Community Cuff:
Manually-Powered Blood Pressure Cuff for sub-Saharan Africa

BIOMEDICAL ENGINEERING
Carnegie Mellon University

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Executive summary

We propose a **manually-powered, inexpensive, and easy-to-use blood pressure monitoring device** for use by a minimally trained community health worker (CHW) in sub-Saharan Africa (SSA). The focus is to make a device that maximizes usability while minimizing cost. With automatic deflation, intuitive visual cues, a rigid elbow piece, and compact design, the device will be both intuitive and usable by an untrained individual. Additionally, the manual-powering and rechargeable battery will help to minimize cost. The device will help minimally trained CHWs in developing countries accurately monitor blood pressure, so they can identify high-risk individuals who would not otherwise seek treatment before complications arise.

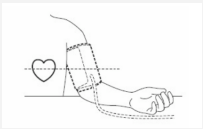
Critical need

High blood pressure (BP) is a major contributor to cardiovascular disease. The prevalence of raised blood pressure is highest in Africa, where it is 46%. Due to socioeconomic health disparities, most health care in SSA is provided by primary care service, particularly CHWs. CHWs are not medically trained and often do not have enough training to accurately use and read blood pressure monitoring devices, so BP readings are either not performed or performed inaccurately due to improper arm placement, inadequate training and poor device deployment.

Description of market

There were 12.1 million individuals with diabetes in SSA in 2010 , many of which had contributing hypertension. A WHO study concluded that 80% of hypertensive patients can be treated by CHWs. Our device could ultimately be used on over 9 million patients. However, with such a critical need, blood pressure monitoring must be accurate. The problem is that the sources of error in the measurement of BP are attributable to both the device and the operator. Because CHWs are minimally trained, they often do not measure BP under proper conditions. Thus, it can be concluded that there is a market for BP devices that ensure accurate readings when taken by even the minimally trained worker.

Novel design



- Rigid elbow piece and SBR forearm sleeve to keep arm at 45 degrees
- Compact design for improved portability
- Automatic deflation
- Intuitive visual cues
- Rechargeable battery charged by walking

Description of design

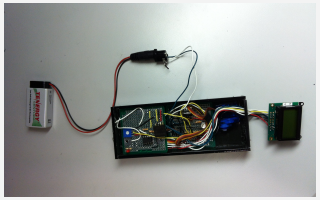
Full cuff design

Rigid elbow piece

Manual pumping

Output

Electronics + casing



Product costs

Part	Cost
SBR sleeve	$0.45
Rigid elbow piece	$0.27
Nylon cuff/bladder	$0.15
Tubing and bulb	$1.36
Electronics	$9.75
Manufacturing	$5.33
Total	**$17.31**

Regulatory pathway

A **510(k)** will be filed in order to approve the device for market. This blood pressure monitoring system is a **Class II device** because it has special controls for which general regulations are not enough to guarantee the safety of the device. Prior to applying for a 510(k), it must be proven that there is substantial equivalence between this device and another predicate device, particularly the non-invasive semi-automatic blood pressure monitor.

Regulation Medical Specialty: Cardiovascular
Review Panel: Cardiovascular
Product Code: DXQ
Submission Type: 510(k)
Regulation Number: 870.1120
Device Class: 2

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