with current guidelines for ABI measurement and calculation published by NICE, ESC, TASC2 and AHA. Automated systems which measure the pressure in one arm only, may miss or incorrectly classify cases of PAD.

Contoured Cuffs

The Dopplex Ability system has specially designed contoured ankle cuffs to give improved accuracy of ABIs. These unique cuffs correctly fit the shape of the ankle providing correct compression of the arteries resulting in superior measurements and enhanced patient comfort. Large adult cuffs are also available to fit large or oedematous limbs.

Duo-sense™ cuff - designed for the ankle



Patented Duo-sense™
contoured cuff

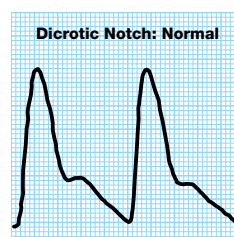
Standard blood
pressure cuff

The Value of PVR Waveforms

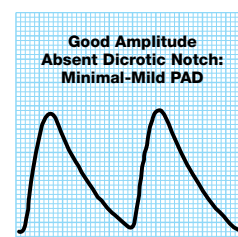
Dopplex Ability also records the ankle pulse volume waveforms which provide pictorial evidence to aid a clinician's diagnosis; this is of particular value in patients who are prone to arterial calcification, such as diabetics.

A well recognised limitation of the ABI concerns the fact that it becomes inaccurate or non-diagnostic in the presence of arterial calcification. PVR analysis provides a second line of investigation that can highlight when this has occurred whilst also providing qualitative information with regard to the arterial status of the limb.

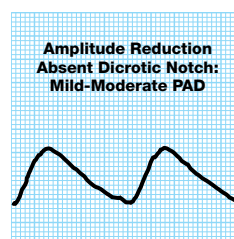
The superior diagnostic capabilities of the Dopplex Ability were highlighted in a recent clinical study by Davies et al. (2014): a patient's ABIs using the Ability were found to be within the normal range (confirmed by Doppler shown on the Ability printout below). However, inspection of the PVRs indicated moderate to severe PAD suggesting that arterial calcification had caused artefactual elevation of the ABIs to within the normal range. The patient was subsequently referred to a vascular surgeon; moderate to severe PAD was confirmed and the patient thereafter underwent successful angioplasty.



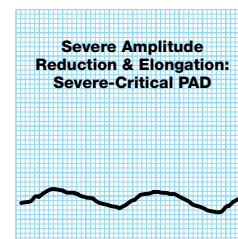
Grade A: Normal



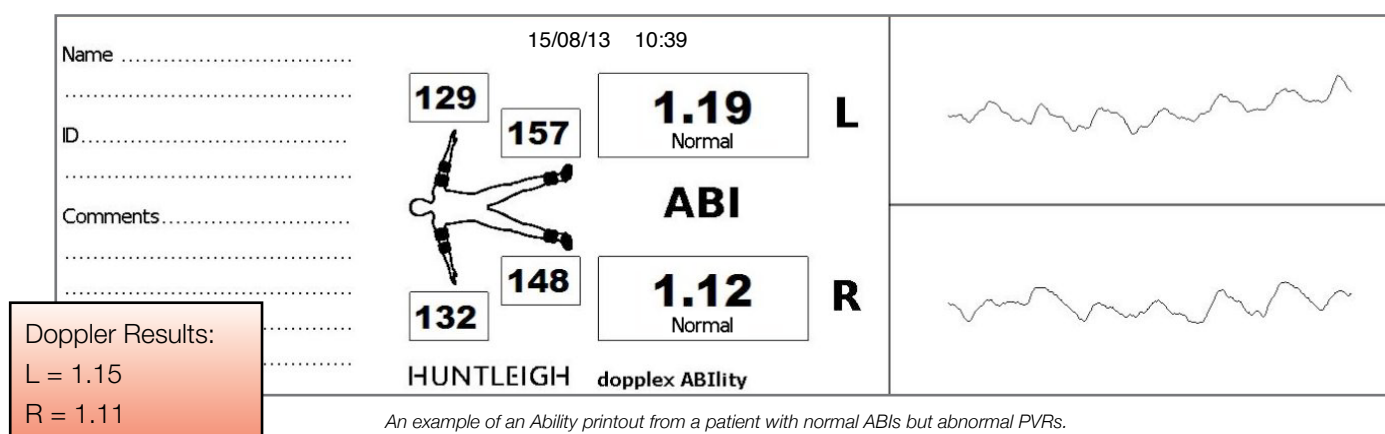
**Grade B:
Mildly Abnormal**



**Grade C:
Moderately Abnormal**



**Grade D:
Severely Abnormal**



Dopplex Ability is the only ABI automated system that is based on Volume Plethysmography and records the PVR waveform.

International Guidelines (ESC, 2011) state that ABI should be undertaken on patients with suspected PAD as a first line test

and PVR waveforms as a second line test especially when the ankle arteries are incompressible or the ABI > 1.4. The Dopplex Ability printout provides both of these requirements on one unique printout to aid the clinician in their diagnosis.

Dopplex Ability – Clinically Proven



Recent clinical studies undertaken by the following authors have shown that Dopplex Ability is effective at measuring ABIs in many patient groups:

Lewis, Hawkins, Barree, Cawley and Dayananda (2011) have shown on 295 limbs (55% diabetic):

- Good agreement between Dopplex Ability and Doppler measurements.
- Dopplex Ability measurement takes significantly less time than Doppler.
- The need to rest the patient is eliminated by the simultaneous cuff inflation of Ability.
- Ability has the potential to be used as a screening tool for PAD in primary care settings.
- Dopplex Ability improves the whole patient experience.
- Minimal training is required due to its ease of use.

Lewis, Mahoney and Evans (2012) have shown on 149 limbs:

- Excellent correlation and good agreement between Ability and Doppler measurements.
- The time taken to perform the automatic ABI tests was significantly quicker than with Doppler.
- PVR waveforms showed good agreement with Doppler waveforms.
- Using an ABI cut off of 0.8, Sensitivity=82%, Specificity=97%, Accuracy=94%.

Lewis (2012) has concluded that:

- Automated ABI reduces operator error, allows a less highly skilled clinician to perform the test, and enables pressures at the arms and ankles to be measured simultaneously which would consequently reduce the test time as patients would not need to be rested.
- Automated ABI systems based on oscillometric technology poorly correlate with Doppler ABI especially in the presence of moderate to severe PAD.
- Ability has been clinically validated over a range of ABIs from 0.4–1.4 and produces a PVR waveform from both ankles which is particularly useful when the ABI is >1.3.
- Ability is ideal for use in general practice for screening and diagnosing PAD and can be easily used by a practice nurse or healthcare assistant.

Tadej (2013) has shown that:

- The introduction of Ability into a new clinical pathway can reduce inappropriate referrals and lead to the prioritisation of clinical services.
- The Dopplex Ability opens up a new chapter in the ABI testing relating to patients “at risk” of developing PAD.

Davies, Lewis and Williams (2014) have shown on 736 limbs:

- 8% had an ABI > 1.3 suggesting possible arterial calcification. Of these, 10% had PAD as indicated by analysis of PVRs.
- PVR waveforms can be easily utilised as an adjunct to ABI measurements to identify patients who may benefit from further vascular assessment and intervention.

Lewis (2014) has shown on 390 limbs (27% diabetic)

- Ability had excellent correlation and agreement against Ultrasound Duplex Scans.
- Overall accuracy of Ability ABI was 88% compared to Duplex.
- Overall accuracy of Ability using PVR waveforms increased to 95% when compared to Duplex Scans.
- Range of ABIs measured with Ability were 0.29 - 1.57.

Davies, Kenkre and Williams (2014) undertook a GP study and reported that:

- Doppler ABI measurements are infrequently and often incorrectly used (42% out of compliance with current ABI guidance).
- Lack of time and inadequate training have been identified as factors associated with this finding.

Documentation and Reporting

DR4 Software Package

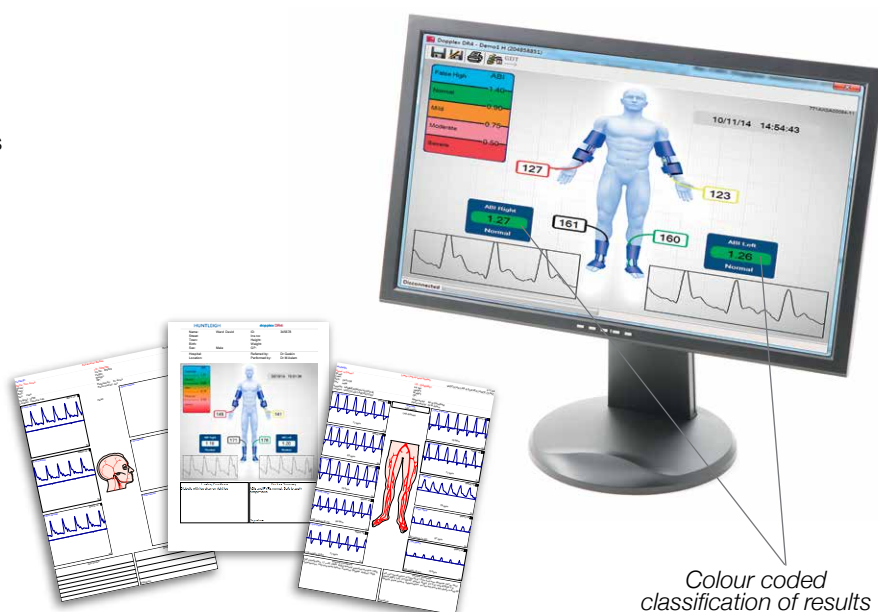
DR4 is a unique vascular reporting software package for use in conjunction with the Dopplex Ability, MD2 and MD200 Doppler units. It enables automated ABIs and Doppler vascular studies to be undertaken and saved in a patient database. It also provides full page documented hard-copy printouts and

pdf file capability for interfacing to Electronic Patient Record Systems.

It is easily installed and does not require any modification to your computer.

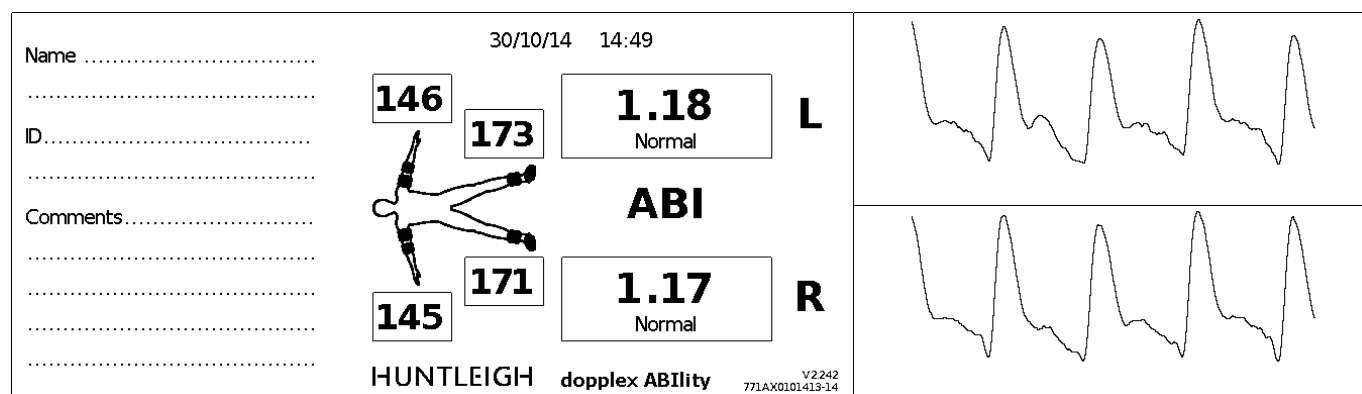
Applications available in version 4.0 include:

- Ability:
 - Automatic ABI studies with PVR waveforms
- Doppler:
 - Upper and lower limb arterial pressure and flow studies
 - Lower limb venous studies
 - Extra-cranial blood flow studies
 - Penile pressure and flow studies
 - Podiatry and chiropody studies
 - Pre/post operative studies
 - Surgical studies with flow calculations
 - Doppler waveform parameter calculations
- Compatible with XP, Vista, Windows 7 and 8
- USB and serial cables included for Doppler



Integral Printer

A complete printout of all results including systolic pressures, ABIs and Pulse Volume waveforms on either thermal paper or adhesive backed label paper is produced by the integral printer, recording time and date automatically. The ankle pulse volume waveforms can be used to aid the clinician's diagnosis especially in patients with medial calcification often found in the diabetic population.



Typical example of Ability printout

Specification

Product Order Code	DA100PB
Printer	Integral 58mm thermal
NiMH Battery	Integral
USB connector	mini
Warranty	1 year
Accessories	Supplied with one set of adult cuffs, two rolls of paper, pack of sleeves, mains cable and training pack for use
Standards Compliance	Complies with IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007). CB report reference E364052-A2-CB-1, EN60601-1-2, 93/42/EEC as amended by 2007/47/EC
Weight	3Kg
Dimensions	Height 160mm, Depth 240mm, Width 260mm

Accessories and Consumables



FIXING PLATE -

Allows easy fixing of the unit to trolley, wall mount and coach bracket.



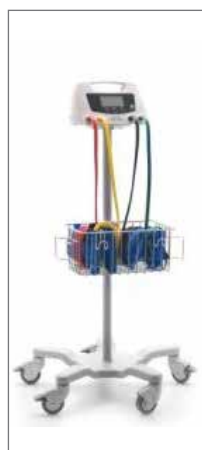
WALL MOUNT -

Multi-swivel wall mount with optional basket and tube management (requires fixing plate).



CARRY BAG -

Lightweight, durable case holds main unit, power cable, cuffs and tubing with additional space for extra cuffs and sleeves (designed to be used in bag).



TROLLEY -

5 Castor adjustable height trolley with tube management and integral basket for storage. (requires fixing plate)



ADULT ARM AND ANKLE CUFFS -

Arm: 22-36cm
Ankle: 18-28cm



SLEEVES -

Disposable sleeves to aid as infection control barrier between cuff and patient limbs.



LARGE ADULT ARM AND ANKLE CUFFS -

Arm: 34-46cm
Ankle: 24-35cm



PAPER -

Standard thermal paper or adhesive backed thermal label paper is available for printing results and waveforms.

References on request

ESC: European Society of Cardiology

AHA: American Heart Association

NICE: National Institute for Health and Care Excellence

TASC2: Trans-Atlantic Inter-Society Consensus

HUNTLEIGH ...performance for life

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VASCULAR ASSESSMENT AND TREATMENT

WELSH WOUND INNOVATION

We would like to express our sincere appreciation to the Welsh Wound Innovation Centre for their assistance and for allowing access to their facility and resources.