HIGH RESOLUTION WAVE GENERATOR PERMITS TEST AND CALIBRATION OF MEDICAL INSTRUMENTATION DEVICES

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Abstract: A high dynamic, low noise, wave generator permits test and calibration of medical instrumentation devices. It can provide both bioelectric signal and usual electrode offset levels, can generate hours of arbitrary waveforms and can be controlled by a laptop or a PDA for user convenience. It can be used for the measurement of basics properties of the medical device and to objectively test the acquisition hardware quality in relation to a data processing software. The tester has been designed for EEG applications but can be used for all kinds of biosignals generation. A study of EEG acquisition hardware quality in relation to a spike and wave detection software is presented as an illustration of its utility.

Introduction

Accuracy of medical instrumentation devices (e.g. EEG, ECG, EMG) suffers from drift with time. To keep the high quality required, the frequent use of a calibration tool is helpful.

To be able to best simulate the body and associated electrodes, and hence to calibrate the medical device in the most accurate way, the calibrator must be able to generate the human bioelectric signal with low noise and high resolution as well as the relatively large offset of the electrodes (up to +/- 300mV). Furthermore, whereas generating a sine or square wave only permits to calibrate the medical device, generating realistic patterns permits to objectively test the acquisition hardware quality in relation to a software (activity classification, automatic pattern detection, etc.).

While some previous medical devices calibrators have already been proposed [1]-[4], they seem to lack the ability to generate the offset, and are limited to a few minutes of arbitrary signal (if any) or have a low resolution.

We present here a high dynamic, low noise, wave generator that can provide both bioelectric signal and usual electrode offset levels. It can generate hours of arbitrary waveforms and can be controlled by a laptop or a PDA for user convenience. The tester has been designed for EEG applications but can be used for all kinds of biosignals generation.

In this paper, a study of the quality of an EEG acquisition hardware in relation to a spike and wave detection software is presented as an example of its utility.

Materials and Methods

Since the electrode offset and the signal are not in the same frequency band, it is possible to use two different DACs, with two different filters, to be able to obtain both high dynamic (because we actually sum the dynamic range of the two DACs) and low noise (only the required bandpass is used).

Figure 1 shows the block diagram of the wave generator.

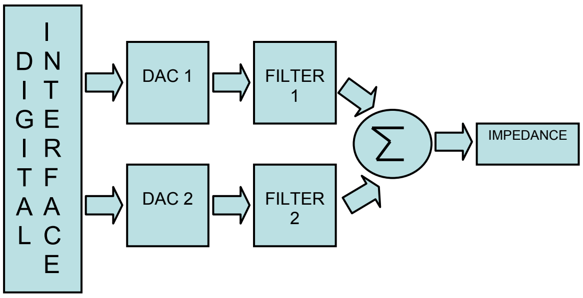

Figure 1: Block diagram of the wave generator

The wave generator is divided into three parts:

- a laptop or a PDA that handles the user interface and stores the data;
- a digital interface that bufferises the data and provides the proper timing operation;
- an analog part that produces and filters the signal and offset, sum them and adjust (according to the user choice) the output impedance.

The bandpass is 0.16~100Hz for the signal and DC~0.16Hz for the offset. Both signal and offset are coded with 16bits, the maximum signal value being 1mVpeak-to-peak and the maximum offset value being 300mVpeak-to-peak. The sampling frequency is 1 kHz. The measured noise (BP = 0.16~100Hz) is 0.2µVrms.

In this prototype, the same signal appears on all 32 channels, but since the architecture has a high modularity, it can be extended easily to many signals

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(the only restriction being the data transfer bandwidth between the laptop or PDA and the digital interface).

The kind of calibration and test that the generator can achieve is divided in two parts. The first is the measurement of basics properties of the medical device, including:

- channels calibration measurement and correction,
- bandpass measurement,
- noise measurement (as a function of electrode impedance),
- offset rejection measurement,
- time to recover from saturation (artifact).

This kind of test is suitable for rapid calibration and evaluation of the device, simply by connecting the generator to its input and play a pre-selected sequence of waves and output impedances.

The second kind of test is more focused on research and development of medical devices or on the comparison between different medical devices. It consists in objectively testing the acquisition hardware quality in relation to a software (activity classification, automatic pattern detection, etc.). Therefore, a test bench (see Figure 2.) is used. It is made of:

- the PC transmitting the initial data to the wave generator;
- the wave generator permitting to generate realistic and at the same time reproducible human bioelectric signals;
- the cables connecting the wave generator to the medical device;
- the medical device amplifying and digitalizing the signal;
- the software to process the data;
- the interference or artifact generator.

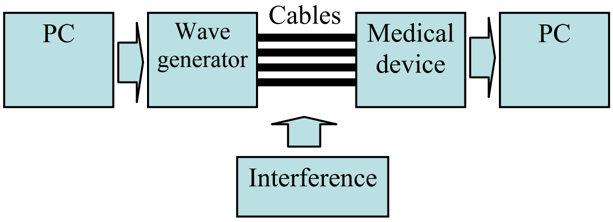

Figure 2: Test bench of the medical device

It is now possible to correlate the data before and after the whole process or the data after the process for different tests cases (artifact, interference, surrounding, etc.) or medical devices. This is only possible with the test bench because in real life it is not possible to have access to the signal anywhere up to the original human bioelectric signal, or to have reproducible signals, or to have a totally immobile configuration of patient, cables and medical device.

This is also closely related to the utility of having a global test bench for better understanding of the signal and interference propagation. It is useful to understand and quantify the interferences [5-6].

To choose a good reference signal, it is important to realize that even without artifacts or interference, the signal is already distorted due to the frequency response of the medical device. So, to compare the ability of a medical device to reject artifact and interference, the reference signal should be the signal at the output of the device in a interference-free and artifact-free surrounding and not the signal at the input of the device.

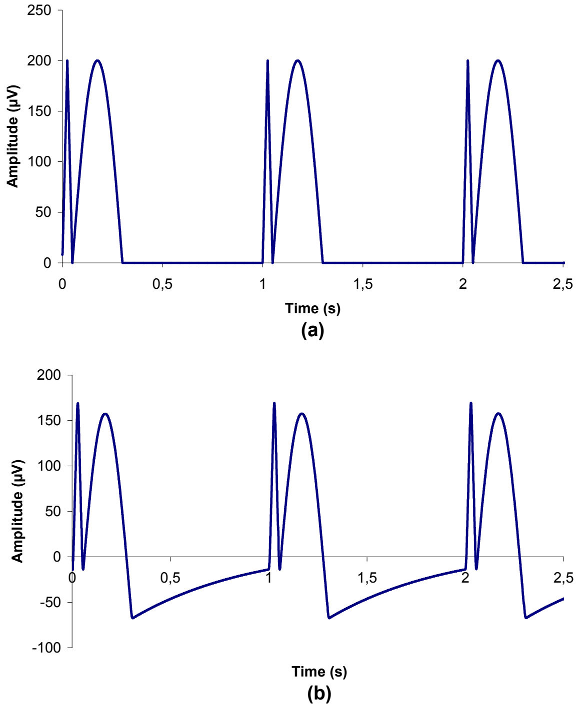

Figure 3: spike and wave (a) before and (b) after the electroencephalograph

To illustrate this, a spike and wave (typical electroencephalograph pattern) is shown in Figure 3 before (Figure 3a) and after (Figure 3b) being recorded by a electroencephalograph (EEG) in a a interference-free and artifact-free surrounding.

This way, in this article, the reference signal will not be the signal at the output of the wave generator (the signal in the brain, never reached) but the signal at the output of the EEG in 'perfect conditions' (when there is no interference and no artifact). This situation being never perfectly reached in practice, the reference signal has been taken from simulation.

Results

The example chosen to illustrate the utility of the wave generator is a study of the quality of an EEG acquisition hardware in relation to a spike and wave detection software.

The medical device is a typical commercial EEG recording at 200Hz. No signal processing is used other that the ones mentioned in the software detection. Ten measurement electrodes (including the mastoid) and a reference electrode have been used resulting in nine derivations. A 5kΩ electrode impedance is used.

First, the EEG has been calibrated and its basic properties have been measured tanks to the wave generator:

- the channels are calibrated to match within 1%,

- the bandpass is 0.16Hz~70Hz,
- the noise is lower than 5.5µVpeak-to-peak in the bandpass if the electrode impedance is zero and 6µVpeak-to-peak if the electrode impedance is 50kΩ,
- no change due to electrode offset has been measured.

As an illustration of an offset voltage change, Figure 4 shows the EEG response to a 200µV offset change added to a 60µV peak-to-peak 2Hz sine.

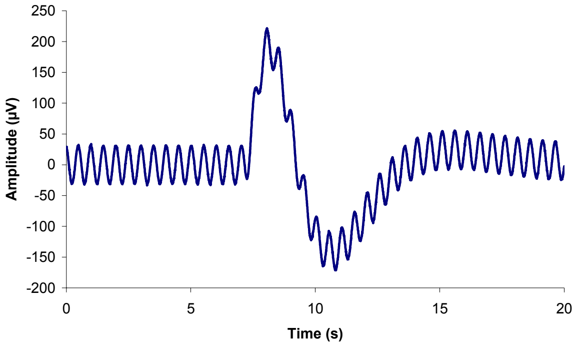

Figure 4: EEG response to a 200µV offset change added to a 60µV peak-to-peak 2Hz sine

Then, the test bench shown in Figure 2 has been used to test the device.

The wave generator produces spikes and waves at 1Hz. Each recording has a two minutes duration and so the total number of spikes and waves is 9 derivations * 120 seconds = 1080 spikes and waves per sample. The spike and slow wave (SSW) complex is formed by a spike (which is different from the background activity, has a pointed peak and a duration of 20ms to 70ms [7]) followed by a slow wave, which last 150ms to 350ms. The 'typical' SSW that is used for the experiment has a 50ms spike and a 250ms wave. A typical amplitude of scalp EEG recording of SSW is 200µVpeak-to-peak.

The signal is transmitted by one meter cables to the EEG. It is then digitalized and processed by an automatic spike and wave detection software.

The detection algorithm is divided into two part:

- a pre-processing, that points out the principal characteristics of the spike and wave;
- a template matching with a reference spike and wave.

In this case, the reference spike and wave is obtained by simulation for a totally interference-free surrounding.

The pre-processing algorithm used has been inspired by the Pan and Thomkins algorithm [8] used for QRS detection in the electrocardiogram (ECG).

It is divided into different steps (see also Figure 5.):

- high pass filtering (0.16Hz) to get a stable baseline (Figure 5a);
- derivation to stress the spike representation of the pattern (Figure 5b) ;
- squaring (keeping the sign) to minimize small fluctuations on the signal (Figure 5c)
- 50 ms averaging to smooth the curve (Figure 5d).

The algorithm has been tested on three patients scored by tree specialists and has shown results (sensitivity and specificity) close to what the specialists could do [9].

Since the generated spike and wave periods are known, it is possible to calculate how many spikes and waves are missed by the software and how may of them are falsely detected (false alarm). It is also possible to correlate the output and the reference signals to estimate the distortion during the transmission.

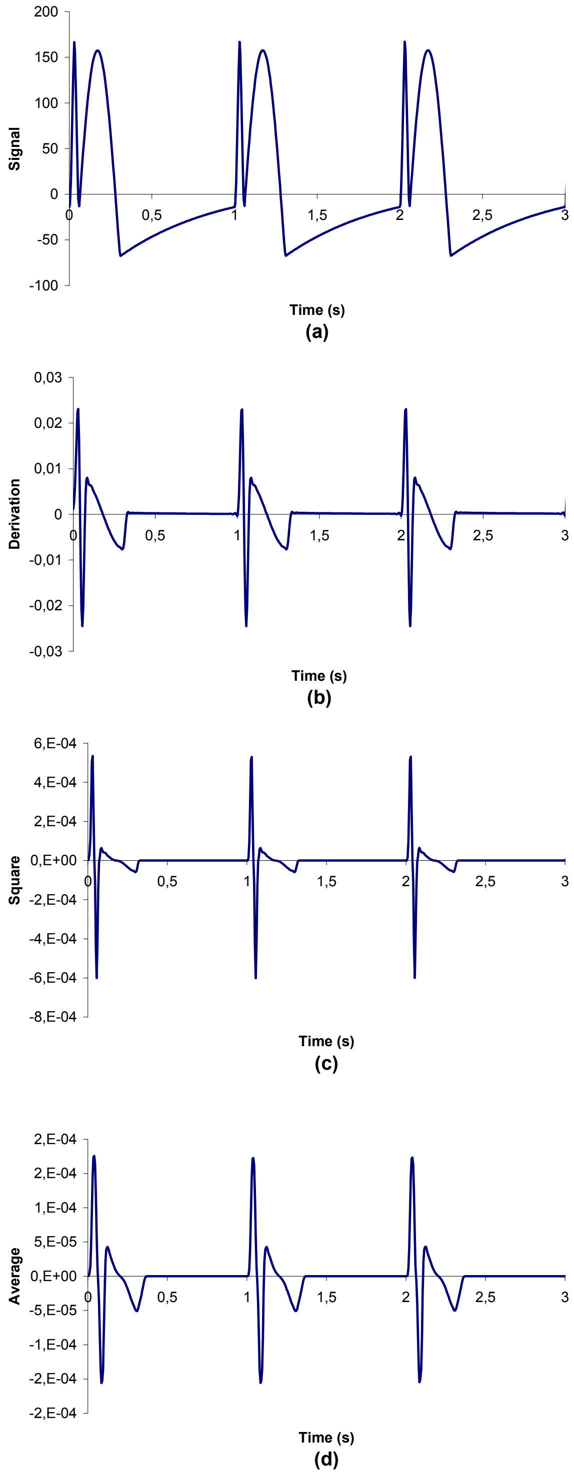

Figure 5: Pre-processing of the spike and wave

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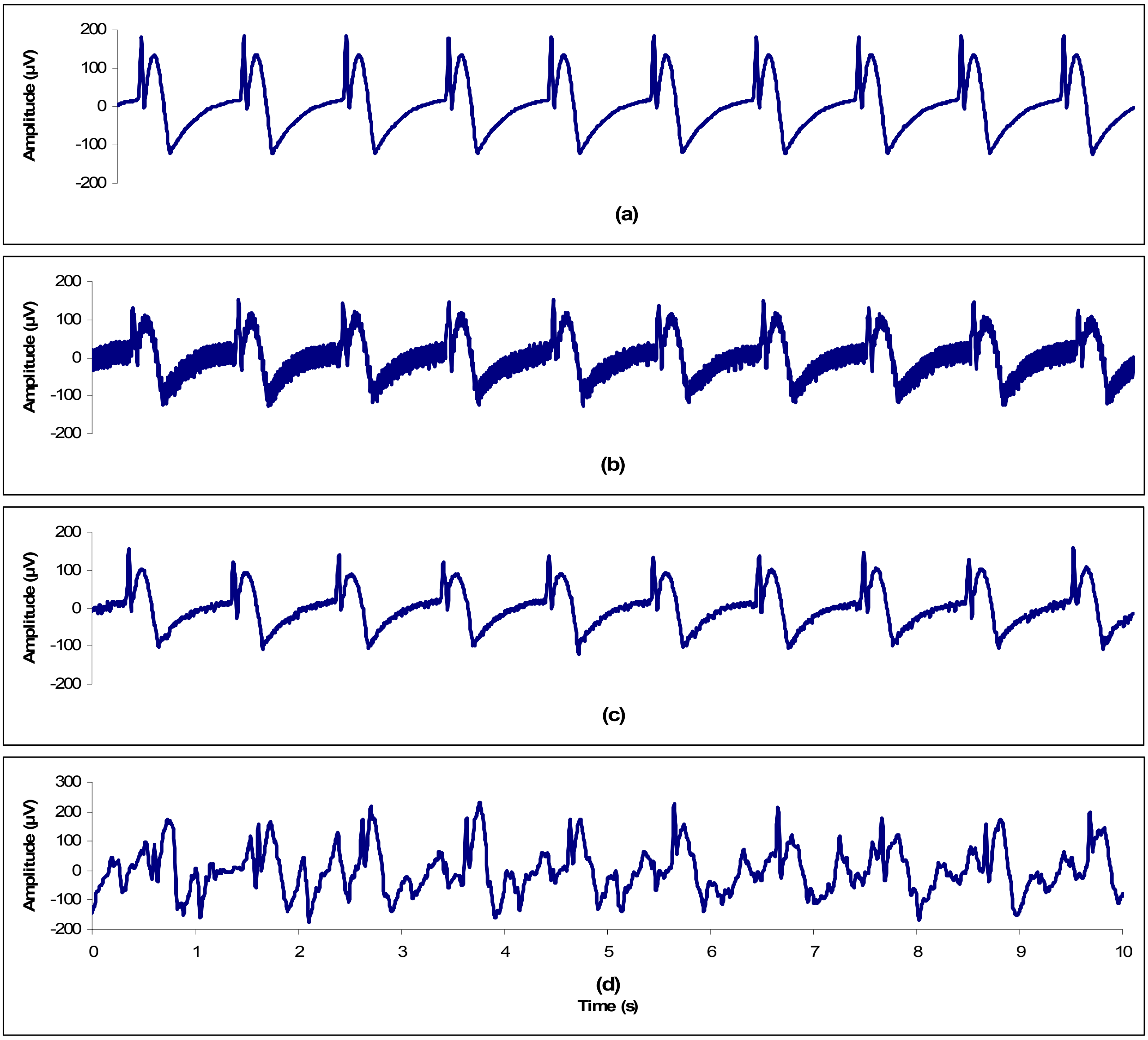

Figure 6: Ten seconds recording of spike and wave with (a) no interference or artifact (b) 50Hz power cable at 10cm form the EEG recording cables (c) the same as b with a 4th order Notch filter (d) movement artifact on the cables

This has been done for four recording situations:

- no interference or artifact (quiet surrounding);
- 50Hz power cable at 10cm form the EEG recording cables;
- the same as before but the data is filtered with a 4th order Notch filter;
- movement artifact on the cables made by the experimenter.

A ten second sample of each recoding is shown on Figure 6.

Table 1 shows the correlation of the raw and pre-processed data with the reference spike and wave and the results of the detection algorithm.

Table 1: Analyze of the recording

	Raw data correlation	Processed data correlation	Missed spikes and waves	False alarms
no interference or artifact	97.64%	98.5%	0	0
50Hz hum	96.09%	97.54%	0	0
50Hz hum and Notch filter	97.21%	97.54%	0	0
movement artifact	94.51%	91.91%	17.22% (186)	0.19% (2)

It can be seen in Table 1 that the software makes good detection in a quiet surrounding or in a surrounding with ambient 50Hz interference. Even if the detection algorithm would not be resistant to 50Hz interference, it is still possible to obtain a clear signal with a Notch filter, as it can be seen in the first column of Table 1.

Movement artifacts however produce missed spikes and waves and false alarms. It is difficult to imagine that this could be corrected by software because of the random shape it ads on the signal.

Discussion

So, for this configuration of EEG and spike detection algorithm, no special care must be taken for 50Hz interference as it can be removed by software without causing any loss of sensitivity or specificity. However, if movement artifacts are present, a hardware improvement is mandatory to get good detection results.

Conclusions

The wave generator presented is suitable for testing medical devices. It can generate hours of signal with high resolution and low noise, as well as electrode offset.

It can be used for the measurement of basics properties of the medical device (including: channels calibration measurement and correction, bandpass measurement, noise measurement as a function of electrode impedance, offset rejection measurement and time to recover from step) and to objectively test the acquisition hardware quality in relation to a software.

An example to illustrate the utility of the wave generator (a study of EEG acquisition hardware quality in relation to a spike and wave detection software) has lead to quantification of the sensitivity and false alarms as a function of the interference of artifact present and helps directly for practical decision for quality enhancement.

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