



BlueDop and NICE Guidance

NICE GUIDANCE	BLUEDOP
<p>NICE 1.1: There is not enough evidence to recommend routine adoption of automated ankle brachial pressure index (ABPI) measurement devices to detect peripheral arterial disease in people with leg ulcers. They should only be used in the context of research for these people.</p>	<p>BlueDop: Although BlueDop was evaluated in conjunction with automated oscillometry devices, BlueDop is not automated. BlueDop is a doppler-based system that assesses the blood flow from a waveform at the Dorsalis pedis and Posterior tibial vessels. Automated oscillometry-based systems have cuffs and have been shown in this document to have unreliable results, stating that automated devices have good specificity but only moderate sensitivity for detecting PAD; in contrast, BlueDop's Pivotal trial results of 276 limbs showed a sensitivity rate of 95%.</p>
<p>NICE 2.6: Oscillometry-based devices assess oscillations in the vessel wall, and plethysmography-based devices assess blood volume changes. These devices either estimate blood pressure directly or use a pressure cuff to help with the measurement. Diabetes, rheumatoid arthritis, systemic vasculitis, atherosclerotic disease and advanced chronic renal failure can cause calcium build-up and hardening of the arteries, which can make ABPI measurements appear misleadingly normal.</p>	<p>BlueDop: Doppler-based devices use a doppler probe and provide doppler waveform signals as an output. Clinical experts highlighted the value of information provided by doppler waveform signals in these situations. BlueDop is a cuffless lower limb, doppler based system, and therefore is not affected by incompressible arteries or reactive hyperemia, whereas a Toe Brachial Index (TBI) requires a cuff and is sensitive to reactive hyperemia.</p>
<p>NICE 2.8: With traditional ABPI people with leg ulcers need to lie down before and throughout the test. The test takes up to 1 hour and may be painful and uncomfortable for people with leg ulcers.</p>	<p>BlueDop: BlueDop can be performed immediately upon the patient entering the clinic and only takes up to 5 minutes for the full bilateral assessment. BlueDop results are further enhanced due to the patented algorithm for an ABPI_m (mean) which give a sensitivity rate of 95%.</p>
<p>NICE 3.1: A patient expert explained that leg ulcers are unpleasant and painful.A company (BlueDop Medical) also noted that their product was cuffless, which may increase comfort for people having ABPI assessment.</p>	<p>BlueDop: The Blue Doppler probe takes the ankle pressure reading without cuffs. No cuffs = No pain from compression of tender areas of the gaiter region of the limb, which can be further exacerbated by a venous leg ulceration.</p>
<p>NICE 3.5: Automated devices may increase the risk of inappropriate treatment in people with PAD. Clinical experts further noted that NWCSP guidance states that ABPI assessment should be done by someone with expertise to recognise symptoms of and red flags for peripheral arterial disease.</p>	<p>BlueDop: BlueDop takes the ABPI result with the waveform and mathematically translates it into a color-coding risk stratification system of green, amber, and red taking away ambiguity and streamlining patient care. BlueDop also provides the patients perfusion pressure, which in wound care is used to assess the probability of healing.</p>
<p>NICE: Provided guidance reviewing only venous leg ulcers (VLU) and no other lower limb complications.</p>	<p>BlueDop: BlueDop excels at not only Venous Leg Ulcers (VLU), but also Arterial Leg Ulcers (ALU), Mixed Leg Ulcers (MLU), Diabetic Foot Screening (DFS), and pressure ulcers (PU).</p>



Benefits of BlueDop vs Oscillometry-based ABPI

- High specificity (ability to detect PAD)
- Uses Mean Arterial Pressure (averag systolic & diastolic)
- Unaffected incompressible arteries, affecting 30% of PAD
- Painless (no lower limb cuffs)
- Reduction in spread of infectious material
- Provides multiple data points vs. just an ABPI number