# PHYSIOLOGICAL WAVEFORM EXTRACTOR-GENERATOR

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**Abstract**

Biomedical engineering staff at hospitals regularly troubleshoot cardiac monitors and defibrillators. Some of the reported problems involve incorrect device interpretation of the ECG waveforms. Occasionally, some of these cases are difficult to investigate especially if the event does not occur regularly. Recently, we encountered two cases in our department which fall under the above criteria. In each case, a defibrillator issued a false negative shock advisory.

Considering the above, we developed a simple practical method to evaluate such a device. In this method, the patient's waveform is extracted from the paper record, re-generated, and applied to the device in-question. This procedure will allow the staff to test the device quickly and confirm or dismiss the reported error.

## Introduction

In the field of biomedical engineering, solving intermittent equipment problems can be challenging. In some cases the reported problem indicates a device interpretation that is believed to be incorrect. The reports most often come with paper records submitted by a nurse, paramedic, or physician. If clinicians and/or biomedical engineers cannot solve the problem, the paper record is commonly sent to the manufacturer for an expert opinion. Primary examples of such equipment include arrhythmia monitors and defibrillators [1]. A survey of leading manufacturers of cardiac monitors and automated defibrillators indicates that paper records are analyzed visually using no sophisticated testing methods. The limitations with such a process are the costs involved in shipping the devices and documents to the manufacturer as well as the time required to investigate the problem. These inefficiencies highlight the need for a tool that allows the staff to troubleshoot these devices on-site. Accordingly, we have developed a software-hardware based system capable of digitally extracting the waveform from the paper record and applying it to the device in-question. In addition to being convenient, this method validates clinician claims and provides an opportunity to fully document test results. Further, although most detection algorithms have a high rate of accuracy, this method provides the ability to apply and evaluate these algorithms on-site.

## System Hardware and Software

Figure (1) shows the system block diagram.

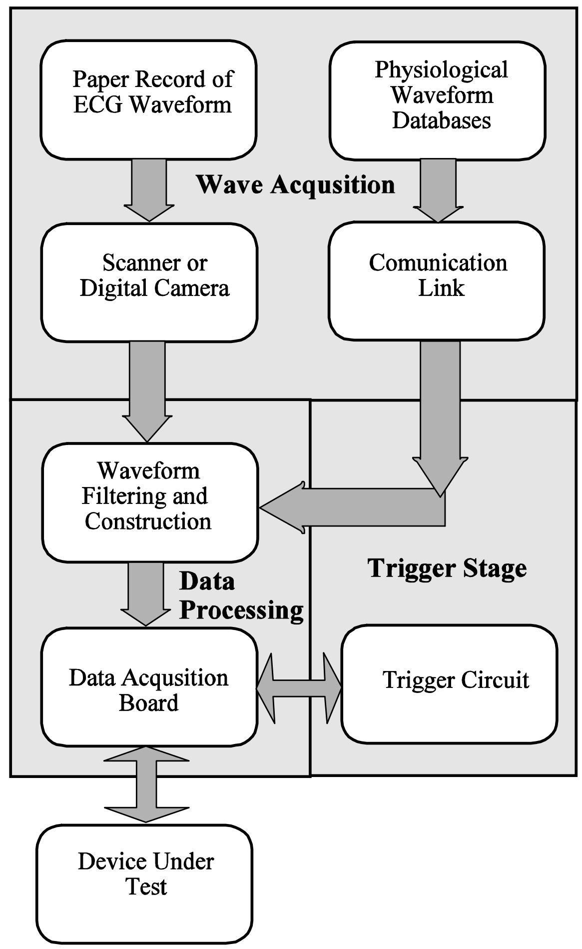


Fig. 1: A block diagram of the system.

As shown in figure (1), the system can be divided into the following stages:

a)Wave acquisition: This stage is responsible for acquiring and delivering the waveform to the computer. The source of the waveform can either be a hard copy record (paper strip) or a file from a database. If the former is used, the waveform image from the paper strip will be transformed to an image file (bit map format). A desk scanner or a digital camera can be used for this purpose [2]. In this study, a generic HP desktop scanner was used to capture the waveform image from the paper strip. To ensure a quality image within a manageable file size the scanned image should be transformed using a gray colour format with a resolution ranging between 200 and 300 dpi. An algorithm, using Matlab software (Math Works Inc.) was implemented to extract the ECG waveform. The program analyzes the image and creates a data file suitable for re-generating the waveform. Next, the data is low-pass filtered (smoothed) to reduce the quantization effects introduced during the scanning process [3]. Figure (2) shows a sample of an ECG waveform captured from a paper strip. The wave shown in this figure represents one of the two reported cases mentioned earlier. Notice the circled comment and the distortion in the bottom left corner.

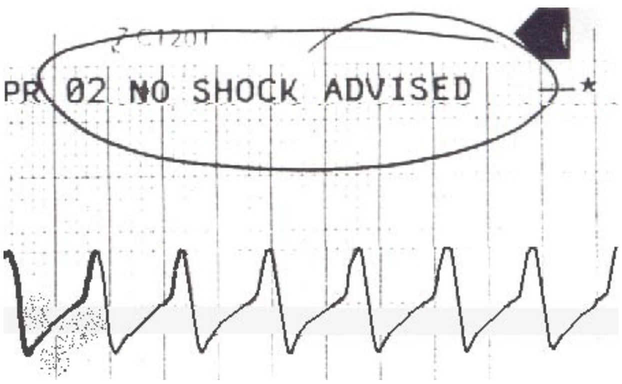


Fig. 2: The scanned image of the ECG waveform.

If the source of the waveform is on-line, the file can be downloaded from its archive. A list of annotated database sites is shown below:

1. **CU -** Creighton University, part of MIT-BIH database.
2. **ESC** - European Society of Cardiology.
3. **MIT-BIH -**Massachusetts Institute of Technology and Beth-Israel Hospital.
4. **NST -** Noise Stress Test, part of MIT-BIH database.

An alternative to using the on-line database is to acquire the waveforms from a CD. The sites listed above as well as the American Heart Association (**AHA**) (through ECRI) produce and provide these CDs. It is critical to mention that the waveforms collected in these databases are annotated by cardiologists and evaluated extensively through many clinical simulations. Accordingly, manufacturers rely on these comprehensive databases to test and evaluate the sensitivity and reliability of their products [4].

b) Data Processing: This stage is embedded within a personal computer. It consists of two sections: an algorithm which filters the data and constructs the waveform along with a data acquisition card which generates and delivers the waveform. The filtering process includes removing the strip grid-lines, any background distortion, and filling the gaps introduced during scanning. More details about the filtering process can be found in [2,3].

The waveform construction involves thinning the scanned ECG wave and building the new segment according to the averaged pixels of the scanned image [5]. The construction also includes the restoration of zero voltage and the development of base line [6]. The resultant data is saved as an array in an ASCII file. Figure (3) shows an image of the filtered waveform.

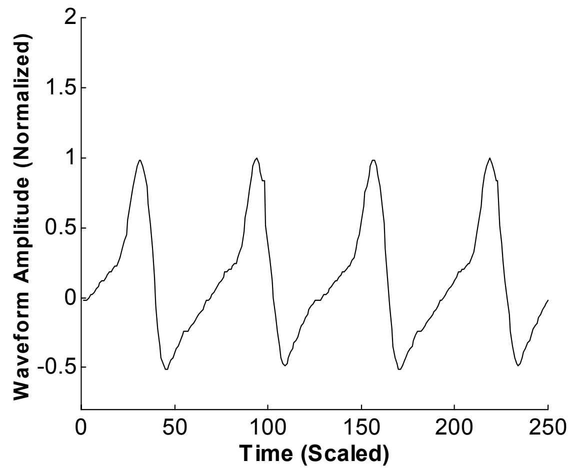


Fig. 3: The image of the filtered waveform.

Using Labview software (National Instruments), the constructed waveforms are reproduced by a stand-alone algorithm. These signals are delivered to the tested device through a data acquisition board. The board used in this system is a 12-bit card (PCI-6024E National Instruments) which provides two TTL compatible trigger lines and is guaranteed for 200 kS/sec sampling rate. The output (analog) channel of this board was configured to operate within ±5 volt. Figure (4) shows the front panel of waveform generator.

c) Trigger stage: This stage controls the number of scanned segments and their rate of repetition. The software provides two options: continuous pulses vs limited number of pulses. Further, the software allows the user to choose the type of trigger required: hardware vs software, internal vs external, rising-edge vs falling-edge, and with or without time delay (see Figure (4)). The trigger circuit implemented for this system is a single pulse hardware-triggered. The trigger pulse, which is compatible to that of a TTL level, is used to trigger the data acquisition board.

Finally, the system described above can be used to test the following devices: 12 Lead ECG machines, arrhythmia systems, automated defibrillators, ECG monitors, intra-aortic balloon pumps, Holter scanners, and pacemakers.

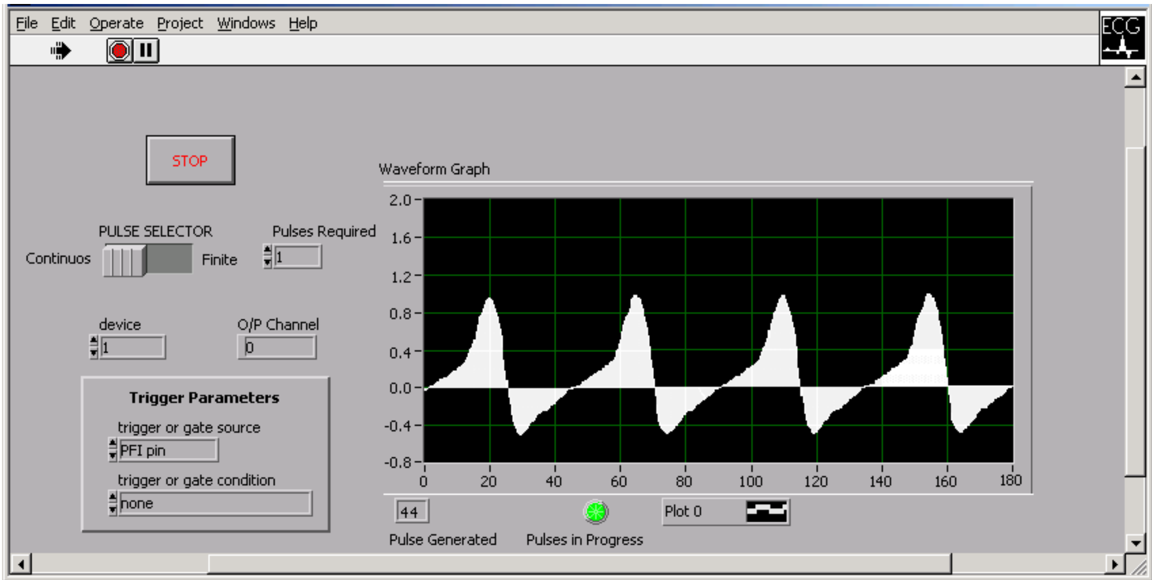


Fig. 4: The front panel of the waveform generator.

**Discussion**

Although the algorithms available within clinical systems to detect arrhythmia have a high rate of success, there is not an existing system that guarantees 100% accuracy [7]. Therefore, implementing special algorithms to evaluate these devices will ensure more effective and efficient on-site testing methods.

This paper describes the design of a physiological waveform extractor-generator capable of capturing an ECG waveform from a strip of paper and re-generating it to test a cardiac monitor or an automated defibrillator. In addition to re-generating the patient's data on-site, the system can be used to acquire various waveforms off-site. This can be achieved by downloading the data from on-line databases. The main advantage of this system is the ability to provide on-site verification without a lengthy process involving the manufacturer. In addition to the above, the system can be a valuable educational tool as it has the capability to capture morphologies from text books or journals and play them back.

In order to test the system, it is essential to use different waveforms than the one implemented by the software. This testing procedure follows the AAMI standard, which stipulates that any recorded segment used to develop the algorithm should not be used to test it [8,9]. Our new system was tested successfully and additional functions and modifications are in progress.

**Acknowledgment**

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