

ABSTRACT

A wearable cardioverter-defibrillator (WCD) is a device temporarily used by patients awaiting an implantable cardioverter-defibrillator (ICD). These patients are at high risk for sudden cardiac arrest (SCD), a life-threatening event that causes 450,000 deaths per year in the US alone. The main problem with the only WCD on the market right now, the Zoll LifeVest, is a high rate of patient noncompliance. In other words, patients would rather risk their lives than wear the device. Therefore, our mission was to design a more comfortable, intuitive, and user-friendly solution to protect patients from SCA and encourage high compliance.

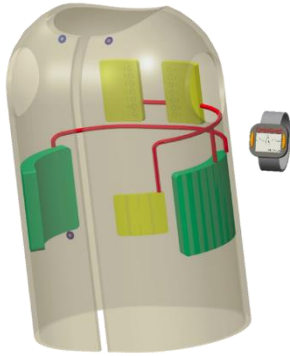


Figure 1

Our solution, the QRSTee (Figure 1) addresses all of the concerns of patients and clinicians. It is significantly more comfortable and easy to use for the patient, with a much improved aesthetic. Because of the technical complexity of the project, each component was analyzed, brainstormed, prototyped, and tested separately in order to ensure functionality in the overall system. A functional prototype of each component has been built and tested, as well as several iterations of overall form factor mock-ups. Several rounds of human factors testing have also been done.

We have performed a preliminary patent search and found that we have freedom to operate. We have filed for intellectual property protection in the form of a provisional patent as of January 20, 2014. The main novel aspects of our design are in the ergonomics and configuration specifically designed to minimize lumbar spine compression and confer even weight and pressure distribution as well as the shocking electrodes.

According to the FDA, the QRSTee is a Class III device because of the inclusion of a defibrillator. However, because we are not changing the way a defibrillator works, which contributes to the most “risk” associated with the device, the clinical trials are expected to be greatly expedited. There are also existing CPT codes for this device to be reimbursed.

This kind of device employs a durable medical equipment rental model, in which the insurance company rents the device from the manufacturer for the required period of time upon clinician prescription. The DME rental model allows for an enormous profit margin, because a single device can serve several patients. Therefore, the QRSTee can be priced lower than the only competitor, the Zoll LifeVest, with marginal costs and still have a sustainable profit margin.

Zoll themselves estimate a \$1.9 billion annual market in the US alone for this device, and another \$500 million in Germany. To put it in perspective, Zoll currently makes an annual revenue of about \$110 million on this device and is growing at about 60% annually. This represents ~5% of the total market, leaving a largely unpenetrated market open. With an aging population, increased prevalence of heart conditions, increasing regulation on implantable devices, and skyrocketing medical costs, “bridger devices” such as WCD’s are becoming more attractive to clinicians.

The QRSTee is a comfortable, convenient, and easy-to-use solution in an expanding, unpenetrated market. It has been designed specifically to address the concerns of patients and clinicians. It will increase wearer compliance, improve patient quality of life, and save lives.

CLINICAL PROBLEM

The leading cause of death in the US is sudden cardiac arrest (SCA), in which a person's heart stops with no forewarning. The only treatment is to defibrillate the heart, or deliver a life-saving shock, as soon as possible. For each minute that passes without treatment, the person's chance of survival decreases by 10%. Unfortunately, over 80% of SCA's occur at home in absence of medical personnel and 40% are completely unwitnessed. Certain conditions, such as having gone through an acute heart attack or open heart surgery, can increase a person's risk for SCA. In these cases, the long-term solution is an implantable cardioverter-defibrillator (ICD), which is surgically implanted over the heart. However, it costs over \$150,000 and requires thorough documentation and regulation in order to be covered by insurance, often through several kinds of tests. This leads to a 3-month waiting period for the device, during which the patients are still highly vulnerable to SCA but are without any form of protection. Because of the high mortality associated with SCA (95%), it is imperative that these patients are provided with an external device that can adequately protect them and provide treatment if necessary during this time period.

The current standard of care is the Zoll LifeVest, a WCD which consists of a bra-like upper body harness along with a 3-pound control box that has to be worn at all times with a shoulder strap or waist band. While it is functional, the Zoll LifeVest suffers from one critical pitfall: high patient

noncompliance, meaning that patients knowingly risk their lives by not wearing the device. According to Zoll's own clinical studies, the noncompliance rate can be as high as 15-25%, as shown in Table 1. In one study in particular, a total of six patients died, of which five weren't wearing the device at the time of the event.

Table 1

	ZOLL STUDY 1	ZOLL STUDY 2
AVERAGE WEAR TIME	19.9 hours/day	19.1 hours/day
WEAR-TIME NONCOMPLIANCE	17.08%	20.42%
QUITTING NONCOMPLIANCE	307/2169 (14.15%)	65/289 (22.49%)
OTHER ISSUES	50% of the patients had a wear-time <u>noncompliance</u> of at least 10%	6% of patients reported some sort of <u>skin irritation</u>

After speaking directly with several clinicians and patients in an IRB-approved study, we narrowed the main reasons for noncompliance to four main factors: discomfort, inability to sleep, high frequency of alarms, and poor image. Most of these complaints had to do with the bulky box and the hard, plastic electrodes of the LifeVest. The QRSTee addresses these patient and clinician concerns in a way that will increase compliance, leading to more lives saved.

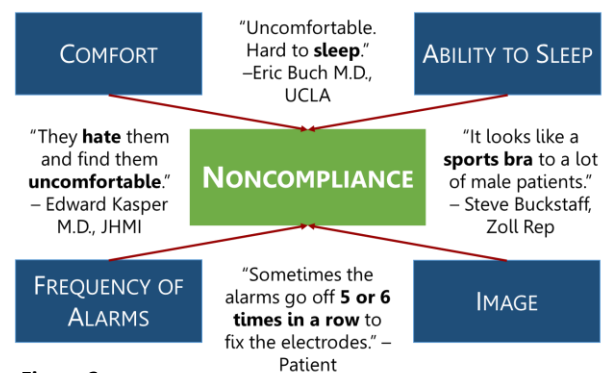


Figure 2

DESIGN

The goals and constraints we set for the QRSTee are detailed in Tables 2 and 3. The main goals were to improve image, comfort, ergonomics, and overall aesthetics, while the main constraints had to do with technical functionality. A detailed description of the final design of the QRSTee is shown in Figure 3 with a description of each component and its function. A block diagram of a WCD is shown in Figure 4. A side-by-side comparison with the components of the Zoll LifeVest is also shown in Table 4.

Tables 2 and 3

GOAL	QUANTIFICATION	CONSTRAINT	QUANTIFICATION
Increased comfort	IRB human factors testing with survey	Good quality ECG signal	Comparable to medical grade
More consistent electrode-skin contact	<1 min. maintenance alarms per day with routine activity	Must be cleanable	Cleaning process takes < 10 min
Better weight distribution of components	Each component should be no more than > 1.0 lbs	Must be continuously wearable in all locations	Can be worn without discomfort, IRB human factors testing
Secondary mechanism of verification	Correctly identifies secondary symptoms with > 90% accuracy	Correct positioning of shocking electrodes	Placed in standard position
		Usable by patients of limited technological literacy	IRB human factors testing

Figure 3

A. SHOCKING ELECTRODES

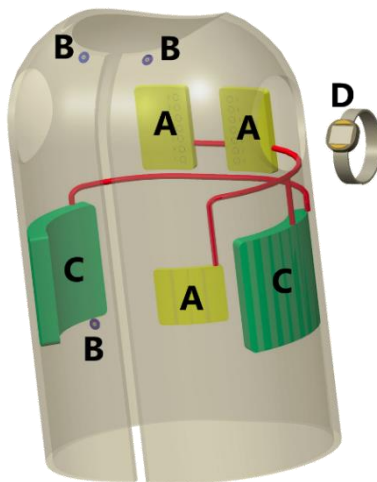
Standard shocking electrodes

B. SENSING ELECTRODES

Standard adhesive stickers
Back of electrodes snap onto the garment

C. DEFIBRILLATOR

Distributed weight
Removable battery for charging



D. USER INTERFACE

Watch-like interface
Easily accessible
Light-weight
Houses override mechanism
Communicates wirelessly with garment

GARMENT

Breathable
Waterproof
Comfortable

Table 4

	ZOLL LIFEVEST	QRSTEE
SENSING SYSTEM	Hard, plastic electrodes	Long-term adhesive stickers that snap in
OVERALL FORM FACTOR	Bra-like harness	Sleeveless shirt
USER INTERFACE	Integrated into the bulky box	Watch-like device
DEFIBRILLATOR COMPONENT PLACEMENT	Integrated into the bulky box	Evenly distributed on both sides of the torso
ASSEMBLY	Several difficult steps required	Slip on and forget

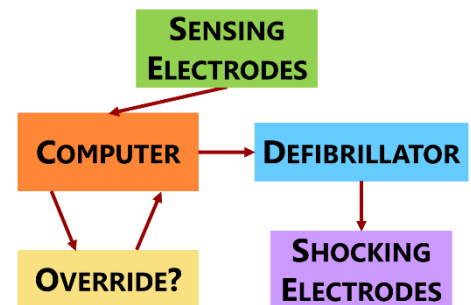


Figure 4

The main features of the QRSTee are a garment made from a waterproof, breathable, stretchable fabric, long-term adhesive electrodes that snap into the garment to sense ECG, pockets on opposite sides of the garment about six inches below the arms containing all the computing components, and a watch-like user interface that communicates wirelessly with the garment and allows for user override of a shock if necessary.

INTELLECTUAL PROPERTY

The original WCD patent became public domain in 2010, giving us freedom to operate. All subsequent Zoll patents include additional features upon which we do not infringe. There are no other competitors in the WCD space. The key relevant patents are shown in Table 5.

Table 5

PATENT NO.	PATENT NAME	SUMMARY OF CLAIMS
4928690	Portable device for sensing cardiac function and automatically delivering electrical therapy	Original wearable defibrillator
8369944	Wearable defibrillator with audio input/output	Receiving audio input from the patient
WO2012082547 A1	Water resistant wearable medical device	Waterproof accessory kit for use with a wearable medical device
WO2011146448 A1	Wearable therapeutic device	Gel-release mechanism for shocking electrodes
WO2013033238 A1	Wearable monitoring and treatment device	Controller configured determine confidence level of information from sensing electrodes

The QRSTee is novel in that it is a WCD that has a T-shirt-based form factor, a divided configuration of components for ergonomic weight distribution, a waterproof, breathable fabric that does not require machine-wash, textile shocking electrodes, and a wireless two-way communication user interface. Specifically, this is the first application of conductive textile to shocking electrodes for external defibrillation. The form factor is also novel with respect to wearable defibrillators. We filed a provisional patent on January 20, 2014.

WORKING PROTOTYPE

VERIFICATION TESTING

Step 1: Sensing Mechanism

After several rounds of testing involving various different sensing mechanisms, adhesive electrodes were found to produce the most consistent and robust signal, as shown in Figure 5. One of the main drawbacks of the LifeVest is the frequency of maintenance alarms, which arise from poor electrode-skin contact, resulting in loss of signal. The hard, metal electrodes are also a significant source of discomfort, as they must be pressed into the skin for good contact. Long-term adhesive electrodes resolve both of these problems because they are light, require no additional pressure, and ensure good skin contact. The successful measurement of an ECG signal using adhesive electrodes is shown in this video: <http://youtu.be/90RWiVw2tA>.



Figure 5

Step 2: User Interface

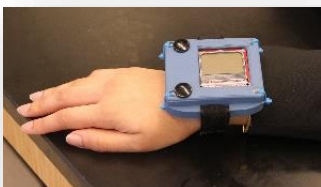


Figure 6

The user interface is a watch-like device that communicates wirelessly with the garment, as shown in Figure 6. We have built a working prototype of this

The second step in the process is communicating impending shocks to the user and allowing them to override if necessary. In the LifeVest, this is done through the bulky box that must be worn at all times. However, in the QRSTee, the

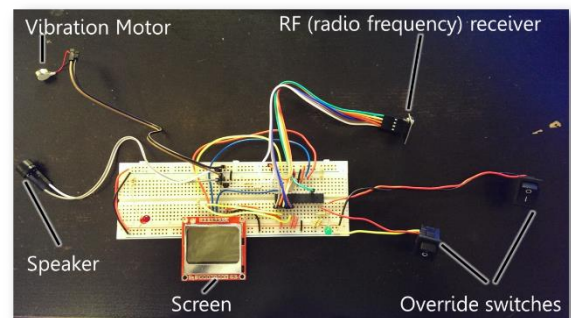


Figure 7

user interface. An earlier breadboard version is shown in Figure 7. The prototype iteration shown in this video demonstration was intentionally designed with functionality as the primary focus and therefore does not yet meet the size and shape requirements of our final design: <http://youtu.be/iSHsnMUPfeA>.

The working prototype uses a system of colored LEDs to mimic the state of the defibrillator, and the algorithm measures heart rate from the ECG signal instead of arrhythmia detection. The heart rate and system status ('System normal', 'Impending shock', 'Shock delivered') is displayed on the screen of the user interface, as shown in Figure 8. Below a certain threshold heart rate, the system is normal, indicated by a green LED on the garment. When the heart rate rises above the threshold, the garment switches to impending shock mode, indicated by a yellow LED, and waits for a manual override of the shock. If the wearer overrides the shock using a button on the user interface, the system returns to normal (green LED on the garment). If the wearer does not override the shock, then the system delivers a shock, indicated by a red LED on the garment.

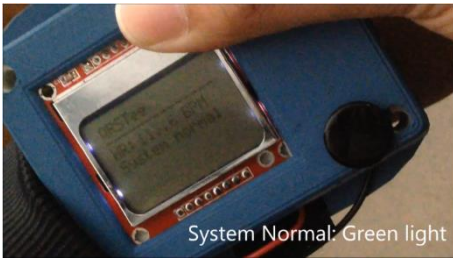


Figure 8

Step 3: Defibrillation

The last technical component in the process is the actual shock delivery. The defibrillator is currently housed in the bulky box in the LifeVest. One key innovation of our design is dividing the components and spacing them out across the torso for improved weight distribution. Based on form factor testing we performed, the ideal placement of weight was determined to be about six inches below the arms on either side, where it was least obtrusive to the wearer. In order to prove feasibility, we disassembled an AED (Automatic External Defibrillator) circuit and split up the components as desired, as shown in Figure 9. We took the prototype to the Simulation Center at Johns Hopkins Hospital and verified that it could withstand multiple shocks, as shown in Figure 10. The QRSTee is not changing the way a defibrillator works or the circuit itself, only the configuration and placement; therefore, there is no reason to believe it will not behave as a normal defibrillator does.

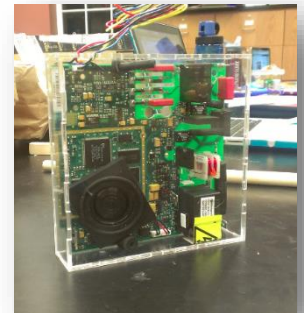


Figure 9



Figure 10

The second part of the defibrillation system is the shocking electrodes. Another key innovation of our design is the use of textile shocking electrodes for reduced cost and added comfort. We tested them against standard shocking electrodes at the Simulation Center. The textile shocking electrodes were able to withstand multiple shocks, as shown in Table 6.



Figure 11

Table 6

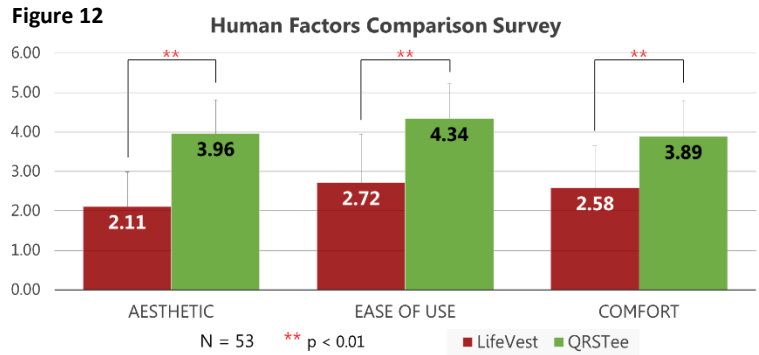
	STANDARD ELECTRODES	TEXTILE ELECTRODES
ENERGY DELIVERED	251.5 J	253.19 J
CURRENT	13.7 A	13.7 A
IMPEDANCE	154.7 Ω	156.5 Ω

VALIDATION TESTING

Because our end goal was increased patient compliance, human factors plays a significant role in

both our design process and the testing. Figure 11 shows the basic aesthetic of the QRSTee in comparison to the LifeVest. Upon doing a center of mass (COM) calculation on the LifeVest and the QRSTee, we found that the QRSTee's COM is 11 centimeters closer to that of a patient, which is significantly more comfortable.

In an IRB-approved 53-person study, we asked student volunteers to try on two nonfunctional mock-ups, one of the LifeVest and one of the QRSTee, and then rate them on a scale of 1 to 5 (5 being the best) on aesthetic, comfort, and ease of use. The results are shown in Figure 12.



The last part of human factors testing is assembly. Patients told us the LifeVest can take up to 30 minutes to put on every morning. We sought to reduce this to a “slip-on-and-forget” model in the QRSTee. We did a side-by-side comparison of the QRSTee and the LifeVest, as shown in this video:

QRSTEE

1. Put on garment
2. Zip up
3. Put on watch

DONE

LIFEVEST

1. Attach sensing electrodes
2. Attach vibration mechanism
3. Put shocking electrodes into pockets
4. Put on garment
5. Plug into user-interface box

http://youtu.be/5_ER-fKBkXA. It is clear that the QRSTee is significantly easier than the LifeVest to assemble. The QRSTee took less than 20 seconds to assemble, while the LifeVest, with many more steps as shown in Figure 13, took almost 3 minutes.

POTENTIAL MARKET AND IMPACT

The market as estimated by Zoll is large (> \$1 billion annually), rapidly growing, and mostly unpenetrated. The Zoll LifeVest is currently the only commercially available WCD on the market. Several trends are also making “bridger devices” such as these more popular among clinicians because they give clinicians time to make a well-informed decision in the best interests of the patient.

The market can be broken down into several key components. Over 150,000 ICD’s are implanted each year in the US, and every one of those patients is eligible for the QRSTee. There is potential for the QRSTee worldwide as well because of the convenience and ease of incorporation into daily life. Only 20% of those qualifying for an ICD actually receive one globally, because of high cost, lack of access, and lack of proper insurance coverage. The QRSTee presents a more affordable and easy solution to use for patients who cannot get an ICD immediately or at all. The large profit margin on the device provides ample flexibility in pricing schemes for a global population. Though the costs of testing and approval may be high, the payback period is short.

The QRSTee presents a simple, elegant solution to a problem currently dominated by one antiquated, suboptimal solution in a burgeoning market, both domestic and globally. It was designed specifically with patient and clinician feedback in mind and has shown promise on several levels to increase patient compliance, improve quality of life, and save lives.