12-Lead ECG Training Device

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Abstract

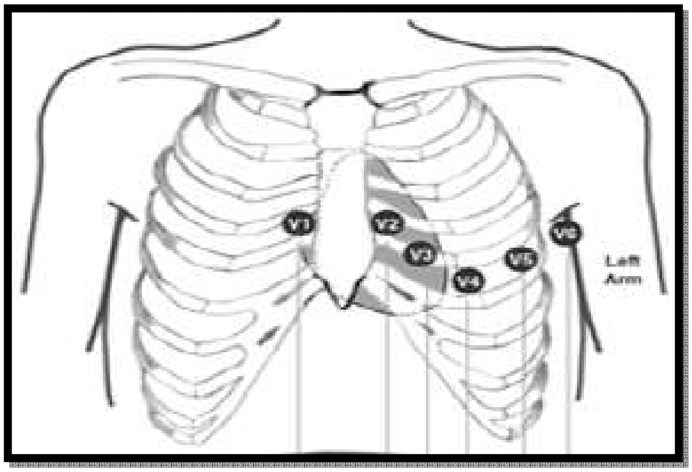
Electrocardiograms (ECG) are used to measure the electrical activity of the heart and diagnose arrhythmias. Currently there is no training mannequin that teaches both 12-lead electrode placement and ECG signal interpretation in one device. The purpose of this project is to develop an adult mannequin that teaches placement of electrodes based on anatomical landmarks and provides the student with feedback about the accuracy of their placement. The same mannequin should also produce a variety of ECG output signals to teach diagnostics using 12 – lead ECG. Our chosen design uses light emitting diodes (LEDs) to mark the correct 12-lead ECG electrode placement. The device also includes a 15-lead ECG electrode placement mode. An ECG signal simulator will be incorporated in the future. Initial testing shows that our mannequin is an effective training tool for teaching 12-lead ECG electrode placement. Subjects averaged an improvement of 2.4 electrodes placed correctly between a pre-test and post-test when training with our mannequin device compared to an average change (from pre- to post-test) of -0.6 electrodes placed correctly when training one-on-one with an instructor.

Introduction

An electrocardiogram (ECG) records the electrical activity of the heart and can be used to diagnose the type and location of arrhythmias of the heart (Yanowitz, 2006). The heart has nodes that produce electrical signals. The signal travels through the heart and surrounding tissue. The ECG electrodes measure this signal at select locations. An ECG lead is comprised of two electrodes. A lead is used to determine the electrical activity through a specific area of the heart. A 12 – lead or 15 – lead ECG can be used to more specifically locate the cause of a heart arrhythmia when compared to a standard 3- or 6 - lead ECG.

Ten electrodes are used for a 12 – lead ECG and fourteen electrodes used for a 15 – lead ECG (Yanowitz, 2006). There are four electrodes placed on each of the four limbs. These are the same four electrodes that would be used for a 3 – lead ECG. Two electrodes are placed at the center of the chest at the fourth intercostals on the right and left sternal boarders; these electrodes are labeled V1 and V2 respectively. For a 12- lead ECG, electrodes V3 – V6 are placed on the left chest (figure 1). For a 15 – lead ECG, four additional electrodes are placed on the right chest, mirroring electrodes V3 – V6 on the left chest.

Figure 1: 12-lead ECG Electrode Placement



V1: Fourth intercostal space to the right of the sternum

V2: Fourth intercostal space to the Left of the sternum

V3: Directly between leads V2 and V4

V4: Fifth intercostal space at midclavicular line

V5: Level with V4 at left anterior axillary line

V6: Level with V5 at left midaxillary line (Directly under the midpoint of the armpit)

Effective training methods are an important part of using an electrocardiogram (ECG) to accurately diagnose heart arrhythmias. Current methods for training emergency medical services (EMS) personnel to perform ECG recordings use either a mannequin (Laerdal 12-Lead Task Trainer, figure 2) that shows the correct placement of the electrodes or a human to practice on. The mannequins currently in use have visible electrode placement markers. This does not allow students to learn how to place the electrodes anatomically; they only need to match each electrode to a visible snap. The objective of this project is to develop an adult mannequin that can be used for 12 or 15 – lead ECG training and addresses the problems with the current training methods. Students should determine the placement of the electrodes on the chest of the mannequin using anatomical landmarks (i.e. the rib cage) and the mannequin should provide feedback about the accuracy of the placement. The mannequin should also produce a variety of ECG signals to be displayed when the electrodes are placed correctly.

Figure 2: Laerdal 12-Lead Task Trainer

Connects to ECG simulator and has connections for limb leads and V1-V6. Electrode sites are visible.

Device Design

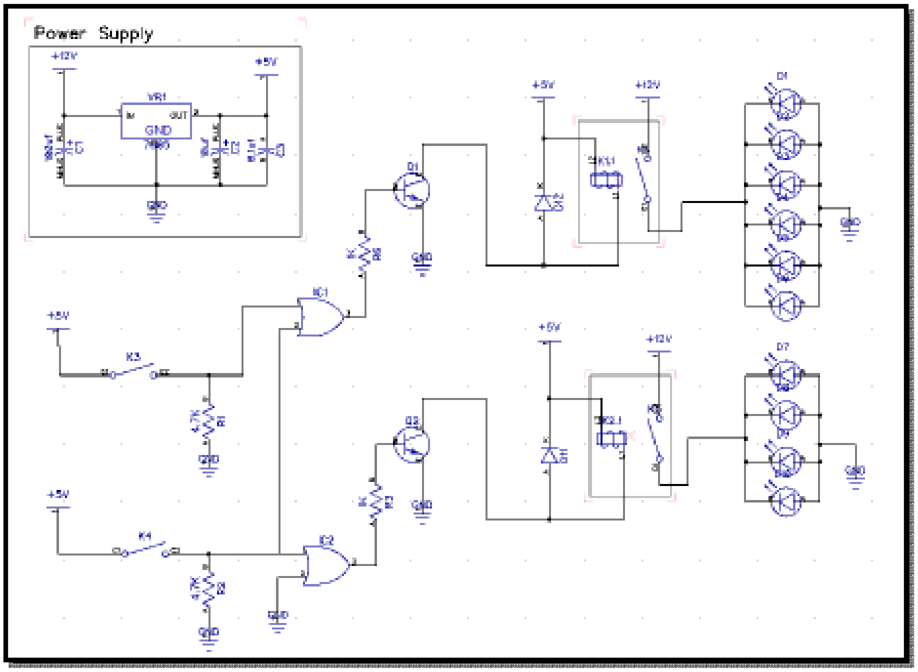
General design description

Our final prototype is based on an LED-marked electrode placement design. The design consists of a power supply, circuit, LEDs and an existing training mannequin. The 12 V DC power supply provides the necessary voltage to power a circuit inside the chest cavity of the mannequin, which in turn lights up a set of 10 LEDs under the surface of the mannequins skin in order to mark correct electrode placement locations. Each LED marks the correct electrode placement for electrode locations V1-V10. The illumination of the LEDs is controlled by two switches attached to the circuit inside the mannequin. One switch lights up 6 LEDs and a second switch lights up all 10. Six LEDs are used for a 12-lead ECG reading, and ten LEDs are used for a 15-lead ECG reading. The LEDs run from the circuit inside the chest cavity up to the underside of the mannequin's skin. When the LEDs are illuminated by the switches, red circles appear on the skin of the mannequin's chest marking correct electrode placement locations.

Circuitry

A circuit with logic was incorporated into the design to allow for feedback of both 12 and 15 – lead configurations. One of two switches is associated with either the 12 or 15 – lead configuration. The 12 – lead switch turns on 6 LEDs, while the 15 – lead switch turns on the same 6 LEDs plus an additional 4 LEDs. The 15 – lead switch is attached to two OR gates, while the 12 – lead switch is only attached to one OR gate with an output to the 6 LEDs. 12V LED clusters were used to provide the visual feedback from the circuit. Since the OR gates require a 5 V signal, relays were used to allow the logic signal to control the LEDs. When the switch is pressed, the output from the OR gate triggers a relay that allows power to the appropriate LEDs. The logic signal is not strong enough to power the mechanical relays so the signal triggers a transistor which opens the pathway from +5 V to ground when the switch is pressed. The portion of the circuit past the OR gate is identical for each set of LEDs, with the exception of the number of LEDs. A schematic of the circuit can be found in figure 3. The circuit is soldered to a small board so that it is more durable than if it was placed on a breadboard.

Figure 3: Circuit Schematic



Device in Use

The main purpose of our design is to aid in training/testing students in the application of a12-lead ECG. During testing, students would place electrodes on the mannequin's chest in the locations of V1-V10 that they believe to be correct. After placement is completed, an instructor can press one of the two switches thus illuminating the LEDs to show correct of incorrect placement of the student's electrodes. During training, this same process can be repeated with the student being able to check his or her own electrode placement.

Cost

The materials used this semester mostly centered on those required for the circuit as the mannequin was donated by our client. The materials altogether cost approximately $150.87.

Experimental Testing

The efficacy of the device was assessed by allowing 10 subjects to practice placing 12-lead ECG electrodes. The 10 subjects were all college students who had no prior knowledge of ECG electrode placement. The subjects were randomly assigned to one of two groups. The first group (n=5) watched a short video that instructed them on how to properly place electrodes for a 12-lead ECG. After the video, each subject was pre-tested by placing electrodes V1-V4 on our mannequin. The number of electrodes placed correctly was recorded. After the pre-test, each subject was allowed 10 minutes to practice placing electrodes on our device. After 10 minutes of training, each subject was post-tested using the same procedure as the pre-test. The number of electrodes placed correctly was recorded.

The second group (n=5) watched the same video and was pre-tested using the same procedure as group 1. After the pre-test, each subject was allowed 10 minutes to look up any information and ask an instructor any question about 12-lead ECG electrode placement. After 10 minutes of training, each subject was post-tested using the same procedure as the pre-test. The number of electrodes placed correctly was recorded.

The two training methods were compared by using statistical directional t-tests to compare the pre- and post-test scores of each group and to compare the improvement (post score – pre score) of each group. We hypothesize that the group training with our mannequin will do at least as well, if not better, on the post-test than the group that trains with an instructor.

Results

The mean pre-test score for group 1 (mannequin training) was 1.6 electrodes (SD=1.5). The mean pre-test score for group 2 (instructor training) was 1.8 electrodes (SD=1.48). No significant difference was found between these values (p=0.84). The mean post-test score for group 1 was 4 electrodes (SD=0) leading to a mean improvement of 2.4 electrodes (SD=1.5) after training. The mean post-test score for group 2 was 1.2 electrodes (SD=1.79) indicating the subjects actually did worse after training (mean improvement=-0.6 electrodes, SD=2.2). Results are summarized in Table 1.

Table 1: Results Summary

	Mean Pre-test Score (SD)	Mean Post-test Score (SD)	Mean Improvement (=Post - Pre) (SD)
Mannequin	1.6 (1.5)	4 (0)	2.4 (1.5)
Instructor	1.8 (1.48)	1.2 (1.79)	-0.6 (2.2)

A significant difference was found between the pre- and post-test scores of group 1 (p=0.012) but not between the pre- and post-test scores of group 2 (p=0.709). A significant difference was also observed between the improvement of group 1 and group 2 (p=0.036).

Discussion

The purpose of this project was to design a device that could be used to efficiently teach EMT students how to place electrodes for a 12-lead ECG. Mannequins currently on the market allow students to practice placing these electrodes, but utilize visible snaps or magnets that do not allow students to learn placement based on actual anatomical landmarks. To learn the appropriate placement, students currently have to practice on actual patients which requires a trained professional to be present to check their work. A mannequin that allows students to practice placing 12-lead ECG electrodes based on anatomical landmarks and also provides them with feedback about how to improve would make this process much more time efficient.

Our results indicate that training with a mannequin that marks correct 12-lead ECG placement with hidden LEDs is an effective method for teaching students how to correctly place electrodes for a 12-lead ECG reading. While the two experimental groups performed similarly on the pre-test, all subjects in the mannequin training group placed all electrodes correctly on the post-test while none of the subjects in the instructor training group placed all electrodes correctly on the post-test.

There are flaws in our testing procedure, however. We were unable to test with a group of actual EMT students who would have been a much more accurate representation of whom the device is targeted to. A larger sample size would also improve the accuracy of our results. There are also drawbacks to our mannequin prototype. The mannequin body is designed to be used as a CPR mannequin and therefore is not completely anatomically correct. The rib cage does not extend all the way around the torso so we were unable to correctly mark location for V5 and V6. Finally, because we only had one prototype to work with, subjects in group 1 were allowed to train on the same mannequin they were tested on. Subjects may have been able to memorize the correct placement of the electrodes rather than feel for intercostal spaces. Ideally, we would have a set of mannequins that are all slightly anatomically different to represent variation in human body types.

Future work for this project will involve creating a more anatomically correct mannequin that has a complete ribcage and would be adaptable to represent both male and female patients of varying body shapes. To make the device more marketable, an ECG signal generator should be incorporated. This would allow the mannequin to output an appropriate ECG signal when a student has placed all electrodes correctly. Further research will have to be done to determine what type of material can be used for the mannequin's skin in order to conduct an electrical signal.

Conclusion

We have developed a mannequin device that can be used to train students to place 12-lead ECG electrodes. Initial testing indicates that an LED marked mannequin is likely to be as effective as human subjects for teaching students to perform 12-lead ECGs. Several improvements, such as modifying the mannequin anatomy and incorporating an ECG signal generator, need to be made before the device is marketable.

References

Laerdal Medical. 20 Sept 2008. <www.laerdal.com>

Lunt, B. 1999. “Safety With Electricity.” The Technology Interface. 3(3).
“ECG Stress Testing.” CardioSmart. 2008. American College of Cardiology. 20 Sept 2008. <www.cardiosmart.org>

Yanowitz, F G. “The Standard 12-Lead ECG.” ECG Learning Center. 2006. University of

Utah School of Medicine. 24 Sept 2008. <http://library.med.utah.edu/kw/ecg/index.html>

Appendix A: Safety and Ethical Considerations

The biggest safety concern with this design is the current amperage in the circuit. A current of 100 mA is enough to push the human heart into fibrillation (Lunt, 1999). The largest current we measured in our circuit was 50 mA. This is well below 100 mA. Also, the circuitry is hidden inside the mannequin and should not come into direct contact with the user. Since this device will be used to train medical personnel how to perform a 12-lead ECG, electrode sites must be marked extremely accurately to ensure users are trained correctly.

Appendix B: Human Factors Considerations

Human factors and ergonomics are important considerations in the design of the ECG trainer. The device will only be used by students learning to do ECGs so it did not need to be designed for use by the wide population. The device mimics the exertions and setting of performing an actual 12- or 15 – lead ECG so the abilities and skills needed to perform an ECG in the field are matched.

The device is intuitive and easy to use. An instruction manual should not be necessary to use the device. An additional benefit of not needing an instruction manual is that the device can be used by people who speak any language. The device is adaptable for 12 and 15 – lead ECGs so two separate devices are not needed. The buttons to activate the 12 and 15 lead feedback mechanism should be easily located by the user. The buttons are clearly labeled with which one is for the 12-lead and 15-lead feedback. The circuitry is hidden inside the device so that it is not confusing to the user. This also has the added benefit of protecting the circuit from damage.

This device will not be used in hospital or any medical setting, but it still has the potential to lead to diagnostic errors. If the location of LEDs for the placement feedback is not correct, the user will learn the wrong placement for the electrodes. Keeping in mind these considerations for the design of the device will result in an improved ECG electrode placement training method.

Appendix C: Product Design Specifications

12 Lead ECG Trainer
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Function:
An adult mannequin will be developed to be used for 12 and 15-lead ECG training. The mannequin should produce a variety of ECG signals. Students should place ECG electrodes on the chest using anatomical landmarks and the device should provide feedback about correct and incorrect placement.

Client Requirements:
- Placement of electrode leads should be found using anatomical landmarks
- Individual visual indicators for correct/incorrect placement of each electrode lead
- ECG signal output when all electrodes are placed correctly
- Endure daily use by students
- Withstand cleaning using standard cleaning procedures

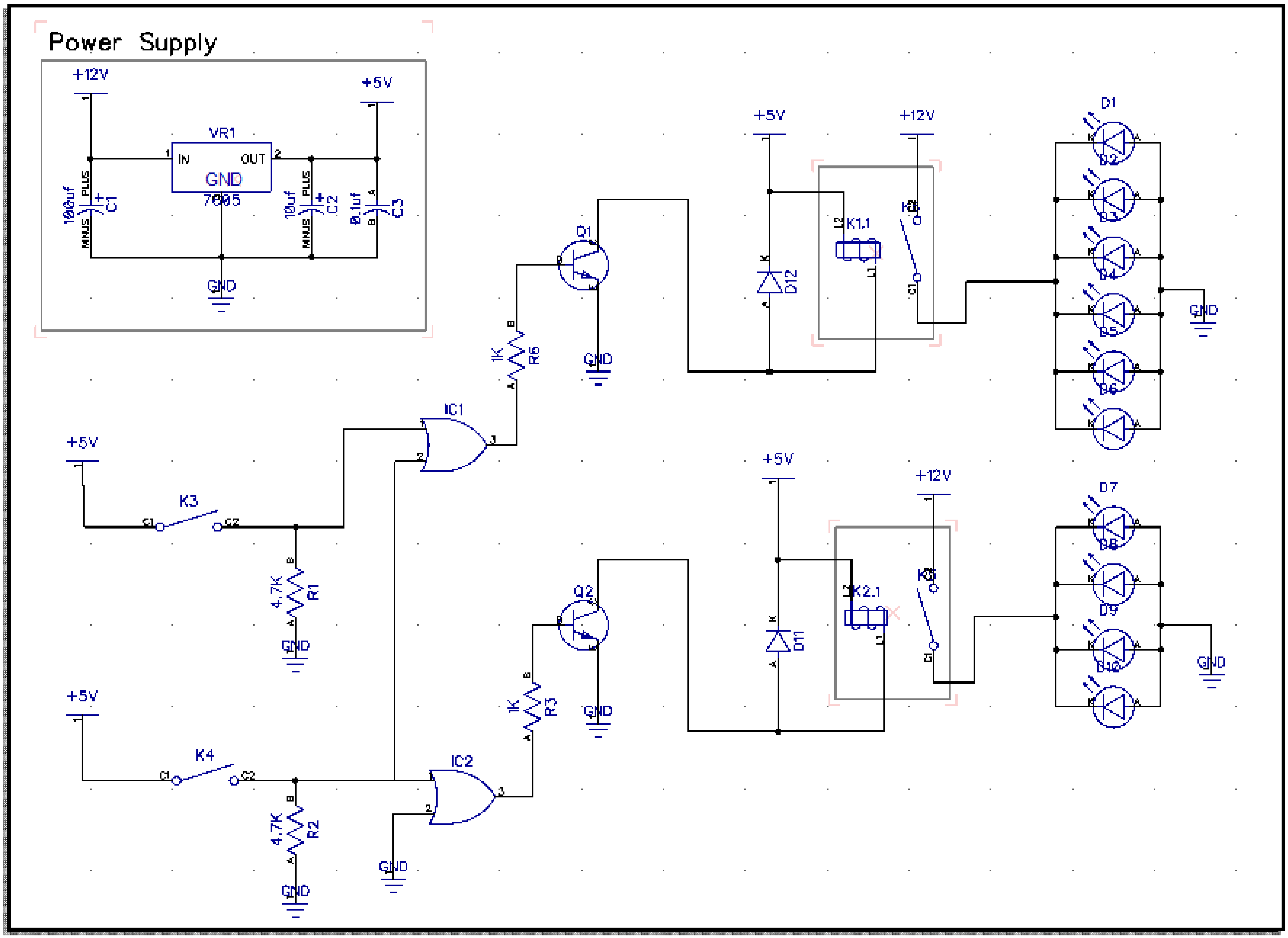
Design Requirements
1. Physical and Operational Characteristics
    a. *Performance requirements:* The placement of the electrode leads should be found using anatomical landmarks including the clavicle, ribs, and sternum. Feedback should be given about the accuracy of the placement. When the electrodes are correctly placed, a variety of heart arrhythmias should be displayed. The device should withstand daily use by students and should be able to be cleaned using standard cleaning procedures.
    b. *Safety:* All circuitry should be insulated and hidden from the user to prevent shock. Wiring should be protected so that cleaning does not short-circuit the wiring.
    c. *Accuracy and Reliability:* Electrodes must be placed within a 1 cm radius of the correct location to register as "correct placement." The device should not disrupt or alter the transmission of the ECG signal.
    d. *Life in Service:* The device should last five years of weekly use with cleaning after each use.
    e. *Operating Environment:* The device should be water resistant to withstand cleaning. The device will be used in an indoor classroom environment by numerous students.
    f. *Size:* The device should fit model the anatomy of a human adult torso.
    g. *Weight:* The device should be easily lifted by an average adult.

h. *Materials:* Ideally a materially that mimics the electrical conductance properties of skin should be used. The material should be dark enough to hide underlying circuitry but also be able to transmit light from LED placement markers.

2. Production Characteristics
    a. *Quantity:* One unit to be used by Dane County EMS
    b. *Target Production Cost:* Cost must be affordable for the Dane County EMS.
3. Miscellaneous
    a. *Customer:* The client wants a visual indicator for correct/incorrect placement of *each* electrode lead and an ECG printout when all leads are positioned correctly.
    b. *Competition*
        i. *12 Lead ECG Placement Trainer,* Armstrong Medical
            1. Correct placement for electrodes are visibly marked, magnets pull to correct location
            2. expensive ($865)
        ii. *12 Lead Task Trainer*, Laerdal
            1. Correct placement for electrodes are visibly marked
            2. expensive ($8299)

Appendix D: Budget

Material	**Description**	**Company**	**Part Number**	**Quantity**	**Cost per Unit ($)**	**Total Cost (inc tax & shipping) ($)**
Switch	SWITCH PB SPST ALT ACT BLACK	Digikey	504PB-ND	2	1.54	3.08
Switch	SWITCH PB SPST ON-OFF BLACK	Digikey	501PB-ND	2	1.36	2.72
Switch	SWITCH PB SPST N/C MOM SOLDER	Digikey	503PB-ND	2	1.64	3.28
LED light source	Red	Digikey	492-1139-ND	1	9.90	9.90
LED light source	White	Digikey	365-1346-1-ND	2	4.74	9.42
OR gates	8-INPUT NOR/OR GATE	Jameco	CD4078	3	0.45	1.35
Fiber Optic Cable	3mm Plastic Unjacketed Fiber	Fiber Optic Products	-	10 feet	1.17 / ft	11.70
LED clusters	4 LED array, 9/16" diameter, Red	TheLedLight.com		10	8.95	97.75
Voltage Regulator	5 V	Radio Shack	276-1770	2	1.59	3.36
Voltage Regulator	12 V	Radio Shack	276-1771	2	1.59	3.36
Relay	SPDT relay	Radio Shack	275-240	1	4.69	4.95
TOTAL COST						**150.87**


Power Supply
+12V
+5V
VR1
IN
OUT
GND
7805
100uf
C1
10uf
C2
0.1uf
C3
GND
+5V
K3
4.7K
R1
GND
+5V
K4
4.7K
R2
GND
IC1
IC2
GND
1K
R6
1K
R3
Q1
Q2
GND
GND
+5V
D12
K1.1
+12V
+5V
D11
K2.1
+12V
D1
D2
D3
D4
D5
D6
GND
D7
D8
D9
D10
GND