ABSTRACT
A non-invasive system to accurately and consistently monitor patients with congestive heart failure (CHF) has been designed, developed, and undergone preliminary testing. The system measures both bioimpedance and heart rate of a CHF patient after a hospital discharge. It consists of an electrode-embedded floor mat and a mountable visual display. The mat form factor is intended to integrate into a patient’s home and promote user compliance by incorporating the measurements into the patient’s daily routine. The low profile mat can be placed in front of a bathroom sink or by the bedside. Data from the mat is wirelessly transmitted both to a visual display for immediate user feedback and to a website for remote monitoring by a physician. This device will enable clinicians to monitor bioimpedance and heart rate over time and intervene as needed before an emergency re-hospitalization is required.

INTRODUCTION
Congestive heart failure is of great detriment not only to the quality of life of those afflicted [1], but also to the healthcare system as a whole [2]. The incidence of CHF has risen in the United States, in part, due to an aging population and improvements in the treatment of acute events such as myocardial infarctions [3]. An estimated five million people are presently diagnosed with CHF in the United States with over 400,000 new diagnoses annually [4]. Every year, over one million patients are hospitalized for CHF, costing the US healthcare system close to $29 billion [2]. Although there are numerous etiologies of heart failure (coronary heart disease, valvular disease, infectious and inflammatory conditions, metabolic derangements), monitoring of the clinical symptoms is similar across the majority of patients.

Hospital readmissions are common in patients with CHF. According to a recent study, almost one in two patients will be readmitted to the hospital within four to six months of discharge [5]. It has been estimated that up to 50% of early readmissions due to CHF-related ailments may be prevented if symptoms are recognized early enough for preventative care to be administered [6]. Proactive and routine monitoring of patients in their home environment allows for early diagnosis and preemptive treatment of a decompensation event, which can prevent hospitalizations or minimize the length of stay in the hospital if readmission is unavoidable. The decreased number of hospital days also acts to alleviate economic burdens on the healthcare system.

Figure 1. Frequent re-hospitalizations occur after the diagnosis of heart failure. Many of the clinical symptoms (shortness of breath, fatigue, difficulty in exercise) that force patients to seek clinical help are either too indeterminate or present so late that re-hospitalization is required. [7]

CLINICAL BACKGROUND
Congestive heart failure is characterized by fluid overload. It is a result of complex physiological mechanisms that are activated in patients with cardiomyopathy. Ischemic cardiomyopathy, secondary to coronary heart disease, frequently leads to left ventricular systolic dysfunction and accounts for 50% of cases of CHF. Ventricular systolic dysfunction, also known as systolic heart failure, can result in a drop in cardiac output, a direct consequence of which is insufficient oxygen and nutrient delivery to major organs in the body, including brain and kidneys. One major compensatory homeostatic mechanism employed by the body to maintain adequate perfusion to critical organs is retention of salt and water by the kidneys, thus increasing total body water content. Increasing intravascular fluid attempts to maintain
adequate cardiac output by increasing preload (Frank-Starling mechanism). In addition, there is a compensatory increase in arterial resistance to maintain adequate blood pressure. Given that the circulation system is a closed loop, added volume and pressure within the system increases preload and afterload, which further stresses the heart. These combined stresses dramatically increase the workload on the heart, which is already compromised secondary to prior insult. Over time, the excessive amount of retained fluid is driven from the intravascular to the extravascular space through hydrostatic pressure and diffusion. Accordingly, both intravascular and interstitial fluid status are currently being assessed as a proxy for overall disease status and severity [8].

**Current Clinical Guidelines and Procedures**

Patients are typically admitted to the hospital for the first time after a major cardiac event. This occurs when the body is finally unable to compensate for an increasingly ineffective heart or an acute event such as a heart attack. The patient is stabilized and then “dried out” in the hospital through the use of diuretics. A patient can safely clear approximately one liter of fluid from their system per day. Any more than this amount can damage the osmotic balance in tissues. Due to this limitation, patients with severe overload are required to stay in the hospital for multiple days. In the hospital setting, user compliance is a secondary issue since patients are monitored and given medications as prescribed.

Upon discharge, patients are recommended to: a) eat a low sodium diet, b) restrict their fluid intake, c) enroll in an exercise program, d) lose weight if overweight, and e) comply with their medications, which include diuretics to manage the accumulation of fluid. Patients are also encouraged to monitor changes in their weight as changes greater than two to three pounds in a day or over five pounds in a week may indicate rapid accumulation of fluid. Despite these guidelines, patient compliance with prescribed home treatment is extremely low [9].

Patients may also be required to return for routine check-ups. During a routine check-up, a medical practitioner typically measures vital signs, looks for accumulation of fluid in the periphery (pitting edema) and speaks with the patient about any self described changes in activity or symptoms. The practitioner may also measure the jugular venous pressure as an indirect measurement of pressure in the right atrium. The current technique for measuring jugular venous pressure is non-invasive, however, obtaining an exact measurement is difficult and subjective.

Outside of the doctor’s office, patients can track changes in weight to help monitor their fluid status. However, changes in weight can often be associated with other conditions unrelated to fluid status and thus may not always provide accurate indication. Furthermore, changes in weight is considered to be a late indicator of increased body fluid; by the time a person’s weight has made significant changes, he/she may already need hospitalization for treatment. In an effort to detect changes in fluid status sooner, the use of a few different technologies such as ultrasound, pulse oximetry and bioimpedance have been explored. Of these research areas, bioimpedance has sparked the most interest as an early indicator for increased intravascular fluid.

Bioimpedance measures the body’s resistance to the flow of electrical current; since water has a much lower resistance to current than tissue and blood cells, increased levels of fluid will result in a lower overall resistance. Bioimpedance holds great promise as a direct measurement of fluid status. We propose that easily obtained, adjunct measurements such as heart rate can be coupled with bioimpedance measurements to create an integrated metric that is more predictive than each measurement alone.

**PROBLEM STATEMENT**

To develop a non-invasive device that accurately measures and monitors fluid status in patients with congestive heart failure. Chronic hospital readmissions have profound negative effects on both the patients and the hospitals treating them. There is an unmet need for better-at-home diagnostics that can help reduce preventable re-hospitalizations and decrease unavoidable inpatient stays. The system will need to:

1. be implemented in the home of a patient discharged after
2. detect clinically relevant parameters early enough to allow successful preventative interventions to be administered by the healthcare provider
3. be so simple and unobtrusive that compliance is an afterthought

**PRIOR ART**

Bioimpedance has been clinically proven as a tool to track congestive heart failure. Intrathoracic measurements, using Medtronic’s Optivol system for example, have predicted worsening heart failure with predictiveness of roughly fourteen days prior to a cardiac event requiring hospitalization [8,11].

Expanding beyond implanted technologies, there also exists several technologies that utilize transthoracic impedance measurements as a metric (CardioDynamics, Corventis, NMT). While these technologies have great potential in predicting cardiac episodes, a major limiting usage factor is associated patient compliance. For non-wearable devices such as the NMT ZOE, leads must be placed across the chest which requires the end user to remove a piece of obstructive clothing. For a wearable device, such as the Corventis Avivo, the aesthetics of a protruding device, which may visible through the patient’s clothing, can prove to be an issue. Further issues include the necessity of electrode-skin contact which forces the need for some men to remove chest hair. For some, these issues may not seem like huge barriers to overcome given the lifesaving benefits of the aforementioned technologies. However, studies have demonstrated that the compliance for CHF patients to check their weights daily is less than 50% [12]. Using the simple technique of daily weight measurement as a baseline, one can clearly see that any incremental
difficulties or inconveniences to the patient will likely result in a sharp decline in compliance.

Outside of the congestive heart failure space, pedal bioimpedance measurements are commonly used in body composition scales. This method of measuring bioimpedance has been demonstrated to work effectively in terms of determining body fat percentage but has yet to be directly translated to clinical use to monitor fluid status in congestive heart failure patients [13]. However, as previously mentioned, the scale form factor has an issue with non-compliance. While bioimpedance technology has demonstrated physiological relevance, current implementations are either too invasive, cumbersome, non-user friendly, or in a format that demonstrated compliance issues.

FUNCTIONAL REQUIREMENTS
1. **Long term compliance** - the device should be easy to use and promote long term user compliance. An ideal long term compliance would exceed 75%.
2. **Non-invasive** - the device should not break the skin and should be as comfortable to use as possible.
3. **Predictive** - measurements from the device should be able to predict cardiac decompensation at least one week before the event is likely to occur.
4. **Wireless** - data from the device should be transmitted without wires to both user and physician interfaces.
5. **Cost appropriate** - the device should cost as much or less than similar home medical devices, and no more than $200.
6. **Long battery life** - batteries should have to be changed or recharged infrequently. The device should last longer than a few months.
7. **Short setup and learning curve** - the system should be easy to use. Setup and installation in the home should take less than one hour.

STRATEGY AND CONCEPTS

Bioimpedance was chosen as the core technology due to its clinical validation as well as engineering approachability. As changes in long term heart rate can also be an indicator of changes in fluid status, heart rate was chosen as the second metric to measure.

As was previously discussed, issues with user compliance plague the majority of current bioimpedance technologies. Thus, a key part in the design concept was to develop a form factor that would alleviate this issue. It was quickly realized that a wearable monitor was unnecessary. Congestive heart failure is a chronic, relatively slow progressing disease; as such, the resolution accompanied by continuous or high frequency monitoring from a wearable device was not deemed necessary. Furthermore, wearable devices can be victim to subjective aesthetics as well as compliance issues which may be due to characteristics such as comfort. With these considerations in mind, a floor mat design was implemented. A well-placed floor mat that automatically produces a measurement when stood upon would result in high compliance since it would require little to no thought from the user.

The ideal placement of the mat would be by the patient’s bedside or in front of the patient’s bathroom sink. These locations accomplish two tasks: 1) there is a high probability that the user would stand on the mat at least once a day, and 2) there is high chance that the user would be barefoot, an important consideration as electrodes require direct skin contact.

In conjunction with the mat, a display is presented either on the user’s nightstand or located on his/her bathroom mirror. The user interface provides qualitative information about the patient’s current fluid status and reinforces the use of the device. Such real time updates would allow the user to assess his/her health state and take precautionary measurements more readily and potentially preclude future hospital visits.

The device monitors the patient’s ratiometric change in impedance; in other words, the patient’s current condition relative to his/her healthy baseline. This baseline is determined at the doctor’s office after the patient has been treated for a congestive heart failure.
DETAILED DESIGN

The mat has four electrodes and two force sensitive resistors. Both the electrodes and resistors are connected to a printed circuit board which can measure impedance and heart rate. When the user steps on the mat, the force sensitive resistors notify the system to begin capturing data. The data is then transmitted via radio to the user display. The printed circuit board, radio transmitter and battery are housed in an enclosure located at the front of the mat. A separate radio receiver and battery are intended to be housed in the display unit; however, this design of the display was not implemented in the current prototype. The components of the product consist of two mat prototypes, a printed circuit board, and two user interfaces.

Mat Prototypes

Both mat prototypes are 15x24” and have four electrodes - the back two electrodes drive current while the front two sense voltage. The width (15”) is amenable to wide range of foot sizes while the length (24”) provides an appropriate stance width such that the user is not faced with an awkward stance position. The four electrode layout are designed to maximize the surface area with which we can obtain a measurement. Additionally a 2.0” wide and 0.5” tall ridge along the middle of the mat was implemented to provide physical orientation, discouraging the user from putting both feet on a single set of electrodes. An enclosure located at the front of the ridge houses the printed circuit board, battery and radio transmitter.

Metal Mat

The initial design revolved around materials that are commercially used in typical mats and body composition scales. The mat materials consisted of neoprene, polystyrene, and aluminum (McMaster Carr). These materials are mechanically robust and easy to clean. Aluminum electrodes (1/16” thickness) were fabricated because they are highly conductive, relatively cheap, and easy to machine and form. Neoprene was employed to provide compliance to the mat to improved user comfort while also providing a minimal slip surface on the underside of the mat (1/4” and 1/16” thickness, 40A hardness). Lastly, the polystyrene was used as
a rigid backbone layer to which the other materials were mounted (1/8” thickness). This particular plastic was used due to its high strength, low cost, formability/machinability, and insulating properties as to minimize aberrant arcing. Additionally, all outer corners were filleted to minimize users’ injuring themselves on sharp aluminum corners.

**Figure 6. Fabric mat prototype**

**Fabric Mat** The fabric prototype, while maintaining the function design of the first prototype (size and location of electrodes, electronics and wiring), was designed to be more user friendly. The fabric mat is flexible, comfortable to stand on and “approachable” as it resembles many floor mats that currently exist on the market. Additionally, the conductive fabric electrodes implemented in this prototype provides good conductivity.

The electrodes are made of Argenmesh, a conductive silver mesh fabric with a resistivity of less than 0.1 Ohm/sq. Argenmesh has very good conductivity, produces a consistent signal and is relatively inexpensive. Each electrode measures 10” x 6” and is stitched to a non-conductive fabric base, which is adhered to a 24” x 15” sheet of flexible closed foam. The foam sheet adds both rigidity and comfort as it provides padding between the user’s feet and the floor. Wires sewn to the inner corners of each electrode and soldered to the force sensitive resistors (located under the rear electrodes) are connected to the printed circuit board which is housed in an acrylic enclosure. The 2” x 12” foam ridge provides user orientation cues and conceals the wiring.

**Electronics**

**Printed Circuit Board** The printed circuit board has front end circuitry for determining both impedance and heart rate. It also interfaces with two different force sensitive resistors, located under each heel electrode. The device is powered by a Lithium Ion 600 mAH battery that can be recharged using an included USB port. The PCB connects to a Texas Instruments eZ430-RF2500 radio board to transmit data wirelessly to a computer or a display.

**Figure 7. Diagram of impedance circuit**

**Impedance Circuit** The impedance circuit uses four electrodes to determine the impedance of the body. The electrodes are configured as shown in Figure 7. A sinusoidal current of 500 μAmp at 50 kHz is forced through the body by electrodes I+ and I- [14]. The voltage across the body that results from being excited by this sinusoidal current is sensed and amplified by an instrumentation amplifier.

**Heart Rate Circuit** An electrocardiogram voltage is sensed using an instrumentation amplifier configured the same as in the impedance circuit. When measuring ECG, a switch on the PCB changes the I+ electrode to be the reference electrode.
**Force Sensitive Resistors** Force sensitive resistors (Tossen Robotics) were placed under the I+ and I- electrodes. The resistance of these sensors changes significantly when a user steps on the mat (from several MΩ to a few kΩ or less). The resistance is measured by the circuit shown in Figure 6. When a resistor is to be measured, the appropriate channel on the microcontroller is set high. The system then acts as an RC filter. The microcontroller counts up until the input line has gone high. A resistance threshold is set, below which a user is considered to be on the mat.

![Figure 8: Diagram for the Force Sensitive Resistors](image)

**User Interface** The physical display is an integral part of the device as it promotes user compliance through the use of immediate feedback. The display interface was designed to be very simple to minimize confusion and better accommodate the product’s target market. The interface uses bright and easy to understand colors and classifications to convey the user’s condition (which reflects both fluid status and heart rate).

When the mat is not engaged, the display is turned off to save energy. The second a user steps on the mat, the display receives a signal from the mat to turn on and indicate on the display that a measurement is taking place. Once an accurate measurement has been made, the results are shown on the display. The user’s condition is classified into three discrete states: “Good,” “Okay,” and “Poor” and subsequently displayed on the screen with its corresponding color (green for “Good”, yellow for “Okay” and red for “Poor”). The “Poor” indicator prompts the user to speak with his/her physician as there is an actionable item to manage his/her condition.

The classification of the user’s current condition is determined based on the current reading relative to the user’s healthy baseline. The decision to simplify the patient’s condition to three discrete states was based on two observations: (1) impedance varies considerably from person to person, so a healthy impedance value depends highly on the individual; (2) most patients will not understand how to interpret values for impedance. While heart rate is used to determine the patient’s overall condition, it is also displayed independently above the main indicator as most patients are likely to be familiar with heart rate. In the case that the mat is unable to obtain a good reading, an error message is displayed after some predetermined period of time. This period of time may be determined through user testing.

**Physician Interface** The physician interface, a website that requires a login, was also designed to be simple and straightforward to minimize the time required by the doctor to understand the patient’s condition. Through this site, the physician can access the historical data captured by the device of all of his/her patients. Unlike the user display, the physician can access the actual impedance and heart rate values. Historical data is displayed graphically to demonstrate trends as well as through a filterable table that highlights measurements that may require the physician’s attention. Measurements that are considered “Okay” and “Poor” as seen by the user are highlighted in yellow and red, respectively in the table. Furthermore, the physician can set up alerts to be notified if the patient’s condition deteriorates. Ideally, this interface can be integrated with existing medical record systems.

**Data Flow** In the current implementation of the device, data is transmitted from the printed circuit board via the radio transmitter to a radio receiver that is plugged into a computer via serial to USB converter. The data is then imported and processed by Matlab and written to an online mySQl database. The database is synced to both the physician website and a mockup website of the user display. The user display was presented using a website for this prototype because it allowed for demonstration of a fully functional interface for both user and physician with just one radio receiver. In a future implementation, a Wi-Fi or Bluetooth transmitter may be added to the mat or the display so that the data can be uploaded to a database directly.
Figure 9: Patient interface (above) and health care provider interface (below)
TESTING & REFINEMENT

Bioimpedance To begin to evaluate the impedance, four individuals stepped on the fabric mat. The impedance was measured with the circuitry described previously. One method to validate the impedance measurement is to compare the body fat % one can extrapolate from the resistance values measured with the mat versus the body fat % from a commercially available body composition scale. The body fat % was estimated using a fat free mass estimation equation presented in [14].

Table 1 Correlation between prototype and commercial bioimpedance measurement

<table>
<thead>
<tr>
<th>Individual</th>
<th>Gender</th>
<th>Impedance (Ohms)</th>
<th>Body Fat % (Mat)</th>
<th>Body Fat % (Scale)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>565</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>529</td>
<td>22.5</td>
<td>21</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>376</td>
<td>10</td>
<td>?</td>
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<tr>
<td>4</td>
<td>M</td>
<td>423</td>
<td>15</td>
<td>?</td>
</tr>
</tbody>
</table>

Electrocardiogram While the circuitry to acquire an electrocardiogram has been fully developed and integrated on the printed circuit board, this functionality has not yet been tested.

Force Sensitive Resistors The force sensitive resistors were originally tested on the metal mat without the electrodes secured to the mat base. In this configuration, a resistance threshold of 2700 counts was set. The mat was most responsive when individuals stepped in the center of the mat. As individuals stepped toward the periphery of the mat, it became less sensitive to changes in resistance and was not always able to detect a user on the scale. After preliminary testing, the electrodes were secured to the mat. However, this resulted in changes in the resistance response of the sensors. Future work will be needed to properly calibrate the force sensitive resistors in this configuration to ensure that it will reliably detect a user.

FUTURE WORK

A proof of concept prototype is presented in this work. Future work would include optimization of the mat prototypes for manufacturing and design for assembly. Given that all parts were one-offs, DFM and DFA were not considered for this round of testing. Future design may also focus on modular aspects of the mat. This adds flexibility to the design not only from a manufacturing and assembly perspective, but from a user one as well. If parts fail in the long term, they may be replaced individually rather than replacing the entire mat itself. This is especially true for the fabric mat since this particular electrode format is not amenable to being washed and may become compromised after prolonged use. Future implementations of the mat will need to be tested for reliability of the measurement, durability, usability and comfort.

The user display will also require rigorous testing to determine durability (the device should be able to withstand the occasional drop as well as moisture), setup time and ease, readability, and overall usability. The user testing for the physician interface will need to consider setup time and ease, accessibility of data and any other relevant components and integration with existing medical record systems.

While the circuitry was present, heart rate data was not obtained in this work. Future work should evaluate the electrocardiogram signal coming from the feet, and perform the signal processing required to extract a reliable measurement of heart rate. This heart rate measurement could be validated by comparing the heart rate measured through the feet to that measured at the chest by a conventional ECG monitor. Minimal validation of the impedance measurement was made. Future work should validate this measurement, first in healthy individuals, and then in congestive heart failure patients. The impedance recorded by this system should be at least as repeatable and as accurate as products commercially available today.

Once reliability of the measurement has been determined, a clinical test could be conducted to determine the ability of impedance measurement in predicting of cardiac decompensation, hospital readmissions, as well as the utility of such an approach in improving outcomes. Additionally, a pilot study could assess the entire system from a user compliance point of view by including user interface interaction as an element of the study. Extrapolating even further, a pilot study to assess user compliance and actual user interface interaction will be of great importance.

CONCLUSION

A non-invasive and wireless system for measuring fluid status has been developed. The system is designed for high compliance in congestive heart failure monitoring and management. Two mat prototypes were developed with metal and fabric electrodes. A printed circuit board was manufactured that is capable of measuring impedance and heart rate. Data is transmitted wirelessly to a computer, where the data can be presented to either a patient, healthcare provider, or caregiver.

References


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