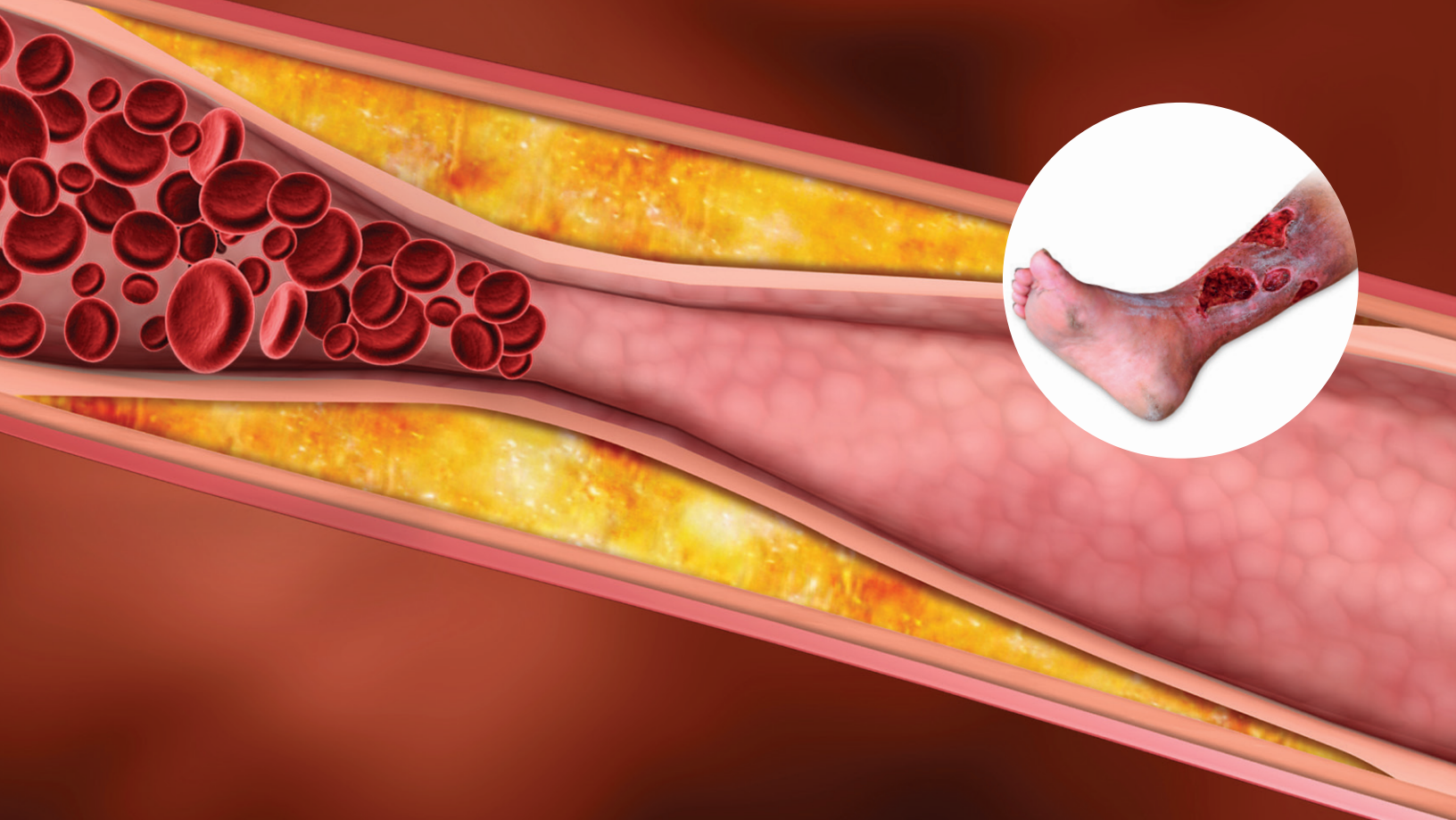




dopplex® ABILITY

AUTOMATIC ANKLE BRACHIAL INDEX SYSTEM



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 older than age 60 (NICE, 2018)
- Silent — up to two-thirds of PAD patients in the community have no symptoms (ESC, 2017)
- Lethal — associated with a three to sixfold increased risk for death from cardiovascular causes (NICE, 2018)

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, 2018 and ESC, 2017).

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 etiology 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 revolutionized the ABI process and provides automatic, easy, fast and accurate measurements with an immediate printout of results from the integral printer or optional Dopplex® DR4 software package.

Complies
with
international
guidelines

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 prioritization 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
- CVD screening — identifying risk factors

Cost effective

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

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

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.



Dopplex Ability technology versus oscillometric

The *Dopplex 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 *Dopplex Ability* does not depend on detectable pulses being present and can therefore measure ankle pressures as low as 55 mmHg and ABIs as low as 0.29 (Lewis, 2016).

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.

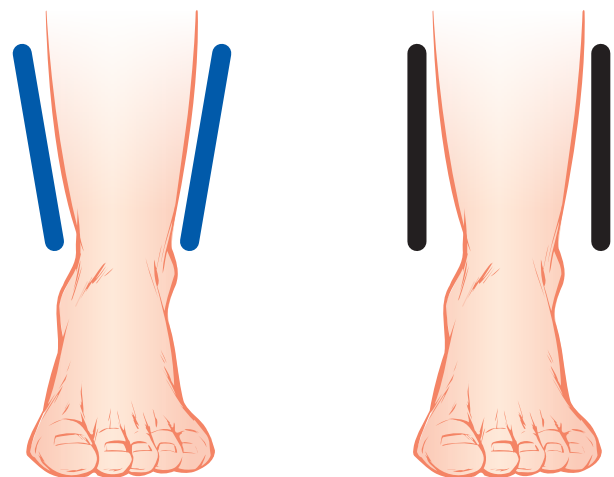
Simultaneous arm pressures

The *Dopplex Ability* is also superior to other ABI automated systems as it measures the blood pressures in both arms before utilizing 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 that measure the pressure in one arm only may miss or incorrectly classify cases of PAD (Vowden and Vowden, 2018).

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 and 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

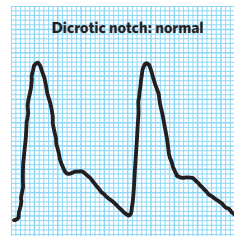
Standard blood
pressure cuff

The value of PVR waveforms

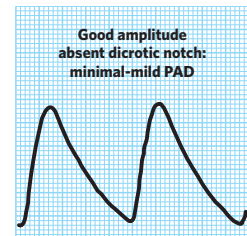
Dopplex Ability also records the ankle pulse volume waveforms which provide pictorial evidence to aid a clinician's diagnosis; this is of particular value in patients who are prone to arterial calcification, such as those with diabetes-

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

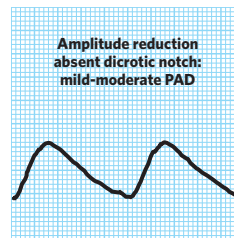
The superior diagnostic capabilities of the *Dopplex Ability* were highlighted in a recent clinical study by Davies et al. (2014): a patient's ABIs using the *Dopplex Ability* were found to be within the normal range (confirmed by Doppler shown on the *Dopplex Ability* printout below). However, inspection of the PVRs indicated moderate to severe PAD, suggesting that arterial calcification had caused artifactual 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.



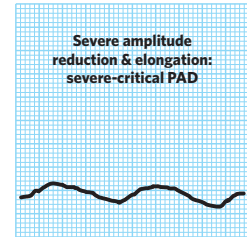
Grade A: Normal



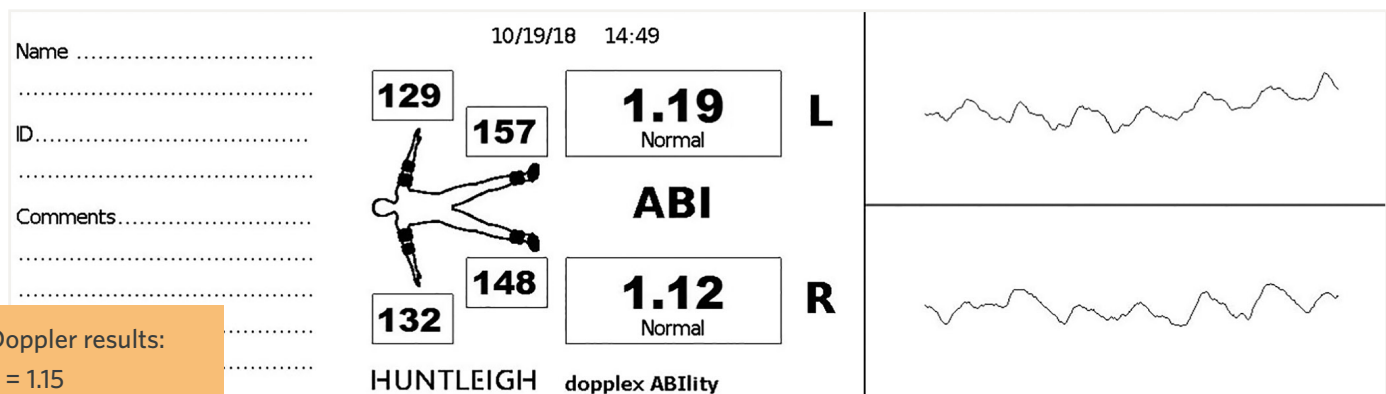
**Grade B:
Mildly abnormal**



**Grade C:
Moderately abnormal**



**Grade D:
Severely abnormal**



*An example of an *Dopplex Ability* printout from a patient with normal ABIs but abnormal PVRs*

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

International guidelines (ESC, 2017) 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 his or her diagnosis.

Dopplex Ability — Clinically proven

Clinically
proven.
Fast, accurate
and easy.

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 (2010) 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 *Dopplex Ability*.
- *Dopplex 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 *Dopplex 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 cutoff of 0.8, sensitivity=82%, specificity=97%, accuracy=94%.

Tadej (2013) has shown that:

- The introduction of *Dopplex Ability* into a new clinical pathway can reduce inappropriate referrals and lead to the prioritization 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 utilized as an adjunct to ABI measurements to identify patients who may benefit from further vascular assessment and intervention.

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.

Aslam and Shaw (2015) compared *Dopplex Ability* and an oscillometric device (MESI) with Doppler and concluded:

- The MESI oscillometric device had poor correlation and sensitivity for detecting PAD. It also had difficulty measuring ABIs below 0.8 and hence could not be reliably used to provide an accurate ABI.
- The *Dopplex Ability* unit had comparable results with Doppler and very good sensitivity and specificity.

Lewis (2016) has shown on 378 limbs (27% diabetic):

- *Dopplex Ability* had excellent correlation and agreement against ultrasound duplex scans.
- Overall accuracy of *Dopplex Ability* ABI was 88% compared to duplex.
- Overall accuracy of *Dopplex Ability* using PVR waveforms increased to 95% when compared to duplex scans.
- Range of ABIs measured with *Dopplex Ability* were 0.29-1.57.

Aslam (2016) compared *Dopplex Ability* to a two-cuff oscillometric device (Watch BP, Office ABI, Microlife) and concluded:

- The *Dopplex Ability* had a good correlation with Doppler, $r = 0.90$, and has the potential to be used in place of Doppler prior to compression bandaging.
- The oscillometric device had poor correlation, $r = 0.61$, and could not be used to provide ABIs prior to compression bandaging.

Documentation and reporting

Dopplex DR4 software package

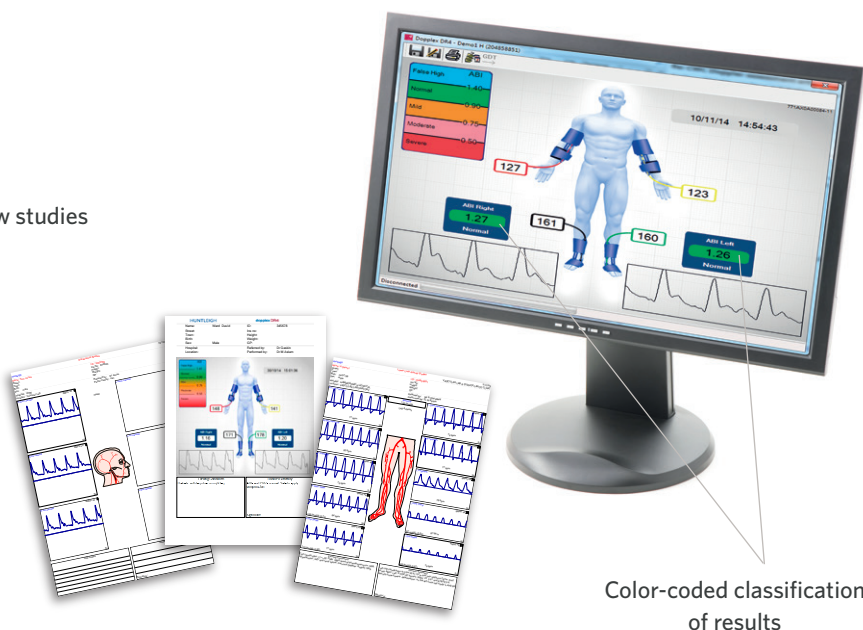
Dopplex DR4 is a unique vascular reporting software package for use in conjunction with the Dopplex Ability and MD2 Doppler units. It enables automated ABIs and Doppler vascular studies to be undertaken and saved in a patient database.

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.

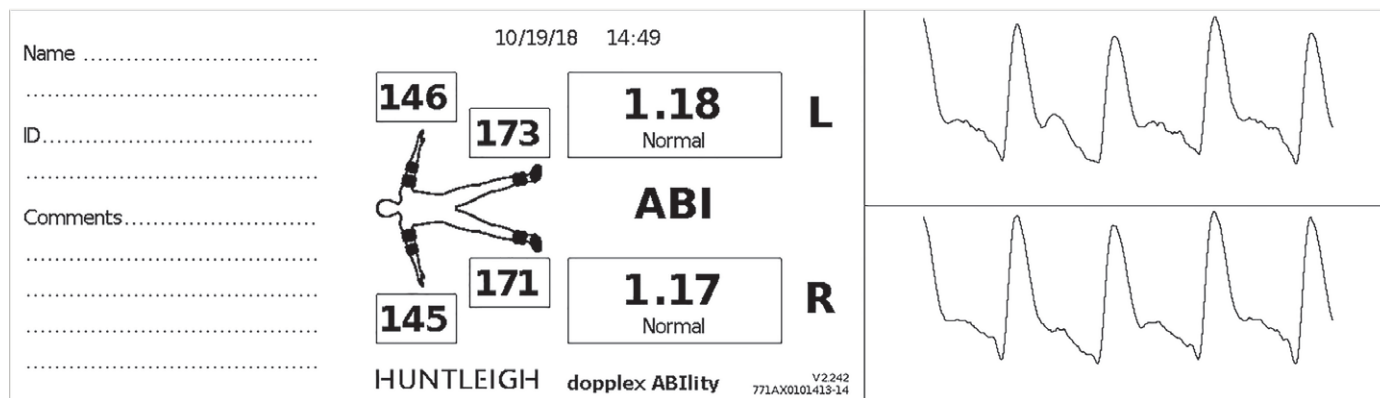
Applications available in version 4.1 include:

- Dopplex Ability:
 - Automatic ABI studies with PVR waveforms
- Doppler:
 - Upper and lower limb arterial pressure and flow studies
 - Lower limb venous studies
 - Extracranial blood flow studies
 - Penile pressure and flow studies
 - Podiatry and chiropody studies
 - Pre- and postoperative studies
 - Surgical studies with flow calculations
 - Doppler waveform parameter calculations
- Compatible with Windows 7, 8 and 10
- 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 patients with diabetes.



Typical example of Dopplex Ability printout

Technical specification

Product order code	DA100PB
Printer	Integral 58 mm thermal
NiMH battery	Integral
USB connector	Mini
Warranty	2-year
Accessories	Supplied with one set of adult cuffs, two rolls of paper, pack of sleeves, power 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	6.6 lbs (3 Kg)
Dimensions	Height 6.2" (160 mm), Depth 9.4" (240 mm), Width 10.2" (260 mm)

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

Five-Caster adjustable height trolley with tube management and integral basket for storage (requires fixing plate).



ADULT ARM AND ANKLE CUFFS

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



SLEEVES

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



LARGE ADULT ARM AND ANKLE CUFFS

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



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



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.

HUNTLEIGH