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TELESPIRO: A LOW-COST MOBILE SPIROMETER FOR RESOURCE-LIMITED SETTINGS

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ABSTRACT

Chronic obstructive pulmonary disease (COPD), a disabling combination of emphysema and chronic bronchitis, relies on spirometric lung function measurements for clinical diagnosis and treatment. Because spirometers are unavailable in most of the developing world, this project developed a low cost point of care spirometer prototype for the mobile phone called the "TeleSpiro." The key contributions of this work are the design of a novel repeat-use, sterilisable, low cost, phone-powered prototype meeting developing world user requirements. A differential pressure sensor, dual humidity/pressure sensor, microcontroller and USB hardware were mounted on a printed circuit board for measurement of air flow in a custom machine-lathed respiratory air flow tube. The embedded circuit electronics were programmed to transmit data to and receive power directly from either a computer or Android smartphone without the use of batteries. Software was written to filter and extract respiratory cycles from the digitised data. Differential pressure signals from Telespiro showed robust, reproducible responses to the delivery of physiologic lung volumes. The designed device satisfied the stringent design criteria of resource-limited settings and makes substantial inroads in providing evidence-based chronic respiratory disease management.

Index Terms— mHealth, Spirometer, Point of Care Health Delivery, COPD, Asthma, Lung Volume, Low-Cost, Global Healthcare

1. INTRODUCTION

Wireless network penetration into developing world geographic areas have made mobile health care of interest in resource-limited settings [1]. Mobile phone portability, USB communication, data storage and the ability to support external hardware to collect and store medical data enables a new way to address the growing global burden of chronic disease [2]. Chronic lung disease in the developing world is both staggering and growing as a result of increased air pollution, tobacco use, indoor cooking and workplace exposures. Chronic obstructive pulmonary disease (COPD), which involves destruction of lung elastic recoil with concomitant chronic bronchitis, results from these inhalational exposures and affects 210 million people globally [3].

Spirometry is the foundation of these tests, and the value of using specific spirometric (ventilatory flow) measurements of COPD lung changes is well established, especially when a clinician must distinguish between various aetiologies of chest pain or cough symptoms [4]. A variety of measurments can be obtained and interpreted from spirometry; however the forced expiratory volume in one second (FEV1) divided by the forced vital capacity (FVC) over the entire exhalation, unmasks obstructive changes to the patient's lung parenchyma [5]. The forced vital capacity (FVC) is the difference between the volume in the lungs at full inhalation and the residual volume of air left in the lungs after maximal exhalation. The FEV1/FVC ratio reveals whether there is smaller airway collapse within the lung also known as obstruction. Spirometric lung function tests measured by a spirometer remains a cornerstone of COPD clinical care. Developing a low cost device would thus greatly improve management of COPD, asthma and lung diseases by providing an objective basis to diagnose and manage symptoms.

Several low cost spirometry prototypes in the literature have made advances in design [6] [7] [8] [9]; however none of these prototypes have been used in published clinical trials, do not adhere to international accuracy requirements and cost more that $80 a piece. Implementing spirometry in resource-limited settings requires consideration of price point, sterility, user interface, power supply, dearth of skilled clinicians and ability to generate useful dynamic lung flow data. Per capita health spending in Africa and South Asia is less than $40 per year, far less than the cost of most spirometers [10]. However, even a cost of $15 per spirometer could be justified if amortised over several years given the benefit of keeping chronically ill patients out of the hospital. The dearth of adequate low cost spirometers represents an opportunity for substantial design innovation and for employing more sophisticated signal processing techniques on spirometric data. The aim of this study is to develop a spirometer which connects to a mobile phone and that costs less than $15 while also meeting internationally accepted clinical requirements [11].

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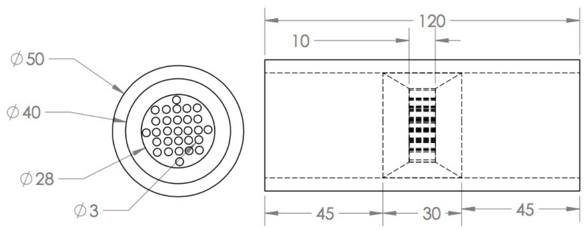

Fig. 1. Specification and views of the Telespiro air tube with the removable resistive disc element (in mm). The tube was designed in Solidworks software (Dassault Systems Corp., France). The inner constriction is $30mm$ in length ($10mm$ long at the narrowest diameter $28mm$ machine lathed with $\pm 0.1mm$ accuracy. The middle side view shows the disc in place in the tube; however it can be easily removed by loosening an external screw. The resistive element disc has 29 evenly spaced $3mm$ holes drilled perpendicularly to the disk's circular surface. The holes drilled into the respiratory tube for connection to a pressure sensor are not shown.

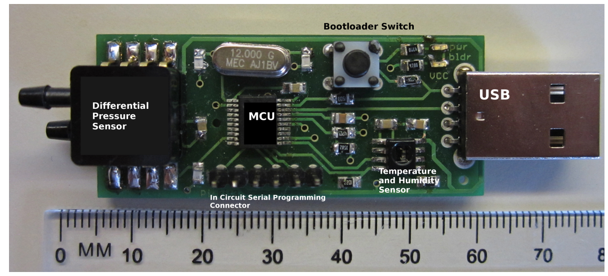

Fig. 2. The Telespiro circuit board. The designed device has the following hardware elements: printed circuit board with back sided voltage ground, male USB 2.0 port, differential pressure sensor (MPXV7007DP, Freescale), a combined digital humidity/temperature sensor (HIH6130, Honeywell), microcontroller (PIC18F14K50, Microchip) with 10 bit analogue to digital conversion (ADC) and an oscillator operating at 12MHz. The two pins on the pressure sensor face the respiratory tube for data collection and are connected to the respiratory tube via fitted PVC sleeves.

2. METHODS

The Telespiro design required several related hardware (breathing tube, electronics) components and software programs (microcontroller, mobile platform) for device operation on a mobile smartphone handset. Pneumotachometric pressure-based flow detection was selected because of its widespread clinical use as well as the intrinsic cost and calibration limitations of ultrasonic and hot-wire anemometry based air flow detection. A symmetric tube design (see figure 1) with a narrow middlge section and removable disc element was machined from medical-grade autoclavable polyoxymethylene. The disc was designed in order to avoid stationary filter elements in the air stream that could collect infectious particulate without possibility of cleaning. This is of utmost importance in the world's poorest areas wherein people suffer from disproportionately high levels of multi drug resistant tuberculosis, pneumonia and parasitic infection.

Because international spirometer standards set by the American Thoracic Society (ATS) and European Respiratory Society (ERS) [11] dictate a maximal airflow resistance value ($150Pa/L/s$) and minimum accuracy for device approval, the diameter of the narrowest part of the tube ($28mm$) and length ($120mm$) was selected to provide resistance of $148Pa/L/s$ as calculated by from the Pouseille equation

$$R = \frac{8\mu\Delta x}{\pi r^4} \tag{1}$$

The small disc (a removable piece of solid material with holes large enough to clean with a small brush, water and bleach or soap) fit into the tube constriction. Similar to a Fleish pneumotachometer, the disc was designed with multiple identical holes to create a sufficient pressure differential.

Collecting spirometric data from the Telespiro tube required portable low cost electronic components connected to and drawing power from a mobile phone. Though a wireless data transmission would enable easier use, Bluetooth transmitter costs made a wireless device prohibitive given per capita health spending in most developing nations. Without a physical connection to the phone, a wireless device would require an external power supply. More importantly, wireless pairing a medical device creates the potential for data loss or incorrect usage. A USB cable was thus required, allowing easy and intuitive connectivity to USB on a phone or computer. The electronics components and sensors were mounted on a custom circuit board (see figure 2) for connection to the machined respiratory tube and phone. The soldered PCB sensor unit was roughly the size of a USB flash drive, small enough to fit inside the designed breathing tube itself for transport. The total bulk manufacturing cost of the final device was estimated at $11.75, which included all Telespiro pieces excluding the phone handset itself.

3. RESULTS

Initial Telespiro testing was performed in MATLAB (Mathworks, Massachusetts, US) on a serial to USB computer interface before implmentation on a mobile platform. Using a sampling frequency of 250Hz, all signal data were recorded from a single subject breathing at tidal volume into and out of the flow tube end with the resistive disc in place. The subject's mouth was positioned on the Telespiro tube inlet. After a few breaths, a maximal respiratory effort was performed as would be done to obtain a FEV1/FVC ratio in clinic. A $-7kPa - 7kPa$ differential pressor sensor was selected because the maximal expiratory maneuver and tidal volumes

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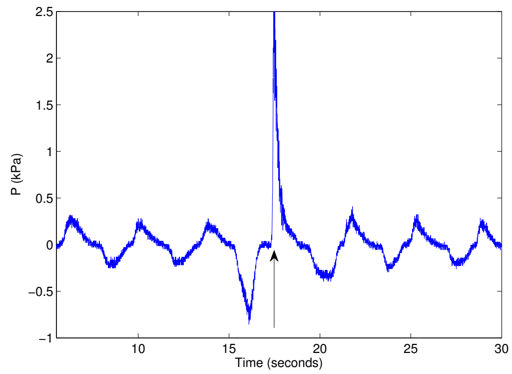

Fig. 3. Unfiltered, detrended respiratory differntial pressure signal from a series of normal breaths with a single maximal expiratory maneuver. The subject breathed directly in and out of the tube. The tracing shows multiple tidal volume breaths with one maximal spirometric expiratory effort. The beginning of the maximal effort is marked with an arrow. Integration of the maximum peak enables FEV1/FVC measurement after volume syringe calibration.

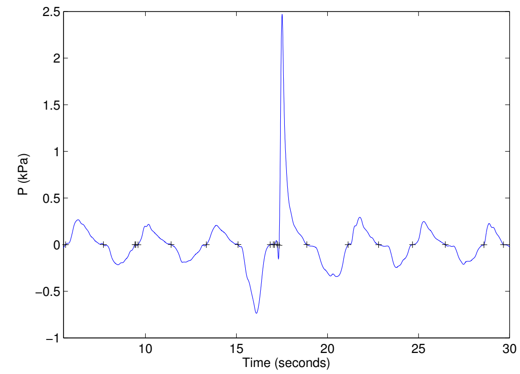

Fig. 4. Filtered pressure signal with detection of changes in respiratory flow direction. The discrete wavelet filtered pressure trace was marked (+) by a zero crossing breath initiation/termination algorithm. Automated detection of proper spirometry technique on the mobile phone provides the possibility of real time user feedback.

were well within the reliable voltage output range. The unfiltered, detrended signal (see figure 3) showed robust pressure signal responses to normal breathing and maximal expiratory maneuvers. Modern differential transducers generally perform well under static conditions with constant applied pressure; however, dynamic common-mode rejection behavior can occur when the applied pressure oscillates in the absence of flow. This small oscillatory noise was observed in the unfiltered signal in figure 3.

The raw Telespiro signal was filtered with a biorthogonal discrete wavelet transform (DWT), a standard approach for filtering nonstationary biomedical signals. The motivation for the choice of five decimation levels and wavelet basis function comes from the manifest similarity of the waveform and frequency bandwidth with the electrocardiogram. The bior3.3 wavelet filter, where each number is the number of low pass and high pass vanishing moments, was used to decompose the signal with a basis function. The denoised original signal was determined to be the 5th approximation of the signal (see figure 4). After filtering, a zero-crossing algorithm was written to detect the beginning and end of each respiratory cycle (marked in figure 4 with black crosses). Each positive crossing point was accepted only if the gradient of the filtered signal exceeded an empirically set threshold. In future work, this will require optimisation over a large number of test examples. The subsequent zero crossing was considered to be the end of the breath if any only if the inter-crossing interval was greater than 0.15 seconds in order to reduce false positive crossings due to noise. Though not precise for every breath, the detection of the inspiration and expiration breath cycles is sufficient to enable detection of a spirometric maneuver.

For mobile device use, the Telespiro components were assembled into a handheld instrument easily operable using two hands with a mobile phone or tablet as shown in figure 5. The USB cord in the device handle connected Telespiro with the mobile device for power and data transmission. For prototype testing, the user held the mobile device in one hand and breathing apparatus in the other.

The Telespiro Android application displayed the pressure differential waveform without flow/volume conversion. The lung function differential pressure trace (and eventually the spirogram as used in clinical practice) was displayed graphically on the tablet as shown in figure 5. Upon connection to the Android device, the Telespiro application opened a real time spirogram graph on the tablet screen as shown in figure 5. The displayed signal required downsampling from the actual signal sampling frequency (250Hz) to show the user the spirogram in real time. The Telespiro Android application with real time signal display, clinical user questions and feedback capabilities is under development.

4. DISCUSSION AND CONCLUSIONS

Telespiro is a novel low-cost spirometer prototype for point of care respiratory testing in resource limited settings. Differential pressure signals from Telespiro showed robust, reproducible responses to the delivery of physiologic lung volumes. The designed device satisfied the stringent design criteria of resource-limited settings, ERS/ATS criteria and will be ready for more robust trials and regulatory approval testing. The substantial improvements made in this project to meet resource-limited setting requirements include: low price point of less than $12 per device in manufacturing with easy to obtain materials for assembly, intuitive (health care worker or

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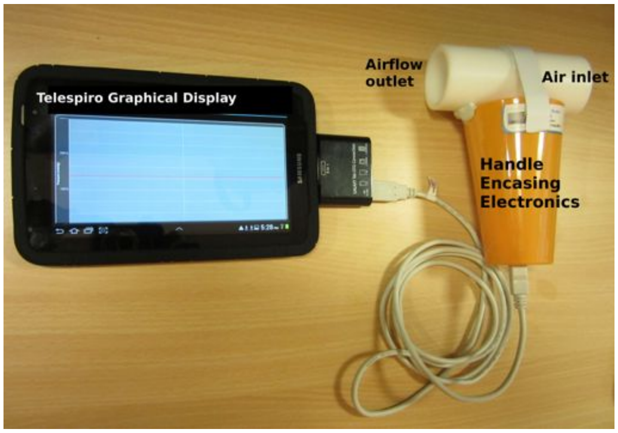

Fig. 5. Telespiro components assembled into a user friendly hand held device shown connected to a 7 inch Samsung Galaxy tablet operating Android 4.0. The tube, PVC sleeving and pressure sensor mounted PCB are fixed within the handle to prevent displacement of the PVC sleeving. A USB cord is plugged into a tablet input adaptor.

patient) two-hand interface for use with a mobile phone, tablet or computer, sterilsation for reuse with minimal equipment (open tube with removable washable piece), full operability without the use of additional AC or DC power supply, small device components that fit into a compact portable instrument, ambient temperature/humidity measurement, no need for replaceable parts such as filters or specialised mouthpieces (user can blow right into the tube itself), operability without need of computer once Android development complete, lossless signal filtering with preliminary breath detection algorithms for generation of clinical data display, opportunity to store of patient lung function data for followup and continuity of care using electronic medical record system built for mobile devices (e.g. Sana Mobile based on OpenMRS).

Further developments of the Telespiro device will be necessary for more broad implementation. These include pressure sensor dynamic calibration, display of flow/volume loops, automated FEV1/FVC calculation, full Android application development (with user feedback and automated calculation of clinical criteria scoring) and more sophisticated volume loop detection algorithms producing accurate spirometric readings while ignoring incorrect spirometric maneuvers. Telespiro's Android application also will have connectivity to a mobile medical record system. Diagnosing and managing patients with obstructive lung disease in the resource-limited setttings would be a substantial benefit over current practice. Patients in developing countries do not have access even to basic access to health data or diganostic equipment. Affordable, novel point of care health technologies like Telespiro with integrated electronics, signal processing, data storage and intuitive user interface aim to address these shortages of devices to reduce the burden of global chronic respiratory disease.

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