NONINVASIVE ELECTROMAGNETIC SENSORS
FOR CONTINUOUS MONITORING OF HUMAN VITAL SIGNS
AND ASSESSMENT OF LUNG FLUID CONTENT

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ABSTRACT

Noninvasive Electromagnetic Sensors
for Continuous Monitoring of Human Vital Signs
and Assessment of Lung Fluid Content

By: Ruthsenne R. G. Perron

Early detection and continuous assessment of lung fluid content or abnormal fluid buildup in the lungs, is the foundation to the management and treatment of life threatening diseases such as heart failure (HF), and other cardiopulmonary related illnesses. However, available modalities are either invasive and/or not suitable for continuous monitoring. The Cardiopulmonary Stethoscope (CPS) system, aims to address this need. The CPS system is a noninvasive, portable, low-cost device, capable of monitoring vital signs (VS) such as heart rate (HR), respiratory rate (RR), and most importantly, detect changes in lung fluid content. This study is related to the development of the system and its use in clinical trials.

Contributions of this dissertation included the following: (1) A textile based sensor for remote monitoring and wearable applications was developed and clinically validated for HR and RR measurements on healthy patients. (2) Specific Absorption Rate (SAR) measurements were conducted with the DASY4 system
using safety compliance guidelines set forth by the FCC. With 32 mW input power, the measured SAR was 0.4 W/kg which is only 1/4\(^{th}\) of the FCC limit of 1.6 W/kg for 1g avg. (3) HR and RR measurements were clinically validated on seven healthy participants at rest and during exercise. Measured differences between the CPS device and standard hemodynamic devices were all within the limits of agreement, which were calculated using Bland-Altman analysis. (4) In collaboration with the Queen’s Medical Center, sensitivity to changes in lung fluid content was also clinically validated with thirteen heart failure (HF) and eight hemodialysis (HD) patients. Polynomial regression fit of the overall changes in phase was generally in good agreement with the trend of the pulmonary arterial pressure measurements from the HF patients and fluid removed during hemodialysis treatment. HR and RR measurements also showed strong correlation (Pearson – Heart rate (HF): \( r = 0.79, \) p<0.05, (HD): \( r = 0.85, \) p<0.05; Respiratory rate (HF): \( r=0.71, \) p<0.05, (HD): \( r=0.42, \) p<0.05). (5) Simulation and experimental results have shown that sensor placement need to be considered in evaluating tradeoffs between monitoring vital signs and enhancing sensitivity to changes in lung fluid content.
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<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\varepsilon_r$</td>
<td>Relative Dielectric Constant</td>
</tr>
<tr>
<td>$\tan\delta$</td>
<td>Loss Tangent</td>
</tr>
<tr>
<td>$</td>
<td>E</td>
</tr>
<tr>
<td>3D</td>
<td>Three-Dimensional</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>BP</td>
<td>Bandpass</td>
</tr>
<tr>
<td>BPM</td>
<td>Beats Per Minute</td>
</tr>
<tr>
<td>BrPM</td>
<td>Breaths Per Minute</td>
</tr>
<tr>
<td>CENELEC</td>
<td>European Committee for Electrotechnical Standardization</td>
</tr>
<tr>
<td>CHS</td>
<td>Committee on Human Studies</td>
</tr>
<tr>
<td>CP-Stethoscope</td>
<td>Cardiopulmonary Stethoscope</td>
</tr>
<tr>
<td>CPW</td>
<td>Coplanar Waveguide</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>dB</td>
<td>Decibel</td>
</tr>
<tr>
<td>DSP</td>
<td>Digital Signal Processing</td>
</tr>
<tr>
<td>DUT</td>
<td>Device Under Test</td>
</tr>
<tr>
<td>EKG, ECG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>EM</td>
<td>Electromagnetic</td>
</tr>
<tr>
<td>FCC</td>
<td>Federal Communications Commission</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FDTD</td>
<td>Finite Difference Time Domain</td>
</tr>
<tr>
<td>FEM</td>
<td>Finite Element Method</td>
</tr>
<tr>
<td>Fp</td>
<td>Fractional Volume of the Lung Tissue</td>
</tr>
<tr>
<td>GUI</td>
<td>Graphical User Interface</td>
</tr>
<tr>
<td>HD</td>
<td>Hemodialysis</td>
</tr>
<tr>
<td>HF</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>HFSS</td>
<td>High Frequency Structure Simulator</td>
</tr>
<tr>
<td>HR</td>
<td>Heart Rate</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>ICG</td>
<td>Impedance Cardiography</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>IEEE</td>
<td>Institute of Electrical and Electronics Engineers</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>JABSOM</td>
<td>John A. Burns School of Medicine</td>
</tr>
<tr>
<td>LP</td>
<td>Lowpass</td>
</tr>
<tr>
<td>MCU</td>
<td>Microcontroller Unit</td>
</tr>
<tr>
<td>MHz</td>
<td>Megahertz</td>
</tr>
<tr>
<td>MPH</td>
<td>Miles Per Hour</td>
</tr>
<tr>
<td>mW</td>
<td>Milliwatt</td>
</tr>
<tr>
<td>NaCl</td>
<td>Sodium Chloride</td>
</tr>
<tr>
<td>NaN</td>
<td>Not A Number</td>
</tr>
<tr>
<td>OET</td>
<td>Office of Engineering and Technology</td>
</tr>
<tr>
<td>PAC</td>
<td>Pulmonary Artery Catheterization</td>
</tr>
<tr>
<td>SAR</td>
<td>Specific Absorption Rate</td>
</tr>
<tr>
<td>SVM</td>
<td>Support Vector Machine</td>
</tr>
</tbody>
</table>
PAWP .... Pulmonary Arterial Wedge Pressure
PCPTF ........ Pure Copper Polyester Taffeta
PCWP .. Pulmonary Capillary Wedge Pressure
PEC ........ Perfect Electric Conductor
PEP ........ Polyethylene Powder
QMC ....... Queen’s Medical Center
RF ................ Radiofrequency
RMSE .... Root-Mean-Square Error
RR ................ Respiratory Rate
RX, Rx ................ Receiver
SAM ........ Specific Anthropomorphic Mannequin
SAR .......... Specific Absorption Rate
SD ................ Standard Deviation
SMA ........ SubMiniature Version A
SNR .......... Signal-to-Noise-Ratio
SPDT ...... Single Pole Double Throw
STFT ........ Short Term Fourier Transform
TX, Tx ................ Transmitter
WPAN ........ Wireless Personal Area Networks
CHAPTER 1

INTRODUCTION

1.1. Motivation

Pulmonary edema or abnormal/excess fluid accumulation in the lungs [1], [2], has been well established by the medical community as one of the key indicators of several chronic diseases or health conditions such as heart failure (HF) [3], [4].

The lung consists of millions of tiny air sacs called alveoli, which transfer oxygen to the blood vessels in the lungs, also known as capillaries. Under certain health conditions, the heart does not efficiently pump blood out of the lungs [5], which causes pressure to build up in the lungs. This causes the protective barrier between the alveoli and capillaries to break, resulting fluid to leak and accumulate into the gas exchanging air sacs, which develops into pulmonary edema. A diagram of the gas exchange between the air sacs and the capillaries [6] as well as the fluid accumulation in the air sacs [7] are illustrated in Figure 1.1a and b, respectively.
Figure 1.1. (a) Diagram of the gas exchange between the air sacs and the blood vessels [6]. (b) Fluid from the blood vessels leaks into the air sacs resulting pulmonary edema [7].

Pulmonary edema is also applicable in the management of other health conditions such as those shown in Figure 1.2, which includes blood infections [8], acute lung diseases/injuries [9], burns [10] and dehydration [11].

Figure 1.2. Medical conditions such as heart failure, pneumonia, sepsis, and dehydration are also related to pulmonary edema.

The biggest source of expenditures for heart related diseases is hospitalization, which accounts for more than 50% of the $39 billion annual cost of heart failure related expenses [16]. According to [17], 1 out of 4 heart failure patients is at risk for reoccurrence of a second heart failure within 30 days of discharged from the hospital. Since pulmonary edema is commonly used to manage and monitor heart failure, a device that could continuously and noninvasively detect changes in lung fluid in the hospital, and at home, would
significantly affect the healthcare industry. In 2014, interviews conducted through the National Science Foundation I-Corps program with physicians from various medical centers in the U.S., revealed a significant need for a noninvasive, low-cost and continuous monitoring of lung water content. In a personal interview with Dr. Alexander, Director of Cardiology at Veterans Affairs stated “Noninvasive measurement of lung water content is the Holy Grail.” [18]

1.2. Existing Solutions

In the early 1950’s, Haddy et al. has stated that quantification of pulmonary edema or fluid accumulation in the lungs is a difficult problem because the organ is relatively inaccessible and standards of reference are difficult to establish [19]. This statement is still pertinent today as most of the available modalities to measure lung water content are invasive, indirect, and not suitable for continuous bedside monitoring [5]. Examples of these modalities are illustrated in Figure 1.3.

Figure 1.3. Current methods to assess lung water content are either expensive, indirect, invasive or not suitable for continuous bedside monitoring.

Imaging methods such as chest radiography or Computed Tomography (CT) provides estimation of total lung water content [23], but are expensive and
not suitable for continuous measurements [5]. It can only detect 30% increase in lung water content [24]. Patients are also exposed to ionizing radiation. The Swan-Ganz catheter [25] also known as the Pulmonary Artery Catheter (PAC), has been the clinical “gold standard” for fluid management. Catheterization is an invasive procedure that requires highly skilled surgeon and accuracy of results are highly dependent on the proper use of the catheter and interpretation of the results by the operator. The PAC contains a thermistor that measures extravascular lung water (EVLW) which is an estimate of the accumulated fluid content in the interstitial and alveolar spaces in the lungs relative to a person’s weight [26]. This technique is called indicator dilution method [5]. The indicator dilution technique can detect 10%-20% changes in lung water content [27], [28]. A balloon at the tip of the catheter is also used to measure pulmonary capillary wedge pressure (PCWP) or pulmonary arterial wedge pressure (PAWP). Normal range PCWP range is 6 – 12 mmHg, but calibration errors may result pressure deviation of up to ±4 mmHg. PCWP measurements are also highly dependent on interpretation of the operators. A study [29] examined 496 intensivists’ knowledge of appropriate use of the PAC and found that only 67% of the answers were correct. Some studies has also shown that it may result in further complications such as infections, pulmonary artery rupture [30], perforations and increased mortality rates in critically ill patients [31], [32]. Incorrect placement of the balloon tip or air bubbles or blood in the balloon may lead to inaccurate readings during PCWP measurement [33]. Obstruction in the arteries for the indicator dilution method may lead to underestimation of EVLW which results in
false negatives [34], [35], [36]. Unlike an invasive catheter, weighing patients is noninvasive, however, it is an indirect way of measuring lung water content because fluid can accumulate elsewhere in the body, and is therefore inaccurate. According to [37], a weight gain of ≥2 kg over 2 – 3 days would be sufficient basis to alert medical personnel. However, Lewin et al. found that a ≥2 kg weight gain criterion only detected 17% of the HF patients who were clinically unstable or in clinical deterioration [38]. Moreover, weight variability can be attributed to many factors such medication, and salt intake, which may result in false positive or false negative diagnosis [39]. Another method is based on Impedance Cardiography (ICG), which has been extensively studied and in some cases had good correlation with other clinically accepted methods but has yet to achieve broad clinical acceptance. Reviews by [40] and [41], has attributed it to conflicting results, and lack of uniformity in the measurement procedure. In one of the human clinical studies [41] for fluid assessment of heart failure patients using Optivol [22], an FDA approved, implantable ICG based device, researchers concluded that it did not improve patient outcome and increased heart failure readmission rates [41]. It also requires an average of 34 days after implantation to establish a baseline [40] which is not ideal for heart failure patients since 1 in every 4 patient is at risk of readmission within 30 days [17]. In a similar study by Vollmann et al. [42], only 60% of the clinical events with fluid overload was detected. Summary of the limitations, accuracy, sensitivity, accessibility, availability and risks of the existing solutions are included in Table 1.1.
Table 1.1. Summary of existing solutions to measure pulmonary edema.

<table>
<thead>
<tr>
<th>Device/Technique</th>
<th>Accuracy/Sensitivity</th>
<th>Accessibility/ Frequency of Assessment/Risks</th>
</tr>
</thead>
</table>
| Weight Scale (Measures total body weight) [37] - [39] | - Weight gain of ≥2 kg over 2 – 3 days criterion detected only 17% of the patients who were in clinical deterioration  
- Accumulation of fluid may not be in the lungs  
- Weight variability can also be attributed to medication, salt intake causing false negatives or false positives | - Bedside  
- Intermittent  
- No risk                                                  |
| Chest X-Ray (Measures lung density) [23], [24] | - Can only detect 30% increase in lung water content.  
- Materials that fill air sacs such as pus from a lung injury have the same density as water.  
- Not accurate in detecting modest changes in lung water content. | - Limited bedside  
- Intermittent  
- Exposure to ionizing radiation                                  |
| Impedance Cardiography (Measures electrical impedance) [22], [40]- [42] | - Detected only 60% of the clinical events with fluid overload.  
- Factors such as blood volume, blood flow, presence of lung diseases affects accuracy.  
- Optivol requires 34 days to calibrate.  
- Increased hospital readmission rates due to high false positives | - Bedside  
- Continuous  
- Invasive/noninvasive  
- Infection                                                  |
Table 1.1. Summary of existing solutions to measure pulmonary edema. cont.

<table>
<thead>
<tr>
<th>Device/Technique</th>
<th>Accuracy/Sensitivity</th>
<th>Accessibility/ Frequency of Assessment/Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator Dillution Technique using PAC (Measures volume or temperature distribution of an indicator agent) [35], [36], [43] – [50]</td>
<td>- EVLW can only detect 10-20% changes in lung water content. - Operator dependent - Obstruction in the arteries may lead to underestimation.</td>
<td>- Bedside - Intermittent - Invasive - Infection - Ruptured pulmonary arteries - Increase mortality rates in critically ill patients</td>
</tr>
<tr>
<td>PCWP Measurement using PAC (Measures arterial pressure in the lungs) [27], [28], [30] - [32]</td>
<td>- Operator dependent - Interpretation error of data - Normal range PCWP range is 6 – 12 mmHg, but calibration errors may result pressure deviation of up to ±4 mmHg.</td>
<td>- Bedside - Intermittent - Invasive - Infection - Ruptured pulmonary arteries - Increase mortality rates in critically ill patients</td>
</tr>
</tbody>
</table>

1.3. Proposed Technology

To address these needs, our group proposes the Cardiopulmonary Stethoscope (CP-Stethoscope) system, a novel, noninvasive, low-cost, microwave-based system for continuous assessment of vital signs such as respiratory rate (RR), heart rate (HR) and changes in lung fluid content. Diagram of the proposed CP-Stethoscope system is included in Figure 1.4.
Figure 1.4. Cardiopulmonary Stethoscope system, a noninvasive, low-cost microwave-based system for continuous assessment of vital signs such as respiratory rate, heart rate and also changes in lung water content.

The proposed integrated system consists of coplanar waveguide (CPW)-based EM sensors that couples energy into the body [51], [52], [53]. An RF transmission and reflection coefficient subsystem [54] has also been developed to eliminate a bulky network analyzer, and microcontroller unit with DSP capabilities for real time extraction of vital signs from a single microwave measurement. A Bluetooth module was also be implemented to wirelessly transmit data to a mobile device, and a mobile app to enable remote monitoring of patients.
1.4. Previous Work

1.4.1. Animal Experiments

Feasibility of detecting changes in lung fluid content with a microwave based technology was first validated by our group with a patented EM sensor design [51] - [53] through numerical simulation [55], [56] and animal and isolated lung experiments, [57], [58], [59], [60], [61].

Figure 1.5. (a) Results from canine experiment: Changed in phase vs. pulmonary arterial pressure [57] [61]. (b) Results from isolated lung experiment: Changed in phase vs. weight of the lung [60].

These measurements correlated the changes in the phase of the transmission coefficient of the microwave signal across the thorax of the canine with the changes in the pulmonary arterial pressure during blood infusion which is illustrated in Figure 1.5a. Similarly, in Figure 1.5b, sensitivity of the sensor to detect changes with infused blood into the lungs was validated as indicated by a good correlation between the measured changes in the phase of the transmission coefficient of the microwave signal with the increased weight of the isolated lung.
1.4.2. Phantom Experiments

Using a computer controlled manikin to vary the respiratory rate, we also observed that changes in the phase of the reflected and transmitted signal correlated with the respiratory cycle [62]. The number of peaks in the measured microwave signal corresponded with the transition in the inhalation and expiration of the respiratory cycle. Results from these experiments where the respiratory rate varied from 12 to 20 breaths/min are included below in Figure 1.6.

Figure 1.6. Results from computer controlled phantom manikins with variable respiratory rate [62].

In both animal and phantom experiments, the phase of the transmission coefficient have shown the best sensitivity to both changes in fluid content as well as respiratory patterns. However, these measurements required direct and proper alignment of the two sensors across the thorax. Implementation of this configuration in a clinical environment would be difficult and challenging, especially for patients that are not mobile and are in unstable conditions.

Although previous experiments have validated the sensitivity of the sensors to detect changes in lung fluid content in animal, isolated and phantom
lung experiments, clinical viability of the system has not been fully evaluated during human clinical trials.

1.5. Objective

The objective of this study is to address these challenges and further enhance the capabilities of these measurement procedures and help identify parameters that will affect its sensitivity to detect changes in lung fluid content and vital signs.

First, characterization and optimization of the EM sensors will be necessary to ensure proper coupling and further improve sensitivity. Design of the EM sensors will also take into account practical implementation both in clinical and home care use. Second, safety of the patients is paramount in these experiments; therefore, evaluation of the specific absorption rate (SAR) of the EM sensors will also be addressed. Study protocols for human clinical trials will also be developed to acquire permission from an Institutional Review Board (IRB) to conduct human clinical trials. Human clinical trials will include both the validation of human vital signs such as heart rate and respiratory rate in healthy patients and relative changes in fluid content in heart failure and dialysis patients. Lastly, develop a dynamic and accurate 3D human model to better understand propagation characteristics of the sensors in a complex environment such as the human thorax and identify parameters that affect the sensitivity of the sensors to changes in lung fluid content and experimentally validate results on phantom thorax model.
Initial design of the EM sensor was adopted from [52], which is based on a coplanar waveguide (CPW) design. Our previous work investigated several feeding structures of the EM sensors [63] to broaden the operating frequency range to target both in-depth signals (changes in fluid content) and surface signals (vital signs, heart rate and respiratory rate). These were reflection coefficient based measurements using a single EM sensor to eliminate the challenges with the direct front-to-back two-sensor alignment configurations. Initial results were promising but the phase of the reflected signal was significantly weaker than the previous transmitted signal [64]. To address these challenges, a new side-by-side configuration, based on transmission coefficient measurement was investigated. Furthermore, several sensor design and prototypes for safety testing and textile integration were also examined.
2.1. Sensor Configuration

To compare the front-to-back, single sensor, and side-by-side sensor configuration, sensitivity to changes in lung fluid content was simulated on a planar 3D model in High Frequency Structure Simulator (HFSS, Ansys) [65]. HFSS is a 3D full wave EM field simulator that utilizes a full-wave frequency domain electromagnetic field solver based on the Finite Element Method (FEM). Setup of the simulated configurations on a phantom model of skin, lung and muscle tissue is illustrated in Figure 2.1.

Figure 2.1. Sensor configurations which include (a) front-to-back, (b) single sensor, (c) side-by-side to compare sensitivity to changes in fluid content. (d) Material layers in the side-by-side configuration.

Operating frequency of 915 MHz was chosen for these simulations as well as the remaining simulations in this paper since our previous studies [57] have indicated that it was ideal for both surface and in-depth signals. To emulate
changes in lung fluid content from normal to edema state, fractional volume of
blood, lung tissue and air volume in the lung were adjusted and multiplied with
their corresponding permittivity and conductivity using (2.1) and (2.2),
respectively [66]. In equations (2.1) and (2.2), \( F_b \) is the fractional volume of
blood, \( F_p \) for lung tissue and \( F_a \) for air. Electrical properties of the lung were
adjusted from \( \varepsilon_r = 20.6 \) and \( \sigma = 0.42 \text{ Sm}^{-1} \) for normal lung and \( \varepsilon_r = 30.68 \) and \( \sigma = 0.59 \text{ Sm}^{-1} \) for edema lung, respectively [67]. The sensor was coaxially fed and
excited with a waveport at the end of the cable. The sensor was constructed with
PEC material with the center conductor terminated with a 50Ω load.

\[
\varepsilon_{\text{edema_lung}} = F_b \ast \varepsilon_{\text{blood}} + F_p \ast \varepsilon_{\text{tissue}} + F_a \ast E_o \tag{2.1}
\]

\[
\sigma_{\text{edema_lung}} = F_b \ast \sigma_{\text{blood}} + F_p \ast \sigma_{\text{tissue}} \tag{2.2}
\]

As illustrated in Figure 2.1, the magnitudes of all of the reflection
coefficients were below -10 dB which means that all the EM sensors were well
matched and coupled to the skin. Results from these experiments are included in
Table 2.1 which indicated that the single sensor arrangement had the weakest
sensitivity with total of 0.05° phase change from normal to edema lung. Although
the front-to-back configuration had the biggest change in phase at 24.8°, the
side-by-side configuration provided acceptable phase change with 9.1° and does
not require a direct sensor alignment, like the front-to-back configuration.
Therefore, the ideal sensor configuration is the side-by-side.
Table 2.1. Sensor configuration and sensitivity to changes in lung fluid content.

<table>
<thead>
<tr>
<th>Sensor Configuration</th>
<th>∆Phase (deg) from normal to edema lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front-to-Back</td>
<td>24.8</td>
</tr>
<tr>
<td>Single Sensor</td>
<td>0.05</td>
</tr>
<tr>
<td>Side-by-Side</td>
<td>9.1</td>
</tr>
</tbody>
</table>

2.2. Sensitivity and Mutual Coupling Effect

For the side-by-side configuration, one of the parameters used to evaluate the tradeoff between sensitivity and mutual coupling was the distance between sensors. Setup of the experiment is included in Figure 2.2. Similar to the previous section, the permittivity and conductivity of the lung were adjusted to represent normal, half edema, to edema lung. The distances between the sensors varied from 8mm, 10mm, 30mm and 40mm. Three variations of lung states (% of edema: 20% (normal), 30% (half), 40% (full)) for each of the four gaps were simulated, for a total of twelve simulations.

Simulation results of the magnitude and phase of S21 are included in Figure 2.3. Wider gaps between the sensors resulted in a bigger change in the phase of S21. However, it also decreased the signal strength, as seen in the simulation when the gap is 40mm. With 40mm gap, it resulted with the biggest S21 phase change with about 60°. However, S21 magnitude was less than -60
dB compared to -45 dB at 8mm gap. On the contrary, although the 8mm gap resulted in the strongest signal strength, the change in S21 phase was minimal with less than 1°. From these simulations, it can be concluded that the ideal gap that provides the optimum tradeoff between sensitivity and mutual coupling is from 10mm to 30mm.

![Graph showing S21 Magnitude (dB) and Phase (deg) vs. Edema (%) for different gaps](image)

Figure 2.3. Wider distance between sensors increases sensitivity to changes in lung water content but also decreases signal strength.

### 2.3. Wearable Sensor

With advancements of wearable technology [68] such as the Smart Shirt [69] and textile-based Bluetooth antenna [70] in Figure 2.4, this part of the study aims to develop a sensor that is textile based for applications such as dehydration detection for soldiers or first responders in the field.

Three types of conductive textile materials including woven copper fabric, knitted silver-plated fabric, and 2-ply steel thread were investigated to evaluate the effect of the textile material’s conductivity to detect changes lung fluid.
content. Two sewing techniques, *applique*, and embroidery, were also investigated for the fabrication of a robust and structurally stable textile EM coupler and feeding arrangement. Parameters such as coupling efficiency, ease of fabrication, durability and stability of the feeding structure to minimize susceptibility to motion artifacts were the criterions to determine the best suitable sensor.

![Image](a) (b)

Figure 2.4. Example of textile based technology (a) Smart Shirt [69] (b) Textile Bluetooth Antenna [70].

### 2.4. Conductive Materials

Woven copper fabric, knitted silver-plated fabric, and 2-ply steel thread were used to construct the coplanar waveguide (CPW) structure of the EM couplers. These conductive textile materials which are illustrated in Figure 2.5 were chosen for their low resistivity and conformability to the human body. Summary of the surface resistivity and thickness of the conductive materials are included in below.
1. Woven Copper Fabric or pure copper polyester taffeta (PCPTF) fabric [71] is coated with pure copper. It is lightweight and flexible. It is 0.08 mm thick, weighs 80 g/m2 and has a surface resistivity of less than 0.05 Ω/sq.

2. Knitted Silver Plated Fabric [71] is a medical grade fabric with 76% nylon, 24% elastic fiber and has a 99% pure silver coating. It is 0.4 mm thick, weighs 145.8 g/m2 and has a surface resistivity of less than 0.5 Ω/sq. It is also lightweight, flexible and stretchable. The silver plated knitted fabric was used in [70] to construct a textile patch antenna for Wireless Personal Area Networks (WPAN).

3. Steel thread (2-ply) [72] is thin, flexible and sturdy, and has a low surface resistance, 51.2 Ω/m. There are many conductive threads but some are not suitable for embroidery because they are too thick/thin, have low conductivity, or suffer from fraying of the metal fibers.

![Conductive wearable textiles](image)

Figure 2.5. Conductive wearable textiles (a) woven copper [71], (b) knitted silver plated elastic fabric [71], (c) 2-ply steel thread [72].

2.4.1. EM Textile Coupler Simulation

Simulation studies were first conducted to characterize and examine the effect of the textile material’s conductivity to detect changes in lung fluid content. As shown in Figure 2.6, two coaxial-fed EM couplers placed side-by-side on a
simplified multilayer phantom model of the lung and muscle tissue was simulated at 915 MHz. In addition to the conductive textiles, PEC material was also simulated to serve as a baseline.

Figure 2.6. Simulation setup (a) Two couplers constructed with the conductive textiles placed side-by-side on multilayer phantom model. (b) Dimension and electrical properties of the muscle and lung tissues for normal and edema lung state at 915 MHz.

Obtained simulation results showed that all of the conductive textile materials were well coupled to the muscle tissue with S11 and S22 magnitudes less than -20 dB. Measured S21 magnitude ranged between -54 dB to -55 dB for normal lung and -56 dB to -58 dB for edema lung for the various textiles as well as the PEC case. Between the three textiles, the steel thread textile material had the least amount of transmission losses which was 0.2 dB better than copper and 1.1 dB better than silver as shown in Table 2.2. The measured phase change of the transmission coefficient from the normal lung to lung with edema for all textiles and PEC case, ranged between 18 to 20 degree. These simulation results have shown that all three conductive textiles were well matched to the
phantom muscle tissue, have minimal difference in transmission losses, and are sensitive to changes in lung water content.

Table 2.2. Summary of the coupling efficiency of the conductive textiles.

<table>
<thead>
<tr>
<th>Conductive Material</th>
<th>Lung State</th>
<th>S11 Magnitude (dB)</th>
<th>S22 Magnitude (dB)</th>
<th>S21 Magnitude (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEC (Benchmark)</td>
<td>Normal</td>
<td>-21.4</td>
<td>-21.5</td>
<td>-54.2</td>
</tr>
<tr>
<td></td>
<td>Edema</td>
<td>-21</td>
<td>-20.9</td>
<td>-57.1</td>
</tr>
<tr>
<td>COPPER</td>
<td>Normal</td>
<td>-21.5</td>
<td>-21.3</td>
<td>-54.2</td>
</tr>
<tr>
<td></td>
<td>Edema</td>
<td>-20.9</td>
<td>-21.1</td>
<td>-57.1</td>
</tr>
<tr>
<td>SILVER</td>
<td>Normal</td>
<td>-21.8</td>
<td>-21.9</td>
<td>-55.3</td>
</tr>
<tr>
<td></td>
<td>Edema</td>
<td>-21.4</td>
<td>-21.5</td>
<td>-58.4</td>
</tr>
<tr>
<td>STEEL</td>
<td>Normal</td>
<td>-21.4</td>
<td>-21.5</td>
<td>-54</td>
</tr>
<tr>
<td></td>
<td>Edema</td>
<td>-21</td>
<td>-21</td>
<td>-56.9</td>
</tr>
</tbody>
</table>

In fact, it may be worth noting that even 1% change in lung water content, which resulted in 1.6 degree change in the phase of the transmission coefficient, is easily detectable in these simulations. This agrees with results found in earlier animal studies [57] where 1% change in lung water content corresponds to 1 degree phase change of the transmission coefficient. Sensitivity to 1% change in lung water content is far more significant compared to a chest x-ray (sensitive after 30% lung water increase [23]), and EVLW measurements which can detect 10-20% lung water changes [49]. Furthermore, a study [46] with critically ill patients has shown that there is about 65% mortality rate in patients with EVLW levels greater than 15 ml/kg compared to 33% in patients with less than 10 mL/kg. Essentially, the 5ml/kg difference increases mortality rate from 33% to
65% for a critically ill patient. At this point however, clinical significance of sensitivity to 1% change in lung water content has not been investigated which may or may not be needed as fluctuation could be as much as 1-3%. On the other hand, availability of a device like the CP-Stethoscope that is capable of continuous monitoring and sensitive to small changes is critically important for effective intervention and remediation, as it may detect early and progressive stages of diseases such as heart failure.

2.4.2. Fabrication Techniques

Two sewing techniques, applique’ and embroidery, were examined for the fabrication of the coupler prototype.

2.4.3. Applique

The woven copper and knitted silver plated textiles were fabricated using a sewing technique called applique’ where the conductive textile is attached to a supporting nonconductive fabric structure (cotton and felt). Method of attachment can include fabric glue, sewing or the usage of adhesive sheets. However, the attachment procedure must not affect the electrical properties of the conductive textile. Similar to the results found in [70], fabric glues are stiff and brittle and the glue should not seep through the fabric, otherwise it would change the surface resistivity of the conductive textile. Consequently, the conductive textile coupler was sewn to the stabilizer fabrics.
2.4.4. Embroidery

The second fabrication technique was embroidery of the conductive 2-ply steel thread. Using an embroidery machine, pattern of the CPW geometry was sewn onto the support fabrics, with 20 mm long, 1 mm separation, and 0-degree angle stitches. The stitch parameters can be further adjusted to determine the appropriate thread density, which affects the coupling efficiency and rigidity of the structure. S-parameter results from side-by-side measurement in a human experiment and using three different types of textile EM couplers, and schematic diagram of the material layers including the conductive textile material, supporting fabrics and the coaxial feed are shown in Figure 2.7. Preliminary results of the S11 magnitude when the sensors were placed on a human skin were below -10 dB.

Figure 2.7. S-parameter results from side-by-side measurement in a human experiment and using three different types of textile EM couplers, (a) copper fabric (b) silver fabric and (c) embroidered steel thread, (d) schematic diagram of the fabricated coupler layers. [73]
2.4.5. Feed Options

Several feeding structures such as microstrip, stripline and direct coaxial feed described in our previous studies [63] were considered. The microstrip and stripline fed ports were beneficial due to their planar structure; however, the transition to the SMA connector was difficult to stabilize and was prone to breaking. Consequently, all of the couplers were fed using coaxial cables. The cable was sewn to the back of the coupler and conductive thread was used to connect the center conductor of the cable to the center transmission line of the EM coupler. Since the center conductor of the cable is thin and is prone to breaking, a fabric patch with adhesive was ironed and sewn on the back of the coupler to minimize the twisting of the cable.

2.4.6. Preliminary Experimental Results and Observations

Initial observations indicated that fabrication of the EM coupler using the applique’ technique was not ideal. The conductive fabrics had to be sewn precisely, otherwise, uneven tension on the fabric will result in wrinkling or folding, making it difficult to maintain proper structure or shape of the coupler. Fraying around the edges of the coupler also occurred causing the conductive fabric to unravel and eventually separate from the supporting fabrics. On the contrary, the embroidered pattern of the coupler was accurate, and shape was maintained and secured on the supporting fabrics.
The fabricated EM couplers were placed on a human torso and all of the conductive textiles were found to be well matched (<-10 dB) to the human skin. However, when using these different textile materials in typical human measurements, these textiles have different physical characteristics e.g. folding and wrinkling that makes it difficult in some material to maintain stable contact with the human skin. It is these physical implementation issues that makes textiles such as those shown in Figure 2.7a and Figure 2.7b difficult from practical point of view. On the contrary, the embroidered coupler in Figure 2.7c, was stable on the skin (S21=-52.1 dB) which was also in better agreement with the simulation results. Therefore, the embroidered steel thread was chosen for the human clinical validation studies, which will be discussed in Chapter 4.

2.5. EM Sensor for Safety Compliance Experiment

For the safety compliance experiments, which will be discussed in the proceeding chapter, the shell containing the phantom liquid was made out of plastic material and 2 mm thick. Dielectric constant (\(\varepsilon_r\)) of the shell was 2.5 and the loss tangent (\(\tan \delta\)) was 0.05. Since the EM sensor was designed to couple to human skin, a thin phantom skin tissue (thickness: \(\leq 1\) mm) was placed between the sensor and the plastic container for matching. However, to ensure that the additional skin tissue did not absorb the input power and prevent it from propagating through the liquid tissue medium, another sensor with the same aperture size as the human sensor, was designed and fabricated to couple to the plastic container. Setup of the simulation for both the human and plastic EM sensor is included in Figure 2.8a and Figure 2.8b, respectively.
Similar to the setup in Figure 2.8b, the human sensor was in direct contact with the skin, while the plastic sensor was placed on the plastic shell material. Electrical properties of the materials used in these simulations were based on the operating frequency of 915 MHz. Simulation results of the magnitude of the reflection coefficient (S11) for the human and plastic sensors are -13.6 dB and -14.7 dB, respectively, which were below -10 dB, and therefore, were properly matched.

Similar to the simulations, the fabricated sensors were coaxially fed. The PEC structure was constructed with a copper tape and the center conductor was terminated with a 50Ω resistor. Illustrated in Figure 2.9 below are photos of the fabricated human and plastic EM sensors for the safety compliance experiments that will be discussed in the proceeding chapter.
2.6. Summary

Presented in this chapter were efforts to further optimize the sensitivity of the EM sensor to detect changes in lung fluid content by evaluating parameters such as the sensor configuration and evaluating the tradeoff between sensitivity and effects mutual coupling. The proposed side-by-side configuration was more sensitive compared to the original front-to-back S21 measurement, and single sensor S11 measurement. The side-by-side configuration also eliminated the challenges with sensor alignment that was seen in the front-to-back configuration. Wider distances improved sensitivity but also decreased signal strength. The optimal distance between the two sensors for the S21 measurement ranges from 10mm to 30mm.

Two EM sensor designs, textile-based sensor and plastic sensor were also designed and fabricated. The textile-based sensor was designed for hydration measurements for military personnel in the field. The objective was to develop a sensor that can be worn by soldiers and transmit real time vital signs. Three conductive textiles were evaluated for their coupling efficiency and ease of
integration into clothing. The embroidered sensor using a 2-ply steel thread proved to be the most suitable for this application.

Lastly, a plastic sensor was also developed for the safety compliance experiments. The original EM sensor was designed for human skin but the phantom shell containing the phantom liquid for the evaluation of Specific Absorption Rate was made out of plastic material. Therefore, a phantom skin was placed between the original EM sensor and the plastic shell to prevent mismatch. However, to ensure that the input power was not absorbed by phantom skin, a sensor of the same aperture, designed to couple to the plastic shell was developed for comparison. Simulation results of the S11 magnitude for both the human and plastic sensor were below -10 dB which indicated that both designs are well matched to the respective materials.
3.1. SAR Introduction

To conduct human clinical trials, the Center for Human Studies requires that a research protocol must be submitted and approved by the Institutional Review Board (IRB). Part of the protocol needed to clearly identify and address the risks and safety of the study participants. Since the system is microwave-based technology, safety measurements were conducted by following the guidelines set forth by the Federal Communications Commission (FCC) for safety compliance. In 1997, the FCC adopted the guidelines set by ANSI and IEEE and developed a document called OET Bulletin 65 [75] to provide assistance in determining whether proposed or existing transmitting facilities, operations or devices comply with limits for human exposure to radiofrequency (RF) fields.

Safety standards for human exposure to RF energy are evaluated by the Specific Absorption Rate (SAR), which quantifies the rate at which energy is absorbed per unit mass in an exposed object. Exposure to very high RF intensities may result in tissue damage due to thermal effects or heating of the tissue. SAR is the time derivative of the incremental energy (dW) absorbed by or
dissipated in an incremental mass \((dm)\) contained in a volume \((dV)\) of a given density \((\rho)\):

\[
SAR = \frac{d}{dt} \left( \frac{dW}{dm} \right) = \frac{d}{dt} \left( \frac{dW}{\rho dV} \right) \tag{3.1}
\]

SAR should be considered an “absorbed dose rate” and is related to electric fields at a point by:

\[
SAR = \frac{\sigma |E|^2}{\rho} \tag{3.2}
\]

Where:

\(\sigma\) = conductivity of the tissue (S/m)

\(\rho\) = mass density of the tissue (kg/m3)

\(|E|\) = magnitude of the measured electric field (V/m)

Table 3.1. FCC limits for specific absorption rate (SAR)

<table>
<thead>
<tr>
<th>FCC Guideline</th>
<th>SAR [W/kg]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Controlled/Occupational</td>
</tr>
<tr>
<td>Whole Body</td>
<td>0.4</td>
</tr>
<tr>
<td>1g. Av (Partial Body)</td>
<td>8</td>
</tr>
<tr>
<td>10g. Av (Hands, wrists, feet and ankles)</td>
<td>20</td>
</tr>
</tbody>
</table>

3.2. SAR Experiment

3.2.1. Setup

SAR experiments were conducted at Kyocera Wireless Labs in San Diego, CA using the DASY4 system (Schmid & Partner Engineering AG – SPEAG, Zurich, Switzerland) [76], an automated near-field scanning system that
measures SAR levels on biological tissues. Setup of the SAR experiments is shown in Figure 3.1 which includes the DASY4 components and the Specific Anthropomorphic Mannequin (SAM 12) phantom model that holds about 25 liters of tissue equivalent liquid. The EM sensors were placed on the thoracic region of the phantom. The shell is in compliance to the specifications in IEEE 1528-2003 [77], CENELEC 50361 [78] and IEC 62209 [79]. The shell thickness is 2 ± 0.2 mm, and is 1000 mm long and 500 mm wide. Reference markings on the phantom shell allow the complete setup of all predefined phantom positions and measurement grids with respect to the robot. System parameters of the SAR experiments at 915 MHz are included in Figure 3.2.

Figure 3.1. Setup of the SAR measurements conducted in Kyocera Wireless Labs (San Diego, CA) with the DASY4 system and the Specific Anthropomorphic Mannequin (SAM) twin phantom that holds the human phantom tissue. The EM coupler was placed on the flat thoracic section of the phantom. [80]
The plastic sensor (without the skin tissue in between the sensor and the plastic container) was first used to determine the highest input power that would result in acceptable SAR levels (less than the FCC guidelines). Table 3.2 includes the four input power settings that were tested and the measured SAR levels. Although these input power settings were significantly higher than what is required for the system (1-10 mW), this part of the study was designed to determine the worst-case scenario.

Table 3.2. Measured SAR levels with various input power

<table>
<thead>
<tr>
<th>Input Power (dBm)</th>
<th>Input Power (mW)</th>
<th>Measured SAR (W/kg) [1g Av]</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>10</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>15</strong></td>
<td><strong>32</strong></td>
<td><strong>0.42</strong></td>
</tr>
<tr>
<td>17</td>
<td>50</td>
<td>0.99</td>
</tr>
<tr>
<td>20</td>
<td>100</td>
<td>2.1</td>
</tr>
</tbody>
</table>

*Limit is 1.6 (W/kg)"
Detailed protocol of the SAR measurements is included in Appendix A.

Summary of the procedure for the SAR measurements are as follows.

Setup 1: Plastic applicator on the flat section of the phantom shell:
1. Measure output power from the DC power supply with a power meter
2. Place DUT (applicator) on the flat section of the phantom shell
3. Set scan area, grid size, and other setting on the DASY4 software
4. Perform Area Scan, Zoom Scan and SAR Values
5. Verify initial output power with a power meter

Setup 2: Human equivalent muscle tissue between the human applicator and the flat section of the phantom shell:
1. Measure output power from the DC power supply with a power meter
2. Place human equivalent skin tissue (thickness ≤1 mm) on the flat section of the phantom shell
3. Place DUT (applicator) on the human equivalent skin tissue
4. Set scan area, grid size, and other setting on the DASY4 software
5. Perform Area Scan, Zoom Scan and SAR Values
6. Verify initial output power with a power meter

3.2.2. Results

According to the measured SAR results, the maximum input power would be 50 mW with a SAR level of about 1 W/kg. However, 32 mW input power (SAR = 0.42 W/kg), was chosen for the remaining SAR measurements to account for any variability in the design and size of the sensors. Results from the SAR measurements for both the plastic and human sensor with input power at 32 mW are included in Table 3.3.
Table 3.3. SAR Measurement Results (Input Power: 32 mW, Freq: 915 MHz)

<table>
<thead>
<tr>
<th>Sensor (Scale) (a = 100%), (b = 75%)</th>
<th>Device #</th>
<th>Applicator Design</th>
<th>Magnitude of S11 (dB)</th>
<th>SAR (W/kg) Limit [1g. Av]</th>
<th>Measured [1g. Av]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastic Sensor</td>
<td>1</td>
<td>1(a)</td>
<td>-22.84</td>
<td>1.6</td>
<td>0.416</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1(b)</td>
<td>-13.15</td>
<td>1.6</td>
<td>0.415</td>
</tr>
<tr>
<td>Human Sensor</td>
<td>3</td>
<td>2(a)</td>
<td>-27.46</td>
<td>1.6</td>
<td>0.435</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2(b)</td>
<td>-31.52</td>
<td>1.6</td>
<td>0.319</td>
</tr>
</tbody>
</table>

Measured magnitude of the reflection coefficient (S11) for all of the sensors are well below -10dB, which means that all were properly matched and that the signal was coupled to the liquid phantom. Furthermore, the measured SAR (1g. Av) for both the plastic and human sensor were similar at about 0.4 W/kg (nearly 1/4th below the FCC limit), which indicates that the additional phantom skin placed between the human sensor and the plastic container did not absorb or impede the signal. To put the SAR levels in perspective, Figure 3.3 below shows the measured results of the EM sensor have significantly lower SAR levels compared to commercially available common cell phone models.
Commercially available mobile devices have higher SAR levels compared to the EM sensor.

Results and documentation from the SAR measurements significantly played a role in the approval of the proposed IRB protocols, which will be discussed in the proceeding section.

### 3.3. IRB Development

With the measured Specific Absorption Rate results well below the FCC limit, the next step was to evaluate feasibility of extracting vital signs such as heart rate (HR) and respiratory rate (RR) on humans and benchmark results with an FDA approved vital sign monitoring device. In order to conduct human studies, a study protocol was submitted to the Center for Human Studies and approved by an Institutional Review Board (IRB).
The outline and summary of the study protocol submitted to the IRB for the human vital sign validation experiments on healthy participants is included below. The entire protocol is included in Appendix B.

- Objective
- Methods
  - Participants
  - Exclusionary Criteria
  - Instrumentation
  - Instrument Safety (SAR)
- Procedures
  - Pre-screening
  - Informed consent
  - Site
  - Schedule
  - Experiment Protocol
- Data Analysis
- Confidentiality
- Disposition of the Data

Since the objective was to evaluate feasibility of extracting vital signs, normal vital signs from healthy participants was determined to be ideal for preliminary measurements. Participants were screened using a medical history questionnaire that was evaluated by a medical doctor and other exclusionary criteria to ensure healthy participants. Detailed measurement protocol and calibration certificates for devices used in the SAR experiments was a vital component to ensure the IRB that study participants will not experience adverse effects from using the EM sensor. The study protocol included exercises from
series of normal breathing at rest, breath holds and running on a treadmill to vary the heart rate and respiratory rate of the patients. Lastly, an informed consent document was developed which explained the objective, risks, benefits, confidentiality and study protocol to study participants in non-technical terms.

3.4. Summary

In this chapter, safety compliance of the EM sensor was addressed through SAR measurements which quantify the rate at which energy is absorbed per unit mass in an exposed object. Specific Absorption Rate levels of the sensor were measured at Kyocera Wireless Labs in San Diego at their FCC cellphone compliance facility. The testing facility included a DASY 4 system from SPEAG and the Specific Anthropomorphic Mannequin (SAM) twin phantom that holds the human phantom tissue. With an input power of 15 mW, the measured SAR level was 0.44 W/kg, is which only about 1/4th of the maximum FCC limit at 1.6 W/kg for 1g avg.

With the successful SAR measurements, study protocols for human vital sign validation experiments were developed and submitted to the Center for Human Studies which was later approved by an IRB.
CHAPTER 4

HUMAN VITAL SIGN VALIDATION

4.1. Introduction

Human vital sign evaluation experiments were conducted in collaboration with the Telehealth Research Institute, at John A. Burns School of Medicine (JABSOM) to validate the feasibility of extracting vital signs such as heart rate (HR) and respiratory rate (RR) from healthy participants. Healthy participants were the initial target population for these experiments for the convenience of patient availability and to establish a baseline for normal HR and RR. Some of the exclusion criteria included: currently under care of a physician, drug allergies, cardiac related medical history, and medications. Each participant was also required to complete a medical history questionnaire, which was used by a physician to screen and approve the participants. The complete medical questionnaire is included in Appendix B. An individual study volunteer orientation was conducted for each volunteer to inform them of the risks, benefits, procedures and objectives of the study. All participants signed an informed consent form prior to participating in the clinical trials. This study (CHS #18228), was approved by the Office of Research Compliance for Human Studies.
Program at UH Manoa, which administers the Institutional Review Board that evaluates, approves, and monitors new and continuing research protocols involving human research participants. Three protocols were conducted under this human vital sign study, which included a parametric evaluation of the textile sensor used for these experiments, vital sign evaluation when patients were at rest, and during exercise on a treadmill.

4.2. Side-by-Side vs. Front-to-Back

Prior to the human vital sign validation, preliminary tests were first conducted to validate the simulation results in Chapter 2 which indicated that the new side-by-side sensor configuration is more suitable for the human clinical trials compared to the previous front-to-back and single sensor configurations. Based on the coupling efficiency and ease of fabrication, the embroidered steel thread sensors were chosen over the copper and silver plated fabric for these experiments. The sensors were placed directly on the skin and connected to a network analyzer. Transmission and reflection coefficient measurements were conducted at 915 MHz. Placement of the sensors for the various configurations are illustrated in Figure 4.1. While sitting on a chair, the study participant was asked to perform a series of normal breathing and breath-holds.

Measured magnitude of the reflection coefficient ranged from -15 to -17 dB, which indicated well matched sensors on the skin. A moving averaging window was applied to all of the measured data to improve the signal-to-noise ratio (SNR). The configurations were evaluated based on the signal strength and SNR of the measured waveforms. No additional data processing was conducted
to calculate the vital signs for these preliminary experiments. Calculation of the vital signs will be discussed in the proceeding section.

Figure 4.1. Sensor configurations (a) Front-to-Back S21 measurement, (b) Single Sensor S11 measurement, (c) Side-by-Side S21 measurement.

The figures below contain the measured waveforms of the phase and magnitude of the transmission and reflection coefficients. From the measured waveforms in Figure 4.2, it is clear that the S21 phase from the side-by-side configuration were almost twice the amplitude of the S11 phase from the single sensor configuration. The S21 phase of the front-to-back configuration is larger than the side-by-side configuration waveforms. However, the signal strength of the front-to-back configuration is much weaker by nearly 20 dB, which can be seen in Figure 4.3(a). Consequently the heartbeat and respiration waveform from the side-by-side configuration is less noisy and therefore require less signal processing for the extraction of the vital signs. Hence, it can be concluded that the proposed side-by-side sensor configuration provides a stronger and cleaner signal that is suitable for the human vital sign validation experiment.
Figure 4.2. Single Sensor vs. Side-by-Side configuration. (a) Magnitude of S11 from the single sensor and S21 from the side-by-side configuration. (b) S11 and S21 phase during normal breathing and breath-holds. (c) Heartbeat waveform during a segment of breathhold and respiration waveform.

Figure 4.3. Front-to-Back vs. Side-by-Side configuration. (a) Magnitude of S11 from the single sensor and S21 from the side-by-side configuration. (b) S11 and S21 phase during normal breathing and breath-holds. (c) Heartbeat waveform during a segment of breathhold and respiration waveform.
4.3. Gap Evaluation

Similar to the previous simulations, the distance or gap size between the sensors for the side-by-side configuration was also evaluated. S21 measurements were conducted for three sensor gaps: 1 cm, 2 cm and 15 cm. Unlike the S21 simulations, which evaluated the sensitivity to changes in lung water content relative to the gap size, these S21 measurements were evaluated for sensitivity to the respiratory cycle and heartbeat. However, the trends observed in the simulation are also present in these measurements. In the simulations, increasing the gap size resulted in weaker signal strength by 15 dB. Similarly, increasing the gap size in these measurements also decreased the magnitude from -45 dB to -48 dB. Furthermore, the amplitude of the S21 magnitude waveform significantly decreased from 8 dB to 1 dB which is illustrated in Figure 4.4(a). These agreement in trends in the simulation and preliminary human studies are promising but more measurements are needed with a diverse study population to ensure that sensitivity of the sensors are not significantly affected by differences or variation in patient demographic such as size. This will be further evaluated in the proceeding section, which evaluates the efficacy of the sensor to calculate and monitor vital signs such as heart rate and respiration rate from participants of different sizes.
4.4. Vital Sign Validation with Various Patient Sizes at Rest

4.4.1. Experimental Setup and Procedure

Data from three adult males with an average age of 26.33 were analyzed. Each male represented a small, medium and large body built as indicated by their height, weight and chest circumference. In addition to evaluation of the vital signs, the purpose in the variation of the sizes was to evaluate if the patient size is a limiting factor to accurately detect and calculate vital signs. Participants were asked to sit on a chair for the installation of the three EKG electrodes from the Propaq LT, Welch Allyn [81] and the two EM sensors on the chest. Placement of
the EKG electrodes and the EM sensors are illustrated in Figure 4.5. The embroidered sensors were attached to a network analyzer and placed side-by-side (2-3 cm apart) near the bottom left of the sternum. Tape was used to stabilize the contact of the sensors to the skin which is illustrated in Figure 4.5.

Table 4.1. Demographic of study participants.

<table>
<thead>
<tr>
<th>Male #</th>
<th>Age</th>
<th>Weight (lbs.)</th>
<th>Height</th>
<th>Chest Circumference (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>27</td>
<td>130</td>
<td>5'7&quot;</td>
<td>83.36</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>175</td>
<td>5'4&quot;</td>
<td>93.98</td>
</tr>
<tr>
<td>3</td>
<td>27</td>
<td>190</td>
<td>6’</td>
<td>109.22</td>
</tr>
</tbody>
</table>

While sitting on a chair for 2 – 3 minutes, participants were asked to perform a series of normal breathing followed by breath holds. The breath holds were included to establish a RAW data baseline for the heartbeat to compare with the extracted heartbeat. Simultaneous HR and RR measurements were recorded from the Propaq LT and the CP-Stethoscope for all of the experiments.

4.4.2. Signal Classification and Extraction

The single microwave signal consists of in-depth signals (changes in lung water content), and surface signals (heart rate and respiratory rate). Changes in lung water content are slow changing, strong and have a linear trend. The respiratory waveform is sinusoidal and has a rate of 12 – 20 breaths/min or 0.2 Hz – 0.33 Hz for normal adults at rest. The heart waveform has more peaks that are distinguishable and heart rate for normal adults at rest ranges from 60 – 100
beats/min or 1 Hz – 1.6 Hz [82]. Several digital signal processing algorithms such as multiple signal classification [83], wavelet transform [84], and wavelet decomposition [84] were initially considered to extract or separate the HR, RR and changes in lung water content. Although these algorithms were more than sufficient to extract the vital signs, key consideration was computational efficiency and simplicity for real time viewing and processing of the data. Consequently, the best suitable sets of algorithms were combinations of windowed linear regression or averaging, Short Term Fourier Transform (STFT), bandpass (BP), and the threshold-based peak detection method [85].

Regress function was first applied to the signal. The residual signals were then subtracted from the original signal which provided a piecewise linear plot which can be used to estimate the changes in lung water content. With the remaining signal, a windowed STFT was applied and the resulting averaged spectrum contained two major peaks which corresponded to the respiratory and heart waveform. A low pass (LP) filter was used to separate the respiratory waveform from the heart waveform. Lastly, the residual signal was band-pass filtered with a 3dB passband of 1 – 1.6 Hz. A threshold-based peak detection method was used to calculate the heart rate. A block diagram of the DSP algorithms used to extract the vital signs and changes in lung water content is illustrated in Figure 4.6.
Figure 4.6. DSP algorithm used to extract vital signals as well as changes in the lung fluid from the single microwave signal.

A custom GUI, as seen in Figure 4.7 was also developed in Matlab that acquired the transmitted signal from the network analyzer and integrated the signal extraction algorithms for real-time extraction and viewing of the RAW waveforms and calculated vital signs.

Figure 4.7. GUI developed in Matlab with integrated DSP algorithms for real-time extraction and viewing of the vital signs.
4.4.3. Vital Sign Results and Discussion (At Rest)

Measured S11 and S22 magnitude ranged from -15 to -17 dB, while the S21 magnitude ranged from -53 to -57 dB, which indicated well matched sensors on the skin with sufficient transmitted signal strength on all study participants. The figures below include the raw S21 phase waveforms, extracted heartbeat and respiration waveforms, calculated HR, and RR from both CP-Stethoscope and Propaq LT for the three study participants.

As seen in Figure 4.8, the S21 phase waveform clearly indicates the expiration and inhalation pattern during the breathing cycle with amplitudes ranging from 10 – 20° peak-to-peak for all three participants. This is 10 – 15° greater than the respiration cycle amplitude from the reflection coefficient method using a single coupler arrangement reported in our publication [64]. The heartbeat waveform with amplitudes ranging from 1 – 3° is easily identifiable when the study participants held their breath. The small male participant’s respiration and heartbeat waveform amplitude was slightly greater than the medium and large male participants by 5 – 10° and 1 – 2°, respectively. However, regardless of the differences in the amplitude, the CP-Stethoscope system was able to extract and calculate the heart and respiration rate with considerable accuracy when compared to the measured rates from the benchmark device, Propaq LT. A difference between the two systems was also observed between the extracted and measured heart rate for the medium male participant with a difference of 15 – 20 BPM. Source of this discrepancy will be further investigated in future human clinical studies. Summary of the results from
the human clinical studies are included in Table 4.2. Correlation of the mean of the HR and RR for all three patients was analyzed using Pearson correlation coefficient [86] which were found to be in good agreement with $r = 0.7$, $p = 0.51$, $r = -0.64$, $p = 0.55$, respectively. Based on these results, it can be concluded that the proposed microwave system with the new textile EM coupler and the novel side-by-side S21 measurement arrangement have sufficient sensitivity to extract vital signs accurately regardless on the size of the participants.

Figure 4.8. Results from small male participant while in a sitting position.
Figure 4.9. Results from medium male participant while in a sitting position.
Figure 4.10. Results from large male participant while in a sitting position.

Table 4.2. Summary of HR and RR results while patients were sitting up.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Heartbeat Amplitude (deg)</th>
<th>Respiration Amplitude (deg)</th>
<th>Heart Rate (BPM)</th>
<th>Respiration Rate (BrPM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>CP-S</td>
<td>Propaq LT</td>
</tr>
<tr>
<td>SM</td>
<td>2</td>
<td>15 - 20</td>
<td>75 - 80</td>
<td>75 - 78</td>
</tr>
<tr>
<td></td>
<td>mean</td>
<td></td>
<td>77.5</td>
<td>76.5</td>
</tr>
<tr>
<td>MM</td>
<td>1</td>
<td>5 - 10</td>
<td>60 - 75</td>
<td>80 - 90</td>
</tr>
<tr>
<td></td>
<td>mean</td>
<td></td>
<td>67.5</td>
<td>85</td>
</tr>
<tr>
<td>LM</td>
<td>1</td>
<td>10 - 15</td>
<td>60 - 78</td>
<td>75 - 80</td>
</tr>
<tr>
<td></td>
<td>mean</td>
<td></td>
<td>69</td>
<td>77.5</td>
</tr>
</tbody>
</table>
4.5. Vital Sign Validation During Stress Test

4.5.1. Experimental Setup and Procedure

To further evaluate the accuracy of the CP-Stethoscope to monitor human vital signs, a stress test based on a modified Bruce Protocol [87] was conducted to vary the HR and RR of the study participants. Data from four male participants with an average age of 25.75 were analyzed.

Table 4.3. Patient demographic for Stress Experiments.

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Age (yrs.)</th>
<th>Weight (lbs.)</th>
<th>Height (ft, in)</th>
<th>Chest Cir.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26</td>
<td>157</td>
<td>5’10</td>
<td>35</td>
</tr>
<tr>
<td>2</td>
<td>28</td>
<td>155</td>
<td>5’10</td>
<td>36</td>
</tr>
<tr>
<td>3</td>
<td>26</td>
<td>135</td>
<td>5’7</td>
<td>36</td>
</tr>
<tr>
<td>4</td>
<td>23</td>
<td>155</td>
<td>5’9</td>
<td>34</td>
</tr>
<tr>
<td>Average</td>
<td>25.75</td>
<td>150.5</td>
<td>5’8</td>
<td>35.25</td>
</tr>
</tbody>
</table>

The copper based EM sensors were used for these experiments since it provided better coupling than the current textile based sensor. From additional preliminary tests, it was also determined that the strength of the heartbeat signal was stronger when the EM sensors were placed side-by-side to the left of the sternum. Furthermore, preliminary test with the modified Bruce Protocol at 3 MPH have indicated a limitation of the Propaq LT to accurately measure respiration rate during exercise. RR such as 53 breaths/min (BrPM) was observed while patients were running on the treadmill which is significantly greater than the normal breathing rate for the participants. Therefore, a respiratory belt unit (Vernier Software and Technology, Portland, OR, USA) [88]
was used as the benchmark device for the RR measurements. The air-filled respiratory belt consisted of an air-pressure sensor to determine the end of the inspiration and expiration of the respiration cycle. Accuracy of the measured HR from the Propaq LT at 3 MPH was revalidated by counting the pulse of the patients on the radial artery, located on the inside of the wrist near the thumb while the participants were running with their hand rested on the handle bar of the treadmill. Measured HR and RR were recorded simultaneously from all three devices throughout the experiments for all of the participants.

A LabView-based GUI was developed to view and store the data in real time from the respiratory belt and the RR was calculated using peak detection method. The front panel of the GUI is illustrated in Figure 4.11.

![Figure 4.11. GUI developed in LabView to view and acquire data from Vernier’s Respiration Belt which was used a benchmark device for the RR measurement.](image)

The breathing exercises from the previous experiments were added at the beginning of the tests while the patients were standing on the treadmill, followed by the modified Bruce Protocol which included four 3-minute stages or levels of
exercise. The stages included a warm up period of walking, exercise (jog and run), and cool down. The test was concluded with a 1-minute normal breathing cycle while the patient was standing on the treadmill. Protocol summary for this study is included in below Table 4.4.

Table 4.4. Stress Test Procedure with the Modified Bruce Protocol.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Time</th>
<th>Duration</th>
<th>Tasks</th>
<th>Speed [mph]</th>
<th>Incline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: At Rest (Acquire Data)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1: At Rest</td>
<td>00:00</td>
<td>01:00</td>
<td>Breathe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2: Warm Up</td>
<td>02:20</td>
<td>03:00</td>
<td>Walk</td>
<td>1.7</td>
<td>0</td>
</tr>
<tr>
<td>3: Warm Up</td>
<td>06:20</td>
<td>03:00</td>
<td>Walk</td>
<td>1.7</td>
<td>10</td>
</tr>
<tr>
<td>4: Exercise</td>
<td>10:20</td>
<td>03:00</td>
<td>Jog</td>
<td>2.5</td>
<td>12</td>
</tr>
<tr>
<td>5: Exercise</td>
<td>14:20</td>
<td>03:00</td>
<td>Run</td>
<td>3.0</td>
<td>15</td>
</tr>
<tr>
<td>6: Exercise</td>
<td>18:20</td>
<td>03:00</td>
<td>Jog</td>
<td>2.5</td>
<td>12</td>
</tr>
<tr>
<td>7: Cool Down</td>
<td>22:20</td>
<td>03:00</td>
<td>Walk</td>
<td>1.7</td>
<td>10</td>
</tr>
<tr>
<td>8: Cool Down</td>
<td>26:20</td>
<td>03:00</td>
<td>Walk</td>
<td>1.7</td>
<td>0</td>
</tr>
<tr>
<td>Test Complete</td>
<td>30:20</td>
<td>00:00</td>
<td>End</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.5.2. Wireless Assimilation

From the previous human experiments, it became more apparent that the current system with the bulky network analyzer limited patient’s mobility. With the objective of using this system as a bedside and home care monitoring device, efforts were made to eliminate the bulky and expensive network analyzer. A
A mobile app was also developed for real-time processing and viewing of vital signs. Block diagram of the wireless assimilation system and screenshot of the mobile app is shown in Figure 4.12(a) and (b), respectively. Detailed description of the system is included in [54]. Using the MCU, C code was developed to convert the analog I and Q signals to digital data at a sampling rate of 80 Hz. Every four samples were averaged to minimize conversion error which resulted with an effective sampling rate of 20 Hz. From the digital I and Q data, the raw phase and magnitude of the transmission coefficient were obtained. Signal extraction techniques from the previous experiments were also applied to the transmitted microwave signal for these clinical trials to extract the RR and HR. Complete setup of the experiment is included in Figure 4.13.

Figure 4.12. (a) Block diagram of the wireless assimilation system [54] used to acquire and display data in real time during the stress test. (b) Screen capture of the developed mobile app that displays the raw phase of the transmitted signal as well as the calculated heart rate and respiratory rate in real time.
Figure 4.13. Photo of a study participant running on a treadmill with the EM sensors, and the benchmark devices, ECG leads for the HR and respiration belt for the RR.

4.5.3. Vital Sign Results and Discussion (Stress Test)

Comparison plots of the calculated values for one experiment from the three devices are included in Figure 4.14. The plots contain the extracted RR and HR from the CP-Stethoscope, and the measured RR from the Respiration Belt and HR from the EKG electrodes of the Propaq LT. According to [89], depending on the artifacts generated, on average, 42.6 ± 23.2 seconds was required to acquire accurate reading from the Propaq LT. This was also observed on the ECG values from Propaq LT during the treadmill test. Based on the protocol, the corresponding HR increased or decreased with respect to the changes in the activity such as from the at rest stage to the warm up stage. The increased in HR
was observed 30 seconds after the 2:20 minute mark, which represents the start of the warm up period. To account for this, the entire ECG data at the start of the exercise was shifted by 20 seconds to the left or the data was delayed by 20 seconds. According to [81], in an ideal scenario with minimal noise, the measured ECG values are within 3% accuracy. This value was used to calculate the standard deviation for each measured value for the HR calculations. Tolerances of ±2 breaths for RR values were used to calculate the standard deviation.

Bland Altman [90] analysis was carried out to determine the mean differences between the devices (bias) and the standard deviation of the differences (precision) together with 95% confidence interval (limits of agreement). Graphical representation of this analysis by plotting the differences of the HR values (CPSHR – ECGHR) and RR values (CPSRR-BeltRR) against the HR and RR mean, respectively, is included in the figure below for one of the four study participants. Detailed results are included in Appendix E. The Pearson correlation coefficient was calculated to measure correlation agreement between the CPS data and the benchmark data, which is included in Table 4.5. All were in good agreement with exception to the respiratory rate of participant #3.
Figure 4.14. (a) Results from a stress test with one of the study participants illustrating the variation of HR and RR from various treadmill speed and ramp grade. (b) Bland Altman Scatter plot for HR and RR with the calculated Pearson correlation coefficient.
Table 4.5. Summary of Pearson Correlation Coefficient from Stress Test Clinical Trials.

<table>
<thead>
<tr>
<th>Participant #</th>
<th>HR r</th>
<th>HR p</th>
<th>RR r</th>
<th>RR p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.12</td>
<td>0.69</td>
<td>0.66</td>
<td>0.01</td>
</tr>
<tr>
<td>2</td>
<td>0.95</td>
<td>0.01</td>
<td>0.45</td>
<td>0.08</td>
</tr>
<tr>
<td>3</td>
<td>0.64</td>
<td>0.01</td>
<td>0.08</td>
<td>0.79</td>
</tr>
<tr>
<td>4</td>
<td>0.88</td>
<td>0.01</td>
<td>0.66</td>
<td>0.01</td>
</tr>
<tr>
<td>Overall</td>
<td>0.61</td>
<td>0.01</td>
<td>0.34</td>
<td>0.00</td>
</tr>
</tbody>
</table>

4.6. Summary

Human clinical validation of the heart rate (HR) and respiratory rate (RR) were conducted on healthy study participants at rest and during exercise. HR and RR values were compared with measurements from the Propaq LT and Vernier Respiration Belt. The side-by-side placement of the sensors on the thorax improved the sensitivity of the sensors for HR and RR measurements. It also eliminated the direct alignment problem that was observed in the front-to-back sensor configuration. The textile-based sensor that was discussed in the previous section was used in the parametric and patient variation experiments. Results from these experiments confirm that the textile based sensors can be used to measure HR and RR when patients are at rest regardless of the size of the patient. For the stress test experiments, the copper based sensors were used since it provided consistent coupling to the skin even during movement. Since the metal sensor was flatter and thinner than the textile sensor, it was easier to secure it to the body.
Results from the stress test exercise showed that the measured values are within the standard deviation for most cases (see Appendix E). The Bland-Altman scatter plot in Figure 4.14 also illustrated the mean of the differences are within limits of agreement. The calculated Pearson correlation coefficient indicated strong correlation for HR and RR for all of the patients with exception to participant #1 for HR and participant #3 for RR. The overall Pearson correlation coefficient was strong for HR ($r = 0.61, p < 0.05$) but weaker for RR ($r = 0.34, p < 0.05$).
CHAPTER 5

LUNG FLUID VALIDATION

5.1. Introduction

With the successful human vital sign validation experiments, the next stage in the clinical trials was to evaluate the accuracy of the CP-Stethoscope to assess changes in lung fluid content, heart rate and respiratory rate from hospitalized patients. Clinical trials were conducted in collaboration with the Queen’s Medical Center (QMC). Two protocols were conducted for the lung fluid validation experiments, one for HF patients, and the other was for dialysis patients.

5.2. Lung Fluid Validation with Heart Failure Patients

5.2.1. Development of the Heart Failure Study Protocol

In addition to comparing the HR and RR measurements from the CP-Stethoscope with standard vital sign monitoring device in hospitals, lung water measurements from the CP-Stethoscope were compared with pulmonary
capillary wedge pressure (PCWP) obtained from pulmonary artery catheterization (PAC). Eligible subjects included those patients at QMC with pulmonary artery catheterization for clinical indications at the discretion of the treating physician. Subjects were at least 18 years old and hospitalized at 1 of 4 specific areas indicated in the protocol. Some of the exclusionary criteria included presence of intra-aortic balloon pump or active cardiac pacing. Patients who were unstable to the point where the experiment would interfere with patient care were also excluded. Informed consent was obtained from the patient or, if the patient was unable to provide informed consent, from the patient’s surrogate, consistent with hospital Policy and Procedure. Target enrollment was 25 patients. This new study protocol (#RA-2014-306, CHS #22225) was evaluated and approved by The Queen’s Medical Center Research & Institution Review Committee and the Office of Research Compliance for Human Studies Program at UH Manoa. The complete protocol is available in the Appendix C.

5.2.2. Experimental Setup and Procedure

Currently, 16 male and 5 female patients with age ranging from 21 to 74 and a mean age of 54.51 have participated in these experiments. Detailed patient demographic is included in Table 5.1. The sensors and the wireless data assimilation system developed for the human vital sign experiments were also used for these experiments. Measurements were conducted while the patients were in a supine position on the bed. Since the patients were mostly in the supine position with limited movement, proper contact with the skin and the sensor was easily maintainable without the water based gel between the sensors.
and skin. Placement of the sensors on the chest is similar to the setup in the vital sign experiments. Data were collected simultaneously over 1-hour period from the CP-Stethoscope and the benchmark devices. RR and HR values were collected every five minutes from the vital sign monitoring device in the hospital. PCWP measurements were conducted four times, one every 15 minutes over the 1-hour period. However, some experiments were limited to less than four PCWP measurements due to patient condition. The first PCWP measurement was conducted at the beginning of the experiment. Results for the changes in lung fluid content measurements are included in the proceeding section.

Table 5.1. Patient Demographic for the Validation of Changes in Lung Fluid Content.

<table>
<thead>
<tr>
<th>Patient Type</th>
<th># of Experiments</th>
<th># of Patients</th>
<th># of Male</th>
<th># of Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF</td>
<td>17</td>
<td>13</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>HD</td>
<td>10</td>
<td>8</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>21</td>
<td>16</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Mean Age ± SD</th>
<th>Mean Weight ± SD (kg)</th>
<th>Mean Height ± SD (cm)</th>
<th>Mean BMI ± SD (kg/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF</td>
<td>55.77 ± 17.21</td>
<td>91.28 ± 33.41</td>
<td>172.53 ± 10.29</td>
<td>30.49 ± 6.92</td>
</tr>
<tr>
<td>HD</td>
<td>53.25 ± 8.03</td>
<td>108.22 ± 36.88</td>
<td>169.83 ± 6.55</td>
<td>37.11 ± 10.65</td>
</tr>
</tbody>
</table>

5.2.3. Results and Discussion

Bland-Altman statistical analysis and Pearson correlation coefficient was conducted to evaluate the agreement between the measured HR and RR values from the CPS system with a standard hemodynamic device used in the hospital.
for monitoring HR and RR. Direct comparison of the changes in phase from the CPS system similar to the data analysis used for HR and RR is not an accurate comparison because the measured values, pressure (mmHg) from the Swan-Ganz catheter and change in phase (degrees) from the CPS system are different. At this point, the best way to compare the pressure and change in phase of the signal is to evaluate the overall trend. Graphical representation of the data analysis on a patient data is included in Figure 5.1. In Figure 5.1a, the overall trend of the measured PCWP and phase is similar with exception to the second to the last data point on the third day. However, recorded observations during the clinical trial at that particular time have indicated that the pressure waveforms from the catheter were not as stable. HR and RR values for all of the HF patients are within the limits of agreement with about five outlier data points for the entire data set of thirteen HF patients. The five outlier data points could be attributed to noise in the microwave signal that are not within the threshold settings for the DSP. The table for RR values for HF7 and HF8 were labeled as NaN (Not a Number) because the RR values were a perfect match; therefore there was no difference between the calculated RR from both devices. As seen in Table 5.2, a strong correlation was found for the calculated overall Pearson correlation coefficient with $r = 0.79$, $p<0.05$ for HR and $r = 0.71$, $p<0.05$ for RR. Detailed results for the thirteen HF patients are included in Appendix E.
Table 5.2. Summary of Pearson Correlation Coefficient of HR and RR from Heart Failure Clinical Trials.

<table>
<thead>
<tr>
<th>Participant #</th>
<th>HR r</th>
<th>HR p</th>
<th>RR r</th>
<th>RR p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF1</td>
<td>0.99</td>
<td>0.07</td>
<td>-0.5</td>
<td>0.67</td>
</tr>
<tr>
<td>HF2a</td>
<td>-0.99</td>
<td>0.01</td>
<td>-0.89</td>
<td>0.11</td>
</tr>
<tr>
<td>HF2b</td>
<td>0.63</td>
<td>0.07</td>
<td>0.03</td>
<td>0.95</td>
</tr>
<tr>
<td>HF3a</td>
<td>0.03</td>
<td>0.93</td>
<td>0.48</td>
<td>0.11</td>
</tr>
<tr>
<td>HF3b</td>
<td>0.79</td>
<td>0</td>
<td>-0.35</td>
<td>0.25</td>
</tr>
<tr>
<td>HF4</td>
<td>0.99</td>
<td>0</td>
<td>-0.01</td>
<td>0.98</td>
</tr>
<tr>
<td>HF5a</td>
<td>0.19</td>
<td>0.53</td>
<td>-0.15</td>
<td>0.63</td>
</tr>
<tr>
<td>HF5b</td>
<td>0.12</td>
<td>0.69</td>
<td>-0.25</td>
<td>0.42</td>
</tr>
<tr>
<td>HF5c</td>
<td>0.29</td>
<td>0.39</td>
<td>-0.12</td>
<td>0.72</td>
</tr>
<tr>
<td>HF6</td>
<td>0.24</td>
<td>0.45</td>
<td>0.22</td>
<td>0.5</td>
</tr>
<tr>
<td>HF7</td>
<td>0.03</td>
<td>0.93</td>
<td>NaN</td>
<td>NaN</td>
</tr>
<tr>
<td>HF8</td>
<td>0.66</td>
<td>0.02</td>
<td>NaN</td>
<td>NaN</td>
</tr>
<tr>
<td>HF9</td>
<td>-0.27</td>
<td>0.39</td>
<td>0.11</td>
<td>0.73</td>
</tr>
<tr>
<td>HF10</td>
<td>0.3</td>
<td>0.35</td>
<td>-0.16</td>
<td>0.62</td>
</tr>
<tr>
<td>HF11</td>
<td>0.32</td>
<td>0.44</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>HF12</td>
<td>0.58</td>
<td>0.05</td>
<td>0.09</td>
<td>0.79</td>
</tr>
<tr>
<td>HF13</td>
<td>0.63</td>
<td>0.05</td>
<td>0.18</td>
<td>0.63</td>
</tr>
<tr>
<td>Overall</td>
<td>0.79</td>
<td>0</td>
<td>0.71</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 5.1. Results from heart failure patients. (a) Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Bland-Altman Scatter plots and calculated (b) HR and (c) RR from CPS and standard vital sign monitoring devices.

Analysis of the trend from the changes in phase shows promising results for initial clinical validation of the CPS system to detect changes in lung fluid content. However, appropriate comparison or accurate data analysis of measured values is premature at this stage in the trials. More data is needed and
if available, greater dynamic range for measured pressure values. So far, difference or variation in pressure values from the Swan-Ganz catheter are minimal and considered clinically insignificant. Although considered clinically insignificant, the trend of the phase values is promising because even with minimal changes, the CPS system may possibly have sufficient sensitivity to detect such minute changes.

5.3. Lung Fluid Validation with Hemodialysis Patients

With low enrollment and minimal PCWP changes, the IRB was modified to extend the monitoring period from 1 hour to two – 1 hour measurements over a 24 hour period for patients with catheter still in place. The enrollment criteria were also modified to include hemodialysis patients to evaluate correlation with fluid removed during hemodialysis treatment and changes in microwave signal. Including hemodialysis patients has allowed us to conduct additional human experiments and assess potential clinical use of the develop CP Stethoscope device. These IRB revisions are also expected to help in improving eligibility criteria of ICU patients and will lead to the possibility of including some dialysis patients with Swan-Ganz catheters. The revised IRB is included in Appendix C.

5.3.1. Extension and Revision of the Protocol to Include Hemodialysis Patients

Measurements were conducted on eight hemodialysis patients for a period of 4 to 5 hours. Fluid removed, from Hemodialysis Machine (Phoenix®
Hemodialysis System, Gambro Baxter [91] ) and RR and HR, from hospital standard vital sign monitoring device was recorded simultaneously with the CP-Stethoscope every five minutes. Detailed results of the hemodialysis studies are included in Appendix E.

5.3.2. Results and Discussion

Strong and moderate overall calculated Pearson correlation coefficient (HR: $r = 0.85$, $p < 0.05$, RR: $r = 0.42$, $p < 0.05$) for HD patient is shown in Figure 5.2. As seen in Figure 5.2b, the linear trend of the phase is nearly overlapped with the trend in fluid removed which illustrates good agreement. This is the case for most of the hemodialysis patients with exception to HD3 and HD7. However, notes taken during these experiments have indicated significant motion artifacts and personnel or patient interference with the sensors during these two experiments. HR and RR correlation results are not as significant as the heart failure patients. However, closer examination of the data indicated that most of the data are within the standard deviation within the limits of agreement as seen in Figure 5.2b-c. Additional results of HD patients are included in Appendix E.
Table 5.3. Summary of Pearson Correlation Coefficient of HR and RR from Hemodialysis Clinical Trials.

<table>
<thead>
<tr>
<th>Participant #</th>
<th>HR</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>r</td>
<td>p</td>
</tr>
<tr>
<td>HD1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>HD2</td>
<td>0.37</td>
<td>0.04</td>
</tr>
<tr>
<td>HD3</td>
<td>0.38</td>
<td>0.03</td>
</tr>
<tr>
<td>HD4a</td>
<td>0.1</td>
<td>0.49</td>
</tr>
<tr>
<td>HD4b</td>
<td>0.34</td>
<td>0.02</td>
</tr>
<tr>
<td>HD4c</td>
<td>0.07</td>
<td>0.63</td>
</tr>
<tr>
<td>HD5</td>
<td>0.19</td>
<td>0.22</td>
</tr>
<tr>
<td>HD6</td>
<td>0.54</td>
<td>0</td>
</tr>
<tr>
<td>HD7</td>
<td>0.01</td>
<td>0.98</td>
</tr>
<tr>
<td>HD8</td>
<td>-0.23</td>
<td>0.13</td>
</tr>
<tr>
<td>Overall</td>
<td>0.85</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 5.2. Results from hemodialysis patient 6. (a) Comparison of changes in phase with the fluid removed during hemodialysis treatment. Bland-Altman Scatter plots and calculated (b) HR and (c) RR from CPS and standard vital sign monitoring devices.
5.4. Summary

Human clinical validations for lung fluid measurements and vital signs have been conducted on thirteen HF patients and eight HD patients. The changes in the phase measured by the CPS system were compared with PCWP from the Swan-Ganz catheter with heart failure patients and the amount of fluid removed with patients who were currently undergoing hemodialysis treatment. HR and RR measurements were within the limits of agreement as indicated by the Bland-Altman plots as well as very strong positive correlation for the overall HR and RR as see in Table 5.4.

Table 5.4. Summary of Pearson Correlation Coefficient of overall HR and RR from Heart Failure and Hemodialysis Clinical Trials.

<table>
<thead>
<tr>
<th>Study</th>
<th>HR r</th>
<th>p</th>
<th>RR r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Failure</td>
<td>0.79</td>
<td>0</td>
<td>0.71</td>
<td>0</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>0.85</td>
<td>0</td>
<td>0.42</td>
<td>0</td>
</tr>
</tbody>
</table>

Preliminary analysis using polynomial curve fit lines of the changes in phase from the CPS system shows promising results with the measured pressure values and fluid removed. However, a more accurate and appropriate comparison of the changes of phase values with the benchmark devices are needed. Currently, direct comparison of the measured values is not suitable because the parameters that are measured are different. A ratio of the overall changes for the devices may be used in the future given a larger data set where a proper ratio may be derived. For example, a change of 5 mmHg from the catheter may be equivalent to a 10 degree phase change and this may also differ for each patient.
CHAPTER 6

3D HUMAN THORAX - SIMULATION
AND PHANTOM VALIDATION

6.1. Introduction

With promising results from the initial heart failure and hemodialysis clinical trials, the objective of this chapter is to develop an accurate and dynamic 3D anatomic model of a human thorax. This will further investigate propagation characteristics of the CP-Stethoscope during the human clinical trials to help identify parameters that will affect its sensitivity to changes in lung water content and vital signs. Successful implementation of such an approach may be inferred from previous homogenous 2D modeling [63]. However, a more accurate and dynamic model is needed to properly characterize wave propagation phenomenon in a complex environment such as that of a human thorax.

In this chapter, a 3D human voxel model was first evaluated to determine if it demonstrated the complexity of the human thorax as well as provided sufficient structural flexibility and adaptability to emulate physiological events such as a heart beating, the expiration and inhalation during the respiratory
cycle, and changes in lung fluid content. A question that has often been asked is “How does sensor placement effect on the sensitivity of detecting changes in lung fluid content?” With a complex, accurate and dynamic model, efforts to minimize computational cost is also discussed in this chapter. The chapter concludes with description of experimental validation using a phantom cross section of the thorax.

6.2. Simulation Procedure

6.2.1. Human Voxel Model Selection

After comparing various human 3D models, the human voxel model in HFSS best fit the objectives. The use of tetrahedral elements in FEM allows for curved surfaces, such as the human body, to be more accurately represented using adaptive meshing techniques [92]. Moreover, some SAR simulation studies using HFSS [93] have shown faster convergence when compared with CST microwave studio simulation software which is based on FDTD. The FCC has also approved the use of FEM for numerical modeling techniques to determine safety compliance [75]. The HFSS human model has a millimeter level of accuracy with over 300 geometries such as bones, organs, and muscles. The entire human model consisted of half a million tetrahedra. Figure 6.1 shows a side-by-side comparison of a transverse cross section of a human thorax to with the FEM thoracic mesh model to illustrate the level of accuracy of the human 3D voxel model.
6.2.2. Sensor Coupling

Since the EM sensor was designed to couple to human skin, the sensor has to be in direct contact with surface of the 3D model. However, the uneven surface and curvatures of the 3D model resulted in air gaps between the sensor and the model which caused an impedance mismatch. To overcome the mismatch, a thin layer of skin material was placed between the sensor and the skin which is illustrated in Figure 6.2. Resulting magnitude of the reflection coefficient was -14.5 dB.
6.2.3. Computational Cost

Since the heart and lungs are in the thoracic region of the human model, geometries beyond the thoracic region were omitted to minimize computational cost. Similar to the previous simulations, fluid accumulation in the lungs were modeled by adjusting the fractional lung tissue volume from 15% (normal lung) to 45% (edematous lung) using (2.1) and (2.2) at 915 MHz. Simulation setup and results to minimize computation costs are illustrated in Figure 6.4a.

To further minimize computational cost, a symmetrical boundary in the sagittal plane, which separates the left and the right side of the thorax was also included. This setup is shown in Figure 6.4b. Simulation parameters are included in Table 6.1.

Figure 6.3. Simulation setup of the changes in lung water content using a.) Full thoracic model and b.) Half model with a vertical symmetry plane boundary.
Figure 6.4. Results indicated a good agreement between the whole and half model with symmetry plane boundary to further minimize computational cost.

Table 6.1. Simulation Parameters

<table>
<thead>
<tr>
<th>Description</th>
<th>Detailed Information</th>
<th>Simulation Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>915 MHz</td>
<td>(Half Model – 1 variation)</td>
</tr>
<tr>
<td>Excitation</td>
<td>2 waveports</td>
<td></td>
</tr>
<tr>
<td>Boundary</td>
<td>Radiation</td>
<td></td>
</tr>
<tr>
<td>Simulation Basis Order</td>
<td>Mixed</td>
<td></td>
</tr>
<tr>
<td>Convergence Criterion</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Min. Consecutive Passes</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td># of Variations</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Total Simulation Time</td>
<td>Full Model: 16hr:53min:34sec</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Half Model: 9hr:21min:23sec</td>
<td></td>
</tr>
<tr>
<td>System Information</td>
<td>Processor: Intel Core i7-4930K, 64 bit RAM: 64 GB</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFSS ComEngine Memory: 287M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Field Recovery Memory: 12.7G</td>
<td></td>
</tr>
<tr>
<td>Total # of Adaptive Passes</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Mesh (volume, adaptive):</td>
<td>307302 tetrahedra</td>
<td></td>
</tr>
<tr>
<td>Simulation Time</td>
<td>Real Time: 11m:25s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CPU Time: 47m:56s</td>
<td></td>
</tr>
</tbody>
</table>

HFSS ComEngine Memory: 287M
Field Recovery Memory: 12.7G
System Information
Processor: Intel Core i7-4930K, 64 bit
RAM: 64 GB
The accuracy of the half model is in good agreement with the full model and reduced total simulation time by nearly half as shown in Figure 6.4 and Table 6.1, respectively. Therefore, the half model with the symmetry plane was used for the emulation of vital sign simulations, which will be discussed in the proceeding section.

6.3. Emulation of Vital Signs

To properly characterize the performance of the sensors during clinical trials, the 3D model was dynamically simulated to reflect, as much as possible, vital signs changes during a typical clinical trial. Specifically, parts of the model were scaled or moved to emulate a heartbeat and the breathing cycle.

6.3.1. Dynamic 3D Model Simulation Setup

The cardiac cycle consists of systole and diastole [94], and where systole represents the contraction of the heart to pump blood to the body and diastole is the relaxation of the ventricles to allow blood to fill in. To mimic the contraction and relaxation of the heart, the size of the heart was equally scaled up and down in an alternating manner. There are eight simulated heartbeats in one respiratory cycle. With three respiratory cycles in a minute, the resulting heart rate would be 24 beats per minute (BPM). This rate was only a fraction of a normal adult heart rate which ranges from 60-100 (BPM) in a typical healthy person. However, each additional data point would significantly increase processing time. Consequently, to minimize processing time initial heartbeat simulations were set to 24 BPM.
For the respiratory cycle, the two main moving components in this model included the ribcage, and the lungs. The ribcage consisted of ribs, sternum, and costal cartilage. During inhalation, the lungs expand and the ribs rotate upwards and outwards. This motion is similar to the rotation of a bucket handle which increases the transverse (left to right) diameter of the thorax [95]. The second movement is the sternum and the costal cartilage moving upward which also increases the thorax diameter between front and back. This motion is similar to that of a water pump handle. Diagram of these motions are illustrated in Figure 6.5. After a complete cycle of inhalation and exhalation, the conductivity and permittivity of the lung were also adjusted from normal to edema in three stages (20%, 30% and 40% edema) to mimic changes in lung water content using [66]. The setup of the simulation in HFSS is illustrated in Figure 6.6.

Figure 6.5. Diagram of the thoracic movement during inhalation in the respiratory cycle [96]. (a) Ribs rotates upward and outward similar to a bucket handle. (b) Sternum and costal cartilage moves upward and outward similar to a waterpump handle. (c) Combined movement that causes the thorax to expand during inhalation.
Figure 6.6. Setup of the HFSS simulation model illustrating the positions of the ribcage and the lungs during inhalation cycle. The red outline is the position of the ribcage at the peak of inhalation. The dots labeled start and peak also represents the initial and final position of the ribcage and sternum. (a) Left side view. (b) Right side view.

6.3.2. Results and Discussion

Figure 6.7 contains the results of the three respiratory cycles with the first cycle at 20% edema (normal lung) to the last cycle at 40% edema (edematous lung). As the fluid content increased, the S21 magnitude and phase changes were 1 dB, and 6.5 degrees, respectively. The amplitude of the breathing cycle changed from 1.4 dB to 0.75 dB. S21 phase results are included in Figure 6.8. Using the algorithm to extract vital signs from the previous human experiments, the linear trend from the changes in fluid content as well as the respiration cycles and heartbeats were extracted from the S21 phase and magnitude, which is illustrated in Figure 6.9 and Figure 6.10, respectively. The waveform generated from the heartbeat as well as the respiration cycle were similar to the ones that
were extracted from the human clinical trials. Therefore, it can be concluded that the human torso model in HFSS is a sufficiently accurate to mimic the complexity of the human organs as well as model dynamic physiological events such vital signs, respiration cycle and more importantly changes in lung fluid content. Clearly, the model in its present form represent a first step towards more accurate representation of the physiological changes in a typical clinical trial, a task that our team is presently pursuing.

Figure 6.7. S21 magnitude simulation results from the three respiratory cycle with eight heartbeats per cycle. The three respiratory cycle each represent lung water content from normal lung (20% edema) to full edema lung (40%).
Figure 6.8. S21 phase simulation results from the three respiratory cycle with eight heartbeats per cycle. The three respiratory cycle each represent lung water content from normal lung (20% edema) to full edema lung (40%).
Figure 6.9. Extracted values from the S21 phase (a) Linear trend of the changes in fluid content, (b) respiration cycles, and (c) heartbeats.

Figure 6.10. Extracted values from the S21 magnitude (a) Linear trend of the changes in fluid content, (b) respiration cycles, and (c) heartbeats.
6.4. Effect of Sensor Placement – 3D Model

Simulation

To investigate how the sensor placement affects the sensitivity of the EM sensors to detect changes in lung fluid content, a full thoracic model was needed. Unlike the previous half thoracic model, these simulations were conducted with the full thoracic model to account for a full representation of the EM scattering and propagation effects in inhomogeneous 3D model of a thorax. Changes in the lung fluid content in both the left and right lungs were modeled similar to the previous simulations from normal (20%) to edematous (40%) lung at rate of 2% increase for a total of eleven lung states. A total of eight sensors were added to the human 3D model as illustrated in Figure 6.11.

![Figure 6.11](image)

Figure 6.11. Eight sensors placed at various locations to evaluate how it affects the sensitivity of the system to detect changes in lung fluid content. (a) Isometric view and (b) bottom view of the thorax wireframe.

Paths between various transmitter and receiver sensor pairs were evaluated. Transmitters (Tx) 3 and 7 were selected as examples to illustrate how their placement around the thorax relative to the other receivers (Rx) affect the
sensitivity to detect changes in lung fluid content. Results of six cases of sensor pairs (S37, S47, S17, S57, S23 and S43) from these simulations are illustrated in Figure 6.12.

Figure 6.12. Simulation setup and results of the thorax as fluid increased in the lungs illustrating that sensor pairs with blue and black circles are more sensitive to the changes in fluid in the lungs compared to the sensor pairs with red and black circles (Tx: black, Rx:red).
As seen in Figure 6.12a, with sensor 7 as the transmitter and sensors 3 and 4 as the receivers, a -4 dB change in S47 was observed with a 20% to 40% change in the lung fluid content compared to a minimal change of less than 0.25 dB for S37. Similarly in Figure 6.12b, S57 changed by -4 dB compared to less than 0.25 dB for S17. In Figure 6.12c, sensor 3 was selected as the transmitter. A -1.5 dB change was observed for S43 compared to less than 0.25 dB for S23. From these results, it is clear that sensor placement is important and trade off needs to be considered between sensitivity to changes in vital signs and accurate and early determination of lung water content.

It was also observed that S43 was 2.5 dB less than S47. This is in agreement with the previous results in Chapter 2 where the distance between the sensors also affects the sensitivity and strength of the signal. As seen in Figure 6.13, the magnitude of the transmission coefficient of the sensor pair with the shortest path, S43, had the stronger signal at -60 dB, whereas S47 with the longer path and weakest signal at -95 dB.

<table>
<thead>
<tr>
<th></th>
<th>Mag (dB) w/ 20% edema</th>
<th>ΔMag (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S43 – Path A</td>
<td>-60 dB</td>
<td>1.5</td>
</tr>
<tr>
<td>S47 – Path B</td>
<td>-95 dB</td>
<td>4</td>
</tr>
</tbody>
</table>

Figure 6.13. Sensor pairs with shorter path (S43 – Path A), have a stronger signal strength but is also less sensitive to changes in lung fluid content.
6.5. Experimental Validation of the Effect of Sensor Placement

Experimental validation of the sensor placement effects were also conducted on a cross section of a phantom thorax. The experimental setup illustrated in Figure 6.14 consisted of three main components, 1) phantom tissue, 2) mist system, and 3) RF switch. The wireless data acquisition system [54] from the previous human clinical trials was also used for these experiments. A summary of these components and experimental procedure will be discussed in the proceeding sections.

Figure 6.14. System components of the experimental setup of the phantom validation experiment. Three main components include the phantom tissue, mist system and the RF switch.

6.5.1. Experimental Setup

6.5.1.1. Phantom Tissue

The model shown in Figure 6.15a consisted of phantom muscle, heart, lungs and Styrofoam for the phantom box shell. Sensors were placed between the Styrofoam and the phantom muscle (≈2 cm thick). Materials used to create the synthetic heart and muscle tissue included, TX151, polyethylene powder.
(PEP), Agar, NaCl and H₂O. Portions for each material were adjusted to emulate the permittivity and conductivity of the human heart and muscle at 915 MHz. A dielectric probe kit was used to determine the electrical properties of the phantom muscle tissues. Experimental setup of the dielectric measurements is illustrated in Figure 6.15b.

Figure 6.15. (a) Phantom thorax layers including sponges, muscle wall, and heart tissue. (b) Electrical properties of the phantom tissues were measured with a dielectric probe kit (Agilent) and a network analyzer (PNA E8364B).

Measurements were conducted with a network analyzer (PNA E8364B) and a dielectric probe (Agilent). The dielectric probe was calibrated using de-ionized water, metal block, and teflon. The mixture solution and the measured values compared with the theoretical values of muscle and heart tissue at 915 MHz are included in Table 6.2 below. A set of sponges were used to model the lungs which collected water from the mist system to emulate changes in lung fluid content.
Table 6.2. (a) Mixture solution for the phantom muscle and heart tissue at 915 MHz. (b) Theoretical and measured permittivity and conductivity of the heart and muscle tissue.

<table>
<thead>
<tr>
<th>Tissue</th>
<th>H₂O (%)</th>
<th>NaCl (%)</th>
<th>TX151 (%)</th>
<th>PEP (%)</th>
<th>Agar (%)</th>
<th>ε'ₜ</th>
<th>ε'ₘ</th>
<th>σₜ (Sm⁻¹)</th>
<th>σₘ (Sm⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muscle</td>
<td>73</td>
<td>0</td>
<td>15</td>
<td>9</td>
<td>3</td>
<td>54.9</td>
<td>51</td>
<td>0.95</td>
<td>0.92</td>
</tr>
<tr>
<td>Heart</td>
<td>78</td>
<td>0.1</td>
<td>21.9</td>
<td>0</td>
<td>0</td>
<td>59.8</td>
<td>59.5</td>
<td>1.24</td>
<td>1.73</td>
</tr>
</tbody>
</table>

6.5.1.2. Mist System

A misting system with six mist sprays was used to evenly distribute water over the sponges to emulate changes in lung fluid content. Flow rate was determined by measuring the amount water collected in a container at the bottom of the box over a one minute period. The averaged measured flow rate was about 72 cc/min. Several experiments were conducted to ensure equal water distribution throughout the sponges. Small plastic containers (3 cm wide, 1 cm tall), were evenly placed at the bottom of the box shown in Figure 6.16a. Water collected in each of the containers was measured after one minute. In total, about 72 cc of water was collected and the difference between the smallest and biggest amount of water collected, excluding the containers around the edges or partially covered, was 0.5 cc. Results from the water distribution experiment are included in Figure 6.16b.
Figure 6.16. (a) Setup of the water distribution measurement with the small plastic containers used to collect the water over 1 minute period. (b) Averaged water distribution over 1 minute period ranged from 0.6 cc to 1.2cc.

6.5.1.3. RF Switch

A 2-port to 8-port RF switch system was developed [97] to connect the eight sensor array to the wireless data acquisition system that was previously used in the human clinical trials used to measure the phase and magnitude of the transmission coefficient. The switch consisted of a two layer stack of 1-to-8 switch trees. The top and bottom layers of the switch were identical, each with seven single pole double throw switches (Skyworks SKY13431-374LF SPDT) [98]. The top switch layer determined the transmitter port while the bottom layer determined the remaining receiver ports. The two 8-switch trees were combined with eight SPDT switches. Photograph of the fabricated two layer switch is included in Figure 6.17.
Figure 6.17. (a) Side view and (b) Top view of the fabricated 2-port to 8-port RF switch system using a two layer stack design, top layer to select transmitter and bottom layer for receivers. Top and bottom layer were combined with eight SPDT switches.

The switch was digitally controlled with a microcontroller (STM32F407 [99]) to specify one transmitter port and set the remaining ports as receivers, one at a time. One complete cycle of the transceiver (TxN, RxN) pairs (Tx1, Rx:2-8 to Tx8, Rx:1-7) took about two seconds. A path example of the transceiver pair Tx1, Rx3 is illustrated in Figure 6.18.

![Figure 6.18. Path example of the transceiver pair Tx1,Rx3 with the top layer selecting Sensor1 as the transmitter and bottom layer returning the transmitted signal from Sensor1 to Sensor3 through the bottom layer.](image)
This provided insight as to what each transceiver pair was measuring nearly simultaneously as the fluid accumulated in the sponges. Additional details of the 2-port to 8-port RF switch system is included in Appendix F.

6.5.2. Experimental Procedure

The switch-controlled eight sensors were placed evenly around the phantom thorax box as shown in Figure 6.19a, which is similar to the simulation setup in the previous section.

![Figure 6.19](image)

Figure 6.19. (a) Setup of the phantom validation experiment with switch-controlled sensors. (b) Sensor placement relative to the top and bottom thorax layers. For the first set of experiment, the sensors were positioned near the top layer of the thorax. The sensors were repositioned near the bottom layer for the second experiment.

Two sets of experiments were conducted to evaluate the sensitivity of the sensors to changes in lung fluid content. First, by placing sensors at the top or bottom of the model as shown in Figure 6.19b and second, by varying the fluid insertion rate. For the first setup, the sensors were placed on the top layer of the phantom thorax. At this position, the sensors were expected to have the quickest sensitivity to changes in lung fluid since the top layer is the closest to the mist system and will be saturated first. For the second position, the sensors were
repositioned towards the bottom layer which was about 9 cm away from the top of the box. By adjusting the position of the sensors from the top to the bottom layer, sensitivity to the water changes in the lungs should also be reflected in the measured signal. Since it was farther away from the top, it was expected to see the changes at a much later time compared to the top position. For both top and bottom layer setup, fluid was inserted at about 72 cc/min continuously after a baseline was initially established within the first minute.

Table 6.3. Experimental protocol for the phantom lung validation.

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Duration (min)</th>
<th>Setup 1 Top Layer Continuous Flow Rate</th>
<th>Setup 2 Bottom Layer Continuous Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>Establish baseline</td>
<td>Establish baseline</td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>START Water</td>
<td>START Water</td>
</tr>
<tr>
<td>16</td>
<td>3</td>
<td>STOP Water</td>
<td>STOP Water</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Duration</th>
<th>Setup 3 Top Layer Interval Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>Establish baseline</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>START Water</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>STOP Water</td>
</tr>
<tr>
<td>7</td>
<td>3</td>
<td>START Water</td>
</tr>
<tr>
<td>10</td>
<td>3</td>
<td>STOP Water</td>
</tr>
<tr>
<td>13</td>
<td>3</td>
<td>START Water</td>
</tr>
<tr>
<td>16</td>
<td>3</td>
<td>STOP Water</td>
</tr>
</tbody>
</table>

For the second set of sensitivity experiments, one setup (setup 1) was conducted with continuous fluid insertion rate at 72 cc/min, and the other with interval fluid insertion rate (setup 3). For the interval fluid insertion rate, after a baseline was established for one minute, water was inserted at the 1 minute mark for three minutes. At the 4 minute mark, water insertion was halted for three minute duration. This process was repeated alternately for 16 minutes every
three minutes for a total of three on and off segments. Table 6.3 consists of the summary of these experimental setup and procedures.

6.5.3. Experimental Results

Experimental results for setup 1 and setup 2 are shown in Figure 6.20 from the same pair, sensors 8 and 6 as an example. When the sensors were placed near the top (setup 1), the signal significantly changed shortly after the water was turned on at the 1 minute mark. On the contrary, when the sensors were placed near the bottom (setup 2), significant changes in the signal was observed at about the 10 minute mark which was about the same time that the signal was nearly constant when the sensors were at the top layer. Prior to the signal staying constant at the 8 minute mark for setup 1, the signal increased at the 6 minute mark. Since the sensors were placed near the top layer for setup 1, the changed in direction of the signal could be attributed to the sponges on the top layer being saturated and water leaking out of the top sponges into the bottom sponges. Similar phenomenon was observed for the bottom sponges during setup 2 at the 16 minute mark.
Figure 6.20. Experimental phantom validation with sensors near the top (red) and bottom (blue) of the phantom box.

Results from the second sensitivity experiment which compares changes in the microwave signal to the changes in fluid insertion rate are included in Figure 6.21. Results for three minute interval of on and off fluid insertion rate and continuous fluid insertion rate at 72 cc per minute are included in Figure 6.21a and b, respectively. As seen in Figure 6.21a, the signal changed for every water “on” segment followed by a near constant signal during water “off” segments. The slope of the line for each water “on” segment gets steeper as fluid accumulates in the sponges. This clearly differs with the results in Figure 6.21b where the change in the signal constantly decreased which corresponds to the constant fluid insertion rate.
Figure 6.21. Results from experimental phantom validation with variation in fluid insertion rate (a) water is added at 72 cc/min for three minutes, followed by no water for another three minutes (b) water was added continuously at 72 cc/min for nine minutes.

From these results, it may be concluded that the resulting variation in the signal due to changes to the position of the sensors and the insertion rate does indeed validate the sensitivity of the device to changes in lung fluid content.

For the evaluation of how sensor placement affects the sensitivity of the system, paths between transmitter and receiver sensor pairs from setup 1, similar to the simulation in the previous section were evaluated. Transmitters (Tx) 2, 4 and 6 were selected as examples to illustrate how their placement around the thorax relative to the other receivers (Rx) affect the sensitivity to detect changes in lung fluid content. Results of six cases of sensor pairs (S24, S14, S56, S26, S42 and S62) from these simulations are illustrated in Figure 6.22. In Figure 6.22a, sensor 4 was set as the transmitter with sensors 1 and 2 as the receivers. A constant 11 dB change was observed for S24 compared to S14. Although S14 changed nearly as much as S24, the signal fluctuated up and
down during the constant fluid insertion rate and turning off the water at the 10 minute mark did not change the signal. For S14 however, the signal was constant from the start of the water insertion at 1 minute till the water was shut off at the 10 minute mark for a total change of 11 dB. Shortly after the 10 minute mark when the water was shut off, the signal changed to the opposite direction. Since water was no longer being added at this point, the remaining water in the sponges were flowing down to the bottom layer of sponges leaving the top layer of sponges with less water and hence the change in the signal in the opposite direction. In Figure 6.22b, sensor 6 was set as the transmitter with sensors 5 and 2 as the receivers. There were also minor fluctuations in S26 and it changed direction at the 5 and 8 minute marks even with a constant fluid insertion rate. Similar to S14, no changes occurred at the 10 minute mark when the water was turned off. On the contrary, change in S56 was constant for a total change of 5 dB and the signal changed direction at the 10 minute mark when the water was turned off. In Figure 6.22c, sensor 2 was set as the transmitter with sensors 4 and 6 as the receivers. Similar to S26, S62 has a signal trend with fluctuations with constant fluid insertion rate. Trend of S42 is similar to S24 with total constant change of 9 dB. The difference in total signal change for S24 and S42 may be attributed to the slight variation in switch path losses.
Figure 6.22. Phantom validation setup and results of the thorax as fluid increased in the lungs illustrating that sensor pairs (Tx: black, Rx:blue) that are more sensitive to the changes in fluid in the lungs compared to the sensor pairs with obstructed path (Tx: black, Rx:red).
It was also observed that S65 was 6 dB less than S24. This is in agreement with the previous results in Chapter 2 and the simulations where the distance between the sensors also affects the sensitivity and strength of the signal. As seen in Figure 6.3, the magnitude of the transmission coefficient of the sensor pair with the shorter path, S65, had a slightly stronger signal at -45.5 dB, whereas S24 with the longer path and weaker signal at -47.5 dB but has a greater overall change with 11 dB.

<table>
<thead>
<tr>
<th></th>
<th>Mag (dB) w/ 20% edema</th>
<th>ΔMag (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S65 – Path A</td>
<td>-45.5 dB</td>
<td>5</td>
</tr>
<tr>
<td>S24 – Path B</td>
<td>-47.5 dB</td>
<td>11</td>
</tr>
</tbody>
</table>

Figure 6.23. Sensor pairs with shorter path (S65 – Path A), have a stronger signal strength but is also less sensitive to changes in lung fluid content.

### 6.6. Summary

To further investigate propagation characteristics of the CP-Stethoscope during the human clinical trials to help identify parameters that will affect its sensitivity to changes in lung water content and vital signs, a dynamic 3D human voxel model was developed to emulate physiological events such as a heart beating, the expiration and inhalation during the respiratory cycle, and changes in lung fluid content. Simulation results have indeed confirmed that the simulated heartbeat, breathing and fluid accumulation in the lungs have similar trend and waveforms when compared to the clinical trials. Due to the complexity of the model, efforts were also made to improve the efficiency of the simulations by decreasing the simulation cost. Using a symmetry boundary, the full thorax
model was cut in half in the sagittal plane which divides the left and right side of
the body. Results from the full and half model were in good agreement and the
half model decreased simulation time by nearly 50%. It has also been
determined that the placement of the sensors affect the sensitivity to changes in
lung fluid content. Total changed of the signal between certain sensors was as
much as 1.5 dB to 4 dB for typical 20% to 40% changes in lung fluid content.

These simulations were also experimentally validated on phantom thoracic
models. To validate the accuracy and setup of the phantom experiments, several
experiments such as variation in the fluid insertion rate, fluid distribution, and
sensor placement were conducted. To properly assess the effect of the sensor
placement, even fluid distribution throughout the phantom model was first
established with a minimal difference of 0.5 cc/min was observed from the
highest to the lowest distribution. The signal also correlated with the variation in
the fluid insertion rate. Constant trend in the signal was observed for the
continuous fluid insertion rate. Three-minute intervals of fluid insertion also
showed the signal decreasing when the water was on and the signal staying
constant or no change when the water was turned off. Varying the placement of
the sensors between the top and middle layer of the phantom and variation in the
fluid insertion rate correlated with the delayed signal changed for the bottom
layer whereas the signal changed immediately after the water was turned on
when the sensors were placed on the top layer. Similar to the simulation results,
this study has provided significant insight regarding the trade-offs involved in the
accurate monitoring of vital signs and sensitivity to changes in measuring
changes in lung fluid content. Comparison of the simulation and experimental results are illustrated in Figure 6.24 and Figure 6.25.

Comparing the simulation and experimental results on the same graph was initially considered. However, to accurately compare the results on the same graph, each object that is included in the simulated model would have to also be a direct replica on the experimental setup such as exact same size and shape of the heart as well as other organs. The difference between the simplified experimental setup and the detailed simulation setup is illustrated in Figure 6.24 where the trends of the transmitted signal are different. In Figure 6.23 however, since the path of the transmitted signal is shorter and mainly through the lungs, which is similar for the experiment and simulated model, the trends of the signal are comparable. To this end, the results were plotted separately which still illustrates that sensors placed appropriately with respect to the lung is indeed more sensitive to changes in lung fluid as indicated by constant change in the microwave signal as fluid increased in Figure 6.23.
Figure 6.24. Experiment and simulation results for sensor pairs that are sensitive to changes in lung fluid content.

Figure 6.25. Experiment and simulation results for sensor pairs that are not as sensitive to changes in lung fluid content.
Early detection and continuous assessment of pulmonary edema or abnormal fluid buildup in the lungs, is critically important to the management and treatment of life threatening diseases such as heart failure, sepsis, and other cardiopulmonary related illnesses. However, available modalities are either invasive and/or not suitable for continuous monitoring. A novel radiofrequency (RF) based technology called Cardio-Pulmonary Stethoscope (CPS) system aims to address this need. The CPS system is a noninvasive, portable, low-cost device, capable of monitoring vital signs (VS) such as heart rate (HR), respiratory rate (RR), and most importantly, detect changes in lung fluid content. Previous experiments have only been conducted on phantom models for HR and RR measurements, and sensitivity to changes in lung fluid content were evaluated on animal and isolated experiments.

This study improved the existing CPS system and expanded its capabilities. Contributions of this dissertation include the following: (1) Development of textile based sensor for remote monitoring and wearable applications and plastic sensor for safety experiments. Sensor design guidelines
and optimal sensor arrangements were also discussed. (2) Evaluated safety compliance and development of study protocols for human clinical validations. (3) HR and RR measurements were clinically validated on healthy participants at rest and during exercise. (4) Sensitivity to changes in lung fluid was also validated with heart failure and hemodialysis (HD) patients. (5) Dynamic human 3D simulation and phantom validation provided significant insight regarding the trade-offs involved in the accurate monitoring of vital signs and sensitivity to changes in measuring changes in lung fluid content.

More specifically, three conductive textiles were evaluated based on ease of fabrication and sensitivity to changes in lung fluid. An embroidered steel thread was found to be most sensitive and ideal for practical implementation. A plastic-based sensor was designed and fabricated to ensure proper and accurate safety validation measurements. Specific absorption rate measurements were conducted on the Dasy4 system for the safety compliance of the CPS system. With a maximum input power of 32 mW, the measured specific absorption rate was 0.4 W/kg which is only 1/4th of the FCC limit of 1.6 W/kg for 1g avg. Study protocols for clinical validation of the HR, RR and changes in lung fluid measurements were developed for healthy, heart failure and hemodialysis participants. All study protocols have been approved by an Institutional Review Board (IRB).

Accuracy of the CPS system for HR, RR, and changes in lung fluid measurements were clinically evaluated on thirteen heart failure (HF) and eight hemodialysis (HD) patients with a strong overall Pearson Correlation Coefficient
Agreement (Heart rate - HF: r = 0.79, p<0.05, HD: r=0.85, p<0.05; Respiratory Rate: HF: r=0.71, p<0.05, HD: r=0.42, p<0.05). Additional HR and RR measurements were also conducted on seven healthy participants at rest and during exercise. For HR and RR measurements, the CPS system was compared against standard clinical hemodynamic monitoring devices such as Propaq LT. Similar to the HF and HD patients, overall Pearson correlation coefficient agreement was strong for HR (r=0.61, p=0) and moderate for RR (r=0.34, p=0).

Phase changes in lung fluid obtained from the CPS system were compared with changes in pulmonary capillary wedge pressure obtained during pulmonary artery catheterization for the HF patients and changes in fluid removed for HD patients. Overall trend of the phase were mostly comparable with the trend from the wedge pressure for HF patients. However, some pressure changes were too minimal to appropriately compare with the changes in the phase of the microwave signal and the three or four data points within the one hour period may skew results when testing for data agreements. Consequently, more data points are needed to accurately compare changes in the phase with the pressure changes from the catheter. Linear trend line of the changes in phase and the fluid removed from the dialysis patients were in good agreement. Furthermore, the Bland-Altman Agreement (BAA) plots have illustrated that the mean differences between the CPS system and the standard monitoring devices were generally within the calculated limits of agreement.

To further investigate propagation characteristics of the CP-Stethoscope during the human clinical trials to help identify parameters that will affect its
sensitivity to changes in lung water content and vital signs, a dynamic 3D human voxel model was developed. Physiological changes such as heartbeat and respiratory cycle was emulated and extracted results were similar to the results from the clinical trials. Parameters such as the placement of the sensors were also evaluated to determine how it affected the sensitivity of the system to the changes in lung fluid content. Simulation and experimental results have shown that sensor placement need to be considered in evaluating tradeoffs between monitoring vital signs and enhancing sensitivity to changes in lung fluid content.

With the findings from this study and additional future expansion of capabilities of the current CPS system, the future outlook of an independent measurement of multiple vital signs and lung fluid content from a single, noninvasive, low-cost device and suitable for both clinical and remote health care delivery applications is promising.
APPENDICES
The completion of this dissertation would have not been possible without the tireless effort and contribution of many of HCAC, JABSOM and QMC team members. As such, I would like to acknowledge the following individuals and their contribution to this dissertation.

**Principal Investigators:**
- Dr. Magdy F. Iskander, Hawai‘i Center for Advanced Communications
- Dr. Todd Seto, Queen’s Medical Center
- Dr. Nuri Celik, Hawai‘i Center for Advanced Communications
- Dr. Ben Berg, John A. Burns School of Medicine – SimTiki Research Center
- Dr. Hyoungsun Youn, Hawai‘i Center for Advanced Communications

**Contributors**

**Dr. Hyoungson Youn**  
*Contributions:*
- (Co-PI) 2011 NSF Fundamental Research Grant - Award #1127956
- EM sensor characterization and optimization using HFSS and FEKO.
- Phantom experiments to validate sensitivity of the sensors to changes in lung fluid content and respiratory rate.
- Conducted Specific Absorption Rate measurements at Kyocera Wireless (San Diego, CA) to evaluate levels of RF emissions from the EM sensor. SAR measurements were a key component to obtaining IRB approval for the validation of heart and respiratory rates on healthy participants.
- Supervised undergraduate and graduate students in the CP-Stethoscope project.
Dr. Nuri Celik  
*Contributions:*  
- (Co-PI) 2011 NSF Fundamental Research Grant - Award #1127956  
- Developed digital signal processing algorithms to extract vital signs and changes in lung fluid content from a single microwave measurement for the phantom and human clinical trials.  
- Supervised phantom experiments to validate sensitivity of the sensors to changes in lung fluid content and respiratory rate.  
- Conducted human clinical trials on healthy participants to validate sensitivity to heart and respiratory rate.  
- Developed single frequency low-cost receiver with discrete RF components to replace bulky network analyzer.  
- Conducted RF interference measurement in the anechoic chamber  
- Provided overall guidance with the initial human clinical trials and supervised undergraduate and graduate students in the CP-Stethoscope project  
- Won Best of Show at NSF’s I-CORP Program which brought more awareness to the project and led to additional partnerships and funding opportunities.

Queen’s Medical Center  
*Team Members: Dr. Todd Seto, Fiona Kennedy, May Vawer, Dr. Chris Fiack, Dr. Santhosh Mannem*  
*Contributions:*  
- Dr. Seto is the Co-PI for the NIH Grant of the NIH Grant # 1R21HL124457-01 to validate efficacy of the CP-Stethoscope to monitor heart and respiratory rate and detect changes in lung fluid content.  
- The QMC team assisted with the development of the clinical study protocol for vital sign and lung fluid measurements on heart failure and hemodialysis patients.  
- They provided medical expertise for cardiovascular and pulmonary related diseases.  
- Fiona Kennedy and Dr. Fiack conducted the human clinical trials.
Dr. Eunjung Lim
- Performed statistical analysis of the human clinical trials at QMC. She provided the statistical analysis summary that was included in Chapter 5.
- Provided insight as to which statistical analysis method is appropriate to use to evaluate correlation or agreement between data sets.
- Suggestion, Bland-Altman Analysis method to evaluate the agreement between the CP-Stethoscope and the benchmark clinical devices to measure heart and respiratory rate.

Dr. Ben Berg and Kris Hara
*Contributions:*
- Lead the initial development of the study protocol for vital sign validation on healthy participants.
- Conducted human clinical trials on healthy participants to validate sensitivity to heart and respiratory rate.
- Provided access to SimTiki research facilities.

Dr. Farhan Qazi
*Contributions:*
- Contributed the DSP algorithm which improved the accuracy of the RR and HR
- Developed DSP to remove motion artifacts
- Improved filter designs to account for variable sampling rate

Gui Chao Huang
*Contributions:*
- Lead the effort in investigating various sensor feed designs (microstrip and stripline base) and also accounted for epoxy material over the junction.
- Simulated and developed wideband EM sensors and corresponding feeding structures in HFSS.
- Developed MatLab script to generate sensor geometry for HFSS simulations.
- Designed the RF – front end circuit and calibration method for the wireless transceiver device that was used for the clinical trials.
**Darcy Bibb**

*Contributions:*
- Implemented and miniaturized wireless transceiver device that Dr. Celik originally designed.
- Fabricated the calibration kit that was used to determine the IQ offset for the wireless transceiver device.
- Designed and fabricated of the 1-to-4 RF switch used for the phantom validation measurements.
- Optimized the DSP and made it compatible with ARM MCU for the wireless transceiver device for real-time processing of the vital signs and changes in lung fluid content.
- Programmed MCU for data acquisition and wireless transmission for the wireless transceiver.
- Developed first version of the CP-Stethoscope App.

**Jason Tanabe**

*Contributions:*
- Lead the effort in developing the CP-Stethoscope App for real-time assessment of vital signs and lung fluid content
- Developed switch logic and programmed the MCU to provide digital control for the RF switch.

**Leyna Tamaye**

*Contributions:*
- Helped develop phantom model to evaluate the effects of the sensor position on the human thorax.
- Fabricated sensors for the phantom validation measurements.
- Helped develop phantom model to evaluate the effects of the sensor position on the human thorax.
- Fabricated sensors for the phantom validation measurements.
A.1. Summary

The SAR measurements were performed in accordance to the FCC SAR Evaluation guideline document called FCC OET Bulletin 65 Supplement C [75] for body worn transmitting devices. FCC OET Bulletin 65 Supplement C is used and accepted as an industry standard for SAR level evaluations. Based on the measurements made at Kyocera Wireless, it is shown that with an output power of 30 mW and operating frequency of 915 MHz, the highest measured SAR level (1g Av.) for the microwave coupler (applicator) is 0.475 (W/kg), which is 1/3 lower than the FCC SAR limit set at 1.6 (W/kg). As may be seen from Table 3, this power level is about 15 dBm, which is much more than the power needed in making the microwave measurements. Detailed explanation of the SAR
measurement procedures and measurement system calibration/validation is further discussed in the proceeding sections.

**A.2. Specific Absorption Rate (SAR)**

Specific-absorption-rate measurements are critical for understanding the effects of non-ionizing radiation, such as the emissions from devices that is based on radio frequency (RF) technology on biological tissues. Energy emitted from these devices, such as cell phones, are commonly referred to as electromagnetic or RF radiation. Exposure to very high RF intensities may result in tissue damage due to thermal effects or heating of the tissue. Safety standards for human exposure to RF energy are evaluated by the Specific Absorption Rate (SAR), which quantifies the rate at which energy is absorbed per unit mass in an exposed object.

Specific absorption rate or SAR is the time derivative of the incremental energy (dW) absorbed by or dissipated in an incremental mass (dm) contained in a volume (dV) of a given density (σ):

\[
SAR = \frac{d}{dt} \left( \frac{dW}{dm} \right) = \frac{d}{dt} \left( \frac{dW}{\rho dV} \right) \tag{A-1}
\]

SAR should be considered an "absorbed dose rate" and is related to electric fields at a point by:

\[
SAR = \frac{\sigma |E|^2}{\rho} \tag{A-2}
\]

Where:

\( \sigma \) = conductivity of the tissue (S/m)

\( \rho \) = mass density of the tissue (kg/m³)
$|E|$ = magnitude of the measured electric field (V/m)

To account for near-field energy coupling effects, transmitters are evaluated with electric field measurements inside homogeneous tissue models or computer modeling techniques using anatomically equivalent tissue models.

### A.3. Description of Test System

To ensure that the safety requirements were met with the coupling device, the SAR measurements were performed with DASY4 [76], an automated near-field scanning system shown in the figures below.

![SAR Measurement system, DASY4 (SPEAG, Switzerland)](image)

Figure A.1. SAR Measurement system, DASY4 (SPEAG, Switzerland)
A.4. DASY4 System Components

Summary of components:

- Measurement server for signal filtering and controls the high precision 6-axis robot
- Computer with Windows XP and DASY4 software
- Dosimetric probe with an optical surface detector system calibrated for use in liquid with high permittivity
- Probe alignment unit
- Data Acquisition Electronic (DAE)
- Electro-optical converter (ECO)
- SAM twin phantom
- Tissue simulating liquid
- Validation dipole kits to verify proper functioning of the system
Detailed description of the system components are discussed below.

A.4.1. DASY4 E-Field Probe System

The SAR measurements were conducted with the dosimetric E-field probe ET3DV6 which is designed and calibrated for liquid materials with high permittivity. It is also outfitted with an optical surface detection sensor to prevent collisions with the phantom shell.

**Construction**
- Symmetrical design with triangular core
- Built-in optical fiber for surface detection system (ET3DV6 only)
- Built-in shielding against static charges
- PEEK enclosure material (resistant to organic solvents, e.g., DGBE)

**Calibration**
- ISO/IEC 17025

**Frequency**
- 10 MHz to 2.3 GHz
- Linearity: ± 0.2 dB (30 MHz to 2.3 GHz)

**Directivity**
- ± 0.2 dB in HSL (rotation around probe axis)
- ± 0.4 dB in HSL (rotation normal to probe axis)

**Dynamic Range**
- 5 µW/g to > 100 mW/g; Linearity: ± 0.2 dB

**Optical Surface Detection**
- ± 0.2 mm repeatability in air and clear liquids over diffuse reflecting surfaces

**Dimensions**
- Overall length: 330 mm (Tip: 16 mm)
- Tip diameter: 6.8 mm (Body: 12 mm)
- Distance from probe tip to dipole centers: 2.7 mm

**Application**
- General dosimetric measurements up to 2.3 GHz
- Compliance tests of mobile phones
A.4.2. Data Acquisition Electronics (DAE)

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<td>Serial optical link for communication with DASY4/5 embedded system (fully remote controlled)</td>
</tr>
<tr>
<td></td>
<td>2 step probe touch detector for mechanical surface detection and emergency robot stop</td>
</tr>
<tr>
<td>Measurement Range</td>
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<tr>
<td>Input Offset Voltage</td>
<td>± 0.2 dB in HSL (rotation around probe axis)</td>
</tr>
<tr>
<td></td>
<td>± 0.4 dB in HSL (rotation normal to probe axis)</td>
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<tr>
<td>Dynamic Range</td>
<td>5 µW/g to &gt; 100 mW/g; Linearity: ± 0.2 dB</td>
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<tr>
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<tr>
<td>Battery Power</td>
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</tr>
<tr>
<td>Dimensions</td>
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</tr>
<tr>
<td>Calibration</td>
<td>ISO/IEC 17025</td>
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</tbody>
</table>

A.4.3. DASY4 Measurement Server

166MHz low power Pentium MMX
32MB chip disk and 64MB RAM
Serial link to DAE4 (with watchdog supervision)
16 Bit A/D converter for surface detection system
Two serial links to robot
Ethernet link to PC (with watchdog supervision)
Emergency stop relay for robot safety chain
Two expansion slots for future applications

A.4.4. Sam Twin Phantom Shell

The phantom that was used for the SAR measurements is called Specific Anthropomorphic Mannequin (SAM 12) which holds about 25 liters of tissue
equivalent liquid. A cover is used to prevent liquid evaporation when it is not being used. The shell corresponds to the specifications in IEEE 1528-2003, CENELEC 50361 and IEC 62209. The shell thickness is $2 \pm 0.2$ mm, and is 1000 mm long and 500 mm wide. Dielectric constant ($\varepsilon_r$) of the phantom shell is less than 5 and the loss tangent ($\tan \delta$) is less than 0.05. Reference markings on the phantom shell allow the complete setup of all predefined phantom positions and measurement grids with respect to the robot. The measurements were conducted on the flat phantom. The figures below show the phantom from the top and bottom view.

![Figure A.3. SAM Phantom Shell (top and bottom view)](image)

System validation enables verification that the system is performing according to specifications. Problems that it can detect includes:

- inappropriate liquid
- malfunction of probe
- malfunction of surface detector
- evaluation problems
A.4.5. Calibration Certificates of Measurement

Equipment

In addition to the system validation, the E-field probe and the data acquisition system has to be calibrated once a year to ensure that it is functioning properly and that the measured data is accurate. The calibration certificates of the E-field probe and the DAE system contains the last date of calibration, and method and components used for calibration. The certificates are shown below.
CALIBRATION CERTIFICATE

Object

DAE4 - SD 000 D04 BJ - SN: 603

Calibration procedure(s)

QA CAL-06.v20
Calibration procedure for the data acquisition electronics (DAE)

Calibration data:

September 15, 2009

Condition of the calibrated item

In Tolerance

This calibration certificate documents the traceability to national standards, which realize the physical units of measurements (SI). The measurements and the uncertainties with confidence probability are given on the following pages and are part of the certificate.

All calibrations have been conducted in the closed laboratory facility: environment temperature (22 ± 3)°C and humidity < 70%.

Calibration Equipment used (M&TE critical for calibration)

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Calibrated by:

Name: Dominique Staffin
Function: Technician
Signature: [Signature]

Approved by:

Name: Fin Bonhoff
Function: R&D Director
Signature: [Signature]

Certificate No: DAE4-603_Sep09
Page 1 of 5

Issued: September 15, 2009

This calibration certificate shall not be reproduced except in full without written approval of the laboratory.
# Calibration Certificate

**Client:** Kyocera USA  
**Certificate No:** ET3-1664_Jun09

## Calibration Certificate Details

**Object:** ET3DV6 - SN:1664

**Calibration Procedure(s):** QA CAL-01_v6 and QA CAL-23_v3  
Calibration procedure for dosimetric E-field probes

**Calibration Date:** June 22, 2009

**Condition of the Calibrated Item:** In Tolerance

This calibration certificate documents the traceability to national standards, which realize the physical units of measurements (SI). The measurements and the uncertainties with confidence probability are given on the following pages and are part of the certificate.

All calibrations have been conducted in the closed laboratory facility: environment temperature (22 ± 3)°C and humidity < 70%.

**Calibration Equipment used (M&TE critical for calibration):**

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<th>ID #</th>
<th>Cal Date (Certificate No.)</th>
<th>Scheduled Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power meter E4419B</td>
<td>QB41293374</td>
<td>1-Apr-09 (No. 217-01030)</td>
<td>Apr-10</td>
</tr>
<tr>
<td>Power sensor E4412A</td>
<td>MY41495277</td>
<td>1-Apr-09 (No. 217-01030)</td>
<td>Apr-10</td>
</tr>
<tr>
<td>Power sensor E4412A</td>
<td>MY41498087</td>
<td>1-Apr-09 (No. 217-01030)</td>
<td>Apr-10</td>
</tr>
<tr>
<td>Reference 3 dB Attenuator</td>
<td>SN: 55054 (3c)</td>
<td>31-Mar-09 (No. 217-01026)</td>
<td>Mar-10</td>
</tr>
<tr>
<td>Reference 20 dB Attenuator</td>
<td>SN: 55086 (20b)</td>
<td>31-Mar-09 (No. 217-01028)</td>
<td>Mar-10</td>
</tr>
<tr>
<td>Reference 30 dB Attenuator</td>
<td>SN: 55129 (30b)</td>
<td>31-Mar-09 (No. 217-01027)</td>
<td>Mar-10</td>
</tr>
<tr>
<td>Reference Probe ES3DV2</td>
<td>SN: 3013</td>
<td>2-Jan-09 (No. ES3-2013_Jan09)</td>
<td>Jan-10</td>
</tr>
<tr>
<td>DAE4</td>
<td>SN: 660</td>
<td>9-Sep-08 (No. DAE4-660_Sep08)</td>
<td>Sep-09</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Standards</th>
<th>ID #</th>
<th>Check Date (in house)</th>
<th>Scheduled Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF generator HP 8648C</td>
<td>US3642U01700</td>
<td>4-Aug-09 (in house check Oct-07)</td>
<td>In house check: Oct-09</td>
</tr>
</tbody>
</table>

**Calibrated by:**  
Marcos Fehr  
Laboratory Technician

**Approved by:**  
Kajsa Pokovic  
Technical Manager

Issued: June 22, 2009

Certificate No: ET3-1664_Jun09  
Page 1 of 9
## A.4.6. Test Equipment List

<table>
<thead>
<tr>
<th>Name of Equipment</th>
<th>Type/Model</th>
<th>Manufacture</th>
<th>Serial Number</th>
<th>Date of Last Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosimetric E-field Probe</td>
<td>ET3DV6</td>
<td>SPEAG</td>
<td>1664</td>
<td>6/22/090</td>
</tr>
<tr>
<td>Data Acquisition Electronics</td>
<td>DAE4</td>
<td>SPEAG</td>
<td>603</td>
<td>9/15/09</td>
</tr>
<tr>
<td>Communication System</td>
<td>LPD 900</td>
<td>SPEAG</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Robot</td>
<td>RX90BL</td>
<td>Staubli</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Phantom</td>
<td>SAM 12 – Flat Section</td>
<td>SPEAG</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Software (Measurement)</td>
<td>DASY4, V4.7 Build 71</td>
<td>SPEAG</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Software (Postprocessing)</td>
<td>SEMCAD, V1.8 Build 184</td>
<td>SPEAG</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Dielectric Probe Kit</td>
<td>85070D</td>
<td>Agilent</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Network Analyzer</td>
<td>8753E</td>
<td>HP</td>
<td>US37390585</td>
<td>10/09</td>
</tr>
<tr>
<td>DC Power Supply</td>
<td>718-5D</td>
<td>Leader</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Power Meter</td>
<td>8541C</td>
<td>Gigatronics</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
A.5. Measurement Setup and Procedure

Outline of the measurement procedures from the FCC recommended guidelines [75] are as follows: Refer to [75] for more details.

**Set-up 1: DUT (applicator/coupler) on the flat section of the phantom shell:**
1. Measure output power from the DC power supply with a power meter
2. Place DUT (applicator) on the flat section of the phantom shell
3. Set scan area, grid size, and other setting on the DASY4 software
4. Perform Area Scan, Zoom Scan and SAR Values
5. Verify initial output power with a power meter

**Set-up 2: Human equivalent muscle tissue between DUT (applicator/coupler) and the flat section of the phantom shell:**
1. Measure output power from the DC power supply with a power meter
2. Place human equivalent skin tissue (thickness ≤1 mm) on the flat section of the phantom shell
3. Place DUT (applicator) on the human equivalent skin tissue
4. Set scan area, grid size, and other setting on the DASY4 software
5. Perform Area Scan, Zoom Scan and SAR Values
6. Verify initial output power with a power meter

Placement of the applicator on the flat section of the phantom shell is illustrated below.

![Image of Set-up of applicator on the flat section of the phantom shell.](image-url)

Figure A.5. Set-up of applicator on the flat section of the phantom shell.
The following figures contain the schematic and fabricated applicators that were tested. In addition to the original size, the applicators were also scaled down by 75%.

Applicator #3 was tested with human equivalent skin tissue (frequency: 915 MHz; $\sigma = 0.85$ S/m; $\varepsilon_r = 46$) between the applicator and the phantom shell for impedance matching. Applicator #1 & #2 were directly placed in contact with the flat section of the phantom shell during the measurements. The characteristic impedance of Applicator #1 and #2 was designed to match 50$\Omega$ when it is in contact with the phantom shell. Applicator #3 has a characteristic impedance of 50$\Omega$ when it is in contact with human skin tissue.

Table A.1. Fabricated Applicators with Schematic Diagram

<table>
<thead>
<tr>
<th>Applicator Design #</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Schematic</strong></td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>(Original Size)</td>
<td>(units in inches)</td>
<td>(units in inches)</td>
<td>(units in inches)</td>
</tr>
<tr>
<td><strong>Fabricated</strong></td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>Applicators</td>
<td>(Original Size)</td>
<td>(Original Size)</td>
<td>(Original Size)</td>
</tr>
<tr>
<td><strong>Design Purpose</strong></td>
<td>Impedance matched ($\approx 50\Omega$) when in contact with <strong>phantom shell</strong> (dielectric constant ($\varepsilon_r$) &lt; 5) (loss tangent (tan $\delta$) &lt; 0.05)</td>
<td>Impedance matched ($\approx 50\Omega$) when in contact with <strong>phantom shell</strong> (dielectric constant ($\varepsilon_r$) &lt; 5) (loss tangent (tan $\delta$) &lt; 0.05)</td>
<td>Impedance matched ($\approx 50\Omega$) when in contact with <strong>human skin tissue</strong> (dielectric constant ($\varepsilon_r$) = 46) (conductivity ($\sigma$) = 0.85 S/m)</td>
</tr>
</tbody>
</table>
A.5.1. Additional Test Parameters

Tissue Simulating Liquids
Frequency = 915 MHz; $\rho = 1000$ kg/m$^3$
conductivity ($\sigma$) = 1.03 S/m; relative permittivity ($\varepsilon_r$) = 54.6
Temperature
Room = 21.8 +/- 1 °C Liquid = 22.0 +/- 1 °C
Area Scan (61x71x1): Measurement grid: dx=15mm, dy=15mm
Zoom Scan (7x7x7)/Cube 0: Measurement grid: dx=5mm, dy=5mm, dz=5mm
Sensor-Surface: 4mm (Mechanical Surface Detection)

The table below consists of the FCC guideline for SAR limits for

occupational/controlled and general/uncontrolled RF exposure.

Occupational/controlled exposure applies to individuals who are exposed as a
consequence of their employment and is fully aware of the potential for exposure.

General and uncontrolled exposure applies to the general public or individuals

Figure A.6. Set-up of the entire SAR measurement system with the applicator mounted on the phantom.
who are exposed as a consequence of their employment but is not aware of the potential exposure [75].

Table A.2. FCC guideline for SAR limits for occupational and general RF exposure. [75]

<table>
<thead>
<tr>
<th>SAR [W/kg]</th>
<th>Controlled/Occupational</th>
<th>Uncontrolled/General Population (localized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Body</td>
<td>0.4</td>
<td>0.08</td>
</tr>
<tr>
<td>1g. Avg. (Partial Body)</td>
<td>8</td>
<td>1.6</td>
</tr>
<tr>
<td>10g. Avg. (hands, wrists, feet, and ankles)</td>
<td>20</td>
<td>4</td>
</tr>
</tbody>
</table>

A.5.2. SAR Test Results

The following table consists of the output power levels tested to determine the appropriate range to generate SAR levels that is within the FCC limits.

Although the SAR level measured (.99 W/kg) at 17 dBm is below the guideline, 15 dBm was chosen to account for the varying sizes and designs of the applicators. The measured SAR value (0.416 W/kg) at 15 dBm was 1/3 lower than the limit for 1g. Avg.

Table A.3. Initial power test to determine the maximum output power needed to generate SAR values that are within the FCC guideline.

<table>
<thead>
<tr>
<th>dBm</th>
<th>Output Power</th>
<th>Measured SAR for 1g Avg. (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>10</td>
<td>0.12</td>
</tr>
<tr>
<td>15</td>
<td>31.62</td>
<td>0.416</td>
</tr>
<tr>
<td>17</td>
<td>50.12</td>
<td>0.99</td>
</tr>
<tr>
<td>20</td>
<td>100</td>
<td>2.1</td>
</tr>
</tbody>
</table>

The table below is a summary of the measured SAR values. All of the applicators tested produced SAR levels that are significantly lower than the FCC
SAR limits. The highest SAR level measured was 0.475 W/kg for 1g. Av, which is only 1/3 of the 1.6 W/kg SAR level limit set by the FCC.

Table A.4. Three types of applicators were used in the 1g. avg. SAR measurements (with maximum output power at 15 dBm or 31.6 mW) with the letter (a) indicating full size applicator and (b) indicating the same applicator design but with the size reduced to 75%.

<table>
<thead>
<tr>
<th>Applicator Schematic (a = 100 %) (b = 75%)</th>
<th>Device #</th>
<th>Applicator Design</th>
<th>Frequency (MHz)</th>
<th>S11 (dB)</th>
<th>Measured 1g. Avg. SAR (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>1(a)</td>
<td>915</td>
<td>-22.84</td>
<td>0.416</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1(b)</td>
<td>915</td>
<td>-13.15</td>
<td>0.415</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2(a)</td>
<td>915</td>
<td>-28.43</td>
<td>0.475</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2(b)</td>
<td>915</td>
<td>-26.42</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>3(a')</td>
<td>915</td>
<td>-27.46</td>
<td>0.435</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>3(b')</td>
<td>915</td>
<td>-31.52</td>
<td>0.319</td>
</tr>
</tbody>
</table>

*human equivalent skin tissue (frequency: 915 MHz; σ = .85 mho/m; εr= 46) between the applicator and the phantom shell (flat section).

Documentation of the SAR measurement parameters and results are included in the following figures.
Test Laboratory: Kyocera Wireless Corp.

**Device_1_M915 Flat with 15dBm 0mm Air Space, 10-13-09**

Communication System: LPD 900, Frequency: 915 MHz, Duty Cycle: 1:8.3
Medium: M915, Medium parameters used: \( f = 915 \text{ MHz}; \sigma = 1.03 \text{ mho/m}; \varepsilon_r = 54.6; \rho = 1000 \text{ kg/m}^3 \)
Phantom: SAM 12, Phantom section: Flat Section
**DASY4 Configuration:**
Probe: ET3DV6 - SN1664, ConvF(6.11, 6.11, 6.11), Calibrated: 6/22/2009
Sensor-Surface: 4mm (Mechanical Surface Detection),
Electronics: DAE4 Sn603, Calibrated: 9/15/2009
Measurement SW: DASY4, V4.7 Build 71
Postprocessing SW: SEMCAD, V1.8 Build 184
**Temperature:**
Room \( T = 21.8 \pm 1 \text{ deg C} \), Liquid \( T = 22.0 \pm 1 \text{ deg C} \)

**LPD 915/Area Scan (61x71x1):** Measurement grid: \( dx=15\text{mm}, dy=15\text{mm} \)
Maximum value of SAR (interpolated) = 0.427 mW/g

**LPD 915/Zoom Scan (7x7x7)/Cube 0:** Measurement grid: \( dx=5\text{mm}, dy=5\text{mm}, dz=5\text{mm} \)
Reference Value = 19.4 V/m; Power Drift = -0.098 dB
Peak SAR (extrapolated) = 1.07 W/kg
SAR(1 g) = 0.416 mW/g; SAR(10 g) = 0.209 mW/g
Maximum value of SAR (measured) = 0.468 mW/g

0 dB = 0.468 mW/g

**Device: 1**
Applicator: 1a
SAR (1g Av): 0.416 W/kg
Test Laboratory: Kyocera Wireless Corp.

Device_1_M915 Flat with 15dBm 0mm Air Space, 10-13-09

Communication System: LPD 900, Frequency: 915 MHz, Duty Cycle: 1.83
Medium: M915, Medium parameters used: f = 915 MHz; \( \sigma = 1.03 \text{ mho/m}; \varepsilon_r = 54.6; \rho = 1000 \text{ kg/m}^3 \)
Phantom: SAM 12, Phantom section: Flat Section

**DASY4 Configuration:**
Probe: ET3DV6 - SN1664, ConvF(6.11, 6.11, 6.11), Calibrated: 6/22/2009
Sensor-Surface: 4mm (Mechanical Surface Detection), Electronics: DAE4 Sn603, Calibrated: 9/15/2009
Measurement SW: DASY4, V4.7 Build 71
Postprocessing SW: SEMCAD, V1.8 Build 184

**Temperature:**
Room T = 21.8 +/- 1 deg C, Liquid T = 22.0 +/- 1 deg C

**LPD 915/Area Scan (61x71x1):** Measurement grid: dx=15mm, dy=15mm
Maximum value of SAR (interpolated) = 0.427 mW/g

**LPD 915/Zoom Scan (7x7x7)/Cube 0:** Measurement grid: dx=5mm, dy=5mm, dz=5mm
Reference Value = 19.4 V/m; Power Drift = -0.096 dB
Peak SAR (extrapolated) = 1.07 W/kg
SAR(1 g) = 0.416 mW/g; SAR(10 g) = 0.209 mW/g
Maximum value of SAR (measured) = 0.468 mW/g

0 dB = 0.397 mW/g

Device: 2
Applicator: 1b
SAR (1g Av): 0.415 W/kg
Test Laboratory: Kyocera Wireless Corp.

**Device_3_M915 Flat with 15dBm 0mm Air Space, 10-13-09**

Communication System: LPD 900, Frequency: 915 MHz, Duty Cycle: 1.8.3
Medium: M915, Medium parameters used: f = 915 MHz; σ = 1.03 mho/m; ε = 54.6; ρ = 1000 kg/m³
Phantom: SAM 12, Phantom section: Flat Section

**DASY4 Configuration:**
Probe: ET3DV6 - SN1664, ConvF(6.11, 6.11, 6.11), Calibrated: 6/22/2009
Sensor-Surface: 4mm (Mechanical Surface Detection),
Electronics: DAE4 Sn603, Calibrated: 9/15/2009
Measurement SW: DASY4, V4.7 Build 71
Postprocessing SW: SEMCAD, V1.8 Build 184

**Temperature:**
Room T = 21.8 +/- 1 deg C, Liquid T = 22.0 +/- 1 deg C

**LPD 915/Area Scan (61x71x1):** Measurement grid: dx=15mm, dy=15mm
Maximum value of SAR (interpolated) = 0.646 mW/g

**LPD 915/Zoom Scan (7x7x7)/Cube 0:** Measurement grid: dx=5mm, dy=5mm, dz=5mm
Reference Value = 20.1 V/m; Power Drift = 0.002 dB
Peak SAR (extrapolated) = 1.34 W/kg
SAR(1g) = 0.475 mW/g; SAR(10g) = 0.236 mW/g
Maximum value of SAR (measured) = 0.521 mW/g

Device: 3
Applicator: 2a
SAR (1g Av): 0.475 W/kg
Test Laboratory: Kyocera Wireless Corp.

**Device_4_M915 Flat with 15dBm 0mm Air Space, 10-13-09**

Communication System: LPD 900, Frequency: 915 MHz, Duty Cycle: 1:1
Medium: M915, Medium parameters used: \( f = 915 \) MHz; \( \sigma = 1.03 \) mho/m; \( \varepsilon_r = 54.6; \rho = 1000 \) kg/m³
Phantom: SAM 12, Phantom section: Flat Section

**DASY4 Configuration:**
Probe: ET3DV6 - SN1664, ConvF(6.11, 6.11, 6.11), Calibrated: 6/22/2009
Sensor-Surface: 4mm (Mechanical Surface Detection),
Electronics: DAE4 Sn603, Calibrated: 9/15/2009
Measurement SW: DASY4, V4.7 Build 71
Postprocessing SW: SEMCAD, V1.8 Build 184

**Temperature:**
Room \( T = 21.8 \pm 1 \) deg C, Liquid \( T = 22.0 \pm 1 \) deg C

**LPD 915/Area Scan (61x71x1):** Measurement grid: \( dx=15 \) mm, \( dy=15 \) mm
Maximum value of SAR (interpolated) = 0.319 mW/g

**LPD 915/Zoom Scan (7x7x7) Cube 0:** Measurement grid: \( dx=5 \) mm, \( dy=5 \) mm, \( dz=5 \) mm
Reference Value = 18.6 V/m; Power Drift = -0.098 dB
Peak SAR (extrapolated) = 1.71 W/kg
SAR(1 g) = 0.390 mW/g; SAR(10 g) = 0.124 mW/g
Maximum value of SAR (measured) = 0.379 mW/g

![Graph showing SAR levels](image)

Device: 4
Applicator: 2b
SAR (1g Av): 0.390 W/kg
Test Laboratory: Kyocera Wireless Corp.

**Device_5_M915 Flat with 15dBm 0mm Air Space, 10-13-09**

Communication System: LPD 900, Frequency: 915 MHz, Duty Cycle: 1:1
Medium: M915, Medium parameters used: f = 915 MHz; \( \sigma = 1.03 \text{ mho/m}; \ \varepsilon_r = 54.6; \rho = 1000 \text{ kg/m}^3 \)
Phantom: SAM 12, Phantom section: Flat Section
**DASY4 Configuration:**
Probe: ET3DV6 - SN1664, ConvF(6.11, 6.11, 6.11), Calibrated: 6/22/2009
Sensor-Surface: 4mm (Mechanical Surface Detection),
Electronics: DAE4 Sn603, Calibrated: 9/15/2009
Measurement SW: DASY4, V4.7 Build 71
Postprocessing SW: SEMCAD, V1.8 Build 184
**Temperature:**
Room T = 21.8 +/- 1 deg C, Liquid T = 22.0 +/- 1 deg C

**LPD 915/Area Scan (61x71x11):** Measurement grid: dx=15mm, dy=15mm
Maximum value of SAR (interpolated) = 0.395 mW/g

**LPD 915/Zoom Scan (7x7x7)/Cube 0:** Measurement grid: dx=5mm, dy=5mm, dz=5mm
Reference Value = 23.4 V/m; Power Drift = -0.057 dB
Peak SAR (extrapolated) = 1.41 W/kg
SAR(1 g) = 0.435 mW/g; SAR(10 g) = 0.170 mW/g
Maximum value of SAR (measured) = 0.513 mW/g

*human equivalent skin tissue between the applicator and the phantom (flat section)
APPENDIX B

STUDY PROTOCOL: HUMAN VITAL 
SIGN VALIDATION 

(Dr. B. Berg and Dr. H. Youn, Lead)
B.1. Approval Letters

UNIVERSITY OF HAWAI'I
Institutional Review Board

MEMORANDUM
April 13, 2011

TO:            Maggy J. Wender, Ph.D.
                Herbert R. Buth, M.D.
                Project Director
                College of Engineering
                Hawaii Studies Program

FROM:         Nancy R. Key
                Director

SUBJECT: CHS IRB # M5. "Proactive Interventions to Reduce Empty
              Beds in Hawaii's Healthcare System"

This is a notification that we received your request to approve the project. It is
 comply with 45 CFR 46.0102(d), the regulations issued by the Office of Human
 Research Protection. The information presented above checks all of the required
 elements, and the project, is approved for your reference effective April 12, 2011.

This memorandum is your record of CHS approval of this study. Please maintain it with
 your study records.

CHS approval for this project will expire on April 12, 2012. If you expect your project to
 continue beyond April 12, 2012, you must apply for renewal of your CHS
 approval prior to the expiration date. If you fail to renew your approval, it is
 likely the entire project must be promptly ceases the CHS.

You must report any changes to the research plan to CHS. Changes that are
 substantial must be submitted for review and approval by CHS and other
 authorized agencies.

Please contact the office when you have any questions or need assistance. We appreciate
 your cooperation, and look forward to your success.

Nancy R. Key
Director

Office of Research Compliance
Hawaii Studies Program

UNIVERSITY OF HAWAI'I
Institutional Review Board

MEMORANDUM
April 13, 2011

TO:            Maggy J. Wender, Ph.D.
                Herbert R. Buth, M.D.
                Project Director
                College of Engineering
                Hawaii Studies Program

FROM:         Nancy R. Key
                Director

SUBJECT: CHS IRB # R55. "Proactive Interventions to Reduce Empty
              Beds in Hawaii's Healthcare System"

Your research project identified above, including the revised consent form, is approved
 for your use by the University of Hawaii (UH) Hawaii Studies Program as of R55
 meeting on April 12, 2011.

This memorandum is your record of CHS approval of this study. Please maintain it with
 your study records.

The Hawaii Studies Program approval for this project will expire on April 12, 2012. If you expect your project to
 continue beyond this date, you must submit an application for renewal of the Hawaii Studies Program
 approval. This approval may not be extended beyond the date stated in this memorandum.

If during the course of your project, you intend to make changes in the study, you must submit an
 application to the Hawaii Studies Program prior to implementing any changes. If you fail to report
 changes, the study will not be approved by the Hawaii Studies Program. While it is a requirement to
 notify the Hawaii Studies Program of changes, this notification does not guarantee that the
 project will be approved. If you are unsure whether a proposed change is substantive or
 non-substantive, please contact the Hawaii Studies Program.

Please contact the office when you have any questions or need assistance. We appreciate
 your cooperation, and look forward to your success.

Nancy R. Key
Director

Office of Research Compliance
Hawaii Studies Program

UNIVERSITY OF HAWAI'I
Institutional Review Board

MEMORANDUM
March 21, 2011

TO:            Maggy J. Wender, Ph.D.
                Herbert R. Buth, M.D.
                Project Director
                College of Engineering
                Hawaii Studies Program

FROM:         Nancy R. Key
                Director

SUBJECT: CHS IRB # R55. "Proactive Interventions to Reduce Empty
              Beds in Hawaii's Healthcare System"

Your research project identified above, including the revised consent form, is approved
 for your use by the University of Hawaii (UH) Hawaii Studies Program as of R55
 meeting on March 21, 2011.

This memorandum is your record of CHS approval of this study. Please maintain it with
 your study records.

The Hawaii Studies Program approval for this project will expire on April 12, 2012. If you expect your project to
 continue beyond this date, you must submit an application for renewal of the Hawaii Studies Program
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Please contact the office when you have any questions or need assistance. We appreciate
 your cooperation, and look forward to your success.

Nancy R. Key
Director

Office of Research Compliance
Hawaii Studies Program
B.2. Introduction

B.2.1. Hemodynamic Monitoring Background

In common clinical practice, hemodynamic assessment often does not occur until after an acute cardiac episode. If an accurate, noninvasive measurement of cardiac output (CO) monitoring were available, acutely ill and surgical patients undergoing major operations such as a coronary artery bypass graft would benefit. In addition, many patients with chronic and comorbid diseases that ultimately lead to the need for major operations and other costly interventions might benefit from more routine monitoring of CO [44] have shown that clinician estimation of CO show poor correlation to measured CO values,
thus patients are subject to potential misdiagnosis and mistreatment when CO is part of the therapeutic goal.

The most commonly used method of measuring CO in the ICU is highly invasive, utilizing a flow-directed, thermodilution catheter (also known as the Swan-Ganz catheter [25]), which represents significant risks to the patient. In addition, this technique is costly (several thousand dollars per procedure) and requires a skilled physician and a sterile environment for catheter insertion. As a result, it has been used only in very narrow strata (less than 2%) of critically ill and high-risk patients in whom the knowledge of blood flow and oxygen transport outweigh the risks of the method. In the United States, it is estimated that at least two million arterial catheter monitoring procedures are performed annually.

A noninvasive way to monitor cardiac hemodynamics would provide exceptional clinical value because data similar to invasive hemodynamic monitoring methods could be obtained with much lower cost and no risk. While noninvasive hemodynamic monitoring can be used in patients who previously required an invasive procedure, a larger impact can be made in patients and care environments where invasive hemodynamic monitoring was neither possible nor worth the risk or cost. An example of this is that full hemodynamic assessment has been shown to be a powerful predictor of short term heart failure events.

Furthermore, monitoring of cardiac output, the product of stroke volume (SV) and heart rate (HR), be important parameters in clinical decision-making with reference to acute blood loss. This is particularly important in remote triage and battlefield applications where hemorrhagic shock is a major cause of
morbidity and mortality. In fact, in wounded military personnel, shock usually occurs because of hypovolemia from acute blood loss, thereby making hemodynamic assessment a keystone of management. Subsequent monitoring to screen for ongoing hemorrhage and to assess the efficacy of resuscitation is important in preventing death and mortality in these patients.

In addition to the above clinical applications, hemodynamic monitoring alone and in conjunction with electrocardiographic (ECG) and blood pressure (BP) measurements may be used to express a variety of contractility indices that have a range of applications outside of a purely clinical context. These applications include fitness/exercise physiology assessments, measurements of autonomic function to aid psychophysiological research and general application as a non-invasive research tool.

**B.2.2. Existing non-invasive hemodynamic monitoring technology**

Currently there are several available devices that may be used to noninvasively monitor cardiac hemodynamics. These may be divided into four broad categories of transduction: External chest mechanical signals; External chest electrical signals; and Ultrasound techniques.

Hemodynamic assessment from external chest mechanical signals typically involves measuring the mechanical function of the heart and these technologies include seismocardiography, thoracocardiography, cardiokymography and kinetocardiography. In varying degrees, issues with these systems arise from the size and cost of the technology, the lack of ambulatory
monitoring capability, inability to measure stroke volume and in particular, sensitivity to motion artifact.

Hemodynamic assessment from external chest electrical signals generally refers to impedance cardiography (ICG). However, despite over 50 years of investigation in this device, one of the major controversies surrounding impedance cardiography concerns how well it compares with conventional methods of determining SV and CO, such as thermodilution [100]. Further issues with ICG are the lack of ambulatory systems and their sensitivity to motion artifact.

Hemodynamic assessment due to ultrasound is via echocardiography and this is the most widely used technology for assessment of mechanical function of the heart and ventricular wall motion. Recently a hand-held, battery powered echocardiograph-Doppler instrument has become available and through this stroke volume measurements become possible [101]. Echocardiography is usually the 'gold-standard' for hemodynamic monitoring. However this requires the availability of a skilled operator and cannot be used in continuous, ambulatory assessment situations.

### B.2.3. Microwave Technology

The above use models and review of currently available hemodynamic monitoring technologies shows that presently no technology exists that provides continuous, portable, low cost, ambulatory, accurate, and artifact free measurements. This research study is to evaluate and further develop a new technology that would meet all of these goals.
The purpose of this microwave coupler/applicator is to provide a passive, noninvasive way of taking measurements fluid content in a human lung. In addition to measuring the fluid content of the lung, this microwave coupler/applicator is also capable of measuring respiratory rate and heart rate. The device is able to measure these points of interest by continuously monitoring the reflection and transmission coefficients of the microwave signal transmitted through the thorax of the person under test. Observing the reflection and transmission coefficients enable the device to detect any changes in the permittivity and conductivity of the intervening tissues which (among other things) characterizes the amount of fluid accumulation in the lung. Included in the signature of the transmitted signal is an indication of the respiratory rate and heart rate. Phantom dog experiments that were conducted indicate that unlike other devices that were previously discussed, this microwave system uses a coupling device that is not affected by movement of the subject [51]- [53], [55]- [61]. The figures below include images of the coupling device and results from dog experiments.
Figure B.1. Specifications of the coupling devices a.) patented original model [51]- [53] b.) current model c.) fabricated applicator.

Figure B.2. Patented Applicators used in previous clinical assay [52], [53].
Figure B.3. Comparison between the commercially available transthoracic electrical impedance and microwave method. (a) Transthoracic electrical impedance – much of the transmitted signal is attenuated in the highly conductive chest wall. Improved design of the Electrical Impedance method with guarded electrodes but still suffers from short circuiting effects. (c) Microwave method: Superior sensitivity, no chest wall short circuiting effect, and no serious difficulty with the coupler contact between the coupler and the human body but suffers from attenuation. [58], [60]
Figure B.4. Experimental results of a dog experiment illustrating correlation between the phase of the microwave transmitted signal and the pulmonary arterial pressure, with the transfusion of blood and the subsequent bleeding of the dog. [58] [61]

Figure B.5. Isolated lung experiments developed to confirm in-vivo experiments on animals. [58]
Figure B.6. Results from an isolated lung experiment that correlates the change in the phase of the signal and the weight of the lungs from the accumulation of liquid. [58]

B.3. Objectives

The currently proposed work is designed to assess the accuracy of the microwave measurement technology on healthy human subjects. Specifically, the present project will:

(a) Provide a data set for further offline signal processing to extract a variety of physiological indices. These indices will be including heart rate and respiratory rate.

(b) Provide simultaneous data recorded via a validated commercial ambulatory cardio-respiratory monitoring system (Propaq LT). This data set will be used to validate the microwave measurements.
B.4. Methods

B.4.1. Participants

Recruitment of subjects will be based on the circumference of their chest or thorax at the level of the mid xiphoid process within the range of 85-105 cm at maximum end inspiration. This is to allow for detectable signals with high signal to noise ratio. We will specifically recruit male participants and women will be ineligible to participate because pregnancy testing is beyond the scope of this study. Volunteers will be sought who fall into the following categories: large male, medium male and small male. Ideally, weight range for the volunteers are as follows; small (less than 110 lbs.), medium (110 to 200 lbs), and large (more than 200 lbs.) Each participant will be between the ages of 18 and 40; will be in good health as determined by medical history and PARQ questionnaires [102]; and free of any obvious physical disability that would preclude completion of any of the experimental procedures. Should an enrolled participant fail to complete the entire study protocol for any reason, he/she will be replaced. At the end of each of the five 1-hour sessions, volunteers will be compensated with a $10 gift certificate.

Flyers to call for volunteer participants will be distributed around UH-Manoa campus. Volunteers will be asked to complete the Biographical/Medical History Questionnaire and the PARQ revised/used by AHA. These will be reviewed by the participating physician Dr. Benjamin Berg, MD, JABSOM who will be responsible for determining which volunteer is eligible to participate in the study. Eligible volunteers will then be asked to schedule an appointment to
discuss the consent form and scheduling. We project six subjects but will recruit twelve to account for withdrawals from the study.

**B.4.2. Exclusionary Criteria**

As noted previously, participants will be excluded from eligibility if there is any evidence of compromised health or physical capacity that would adversely affect participant safety or data quality. More specifically, below is a list of “good health” definition. These factors will be determined by questionnaire prior to enrollment which will be included in the pre-screening process to determine eligible participants which will be reviewed by Dr. Benjamin Berg, M.D. (JABSOM).

- Healthy young adults ages 18-40 years old.
- Self reported “good health”
- Self reported lack of hospitalization within one year.
- Self reported lack of medication use within 60 days.
- Self reported “medical problems” which require regular treatment

In addition, the PARQ revised/used by AHA will also be used to screen out individuals who may not be able to participate in exercise programs. These questions are included below. Any enrolled participant who is unable to fully comply with and complete the experimental procedures will be dismissed and subsequently replaced.

Answer yes or no to the following questions: (If all answers are NO then subjects may be eligible to participate. Any YES answer will disqualify participation.)
1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
2. Do you feel pain in your chest when you do physical activity?
3. In the past month, have you had chest pain when you were not doing physical activity?
4. Do you lose your balance because of dizziness or do you ever lose consciousness?
5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
7. Do you know of any other reason why you should not do physical activity?

B.4.3. Instrumentation

Each subject will be instrumented with the experimental device, the microwave coupler, and a standard commercially marketed medical cardio-respiratory monitoring system, Propaq LT [81]. This is a multi-function ambulatory device capable of non-invasively, continuously and simultaneously monitoring physiological signals such as heart rate and breathing rate using three- or five-lead ECG, pulse oximeter, and a Non-Invasive Blood Pressure (NIBP) cuff. In addition to the conventional clinical environments such as hospitals, the Propaq LT was designed for first on the scene rescuers such as air/ground transport personnel and tactical EMS teams. To account for artifacts,
the Propaq LT system has an automatic cardiovascular artifact rejection for the respiration measurements, signal extraction algorithm for the pulse oximeter and a smartcuff motion-tolerant technology with the NIBP cuff for the heart rate measurements.

Running both the proposed microwave device and the Propaq LT simultaneously will not cause interference and hence we propose that each participant will be prepared with both devices on and periodic data collection will be staggered at time intervals of few minutes. The overall test period should not extend one hour for each of the 5 sessions.

B.4.4. Instrument Safety

Safety standards, recommendations and guidelines for exposure to radio frequency and microwave energy have been developed independently by a number of international and national organizations including the American National Standards Institute (ANSI) and the IEEE (ANSI/IEEE C95.1-1992) [103]. These guidelines have been developed by panels of scientists and medical experts to protect human beings from known harmful levels of exposure to RFEM fields. Based on present knowledge, the IEEE supports the conclusion that exposure at or below the levels recommended in ANSI/IEEE C95.1-1992 is not harmful to human health.

These guidelines assert the following safety considerations:

Exposure to electromagnetic fields at frequencies above about 100 kHz can lead to significant absorption of energy and temperature increases. At frequencies from 10 MHz to 300 GHz, heating is the major effect of absorption of
electromagnetic energy, and temperature rises of more than 1–2 °C can have adverse health effects such as heat exhaustion and heat stroke.

The sensitivity of various types of tissue to thermal damage varies widely, but the threshold for irreversible effects in even the most sensitive tissues is greater than 4 W/kg under normal environmental conditions. These data form the basis for an occupational exposure restriction of 0.4 W/kg, which provides a large margin of safety for other limiting conditions such as high ambient temperature, humidity, or level of physical activity. This factor of 10 was used to provide a large margin of safety for other limiting conditions such as high ambient temperature, humidity, or level of physical activity.

To measure this, all specific absorption ratio (SAR) values are to be averaged over any 6-min period. Peaks of the SAR can range more than an order of magnitude above a whole body average and thus spatial peak SAR values below 8 W/kg as averaged over any one gram of tissue should also not be exceeded.

To ensure that these safety requirements were met with the proposed microwave device, a liquid phantom model at Kyocera Wireless Labs in San Diego was used to evaluate the resulting electric field distribution or SAR inside the phantom. The data gathered from this SAR test indicated that it was 1/3 less than the FCC limit for acceptable SAR levels. Therefore, SAR measurements will not be monitored for each participant and is beyond the scope of this study. Summary of the SAR compliance evaluation procedures and results are included in Table 1 and Table 2. The experimental device that will be used in this study is
Device #5, Applicator Design 3a in Table 2 below (Table 4 in Appendix A). Maximum output power that will be utilized is 30 mW at a frequency of 915 MHz. The recordings will be performed at ambient room temperature. As defined by the FDA, the proposed microwave device is a Non-Significant Risk Device. Measurement procedures and equipment parameters for SAR compliance evaluation are further discussed in Appendix A.

Table B.1. Summary of the SAR Compliance Evaluation testing parameters and results.

<table>
<thead>
<tr>
<th>Test Procedure(s):</th>
<th>FCC OET Bulletin 65 Supplement C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Classification:</td>
<td>Body Worn Transmitter</td>
</tr>
<tr>
<td>Frequency:</td>
<td>915 MHz</td>
</tr>
<tr>
<td>Max. Conducted Power Tested:</td>
<td>15 dBm 31.62 mW</td>
</tr>
<tr>
<td>FCC Guideline SAR (W/kg) [1g Av ]:</td>
<td>1.6 (W/kg)</td>
</tr>
<tr>
<td>Max. SAR level(s) (W/kg) [1g Av ] Measured:</td>
<td>0.475 (W/kg)</td>
</tr>
</tbody>
</table>

Risks from the approved instrument, Propaq LT, a commercially marketed device, are minimal since its components such as the blood pressure cuff, pulse oximeter and electrodes are all non-invasive. Risks from the pulse oximeter and the blood pressure include temporary pressure on the participant's index finger and biceps. Since the electrodes will be used to measure respiration rate, it will only detect electrical signals rather than inject currents into the skin of the participants. Wires or cables that will be attached to these components may result in participants getting tangled during the exercises. To protect the participants from this, research technicians will be specifically trained by Dr. Berg.
to perform procedures in such a way that the wires will not get in the way or pose any danger to the participants. Measures to minimize risk includes taping wires and tubes from the monitoring systems together into a bundle and routing to sensor boxes above waist level.

Table B.2. Measured SAR level for Device #5, the applicator that will be used in the study is 0.435 W/kg, which is 1/3 lower than the FCC’s safety limit at 1.6 W/kg.

<table>
<thead>
<tr>
<th>Applicator Schematic</th>
<th>Device #</th>
<th>Applicator Design</th>
<th>Frequency (MHz)</th>
<th>S11 (dB)</th>
<th>Measured 1g. avg. SAR (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a = 100 %)</td>
<td>1</td>
<td>1(a)</td>
<td>915</td>
<td>-22.84</td>
<td>0.416</td>
</tr>
<tr>
<td>(b = 75%)</td>
<td>2</td>
<td>1(b)</td>
<td>915</td>
<td>-13.15</td>
<td>0.415</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2(a)</td>
<td>915</td>
<td>-28.43</td>
<td>0.475</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2(b)</td>
<td>915</td>
<td>-26.42</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>3(a *)</td>
<td>915</td>
<td>-27.46</td>
<td>0.435</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>3(b *)</td>
<td>915</td>
<td>-31.52</td>
<td>0.319</td>
</tr>
</tbody>
</table>

*human equivalent skin tissue (frequency: 915 MHz; σ = .85 mho/m; εr = 46) between the applicator and the phantom shell (flat section).

B.4.5. Procedures

The following standardized procedures will be utilized throughout the protocol. Given the straightforward nature of this investigation, Dr. Benjamin Berg, M.D. (JABSOM) will determine which participants are eligible and will train
research technicians to adequately oversee every aspect of the study for quality-control purposes. During the study, procedures and measurements will be performed by research technicians that will be present at all times throughout the study. These research technicians will be trained by Dr. Berg, M.D. (JABSOM) as safety monitors. Upon the occurrence of any unexpected event or abnormalities, all procedures will be halted and the principal investigators, and Dr. Berg, M.D. and Dr. Iskander, Ph.D. will be notified immediately. To ensure the safety of the participants, data collection integrity, and to confirm research technicians training, both of the principal investigators will be present during the first three sessions.

**B.4.5.1. Preadmission medical screening**

Volunteers that responded to the flyers will be asked to complete the Biographical/Medical History Questionnaire and the PARQ questionnaire. The questionnaire will be reviewed by the participating physician, Dr. Benjamin Berg, M.D. (JABSOM) who will determine which volunteers are eligible to participate in the study. Eligible volunteers will then be asked to schedule an appointment to discuss the consent form scheduling, and counseling for participation. The questionnaire is included at the end of the protocol.

**B.4.5.2. Informed consent**

Each participant will be presented with the informed consent agreement which describes the study along with the potential risks (the Informed Consent Agreement appears later in this document). Once all of the participant’s questions have been answered, he will sign the agreement.
B.5. Testing Site

Preadmission medical screening and measurement procedures will be performed at the following site.

Holmes Hall 306 2540 Dole Street, Honolulu, Hawaii 96822

B.6. Testing schedule

Each subject will participate in up to five separate sessions for repeated measurements. The maximum duration for each session is 1 hour. During the 1 hour session, participants will perform several tasks under different set of conditions and two data sets will be recorded simultaneously, one from Propaq LT and the other from the EM coupler, the experimental device. The five sessions allows flexibility for rescheduling additional measurements due to technical adjustments, calibration, and subject’s time limitation.

Absolute measurements of hemodynamic parameters are not possible with the microwave technology without prior calibration. Therefore, the following tests are designed to introduce measureable changes in hemodynamic parameters so that relative assessments may be made. They are further designed to determine the sensitivity of the system to motion artifact. Event markers will be made either electronically or on a time-sheet to capture the precise timing of each new event. Microwave measurements as well as the validated external measurements with the Propaq LT system will be made continuously and simultaneously throughout the testing schedule. Each testing schedule will consist of the following steps:
(1) Each participant will complete the medical pre-screen, sign the informed consent agreement, and be outfitted with the microwave system. They will also be fitted with Propaq LT’s pulse oximeter, NIBP, and 3-lead ECG simultaneously with the proposed microwave system.

(2) Under all of the following task conditions microwave, SpO₂, respiratory and blood pressure measurements will be continuously and simultaneously recorded.

(3) Subjects will lie stationary on a cot in the supine position for 2 minutes. Subjects will be instructed to relax and breathe freely.

(4) After 2 minutes of free breathing, subjects will be asked to do a sequence of three breath holds. Each participant will be asked to hold their breath for 5 seconds. This will be required on repeated occasions during each session. No subject will be asked to hold their breath no more than once within 30 seconds. Event markers will be made during this time to indicate the breath holds and these should also be apparent on the respiratory tracings.

(5) After this, subjects will be asked to move at 3 different levels of arm motion (to assess sensitivity to motion artifact) which includes the following:
   a. Bring arms up extended to the side at shoulder level with palms facing to front.
   b. Bring extended arms together with palms facing towards each other until they are shoulder widths apart.
   c. Rotate hands inward so that both palms are facing towards the feet and bring arms down to the side towards the hips.

   The 3 levels of arm motion will be repeated three times sequentially within a minute.

(6) Subjects will then be asked to stand upright and breathe freely for 2 minutes. Changing from a supine to a standing position will result in a measurable change in heart rate and respiration rate.

(7) While standing, subjects will be asked to repeat the 3 levels of arm motion from step 5 within a minute.

(8) Subjects will be asked to perform the following exercises on a treadmill. The total planned treadmill exercise time is 12 minutes and will never exceed 15 minutes.
   1) Moderate warm-up for approximately 5 minutes at 1 mph.
   2) After the 5 minute warm-up, the treadmill speed will gradually ramp up to 3.7 mph over a period of 1 minute.
   3) After 3 minutes at 3.7 mph, the speed of the treadmill will gradually ramp up to 5.0 mph over a period 1 minute.
   4) Treadmill exercise will be completed after 3 minutes at 5.0 mph, for a total exercise interval of 12 minutes (5 min warm up, 1 min ramp, 3 min stage I, 3 min Stage II)

   The following termination criteria will ensure the safety of the subject. Occurrence of any of these events will immediately end the treadmill exercises.
   1) Subjects reach 85% of their maximum heart rate (calculated as 220 – age)
   2) At the request of the subject.
   3) Total exercise time on the treadmill exceeds 15 minutes for any reason.
   4) A subject faints or indicates any sign of pain or dizziness.
   5) Equipment malfunction.
B.7. Data analysis

Data will be stored and exported for offline analysis. This analysis will consist of appropriate signal processing algorithms to enhance signal to noise ratio and extract relevant hemodynamic indices. Appropriate statistical tests will be used to validate the accuracy of the microwave measurements against the external standards for each of the extracted indices. Further data mining may be done to model the relationship between measured indices and the external standards. Measured data will be fitted in correlation matrices which will consists of elements such as the mean error, SD error, RMSE, and correlation coefficient. An assessment of the sensitivity of the measurements to motion artifact will be performed. Sample of the Data Collection Form is included further down below.

B.8. Confidentiality

Participant confidentiality will be ensured through the assignment of a subject number to each individual to be used on all forms and any reference to the individual. A master list linking the subject name to the ID number will be kept in a password protected file that is accessible only to those immediately involved in the analysis of the data. No identification of the individual subject will be disclosed to others outside of the study environment unless required by law.

B.9. Disposition of Data

During the study and analysis, participant data will be stored on a secure, password protected computer that is accessible only to those immediately
involved in the data collection and analysis. Data subsequently will be stored on a secure, password protected computer that is accessible only to the research coordinator after the conclusion of the study, analysis, and any reporting requirements. All data files will be coded with subject ID number only and the master list linking the subject name to the ID number will be kept in a password protected file by a research coordinator. Participants may withdraw data from study use with a written notice to the study principal investigator within a month of the measurement sessions. Otherwise, the data files will be retained for three years after the investigation is terminated. These files may be kept for longer if required or requested by the IRB.
YOU MAY NOT PARTICIPATE IN THIS PROGRAM IF YOU:

- ARE UNDER THE AGE OF 18 OR OVER THE AGE OF 40
- ARE FEMALE
- HAVE BEEN HOSPITALIZED IN THE PAST 60 DAYS
- TAKE ANY MEDICATIONS
- HAVE ANY HEALTH PROBLEMS

You are invited to participate in a research project regarding a microwave sensor patch which is attached to the skin to measure heart rate and breathing rate. The research project will require you to exercise on a treadmill while your heart rate and breathing rate are measured.

- Participation is entirely voluntary.
- The estimated time to participate in this project is no more than 5 sessions, with a maximum of 1 hour per session.
- Your name and contact information is requested so volunteers may be contacted to confirm participation and scheduling.
- Under no circumstances will personal information be given to third parties, and participants will not be contacted for reasons other than relating to this study.
- Volunteers will be provided $10 reimbursement for each 1 hour session for participation.

Thank you very much for your consideration to participate in this project. Please contact Dr. Benjamin Berg for more information.

IDENTIFICATION OF INVESTIGATORS
Principal Investigator Benjamin W Berg MD.

CONTACT INFORMATION: Dr. Berg 808-692-1093 / bwberg@hawaii.edu

ADDRESS: TeleHealth Research Institute – MEB 212
University of Hawaii
John A.Burns School of Medicine
651 Ilalo St
Honolulu, HI 96813
Participants will be asked to answer the following questions from the PARQ revised/used by AHA to screen out these individuals.

Answer yes or no to the following questions: If all answers are NO then subjects will be eligible to participate. Any YES answer will disqualify participation

1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?

2. Do you feel pain in your chest when you do physical activity?

3. In the past month, have you had chest pain when you were not doing physical activity?

4. Do you lose your balance because of dizziness or do you ever lose consciousness?

5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?

6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

7. Do you know of any other reason why you should not do physical activity?
Biographical/Medical History Questionnaire

1. Birthdate: _____ Age: _____ Weight: _____ Height: _____

2. Are you currently under the care of a physician for the treatment of: excessive daytime sleepiness, narcolepsy, insomnia, or any other sleep disorder? Yes / No

3. Do you have any drug allergies? Yes / No
   If so, please list them below
   ______________________________________________________________________
   ______________________________________________________________________

4. Does your medical history include any of the following:
   - Chest pains? Yes / No
   - Heart attack? Yes / No
   - High blood pressure or hypertension? Yes / No
   - General cardiac concerns? Yes / No
   - Kidney disease? Yes / No
   - Liver disease? Yes / No
   - Arthritis? Yes / No
   - Recurrent or chronic pain? Yes / No
   - Frequent headaches? Yes / No
   - Depression? Yes / No
   - Emotional or mental illness? Yes / No
   - Drug abuse? Yes / No
   - Chronic stress? Yes / No

5. Are you currently taking medications for any of the conditions listed above? Yes / No
   If yes, please list them here:
   ______________________________________________________________________
   ______________________________________________________________________

6. Are you currently taking or have you taken any of the following within the last 60 days?
   - Aspirin? Yes / No
   - Ibuprofen (Motrin, Advil, Nuprin, etc.)? Yes / No
   - Naproxen (Aleve)? Yes / No
   - Ketoprofen (Orudis KT)? Yes / No
   - Tryptophan? Yes / No
   - Tyrosine? Yes / No
   - Cortisone or other steroid medication? Yes / No
   - Erythromycin? Yes / No
   - Nifedipine? Yes / No

7. What other prescription or over the counter medications have you taken in the last 60 days?
   ______________________________________________________________________
   ______________________________________________________________________

8. Have you ever participated in a research study before? Yes/No
<table>
<thead>
<tr>
<th>LAST NAME</th>
<th>FIRST NAME</th>
<th>Age</th>
<th>Weight</th>
<th>Height</th>
<th>BMI</th>
<th>Date</th>
</tr>
</thead>
</table>

**Device Name**
- PROPAQ LT
- MICROWAVE

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Time</th>
<th>HR (bpm)</th>
<th>NIBP (mmHg)</th>
<th>Resp (BrPM)</th>
<th>SpO2</th>
<th>Data File Name</th>
<th>HR/ min</th>
<th>Resp/min</th>
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<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>Two 5sec breath holds (one 5 sec breath hold every 30 sec)</td>
<td>12:32</td>
<td></td>
<td></td>
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<td></td>
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<td>Two 5sec breath holds (one 5 sec breath hold every 30 sec)</td>
<td>12:33</td>
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<td>3 Arm Motions (3 sets/min)</td>
<td>12:34</td>
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<td>(standing) Free breathing</td>
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<td>(standing) Free breathing</td>
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<td>3 Arm Motions (3 sets/min)</td>
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<td></td>
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<tr>
<td>Treadmill (5 min. warm-up)</td>
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CITI certificate of participating physician, Dr. Benjamin Berg, MD, JABSOM and project co-investigator, Dr. Nuri Celik, Ph.D. who will also assist with the procedures.
B.11. Informed Consent

Study Title: Non-invasive microwave measurements of human cardiorespiratory hemodynamics.

Protocol Number: CHS #: 18228

Principal Investigator(s):
Name: Dr. Magdy F. Iskander, Ph.D.
Address: Hawaii Center for Advanced Communications
University of Hawaii at Manoa – College of Engineering
1680 East West Road, Post 201
Honolulu, HI 96813
Telephone: (808) 956-3434
After Hours: (808) 232-8598
Email: magdy.iskander@gmail.com

Name: Dr. Benjamin Berg, M.D.
Address: Telehealth Research Institute
University of Hawaii - John A Burns School of Medicine
651 Ilalo St., MEB 212
Honolulu, HI 96813
Telephone: (808) 692-1093
After Hours: (808) 779-5651
Email: bwberg@hawaii.edu

This consent form may contain words or information that you do not understand. Dr. Iskander, Ph.D., Dr. Berg, M.D., or the research study coordinator who is familiar with the study will explain anything that you do not clearly understand. Please ask as many questions as you need to make sure that you understand this research study and why you are being asked to participate.

B.11.1. Investigative Procedures

We invite you to participate in a research study to develop a new non-invasive technology for continuous measurements of human vital signs. The
initial purpose of this experimental device, EM Coupler, is to provide a passive, noninvasive way of taking measurements of fluid content in a human lung. In addition to measuring the fluid content of the lung, this device is also capable of measuring human vital signs such as heart rate and breathing rate, which will be the focus of this study. The experimental device uses the same technology as cell phones and has been measured in a facility where they determined that it is safer than cell phones. According to the Federal Communications Commission (FCC) guidelines of what is considered safe for devices that release energy, the experimental device is 300% safer than cell phones. Exposure to energy levels higher than the ones set by the FCC may possibly increase the risk of damage to human tissue. However, the measured safety level for the experimental device was 1/3 lower than FCC safety limit. To validate the measurements from the experimental device, you will be also be outfitted with the Propaq LT system which is approved and used in hospitals and first on the scene emergency responders (EMS) to detect pulse and heart rate. The Propaq LT system includes a finger clip sensor, a blood pressure cuff and a set of patches called electrodes.

This study will consist of five sessions. The length of your participation per session, including set-up, monitoring your heart rate and breathing rate, and testing will be up to 1 hour. Therefore, the entire length of your participation for this study is a total of 5 hours. Measurements will be conducted in Holmes Hall Room 306 at UH-Manoa. During the 1 hour session, you will perform several tasks under different set of conditions and two data sets will be recorded at the
same time, one from the control device, the Propaq LT and the experimental device, the EM Coupler.

The experimental device will be placed on your bare chest and you simply wear them continuously during the study which will not exceed more than 1 hour. The experimental device includes two flexible sensors. Each sensor is half the size of a credit card and as thin as a paper. The sensors are connected by wires to a machine. The research technicians will first clean several areas on your bare chest with alcohol swabs where the patches will be positioned. The alcohol swabs may feel cold. It may be necessary to shave or clip some hair so the sensors will have good contact to the skin. One sensor will be placed on your skin on the center of your chest. The other sensor will be placed on your skin along your spine at about two inches below your shoulder blades. Adhesive tape will be used to hold the sensors in place. Signals similar to a cell phone signal will be passed through your body between the sensors. One sensor will send the signal while the other sensor will receive the signal. The signal received by the sensor will be used to determine how often you are breathing and how fast your heart is beating. Similar to when you are talking on a cell phone, you will not feel any pain or other sensation from the signal that is sent through your body.

The Propaq LT system includes a finger clip sensor, a blood pressure cuff and a set of patches called electrodes. The finger clip sensor weighs about 2-ounces which are about the weight of a stopwatch or a measuring cup. The finger sensor will be slipped onto the tip of your index finger to detect your pulse. It detects this by passing a light through your finger. Other than a minor and
tolerable pressure on your finger for about 10-20 seconds, you should not feel any pain from the sensor.

The blood pressure cuff is similar to the ones that you see in your physician’s office to measure your blood pressure. The cuff is made out of stretchable fabric that is attached to a rubber tube to pump air into the cuff. You will be asked to put your hand through the cuff loop and it will be tightened just above your elbow on your biceps. The cuff should be wrapped around your biceps comfortably. The blood pressure cuff will be inflated every few minutes and you will feel a slight temporary pressure producing a squeezing sensation or tightness around your biceps. After the last air pump, the pressure will be released as the air is let out of the cuff. This will be repeated several times throughout the session.

The electrode patches are connected by wires to a machine to determine the rate of your breathing. The patches are painless and do not send electricity through the body.

The patches are about twice the size of a quarter and are made out of foam and plastic. The research technicians will first clean several areas on your bare chest with alcohol swabs where the patches will be positioned. The alcohol swabs may feel cold. It may be necessary to shave or clip some hair so the patches stick to the skin. Two of the patches will be positioned below your left and right collarbone and the third electrode will be positioned near the bottom of your left ribcage. Gel will be applied on the electrodes to provide better contact between your skin and the patches. The gel might feel sticky and wet which is
similar to the consistency of a hair gel. The patches may feel cold when it is first applied because of the gel. In rare cases, some people may develop a rash or irritation where the patches were positioned.

You will be required to perform the following tasks:
- Lie stationary on a cot for 2 minutes
- Perform breathing exercises for 2 minutes
- Move your arms to the side, front and back down.
- Stand and relax for 2 minutes
- Move your arms to the side, front and back down.
- Exercise on a treadmill which includes the following:
  o Moderate warm-up for approximately 5 minutes at 1 mph on a treadmill.
  o After the 5 minute warm-up, the treadmill speed will gradually ramp up to 3.7 mph over a period of 1 minute.
  o After 3 minutes at 3.7 mph, the speed of the treadmill will gradually ramp up to 5.0 mph over a period 1 minute.
  o Tasks on the treadmill will be completed after 3 minutes at 5.0 mph.

B.11.2. Risks

Research studies often involve some risks. Although the risks are minimal in this study, we want to take every precaution to ensure your safety. The radiation risks associated with the use of the experimental device are about one-third of the risks associated with use of a cell phone. The risks when using a treadmill is small. It is similar to what the participants would expect from moderate physical activity and routine fitness exercises. Injuries may occur from tripping or getting tangled with the wires. All subjects are screened for medical problems and exercise tolerance and will be fully oriented to the protocol equipment. Protocol exercise treadmill equipment it equipped with an emergency power shutoff, which may be activated by the subject or the attendant research technician. Risks are similar to routine unmonitored self-engaged treadmill exercise. Rarely, people experience chest discomfort, dizziness, and shortness
of breath during the exercise. If you feel any discomfort throughout the experiment, you need it to report it to the research staff immediately. The research staff will be present at all times throughout the study. You may stop the exercises at any time. In the event of a research-related injury, please contact Dr. Benjamin Berg, M.D. at (808) 692-1093 or Dr. Magdy Iskander, Ph.D. at (808) 956-3434.

B.11.3. New Findings

Any significant new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you.

B.11.4. Benefits

Although you may not receive any direct benefit, your participation in this study will lead to the development of a technique which may help benefit patients undergoing surgery in the ICU as well as those with chronic cardiac disease or hypertension. Additionally, this technology has potential in battlefield and triage scenarios for monitoring acute blood loss, as well as for tracking performance in exercise training. In addition, the findings from this study will contribute substantially to general scientific knowledge.

B.11.5. Privacy of Records

All identifying information about you will be kept confidential to the extent allowed by law. Agencies with research oversight, who may review your records include: the University of Hawaii Committee on Human Studies (IRB), U.S. Food
and Drug Administration (FDA), and the National Institutes of Health (NIH) or other government offices.

The results of this study may be presented at meetings or in publications; however, your identity will not be disclosed (shared). If you sign this form, you have given permission to release information to these other people.

**B.11.6. Compensation in Case of Injury**

While the likelihood is small, if you are injured in the course of this research, you alone will be responsible for the costs of treating your injuries. In addition, no financial compensation for such things as lost wages, disability or discomfort is available.

Medical treatment is not available on-site. If you have any questions about this medical care, please talk to the principal investigators for this study, Dr. Benjamin Berg, M.D. at (808) 692-1093 or Magdy Iskander, PhD at (808) 956-3434.

**B.11.7. Compensation for your Participation**

You will be given a $10 gift certificate at each of the five sessions for your time and effort for participating in the study.

**B.11.8. Voluntary Participation**

Your participation in this study is voluntary. You may decide not to participate or you may withdraw from the study at any time. If you decide not to participate or choose to withdraw from this study, there will be no penalty or loss of benefits to which you are otherwise entitled. An appropriate alternative action
is to choose not to participate in this study. There is no charge to participate in this study. You will be reimbursed with up to $5 per day of the scheduled visit for parking costs.

**B.11.9. Right to Refuse to Participate or to Withdraw Early From the Study**

You have the right to refuse to participate or withdrawal from this study at any time without penalty of any kind. Of course, we will tell you anything we learn during the study that may help you decide whether to continue participating, or that is important to your overall health.

If you choose to withdraw from the study, you must notify the study principle investigator at the phone numbers listed on page 1 of this consent form for instructions on withdrawing from the study. If you choose to withdraw data from study use, you must notify the principle investigator within a month of the measurement sessions.

You may be withdrawn from this study without your permission at any time by the investigator conducting this study. Unsafe, uncooperative, or offensive behavior may be cause for your withdrawal from the study.

For further information regarding this study, or in case of any study-related injury, please notify your study principle investigator at the phone number(s) listed on the first page of this form. If you have any questions about your rights as a research subject, you may contact: UH Committee on Human Studies at (808) 956-5007, or (808) 539-3955.
I HAVE BEEN TOLD OF THE POSSIBLE RISKS INVOLVED IN THIS PROJECT, THAT I HAVE BEEN GIVEN SATISFACTORY ANSWERS TO ANY INQUIRIES CONCERNING PROJECT PROCEDURES AND OTHER MATTERS AND THAT I HAVE BEEN ADVISED THAT I AM FREE TO WITHDRAW MY CONSENT AND TO DISCONTINUE PARTICIPATION IN THE PROJECT OR ACTIVITY AT ANY TIME WITHOUT PREJUDICE.

I herewith give my consent to participate in this project with the understanding that such consent does not waive any of my legal rights; nor does it release the principal investigator or any employee or agent thereof from liability for negligence.

_____________________________ ______________________________
Printed name        Signature of individual participant

________________________________________
Date

(If you cannot obtain satisfactory answers to your questions or have comments or complaints about your treatment in this study, you may contact UH Committee on Human Studies, 1960 East-West Road, Room B-104, Honolulu, HI 96822; Phone: 808.956.5007; Email: uhirb@hawaii.edu) cc. Signed copy to subject
APPENDIX C

STUDY PROTOCOL: LUNG FLUID VALIDATION

(QMC Team)
C.1. Approval Letters

Chronic heart failure, and its acute exacerbations, is one of the leading causes of hospitalization, costs and death in the United States. Annually, more than one million patients are hospitalized due to heart [104] failure and this accounts for a total Medicare expenditure exceeding $17 billion [104]. Very high (>25% within 30 days) readmission rates associated with HF significantly increase the costs [105]; hence, reduction of the readmission rates has the highest priority in curbing these costs. Reengineered integrated HF treatment centers have been proposed replacing the traditional HF clinic model [106].
Remote monitoring, homecare, and self-treatment are perceived as vital components of the proposed integrated HF treatment center.

Being able to closely monitor the changes in lung fluid, respiratory and heart rate, are the foundation for proactively preventing worsening of patients’ heart failure and treating acute exacerbations, when they occur. However, a detailed literature review and interviews with more than 100 cardiologists revealed that, there is no reliable, non-invasive, low-cost, and easy-to-use medical sensor to measure the changes in lung fluid content not only for home care applications but also in clinical settings. To overcome these limitations, the PIs proposed the Cardio-Pulmonary-Stethoscope (CPS) which can non-invasively and accurately measure the changes in lung fluid content (demonstrated by animal experiments) [57]- [60], cardiac waveforms, heart rate (HR), and respiration rate (RR) (demonstrated on a few human subjects) [62]. CPS is a novel sensor based on radio frequency (RF) measurements on the patient’s chest.

The goal of this study is to assess the accuracy of a novel, low-cost, non-invasive, integrated radio frequency-based system – the Cardio-Pulmonary Stethoscope (CPS) – to assess lung water, heart rate, and respiratory rate. The CPS is a novel system, developed by investigators at the University of Hawaii, College of Engineering, that can continuously and non-invasively monitor changes in lung water content, and has been demonstrated to be extremely accurate in measuring heart and respiratory rate in human volunteers, and in
assessing lung water volume in animal studies, using a microwave frequency band technology.

Our intent is to examine how CPS measures correlate with information from hospitalized patients obtained from invasive right heart catheterization and other standard monitoring procedures. Specifically, our aims are to evaluate the accuracy of this non-invasive microwave system by:

Comparing changes in total lung water obtained from the CPS with changes in pulmonary capillary wedge pressure obtained during pulmonary artery catheterization among patients at The Queen’s Medical Center who require invasive monitoring for clinical care.

Comparing the accuracy of heart rate and respiratory rate measurements by the CPS with measurements of heart rate and respiratory rate by standard clinical methods.

C.2.2. Significance

C.2.2.1. Importance of Volume Status and Extravascular Lung Water [44]

Although ~80% of the lung is made up of water, gas-exchanging air spaces are protected by various barriers and drains. In multiple disease states, through injury or pressure (or both), these protective mechanisms fail, resulting in the abnormal accumulation of extravascular lung water (EVLW) [5]. Assessment of water volume status is important in the assessment and management of a number of acute and chronic health conditions, including heart failure, hypovolemia, and acute pulmonary injury. For example, the assessment of the
patient with left ventricular systolic dysfunction and progressive dyspnea includes an evaluation of volume status and extravascular lung water – often assessed by measuring weight, jugular venous pressure, presence of an S3 on cardiac exam, or peripheral edema – to guide management. Similarly, patients with symptomatic hypotension are often assessed for their volume status, particularly if dehydration is a consideration and/or when complicating factors (e.g., renal insufficiency, peripheral neuropathy, and concomitant comorbid illnesses) confound the diagnostic exam. Acute lung injury and the acute respiratory distress syndrome are characterized by noncardiogenic pulmonary edema, with evidence of an important correlation between extravascular lung water (and capillary leak) with patient prognosis.

**C.2.2.2. Currently Available Methods to Assess Water Volume Status and Extravascular Lung Water**

Physical exam, laboratory tests, and imaging are important but may not readily distinguish between intravascular and extravascular lung water and are often insufficient without supplemental information. Examples of used methods include assessments of jugular venous pressure, weight change, S3 on cardiac exam, orthostatic vital signs, end-organ function (e.g., renal function), chest radiography, chest tomography, magnetic resonance imaging (MRI) and position emission tomography (PET). These methods are either expensive, invasive, not suitable for continuous bed-side monitoring, or inaccurate particularly for early detection [101], [107].
C.2.2.2.1. Pulmonary artery catheterization or right heart catheterization

Pulmonary artery catheterization or right heart catheterization [25] provides invasive measurements of intracardiac filling pressures (e.g., right atrial pressure, pulmonary capillary wedge pressure), cardiac output, and peripheral vascular resistance. Although used less often than before, right heart catheterization is still commonly used in the operating room and intensive care units, and can be considered the 'gold standard' method. Although it is the criterion standard for assessing volume status, in routine clinical care, it has been associated with increased mortality. In particular, the pulmonary artery wedge pressure is helpful when assessing for pulmonary edema and water volume overload in patients with systolic heart failure. Other methods based on a single-thermal indicator technique have been used to measure extravascular lung water (including intracellular, interstitial and intra-alveolar water). Although side effects and complications are rare (e.g., conduction abnormalities, line infection, vascular trauma), right heart catheterization is reserved for select individuals after close consideration of risks and benefits.

C.2.2.2.2. Electrical impedance (EI) tomography

Electrical impedance (EI) tomography [100] is based on the concept that air and liquid offer different resistances to the flow of electricity through the body. Measuring thoracic bioelectrical impedance in response to low amplitude alternating electric current passed through the body yields a value for resistivity which can be correlated to gravimetric EVLW after correction for weight. Recent refinement using 'dynamic' cross-sectional reconstruction of this information
'gated' to the cardiac cycle (a source of electricity) has improved the test's sensitivity and specificity. However, despite over 50 years of investigation in this device, one of the major controversies surrounding impedance cardiograph (ICG) concerns how well it compares with standard methods of determining stroke volume (SV) and cardiac output (CO), such as thermodilution on right heart catheterization. Further issues with ICG are the lack of ambulatory systems and their sensitivity to motion artifact. Recent version of this approach has been implemented and commercialized in the form of an implantable device that is integrated with pacemakers. Initial experiences with the implantable version have been unfavorable [41], [108], [109].

C.2.2.2.3. Cardio-Pulmonary Stethoscope: A Novel Technological Application with Tremendous Potential

Earlier work by Dr. Iskander [51]- [53], [55]- [61], has demonstrated the feasibility of using microwave-based cardio-pulmonary stethoscope technology to accurately measure heart rate and respiratory rate in healthy volunteers at rest and during activity [62]. In Figure C.1, vital sign parameters including respiration, heartbeat, and electrocardiogram (EKG) are in good agreement with data from the clinically ubiquitous Propaq LT (Welch Allyn) system. The accuracy of information obtained from hospitalized, critically ill patients, however, is currently untested.
Importantly, at microwave frequencies, changes in the dielectric properties of tissues are also closely related to the amount of lung water present. The use of this technology to assess volume of lung water is based on continuous monitoring of the reflection and/or the transmission coefficient to indicate changes in the permittivity of the lung tissue. This method has the advantage of using highly penetrating microwave signals and electromagnetic waves that are attenuated as they travel through the body. Since the microwave (MW) transmission is not dominated by conduction currents (as is the electromagnetic induction (EI) method), the microwave method does not suffer from the short-circuiting effect of the highly conducting tissue surrounding the lung and is less susceptible to motion artifact.

In prior work by Dr. Iskander, the feasibility of using MW transmission to measure lung water was evaluated in dogs after inducing pulmonary edema and measuring in vivo changes in the transmitted 915 MHz microwave signal. A continuous recording of the phase of the microwave transmission coefficient (the
bottom plot in Figure C.2) graphically shows results from a typical lung water measurement experiment on dogs. Top curve shows the change in the pulmonary arterial pressure during the experiment while the lower curve shows corresponding changes in the phase of the microwave measured signal. The experiment starts with the infusion of 100cc of blood from a donor dog in the Femoral vein of the experimental dog and continued on until 1500cc was injected. The figure shows correlated trends between PA and microwave signal. After the 1500cc, bleeding started then injection continued, but the lung was saturated and signals continued to correlate but to a lesser extent.

From these results, it is clear that changes in the phase of the microwave transmitted signal agree very well with changes in the pulmonary edema as indicated by changes in the mean PA pressure.

Because of this encouraging experience, efforts were made to evaluate the accuracy of the method, particularly in detecting early stages of interstitial edema. Several experiments on isolated lungs were conducted through a lobe of an isolated dog’s lung were compared with the lung weight as the edema developed. Typical results from these experiments are shown in Figure 3. These results clearly show the immediate and direct change in the phase of the MW transmitted signal as the weight of the isolated lung was changed (see Figure 3). These results are, therefore, a strong indication of the sensitivity of the microwave method for the early detection of pulmonary edema.
Figure C.3. Results from an isolated lung experiment. [58]

C.2.2.3. **Summary**

The significance of this project is that we will test this novel method to assess changes in lung water content. The method is non-invasive, suitable for continuous and bedside monitoring and, potentially, more accurate than standard methods. If successful, this system has the potential to significantly impact the assessment and management of subjects with heart failure, respiratory failure, and other conditions with increased extravascular lung water.

C.2.3. **Innovation**

The use of microwave technology to measure lung water is innovative, and builds on groundbreaking work by our Co-Investigator, Dr. Iskander. Although electrical impedance technology and its new surgically implantable version are currently available to assess lung water, their use have been limited by concerns about validity and reliability and, indeed, its impact on the clinical care of patients who may potentially benefit from assessment of lung water has been limited.
C.2.4. Approach

C.2.4.1. Overview

We plan to compare measurements of lung water from the Cardio-Pulmonary Stethoscope (CPS) with pulmonary capillary wedge pressure obtained from pulmonary artery catheterization. In addition, we plan to compare heart rate and respiratory rate, as measured by the CPS, with standard measures used clinically.

C.2.4.2. Patient Population

Eligible subjects will include those patients at The Queen’s Medical Center who will undergo pulmonary artery catheterization for clinical indications at the discretion of the treating physician.

C.2.4.3. Eligibility Criteria

1) Adult ≥18 years old
2) Hospitalized at The Queen’s Medical Center on 1 of 4 specific areas
   i. Tower 6E / 3 (Cardiac ICU)
   ii. Tower 4M (Medical ICU)
   iii. Tower 4C (Surgical ICU)
   iv. Cardiac cath lab
3) Planned pulmonary artery catheterization for clinical indications
4) Able to obtain informed consent from subject or surrogate

C.2.4.4. Exclusion Criteria

Presence of intra-aortic balloon pump, AICD, or active cardiac pacing

Scheduled or planned (e.g., CT scan, central line placement) procedure during the 60 minute study period
Unstable to the point where setting up / obtaining data from the CPS would interfere with patient care (e.g., Code Blue)

C.2.5. Cardiopulmonary Stethoscope (CPS)

The CPS (see Figure C.4) consists of: 1) Two innovative broadband radio-frequency sensor arrays that are each shaped like an EKG patch (~32 mm diameter) that adhere to the patient’s chest; 2) A small, lightweight (1.75 lbs) device that sends, receives and analyzes the microwave signal; 3) A small laptop computer that is used to display and process the data. Information obtained from the CPS system includes measurements of change in lung water, heart rate, and respiratory rate.

![Figure C.4](image)

Figure C.4. Schematic illustration of experimental setup for measurement using CP-Stethoscope.
C.2.6. Procedures

C.2.6.1. Identification of Patients

Patients will be identified by the treating physician, who will contact the Research Nurse and/or Principal Investigator to inform them of a potentially eligible subject.

C.2.6.2. Informed Consent

Informed consent will be obtained from the patient or, if the patient is unable to provide informed consent, from the patient’s surrogate, consistent with hospital Policy and Procedure.
C.2.6.3. Electronic medical record review

Electronic medical record review will be performed to obtain the following information, which will be used to descriptively describe the study population.

Information obtain will be:

- Age
- Admission diagnosis
- Location/unit
- Gender
- Reason for right heart catheterization
- Race/ethnicity
- Type of surgery performed (if any)
- Height, weight
- Intubated (yes/no)

C.2.6.4. Data Collection

Example of data collection procedure is shown in Tables 1a and b. Table 1a is for the data collected from the right heart catheter while table 1b is for the data collected from the CPS measurements.

### Discrete Time Points

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<th>Time Point</th>
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<th>Ins and Outs</th>
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<td>PCWP</td>
<td>IV input from baseline</td>
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<td>T2 (30 min)</td>
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<td>T3 (45 min)</td>
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<td>T4 (60 min)</td>
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CPS=Cardio-Pulmonary Stethoscope; RR = Respiratory rate; RHC = Right Heart Catheterization; PCWP=Pulmonary Capillary Wedge Pressure; IV=intravenous.

*Information on pulse and respiratory rate will be obtained from the patient’s bedside monitor.

### Continuous Time Points

<table>
<thead>
<tr>
<th>Time Point</th>
<th>CPS</th>
<th>Other*</th>
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<tr>
<td>Every 10 sec. in 1 hour</td>
<td>Lung water</td>
<td>Pulse</td>
</tr>
</tbody>
</table>

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C.2.6.5. Data Analysis

Data will be stored and de-identified data will be exported for offline data analysis. First, appropriate signal processing algorithms will be used to enhance signal to noise ratio and extract relevant hemodynamic indices. Descriptive statistics will be used to summarize for the patients’ characteristics (i.e., age, gender, race/ethnicity, and BMI), clinical baseline variables (i.e., admission diagnosis, reason for right heart catheterization, location/unit, type of surgery performed, and intubation status).

For specific aim 1, first the continuous measurement of lung water content obtained from CPS will be summarized to a value relevant to each time point to make comparable to the discrete index, change in pulmonary capillary wedge pressure. The value at each corresponding time (i.e., 15, 45, and 60 min), average or area under the curve in each time interval will be potential candidates to represent change in lung content at each time point. At each time point, Lin’s concordance correlation and its 95% confidence interval will be calculated for the percentage changes of water volume from baseline, between the CPS and the pulmonary capillary wedge pressure approaches. Then we will compute partial correlation controlling for time to compare changes in the summarized lung water content from CPS with changes in pulmonary capillary wedge pressure.

For specific aim 2, first profile plots will be generated to visualize and compare microwave measurement against the external clinical method for each of the extracted indices (i.e., heart rate and respiratory rate). Then, we will perform time-series analysis to compute the cross correlation function between
the two measurements from CPS and external clinical method following
autoregressive integrated moving average (ARIMA) modeling. A two-sided t-test
of the cross correlation will be used to assess whether the correlation between
gold standard and CPS is statistically significant. The ARIMA will be performed
using one autoregressive and one moving average term and we will assume no
time lag. For all of the analyses, subject characteristic and clinical baseline
variables will be used to control for baseline difference, if necessary.

In addition, an assessment of the sensitivity of the measurements to
motion artifact will be performed by noting artifacts and correlating them with
patient’s movement and reporting these observations in the experiment report.

Sample size: Twenty five subjects will be enrolled for the study. Based on
preliminary human subject analysis, we expect that a concordance correlation
between change in lung water as measured by CPS approach and the change in
wedge pressure at a given time point will be greater than .60. With 25 patients, if
the true Lin’s concordance correlation coefficient is 0.60, we will be able to
estimate the coefficient with a lower 95% confidence limit of 0.33. If the actual
concordance correlation coefficient is 0.80, the lower 95% confidence limit will be
0.63. With a concordance coefficient of 0.90, our proposed sample size will
provide a lower 95% confidence limit of 0.81.

C.2.7. Instrument Safety

Safety standards [75], recommendations and guidelines for exposure to
radio frequency and microwave energy have been developed independently by a
number of international and national organizations including the American
These guidelines have been developed by panels of scientists and medical experts to protect human beings from known harmful levels of exposure to RFEM fields. Based on present knowledge, the IEEE supports the conclusion that exposure at or below the levels recommended in ANSI/IEEE C95.1-1992 is not harmful to human health.

These guidelines assert the following safety considerations:

Exposure to electromagnetic fields at frequencies above about 100 kHz can lead to significant absorption of energy and temperature increases. At frequencies from 10 MHz to 300 GHz, heating is the major effect of absorption of electromagnetic energy, and temperature rises of more than 1–2 °C can have adverse health effects such as heat exhaustion and heat stroke.

The sensitivity of various types of tissue to thermal damage varies widely, but the threshold for irreversible effects in even the most sensitive tissues is greater than 4 W/kg under normal environmental conditions. These data form the basis for an occupational exposure restriction of 0.4 W/kg, which provides a large margin of safety for other limiting conditions such as high ambient temperature, humidity, or level of physical activity. This factor of 10 was used to provide a large margin of safety for other limiting conditions such as high ambient temperature, humidity, or level of physical activity.

To measure this, all specific absorption ratio (SAR) values are to be averaged over any 6-min period. Peaks of the SAR can range more than an order of magnitude above a whole body average and thus spatial peak SAR
values below 8 W/kg as averaged over any one gram of tissue should also not be exceeded.

To ensure that these safety requirements were met with the proposed microwave device, a liquid phantom model at Kyocera Wireless Labs in San Diego was used to evaluate the resulting electric field distribution or SAR inside the phantom. The data gathered from this SAR test indicated that it was 1/3 less than the FCC limit for acceptable SAR levels. Therefore, SAR measurements will not be monitored for each participant and is beyond the scope of this study.

Summary of the SAR compliance evaluation procedures and results are included in Table C.1. The experimental device that will be used in this study is Device #5, Applicator Design 3a in Table C.2 below. Maximum output power that will be utilized is 30 mW at a frequency of 915 MHz. The recordings will be performed at ambient room temperature.

Table C.1. Summary of the SAR Compliance Evaluation testing parameters and results.

<table>
<thead>
<tr>
<th>Test Procedure(s):</th>
<th>FCC OET Bulletin 65 Supplement C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Classification:</td>
<td>Body Worn Transmitter</td>
</tr>
<tr>
<td>Frequency:</td>
<td>915 MHz</td>
</tr>
<tr>
<td>Max. Conducted Power Tested:</td>
<td>15 dBm 31.62 mW</td>
</tr>
<tr>
<td>FCC Guideline SAR (W/kg) [1g Av ]:</td>
<td>1.6 (W/kg)</td>
</tr>
<tr>
<td>Max. SAR level(s) (W/kg) [1g Av ] Measured:</td>
<td>0.475 (W/kg)</td>
</tr>
</tbody>
</table>
Table C.2. Measured SAR level for the CPS sensor that has been used in the study is 0.435 W/kg, which is less than 1/3 of the FCC's safety limit at 1.6 W/kg.

<table>
<thead>
<tr>
<th>Applicator Schematic (a = 100%) (b = 75%)</th>
<th>Device #</th>
<th>Applicator Design</th>
<th>Frequency (MHz)</th>
<th>S11 (dB)</th>
<th>Measured 1g. Avg. SAR (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>1(a)</td>
<td>915</td>
<td>-22.84</td>
<td>0.416</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1(b)</td>
<td>915</td>
<td>-13.15</td>
<td>0.415</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2(a)</td>
<td>915</td>
<td>-28.43</td>
<td>0.475</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2(b)</td>
<td>915</td>
<td>-26.42</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>3(a’)</td>
<td>915</td>
<td>-27.46</td>
<td>0.435</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>3(b’)</td>
<td>915</td>
<td>-31.52</td>
<td>0.319</td>
</tr>
</tbody>
</table>

As defined by the FDA, the proposed microwave device is a Non-Significant Risk Device. Measurement procedures and equipment parameters for SAR compliance evaluation are further discussed in Appendix A.

**C.2.8. Confidentiality**

Participant confidentiality will be ensured through the assignment of a randomly generated subject number for each subject to be used on all forms and any reference to the individual. A master list linking the subject name to the ID number will be kept in a password protected file that is accessible only to the
study PI. No identification of the individual subject will be disclosed to others outside of the study environment unless required by law.

C.2.9. Disposition of Data

During the study and analysis, participant data will be stored on a secure, password protected computer that is accessible only to those immediately involved in the data collection. De-identified data will be sent to JABSOM biostatistics & data management core for statistical data analysis. Data subsequently will be stored on a secure, password protected computer that is accessible only to the research coordinator after the conclusion of the study, analysis, and any reporting requirements. All data files will be coded with subject ID number only and the master list linking the subject name to the ID number will be kept in a password protected file by a research coordinator. Participants may withdraw data from study use with a written notice to the study principal investigator within a month of the measurement sessions. Otherwise, the data files will be retained for three years after the investigation is terminated. These files may be kept for longer if required or requested by the IRB.
C.2.10. Data Collection Form

Cardio-Pulmonary Stethoscope PCWP Study

Data Collection Form

Subject ID: _______________ Date: _____________________

Location (circle): T4M T4C T6E T3Cath lab

DEMOGRAPHIC DATA
Age: ________________ Gender: Male Female
Race/ethnicity: _______________ Height: _____________ cm in
________________ Weight: _____________ kg lb.
________________

CLINICAL DATA
Admission diagnosis:

Reason for right heart cath:

Type of surgery (if any):

Intubated (circle): Yes No

<table>
<thead>
<tr>
<th></th>
<th>CPS</th>
<th>RHC</th>
<th>Ins and Outs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lung water</td>
<td>Pulse</td>
<td>RR</td>
</tr>
<tr>
<td>T0 (baseline)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1 (15 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T2 (30 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T3 (45 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T4 (60 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:
C.3. Revision with Hemodialysis Patients

The Heart Failure research protocol was further extended to include Hemodialysis patients. The protocol was revised as follows:

**APPROACH**

**Overview:** We plan to measure changes in lung water using the Cardio-Pulmonary Stethoscope (CPS) in 2 populations:

1) **Patients with a PA catheter for clinical purposes:** CPS measurements will be automatically recorded over a 1 hour monitoring period. Comparator measures (e.g., wedge pressure) will be taken at baseline and at 60 minutes (two time points). These measures will be repeated once per day, for as long as the patient has the PA catheter in place for clinical purposes.

2) **Patients undergoing hemodialysis:** CPS measurements will be automatically recorded over a 1 hour monitoring period. Comparator measures (e.g., In/Out, jugular venous distention assessment) will be assessed at baseline and at 60 minutes (two time points).

Both populations allow for comparator measurements using either the PA catheter (e.g., wedge pressure, cardiac output) or measurement of fluid extraction during hemodialysis.

**Patient population:** Eligible subjects will include those patients at The Queen's Medical Center who undergo hemodialysis or pulmonary artery catheterization for clinical indications at the discretion of the treating physician.
APPENDIX D

DIGITAL SIGNAL PROCESSING

ALGORITHM FOR THE EXTRACTION OF

VITAL SIGNS AND CHANGES IN LUNG

FLUID CONTENT

(Dr.’s N. Celik, F. Qazi, and Mr. D. Bibb, Lead)
D.1. Extraction of the Vital Signs and Changes in Lung Fluid Content

Embedded in the single microwave measurement are various vital parameters such as cardiac and respiratory signals as well as changes in lung fluid content. Classification of the signal characteristics as illustrated in Figure D.1 were used to determine the appropriate signal extraction algorithm. Table D.1 below also includes several studies that have used various DSP techniques to extract vital signs.

- **Lung Water Content**
  - Slowly Changing
  - Strong
  - In-depth signals
  - Linear trend

- **Respiration Rate**
  - Sinusoidal
  - 0.05-0.5 Hz

- **Heart Rate**
  - 0.7-3 Hz
  - Peaks

Figure D.1. Characteristics of the lung water content signal, respiration rate and heart rate.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>DSP</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suzuki [110]</td>
<td>Dual frequency microwave radars for VS extraction in an ambulance</td>
<td>-BPF to separate the two freqs. for RR and HR</td>
<td>Does not account for additional personnel in the ambulance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-FFT w/ Hanning window to determine rates from peaks of FFT spectrum</td>
<td></td>
</tr>
<tr>
<td>Host-Madsen O.Lubecke [111]</td>
<td>Doppler radar for heart monitoring</td>
<td>FFT</td>
<td>Requires more complex DSP algorithm to extract VS from background noise such as random motion of the human target, radar, peripheral human subjects and other moving objects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BPF to extract HR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Blind Source Separation for multiple heart rates</td>
<td></td>
</tr>
<tr>
<td>Lohman [112]</td>
<td>Doppler radar sensing of vital signs</td>
<td>Demodulate signal</td>
<td>Only accounts for one person</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LPF to extract heartbeats</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BPF to extract breathing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Windowing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hanning window to enhance waveforms</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Center clipping to remove unwanted peaks</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Auto-correlation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak finding</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Heart and Respiration rate</td>
<td></td>
</tr>
</tbody>
</table>
Based on the signal characteristics of the microwave signal as illustrated in Figure D.2 below highlights the progression of the DSP algorithms used for this study.

Figure D.2. DSP techniques that were investigated for various experiments.

Based on the simplicity and minimal computational cost, the algorithms most suitable for this study is illustrated in a block diagram in Figure D.3.
Figure D.3. Block diagram of the DSP algorithms to extract the changes in lung fluid content, respiratory rate and heart rate

D.2. Optimization of the DSP Algorithm

D.2.1. Summary of Optimized Algorithms

Filter Specifications: For data analysis purposes, due to varying sampling frequencies of different data sets (some had ~20 Hz while others, ~13 Hz), filter design was performed in the main code. This allowed us to use the same DSP function regardless of the sampling frequency whereas, previously, there were different DSP’s different sampling frequencies.

Heart Rate DSP: Changes were made to the DSP to smoothen the filtered heart-waveform using either (a) a moving average filter or (b) a median filter. In the end, the moving average filter was used, the length of which was not an
arbitrary choice, but carefully set, depending on the upper cutoff frequency of the bandpass filter for the heart waveform.

Breathing Rate DSP: The Breathing Rate DSP was modified: instead of the original DSP which uses the DFT to compute the breathing rate, the new breathing rate DSP performs peak counting on the filtered breathing rate waveform, after performing smoothening using, a moving average filter. For this, the length of the moving average filter is decided by the upper cutoff frequency of the respiratory rate.

Removal of Motion Artifacts: Motion artifacts are removed by filtering out the heart and breathing rate waveforms as well as higher frequency components and going through a process of computing the discrete differential, thresholding and cumulative summation (inverse operation to the discrete differential) to remove the discontinuities. The thresholding of the discrete differential of the trend waveform was performed while carefully choosing the threshold levels, in order to remove motion artifacts from the raw phase trend and preserve the actual trend.

D.2.2. Modifications in Filter Design

The Filter Magnitude response, for the same filter length of 300, is improved for the new filter, resulting in a much lower sidelobe pedestal. A Finite Impulse Response (FIR) bandpass filter (with passband specified as 0.7 – 3 Hz) is designed for HR Peak Counting, and two FIR lowpass filters, with cutoff frequencies of 0.7 and 0.07 Hz are designed, for RR Peak Counting and Motion
Artifact Removal, respectively. For all the filters, Hamming window is used and the filter order is 300.

Figure D.4. Magnitude Response for (a) old bandpass filter and (b) new improved bandpass filter.

D.2.3. Modifications in Heart Rate DSP

The original DSP, which performed filtering only, without smoothening the waveform, was prone to counting extra peaks. In the new DSP, these extra peaks are removed via the waveform smoothening performed using a moving average filter. As a result, heart rate measurements are more accurate. The length of the moving average filter is carefully chosen as $N_{M,\text{band}} = \lfloor f_s / f_{c,\text{band}} \rfloor$, where $f_s$ is the sampling frequency and $f_{c,\text{band}}$ is the upper cutoff frequency of the bandpass filter (i.e. $f_{c,\text{band}} = 3$ Hz).
D.2.4. Modifications in Respiration Rate DSP

In the original respiration rate DSP, Short Time Fourier Transform is performed to compute the respiration rate on real-time. In the new DSP, the peak...
counting method, similar to that in the heart rate DSP, is applied. The results are found to be mixed: for patients with respiration rate > 20, the new DSP is found to be superior whereas for patients with respiration rates < 20, the original DSP gives better results. This is demonstrated by the following two examples.

Figure D.7. Heart Failure Patient 11, better results with new DSP.

Figure D.8. Heart Failure Patient 4, better results with old DSP.
D.2.5. Motion Artifact Removal

A DSP was developed to fully removed motion artifacts. This DSP involves passing the raw phase through an FIR lowpass filter (LPF) with cutoff frequency of 0.07 Hz. On the LPF output (which is the raw phase trend), a first order discrete differential is performed. The output of the discrete differential is subjected to adequate levels of thresholding before computing the cumulative sum (inverse operation to discrete differential). This final output is free of motion artifacts.

Figure D.9. Block Diagram, highlighting the process for removing the motion artifacts.
Figure D.10. Sample results for Hemodialysis Patient 4, 2nd Experiment
APPENDIX E

HUMAN CLINICAL VALIDATION

RESULTS

(Queen’s Medical Center and University of Hawaii Team)

E.1. Heart and Respiratory Rate (Healthy Participants)
Figure E.1. Results from treadmill participant 1. Calculated HR and RR (top) and Bland-Altman Plots of HR and RR.

Figure E.2. Results from treadmill participant 2. Calculated HR and RR (top) and Bland-Altman Plots of HR and RR.
Figure E.3. Results from treadmill participant 3. Calculated HR and RR (top) and Bland-Altman Plots of HR and RR.

Figure E.4. Results from treadmill participant 4. Calculated HR and RR (top) and Bland-Altman Plots of HR and RR.
E.2. Heart and Respiratory Rate and Changes in Lung Fluid Content (HF Patients)

Figure E.5. Results from heart failure patient 1. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.6. Results from heart failure patient 2, day 1. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.7. Results from heart failure patient 2, day 2. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.8. Results from heart failure patient 3, day 1. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.9. Results from heart failure patient 3, day 2. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.10. Results from heart failure patient 4. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.11. Results from heart failure patient 5, day 1. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.12. Results from heart failure patient 5, day 2. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.13. Results from heart failure patient 5, day 3. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.14. Results from heart failure patient 6. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.15. Results from heart failure patient 7. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.16. Results from heart failure patient 8. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.17. Results from heart failure patient 9. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.18. Results from heart failure patient 10. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.19. Results from heart failure patient 12. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.20. Results from heart failure patient 13. Comparison of changes in phase with measured PCWP pressure from Swan-Ganz catheter. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
E.3. Heart and Respiratory Rate and Changes in Lung Fluid Content (HD Patients)

Figure E.21. Results from hemodialysis patient 1. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.22. Results from hemodialysis patient 2. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.23. Results from hemodialysis patient 3. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.24. Results from hemodialysis patient 4 session 1. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.25. Results from hemodialysis patient 4 session 2. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.26. Results from hemodialysis patient 4 session 3. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.27. Results from hemodialysis patient 5. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.28. Results from hemodialysis patient 6. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.

Figure E.29. Results from hemodialysis patient 7. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
Figure E.30. Results from hemodialysis patient 8. Comparison of changes in phase with fluid removed during dialysis. Plots of calculated HR and RR from CPS and standard vital sign monitoring devices.
APPENDIX F

RF SWITCH CIRCUIT DESIGN

(D. Bibb, G. C. Huang, J. Tanabe and F. Suela, Lead)

F.1. RF Switch Circuit Design

The RF switching system is based on the Skyworks SKY13431-374LF SPDT switch. This device supports frequencies of 0.5 – 6.0 GHz with switching speed of 100 ns. A pinout and block diagram of this switch is shown in Figure F.1.

The RF path of the switch is selected by applying voltage to the V1 and V2 pins of the device. When voltage signifying a “1” is placed at V1, and “0” at V2, the RFC pin of the switch is connected to RF1, while RF2 is internally terminated to a 50 Ω load. If “0” is placed at V1, and “1” at V2, then RFC is connected to RF2, while RF1 is internally terminated. Valid voltage ranges for a “1” control is 2.5 V to 5.0 V. Valid voltage ranges for a “0” control is 0.0 V to 0.2 V. The 3.3 V
GPIO outputs of the microcontroller are used to drive these switches. The truth table for the switch control scheme is shown in Figure F.2

![Switch Control Truth Table](image)

**Figure F.2.** SPDT switch control truth table

The basic building block of the switching system is a single switch tree which switches an input RF path to one of two other RF output paths, using a single Skyworks SPDT switch. This paradigm is illustrated in Figure F.3 showing a CAD layout of a single SPDT switch on ADS and fabricated single SPDT switch with SMA connectors.
Figure F.3. (a) ADS CAD layout of a single SPDT switch and (b) photograph of the fabricated single SPDT switch with SMA connectors.

The schematic and layout for the microstrip tree were designed using Agilent’s (now Keysight) Advanced Design System (ADS). The microstrip input and outputs of the switching tree are designed on Rogers RO4350 substrate. The substrate used has dielectric height of 0.762 mm, copper layer thickness of 17 μm (1/2 oz.), and dielectric constant of 3.66. Based on these parameters, the line width for 50 Ω microstrip on this substrate is about 1.64 mm. Due to the small size of the switch device and its pins, the 50 Ω microstrip lines are tapered down to the 0.25 – 0.35 mm width of the circuit pads, as can be seen in the layout in Figure F.4. All 90-degree bends used in the microstrip tree are optimally chamfered 90-degree bends (see MSOBND in ADS for formulas). Simple pads are constructed for the V1 and V2 DC voltage control lines so that control wires can be soldered and connected to the switch chip from the microcontroller outputs. DC blocking capacitors are needed if the switch inputs or outputs at RFC, RF1, or RF2 are directly the final inputs or outputs of the complete switch system. These DC blocks are not needed when the input or output of a switch is
connected to the input or output of another switch. Female SMA connectors are used at the input and outputs of the single switches and switch trees. Male-to-male SMA connectors are used between the single switches and switching tree stack.

The 2-to-8 nature of the switching system is created by stacking two 1-to-8 switch trees, and combining each of the 8 outputs of both trees using a single SPDT switch. The input to the top switch tree would connect to the 2-port system’s transmit connection, and the input to the bottom tree would connect to the 2-port system’s receive connection. This can then support 8 sensors on the outputs of the SPDT switches. Any sensor pair can then be configured to be connected to Tx and Rx.

The design of the 1-to-8 switch tree follows the same design paradigm as the single 1-to-2 switch previously described. Beginning with a single switch, two further switches are connected to the original switch’s outputs. This is then extended one layer further, using seven total switches. The final design of the 1-to-8 switch tree using seven switches is shown in Figure F.4a. Both top and bottom switch trees of the complete system are identical.

F.2. RF Switch Fabrication

F.2.1. Milling Files

First step is to import the gerber files into IsoPro which is illustrated in Figure F.4a.
Next, top layer, bottom layer, and bond are isolated. Isolation must be done separately for each layer. All layers except the layer of choice are switched to the “hide” option. The entire layer on the screen is highlighted and isolated by selecting the Mill tab, and choosing isolate. The bond layer is done first as shown in Figure F.4b. After completing the steps above, the drill bit type is changed to contour router and the size is changed to 62 mil. The contour is clipped so when the board is being cut out, it does not move. The steps are repeated for isolating the top layer and bottom layer. Drill bit type should be set to end mill and bit size should be set to 6 mil. Finished product is shown in Figure F.5. Before milling, “bond (62.0 mils)” and “cond2 (6.0mils)” is mirrored by going to the layer table Figure F.6. Also, the hole layer type is changed to “Drill”.

Figure F.4. (a) Imported Gerber files of the 1-to8 RF switch into IsoPro (b) Bond Isolation
F.2.2. Milling SP8T Switch

After setting up the product, the top layer is milled first. All layers except for the “cond (6.0 mil)” layer is changed to hide. The 6.0 mil drill bit properties is adjusted by clicking drill bit pod #10 as seen in Figure F.12. The depth of cut is adjusted as necessary because different parts of the board are higher or lower in
height. The depth of cut should barely scratch the copper off in order to preserve the life of the drill bit. The range of 1.0 to 2.0 usually works.

![Figure F.7. (a) Drill bit options (b) Drill bit properties](image)

Then, the holes of the board are drilled. All layers except for “holes” layer are switched to hidden. The drill bit cannot be found by the software so the .6 mil bit has to be put in manually. The settings are changed too. RPM should be set to 40,000 and the depth of cut is set to 75. Once the holes are drilled, the copper plate is flipped on the machine and the bottom layer is milled. The bottom layer procedure is the same as the top layer. Finally, the contour is cut out. Do not cut out the SP8T switch that will contain the STM32F chip on the same board.

**F.2.3. Milling STM32F**

Milling the stm32f chip is the same process as milling the SP8T: setup the files, mill the top layer, drill the holes, mill the bottom layer, and finally cut out the bond. To make the stm32f chip on the same board as the SP8T switch, the stm32f circuit design is simply placed next to the SP8T design as seen in Figure F.8a.
For the isolations, the top layer contains the top layer traces as well as the bond so they have to be separated. This is done by highlighting (click and drag) only the top layer traces and isolating that. Then, the bond (outline of the board) is highlighted and the selection is isolated. After all the isolations are made, the design is shown in Figure F.8b. Finally, the outer bonds of both the STM32f circuit and SP8T circuit are cut out so that they will be connected on the board.

**F.2.4. Milling SPDT RF Switch**

For milling the SPDT RF switch, the 6 mil drill bit wears out fast so it was preserved by using 11 mil isolation. The isolation is too big to fit in between the traces so 6 mil is still needed. The fabricated microstrip implementation of the 1-to-8 RF switch tree using seven SPDT switches is illustrated in Figure F.14.
Finally, to create the ability to connect any sensor to either transmit or receive layer freely, standalone SPDT switches for each sensor are used. The RFC connection of the switch is connected to the sensor, and one of RF1 and RF2 are connected to one of the top transmit layer or bottom receive layer. This scheme is illustrated in Figure F.10.

F.3. Switch Operation – Path for Transceiver

Selection

In order to illustrate the operation and paths of the switching system shown in Figure F.10, the system can be decomposed to their individual elements. A flattened view of these connections is shown in Figure F.11. Each of the eight sensors connect to a SPDT switch. One side of each SPDT switch is connected to the top 1-to-8 tree, and the other side of the SPDT switch connects to the bottom 1-to-8 tree. Depending on the state of each individual switch, a path can be created from the Tx port of the 2-port system to any of the eight sensors. A return path can then be created from any of the remaining seven sensors to the Rx port of the 2-port system as shown in Figure F.12.
Figure F.11. Flattened view of switching system layout. Top layer for transmitter selection and bottom layer for receiver.

Figure F.12. Example of path from sensor 1 (Tx1) to sensor 3 (Rx3).
F.4. Digital Components and Design

Switching logic and digital control were implemented using an STM32F407 microcontroller unit built directly onto the top tree board. The design of the microcontroller circuit simply needs to include 3.3 V supply and ground connections, GPIO pads to desired pins for switch control, and header pins connected to corresponding programming pins for programming access. The placement and circuit of the STM microcontroller is shown in Figure F.13.

![Figure F.13. Placement of microcontroller on top layer board, as well as implemented circuit. Pins circled in yellow are connected to MCU's programming pins, providing programming access. Pins circled in Red are GPIO pads used to connected digital control of MCU to switch control lines. Component circled in green is a voltage regulator which is connected to all MCU voltage and ground lines.](image)

The pin spacing and layout used to design the PCB for the microcontroller is shown in Figure F.14. Pads with the same dimensions as those shown in Figure F.14 along with simple traces to wire pads are used to generate the entire circuit. Also shown in Fig. 10 is the pinout for a 100-pin STM32F4 device. PA/PB/PC/PD/PE pins can be used as GPIO to connect to and provide control to all switches. All VDD, VSS, VDDA, VSSA, and VCAP pins must be terminated.
properly to supply or ground with appropriate capacitors. STM datasheets for the particular device should be referenced for proper design.

Figure F.14. Pin layout and pinout shown for LQFP100 STM32407VGT6 microcontroller.

The layout for the microcontroller circuit may be easiest to design using CAD software with existing libraries for this package or specific device, such as EAGLE. An example layout designed in EAGLE for this particular circuit is shown in Figure F.15. When fabricating the complete switching system, even though the microstrip circuit are designed using other software like ADS, room for the microcontroller circuit simply needs to be left on the substrate used for the top layer switch tree. The fabrication can then be done in two stages, first fabricating the switch tree on the substrate using ADS design files, then fabricating the microcontroller circuit adjacent to the tree on the same board using the EAGLE design files. The routing can then be modified to cut out the entire top tree board so that both circuits lie on the same physical board.
Connections between the microcontroller GPIO pads and the SPDT switches are made using wire. The stacked nature of the two 1-to-8 trees and the separate SPDT modules for each sensor do not allow PCB traces to extend between boards, so simple hook-up wire is used instead. Figure F.16 shows the wire connections between all the switches and the microcontroller pads.

Figure F.15. CAD layout of microcontroller circuit with pads to GPIO pins, designed using EAGLE.

Figure F.16. Back side of switch tree boards showing physical wire connections between switch control lines and microcontroller GPIO pads.
F.5. Device Programming

For programming of the device, pins PA13, PA14, PB3, NRST, and VSS (GND) are connected to a pin-header with 5 pins which can be used to interface to another device capable of programming, such as an STMF4 Discovery development board. In this case, corresponding pins of the switch’s microcontroller directly connect to the equivalent pins on the SWD header of the Discovery dev board. Jumpers on the development board must be removed so that the programming portion of the development board is in “ST-LINK” mode, which will allow programming of an external device. IDE Software such as CooCox CoIDE or Em::Blocks can then be used to program the device in the same manner as an STMF4 Discovery kit alone. The connection between the switching system and STM32F4 Discovery board for programming are shown in Figure F.17. Code to program the STM32F4 Discovery board is included in Figure F.18.

Figure F.17. Connection using jumper wires between programming header on switch device and SWD header on an STM32F4 Discovery development board.
Figure F.18. Code to program RF switch.

/*
**                             Main.c
**
**
**********************************************************************/

/*
   Last committed:   $Revision: 00 $
   Last changed by:  $Author: $  
   Last changed date: $Date: $  
   ID:                $Id: $  
**********************************************************************/

#include "stm32f4xx_conf.h"
#include "stm32f4xx_gpio.h"

#define TOP 0
#define BOT 1
#define RIGHT 2
#define GPIO_B_PINS GPIO_Pin_0 | GPIO_Pin_1 | GPIO_Pin_2 | GPIO_Pin_12 | GPIO_Pin_13
#define GPIO_C_PINS GPIO_Pin_0 | GPIO_Pin_1 | GPIO_Pin_2 | 
                        GPIO_Pin_3 | GPIO_Pin_6 | GPIO_Pin_7 | \ 
                        GPIO_Pin_8 | GPIO_Pin_9 | GPIO_Pin_10
#define GPIO_D_PINS GPIO_Pin_10 | GPIO_Pin_11 | GPIO_Pin_12 | \ 
                        GPIO_Pin_13 | GPIO_Pin_14 | GPIO_Pin_15 | \ 
                        GPIO_Pin_8
#define GPIO_E_PINS GPIO_Pin_2 | GPIO_Pin_3 | GPIO_Pin_4 | \ 
                        GPIO_Pin_5 | GPIO_Pin_6 | GPIO_Pin_7 | \ 
                        GPIO_Pin_8 | GPIO_Pin_9 | GPIO.Pin_10 | \ 
                        GPIO_Pin_11 | GPIO_Pin_12
typedef struct Switch
{
    GPIO_TypeDef* up_pin;
    uint16_t up_pin_num;

    GPIO_TypeDef* down_pin;
    uint16_t down_pin_num;
} Switch;

void init_gpio();
void init_switches(Switch switches[][8]);
void set_path(Switch switches[][8], int type, int path_sum);
void set_full_path(Switch switches[][8], int top, int bot);
void init_sys_tick();
void delay_ms(u32 n);

static __IO uint32_t sys_tick_counter;

// 0 should be down and 1 should be up -> check pins on board
int main(void)
{
    // define all of the switches
    // 2d array, where first array picks which board (top, bottom, or side).
    // second parameter picks which later within the tree.
    Switch switches[3][8];
    // initialize the gpios to be used
    init_gpio();
    // setup the pins for each switch.
    init_switches(switches);
    // initialize ticker for delay function
    init_sys_tick();
    int top = 0;
    int bot = 0;
    // THIS IS NEEDED because the switches send a signal to the
    // stethoscope telling which state we are currently in. The switches are also
    // powered by the stethoscope. So if they start at the same time, our state
    // might be off.
    delay_ms(5000);
    while(1) {
        // go through all of the switches
        for (top = 0; top < 8; top++) {
            for (bot = 0; bot < 8; bot++) {
                if (top != bot) {
                    // create a path between one combinations of top and bottom
                    set_full_path(switches, top, bot);
                    delay_ms(30000);  // delay_ms(35);
                    // This toggle sends a signal to the stethoscope, telling it to
                    // change state.
                    GPIO_ToggleBits(GPIOD, GPIO_Pin_8);
                }
            }
        }
    }
}
// This function is a counter that just decrements the global sys_tick_counter
void SysTick_Handler(void) {
    if (sys_tick_counter != 0x00) {
        sys_tick_counter--;
    }
}

// This initializes the speed at which to decrement the counter
void init_sys_tick() {
    while (SysTick_Config(SystemCoreClock / 1000) != 0) {}
}

// This function waits till the global sys_tick_counter goes to 0.
// input: n - the amount of milliseconds to delay for.
void delay_ms(__IO uint32_t n) {
    sys_tick_counter = n;
    while (sys_tick_counter != 0) {}
}

// This function initializes all of the GPIO pins to work.
void init_gpio()
{
    GPIO_InitTypeDef GPIO_InitStruct;

    // start all of the clocks for each of the pins
RCC_AHB1PeriphClockCmd(RCC_AHB1Periph_GPIOB, ENABLE);
RCC_AHB1PeriphClockCmd(RCC_AHB1Periph_GPIOC, ENABLE);
RCC_AHB1PeriphClockCmd(RCC_AHB1Periph_GPIOD, ENABLE);
RCC_AHB1PeriphClockCmd(RCC_AHB1Periph_GPIOE, ENABLE);

// initializes attributes of GPIO pins
GPIO_InitStruct.GPIO_Pin = GPIO_D_PINS;
GPIO_InitStruct.GPIO_OType = GPIO_OType_PP;
// PuPd means pull down. THIS IS NEEDED.
GPIO_InitStruct.GPIO_PuPd = GPIO_PuPd_DOWN;
GPIO_InitStruct.GPIO_Mode = GPIO_Mode_OUT;
GPIO_InitStruct.GPIO_Speed = GPIO_Speed_100MHz;
GPIO_Init(GPIOD, &GPIO_InitStruct);

GPIO_InitStruct.GPIO_Pin = GPIO_B_PINS;
GPIO_Init(GPIOB, &GPIO_InitStruct);

GPIO_InitStruct.GPIO_Pin = GPIO_E_PINS;
GPIO_Init(GPIOE, &GPIO_InitStruct);

GPIO_InitStruct.GPIO_Pin = GPIO_C_PINS;
GPIO_Init(GPIOC, &GPIO_InitStruct);

GPIO_InitStruct.GPIO_Mode = GPIO_Mode_IN;
GPIO_InitStruct.GPIO_Pin = GPIO_Pin_11;
GPIO_Init(GPIOC, &GPIO_InitStruct);
}

// setup the gpio information for each switch in switches
void init_switches(Switch switches[][][8])
{


// TOP BOARD
switches[TOP][0].up_pin = GPIOC;
switches[TOP][0].up_pin_num = GPIO_Pin_7;
switches[TOP][0].down_pin = GPIOC;
switches[TOP][0].down_pin_num = GPIO_Pin_6;
switches[TOP][1].up_pin = GPIOC;
switches[TOP][1].up_pin_num = GPIO_Pin_9;
switches[TOP][1].down_pin = GPIOC;
switches[TOP][1].down_pin_num = GPIO_Pin_8;
switches[TOP][2].up_pin = GPIOC;
switches[TOP][2].up_pin_num = GPIO_Pin_10;
switches[TOP][2].down_pin = GPIOE;
switches[TOP][2].down_pin_num = GPIO_Pin_12;

// BOTTOM BOARD
switches[BOT][0].up_pin = GPIOD;
switches[BOT][0].up_pin_num = GPIO_Pin_10;
switches[BOT][0].down_pin = GPIOD;
switches[BOT][0].down_pin_num = GPIO_Pin_11;
switches[BOT][1].up_pin = GPIOD;
switches[BOT][1].up_pin_num = GPIO_Pin_13;
switches[BOT][1].down_pin = GPIOD;
switches[BOT][1].down_pin_num = GPIO_Pin_12;
switches[BOT][2].up_pin = GPIOD;
switches[BOT][2].up_pin_num = GPIO_Pin_15;
switches[BOT][2].down_pin = GPIOD;
switches[BOT][2].down_pin_num = GPIO_Pin_14;
// RIGHT SWITCHES
// The right switches are the connection between
// the top and the bottom board.
switches[RIGHT][0].up_pin = GPIOE;
switches[RIGHT][0].up_pin_num = GPIO_Pin_3;
switches[RIGHT][0].down_pin = GPIOE;
switches[RIGHT][0].down_pin_num = GPIO_Pin_2;

switches[RIGHT][1].up_pin = GPIOE;
switches[RIGHT][1].up_pin_num = GPIO_Pin_5;
switches[RIGHT][1].down_pin = GPIOE;
switches[RIGHT][1].down_pin_num = GPIO_Pin_4;

switches[RIGHT][2].up_pin = GPIOC;
switches[RIGHT][2].up_pin_num = GPIO_Pin_0;
switches[RIGHT][2].down_pin = GPIOE;
switches[RIGHT][2].down_pin_num = GPIO_Pin_6;

switches[RIGHT][3].up_pin = GPIOC;
switches[RIGHT][3].up_pin_num = GPIO_Pin_1;
switches[RIGHT][3].down_pin = GPIOC;
switches[RIGHT][3].down_pin_num = GPIO_Pin_2;

switches[RIGHT][4].up_pin = GPIOC;
switches[RIGHT][4].up_pin_num = GPIO_Pin_3;
switches[RIGHT][4].down_pin = GPIOB;
switches[RIGHT][4].down_pin_num = GPIO_Pin_0;

switches[RIGHT][5].up_pin = GPIOE;
switches[RIGHT][5].up_pin_num = GPIO_Pin_11;
switches[RIGHT][5].down_pin = GPIOB;
switches[RIGHT][5].down_pin_num = GPIO_Pin_2;

switches[RIGHT][6].up_pin = GPIOE;
switches[RIGHT][6].up_pin_num = GPIO_Pin_7;
switches[RIGHT][6].down_pin = GPIOE;
switches[RIGHT][6].down_pin_num = GPIO_Pin_8;

switches[RIGHT][7].up_pin = GPIOE;
switches[RIGHT][7].up_pin_num = GPIO_Pin_9;
switches[RIGHT][7].down_pin = GPIOE;
switches[RIGHT][7].down_pin_num = GPIO_Pin_10;
}

// This function sets the value of a switch. So it sets either the up or the
down pin and turns off the corresponding down or up pin.
// input: s - the switch of interest
//       is_down - determines whether to set down switch or up switch.
void set_switch(Switch s, int is_down)
{
    if (is_down != 0 && is_down != 1) return;
    GPIO_WriteBit(s.up_pin, s.up_pin_num, (is_down ? Bit_RESET : Bit_SET));
    GPIO_WriteBit(s.down_pin, s.down_pin_num, (is_down ? Bit_SET : Bit_RESET));
}

// This function sets the path of a board. So it'll turn on/off switches in a
// path from the root to the leaves. The function works by using the properties
// of bits. The path_num is used to set the bits. So path_num: 0 means the
// switches should be 0,0,0 (up, up, up). Whereas path_num: 1 means the
// switches should be 0,0,1(up, up, down).
// input: switches - all of the switches
void set_path(Switch switches[][8], int type, int path_num) {
    if ((type != TOP && type != BOT) || path_num < 0 || path_num > 7) return;
    int i = 0;
    for (i = 0; i < 3; i++) {
        set_switch(switches[type][i], 1 & (path_num >> (2-i)));
    }
    set_switch(switches[RIGHT][path_num], type);
}

void set_full_path(Switch switches[][8], int top, int bot) {
    set_path(switches, TOP, top);
    set_path(switches, BOT, bot);
}
APPENDIX G

EFFECTS OF SENSOR PLACEMENT ON THE THORAX - (3D SIMULATION AND EXPERIMENTAL RESULTS)

(Experimental Validation: L. Tamaye, D. Bibb, G. C. Huang, J. Tanabe, Lead)
### G.1. Simulation Results

![Graphs showing simulation results for lung fluid content](image)

Figure G.1. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 1 set as the transmitter and the remaining sensors as receivers.
Figure G.2. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 2 set as the transmitter and the remaining sensors as receivers.

Figure G.3. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 3 set as the transmitter and the remaining sensors as receivers.
Figure G.4. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 4 set as the transmitter and the remaining sensors as receivers.

Figure G.5. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 5 set as the transmitter and the remaining sensors as receivers.
Figure G.6. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 6 set as the transmitter and the remaining sensors as receivers.

Figure G.7. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 7 set as the transmitter and the remaining sensors as receivers.
Figure G.8. Simulation results to evaluate sensitivity to changes in lung fluid content with sensor 8 set as the transmitter and the remaining sensors as receivers.
G.2. Phantom Experimental Results

Figure G.9. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 1 set as the transmitter and the remaining sensors as receivers.
Figure G.10. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 2 set as the transmitter and the remaining sensors as receivers.

Figure G.11. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 3 set as the transmitter and the remaining sensors as receivers.
Figure G.12. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 4 set as the transmitter and the remaining sensors as receivers.

Figure G.13. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 5 set as the transmitter and the remaining sensors as receivers.
Figure G.14. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 6 set as the transmitter and the remaining sensors as receivers.

Figure G.15. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 7 set as the transmitter and the remaining sensors as receivers.
Figure G.16. Experimental results to evaluate sensitivity to changes in lung fluid content with sensor 8 set as the transmitter and the remaining sensors as receivers.
APPENDIX H

CP-STETHOSCOPE APP

(J. Tanabe and D. Bibb, Lead)
H.1. Introduction

This app provides real-time assessment of the heart and respiratory rate; RAW waveforms consist of cardiac and respiratory signals as well as changes in lung fluid content. Description of the classes and its functions are included below.

Figure H.1. Screenshot of the main page of the CP-Stethoscope App used for real-time viewing of the vital signs. (b) Classes in the App.
Table H.1. Class: Bluetooth.java and Functions

Class Description:
This class contains all of the core Bluetooth functions

Functions:
public Bluetooth(Context context, Handler handler)
public void showDialog()
public BluetoothState getState()
public Set<BluetoothDevice> getPairedDevices()
public boolean arePairedDevices()
public BluetoothDevice getConnectedDevice()
public void enableBT()
public boolean queryPairedDevices()
public void startDiscovery()
public void cancelDiscovery()
public void connect(BluetoothDevice device)
public void disconnect(int type)
public void cleanup()
public void disableBT()
private void addPairedDevicesToList()
private String bluetoothName(BluetoothDevice device)
private void registerReceiver()
private void handleConnectedThread(BluetoothSocket socket)
private void connected()
private void connectionFailed()
private void disconnected()
private void connectionLost()
private class ConnectThread extends Thread
private class ConnectedThread extends Thread
Table H.2. Class: BluetoothProvider.java and Functions

Class Description:
This class manages any Bluetooth connections by referencing all of a core functions in Bluetooth.java.

Functions:
public BluetoothProvider(final Context context)
public void showDialog()
public void registerReceiver()
public void unregisterReceiver()
public void cleanup()
protected void deviceConnected()
protected void deviceConnectionFailed()
private void addPairedDevicesToList()
private String bluetoothName(BluetoothDevice device)

Table H.3. Class: Grapher.java and Functions

Class Description:
This class handles the graph UI element on the main page. It will build, display, and refresh the graph for the program.

Functions:
public Grapher(LineChart chart, int xRange, int maxXRange)
public void addEntry(float entry)
public void setXRange(int range)
public void clearGraph()
public void setVisible(int visibility)
public boolean isVisible()
private void init()
private void initSet()
private class DefaultValueFormatter implements ValueFormatter
Class Description:
This functions manages all of the user control UI elements to include starting, stopping, or pausing the UI. Will also handle the save function as well as cleanup of the UI elements.

Functions:
private final BroadcastReceiver mReceiver = new BroadcastReceiver()
public static boolean isConnected()
public static void setUpdatePref(boolean updatePref)
protected void onCreate(Bundle savedInstanceState)
protected void onResume()
protected void onPause()
protected void onStart()
protected void onRestart()
protected void onStop()
public void onBackPressed()
protected void onDestroy()
public boolean onCreateOptionsMenu(Menu menu)
public boolean onOptionsItemSelected(MenuItem item)
private void cleanup()
private void writeToFile(String string)
private boolean dirExists(String path)
private void closeFileStuff()
private void initBluetooth()
private void initViews()
private int seconds2DataPoints(int seconds)
private Runnable mUpdateTimer = new Runnable()
Table H.5. Class: RunningNotation.java and Functions

Class Description:
This class controls user displays and prompts pertaining to the current status of the UI.

Functions:
public static boolean isRunning()
public static void cancelNotification(Context context)
public static void makeNotification(Context context)

Table H.6. Class: MyLifecycleHandler.java and Functions

Class Description:
This class contains that base functions that are used in MainActivity.java for basic UI control.

Functions:
public static boolean isApplicationVisible()
public static boolean isApplicationInForeground()
public void onActivityCreated(Activity activity, Bundle savedInstanceState)
public void onActivityStarted(Activity activity)
public void onActivityResumed(Activity activity)
public void onActivityPaused(Activity activity)
public void onActivityStopped(Activity activity)
public void onActivitySaveInstanceState(Activity activity, Bundle outState)
public void onActivityDestroyed(Activity activity)
Table H.7. Class: SeekBarPreference.java and Functions

Class Description:
This class controls the seek bar UI elements contained within the option menu.

Functions:
public SeekBarPreference(Context context, AttributeSet attrs)
public SeekBarPreference(Context context, AttributeSet attrs, int defStyle)
private void initPreference(Context context, AttributeSet attrs)
private void setValuesFromXml(AttributeSet attrs)
private String getAttributeStringValue(AttributeSet attrs, String namespace, String name, String defaultValue)
protected View onCreateView(ViewGroup parent)
public void onBindView(View view)
protected void updateView(View view)
public void onProgressChanged(SeekBar seekBar, int progress, boolean fromUser)
public void onStartTrackingTouch(SeekBar seekBar)
public void onStopTrackingTouch(SeekBar seekBar)
protected Object onGetDefaultValue(TypedArray ta, int index)
protected void onSetInitialValue(boolean restoreValue, Object defaultValue)
public void setEnabled(boolean enabled)
public void onDependencyChanged(Preference dependency, boolean disableDependent)
Table H.8. Class: SettingsActivity.java and Functions

Class Description:
This class controls the seek bar UI elements contained within the option menu.

Functions:
protected void onCreate(Bundle savedInstanceState)
protected void onStart()
protected void onPause()

Table H.9. Class: SettingsFragment.java and Functions

Class Description:
Handles option menu items

Functions:
public void onCreate(Bundle savedInstanceState)
private void initPreferences()
public void onActivityResult(int requestCode, int resultCode, Intent data)
H.2. Detailed Code

H.2.1. Bluetooth.java

```java
package app.miwa.hcac.com.cp_stethoscope;

import android.bluetooth.BluetoothAdapter;
import android.bluetooth.BluetoothDevice;
import android.bluetooth.BluetoothSocket;
import android.content.BroadcastReceiver;
import android.content.Context;
import android.content.DialogInterface;
import android.content.Intent;
import android.content.IntentFilter;
import android.os.Handler;
import android.view.View;
import android.widget.AdapterView;
import android.widget.ArrayAdapter;
import android.widget.ListView;
import android.widget.TextView;
import com.afollestad.materialdialogs.DialogAction;
import com.afollestad.materialdialogs.MaterialDialog;
import com.gc.materialdesign.views.ButtonFlat;
import java.io.BufferedReader;
import java.io.IOException;
import java.io.InputStream;
import java.io.InputStreamReader;
import java.util.ArrayList;
import java.util.HashMap;
```
import java.util.Set;
import java.util.UUID;

/**
 * Created by jason on 1/9/2015.
 */

public class Bluetooth {
    public enum BluetoothState { NO_BLUETOOTH, BLUETOOTH_OFF, DISCONNECTED, CONNECTING, CONNECTED;

    public static final UUID MY_UUID = UUID.fromString("00001101-0000-1000-8000-00805F9B34FB");
    public static final int SCANNED_BLUETOOTH_DEVICE = 0;
    public static final int START_DISCOVERY = 1;
    public static final int FINISH_DISCOVERY = 2;
    public static final int CONNECTING = 3;
    public static final int CONNECTION_FAILED = 4;
    public static final int CONNECTED = 5;
    public static final int DISCONNECTED = 6;
    public static final int CONNECTION_LOST = 7;
    public static final int MESSAGE_DATA = 8;

    private BluetoothAdapter mAdapter;
    private BluetoothState mState;
    private Context mContext;
    private BroadcastReceiver mReceiver;
    private Set<BluetoothDevice> mPairedDevices;
    private BluetoothDevice mConnectedDevice;
    private Handler mHandler;
    private ConnectThread mConnectThread;
    private ConnectedThread mConnectedThread;
/* used for dialog */
private HashMap<String, BluetoothDevice> mDevices;
private ArrayAdapter<String> mListAdapter;
private ArrayList<String> mDeviceNames;
private TextView mContentText;
private ListView mDeviceList;
private MaterialDialog mDialog;
private ButtonFlat mScanButton;

public Bluetooth(Context context, Handler handler) {
    mContext = context;
    mHandler = handler;
    mDeviceNames = new ArrayList<String>();
    mDevices = new HashMap<String, BluetoothDevice>();
    mListAdapter = new ArrayAdapter<String>(mContext,
            android.R.layout.simple_list_item_1, mDeviceNames);
    mAdapter = BluetoothAdapter.getDefaultAdapter();
    if (mAdapter == null) {
        mState = BluetoothState.NO_BLUETOOTH;
    } else if (!mAdapter.isEnabled()) {
        mState = BluetoothState.BLUETOOTH_OFF;
    } else {
        mState = BluetoothState.DISCONNECTED;
    }
    mReceiver = new BroadcastReceiver() {
        @Override
        public void onReceive(Context context, Intent intent) {
            String action = intent.getAction();
            if (BluetoothDevice.ACTION_FOUND.equals(action)) {

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BluetoothDevice device = intent.getParcelableExtra(BluetoothDevice.EXTRA_DEVICE);
        if (!getPairedDevices().contains(device) && !mDevices.containsKey(bluetoothName(device))) {
            mDevices.put(bluetoothName(device), device);
            mDeviceNames.add(bluetoothName(device));
            mListAdapter.notifyDataSetChanged();
        }
        mHandler.obtainMessage(SCANNED_BLUETOOTH_DEVICE, device).sendToTarget();
    } else if (BluetoothAdapter.ACTION_DISCOVERY_FINISHED.equals(action)) {
        if (mDialog != null) {
            mDialog.getCustomView().findViewById(R.id.scanningBar).setVisibility(View.GONE);
            mScanButton.setVisibility(View.VISIBLE);
        }
        mHandler.obtainMessage(FINISH_DISCOVERY).sendToTarget();
    } else if (BluetoothAdapter.ACTION_STATE_CHANGED.equals(action)) {
        if (mAdapter.getState() == BluetoothAdapter.STATE_ON && mDialog != null) {
            mDialog.getCustomView().findViewById(R.id.scanLayout).setVisibility(View.VISIBLE);
            mScanButton.setVisibility(View.VISIBLE);
        }
        mHandler.obtainMessage(FINISH_DISCOVERY).sendToTarget();
    } else if (BluetoothAdapter.ACTION_STATE_CHANGED.equals(action)) {
        if (mAdapter.getState() == BluetoothAdapter.STATE_ON && mDialog != null) {
            mDialog.getCustomView().findViewById(R.id.scanLayout).setVisibility(View.VISIBLE);
        }
    }
mDialog.getCustomView().findViewById(R.id.loadingDevicesBar).setVisibility(View.GONE);
    mScanButton.setVisibility(View.VISIBLE);
    addPairedDevicesToList();
    mListAdapter.notifyDataSetChanged();
}
} else if
(BluetoothAdapter.ACTION_DISCOVERY_STARTED.equals(action)) {
    mHandler.obtainMessage(START_DISCOVERY).sendToTarget();
} else if
(BluetoothDevice.ACTION_ACL_DISCONNECTED.equals(action)) {
    disconnect(CONNECTION_LOST);
}
}
};
registerReceiver();
}
public void showDialog() {
    mDeviceNames.clear();
    mDevices.clear();

    addPairedDevicesToList();

    mDialog = new MaterialDialog.Builder(mContext)
        .title("Bluetooth Connection")
        .callback(new MaterialDialog.ButtonCallback() {
            @Override
            public void onPositive(MaterialDialog dialog) {
                super.onPositive(dialog);
                enableBT();
            }
        });
}
dialog.getCustomView().findViewById(R.id.loadingDevicesBar).setVisibility(View.VISIBLE);
            dialog.setActionButton(DialogAction.POSITIVE, null);
            dialog.setActionButton(DialogAction.NEGATIVE, null);
            mContentText.setText(R.string.connect_bt);
            mDeviceList.setVisibility(View.VISIBLE);
        }

        @Override
        public void onNegative(MaterialDialog dialog) {
            super.onNegative(dialog);
            dialog.dismiss();
        }
    }

    .dismissListener(new DialogInterface.OnDismissListener() {
        @Override
        public void onDismiss(DialogInterface dialog) {
            mAdapter.cancelDiscovery();
            mDialog = null;
        }
    })
    .autoDismiss(false)
    .customView(R.layout.dialog_bluetooth, false)
    .build();

    mContentText = (TextView) mDialog.getCustomView().findViewById(R.id.bdContentText);
    mScanButton = (ButtonFlat) mDialog.getCustomView().findViewById(R.id.scanButton);
    mScanButton.setOnClickListener(new View.OnClickListener() {
@Override
public void onClick(View v) {
    startDiscovery();
    mScanButton.setVisibility(View.INVISIBLE);
}

mDialog.getCustomView().findViewById(R.id.scanningBar).setVisibility(View.VISIBLE);
}
}

mDeviceList = (ListView)
mDialog.getCustomView().findViewById(R.id.devicesList);
if (mAdapter.isEnabled()) {
    mContentText.setText(R.string.connect_bt);
    mDialog.setActionButton(DialogAction.POSITIVE, null);
    mDialog.setActionButton(DialogAction.NEGATIVE, null);
    mScanButton.setVisibility(View.VISIBLE);
    mDeviceList.setVisibility(View.VISIBLE);
} else {
    mContentText.setText(R.string.connect_bt_off);
    mDialog.setActionButton(DialogAction.POSITIVE, "yes");
    mDialog.setActionButton(DialogAction.NEGATIVE, "no");

    mDialog.getCustomView().findViewById(R.id.scanLayout).setVisibility(View.GONE);
    mDeviceList.setVisibility(View.GONE);
    mScanButton.setVisibility(View.GONE);
}

mDialog.getCustomView().findViewById(R.id.loadingDevicesBar).setVisibility(View.GONE);
mDialog.getCustomView().findViewById(R.id.scanningBar).setVisibility(View.INVISIBLE);
    mDeviceList.setAdapter(mListAdapter);
    mDeviceList.setOnItemClickListener(new AdapterView.OnItemClickListener() {
        @Override
        public void onItemClick(AdapterView<?> parent, View view, int position,
                                long id) {
            final String deviceName = (String) parent.getItemAtPosition(position);
            connect(mDevices.get(deviceName));
        }
    });
    mDialog.show();
}

public BluetoothState getState() {
    return mState;
}

public Set<BluetoothDevice> getPairedDevices() {
    return mPairedDevices;
}

public boolean arePairedDevices() {
    if (mPairedDevices != null) {
        return mPairedDevices.size() > 0;
    } else {
        return false;
    }
}
public BluetoothDevice getConnectedDevice() {
    return mConnectedDevice;
}

public void enableBT() {
    if (mAdapter != null) {
        mAdapter.enable();
    }
}

public boolean queryPairedDevices() {
    mPairedDevices = mAdapter.getBondedDevices();
    return arePairedDevices();
}

public void startDiscovery() {
    if (mAdapter.isDiscovering()) {
        mAdapter.cancelDiscovery();
    }
    mAdapter.startDiscovery();
}

public void cancelDiscovery() {
    if (mAdapter.isDiscovering()) {
        mAdapter.cancelDiscovery();
    }
}
public void connect(BluetoothDevice device) {
    if (mState.equals(CONNECTING) || mState.equals(CONNECTED)) {
        return;
    }
    registerReceiver();
    // turn off discovery b/c it takes up a lot of resources
    if (mAdapter.isDiscovering()) {
        mAdapter.cancelDiscovery();
    }
    // if we're doing something, then cancel it
disconnect(DISCONNECTED);

    mState = BluetoothState.CONNECTING;
mHandler.obtainMessage(CONNECTING).sendToTarget();
mConnectedDevice = device;
    // start connecting to device
    mConnectThread = new ConnectThread(device);
mConnectThread.start();
}

public void disconnect(int type) {
    // if we're connecting to something, cancel it
    if (mConnectThread != null) {
        mConnectThread.cancel();
        mConnectThread = null;
    }
    // if we're connected to to something, disconnect
    if (mConnectedThread != null) {
        if (type == CONNECTION_LOST) {
            connectionLost();
        }
    }
}
} else if (type == DISCONNECTED) {
    disconnected();
}

mConnectedThread.cancel();

mConnectedThread = null;

}

public void cleanup() {
    disconnect(DISCONNECTED);
    if (mReceiver != null) {
        mContext.unregisterReceiver(mReceiver);
    }
    mReceiver = null;
}

public void disableBT() {
    if (mAdapter != null) {
        mAdapter.disable();
    }
}

private void addPairedDevicesToList() {
    // put all paired device in the list
    queryPairedDevices();
    for (BluetoothDevice device : getPairedDevices()) {
        mDeviceNames.add(bluetoothName(device) + " (Paired)");
        mDevices.put(bluetoothName(device) + " (Paired)", device);
    }
}
private String bluetoothName(BluetoothDevice device) {
    if (device == null) return null;
    if (device.getName() == null) {
        return device.getAddress();
    } else {
        return device.getName();
    }
}

private void registerReceiver() {
    IntentFilter filter = new IntentFilter();
    filter.addAction(BluetoothAdapter.ACTION_DISCOVERY_STARTED);
    filter.addAction(BluetoothAdapter.ACTION_DISCOVERY_FINISHED);
    filter.addAction(BluetoothAdapter.ACTION_STATE_CHANGED);
    filter.addAction(BluetoothDevice.ACTION_FOUND);
    filter.addAction(BluetoothDevice.ACTION_ACL_DISCONNECTED);
    filter.addAction(BluetoothDevice.ACTION_ACL_CONNECTED);
    mContext.registerReceiver(mReceiver, filter);
}

private void handleConnectedThread(BluetoothSocket socket) {
    mConnectedThread = new ConnectedThread(socket);
    mConnectedThread.start();
}

private void connected() {
    mState = BluetoothState.CONNECTED;
    if (mAdapter.isDiscovering()) {
        mAdapter.cancelDiscovery();
    }
}
// when we connect to device, close the connect dialog
if (mDialog != null) {
    mDialog.dismiss();
}
 mHandler.obtainMessage(CONNECTED).sendToTarget();
}

private void connectionFailed() {
    mState = BluetoothState.DISCONNECTED;
    mConnectedDevice = null;
    mHandler.obtainMessage(CONNECTION_FAILED).sendToTarget();
}

private void disconnected() {
    mHandler.obtainMessage(DISCONNECTED).sendToTarget();
    mState = BluetoothState.DISCONNECTED;
    mConnectedDevice = null;
}

private void connectionLost() {
    mHandler.obtainMessage(CONNECTION_LOST).sendToTarget();
    mState = BluetoothState.DISCONNECTED;
}

private class ConnectThread extends Thread {
    private final BluetoothSocket mmSocket;
    private final BluetoothDevice mmDevice;
public ConnectThread(BluetoothDevice device) {
    // Use a temporary object that is later assigned to mmSocket,
    // because mmSocket is final
    BluetoothSocket tmp = null;
    mmDevice = device;

    // Get a BluetoothSocket to connect with the given BluetoothDevice
    try {
        // MY_UUID is the app's UUID string, also used by the server code
        tmp = device.createRfcommSocketToServiceRecord(MY_UUID);
    } catch (IOException e) { }
    mmSocket = tmp;
}

public void run() {
    try {
        // Connect the device through the socket. This will block
        // until it succeeds or throws an exception
        mmSocket.connect();
    } catch (IOException connectException) {
        // Unable to connect; close the socket and get out
        try {
            mmSocket.close();
        } catch (IOException closeException) { }
        connectionFailed();
        return;
    }
}
connected();
// Do work to manage the connection (in a separate thread)
handleConnectedThread(mmSocket);
}

/** Will cancel an in-progress connection, and close the socket */
public void cancel() {
    try {
        mmSocket.close();
    } catch (IOException e) { }
}
}

private class ConnectedThread extends Thread
{
    private final BluetoothSocket mmSocket;
    private final InputStream mmInStream;

    public ConnectedThread(BluetoothSocket socket)
    {
        mmSocket = socket;
        InputStream tmpIn = null;

        // Get the BluetoothSocket input stream
        try
        {
            tmpIn = socket.getInputStream();
        }
        catch (IOException e)
        {
        }
    }
}
public void run()
{
    BufferedReader reader = new BufferedReader(new InputStreamReader(mmInStream));
    int ch;

    StringBuilder sb = new StringBuilder(35);
    while (true) {
        try {
            while (true) {
                ch = reader.read();
                if (ch == 'd') {
                    break;
                }
                if (ch != '\0') {
                    sb.append((char) ch);
                }
            }
        } catch (IOException e) {
            break;
        }
        mHandler.obtainMessage(MESSAGE_DATA, sb.toString()).sendToTarget();
        sb.setLength(0);
    }
}
public void cancel() {
    try {
        mmInStream.close();
        mmSocket.close();
    }
    catch (IOException e){ }
    catch (Exception e) { }
}

BluetoothProvider.java
package app.miwa.hcac.com.cp_stethoscope;

import android.bluetooth.BluetoothAdapter;
import android.bluetooth.BluetoothDevice;
import android.content.BroadcastReceiver;
import android.content.Context;
import android.content.DialogInterface;
import android.content.Intent;
import android.content.IntentFilter;
import android.view.View;
import android.widget.AdapterView;
import android.widget.ArrayAdapter;
import android.widget.ListView;
import android.widget.TextView;
import android.widget.Toast;
import com.afollestad.materialdialogs.DialogAction;
import com.afollestad.materialdialogs.MaterialDialog;
import com.gc.materialdesign.views.ButtonFlat;

import java.util.ArrayList;
import java.util.HashMap;

import app.akexorcist.bluetotohspp.library.BluetoothSPP;
import app.akexorcist.bluetotohspp.library.BluetoothState;

/**
 * Created by jason on 2/16/2015.
 */

public class BluetoothProvider extends BluetoothSPP {
    /* used for dialog */
    private HashMap<String, BluetoothDevice> mDevices;
    private ArrayAdapter<String> mListAdapter;
    private ArrayList<String> mDeviceNames;
    private TextView mContentText;
    private ListView mDeviceList;
    private MaterialDialog mDialog;
    private ButtonFlat mScanButton;
    private BroadcastReceiver mReceiver;

    public BluetoothProvider(final Context context) {
        super(context);
        mReceiver = new BroadcastReceiver() {
            @Override
            public void onReceive(Context context, Intent intent) {
                String action = intent.getAction();
                if (BluetoothDevice.ACTION_FOUND.equals(action)) {

                    // Further processing...
                }
            }
        };
    }
}
BluetoothDevice device = intent.getParcelableExtra(BluetoothDevice.EXTRA_DEVICE);

// if device is not in the paired list and not in our current list
if (!mBluetoothAdapter.getBondedDevices().contains(device) &&
    !mDevices.containsKey(BluetoothDevice.bluetoothName(device))) {
    mDevices.put(BluetoothDevice.bluetoothName(device), device);
    mDeviceNames.add(BluetoothDevice.bluetoothName(device));
    mListAdapter.notifyDataSetChanged();
}
} else if (BluetoothAdapter.ACTION_DISCOVERY_FINISHED.equals(action)) {
    if (mDialog != null) {
        mDialog.getCustomView().findViewById(R.id.scanningBar).setVisibility(View.GONE);
        mScanButton.setVisibility(View.VISIBLE);
    }
} else if (BluetoothAdapter.ACTION_STATE_CHANGED.equals(action)) {
    if (mBluetoothAdapter.getState() == BluetoothAdapter.STATE_ON && mDialog != null) {
        mDialog.getCustomView().findViewById(R.id.scanLayout).setVisibility(View.VISIBLE);
        mDialog.getCustomView().findViewById(R.id.loadingDevicesBar).setVisibility(View.GONE);
        mScanButton.setVisibility(View.VISIBLE);
        addPairedDevicesToList();
        mListAdapter.notifyDataSetChanged();
    }
}
} else if
(BluetoothAdapter.ACTION_DISCOVERY_STARTED.equals(action)) {
}
}
else if
(BluetoothDevice.ACTION_ACL_DISCONNECTED.equals(action)) {
}
}

registerReceiver();
setupService();
if (isBluetoothEnabled()) {
    startService(BluetoothState.DEVICE_OTHER);
}
}

public void showDialog() {
    mDeviceNames = new ArrayList<String>();
mDevices = new HashMap<String, BluetoothDevice>();
mListAdapter = new ArrayAdapter<String>(mContext,
android.R.layout.simple_list_item_1, mDeviceNames);

addPairedDevicesToList();

mDialog = new MaterialDialog.Builder(mContext)
    .title("Bluetooth Connection")
    .callback(new MaterialDialog.ButtonCallback() {
        @Override
        public void onPositive(MaterialDialog dialog) {
            super.onPositive(dialog);
            enable();
    
    }
dialog.getCustomView().findViewById(R.id.loadingDevicesBar).setVisibility(View.VISIBLE);
    dialog.setActionButton(DialogAction.POSITIVE, null);
    dialog.setActionButton(DialogAction.NEGATIVE, null);
    mContentText.setText(R.string.connect_bt);
    mDeviceList.setVisibility(View.VISIBLE);
}

@Override
public void onNegative(MaterialDialog dialog) {
    super.onNegative(dialog);
    dialog.dismiss();
}
})
.dismissListener(new DialogInterface.OnDismissListener() {
    @Override
    public void onDismiss(DialogInterface dialog) {
        cancelDiscovery();
        mDialog = null;
    }
})
.autoDismiss(false)
.customView(R.layout.dialog_bluetooth, false)
.build();

mContentText = (TextView) mDialog.getCustomView().findViewById(R.id.bdContentText);
    mScanButton = (ButtonFlat) mDialog.getCustomView().findViewById(R.id.scanButton);
    mScanButton.setOnClickListener(new View.OnClickListener() {
        @Override

public void onClick(View v) {
    if (isDiscovery()) {
        cancelDiscovery();
    }
    startDiscovery();
    mScanButton.setVisibility(View.INVISIBLE);
    mDialog.getCustomView().findViewById(R.id.scanningBar).setVisibility(View.VISIBLE);
}

mDialog.getCustomView().findViewByld(R.id.scanningBar).setVisibility(View.VISIBLE);
}
}

mDeviceList = (ListView)
mDialog.getCustomView().findViewByld(R.id.devicesList);
if (isBluetoothEnabled()) {
    mContentText.setText(R.string.connect_bt);
    mDialog.setActionButton(DialogAction.POSITIVE, null);
    mDialog.setActionButton(DialogAction.NEGATIVE, null);
    mScanButton.setVisibility(View.VISIBLE);
    mDeviceList.setVisibility(View.VISIBLE);
} else {
    mContentText.setText(R.string.connect_bt_off);
    mDialog.setActionButton(DialogAction.POSITIVE, "yes");
    mDialog.setActionButton(DialogAction.NEGATIVE, "no");
}

mDialog.getCustomView().findViewByld(R.id.scanLayout).setVisibility(View.GONE);
    mScanButton.setVisibility(View.GONE);
    mDeviceList.setVisibility(View.GONE);
}
mdialog.getCustomView().findViewById(R.id.loadingDevicesBar).setVisibility(View.GONE);

mdialog.getCustomView().findViewById(R.id.scanningBar).setVisibility(View.INVISIBLE);

mDeviceList.setAdapter(mListAdapter);

mDeviceList.setOnItemClickListener(new AdapterView.OnItemClickListener() {
    @Override
    public void onItemClick(AdapterView<?> parent, View view, int position, long id) {
        final String deviceName = (String) parent.getItemAtPosition(position);
        mDeviceList.setEnabled(false);
        if (isDiscovery()) {
            cancelDiscovery();
        }
        if (isBluetoothEnabled()) {
            startService(BluetoothState.DEVICE_OTHER);
        }
        connect(mDevices.get(deviceName));
        Toast.makeText(mContext, "Trying to Connect", Toast.LENGTH_SHORT).show();
    }
});

mdialog.show();

public void registerReceiver() {
    IntentFilter filter = new IntentFilter();
    filter.addAction(BluetoothAdapter.ACTION_DISCOVERY_STARTED);
filter.addAction(BluetoothAdapter.ACTION_DISCOVERY_FINISHED);
filter.addAction(BluetoothAdapter.ACTION_STATE_CHANGED);
filter.addAction(BluetoothDevice.ACTION_FOUND);
filter.addAction(BluetoothDevice.ACTION_ACL_DISCONNECTED);
filter.addAction(BluetoothDevice.ACTION_ACL_CONNECTED);
mContext.registerReceiver(mReceiver, filter);
}

public void unregisterReceiver() {
    if (mReceiver != null) {
        mContext.unregisterReceiver(mReceiver);
    }
    mReceiver = null;
}

public void cleanup() {
    stopService();
    unregisterReceiver();
}

@Override
protected void deviceConnected() {
    if (mDialog != null) {
        mDialog.dismiss();
    }
}

@Override
protected void deviceConnectionFailed() {
    mDeviceList.setEnabled(true);
}
private void addPairedDevicesToList() {
    // put all paired device in the list
    for (BluetoothDevice device : mBluetoothAdapter.getBondedDevices()) {
        mDeviceNames.add(bluetoothName(device) + " (Paired)");
        mDevices.put(bluetoothName(device) + " (Paired)", device);
    }
}

private String bluetoothName(BluetoothDevice device) {
    if (device == null) return null;
    if (device.getName() == null) {
        return device.getAddress();
    } else {
        return device.getName();
    }
}

Grapher.java
package app.miwa.hcac.com.cp_stethoscope;

import android.graphics.Color;
import android.view.View;

import com.github.mikephil.charting.charts.LineChart;
import com.github.mikephil.charting.data.Entry;
import com.github.mikephil.charting.data.LineData;
import com.github.mikephil.charting.utils.ValueFormatter;
import com.github.mikephil.charting.utils.YLabels;
import java.text.DecimalFormat;
import java.text.NumberFormat;
import java.util.ArrayList;

public class Grapher {
    // This class has all of the information to allow for real time graphing
    // It can take in new entries and then it will graph the values in real time

    // MAX_X_RANGE is the maximum possible number of x values
    private final int MAX_X_RANGE;
    private final LineChart mChart;

    // mXRange is the current x range being showed
    private int mXRange;
    // mMaxY is the maximum value for Y currently
    private float mMaxY;
    // mMinY is the minimum value for Y currently
    private float mMinY;
    // x and y data being stored
    private ArrayList<String> mXVals;
    private ArrayList<Entry> mYVals;
    private LineData mData;
    private LineDataSet mSet;

    public Grapher(LineChart chart, int xRange, int maxXRange) {
        MAX_X_RANGE = maxXRange;
        mChart = chart;
        init();
    }
}
public void addEntry(float entry) {
    if (mData == null || mSet == null) {
        return;
    }
    mYVals.add(new Entry(entry, mYVals.size()));
    // if we go passed the x range
    if (mYVals.size() > mXRange) {
        // if we go passed the maximum x range
        if (mYVals.size() > MAX_X_RANGE) {
            // remove a value
            mYVals.remove(0);
        }
        // Hide all the extra values that aren't being shown
        int startIndex = mYVals.size() - mXRange;
        for (int i = 0; i < startIndex; i++) {
            mYVals.get(i).setXIndex(-1);
        }
        // Then change the index of all the values to be pushed into the right place
        for (int i = startIndex; i < mYVals.size(); i++) {
            mYVals.get(i).setXIndex(i-startIndex);
        }
    }
    // Find the max and minimum value for y
    mMaxY = mYVals.get(mYVals.size()-1).getVal();
    mMinY = mMaxY;
    for (int i = mYVals.size() - 1; i > mYVals.size() - mXRange/2; i--) {
        if (i <= 0) {
            break;
        }
    }
}
if (mYVals.get(i).getVal() > mMaxY) {
    mMaxY = mYVals.get(i).getVal();
}
if (mYVals.get(i).getVal() < mMinY) {
    mMinY = mYVals.get(i).getVal();
}

// adjust the viewing range in the graph. So scale it down if it gets too small, or
// scale up if gets too big (goes out of the graph).
float mid = (mMaxY - mMinY)/2 + mMinY;
if (mMaxY - mMinY < 20) {
    mMaxY = mid + 10;
    mMinY = mid - 10;
} else {
    mMaxY += (mMaxY - mMinY) / 4;
    mMinY -= (mMaxY - mMinY) / 4;
}

mChart.notifyDataSetChanged();
mChart.resetYRange(true);
mChart.setYRange(mMinY, mMaxY, false);
mChart.invalidate();

// Change the amount of x values to be shown
public void setXRange(int range) {
    if (range <= 0) return;
    mXRange = range;
    while (mXVals.size() > mXRange) {
        mXVals.remove(mXVals.size()-1);
    }
}
while (mXVals.size() < mXRange) {
    mXVals.add(""));
}
if (mYVals.size() > mXRange) {
    int startIndex = mYVals.size() - mXRange;
    for (int i = 0; i < startIndex; i++) {
        mYVals.get(i).setXIndex(-1);
    }
    for (int i = startIndex; i < mYVals.size(); i++) {
        mYVals.get(i).setXIndex(i-startIndex);
    }
}

mChart.notifyDataSetChanged();
mChart.resetYRange(true);
mChart.invalidate();

// clear all values in the graph
public void clearGraph() {
    mYVals.clear();
    mChart.invalidate();
}

// hide/show the graph
public void setVisibility(int visibility) {
    mChart.setVisibility(visibility);
}

// check if hidden
public boolean isVisible() {
return mChart.getVisibility() == View.VISIBLE;
}

// initialize the colors, size of points, legends, etc of the graph
private void init() {
    // set chart format
    mChart.setDrawYValues(false);
    mChart.setDescription('');
    mChart.setDrawGridBackground(false);
    mChart.setDrawLegend(false);
    mChart.setDrawBorder(false);
    mChart.setDrawGridBackground(false);
    mChart.setHighlightEnabled(false);
    mChart.setTouchEnabled(false);

    // set up labels
    YLabels labels = mChart.getYLabels();
    labels.setFormatter(new DefaultValueFormatter());
    mXVals = new ArrayList<String>();
    for (int i = 0; i < mXRange; i++) {
        mXVals.add('');
    }

    mData = new LineData(mXVals);
    mChart.setData(mData);
    initSet();
    mYVals = mSet.getYVals();
    mChart.invalidate();
}

// initialize the one set being used
private void initSet() {
    mSet = new LineDataSet(null, null);
    mSet.setLineWidth(1.0f);
    mSet.setCircleSize(0f);
    mSet.setColor(Color.parseColor("#40c4ff"));  
    mSet.setCircleColor(Color.rgb(240, 99, 99));
    mSet.setHighLightColor(Color.rgb(190, 190, 190));
    mData.addDataSet(mSet);
}

// change the values for the y axis to use decimal points instead of commas
private class DefaultValueFormatter implements ValueFormatter {
    private NumberFormat mNumberFormat = NumberFormat.getNumberInstance();
    private DecimalFormat mDecimalFormat = (DecimalFormat) mNumberFormat;

    @Override
    public String getFormattedValue(float v) {
        return mDecimalFormat.format(v);
    }
}
BIBLIOGRAPHY


[78] European Committee for Electrotechnical Standardization, "CENELEC - EN 50361 Basic standard for the measurement of specificabsorption rate related to human exposure to electromagneticfields from mobile phones (300 MHz–3 GHz)," Brussles, Belgium, 2001.


