

Cuffless Lower Limb Screening

Introduction to the BlueDop Vascular Expert

Arterial plaques compromising blood flow to the lower limbs is the leading cause of amputation worldwide. Early, accurate detection is the first step in treatment and has been shown to be the most effective way to reduce amputation rates up to 80%.

Peripheral Arterial Disease's (PAD) is directly associated with Diabetes Mellitus. For this reason PAD is one of the fastest-growing disease processes in the world, affecting over 230 million people and steadily increasing. Early detection and treatment of PAD in these patients has been shown to reduce the incidence of and the time to heal lower extremity wounds and reduce amputation. **The reduction in time to heal a wound and reduced amputation rates have a direct impact on these patient's 5-year life expectancy.** BlueDop Medical makes it possible for every Emergency Department, Podiatrist Clinic, General Practice clinic, Diabetic Foot Clinics, Community (Critical Access) Clinic, and Wound Care (Tissue Viability) Clinic to assess and triage vascular patients during their first visit. Because of BlueDop's portability **it works everywhere** and because its does not rely on cuffs at the ankle, **it works on everybody**.

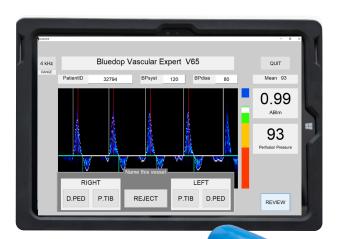
With the rise in diabetes, renal failure, and venous disease, assessing lower extremity blood flow with any cuffed system falls short. Up to 30% of the highest risk patients have incompressible arteries due to calcified vessels or severe lower extremity oedema, making cuffed systems less accurate or unable to produce a reading. **BlueDop overcomes this obstcle with a less than 5-minute cuffless lower limb assessment.**

What Sets BlueDop Apart?

BlueDop assesses both the Dorsalis Pedis and the Posterior Tibial arteries to give the clinician an ABIm and a waveform assessment to stratify patient's lower extremity blood flow.

BlueDop simplifies this into an easy to understand color coded report: No/mild, moderate, or severe disease. Due to BlueDop's revolutionary Technology, an assessment is now not limited by lower extremity oedema, open painful wounds, or calcified blood vessels. And because there is no cuff needed on the patient's ankle, the assessment is **pain-free**.

Additionally, because BlueDop doesn't require a rest period and takes less than 5-minutes to perform, assessing the blood flow to a patient's lower extremity can now be part of the initial encounter vital signs.



BLUEDOP CLINICAL OVERVIEW

ABPIm Explained



BlueDop negates the need for a blood pressure cuff at the ankle and surpasses all the limitations of conventional ABPI by employing a patented technology called "Pressure from Flow".

It does not require a highly skilled Ultrasonography Technician to perform the assessment or a Vascular Consultant to interpret the results. BlueDop's ABPIm is the Ankle mean pressure divided by the Brachial mean pressure.

From a Doppler signal at the ankle, BlueDop Captures and processes the waveform into a mean blood pressure that is then compared to the arm pressure (taken using a simple blood pressure cuff).

Cuffless lower limb screening means that blood flow to any leg can be fully assessed, even in the presence of obese, edematous, diabetic patients and patients with renal failure.

TYPES OF PATIENTS

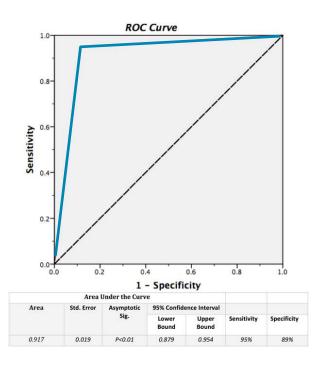
The BlueDop Vascular Expert system can be used on all patient demographics and is especially beneficial in:

- Diabetics
- Pressure Ulcers
- **Renal Impairment**
- Venus Leg Ulceration
- Arterial Leg Ulceration
- Mixed Aetiology Leg Ulceration

COMMUNITY PAD ASSESSMENT TOOLS								
Product Name	Low User Skill Level	Ease of Carrying	>85% Accuracy	No Pain on Assessment	No Risk of Infection	Unaffected by Calcification of Arteries	Unaffected by Edema	No Rest Needed Prior to Assessment
BlueDop ABIm	~	~	~	~	<	~	~	~
Huntleigh ABI	×	~	×	×	×	×	×	×
Huntleigh TBI	×	~	×	~	×	~	~	×
MESI TBI	×	~	×	×	×	×	×	×
Traditional ABI	×	×	×	×	×	×	×	×

Novel Assessment (BlueDop) Device for Detection of Lower Limb Arterial Disease: A Prospective Comparistive Study

Ali Kordzadeh 1, Mekhola Hoff 1, Evripidis Tokidis 1, David H King 1, Tom Browne 1, Ioannis Prionidis 1. JUM, August 2017.



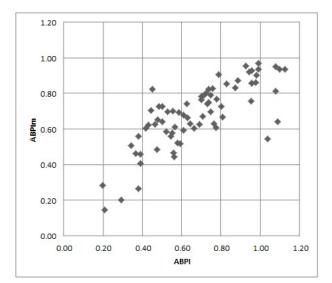
PIVOTAL TRIAL SUMMARY

- Prospective Comparative Study
- 276 Limbs from 166 patients
- BlueDop vs arterial duplex sonongraphy
- 43% of patients were active smokers
- P<.01 with confidence interval
- Sensitivity (True Positive rate) of 95%
- ✓ Specificity (True Positive rate) of 90%
- Overall Accuracy of 92%

BlueDop Cuff free ABIm in Ulcerated Limbs

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Institution: Broomfield Hospital, Chelmsford1, St Georges Hospital2 & Guy's Hospital, London3



CLINICAL ABSTRACT

- Single Center
- 68 Limbs from 45 patients
- BlueDop vs Traditional ABI
- Colour duplex ultrasound as baseline
- Ulcerated limbs could be assessed
- Wound dressings could remain
- Application for Diabetic Foot
- Paired indices by limb in scattergram

Studies & Abstracts

- Novel Assessment (BlueDop) Device for Detection of Lower Limb Arterial Disease: A Prospective Comparative Study. Ali Kordzadeh, MBBS, MSc, MD, VA-BC, Mekhola Hoff, MRCS, PhD, Evripidis Tokidis, MBBS, David H. King, BSc, MSc, Tom Browne, FRCS, Ioannis Prionidis, FRCS, PhD. Journal of Ultrasound in Medicine: official journal of the American Institute of Ultrasound in Medicine, August 2017.
- Monotonic Doppler waveforms: a novel method to detect peripheral arterial disease. Al-Qaisi M, King D, Matson M, Hamady M, Pelling M, Eliahoo J, Gordon F, Nott D. British Society of Interventional Radiology Annual Scientific Meeting, Glasgow, United Kingdom, 4–6 November 2015.
- Assisted Vascular Expert: Smart Triaging with DAVE. King DH, Taylor MG, Nott DM, Al-Qaisi M, Panayiotopoulos Y, Hinchcliffe RJ, Browne T. Doppler. The Society for Vascular Technology of Great Britain & Ireland, 23rd Annual Scientific and General Meeting, Glasgow, United Kingdom, 28 November 2014.
- So you think you know why blood flow is so pulsatile? *King DH, Al-Qaisi M, Nott DM.* The Society for Vascular Technology of Great Britain & Ireland, 22 Annual Scientific and General Meeting, Manchester, United Kingdom, 28th November 2013.
- **Cuff Free ABPI in Ulcerated Limbs.** *King D H, Al-Qaisi M, Taylor M G et al.* The Society for Vascular Technology of Great Britain & Ireland, 21st Annual Scientific and General Meeting, Manchester, United Kingdom, 28 November 2012.

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