

The impact of emerging personal technology on BP management:

Clinical accuracy + consumer price + universal access = healthcare revolution

Dr Chris Elliott¹ FREng

Abstract

We expect to carry a powerful computer in our pockets, a computer that takes superb photographs, locates us on the map and manages email. It is easy to forget that it also makes 'phone calls.

The next generation of Smartphones will include clinically-accurate, accredited sensors that measure blood pressure, ECG and much more. 120 million Smartphones are sold annually in India - soon they will all provide actionable medical data.

Beyond the "Vital Signs", the sensors can collect much more data, on cardiac health and other conditions, and share it in real time with nurses, family doctors and specialists, all within the regulatory framework of the Ministry of Health and Family Welfare

Introduction

The measurement of blood pressure is a vital first step to managing hypertension. There is only one reliable, accurate and absolute non-invasive way of measuring blood pressure – occlusion as first described by Riva-Rocci in 1896. No other technique can be used without personal calibration (and frequent recalibration). Although portable and inexpensive occlusion devices are readily available, few people will buy one and use it unless they already know that they have hypertension and need to monitor their BP.

This paper presents a novel measuring device that uses a variant of Riva-Rocci that is small enough and cheap enough to be built in to every mobile 'phone:

- clinically accurate (ISO 81060-2 and ESH 2010)
- compliant with all CE and FDA requirements for a Class IIA and Class II medical device
- in production in factories capable of supplying in the quantities needed for a 'phone (tens to hundreds of millions per year)
- also measures to clinical accuracy:
 - pulse rate
 - blood oxygen
 - body temperature
 - respiration rate
- incorporates a 1-lead ECG that may be used with other sensors in the 'phone

Several 'phone manufacturers are studying it for their future products.

¹ Founder & Director, Léman Micro Devices, Fellow of UK Royal Academy of Engineering, Regulatory barrister, Gray's Inn

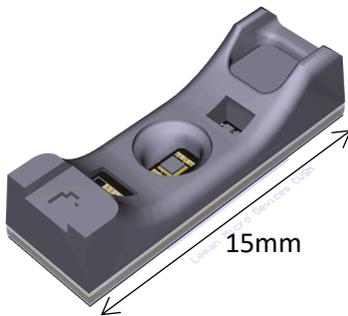
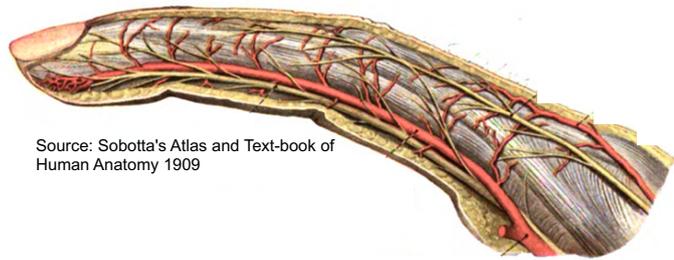
Principle of operation for measuring BP

The Riva-Rocci technique works by applying pressure to the tissue around an artery and finding:

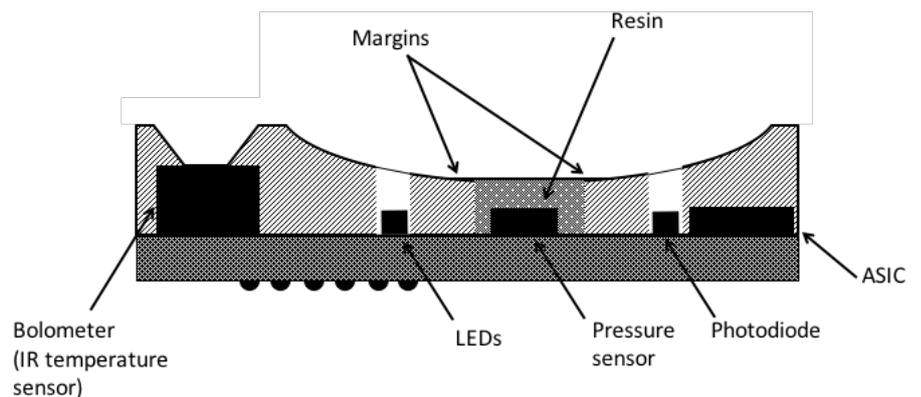
- the highest pressure that does not cause the artery to occlude at any time (DBP)
- the lowest pressure that causes the artery to remain occluded at all times (SBP).

LMD's V-Sensor does the same but unlike a conventional cuff:

- it occludes the arteries of the tip of the index finger
- it instructs the user to press harder or softer to cause occlusion
- it detects occlusion optically, using a pulse oximeter.



The V-Sensor is illustrated to the left and in cross-section below. It is around 15mm long and 5 mm square and curved with a radius of around 15mm, so it fits around the tip of the finger.

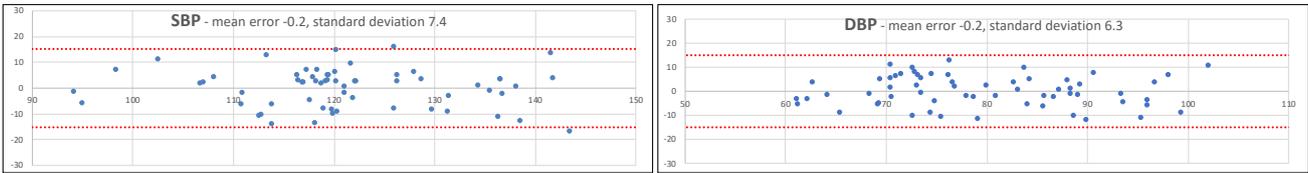


The device has a pressure sensor embedded in a flat epoxy resin that presses on the tip of the finger. The LEDs and a photodiode form a conventional pulse oximeter that illuminates the fingertip. A thermocouple (also called bolometer) measures thermal radiation from the forehead for estimating body temperature. LMD's custom-designed Application Specific Integrated Circuit controls the LEDs and captures and digitizes the data from the photodiode, bolometer and pressure sensor, and communicates with the smartphone.

To measure blood pressure, the user squeezes the phone between his index finger and thumb, with the tip of the index finger resting on the V-Sensor in the back of the phone, as in the drawing to the left. A measurement takes typically 45 seconds and the software takes two such measurements to allow consistency checks.

The accuracy is within the target of ISO 81060-2, which for the principle criterion is a mean error of <5 mmHg and <8 mm standard deviation. The Bland-Altman plots below show the results of a recent development trial.





Other Vital Signs

Pulse rate, SpO2 and respiration rate are measured simultaneously with blood pressure – respiration is derived from the RSA modulation of pulse rate. Body temperature is measured by forehead scanning, with a correction for ambient temperature. All meet the appropriate clinical standards.

Regulatory position

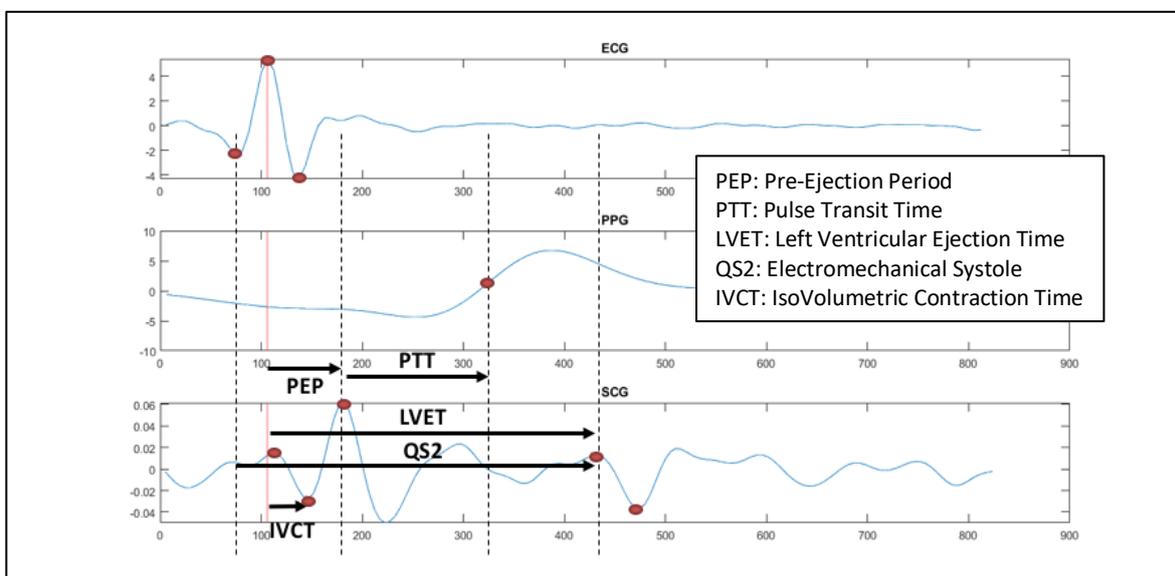
LMD has a QMS accredited to ISO 13485 and formal clinical trials, laboratory tests and documentary assessment of the V-Sensor are scheduled. All have been designed to meet the requirements of the Notified Body to award a CE Mark and the FDA to grant clearance for sale in the USA.

Future growth

The app in the 'phone is very complex and can find much more than just BP. For example, the form of the measured curves allows a reasonable estimate of arterial stiffness and of cardiac output.

The ASIC has the capability to capture a single lead ECG simultaneously with the BP measurement. In order to simplify the process of regulatory approval, this capability has not been implemented in the current prototypes. In the next version, an electrode on the side of the 'phone will touch one hand and the electrically conducting plastic of the V-Sensor body will connect to the fingertip being occluded.

The single lead ECG has considerable diagnostic value and opens up many other possibilities. Most smartphones have very precise accelerometers that can be used to detect the movements of the sternum caused by movements of the heart and its valves. This technique is known as Seismo-CardioGraphy (SCG). The illustration shows typical results obtained with a prototype V-Sensor and shows valve timings relative to the QRS complex.



Beyond the V-Sensor

LMD has a granted patent for a derivative of the V-Sensor that, on paper, makes a truly non-invasive measurement of arterial glucose concentration and also, again on paper, blood alcohol.

Each user is registered and given a unique personal identity code. All of the data from every measurement is saved on LMD's servers, identified only by the code to protect confidentiality. This database will quickly become a valuable research resource and can be re-analysed as new capabilities and insights arise.

Implications

V-Sensor is, at a minimum, a convenient way for people to monitor their BP and other vital signs. It is unobtrusive and, because it is in the 'phone, always with you. But the commercial pressures of the mobile 'phone industry bring another benefit.

India has a massive mobile 'phone market, as well as a growing hypertension issue, but that 'phone market will saturate. The 'phone makers need to persuade their customers to replace the 'phone that they already own, either with a later model of the same brand or a model by a competing brand. They need something to differentiate the new 'phone.

All of the 'phone makers who are studying the V-Sensor say that, if they fit it, it will be in every 'phone that they make. BP monitors now are bought by people who already know that they have hypertension; the V-Sensor puts it literally in the hands of people who have never measured and have no idea of their blood pressure. That will bring a qualitative change in the prevention and treatment of hypertension.