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) and fiber optics 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.

Problem Statement

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 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.

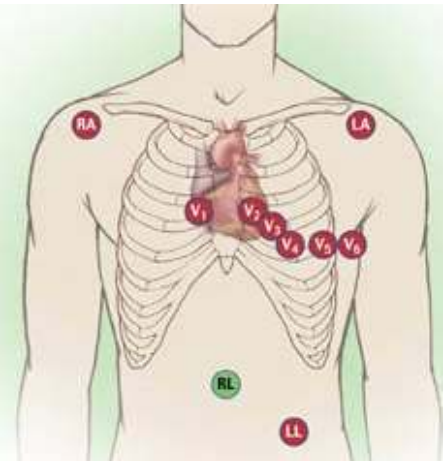
Background

12 – Lead ECG

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)

(American College of Cardiology, 2008)

Existing Devices

There are several existing devices on the market that are currently used to teach students to perform ECGs. The first is the Heart Sim 200 by Laerdal Medical. It is an ECG rhythm simulator that provides basic, modified, and pediatric rhythms. This device connects to other Laerdal mannequins. This is a rhythm simulator that does not teach electrode placement. The

second device is the Laerdal 12-Lead Task Trainer (figure 2). It is an adult male torso with connections for the four limb electrodes in addition to V1-V6 electrodes. The mannequin can be used with a monitor to display heart arrhythmias or for defibrillation. The disadvantage of this mannequin is that the electrodes are placed on the chest with clips, so the placement is visibly obvious and not taught. In addition to not effectively teaching placement, this mannequin is very expensive ($8000+). There are also several other mannequins that offer 4 – lead ECG monitoring (Laerdal Medical, 2008).

Most recently, Amrstrong Medical has released a 12-lead ECG electrode placement training mannequin that utilizes magnets to teach correct placement. This mannequin does not fit our client's needs as the magnets will pull the electrodes to the correct location so the student does not rely completely on anatomical landmarks.

Figure 2: Laerdal 12-Lead Task Trainer

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

Product Design Specifications

The mannequin will be used to train EMS personnel to correctly place the electrodes used for 12-lead ECG monitoring. The device should provide students with feedback about the accuracy of the placement of the electrodes. If the electrodes are within one centimeter of the correct location, the placement should be considered correct. There should be no visual or

textural cues to the placement of the electrodes other than the anatomical landmarks (the ribs and sternum). Once the electrodes have been placed and their accuracy has been confirmed, an ECG signal should be displayed on a monitor. The mannequin should be able to transmit a variety of heart arrhythmias.

This device should able to withstand daily use by students and should be water resistant so the surface can be cleaned between uses. All wires should be hidden within the mannequin so that they are not damaged by cleaning and so they are not visible to the students. The signal generator and feedback system can run on standard AC power or a battery within the mannequin. The device will be incorporated into an existing adult CPR mannequin and should not increase the weight so much that it cannot be easily transported by an average adult. The device should be inexpensive and reproducible

Prototype Design

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 chest piece. From there, small lengths of fiber optic cable are run through the chest piece from the LED to the underside of the 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

The circuit (appendix E) is composed of two on/off switches and 10 clusters of LEDs. One switch controls the 12-lead mode and the other controls the 15-lead mode. The 12-lead mode requires six clusters of LEDs to turn on. These LEDs light the optical fibers that mark V1 – V6. The 15-lead mode requires all ten clusters of LEDs to turn on. This is because a 15-lead ECG uses the same V1 – V6 electrodes plus four more electrodes applied to the opposite side of the chest. A quad 2-input OR logic gate (figure 3) was used in the circuit to allow one of the LEDs to be controlled by both switches (i.e. one switch turns on one LED, the second switch turns on both LEDs). The OR truth table is shown in table 1. Because the logic gate is powered by 5 V and the LEDs require 12 V, a relay was incorporated into the circuit design. The relay is triggered when it receives the 5 V output from the chip and outputs 12 V to the LEDs. A 5 V regulator ensures that the chip receives 5 V while a 12 V regulator ensures that the LEDs receive 12 V.

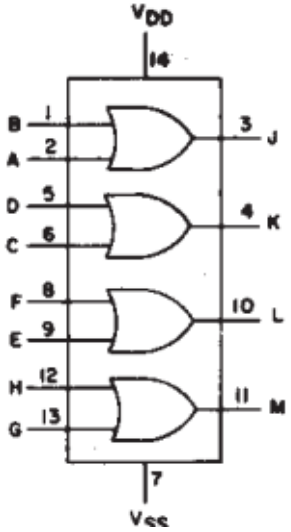


Figure 3: OR gate diagram

The chip has four 2-input OR logic gates. Only two of the gates were used: one for the 12-lead mode and one for the 15-lead mode.

Table 1: OR Truth Table

Input A	Input B	Output
1	0	1
0	1	1
1	1	1
0	0	0

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.

Budget

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 (see budget, appendix B).

Future Work – Prototype Testing

To evaluate the usefulness and efficacy of the developed ECG training mannequin, testing will be completed with 15 emergency medical technician students at the University of

Wisconsin Department of Emergency Medical Services. The students have been previously trained on the placement of ECG electrodes in a 12-lead configuration using class's current method. The goal of the test is to prove that the training mannequin may be used to train and test students to an equal or higher standard than the current method. Because the developed mannequin is expected to improve the efficiency and lower the costs of testing, it must be shown to be at least equal to the current method, if not better. We also want to receive student and instructor feedback on the usability of our device.

To test the training mannequin, the 15 EMT students will be divided into two groups. All students will be randomly assigned a testing number (1-15) for identification purposes. In this way, the students' confidentiality will be protected. In the first testing session, group one will be given a short tutorial on how to use the mannequin. Each student in the group will be pre-tested for their knowledge of 12-lead ECG electrode placement on the new mannequin. Following the pre-test, each student will spend 10 minutes alone with the training mannequin. During this time, each student will become familiar with operating the mannequin. At the end of the 10 minutes, the student will be tested on the placement of electrodes in a 12-lead configuration, in the same setting and method as the pre-test. For both the pre- and post-tests an EMT instructor will be present and record the students' scores (Appendix C). After the post-test, the student will complete a questionnaire (Appendix D) to obtain quantitative and qualitative feedback on their testing experience. After all the students have tested, the instructor will also fill out a qualitative feedback form with any comments they have on the new mannequin.

While the students in group one are being tested, group 2 will also undergo a short tutorial on how to use the old method (the method UW – Dept. of EMS currently uses in their classes) of training and testing. Each student will be pre-tested on their knowledge of ECG electrode

placement with this method. After the pre-test, they will then spend 10 minutes alone training on this method, and will be post-tested. Again, the instructor will record their scores during the pre- and post-tests. After being tested, the students will fill out the same questionnaire. After all students have tested, the instructor will fill out the qualitative feedback form with his or her comments.

At a second testing session conducted one week after the first session, the groups will switch training/testing methods and repeat the procedure outlined above. After all data has been collected, the students' scores will be averaged and the standard deviation calculated. The students' scores and improvements in score from the pre- to post-test will be compared between the old and new training methods. The new method will be considered acceptable if it equals or surpasses the current method in testing and training. The qualitative feedback from the students' and instructors' forms will be analyzed for any potential problems or improvements that could be made to the new mannequin.

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.

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.

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: Product Design Specifications

12 Lead ECG Trainer
Laura Bagley, Cali Roen, Anthony Schuler, Amy Weaver
October 14, 2008

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
- Battery operated
- 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 devices 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 a standard adult CPR mannequin.
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
            2. expensive ($865)
        ii. *12 Lead Task Trainer*, Laerdal
            1. Correct placement for electrodes are visibly marked
            2. expensive ($8299)

Appendix B: 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**

Appendix C: Testing Questionnaire, Instructor Form

Test Administrator
12-Lead ECG Placement Mannequin Training Questionnaire

Date:_____
Tester Initials:_____
Student ID Number:_____
Method used: Current Proposed (Circle One)

1. Pre-test: Number of electrodes correctly placed in a 12-lead configuration:

   1 2 3 4 5 6 7 8 9 10

2. Post-test: Number of electrodes correctly placed in a 12-lead configuration:

   1 2 3 4 5 6 7 8 9 10

In the space below, please comment on the new training mannequin, considering:

- Ease of Use
- Reliability of test method
- Comparison with current method

Appendix D: Testing Questionnaire, Student Form

Student Form
12-Lead ECG Placement Mannequin Training Questionnaire

Date:_____
Student ID Number:_____
Method used: Current Proposed (Circle One)

1. How accurate and consistent is this method in marking ECG electrode placement (1- Not accurate at all; 10-Completely Accurate)?

   1 2 3 4 5 6 7 8 9 10

   Comments:_____

2. How well did this method of testing facilitate your learning (1-Not at all; 10-Learned a lot)?

   1 2 3 4 5 6 7 8 9 10

   Comments:_____

3. How easy was this mannequin to use (1-Not usable at all; 10-Very easy to use)?

   1 2 3 4 5 6 7 8 9 10

   Comments:_____

4. How could the mannequin be improved?

5. Additional Comments:

Appendix E: Circuit Schematic