Neonatal Heartbeat Annunciator for Use in the Developing World

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***Abstract*— The majority of neonatal deaths occur in the developing countries. In many cases, unresponsive infants at birth are alive although birth attendants think they are dead and do not attempt to resuscitate them. In order to address this problem, training for birth attendant skills for resuscitation and having a device to determine the newborn heartbeat are necessary. In this project, a neonatal heartbeat annunciator has been designed and undergone preliminary evaluation. The device is quickly attached and uses electrodes to pick up the ECG signal from the infant's chest. Following electronic processing, the heartbeat is indicated as a flash of LED light and the sound of a high-frequency buzzer. It is hoped that this device will encourage birth attendants to attempt to resuscitate unresponsive babies and help to reduce neonatal mortality.**

I. Introduction

In 2012, approximately 1 million infants died on their first day of life and about 1.2 million stillbirths occurred [1]. According to a report by *Save the Children International*, India with 309,000 infants dead on their first day of life accounted for 29 percent of the global total (2). Most of these deaths occurred in the poverty stricken areas where there is a lack of medical equipment, health professionals and well-trained birth attendants. If unresponsive infants are born, birth attendants might think they are dead and will not attempt any measure of resuscitation. It is believed that if the infant's heartbeat could easily be detected, the birth attendant would be encouraged to attempt resuscitation. It also has been demonstrated that training midwives on neonatal resuscitation can help decrease neonatal mortality (3).

The goal of this project is to design and evaluate a user-friendly device that can be used by minimally-trained birth attendants to immediately detect the heartbeat of depressed, nonresponsive neonates at birth so as to encourage resuscitative actions. Such a neonatal heartbeat annunciator should be small, durable, and inexpensive while quickly detecting heartbeats.

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II. Methodology

The electrocardiogram (ECG) is generated by the electrical activity of the heart. This signal can be used to determine the occurrence of a heartbeat and to determine normal and abnormal rates and rhythms of the cardiac cycle. These small electrical signals found on the body surface can then be sensed by electrodes. A sharp pulse, known as the R-wave usually has the largest amplitude leading to it often being used to detect the occurrence of a heartbeat. The R-wave amplitude ranges from 0.2 to 1.2 mV depending on the placement of the electrodes. The heartbeat annunciator is able to detect these R-wave signals within this given range. Also it meets other specifications such as: input impedance, battery life time, sound level, time to steady response, sensitivity to motion and manufactured cost (Table 1).

A. Electronic Circuit

The neonatal heartbeat annunciator is designed based on the block diagram of Fig. 1 and schematic of Fig. 2. Ag/AgCl electrodes pick up the ECG signal from the infant's chest (Fig. 3). These electrodes are connected to the input non-inverting amplifier that has a first order high pass filter with a cut-off frequency of 16 Hz. The high pass filter converts monophasic R-waves to bi-phasic waves and helps to reduce the low-frequency noise (Fig. 4). The bi-phasic wave is created so that both a positive or negative R-wave will be detected as a heartbeat by the electronic circuit. R-waves can be either positive or negative due to the placement of the annunciator and the electrodes. Creating the biphasic wave will help to reduce missed heartbeat detection resulting from R-wave polarity.

The signal will then go to the second amplifier to increase its amplitude enough to trigger the monostable multivibrator in the next stage. A low-pass filter at the output of this amplifier is used to reduce high-frequency noise. Its cut-off frequency is 120 Hz.

The final stage is a monostable multivibrator. It is used to produce a consistent pulse at the output for each detected R-wave. It changes state once triggered, but returns to its original state after a set delay time of 80 milliseconds. A negative input pulse will trigger the pulse. The capacitor is charged and keeps the output in the logic "high" for 80 ms then returns it to zero. A light emitting diode (LED) and a 2.3 kHz buzzer are used at the output to indicate the detection of each heartbeat. The high level output from the monostable multivibrator drives the LED and buzzer to give the pulse of light and sound beep indicating that a heartbeat has occurred.

This device is powered by a single CR2032 3V lithium coin cell battery with a capacity of 225 mAh. A quadruple low power supply voltage operational amplifier integrated circuit chip (IC) TLV2254[1] was used for the four operational amplifiers in the circuit. It has high input impedance, low noise and a low input bias current of 1 pA. Its supply voltage can be as low as 1.5 V. It is very important to use an IC that has a low input bias current to avoid oscillation and instability. A large input bias current will require a lower bial resistor value in the first amplifier, and it can also cause an offset at the output of this stage.

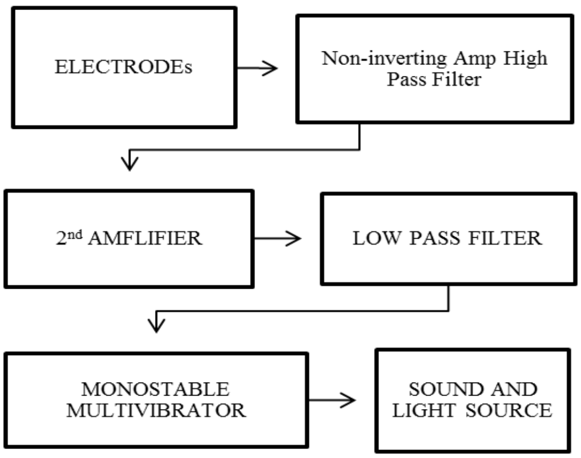

Fig. 1. Block diagram of the neonatal heartbeat annunciator

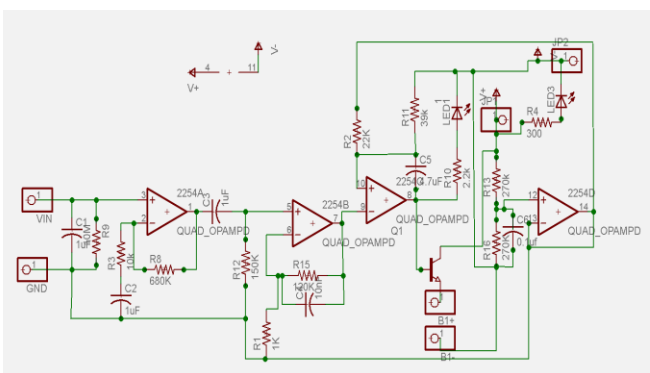

Fig. 2. A schematic diagram of the annunciator electronic circuit

Table 1: Annunciator Design Specifications

Design Specification	**Value**
Input impedance	> 5 MΩ
Signal amplitude range	0.2 – 1.2 mV
Time to steady response	< 3 s
Battery life time	>100 h
Sound level	>75 dB
Sensitivity to motion	Minimal
Manufactured cost	<50 USD

[1] Texas Instruments, Inc., Dallas, TX, U.S.A.

Fig. 3. Sintered Ag/AgCl electrodes cast in silicone elastomer

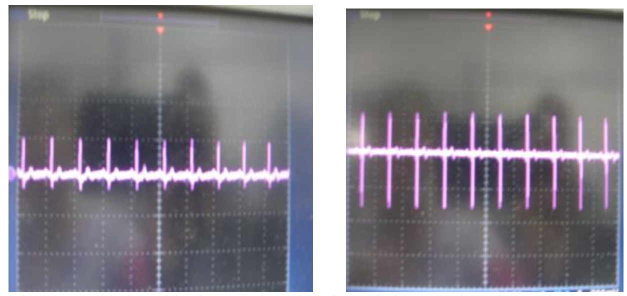

Fig. 4. ECG signal before (left) and after (right) passing through the noninverting amplifiter and high pass filter.

B. Electrodes

The electrodes used with the annunciator are also an important aspect of the design. they have to make good contact with the infant's skin, maintain their position when there is a lot of activity surrounding the baby, and have minimal noise and motion artifact. Three types of silver/silver chloride (Ag/AgCl) electrodes were considered for the annunciator: sintered Ag/AgCl disks, metallic silver disks with an electrolytically-formed silver chloride layer on their surface, and molded plastic "buttons" filled with powdered silver and silver chloride.

The electrodes were molded in a medical grade silicone elastomer[2] such that their exposed surface was located on the side of this structure that contacts the infant's chest. An illustration of the sintered Ag/AgCl electrodes molded in the silicone elastomer is shown in Fig. 3, and Fig. 6 shows the plastic electrodes in a different shape silicone elastomer. In this latter case an oval loop of 20 AWG copper wire is also imbedded in the elastomer to make it malliable and able to retain its shape to better approximate the curvature of the infant's chest. Electrode spacings of either 5 or 9 cm were used. Electrolyte gel was not required for newborn infants are already wet with amniotic fluid, but if the skin is dry, a few drops of normal saline solution should be sufficient to establish conductivity.

C. Package

Another important aspect of this project was the design of a suitable package for the annunciator assembly. The package had to be small, integrated with electrodes and contain the electronic circuit, battery, LED and buzzer. The

[2] A-103 Medical Grade Elastomer, Factor II, Inc. P.O. Box 1339, Lakeside, AZ 85929 USA.

3D CAD design software, Solidworks, was used to design the package and a MakerBot 3D printer was used for the fabrication of the package. Two alternative designs were developed for this project. The first design consisted of two pieces 3D printed from ABS plastic that were connected by a flexible silicone strip that contained the electrodes (Fig. 5). Each piece was situated over an electrode on the opposite side of the silicone strip. One of these packages contained the electronic circuit, heartbeat indicating buzzer and LED This package was 36 x 28 x 12 mm, while the piece at the other end of the silicone strip was the same size and contained the battery, power switch and on-off indicator. A cylindrical package for these components 25 mm in diameter and 12 mm high was also considered.

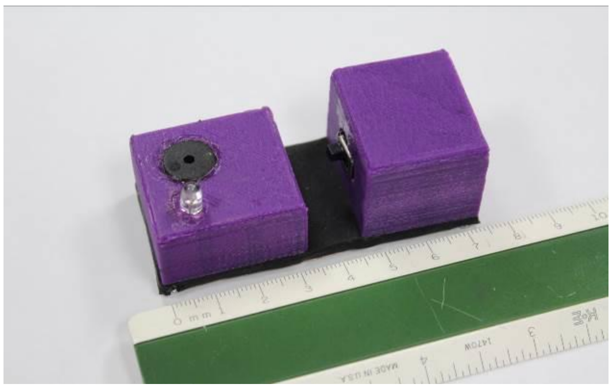

Fig. 5. The two-piece annunciator package

The second package design was a single piece containing all the components that was located in the center of the silicone strip (Fig. 6). The size of this single package was 37 x 35 x 18 mm. The electrodes remain at the same positions on the silicone strip as described in the preceding section.

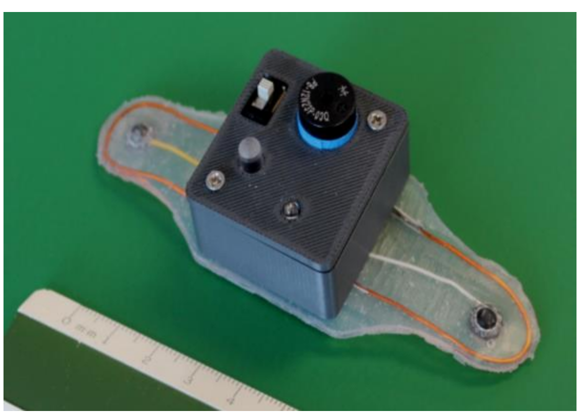

Fig. 6. The single-piece package of the neonatal heartbeat annunciator.

III. Results

This heartbeat annunciator has been tested in the laboratory using an ECG simulator that provides a neonatal ECG signal at various amplitudes. The device was able to detect the heartbeat when the amplitude of the R-wave ranged from 0.17 – 1.3 mV. The current drawn from the power supply has been measured at 2.38 mA for a heart rate of 60 and 4.26 mA at 120 beats per minute. The battery lifetime was found to be approximately 75 hours. The sound level of the buzzer is 85 dB at 10 cm according to its datasheet. The response time for this device to detect a heartbeat after being connected to the simulator was less than 1 second. Comparisons between the specifications and actual performance of the circuit based on this laboratory testing are given in Table 2.

Table 2: Comparison between specification and actual performance of device in the laboratory.

	Design Specification	Actual Performance
Input impedance	> 5MΩ	~10MΩ
Signal amplitude range	0.2 – 1.2mV	0.17 – 1.3 mV
Time to steady response	< 3 s	< 1 s
Battery life time	>100 h	75 h
Sound level	>75dB	85 dB at 10cm
Sensitive to motion	Minimal	
Manufactured cost	<50 USD	

IV. Discussion

The neonatal heartbeat annunciator has been designed to be used by birth attendants in the developing world with varying levels of training and experience. As such it is important to have a device that is simple to use, reliable, robust and makes an impact on health care. Although these are important criteria, their evaluation can only be done once they are deployed in the field, and this has not been done with the annunciator. It is, however, our goal to do this with our clinical collaborators in the United States and in India.

What has been done at this point has been testing the annunciator in the engineering laboratory to show it meets the design specifications with the exception of the battery lifetime and motion artifact. Although battery lifetime is shorter than desired, this can be corrected by using a slightly larger battery or reducing the output pulse duration as mentioned above. In this case, one cannot just be concerned with the electronics, since these changes could affect the annunciator's performance in the neonatal resuscitation environment where it is likely that there is a lot of competing noise and movement as resuscitation is attempted. The important point here is that resuscitation is attempted and our long-term hypothesis is that the use of the annunciator will encourage this.

The size of the printed circuit board (PCB) is 33 x 20 mm, and it uses standard surface mount components. Three of the operational amplifiers of the quad operational amplifier chip are used for the main circuit and the fourth is used for making the positive and negative power supply for the whole circuit by using only one coin cell battery. By using standard components, it is possible that these devices, if found to have a positive impact, could be further developed and manufactured in the developing world. Thus there could be economic as well as clinical impact for the annunciator.

Although the laboratory testing is the first step, the important evaluations have yet to come. These are the clinical tests on newborn infants that will be starting soon. Such factors as motion artifact, mechanical stability of the annunciator on the infant, interference from caretakers, and being able to hear the annunciator during the chaos of resuscitation procedures are all considerations that need to be evaluated under realistic clinical environments along with whether this device contributes to improved obstetrical outcome.

V. CONCLUSION

We are currently developing a neonatal heartbeat annunciator which is quickly able to detect heartbeats from the ECG simulator in the laboratory. The device is small, low power, and easy to attach. It has met most design specifications in these tests. The next step is to clinically evaluate this device on newborn infants in our local hospital, a major pediatric research center, and ultimately in India.

ACKNOWLEDGMENT

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