The Smartphone as a Medical Device

Assessing enablers, benefits and challenges

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***Abstract*—over one billion smartphones have now been shipped worldwide. These mobile devices feature multi-core CPUs and GPUs, megapixel cameras and an array of sensors. Smartphone sensors can now be processed to diagnose a wide variety of medical conditions including cough detection, irregular heartbeat detection, and lung function analysis. The ability to diagnose ailments in the convenience of patients' homes on smartphones that they already possess could lead to early detection, which could ultimately reduce healthcare costs. This paper reviews state-of-the-art examples, examines the technical issues involved in the use of the smartphone as a medical device, and outlines potential benefits and challenges. A case study of an Android smartphone app for wound detection and healing progress analysis by diabetes patients is also presented.**

Keywords—mobile health; smartphone; medical device

I. Introduction

A medical device is an apparatus or equipment that is used in the diagnosis of a disease or medical condition [19]. Examples include ECG machines, ultrasound machines, x-ray machines and spirometers that measure lung function. As of 2006, the medical device market was valued at over $200 billion. Due to their high cost and specialized usage, medical devices are traditionally used by trained clinicians in clinical settings. Coupled with the appointment-driven scheduling at hospitals today, many patients have to wait days or weeks for access to many medical devices. Even the diagnosis of simple and frequent conditions such as coughs requires a scheduled hospital visit, leading to some late diagnoses.

Modern smartphones such as iPhones and the Samsung Galaxy Android phone are increasingly being programmed with algorithms that allow them to diagnose certain medical conditions such as irregularities in heart rate. In addition to calling and texting features, today's smartphones have sensors such as microphones from which the user's audio signals can be processed to detect coughs, sneezing and allergies [2]. High-resolution cameras in these phones can record videos of users' faces, which can be analyzed to yield the user's heart rate [9]. Essentially, the smartphone's sensors or camera image is sampled, processed into medical information and displayed. The built-in general purpose sensors on smartphones are being used innovatively to mirror the functionality of specialized sensors in medical devices. For example, a Spirometer is a device that is used for measuring lung function. In an actual Spirometer, a patient exhales into a long pipe and the airflow from their lungs is then measured and quantified. In the smartphone implementation of a Spirometer by Larson *et al* [3], the user breathes on the smartphone's built-in microphone and the sounds produced are processed. These examples shows that the finite set of sensors on a smartphone can be used innovatively to diagnose a wide range of ailments. Although processing signals from sensors or images from high-resolution phone cameras can be computationally intensive, Smartphones now have multi-core CPUs and Graphics Processing Units (GPUs) that can facilitate faster computations.

There are many benefits to using a smartphone as a medical device. Globally, over a billion people now own smartphones which increases the reach of smartphone medical device apps. Over 40,000 medical apps have now been deployed on smartphones [16]. The ability to detect ailments early in the convenience of patients' homes can lead to early detections, which ultimately reduces healthcare cost.

In this paper, we review state-of-the-art examples of smartphone apps that diagnose medical conditions that we call medical device smartphone apps. The examples presented are not exhaustive but a diverse set, which demonstrate the versatility of smartphones. We define medical device smartphone apps as software programs that implement algorithms, which sample the manufacturer-installed sensors or phone camera and process their outputs to yield diagnostic medical information that is then displayed to its user. We also identify the underlying technology enablers and outline research challenges. We acknowledge that smartphone medical device apps may require FDA clearance in future after emerging policies and regulations are formalized. However, our focus in this paper is purely technical and issues related to FDA clearance are considered outside the scope of this paper. Our smartphone medical device usage is limited as defined above and does not include the following scenarios:

- *Connecting external sensors or proprietary mobile hardware to smartphones:* For example, the Mobile Sensing Platform (MSP) [1] has a broad range of external sensors (barometer, temperature and humidity) that can be used to augment built-in smartphone sensors. Pamplona *et al* [11] combine proprietary external lenses with the smartphone's touch screen in order to detect eye impairments in its users. We also do not include wearable fitness trackers such as Fitbit [20] and Nike+ [21].
- *Custom modifications to smartphone hardware:* For example Poh *et al* [8] embed proprietary sensors in mobile earphones to read a person's blood pressure.
- *Processing smartphone sensors for wellness purposes:* For example, we do not include wellness smartphone apps such as Ubifit Garden [13], which focus on user activity detection and calorie expenditure but do not diagnose a specific medical ailment.

Our definition does include work in which some smartphone sensor processing steps are sent to a server after which results are returned to the smartphone for display. We

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believe that such work that leverages servers to assist today's smartphone hardware will be feasible on future generations of smartphone hardware as smartphone hardware is evolving fast.

The rest of the paper is organized as follows. Section II outlines enabling smartphone hardware and software trends. Section III briefly describes examples of work in which smartphones have been used as medical devices. Section IV presents a novel application in which diabetic wound images taken with the smartphone camera are analyzed to infer their healing status. Section V outlines benefits of using smartphones as medical devices while section VI outlines research challenges. Section VII discusses relevant health policy and section VIII is our conclusion.

II. EMERGING SMARTPHONE TRENDS

A. *Hardware*

Today's smartphones come equipped with multi-core CPUs and Graphics Processing Units (GPUs) that are capable on many Floating Point (FLOPS) arithmetic calculations per second. For instance, the iPhone 4 has a 1.3 GHz dual-core CPU and a 266 MHz tri-core GPU that is capable of over 25 billion (25.5 GFLOPS) instructions per second. Figure 1 shows the computational speed of the CPU and GPU of various smartphones.

	Nexus 4	Galaxy S III	iPhone 5	Moto Droid
CPU	APQ8064	MSM8960	Apple A6	OMAP 3430
	1.7 GHz **Quad**-core	1.7 GHz **Dual**-core	1.3 GHz **Dual**-core	600 MHz
GPU	Adreno 320	Adreno 225	PowerVR SGX543MP3	PowerVR SGX 530
	OpenGL ES 3.0 **OpenCL 1.2** OpenVG 1.1	OpenGL ES 2.0 OpenVG 1.1	OpenGL ES 2.0 Shader Model 4.1	OpenGL ES 2.0 Shader Model 4.1
	NA **40-45 GFLOPS**	400 MHz **19.2 GFLOPS**	266 MHz (**Tri**-core) **25.5 GFLOPS**	200 MHz (1.6 GFLOPS)

Figure 1: CPU and GPU specifications of smartphones and high performance programming support

A modern smartphone, such as the Samsung Galaxy S3 or the iPhone 5S, comes equipped with a large number of sensors that can sample various physiological signs of users, which can then be processed to detect medical symptoms. For example, the audio signals from a user can be processed to detect coughs. Built-in sensors on the Samsung Galaxy S3 include GPS, accelerometer, gyroscope, dual cameras, microphone, light sensor, magnetic field sensor, orientation sensor, atmospheric pressure sensor and proximity sensor.

B. *Software Trends*

Today's smartphones also come equipped with Software Development kits that allow sensor processing medical algorithms to be implemented in on the smartphone in high level languages such as Java and C. This programmability enables a broad range of diverse medical signal and image processing approaches to be implemented on a smartphone. Additionally, OpenGL ES which is useful for displaying medical charts and graphical information is available on most smartphones. The Open Compute Language (OpenCL), a language that is useful in programming the Graphics Processing Unit (GPU) to implement computationally intense medical algorithms, is also available on Google's new Nexus 4 phone. Finally, many low level image processing and computer vision algorithms such as the Fast Fourier Transform (FFT), which are the building blocks of many medical processing techniques, are now available in mobile image processing libraries, such as fastCV [22], a computer vision library from Qualcomm.

Many mobile diagnosis apps follow a programming paradigm proposed by Lane *et al* [23]. It involves three steps: 1) gather raw sensor data 2) process the raw sensor data into information and 3) display results.

III. EXAMPLES OF SMARTPHONES AS MEDICAL DEVICES

We now survey a range of innovative uses of the smartphone as a medical device. Each work is briefly described. Table I summarizes this research.

1) Spirometer: Spirometry is used in the diagnosis of chronic lung diseases such as asthma and Chronic Obstructive Pulmonary Disease (COPD). During spirometry a patient exhales into an air flow-monitoring device called a spirometer, which measures the air flow from the patient's lungs. A home spirometer costs between $1000 and $4000, which many patients find too expensive. Home spirometers increase the chances of early detection of malfunctioning lungs and reduces health costs. Larson *et al* [3,4] propose a smartphone-based spirometer in which the patient's lung function is measured from samples of the patient's breath on the smartphone's built-in microphone. The captured breath is sent to a server where the air flow over time is integrated and plotted to yield Flow vs Time (FT), Volume vs Time (VT) and Flow vs Volume (FV) plots. Derivative measures used in clinical diagnosis are computed and plotted including Forced Expiratory Volume (FEV_1) which is the volume exhaled in the first second and Forced Vital Capacity (FVC) which is the total expelled volume during the expiration. The most important clinically-reported measures are FEV_1 , FVC and FEV_1 /FVC which quantify air flow irregularities caused by lung ailments such as asthma and COPD.

2) Cough Detection: Coughs are the most common symptom of illnesses [2]. As a result, cough detection is useful in the treatment of a wide spectrum of ailments including the common cold, lung cancer, tuberculosis, pneumonia, asthma, bronchitis and allergies. Larson *el al* [2] propose a method for classifying the raw smartphone microphone audio to detect coughing sounds of smartphone users by employing a machine learning classifier. Physiologically, coughs have four main phases including a) an initial deep inspiration and glottal closure b) contraction of the expiratory muscles against a closed glottis c) a sudden glottis opening with an explosive expiration and d) a wheeze or "voiced" sound. Larson *et al* found that much of a cough's intensity could be classified by analyzing the explosive expiration phase (phase c). The cough sound was transformed to the frequency domain where Principal Components Analysis (PCA) was applied. Finally, the Rain Forest (RF) machine learning classifier was employed to classify the coughing sounds.

3) Listen-to-Nose: Various ailments of the respiratory tract manifest themselves as a runny nose, nasal congestion, or sneezing. Nan-Chen *et al* [12] create a smartphone system to classify nasal conditions within audio from the smartphone's microphone and relate them to user context such as locations in which they occurred. Their system does some processing on the smartphone and the rest on a server. The smartphone client uses an audio recognition machine learning framework to discard sounds such as silence and human speech that are not of interest in nasal ailment detection. Other sounds that may incude respiratory signals are forwarded to a server where a Support Vector Machine (SVM) machine learning framework is used to classify the audio and detect respiratory ailments.

4) Heart Rate Detection: Several authors have applied a technique called Photoplethysmography (PPG) to detect the heart rate of a smartphone user from within a video stream of the user's face [9], finger [5,6], ear lobe or other body part. PPG works as follows: Every time a person's heart beats, more blood is pumped into their face, finger or ear lobe. The slight increase in blood volume causes their face to absorb more light and hence reflect less light. PPG uses the smartphone's camera to track these tiny changes in reflected light from video sequences of a person's face and hence calculate their heart rate. The MIT media lab created Cardiio, an iPhone smartphone app based on these principles [10] that has become one of the top five health applications on the iPhone app market. Poh *et al* [9] present a PPG-based method for detecting a user's heart rate by analyzing video streams of their face captured with the smartphone's front-facing camera. The video stream containing the user's face is separated into Red Green and Blue (RGB) color channels. A computational method called Indpendent Component Analysis (ICA) is then applied to each of the three color channels in order to extract the underlying heart rate signal. Phan *et al* [29] and Kwon *et al* [30] have developed alternate techniques using the phones accelerometer readings (not camera) to detect user heart rates.

5) Melanoma Detection: Melanoma is the most lethal type of skin cancer and causes over 75% of skin cancer deaths [26]. Wadhawan *et al* [27]developed an iPhone app that diagnoses melanoma. Their app works by comparing patterns in images of suspicious lesions on the user's skin user with a library of images of cancerous skin. Their app is based on the 7-point checklist, a set of pattern-matching criteria widely used by dermatologists for melanoma detection.

IV. CASE STUDY: DIABETES WOUND HEALING

7.8% of the US population has diabetes, of which 5-6 million patients have chronic wounds. These wounds currently require frequent hospital visits by patients so that their wounds can be cleaned and inspected by a wound expert. Our research group is developing Sugar, a smartphone diabetes app that diabetes patients can use to track their nutrition, physical activity, weight, and blood glucose levels. Additionally, Sugar has a module that enables patients to assess the healing status of their diabetic wounds [28]. Pictures of the patient's wounds are analyzed by applying a series of image processing steps. The smartphone camera image is first decompressed, and then image segmentation is done using the level set segmentation algorithm in order to detect wound areas boundaries. The relative size of red, yellow and black tissues within the wound area indicates how well the wound is healing. Color segmentation is then performed using k-means clustering to demarcate red, yellow and black regions of the wound, whose relative areas are computed as a measure of wound healing progress. Our algorithm runs at interactive rates (3 seconds) on a Google Nexus 4 smartphone. Figure 2 is a screenshot of the wound analysis module of our Sugar smartphone app.

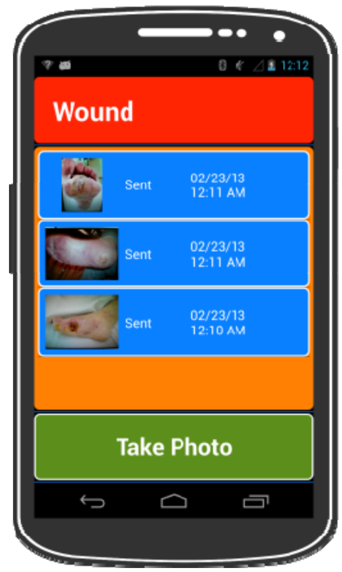

Figure 2: Wound Healing Analysis on Smartphone

I. BENEFITS OF USING SMARTPHONE AS A MEDICAL DEVICE

1) Ubiquitous Deployment: Globally accessible smartphone app markets make apps available to billions of people worldwide. For developers of medical apps, these markets facilitate low cost deployment to a large population of smartphone users. Reduced deployment barriers will make early medical diagnosis ubiquitously accessible, especially for economically disadvantaged populations.

2) Ubiquitous Availability to Users: Users carry their smartphones wherever they go. Recent empirical studies have shown that smartphones are in the same room as their owners over 90 percent of the time [14]. This implies that whenever smartphone owners choose, they can easily diagnose their ailments with medical device apps, a sharp contrast with current health practices wherein patients have to make appointments to see their doctors and wait days or weeks before being attended to.

3) Leveraging new hardware: Smartphone hardware is upgraded often. As smartphones are upgraded, medical apps that were developed for older hardware will run faster and better on new hardware with few modifications.

TABLE I. SMARTPHONE USES AS MEDICAL DEVICES

Ailment/Condition	**Medical Device (Cost)**	**Smartphone (Sensor sampled)**	**Sensor Processing Operations**	**Medical Information Displayed**	**Reference(s)**
Asthma, Chronic Obstructive Pulmonary Disease (COPD), cystic fibrosis	Portable Spirometer ($1000 - $4000)	Smartphone microphone audio	Integration of air flow rate to achieve Flow vs Time (FT), Volume vs Time (VT) and Flow vs Volume (FV) plots	Spirometry graphs	Larson *et al* [3,4]
Cough detection	Leicester Cough Monitor (Academic work)	Smartphone microphone audio	Principal Components Analysis (PCA) of the audio spectrogram followed by Rain Forest (RF) machine learning classifier	Detected coughs	Larson *et al* [2]
Allergic rhinitis and nose-related symptoms (sneezing, runny nose, nasal congestion) of the respiratory tract	Academic papers describing rhinitis detection (N/A)	Smartphone microphone audio	Acoustic recognition model on smartphone and Support Vector Machine classification framework on server	Detected sneezing, coughing and nose blowing	Nan-Chen *et al* [12]
Heart rate detection (including irregular heart rate or atrial fibrillation), blood pressure and blood oxygen saturation	ECG or EKG machine ($1000 - $5000)	Video stream of user's face, index finger or ear lobe	Photoplethysmosgraphy imaging followed by color separation of video stream into RGB color channel. Component Analysis (ICA) is then applied to each of the three color channels to extract the underlying heart rate signal	Heart rate of user (including irregular heart rate)	Poh *et al* [9], J Lee [5,6]
Melanoma detection	Visual diagnosis by dermatologist	Image of suspicious lesions	Texture matching of patterns within images of suspicious lesions on patients skin with a library of images of cancerous skin	Image of skin lesion with 7-point score	Wadhawan *et al* [27]
Wound Analysis for Advanced Diabetes Patients	Silhouette Wound Assessment System ($6450)	Wound Image captured with smartphone camera	Image decompression, segmentation to detect wound boundary, and color segmentation to detect proportion of wound tissue that is healing well	Segmented wound image showing healthy vs unhealthy tissue	Wang *et al* [28]

4) Data for Evidence-based Medicine: Many ailments are mysterious and doctors sometimes grapple with connecting disease symptoms with their causes. An ecosystem of health tracking technologies is emerging. Smartphone-based medical diagnosis in the patient's natural setting, opens up the opportunity to correlate measured physiological readings with other well-being indicators such as activities performed by the user, locations visited, mood and nutrition, which collectively give a more holistic picture and help to quantitatively pinpoint ailment causes. This is the mantra of evidence-based medicine, which is gaining momentum. Smartphone medical measurements can become part of the evidence doctors use to diagnose ailments and to base medical decisions.

II. CHALLENGES IN USING A SMARTPHONE AS A MEDICAL DEVICE

1) Processing complex tasks: While computationally intense algorithms such as Fast Fourier Transforms (FFT) and image processing operations can be computed quickly on today's mobile devices, tasks that have complex memory access patterns such as machine learning are still challenging on smartphones. In some cases, such as Spirometry [3] where time consuming machine learning algorithms are used, the gathered inputs from smartphones are shipped to servers where machine learning algorithms are run. Additionally, processing large input data such as high resolution images, is challenging. Offloading processing to a server or reducing input resolution are viable strategies whenever processing delays are excessive.

2) Battery Consumption: While CPU speed, wireless bandwidth, and computer memory on mobile devices have all increased exponentially over the past two decades, battery capacity has barely doubled in that time. As a result, in most mobile computing applications, available battery power is the most constraining resource [15]. Medical apps usually involve many signal or image processing steps that can drain the phone's battery. If users perceive that a medical app drains their battery, they will reduce its usage and eventually stop using it. Developing energy efficient techniques to prolong the battery life of smartphones running medical apps is crucial.

3) Noisy inputs in mobile environments: Users of smartphone apps will use them while mobile or in outdoor environments –environments that are inherently noisier. Measuring sensor or camera values in these situations can generate erroneous inference. For instance, outdoor or diverse lighting conditions can result in errors in heart rate monitors that detect the level of light reflection from the user's skin. Robust algorithms that compensate for these challenging mobile and outdoor situations will have to be developed.

4) Security: Mobile malware is now prevalent on smartphones and can perform malicious operations such as sending premium texts, accessing sensitive user information and making financial transactions [17]. Recent reports show that malware is already rampant on medical devices [18]. Finding working solutions to these malware and other security breaches is important before smartphone medical device apps can become viable.

III. Health Policy and Regulation of Smartphones for Medical Use

Today's health policy is a reactive one. Patients have to go to hospitalsvwhere their medical ailments are diagnosed and treated. There is currently a push by the Affordable Care Act (ACA) toward a more proactive healthcare policy with an increased focus on prevention, wellness, and diagnosis outside the hospital. Wellness trackers and smartphone medical apps are likely to play an important role in this new healthcare dispensation. The regulation of smartphone medical apps appears imminent [25].

Conclusions

The processing of data from manufacturer-installed sensors or the camera of a smartphone for the purpose of detecting various medical conditions shows some promise. Benefits include low deployment cost and wide distribution. However, many challenges remain, including limitations of current hardware for processing long-running algorithms such as machine learning algorithms. Other challenges include noisy inputs such as spurious accelerometer readings, different indoor/outdoor lighting conditions, and security. Many of these challenges have to be addressed before these medical smartphone apps can receive FDA approval. Based on our experience in developing medical smartphone apps, we believe that three properties which successful smartphone apps must possess [24] are that medical apps must be 1) medically sound 2) patient-centered and 3) technically sound

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