ECG calibration signal database construction based on IEC 60601-2-25 using MATLAB

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Abstract. ECG machines should be calibrated and tested to assure their accuracy. IEC 60601-2-25 standard described signals for calibrating ECG amplitudes and frequencies. The problem was this standard does not clearly describe the formulas of the calibration signals nor the complete database of these signals. The aim of this study was to get a database of ECG calibration signals for testing based on IEC 60601-2-25 standard clause 201.12.1.101. Data were constructed with a series of sinus function in Matlab software to simulate P, Q, R, S, and T segments. The data were visually and statistically compared with the data from commercial CTS database. Data were constructed for 3 different lead of 12 ECG calibration data. Four ECG calibration data with elevation or depletion ST segment were excluded from this study. This study demonstrated that these ECG calibration signals were slightly visually different and statically had differences in some of S wave and most of T wave. This data can be used by designers or manufactures, but for the testing laboratory is recommended using a commercial product.

1. Introduction
Electrocardiograph (ECG) is one of medical devices that is used for recording heart activities by measuring electrical signals produced by the heart muscle [1, 2]. An ECG signal can provide great range of information, particularly the heart’s structure and performance (rate, rhythm, size, position), heart muscle damage, cardiac drug influences, and implanted pacemaker perform [3]. The complex waveform signal is captured using electrodes attached on skin. The amplitude of the signal is very weak, specifically in the range of 0.2-5 mV [2, 4]. However, in actual the strong background noises from human body frequently contaminate the heart signal [2, 4]. An ideal ECG can differentiate ECG signal and background noise by having great common rejection ratio and high gain [2].

To ensure that an ECG operates properly, it must be analysed and calibrated regularly in order to support its performance. An uncalibrated ECG may lead to misreading and furthermore mistaken treatment to patient because of misdiagnose [5].

One of important ECG testing is essential performance and accuracy of medical electrical equipment in accordance with IEC 60601-2-25:2011, especially sub-clause 201.12.1.101. The aim of the test is to measure the accuracy of the amplitude and frequency of the ECG signal by comparing the ECG signal and the CTS (Conformance Testing Services) database. CTS database is an artificial ECG waveform to automatically test the amplitude and interval of measurement during performing ECG testing.
However, the problem is the standard does not clearly describe the formula of the calibration signals nor the complete database of these signals. The standard IEC 60601-2-25 only provides several references value. Therefore, the purpose of this study it to establish a complete database of ECG calibration signals using the sine function in Matlab Software and references value from the standard. It is hoped that this method can be used by manufacturer to gain their product or by other laboratories to help them conducting the test.

2. Method

![Figure 1. Nomenclature of calibration ECGs](image)

An ECG signal consist of P wave as atrial depolarization, QRS complex as ventricular depolarization, and T wave as ventricular repolarization that is shown in Figure 1. The X-axis and Y-axis of electrocardiogram are represented as duration (in minutes) and amplitude (in millivolt), respectively. Each section of P, Q, R, S, and T has intervals and amplitudes that are adjusted from the requirements in the standard (Annex HH in IEC 60601-2-25).

Each segment was constructed by sinus function as Equation 1, where $A$ is amplitude, $f$ is frequency that is determined by duration, and $\varphi$ is phase that distinction with previous segments. Each segment was combined into full signal and then was drawn in Matlab. Matlab function was run to get signal data. Data signal from Matlab was compared with data from CTS Database, by visually and statically. Significant level of CTS database and Matlab construction is analysed using statistical method Mann-Whitney.

$$x = A \cdot \sin(2\pi f t - \varphi)$$

3. Results and Discussion

| Denomination | Peak Voltage | Heart Rate | QRS-form |
|--------------|--------------|------------|----------|
| CAL05000     | ± 0.5 mV     | 60/min     | RS       |
| CAL10000     | ± 1.0 mV     | 60/min     | RS       |
| CAL15000     | ± 1.5 mV     | 60/min     | RS       |
| CAL20000     | ± 2.0 mV     | 60/min     | RS       |
| CAL20002     | ± 2.0 mV     | 120/min    | RS       |
| CAL20100     | ± 2.0 mV     | 60/min     | R        |
| CAL20200     | ± 2.0 mV     | 60/min     | QS       |
| CAL20500     | ± 2.0 mV     | 60/min     | small RS |
| CAL20502     | ± 2.0 mV     | 120/min    | small RS |
12 out of 16 calibration signals have been successfully constructed using Equation 1, as shown in Figure 2-13. The details of 12 signals are indicated in Table 1 which is differentiated by peak voltage, heart rate, and QRS-form. These signals are chosen because they do not have elevation or depression level of ST segment. The peak voltage is the maximum or minimum voltage value of signal, while the heart rate is the number of heart’s contraction (heartbeat) per minute. Normal people heart rate is 60 beat per minute. 120/min heart rate means there are two signals in a minute, or in other words a signal only takes half a minute. QRS-form is the shape of QRS-complex segment.

The graph results show that the CTS database and Matlab signal have the same pattern for all calibration signals. However, to see more closely to the detail, the CTS database peaks are more narrow than the Matlab peaks, even though they have same interval and peak value. These visual results are similar to the statistical results. Mann-Whitney results show that the level of difference between CTS database and Matlab for a whole signal have probability above 0.05, which mean they have no different.

In addition, the data are also compared for each segment using statistical Mann-Whitney method, as shown in table 2. It is demonstrated that CTS database and Matlab are significantly different for some calibration signal of most of T wave and some of S wave.

| Signal | Peak Voltage | Heart Rate | QRS-form |
|--------|--------------|------------|----------|
| CAL30000 | ± 3.0 mV    | 60/min     | RS       |
| CAL40000 | ± 4.0 mV    | 60/min     | RS       |
| CAL50000 | ± 5.0 mV    | 60/min     | RS       |

Figure 2. CAL05000 calibration signal

Figure 3. CAL10000 calibration signal

Figure 4. CAL15000 calibration signal

Figure 5. CAL20000 calibration signal
Figure 6. CAL20002 calibration signal

Figure 7. CAL20100 calibration signal

Figure 8. CAL20200 calibration signal

Figure 9. CAL20500 calibration signal

Figure 10. CAL20502 calibration signal

Figure 11. CAL30000 calibration signal

Figure 12. CAL40000 calibration signal

Figure 13. CAL50000 calibration signal
Table 2. The statistical value of the difference between CTS database and Matlab on each segment

| Calibration | P wave | R wave | S wave | T wave |
|-------------|--------|--------|--------|--------|
| CAL05000    | 0.057  | 0.620  | 0.600  | 0.033* |
| CAL10000    | 0.057  | 0.620  | 0.646  | 0.017* |
| CAL15000    | 0.063  | 0.608  | 0.587  | 0.013* |
| CAL20000    | 0.063  | 0.620  | 0.600  | 0.017* |
| CAL20002    | 0.630  | 0.646  | 0.011* | 0.218  |
| CAL20100    | 0.063  | 0.741  | 0.050* | 0.014* |
| CAL20200    | 0.063  | 0.786  | 0.119  | 0.014* |
| CAL20500    | 0.063  | 1.00   | 0.01*  | 0.001* |
| CAL20502    | 0.195  | 0.335  | 0.057  | 0.075  |
| CAL30000    | 0.063  | 0.620  | 0.646  | 0.013* |
| CAL40000    | 0.063  | 0.608  | 0.608  | 0.015* |
| CAL50000    | 0.063  | 0.620  | 0.646  | 0.016* |

It is still needed further study to create more general function, so that the elevation or depression level of ST segment can be illustrated as well by the function. Because the data compiled by the Matlab have same segment duration and amplitude, it can be used by designers or manufacturers to verify their product. However the testing laboratories are recommended using a commercial product (CTS database) for accurate whole data.

4. Conclusion
The sine function using Matlab can be used to establish ECG database, but the waveform are slightly different and can not be used for the waves that have elevation / depression level of ST segment. This data can be used by designers or manufactures, but for the testing laboratories are recommended using a commercial product.

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