DESIGN AND DEVELOPMENT OF A VALIDATION FRAMEWORK FOR ECG DEVICE STABILISATION

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Abstract

Vehicle ECG instruments rank amongst the most critical of medical devices. However, ensuring their safe use is a challenge, as a number of regulations need to be complied before they are certified to be safe for both patients and medical personnel. Using a validation Framework, all stakeholders involved in ECG instruments can test their instruments and validate them. Currently there is no one-stop validation Framework that is inexpensive and easy to use.

This paper documents the development of a validation Framework for validating ECG instruments. This can be interfaced with ECG databases and ECG devices to conduct the validation testing. The device under test will be interfaced with validation Framework with communication protocols and the frame work will be interacting with the device for testing the validation vectors. The critical test vectors of validation Framework will validate the ECG device for rejection of noise analysis, pacemaker pulse analysis capabilities, T wave rejection analysis, detection of arrhythmias, heartbeat accuracy and response analysis for triangular waveforms. The validation Framework consists of several virtual instruments, constructed in LabVIEW, to generate and compare waveforms corresponding to the aforementioned critical areas.

The system is simple and easy to use with clear visual displays that allows for immediate comparison of waveforms, diagnosis and analysis. All of the test vectors are tested for performance and consistency with design specifications. It was found that the validation Framework was successfully able to validate each of the cases tested. An efficiency comparison with conventional test methods was carried out and it was found that validation Framework reduces the test cycle time significantly.

Key Words: ECG, LabVIEW, Validation Framework

Abbreviations

AHA	American Heart Association
AIMD	Active Implantable Medical Devices
ECG	Electrocardiograph
GHTF	Global Harmonization Task Force
GMD	General Medical Devices
IVD	Vitro Diagnostic Devices
MIT	Massachusetts Institute of Technology
NST	Noise Stress Test Database
PMA	Premarket approval
VHM	Virtual Heart Model

1. INTRODUCTION

Amongst the various medical devices in use today, ElectroCardioGraphs (ECGs) are amongst the most important since they are used to monitor the condition of the heart and detect abnormal cardiac conditions. Securing safety of ECGs is important from both the patients' point of view as also for the manufacturers and retailers of these devices. However, there are several challenges in securing safety of ECG devices. The first is to insulate both patients and users of ECG equipment from any voltage fluctuations or electrical shocks. The second is to ensure that an ECG device detects electrical signals of the heart only, whilst rejecting electrical signals from all extraneous elements / devices. That is the ECG device must be able to accurately detect heart beat rate. The third challenge is to ensure that the ECG devices responds very quickly post application of defibrillators which is important if the ECG signal is to be detected at all. The ECG Device must be able to withstand voltage surges and electrostatic and defibrillator discharge. The fifth challenge is to preserve the integrity of the ECG signal against interference from noise. The sixth challenge is that the ECG device is to be protected against environmental emissions and the seventh challenge is to ensure that the ECG device is able to detect all seven forms of cardiac arrhythmia. The eighth challenge is to ensure that ECGs are able to track the presence and functioning of pacemakers and the ninth challenge is that ECGs should be able to detect and reject tall T wave of the PQRST ECG signal beyond tolerance limits so that heart beat count is not duplicated.

Despite identification of areas of challenge in securing safety of ECGs and the establishment of standards towards the same, ECG manufacturers and designers are hard put to comply with all these standards. Their sheer number couple with time and costs involved preempts compliance. Some of the standards may vary across countries which again inhibits an ECG manufactured in a particular country from being used in another country. In developing countries such as India there are very few means of testing or verifying if ECG devices comply with regulations and compliances. Hence there is a need for an automated validation mechanism that will enable manufacturer, designers and vendors of ECG devices to automatically test and easily validate ECG devices. Such a system will not only enable the safe usage of a vital medical device such as ECGs but will also benefit manufacturers and retailers of these devices since they

will be able to market their products with more confidence. This will lead to increased turnover, improved profitability and larger market share.

There is currently no quick, reliable and automated system of validating safety of ECG devices. However, that such a system be implemented is fast becoming an imperative given the rise in the incidences of cardiac conditions in India on the one hand, and the lack of access to safe medical care on the other. An automated, validation system will benefit both patients and purveyors of ECGs.

2. DESIGN AND IMPLEMENTATION OF THE VALIDATION FRAMEWORK

The design specifications and ECG parameters to be tested by the validation network were identified in the literature review. This validation model is a simplified variation of the validation network developed by Jiang et al., [1]. The hardware components were kept to a minimum while the software simulation was conducted on LabVIEW. This was done so that this validation Framework can be made available and used by as many interested people as possible, without the constraint of costs that would have otherwise accrued in more sophisticated systems.

The Block diagram of the system is given in Figure 1. The validation network constructed in LabVIEW was used to generate waveforms corresponding to each of the seven cases to be tested. For each case, a corresponding input wave from the MIT BHI database was also input into the validation network. Both the waveforms were then tested. The parameters to be tested and the comparison process are depicted in the block diagram in Figure 1.

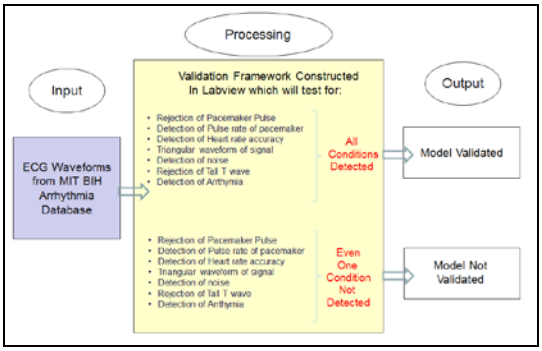

Fig. 1 System Block Diagram

If the Framework can detect all seven critical criteria pertaining to an ECG device as identified in specifications, it is validated. Else the Framework is not validated.

If an ECG device detects a pacemaker pulse along with an ECG pulse, it will read it as a double PQRST wave and given an erroneous result. Hence a safe ECG device must be able to detect the presence of a pacemaker and reject it. In this way, only the PQRST waveform corresponding to the actual heart signal will be accepted and an accurate diagnosis of heart condition can be made. The ECG device must also be able to test for proper functioning of the pacemaker if required. This is an essential condition particularly for those patients who depend on pacemakers for the proper functioning of their hearts. The validation Framework should be able to test and see if an input waveform corresponds to healthy functioning of the heart. It should be able to generate triangular waveforms for testing purposes. This is so that a wide variety of ECG signals can be tested. The validation network should be able to detect and test for noise in an input signal. It should reject tall T wave to prevent reporting of duplicate QRS complex waveforms. It should also be able to detect all cases where the input waveform departs from normal ECG wave so that possible cases of arrhythmia may be detected.

As can be seen from the flow chart, the entire LabVIEW validation Framework is a sequential process. For the Framework to be validated, all seven conditions have to be detected and tested by the Framework. Even if one condition is not detected, the Framework cannot be validated.

The design of the validation Framework involves designing the virtual circuit to generate waveforms corresponding to seven conditions to be tested. This is followed by inputting the ECG Waveforms from MIT database. Lastly, the two waveforms in each case are compared and checked for validation before the result is output. This sequence is depicted in Figure 2.

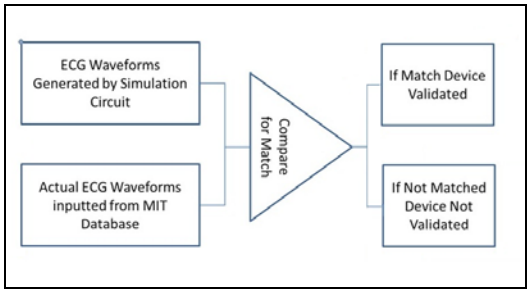

Fig. 2 Design for Generating ECG Waveforms

The design specifications will be according to the circuits required for ECG signal generation. The main circuit requirements are ECG signal sequencing, generating the sequenced wave and output monitor

The main task here will be to generate ECG waveforms corresponding to the seven conditions to be tested. The waveforms generated have to conform to specifications which have been derived from the literature review.

Detection of Presence of Pacemaker and Rejection of Pacemaker Pulse: The validation Framework must be able to detect pulses generated by pacemakers and reject them so as to prevent duplication of ECG wave readings.

According to Stevenson and Soejima [2], for the generation of a Pacemaker pulse the transistor must be able to increase current through the circuit by 2.71 times for every voltage increase of 26 mV. The basic pacing rates should be 32 to 120 bpm in steps of 2 bpm. A basic pacemaker pulse is shown in Figure 3.

Pulse Rate of Pacemaker: The validation Framework must be able to also check and see if the pacemaker is functioning properly. The pacemaker wave generated by the virtual circuit should conform to the following

specifications. The width of the pacemaker pulses can range across 20 values from 0.07 to 1.50 ms and the pulse amplitudes can range across 36 values from 0.2 to 7.5 volts. If the input wave matches with these specifications the pacemaker is functioning properly.

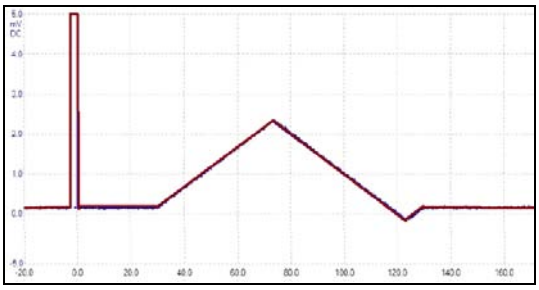

Fig. 3 Pacemaker Pulse Signal

Triangular waveform: The validation network must be able to generate triangular waveforms. This is because ECG waveforms follow a rough triangular pattern. The ability to generate triangular waveforms with varying amplitude and duration enables testing for a wide variety of possible ECG patterns. A triangular waveform has been described as a non-sinusoidal waveform named for its triangular shape. It is a periodic, piecewise linear, continuous real function.

For an input of 5 volts, the lowest point of the triangular waveform must be 2.4 volts above 0 while the maximum point of the waveform must be 4 volts. The hardware circuit serves as a prototype of the virtual circuit to be developed in LabVIEW which should also be able to produce waveforms conforming to these specifications. This sequence has been indicated in Figure 4.

Heart Rate Accuracy: The validation network must be able to test whether an input wave corresponds to a normal heat beat or not. It should be able to detect heartbeats across the entire spectrum of heart beat ranges and detect anomalies if any. This includes detection of heartbeats corresponding to 30 bpm to 200 bpm where the heartbeat of a healthy adult at resting stage is 60 bpm. The process to be followed is to generate a triangular waveform using the circuit identified previously. The waveform should correspond to that of a normal ECG waveform where the normal interval from the beginning of the P wave to the first deflection of the QRS complex is 120 to 200 ms. The normal range of the QRS wave duration is 120 ms and the QT interval is 440 ms. The amplitude of the waveform should be between 0.5 mV to 5 mV. This waveform is given in Figure 5.

This standard waveform is then compared with an input waveform. If the input waveform is an exact match of the system generated waveform the heart the input waveform corresponds to can be considered to be a valid.

ECG Noise: The validation network should be able to test the input ECG waveform to see if it is corrupted by noise signals. It should be able to generate a regular ECG waveform and then mix it with noise signals of amplitude greater than 5 mV. This waveform is then compared with input waveform. If the input waveform matches with the corrupted ECG waveform, it can be considered to be having significant noise components. Else it can be considered to be free from noise. In order that an ECG wave is not corrupted noise due to patient cables, all internal circuits, and output displays should not exceed 30 mV. Any noise signals of amplitude greater than 30 mV will corrupt the ECG waveform as shown in Figure 6.

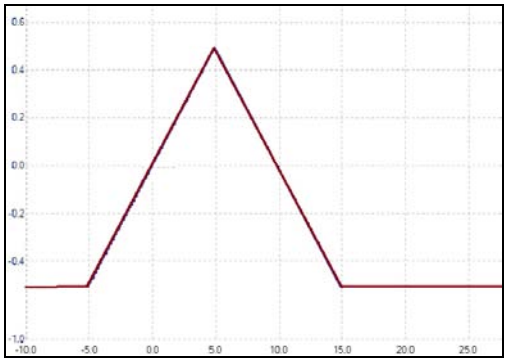

Fig. 4 Triangular waveform

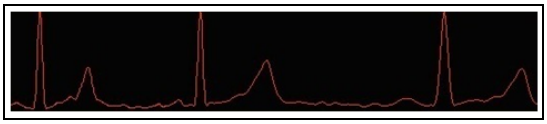

Fig. 5 Regular ECG Waveform

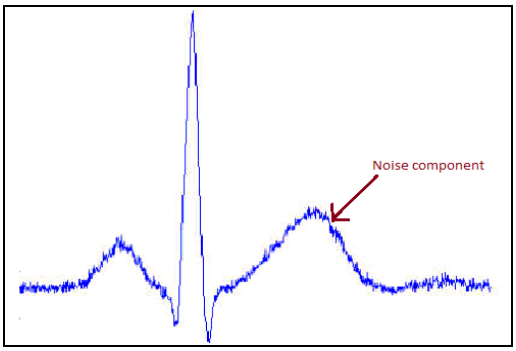

Fig. 6 ECG with noise

If the noise signals exceed threshold limits by more than 75%, the ECG waveform can become indistinguishable as shown in Figure 7.

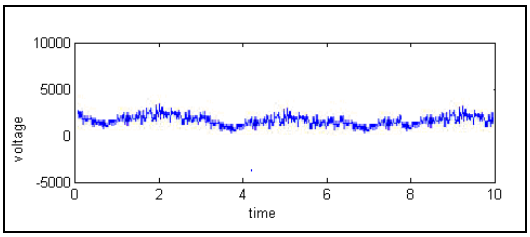

Fig. 7 Noise wave

Rejection of Tall T Wave: The T portion of a normal ECG wave should be at least 1/8th but less than 2/3rd of the amplitude of the corresponding R Wave. The amplitude of a normal T wave should not exceed 10 mm. If the T wave amplitude exceeds 10 mm, the ECG device will read dual QRS complexes resulting in erroneous results. Thus the ECG device must be able to

reject Tall T Waves or ECG waves whose T component is greater than 10 mm.

The validation network will generate triangular waveforms corresponding to regular ECG waveform. This waveform is then compared with the input wave containing tall T component. The output however should be of one QRS complex only. This indicates that the tall T component has been rejected. This sequence has been indicated in Figure 8.

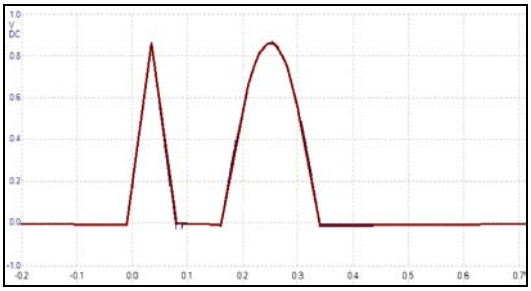

Fig. 8 Tall T Wave

Interfacing device with the Validation Network: To design this validation Framework, the MIT BIH waveforms were downloaded from the internet and stored on the Framework PC. The DAC converts the digital code of the MIT BIH data files into analog signals that replicate a human heart's ECG signal. The DAC is a 12-bit monotonic output type DAC. A monotonic DAC has an output that changes in the same direction for each increase in the input code. The converse is true as well for decreasing input code.

The process of transmission of data from the device to frame work is done in the form of data packets using a set protocol. This ensures, smooth, uninterrupted flow of data. The protocol consists of an ECG Sampling rate of 250 SPS where each sample consists of 2 bytes. ECG device forms ECG packets of 25 samples, each of three channels ECG data 84 bytes from B1 to B84. Each data packet structure contains a SYNC, HEADER and DATA.

3. TESTING AND VALIDATION

The Front Panel Display

The front panel that was set up is indicated in Figure 9. There are three inputs (i) the ECG waveforms from MIT BIH database that are converted into a digital signal by the LabVIEW Framework, (ii) provision for inputting ECG waveforms from remote locations through Ethernet ports and (iii) the ECG waveforms generated by the LabVIEW validation Framework. The waveforms generated in (i) or (ii) are then compared with those generated in (iii) and the result displayed on the output terminal. Figure 10 depicts the controls that have been developed in LabVIEW for varying amplitude, frequency, and sample rate to generate various kinds of ECG waveforms.

The input from Ethernet port for is also given in Figure 10. Using this front panel, the validation network was then tested for each of the seven cases.

The validation frame work is tested with sequence of test cases designed for the requirements.

Fig. 9 Front Panel with input / output displays

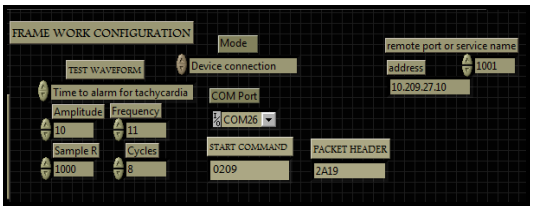

Fig. 10 Control Panel

Execution Results for Input Generation: Here the Framework was tested for two sets of inputs. The first input was from the MIT BIH database to the validation Framework. The second input was generated from the control panel of the ECG Validation Framework itself.

Rationale: The first input waveform corresponds to live, actual ECG recordings. It is equivalent to the output of a regular ECG machine. The second waveform is a measure of the validation Framework's ability to generate ECG waveforms for comparison.

Test Set Up: The test input from the ECG device was enabled and the waveform noted on the display.

Result 1: The test input for the waveform from the validation frame work is depicted in Figure 11.

Fig. 11 Input waveform from Database

Comment on Result: The validation Framework can successfully generate ECG waveform of corresponding frequency and amplitude. It is also successfully able to convert the signals into a digital waveform and display it on the Framework monitor. This indicates that the Framework is able to generate and display different ECG waveforms.

Here the Framework was tested to see if it was able to generate and then detect a pacemaker pulse in ECG input and then reject the pacemaker pulse.

Rationale: The ECG device must not process pacemaker pulse within an ECG pulse. This will be taken as a double ECG pulse which results in erroneous diagnosis. Hence the validation network has to first detect a pacemaker pulse and then reject it for processing. This will ensure that only one pulse

corresponding to actual heart rate taken for heart beat measurements.

Test Set Up: A waveform corresponding to heart pulses produced by a pacemaker was generated by the validation Framework. The waves were of amplitude 10mV with duration of 0.1ms. These parameters were obtained through the control panel on the front interface of the validation Framework.

Result: The results of the test are shown in Figure 12.

Fig. 12 Generation of Pacemaker Pulse

Comment: The input wave generated by the validation Framework corresponded to pacemaker pulses. This indicates that the system has been successfully able to generate, detect and output input pulses corresponding to pacemaker pulses. The pacer waveforms are able to meet specifications of 0.1, 1 and 2 ms of all the standard requirements.

Test was conducted to verify if the validation network is able to produce a waveform with noise waveforms superimposed on it and whether it is able to detect the noise signal and reject it.

Rationale: An ECG machine is subject to disturbances in its working environment. These disturbances get translated into noise signals which distort and interfere with normal ECG waveforms. Hence a validation Framework used to test ECG signals must be able to detect noise signals and eliminate them altogether.

Test Set Up: An ECG waveform with noise signals superimposed was generated by the validation network. This was done by introducing signals of voltage greater than 30mV into a regular ECG waveform.

Result: The result of this test id depicted in Figure 13.

Comment: The validation network has been able to successfully generate a noise waveform and test for 30 mV for 50 Hz.

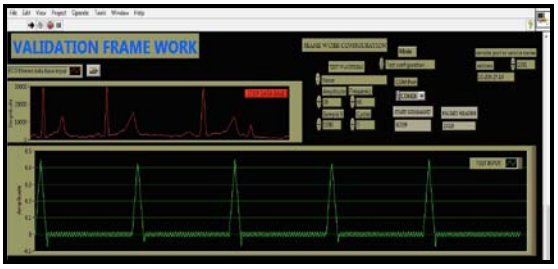

Fig. 13 Generation of Noise Waveform

Heart Rate Accuracy: This test verifies if the validation network is able to test whether an input wave corresponds to a normal heart beat or not.

Rationale: An efficient ECG device must be able to generate heartbeat waveforms conforming to a normal healthy heart. If there is an anomaly the ECG device must be able to detect this so that accurate diagnosis may be made and corrective action taken.

Test Set Up: The amplitude setting of the control panel was set to 0.8 mV. The frequency pulse was set at 100 Hz. These correspond to the parameters necessary to generate a heart beat as was identified in Chapter 5.

Test parameters: QRS pulse widths of 40, 70, 80,100 and 120 ms.

Result: The result of this test id depicted in Figure 14.

Fig. 14 Generation of Heartbeat Waveform

Comment: The waveform generated in Figure 14 for QRS complexes as indicated in design specification. This indicates that the validation network has successfully been able to generate a normal heartbeat waveform for QRS pulse widths of 40, 70, 80, 100 and 120 ms.

This test verifies whether the validation Framework is able to generate an ECG waveform with a tall T component.

Rationale: If an ECG device takes a Tall T component into consideration, this will be considered to be equivalent to a double ECG waveform which will result in erroneous diagnosis. Hence the validation network must be able to generate a tall T wave and then the device to reject it.

Test Set Up: The amplitude setting of the control panel was set to 1 mV. The frequency pulse was set at 100 hz. These correspond to the parameters necessary to generate a tall T wave. Results: The results of this test case are exhibited in Figure 15.

Fig. 15 Generation of Tall T Wave

Comments: It can be seen that the ECG wave generated has a tall T Component. Thus the validation Framework has been successfully able to test for a tall T wave with 0.2 to 2.5 mV amplitude and verified. The validation Framework must be able to generate a triangular waveform. This is so that a variety of ECG waveforms can be generated for testing purposes.

Rationale: There are a wide variety of ECG waveforms that are generated corresponding to different heart conditions. Since the validation Framework is to be used for testing purposes, it should be able to also generate a triangular waveform.

Test Set Up: These settings correspond to the requirements for the generation of a triangular waveform. Test parameter: 20 ms to 200 ms.

Result: The result of this test case is shown in Figure 16.

Fig. 16 Generation of Triangular Waveform

Comments: As can be seen from Figure 6-8 the validation Framework has been successfully able to generate a Tall T Wave with 20 ms to 200 ms amplitude and verified with the device.

Test determines whether or not the validation network is able to generate an ECG waveform.

Rationale: The validation network must be able to generate a regular ECG waveform. Any waveform that deviates from this standard can be considered to be an anomaly and an alert can be generated. This enables the system to detect cases of arrhythmia.

Test Set Up: The amplitude of the control panel was set to 3mV and the interval set to 200ms. These correspond to the parameters necessary to generate a standard ECG waveform.

Result: The result of this test is shown in Figure 17.

Fig. 17 Generation of an ECG Waveform

Comments: The ECG Network has been successfully able to generate an ECG Waveform of R (peak): 0.875ap, S (peak): 0.125 and verified.

Summary: From the test results it can be seen that the validation Framework has been successfully test for all cases for validating an ECG Device. Thus the validation frame work is tested for the design specification given below and results populated. The summary of test specification is given in Table 1.

Table 1 Summary of Test Specifications

Feature	Test Parameter	Specification
Pacing pulse	Pulse duration	0.1, 1, 2ms considering all standard requirements.
Pacing pulse	Rise time and over shoot	10µs settling time, <5% overshoot
Pacing pulse	Double pulse	±1%, ±2.5mV.
Pacing pulse	Overshoot	4ms to 100ms
Pacing pulse	Asynchronous pulses	±1.5, ±2.5ms respectively
Triangle waveform	Pulse duration	20ms to 200ms
QRS pulse	Pulse amplitude	R(peak): 0.875ap, S (peak): 0.125 ap,
QRS pulse	Pulse width	QRS pulse widths of 40, 70, 80,100 and 120 ms.
Data base	MIT	Responded for MIT data base
System Noise	Rejection	Generated noise signals of 50/60 Hz.
QRS pulse	Accuracy	QRS pulse widths 40, 70, 80,100 and 120 ms with various heart rate.
Tall T wave	Rejection capability	T wave of 0.2 to 2.5mV

4. RESULTS AND DISCUSSION

This section will present the results of the testing of the validation network. From literature review it was determined that medical devices play an important role in ensuring proper medical care is delivered to patients. However, in order to be used with confidence and to ensure safety of patients and to service providers, these devices have to conform to safety norms devised by international bodies such as Global Harmonization Task Force (GHTF). Of the various medical devices, ECGs are amongst the most important. This is because they inform about the condition of the heart, detect abnormalities if any and generate alerts such that suitable remedial action may be taken.

Just like other medical devices however, it is essential to secure ECG devices so that they do not cause any harm either to the patients or to personnel. The first step in determining this network was to identify from amongst the nine aforementioned challenges, those that are most critical to secure the device. The author decided to focus on seven essential requirements that an ECG device must conform to and also determined the specifications for each requirement that must be detected by the validation Framework.

The validation Framework was then constructed using LabVIEW. In this experiment, the icons would take the place of hardware circuit components that would have been otherwise required to generate ECG waveforms, according to set specifications, compare

them with actual ECG waveforms from the MIT BIH database and then output the result. The criterion used while constructing the validation network was that that device should be able to generate and detect waveforms corresponding to all the seven cases that were to be tested. If it failed to generate and detect waveforms for even one case, the device was not validated.

Using a combination of virtual instruments a front panel was successfully created in LabVIEW. This panel allowed for an input from a data base, connectivity from ECG device with various protocols and also enabled the validation network to generate ECG waveforms according to standard. The Framework was able to convert signals from the MIT BHI database into digital signals and display on the output monitor. Its ability to generate an ECG waveform with various specifications also displayed successfully. This means that the validation Framework may be used for a host of applications and testing processes. A requirement for the successful validation of an ECG Framework was to check its ability to generate a pacemaker pulse. The validation Framework had also to test for presence of noise in input ECG Signals. This is so that the detected noise could be filtered out. The validation Framework was able to generate noise signal of amplitude 30 mV and frequency 50 Hz and superimpose it on a regular ECG signal. This is an important result from a testing point of view. Noise signals across a range from very low to high frequencies can be generated and the performance of an ECG machine tested.

The validation network was also able to generate ECG waveforms equivalent to normal, healthy, adult heart. The parameters for generating this waveform were set in the control panel for amplitude of 0.8 mV and frequency of 100 Hz and the output observed. It was found that QRS waveforms corresponding to those of a healthy heart were generated. This is significant as any waveform can be compared to this standard waveform.

If an ECG device is not able to detect tall T wave, the entire signal will be read twice resulting in a duplicate and erroneous reading. Hence, there is a need for a validation Framework to detect and reject a T wave. The amplitude setting of the control panel was set to 1 mV and frequency set to 100 Hz and the output observed. It was seen that a tall T wave component was inserted into the output signal. This wave can be compared with like input signals to test for tall T component which can then be rejected. Since ECG waves correspond to an approximate triangle, the validation Framework must be able to generate triangular waveforms of varying amplitude, frequency and pulse rate so that as wide a variety of ECG signals response can be analyzed. In the control section, the amplitude setting was set to 2 V with pulse intervals of 1.50 ms. The output was a triangular waveform. By varying the control parameter settings, the shape of the triangular wave could also be altered suitably. This means that the validation Framework can be used for testing a number of possible responses.

The validation Framework test efficiency is compared to a traditional test set up testing timings and the results are captured in Figure 18. The validation frame work test efficiency in reducing the test timing and thus the advantage of early design approvals. The tests are compared to various available test set ups for ECGs.

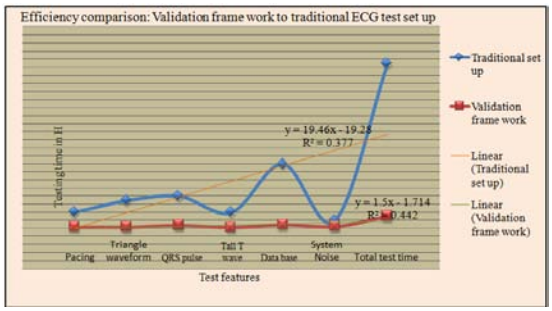

Fig. 18 Efficiency comparison

The performance of the validation Framework can therefore be considered to be satisfactory since it has been able to test for all conditions necessary to secure the safety of an ECG device.

5. CONCLUSION

Thus it can be concluded that the validation Framework has been successfully tested for most of the critical conditions necessary to secure the safe and efficient functioning of an ECG device. It offers a quick and inexpensive one stop solution for manufacturers of ECG equipment, for marketers and vendors of such equipment and for the healthcare sector as a whole for testing ECG devices.

A validation Framework for medical devices can provide a one stop solution for their validation which not only reliable but also saves cycle time for design validation.

6. REFERENCES

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