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A Methodology to Assess Immunity to Radiated Disturbances of Fpaa-Based Front-End Devices for Electrocardiograph Signal Monitoring

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Abstract-The paper is focused on the assessment of the functional immunity of field programmable analog arrays (FPAA) circuit configured to operate as front-end elements to be used in electrocardiography (ECG) signal conditioning, and on the investigation of the possible effects of radiated electromagnetic disturbance in the range from 250 MHz to 3 GHz, on the parameters of the ECG signal. The research is carried out with a methodology which relies on typical ECG signal and both time and frequency domain analysis. Results show that under specific amplitude and frequency conditions, the disturbance can indeed interfere with the normal operation, leading to erroneous diagnosis.

Keywords: electromagnetic compatibility; electromagnetic interference; FPAA; immunity measurements; ECG; biomedical application.

I. Introduction

Testing for electromagnetic compatibility (EMC) compliance is today crucial more than ever in time, and it will be even more relevant in the future due to the use of a large number of sophisticated electronic devices with large scale integrated circuits like ASICs, FPGAs and FPAAs to reduce size and increase clock frequencies, and to the proliferation of wireless circuits used within. Actually, the pervasive use of these devices, most often in close proximity to each others, increases the electromagnetic interference (EMI) problems significantly, which can cause serious damage to the electronic devices' functional features with fatal consequences, some times on human being's safety [1]. In health care, where the use of electronic portable devices for diagnosis and assistance has become common, especially with the new emerging healthcare approaches (e.h., home healthcare and telemedicine) in order to reduce the health care cost and offer more comfort to patients, the risk of EMI becomes higher with heavy consequences particularly on life-supporting devices. In this context, cardiovascular diseases diagnosis is one of the most concerned areas, where the employed electronic devices use the ECG record as the most reliable information source about the state of the heart in diagnosis operation.
The heart function is represented by the ECG signal, which is a complex waveform composed mainly of (P, T) waves and QRS complex. It is actually a measurement taken at the surface of the skin which reflects the electrical phenomena in the heart when the electrical sequence that controls heart function is triggered by the SA (sinoatrial node) node, where the P wave represents atrial depolarization, the QRS represents ventricular depolarization and the T wave reflects the rapid repolarization of the ventricles [2] (Fig.1). A normal ECG record presents regular characteristics limited by normalized values for each part of it (ex: QRS complex's amplitude should not exceed 20 mV while 0.11 s is the limit for the time duration) [3]. Heart anomalies diagnosis is based on the interpretation of the ECG records: actually any kind of heart anomaly can be detected on the ECG signal by examining the morphology (shape) and time duration changes on the different parts of the record.

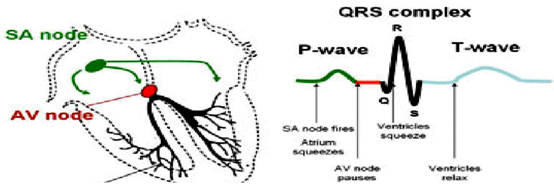

Fig 1. The electrical conduction system of the heart on the ECG record tracing.

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In this study our aim is to evaluate the immunity of an FPAA circuit configured as a biomedical front-end element for ECG signal monitoring. Such evaluation consists in two aspects: the first one is about the assessment of the FPAA circuit functionality under the effect of EM disturbance [4, 5, 6] based on EN 61000-4-3 [7] and EN 60601-1-2 [8] standards, and the second one is to study the possible effect of this disturbance on the morphologic and temporal parameters of different elements on the ECG record.

II. FPAA Configuration

The FPAA configuration is actually a composed operation, usually achieved by mean of AnadigmDesigner®2 software in two steps: in the first step the desired architecture should be defined using the configuration of the different available predefined elements in the Anadigm provided library called Configurable Analog Modules (CAMs), then a virtual simulation for the well function of the designed architecture should be done. However, the second step consists of the implementation of the architecture into the FPAA circuit, by simply transferring the associated configuration data file, via serial cable, and program a serial EPROM on the starter kit with that data file, then the FPAA can configure itself on power-up from that EPROM [9].
In the case of the present application, the FPAA-based front-end conditioning ECG signal configuration was inspired by [10], it consists of an amplification stage characterized by a high voltage gain, a common mode rejection ratio (CMRR = 102) to guarantee the attenuation of the common mode noise, a high input impedance (10 MΩ) to avoid the attenuation of the ECG signal at the input and to provide a good isolation of the patient. A filtering stage is also present to select the signal band of interest that is the frequency range from 0.05 Hz to 150 Hz used for diagnostic purposes or the frequency range from 0.67 Hz to 40 Hz used for monitoring. It is composed of a high pass filter with cut-off frequency of 0.05 Hz to attenuate the DC component and the baseline wandering, a notch filter with a high quality factor (Q = 30) to suppress power line noise, and a low pass filter with cut-off frequency of 150 Hz to eliminate the high frequency noise component, as shown in Fig. 2. This configuration allows to obtain an overall gain G = 1027 (60.23 dB) according to the characteristics of the different used CAMs. This configuration has been implemented into an AN221E04 FPAA circuit mounted on a starter kit board, using Anadigm tool [9], and has consumed 50 % of the FPAA circuit's available resources.

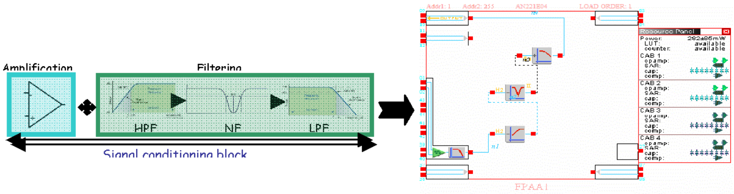

Fig 2. FPAA Configuration as a biomedical signal conditioning block for the ECG signal.

III. Measurement methodology

As shown in Fig.3, unlike the requirements of the methodology described in the EN 61000-4-3, the immunity test we performed was based on a new approach in which we used a generic ECG waveform of 1 Hz frequency and 0 V offset generated by an Agilent 33220A arbitrary waveform generator to feed the device under test (DUT), and we employed the FFT transform as a reliable means to process the signal in the frequency domain to measure the maximum amplitude, the phase and the offset of the ECG signal on the FPAA input/output channels. Actually, the use of the generic ECG waveform and the employment of the FFT transform are justified by the fact that measurements of the different aspect of the EM disturbance effect onto continuous sine wave were really difficult and some times impossible because of the weak nature of the input signal and the huge noise caused by the radiated EM disturbance as reported in [11]. Besides, this measurement methodology didn't give the possibility to quantify any possible effect or damage that EM radiated energy can cause to the time parameters on the ECG signal.
In the actual test, the FPAA was configured as a front-end element to condition the ECG signal, as described in [10]. Measurements were performed under electromagnetic (EM) radiation (3, 10, 20 and 30 V/m) inside a GTEM cell within a frequency interval from 250 MHz up to 3 GHz according to [12], and using two different amplitude modulation: 1 kHz (according to the EN 61000-4-3 standard, for the functional test) and 2 Hz (according the EN 60601-1-2, for biomedical instrument test). Also, we measured for each EM frequency the time durations of the different parts of the ECG signal, namely: the P and T waves, the QRS complex, the PR and QT intervals, the ST segment and the heart rhythm. The evaluation of the change on these parameters is based on comparing the obtained measurements for each one of them to the nominal values cited in medical bibliography [3].

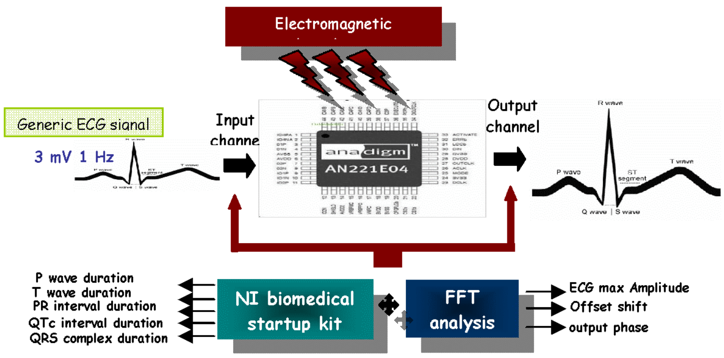

Fig 3. The representation of the immunity test methodology.

However, the difference between the maximum amplitude detected of the ECG signal and the mean value of its amplitude measured using the NI biomedical start-up kit [13] quantify the amount of disturbance detected on the FPAA in/out channels and which is referred to us as the measurement of the additive noise. On the other hand, the offset value and the phase shift between the output and the input signals were measured by employing the FFT transform, where the offset value corresponds to the DC component that FFT analysis calculates as the amplitude of the f_0 component on the ECG spectrum, and the phase shift was calculated as the difference between the input/output signal's phases calculated by the FFT transform. As shown in Fig. 4, the phase shift was pretty stable around zero degrees (0°) for both 2 Hz and 1 kHz modulation over the whole interference frequency range.

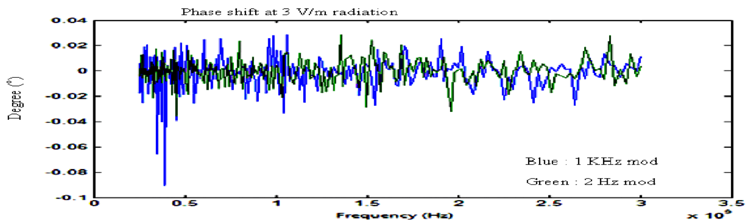

Fig 4. Phase shift between the input and the output at 3 V/m EM radiation using 2 Hz and 1 kHz modulation.

IV. Results

Measurements results shows that the effect on the FPAA due to EM disturbance consists of the of additive noise, a high offset on the FPAA In/Out channels, and alarming modifications of the ECG signal's time parameters which are important in diagnosis and monitoring operations. They are detailed in the following sections:

A. Offset shift

Fig. 5 shows that a high offset affects both the input (left plot) and output channel (right plot), in which latter case it can reach five times the input amplitude. This offset increases as much as we increase the EM radiation amplitude, particularly for low disturbance frequencies from 250 MHz to 1 GHz. The highest offset values (14 mV and 12 mV) are detected for 30 V/m EM radiation at the frequency interval from 562 MHz to 604 MHz using the 2 Hz amplitude modulation, and the frequency interval from 582 MHz to 604 MHz using the 1 kHz amplitude modulation. These frequency intervals correspond actually to the highest EM radiation effect which caused a reset to the FPAA: the FPAA was written off and the output signal was at 0 V. This event has been also observed on the different representations of the additive noise and the other parameters on the FPAA output channel.

B. The Additive noise

As shown in Fig. 6, the additive noise detected on the FPAA in/out channels remains high compared to the amplitude of the useful signal respectively on the input and the output, for all the EM radiated energies used in this test. This additive noise presents a random and unpredictable behavior regarding the different used EM radiated energies and regarding the different used modulation carried on the EM signal and some pick values, of about 14 mV to 15 mV detectable on the input channel, within the frequency region from 250 MHz to 1 GHz for all the used EM radiated energies. However, on the output channel the detected additive noise seems to be stable at the same level of around 400 mV all over the test frequency range, with some picks around 600 mV detected at 3 V/m and 10 V/m EM radiation and some picks around 1.2 V at 20 V/m radiation for the lower test frequency range (up to 1GHz). At 30 V/m EM radiation the additive noise on the output channel have a different behavior where the most significant effect was observed using the 2 Hz modulation with pick value around 2.5 V, which is very huge amount of noise if we compare it with the 3.3 V output signal amplitude.

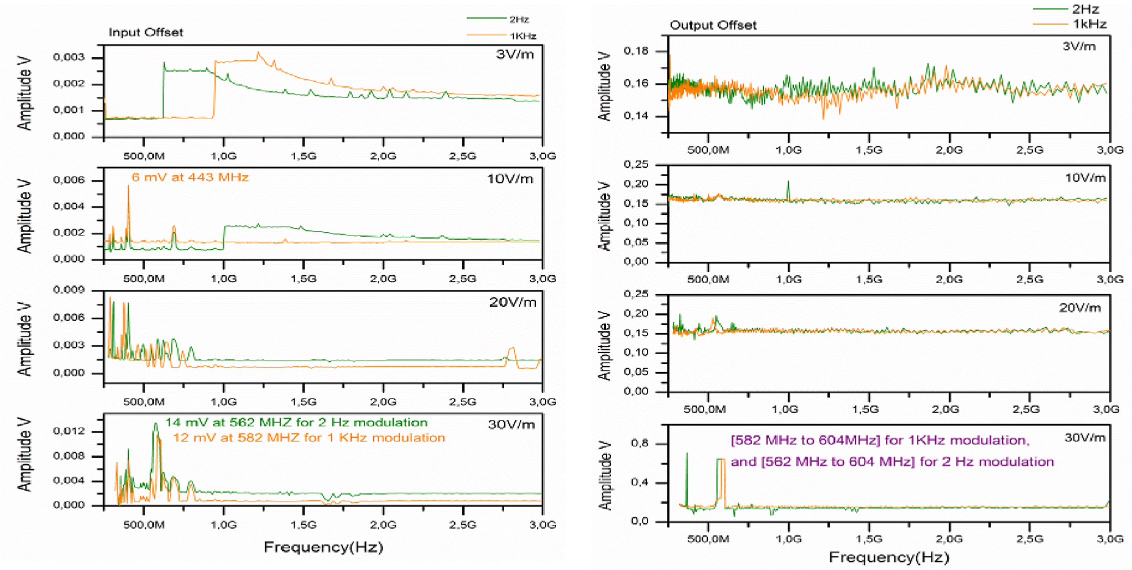

Fig. 5. The evaluation of the Offset shift caused by the different EM radiated energies on the FPAA input/output channels.

C. ECG signal time parameters

Serious modifications were detected on the ECG temporal parameters cited previously, sometimes even for 3 V/m EM disturbance. These modifications concern in particular the P wave duration (Fig. 7, left plot), PR (Fig. 7, right plot), QTc intervals (which reflect the propagation of the stimulus in the conduction system of the heart), and the QRS complex time duration on the FPAA output channel. Such modifications can be either a prolongation of the time duration (in most of the observations) or shorter time duration of the concerned parameter (not in the same manner and not at the same frequencies), and this can lead to wrong diagnosis particularly concerning the efficiency of the conduction system on the heart. It is important to recall that the ECG signal we used to perform this experiment was a generic ECG signal which doesn't present any type of anomaly. Actually, the changes detected on the different cited parameters reflect a variety of serious diseases depending on the affected part.

For instance, the prolongation of the P wave time duration (Fig. 7) can indicate a fail in the atrium conduction, which consist mainly of a variety of diseases like the left atrial enlargement disease and the diseased atrium muscles, while short time duration of the P wave can indicate a hyperkalemia. Furthemore, the modifications on the PR interval time duration are generally interpreted by a variety of first-degree atrioventricular (AV) block disease, which represents in general a fail in the conduction between the atrium and the ventricles specifically at the atrioventricular node.

However, a prolongation of the QTc interval (Fig. 8, left plot) may indicate: heart failure, ischemic diseases, and myocardial infarction, while a short QTc time duration may indicate: early repolarisation, genetic disorder associated with sudden death, hypercalcemia and hyperkalemia. Also, some sever arrhythmia disorder like tachycardia or bradycardia can be interpreted according to the different modification detected on the QRS complex time duration (Fig. 8, right plot).

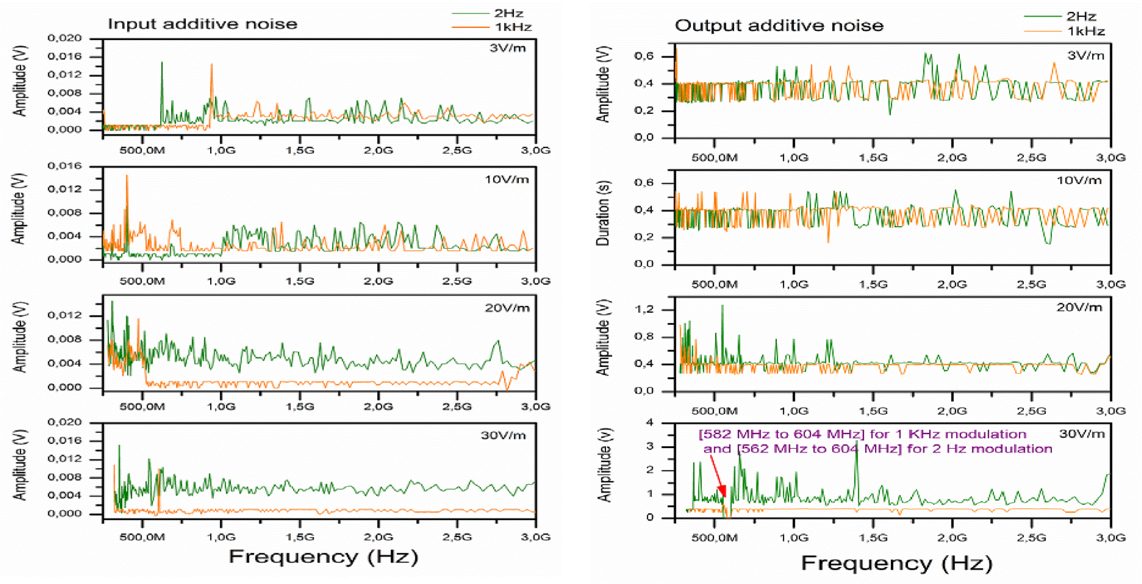

Fig 6. The evaluation of the additive noise on the FPAA input/output channels for the different used EM radiated energies.

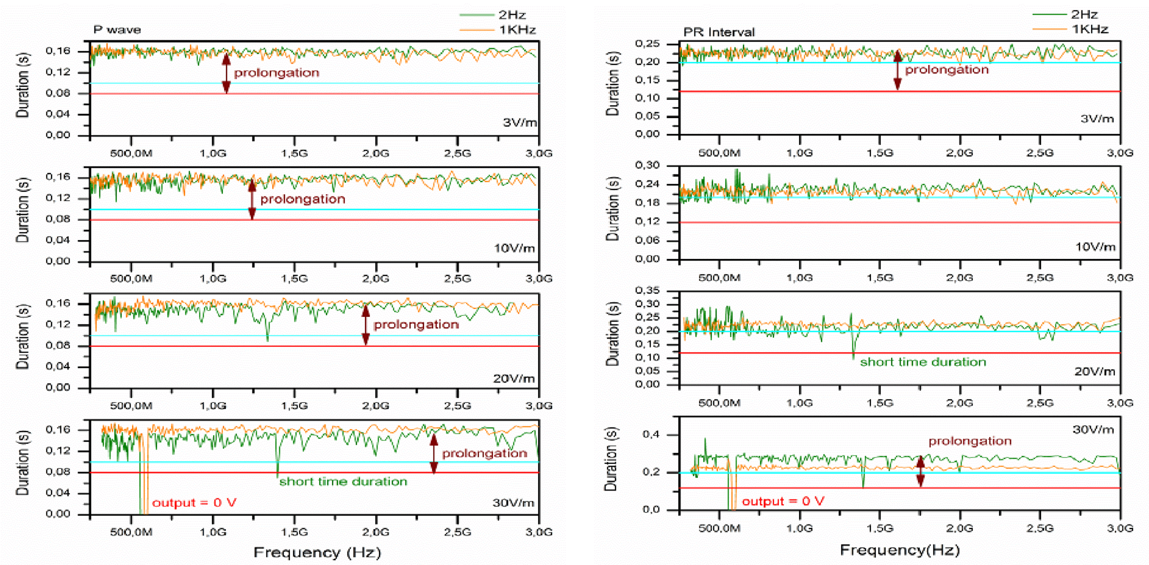

Fig 7. The modifications on the P wave and the PR interval time duration caused by the different levels of EM radiation on the FPAA output channel.

V. Conclusions

The measurements in this study showed that the effect of electromagnetic disturbance of the FPAA input/output channels is not limited to the additive noise and the high offset shift, but is also manifesting as serious modifications on the ECG temporal parameters (P, T waves, PR, QTc intervals and QRS complex) which can lead to incorrect diagnosis and cause dangerous consequences. According to the illustrated results, we can draw a few recommendations that can improve the quality of the immunity test of electronic devices dedicated to biomedical application use such as:

- ✓ The use of the biologic signal specific to the application in question instead of using a sine-wave signal (according to the EN 60601-1-2 [7] standard), gives more realistic aspect to the measurements and the obtained results. This is also supported by the large availability of a lot of specific biomedical databases;

- ✓ Taking measurements of the disturbance effect onto continuous sine wave in such test is not all the time possible and reliable as reported in [11], because of the important coupling effect on the FPAA in/out channels, and also because of the impossibility of measuring the influence of such disturbance on the time parameters of the biologic signal concerned by the application; thus, it is preferable to employ processing means such as FFT transform to get more accurate measurements;

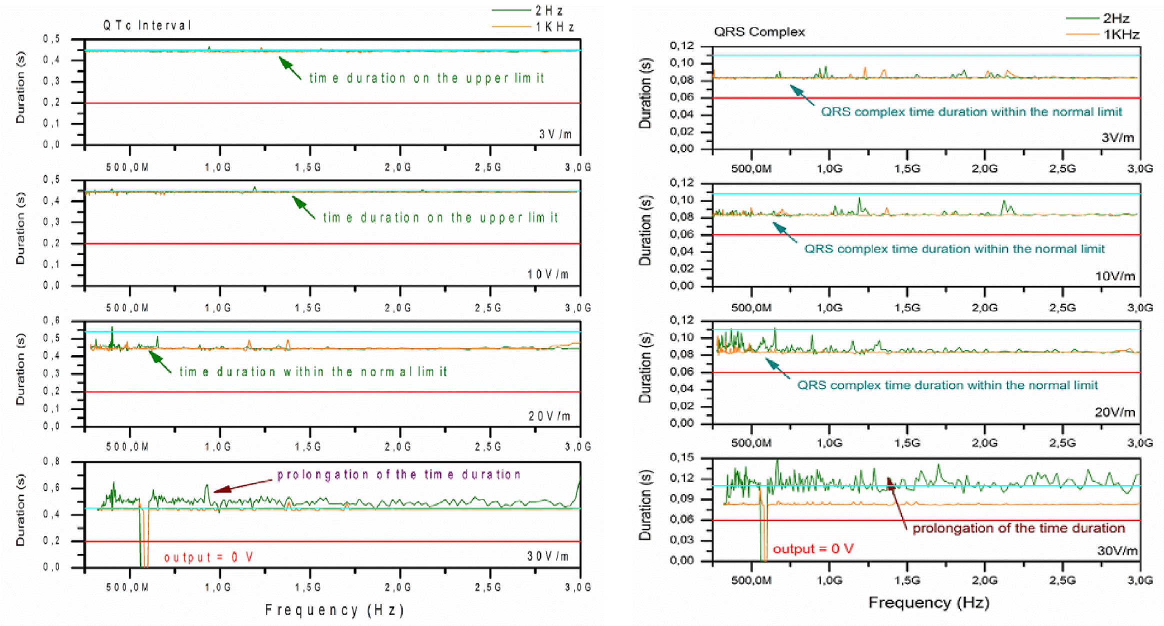

Fig 8. The modifications on the QTc interval and the QRS complex time duration caused by the different levels of EM radiation on the FPAA output channel.

- ✓ Give a particular attention to the lower test frequencies (lower to 1 GHz) because of the pick values and the reset event detected within this region of test frequencies, and Perform the test using different amplitude modulations carried on the EM radiation because the random behaviour of the additive noise regarding the used amplitude modulation frequency .
- ✓ In testing biomedical devices for immunity purposes, all the aspects and parameters of the target biologic signal (morphology and temporal parameters) should be taken in account for more detailed information about the possible influence of the external disturbance onto the concerned signal.

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