A Novel Method for Automatic Standardization of Digital Electrocardiographs

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Abstract

It is crucial to assure the quality of ECG recordings to support correct clinical interpretation. This research aimed at developing an automated standardization method to gauge digital electrocardiography (EC) devices. The proposed microprocessed gauge equipment (MGE) is divided into digital and analogic circuits, and embedded software to control them. Conditioned reference signals (CRS) from Physionet Bank were embedded in the MGE to simulate cardiac activity. The outputs from the MGE (or EC) are then compared with the CRS. All circuits of the MGE are gauged at the self-check mode. CRS are sent to the EC when set at the EC check mode. A commercial EC equipment was used in the MGE validation (IEC60601-2-51:2005), assessed with the statistical R^2 correlation analysis and Kolmogorov-Smirnov (KS). At the MGE self-test, temperature and humidity were changed ($R^2 \geq 0.99$ as designed). The KS test ($P<0.01$) resulted in D=0.012 for amplitude accuracy, 0.0028 for timing accuracy and 0.021 for signal stability against noise influence. All KS values were lower than their respective critical values according to the default standard (5%). Finally, visual inspection between EC signals and CRS on printed graph paper at a standard scale certifies the EC reliability.

1. Introduction

The electrocardiogram (ECG) is the noninvasive clinical examination most used in the investigation of cardiovascular diseases (CVD). Researchers have used the ECG to observe degrees of the myocardium infarction by analyzing the ST segment morphology [1]. It highlights the importance of accurate ECG recordings free of interferences and distortion. Electrocardiographs (EC) must assure precision and accuracy during signal collection to guarantee quality and reliability to the clinical diagnosis. Distorted readings might decrease certainty, potentially leading to misdiagnosis and hampering CVD. Therefore, EC inspection must be assessed regularly [2]. The United States' Food and Drug Administration (FDA) requires compliance certifications of electrical equipment before making it available to the market [3]. EC devices, in special for diagnostic purposes, must be certified by the general IEC 60601-1 and its respective collateral standard IEC 60601-2-5:2005 [4] attending all requirements including the tests of performance.

Portable sealers equipment (PSE) contributes for routine EC inspection. The ECG signals simulated by these instruments are used as reference in the EC input. The measurements take place by a visual comparison of an expert between the simulated ECG signal (reference) and the signal read by the EC (EC output). The measurement is not automated and the results obtained are analyzed subjectively, which might not comply with the performance required by the refereed standards [5,6]. To improve PSE efficiency, embedded objective methods would be required to automatically evaluate the ECs. This study aimed at developing an automated method of ECs measurement by mathematical analysis of the ECG signals.

This approach is embedded at the microprocessor gauge equipment (MGE), allowing calibration of both analogic (AEC) and digital electrocardiographs (DEC) within the criteria prescribed by default standards [4]. After inspection, MGE should provide a record of the signal measured to be used at the scouting report.

2. Methods

The MGE is divided into analogic and digital circuits, and embedded software. It was designed to attend the following requirements:
1) to contain the self-check and self-calibration functions; 2) to be able to assess the parts of the EC (cables and accessories); 3) to perform a global EC check and assess the ECG registration for EC verification; 4) to attend the regulatory requirements of operation and quality of ECG signals; and 5) the ECG signals of reference (SR) would need to be embedded into the MGE.

2.1. MGE hardware

The hardware is divided in two independent circuit blocks: 1) the conditioned reference signals (CRS) that simulates the ECG signal from a database and; (2) the output analysis circuits (OAC) from EC output signals. The embedded software runs on an eight bits microcontroller (μC) (ATMEGA1284P) to controls all the MGE operations through the proposed method. Figure 1 shows the MGE block diagram illustrating both CRS and OAC block circuits. The digital block circuits (μC, memories, input and output of the components) are also displayed.

The CRS block contains a μC that reads the ECG signals stored in flash memory and sends them via serial protocol interface (SPI) to the digital-to-analog converters (DAC) (MCP4922) with two channels and 12-bit resolution. The analog signals are then attenuated by the ATTEN circuit, which in turn provides the output of the MGE. The ATEN is a set of Operational Amplifiers (op amp, TL074) mounted on a low-noise configuration, operating with gain of 1/1000 and with high output impedance (250 kΩ). During the development, the voltage errors are in range of ±0.67% and were attributed to rounding of quantization (read with Tektronix TDS1012 oscilloscope).

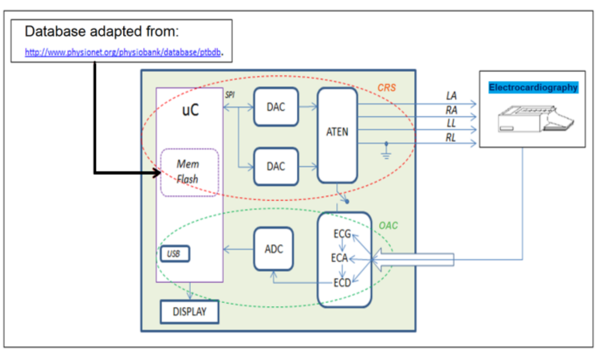

Figure 1. MGE block diagram.

The OAC circuits block operates on three input modes selected by the operator: 1. ECG mode with four channels of analogic signals (unamplified); 2. AEC mode with six channels of amplified analogic signals and; 3. DEC mode with a digital signal channel serialized by Universal Serial Bus (USB). As consequence, output ECG signals from AECs and DECs will be read and analyzed by the OAC circuits' block. In this study, the authors have concentrated the experiments on a commercial DEC model with digital output via USB interface.

The ECG mode contains 24 op amps TL 074 configured to work in a differential mode. It reflects that any signal of equal amplitude and phase presented at the component inputs will result in a null differential output value. In this circuit block, SMD resistors with tolerance of ±0,1% were utilized. The ECG mode was designed to run the MGE self-check and also to inspect the ECs accessories. Additionally, the four analogic signal channels are conditioned and amplified differentially in the Einthoven triangle configuration [7]. So, as result, the circuit has six outputs connected to the inputs of the AEC mode. It is followed by the digitalization of the amplified signals. These signals may be originated from the MGE in ECG mode or from an external source (e.g., the output of the AEC). The circuit contains an analog-to-digital (AD) converter AD7324 with 12-bit resolution and four input channels.

In the DEC mode, the USB port serializes the digital signals and the samples are obtained from an AEC or an external source (e.g. USB output from ECD). These signals are separated so that each channel is a vector of voltage values at a given sampling frequency. These vectors are mathematically compared with the vectors recorded in memory.

2.2. Embedded software

The embedded software controls all functions of the MGE to execute the proposed method. It was divided in two functions: Self-Check and EC Check. In the Self-Check function, the software executes the self-gauging routines of all circuits of the MGE. The EC check function is the MGE work mode that carries out the measurements of the ECs and their accessories.

For self-checking, the MGE device set the hardware in the ECG mode and the CRS block outputs are connected manually to the OAC inputs through micro switches. In this configuration, all MGE circuits are in operation. Thus, the SR recorded in the flash memory is sent to the MGE circuitry and returns to the μC. Identifying a critical value for R^2 correlation Self-Check allows for an automatic quantitative analysis that might help to identify MGE validation or rejection. The sequence described above is shown in the right hand-side of Figure 2.

Gauging the EC function is performed by upstream control routines from the CRS block to MGE outputs. Moreover, it controls the USB port of reading, formatting and stores the data output from the DEC mode. Thus, the EC measurement process, illustrated in Figure 2, comprises the following tasks: a) simulates the SR from the database; b) EC's connection to the MGE; c) EC test with acquisition of the data generated; d) comparative analysis of the EC's data and SR; and e) measurement record task. This sequence is detailed in the left hand-side of diagram presented at Figure 2.

2.3. Signals reference (SR)

The database used in this study contains the digitized signals of ECG tests, collected from healthy subjects and patients with cardiac diseases from Physionet [7]. These signals were compiled and integrated at the CRS.

The electrical potentials of the members [left arm (LA), right arm (RA) and left leg (LL), the right leg (RL) reference] were calculated inside the µC from the bipolar leads I, II and III using the geometry of Einthoven vectors [8]. The signals were then formatted into hexadecimal file (12-bit) and recorded as SR in the MGE. When the MGE is running, these values are converted into analogic signals by the DACs corresponding to the electrical hear activity measured noninvasively. The EC receives the SR from the MGE (LA, RA and LL). The EC internally performs the calculation of leads (I, II, III, aVR, aVL and aVF) providing the final printed-paper record or in digital form.

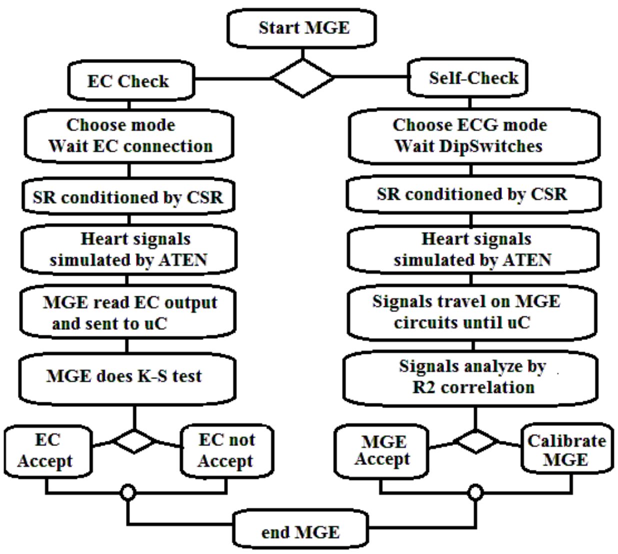

Figure 2. Operational diagram of MGE.

2.4. Gauging

The EC output signals were read and stored in the µC memory of MGE. The gauging is carried out on the EC, using a mathematical analysis of correlation between the SR and the output EC signals. The correlation between the signals was calculated by statistical tests of Kolmogorov-Smirnov (KS) [9] and. acceptable levels of agreement between the both SR and EC signals is issued in a compliance measurement record for the standard levels of amplitude, time and frequency. On the other hand, if divergences are seen at the expected results, the EC is rejected.

The s KS test identifies the point of greatest difference between two distributions, pointed by the D value (Eq. 1). The smaller the D value, the lower will be the difference between the two signals distribution. The KS test recommends that if the quantity of each data sample is greater than 50, the equation is multiplied by 1.63 to give a significance level of $P<0.01$. The gauge validation alters one of the data distributions (for example: voltage or frequency) and executes a new reading to establish the critical value of D. The percent of the signals characteristics such as amplitude is within the allowed variations permitted by the standard [4].

$$D = 1.63\sqrt{\frac{n_1 + n_2}{n_1 n_2}} \quad (1)$$

The EC gauge process was determined by the tolerances defined for D, which evaluates the EC in accordance with the regulatory criteria of operation. To validate the MGE operation, a commercial EC for veterinary applications were used (Contec, model ECG80A). The gauge was based on IEC 60601-2-51: 2005 subsections 50.101.1.1, 50.101.1.2 and 50.101.1.4. The following tolerances for the technical requirements were adopted: accuracy of amplitude measurements (<5%); accuracy of range measurements (<5 ms) and against noise measurement stability (<5%) [4].

2.5. Statistics

When operating in Self-check, the device performs the R^2 correlation between the SR and the signals that travel through the MGE circuits to evaluate MGE characteristics globally (Figure 2). In EC check, the K-S test was applied (significance level of $P<0.01$) to assess the discrepancies between signals having different sampling frequencies. The amplitude accuracy, time interval accuracy and correctness of stability against noise were evaluated. The critical D values were obtained from the KS test for the originals RS and RS with variation of ±5%.

3. Results

To perform the EC gauging, SR from two patients obtained from Physionet database was used: a patient diagnosed with myocardial infarction ventricular (MIV), and healthy patient (HP) [7]. The MGE Self-check was tested regularly over two months at different temperature conditions (17 to 35 ° C) and relative humidity (from 30 to 85%). Throughout the self-check test period, the worst R^2 value was 0.997. The MGE is approved in self-check if the R^2 value obtained was greater than the critical value of 0.99. So the ECs who are on the border of the maximum permitted by the standard are recommended for laboratory evaluation or calibration.

To ensure that there were no errors by self-compensating, a Tektronix TDS1012 oscilloscope evaluated the connections within the MGE circuits. No differences were observed between the expected and the measured values.

The gauging of the commercial EC ECG80A was conducted for amplitude accuracy, range accuracy and stability accuracy against noise, with shown in Table 1. The tests with the commercial EC were performed with a SR from a HP and MIV patients. Each RS has been attributed to a vector of 390 samples (variable n1). The EC output signals were assigned to the variable n2 vector with 3400 samples, which was limited by memory available in the MGE.

The Ds obtained are shown in Table 1. These Ds are smaller than the critical Ds, which indicates that the EC is in accordance with standard [4] in the method proposed in this work.

Table 1. KS test results to the commercial EC evaluated compared to critical Ds

Parameter evaluated	D (read)	*D (critical)
Amplitude accuracy	0.0125	< 0.073
Range accuracy	0.0028	< 0.097
Stability accuracy against noise	0.0205	< 0.072

* Critical value of D at the level of significance P<0.01.

A comparison between the RS and the signal produced by ECG80A was also performed by measurements on graph paper, as shown in Figure 3. The readings made by one skilled in ECs gauging indicate that ECG80A is in compliance with the standard by generating waveforms without evident disparities.

Figure 3. Graphic record of the DI derivation for ECG80A compared with the record of the database.

The signals read on the MGE circuits' connections (output signals or the signals amplified) were absent of distortion or significant noise levels. This was attributed to the low tolerance of the resistors (<0.1%) and adjustments made in earnings during the assembly of MGE.

4. Discussion

The proposed method has advantages over the traditional way of measurement of ECs, which uses waveform simulators [5,6]. The measurement with simulation requires that the EC's output signals were read and the waveforms are compared visually with the standard, in oscilloscopes. These simulators do not ensure the reproducibility of the output signals over time. On the other hand, the MGE performs self-gauging to ensure quality of the SR by comparing it with the output EC signals by mathematical analysis method. It contributes in reducing the measurement subjectivity by presenting a quantitative method, with error less than 1%, which is less than 1/5 of the regulatory tolerances.

5. Conclusions

The proposed method ensures the reliability of the MGE. It features excellent noise immunity. The mathematical comparison of the signals reduces the subjectivity of the ECs measurement. The MGE improves the efficiency of the measurements in the field and can be used in high sensitivity, with errors lower 1%. For being an adjustable microprocessor sealer, its use can be expanded to other types of measurements that are based on small value SR by simply changing the embedded programming.

Acknowledgements

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