Dopplex ABllity
Automatic Ankle Brachial Index System
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 is vital in securing future advances against the disease.
The Solution

The Dopplex Ability has streamlined the ABI process and provides automatic, easy, fast and accurate measurements with an immediate printout of results from the integrated 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 or hospital setting. This can aid in prioritizing 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 3 minutes (Doppler based ABI typically takes 30 minutes)
- No need to rest the patient
- Can be used by healthcare support staff
- Reduces inappropriate referrals

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Payoff</th>
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<tbody>
<tr>
<td>Easy to use and fully automatic</td>
<td>Minimal training required</td>
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<tr>
<td>No need to rest the patient for 15 minutes</td>
<td>Reduces total test time</td>
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<tr>
<td>Rapid bi-lateral ABI measurement in 3 minutes</td>
<td>Simultaneous measurements reduce total test time</td>
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<tr>
<td>ABI test can be conducted by support staff</td>
<td>Increased cost effectiveness</td>
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<tr>
<td>Easy to apply four cuff system</td>
<td>Improves patient experience</td>
</tr>
<tr>
<td>Portable and battery powered</td>
<td>Can be used in clinical and home care settings</td>
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<tr>
<td>Integrated printer</td>
<td>Instant hard copy results for patient records and reimbursement</td>
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<tr>
<td>PC software</td>
<td>Instant electronic results for patient records and reimbursement</td>
</tr>
<tr>
<td>Automatic ABI Classification</td>
<td>Reduces operator error</td>
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<tr>
<td>Accurate reproducible results over wide range of ABIs</td>
<td>Clinically proven results increases efficiency and cost effectiveness</td>
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Dopplex ABIlity
How Does it Work?

Our patented two chamber cuffs use Duo-sense™ Pneumatic Technology to measure systolic pressures that is based on Volume Plethysmography, 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 vs 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 Ability does not depend upon detectable pulses being present and can therefore measure ankle pressures as low as 55 mmHg and ABIs as low as 0.29. Systematic reviews 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 automated ABI 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 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 provide improved accuracy of ABIs. These unique cuffs correctly fit the shape of the ankle, thereby 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.
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 recognized 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 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 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 Ability printout below). However, inspection of the PVRs indicated moderate to severe PAD, suggesting 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.

Dopplex Ability is the only automated ABI 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.
Clinical studies undertaken by the following authors have shown that Dopplex Ability is effective at measuring ABIs in several different 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 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 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
- Dopplex 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
- Dopplex Ability is ideal for use in general practice for screening and diagnosing PAD and can be easily used by a nurse or healthcare assistant

**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 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

**Lewis (2014) has shown on 390 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

**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 and MD2 units and 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.

Applications available in version 4.0 include:
- **Dopplex 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

Integrated 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 integrated 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.
Specifications

<table>
<thead>
<tr>
<th>Product Order Code</th>
<th>DA100PB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printer</td>
<td>Integrated 58 mm thermal</td>
</tr>
<tr>
<td>NI-MH Battery</td>
<td>Integrated</td>
</tr>
<tr>
<td>USB Connector</td>
<td>Mini</td>
</tr>
<tr>
<td>Warranty</td>
<td>1 year</td>
</tr>
<tr>
<td>Accessories</td>
<td>Supplied with one set of adult cuffs, two rolls of paper, pack of sleeves, power cable and training pack for use</td>
</tr>
<tr>
<td>Weight</td>
<td>6.6 lbs (3 kg)</td>
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<tr>
<td>Dimensions</td>
<td>Height 160 mm, Depth 240 mm, Width 260 mm</td>
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</table>

Fixing Plate
Allows easy mounting of the unit to roll stand, wall mount and coach bracket.

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

Wall Stand
5 Castor adjustable height roll stand with tube management and integrated basket for storage (requires fixing plate).

Adult Arm and Ankle Cuffs
- Arm: 22-36cm
- Ankle: 18-28cm

Large Adult Arm and Ankle Cuffs
- Arm: 34-46cm
- Ankle: 24-35cm

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).

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

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

References on request
1. NICE: National Institute for Health and Care Excellence ESC: European Society of Cardiology
2. AHA: American Heart Association
3. TASC2: Trans-Atlantic Inter-Society Consensus
4. Lewis, 2014
5. Caruana, 2005

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ArjoHuntleigh is a world-leading provider of integrated products and solutions that improve the lives of patients and residents with reduced mobility. We help healthcare facilities deliver wellness and effective everyday care, early mobilization, safe patient handling, venous thromboembolism prevention, pressure injury prevention, hygiene routines, bariatric care and diagnostics. With extensive knowledge and experience, we strive to improve efficiency and ensure a safer and dignified environment for caregivers and their patients.