Oscillometric ankle-arm measurement

Health problem addressed
Peripheral artery disease (PAD) is on the rise in developing countries due to an increase in diabetes mellitus. PAD increases cardiovascular risk and is associated with chronic venous ulcers.

Product description
The device is an automated oscillometric blood pressure monitor designed for clinical use. The device allows for screening of three major cardiovascular risks: PAD, AF, and hypertension. It is equipped with two cuffs for simultaneous double arm measurements and ankle brachial index (ABI) assessment, both of which are recommended screening methods for detection of peripheral arterial disease (PAD). The ABI is automatically calculated by the device. The device can also be used as a regular clinical blood pressure monitor. Since it is also equipped with an atrial fibrillation (AF) detection system, it automatically screens for AF during routine blood pressure measurement.

Developer's claims of products benefits
The procedure to test for PAD is commonly performed with Doppler which requires skill, is liable to observer bias and is time consuming. This device is easy to use, the procedure is conducted faster and is less liable to observer bias. The device can also be used with minimal training.

Suitability for low-resource settings
The device is portable and can also be used as a regular blood pressure monitor. Because of its relative low price and multiple configurations (with and without software), it is suitable to be used in small hospitals or healthcare centers. Once fully charged, many measurements can be taken making the device portable and easy to travel with (e.g. to screen in small villages). The device can diagnose PAD, hypertension and atrial fibrillation in a small amount of time. Only limited training is required.

Operating steps
First, a patient is measured simultaneously at both arms in the supine position to determine the arm with the highest BP. Thereafter, a cuff is placed around the arm and ankle to perform the ankle-arm measurement simultaneously. The ankle-cuff is then placed on the other ankle and the procedure repeated.

Regulatory status
The device is both FDA approved and CE marked.

Future work and challenges
Challenges include making doctors and nurses aware that this device is an automated oscillometric device that can reliably assess ABI, convincing them that general use of this device will improve awareness of peripheral artery disease, and convincing them that cardiovascular screening will lead to the prevention of cardiovascular disease and reduce overall healthcare costs.

Use and maintenance
User: Physician, nurse, technician
Training: Can be conducted in 20 minutes by the organization/company providing the device
Maintenance: None

Environment of use
Settings: Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)
Requirements: The device can work on a rechargeable battery, but also with electricity. When the user has access to a PC, the device can be controlled from the PC and a report produced. The device can be used with and without the PC software which is included free of charge. Ambient temperature for device storage and use should be between 10 and 40 degrees Celsius.

Product specifications
Dimensions (mm): 200 x 125 x 90
Weight (kg): 1.1 (including batteries)
Consumables: None
Life time: 5 years
Shelf life: 10 years
Retail Price (USD): 1100

Other features: Software use, mobile, portable, capital equipment
Year of commercialization: 2008
Currently sold in: Canada, Netherlands, Spain, United Kingdom, United States, and some countries in Asia
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