CIP SUMMARY

Clinical Investigation code	BVE-01
Title	Clinical Evaluation of the BlueDop Vascular Expert for Assessing Peripheral Arterial Disease
Objectives	Primary objective: Evaluate the clinical equivalence (assessment of accuracy) of BVE as binary result (either presence or absence of significant peripheral arterial disease) compared to arterial duplex ultrasound in a group of patients referred for evaluation of PAD of the lower limbs when performed by a vascular specialist. Secondary objectives: Evaluate the clinical equivalence (assessment of accuracy) of BVE as binary result (either presence or absence of significant peripheral arterial disease) compared to ABPI in a group of patients referred for evaluation of PAD of the lower limbs when performed by a vascular specialist. Assess the safety of the BVE device. Exploratory objectives: Evaluation of the BVE System for clinical performance including time needed to perform BVE, inter-operator variability and number of BVE non-diagnostic tests.
Device Under Investigation	Bluedop Vascular Expert (BVE) Model: Medical BVE100 Set 1: Tablet s/n 1001+ Charger s/n 1001 + Egg s/n 1002
Number of Subjects Required for Inclusion in Clinical Investigation	188 limbs required (188 subjects max., but enrolled number of subjects may be lower if, for certain subjects, both limbs are included in the study).
Clinical Investigation Design	Prospective, multi -center, nonrandomized, open label, single arm study
Primary Endpoint	Evaluation of clinical equivalence of BVE compared to Arterial duplex in the determination of presence or absence of significant PAD
Major Secondary Endpoints	• Evaluation of clinical equivalence of BVE compared to ABPI in the determination of presence or absence of significant PAD. • Evaluation of BVE safety
Subject Follow-up	N/A – No follow-up visits are planned in the study.
Inclusion Criteria	1. Subject must provide written informed consent prior to any clinical investigation related procedure. 2. At least 18 years of age. 3. Referred for duplex ultrasound of the lower limb (s) with suspected or previous history of peripheral arterial disease 4. Must have an ABPI performed as part of the assessment

	5. Able to obtain a brachial cuff blood pressure reading 6. Must have a valid ankle duplex ultrasound measurement at the Posterior Tibial Artery (PTA) and Dorsalis Pedis Artery (DPA)
Exclusion Criteria	1. Subject is currently participating in another clinical investigation or has participated in another clinical investigation in the past 30 days prior to the start of the present study; 2. Pregnant or nursing subjects and those who plan pregnancy during the clinical investigation follow-up period 3. Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness. 4. Inability of refusal to give informed consent. 5. Lower extremity would or compromised skin of the legs that prevents access to the studied arteries.