

DEVELOPMENT OF A STAND-ALONE DEVICE TO SIMULTANEOUSLY RECORD CARDIOTOCOGRAPHY BIOSIGNALS IN AN OPEN FORMAT FOR TESTING METHODS OF ASSESSING FETAL HEART RATE VARIABILITY

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Abstract: Fetal hypoxia/acidemia recognition improves with computerized analysis of biosignals collected from cardiotocography (CTG), particularly the assessment of short-term variability (STV) of fetal heart rate (FHR). Several methods to compute STV have been described with varied performance results according to acquisition method, sampling and storage rates and algorithm definition. Dawes-Redman algorithm (STV16) is the most widely reproduced in available commercial systems. However, it shows a low correlation with the beat-to-beat variation determined from fetal electrocardiographic signal (fECG). STV240 algorithm has been introduced in an attempt to approximate STV assessment to real beat-to-beat variation. There is no comparison in the literature between these two algorithms, taking as gold standard variability obtained from ECG tracing. With a view to providing reliable records for the standardization and comparison of STV algorithms, most notably, STV16 and STV240, we have designed, assembled and developed a stand-alone device well able to connect with different CTG machines and collect simultaneously biomedical signals of interest, particularly FHR, uterine activity and fECG, from the standard monitor outputs. It generates a file in an open format that allows assessment of computerized parameters of CTG. By means of R-R instantaneous variation from fECG as a reference we have found no agreement by Intra-class Correlation Coefficient between STV16 and STV240, neither with STV calculated from fECG. Nevertheless, the last two correlated closely. Standardisation of algorithms, interoperability and research in computerized CTG need to be provided with simultaneous recordings of biosignals involved, including the ECG raw signal. STV16 and STV240 require individualised normal ranges.

INTRODUCTION

Fetal monitoring by cardiotocography (CTG) is the most widely used technique to identify fetal hypoxia/acidemia, its diagnostic performance improving with computerized analysis of biosignals collected, particularly with the assessment of short-term variability (STV) of fetal heart rate (FHR). Methods to compute STV have different performance results according to algorithm definition, sampling and storage rates and acquisition method: assessment from an external transducer that catches the mechanical activity of fetal heart by a Doppler ultrasound system or internal monitoring by means an electrode attached to the fetus that captures fetal electrocardiographic –ECG– signal.

In time domain, STV16 of Dawes-Redman (the most widely reproduced) and STV240, described by Kouskouti et al., are algorithms introduced in commercial systems. In order to calculate STV they average every minute values of FHR acquired from external monitoring in time intervals of 3.75 sec (STV16) or 250 msec (STV240) [1]. It must be noted that the comparison of algorithms needs simultaneous recordings of biosignals, including direct fetal ECG, if we are to set the actual value of variability [2].

OBJECTIVES

- To design, assemble and develop an autonomous electronic device to allow for the collection of biosignals from different cardiotocograph models. The device collects simultaneously biomedical signals of interest (particularly fetal heart rate, uterine activity and fetal ECG signal) from the standard outputs of the monitor and generates a file in an open format that allows the calculation of computerized parameters of CTG monitoring.
- To establish the accuracy of STV16

and STV240 algorithms assessed from external Doppler ultrasound CTG, taking as gold standard the beat-to-beat variability obtained from the fetal ECG signal.

MATERIAL AND METHODS

IMPLEMENTATION OF THE DIGITIZING DEVICE (DD)

SYSTEM FUNCTIONAL DESCRIPTION

We have developed an energy and operationally autonomous device –it not require a connection to a computer for its operation- able to acquire biosignals of interest by the standard outputs of different CTG machines. Corometrics 250™ CTG monitor was the equipment employed for the present project. In figure 1 we represent the functional block diagram of the device.

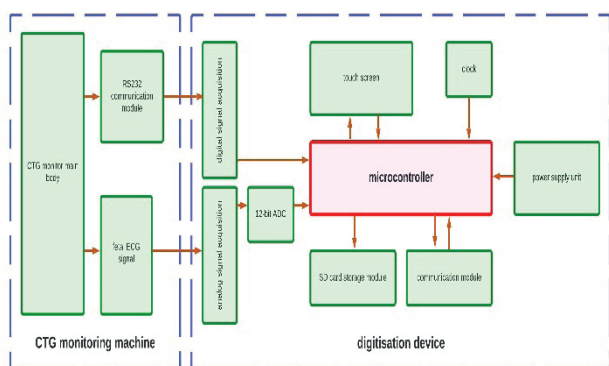


Figure 1. Functional block diagram

Input:

-*Digital signal:* Corometrics 250™ (fetal monitor –FM-, in this case as Data Terminal Equipment –DTE-) has three RS232 Serial Communication Protocol ports. In response to a request command coming from the host digitisation device (as Data Communications Equipment –DCE-) the FM starts the sending of data blocks every 990 to 1100 milliseconds, each containing four values for each channel of FHR (called HR1 and HR2, which enable monitoring of twin gestations) and four values

of the abdominal wall pressure collected by the external pressure transducer that assesses uterine activity (UA), as well as other maternal parameters. FM estimates FHR from the Doppler signal obtained by the external US transducer or from the fetal ECG signal when internal monitoring is performed. In either case, FHR figures are sampled at 4 Hz and have a resolution of 1 bpm. AU is sampled at 4 Hz and has a resolution of 1 mmHg. A converter module RS-232/TTL enables the microcontroller to receive the data blocks.

-*Analog signal:* Corometrics 250™ has an analog output for maternal ECG and fetal ECG signals. Fetal ECG signal has a bandwidth of 100 Hz with an amplitude of 10 V/mV. A sample rate of 1 kHz was chosen, which meets the requirement of $2 \cdot F_{\max} \leq F_s$. The ADS1015 12 bits allows for a ADC converter resolution of 0.8 mV.

Interactions: three consecutive menus operated on the touch screen provide access to the device's functions: the first menu allows us to start the telematic updating process of the time and software, the next screen requesting identification of the pregnant woman and enabling access to the menu of specific functionalities: starting a new case, starting a new file, sending the request command.

Data handling and storage: raw data from data blocks are extracted, decoded and stored. Each monitoring generates a folder on the memory card containing four files:

- cabecera_FicheroAnalogico. dat and cabecera_FicheroDigital. dat contains metadata about date and time of registration, resolution, and sampling rate (Hz), among others.
- ficheroAnalogico. dat contains the voltage value of the fetal ECG signal digitalized at a sampling rate of 1 kHz.
- ficheroDigital. dat contains the information of the signal channels

provided by FM. FHR1 (HR1) is the calculation source of heart rate from external transducer or internal monitoring; FHR2 (HR2) comes from a second external US transducer; Uterine activity (UA) is obtained through the pressure transducer applied on the maternal abdomen; Maternal NIBP is a non-invasive blood pressure measurement; Maternal SpO2 represents maternal oxygen saturation level and MHR is maternal heart rate.



Figure 2. Digitizing device. Main screen

Output

Figure 2 shows the device operating in simulation mode.

Display of digital data on screen: data extracted from bloks are displayed on screen: HR1, HR2, MHR, UA and SpO2. Additional information is also shown: identification number of the case, time and battery charge level. An additional button allows access to the menu to start a new case, a new file or send the request command.

Display on screen of analog signal of fetal ECG: it is displayed in refreshing or still mode. Complementary buttons allow us to select the scale and the number of samples displayed.

SYSTEM TECHNICAL SPECIFICATION

In figure 3 we represent the wiring diagram.

Microcontroller: the microcontroller used is the ESP32, chosen by its ultra-low power consumption, integrated Wi-Fi and its capability to receive updates by FOTA (Firmware Over-The-Air).

Touchscreen: ILI9341 LCD TFT is a 3.2-inch screen that integrates a resistive touch sensor, controlled by the XPT2046 chip that increases its accuracy.

Powering: an 18650 battery and battery charging module provides the device with an autonomy of between 6-10 hours of use.

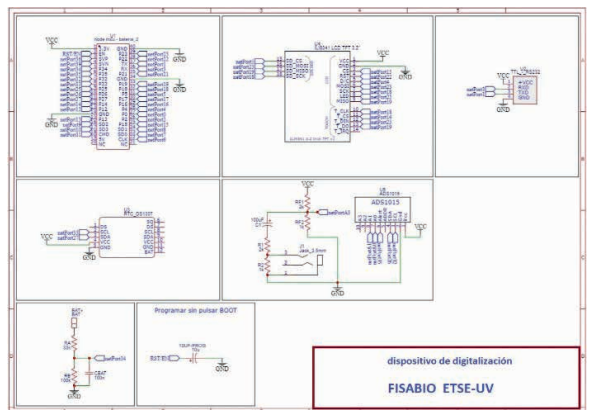


Figure 3. Wiring diagram

Microcontroller programming: the IDE (Development Environment) is the Arduino IDE V 2.0.0.

Testing: a DYNATECH-NEVADA 215A Patient Simulator and a digital oscilloscope were used to establish the accuracy of the fetal ECG signal recording. The integrity of the data recorded from the data blocks issued by the FM was checked by means of a commercial RS 232 recorder (AirDrive RS-232 Recorder) connected in series between FM and DD.

System updating: DD can connect to a Wi-Fi network to check if an update is available, download and install new firmware and restart automatically.

COMPARISON OF METHODS OF STV ASSESSMENT

POPULATION

Ten consecutive CTG records, digitized with the DD in single pregnancies who underwent internal monitoring on clinical indication during June-July 2023 were included. Digitalization was carried out from the start of internal monitoring until delivery. The duration ranged between 10 and 260 minutes.

For the purpose of comparing the STV16 and STV240 algorithms when an external Doppler monitoring is used we studied joined together the fragments from the ten cases where the twin mode was employed (external and internal monitoring on the same pregnant woman). It allows us to collect simultaneously FHR from external Doppler monitoring, FHR from internal monitoring, uterine activity and fetal ECG signal. A total of 52 minutes of recording time was used for this purpose. STV16 and STV240 groups were compared with STV values from ECG signal (ecgSTV).

Instantaneous variability of FHR from ECG signal was calculated from the time that elapsed between R peaks of consecutive waves. Matlab findpeaks function, which identifies values and locations of local maxima, was employed to find them. These values were averaged by the minute to obtain a format in accordance with those achieved with STV16 and STV240 algorithms. Calculations were made on the entire record without removing fragments with episodic changes from the baseline. Artefacts were ruled out by disregarding instantaneous FHR variation values greater than 25 bpm.

Institutional review board approval was obtained.

STATISTICS:

Mean values of STV16, STV240 and ecgSTV groups were compared by paired samples t-test. The agreement between

series was evaluated by means of Intraclass Correlation Coefficients (ICC, McGraw-Wong 1996). The A-1 version shows degree of absolute agreement and C-1 the degree of consistency among measurements. Also, Bland-Altman plots were depicted. For all statistical tests, a significant level of 0.05 was pre-defined. Calculations were computed in MATLAB R2023b.

RESULTS

The DD developed is able to acquire FHR traces obtained from internal and external monitoring together with the fetal raw ECG signal as a model in order to have adequate data to calculate computerized parameters. Therefore, it allows us to contrast the agreement of the algorithms used to estimate STV (STV16 and STV240) from external monitoring with that obtained from the fetal ECG raw signal.

Figure 4 shows a cardiotocographic monitoring comparing FHR depiction obtained from the fetal ECG signal with the frames of FHR provided by the FM from the external US monitoring and the internal monitoring. US Doppler monitoring trace is slightly delayed in relation to the internal monitoring trace because of the methodological extraction of the former (autocorrelation technique on Doppler envelope) which tends to average the durations of successive cycles.

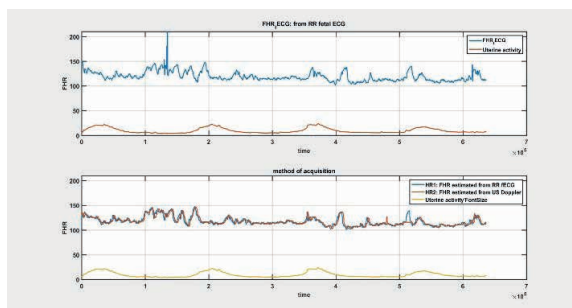


Figure 4. Comparison of traces acquired from ECG signal (top), US Doppler and internal monitoring (bottom). Time in msec

Figure 5 shows instantaneous STV as calculated from the ECG signal and then compared with this same STV averaged by the minute and with the by the minute-STV extracted by means of STV16 and STV240 algorithms. It represents HR1 and HR2 channels in a trace of ten minutes of a case with normal perinatal outcome, corresponding to the tracing in figure 4.

Mean values of STV16, STV240, ecgSTV groups from US Doppler signal acquisition were: 9.85 (+/-8.62), 2.22 (+/- 5.57), 3.68 (+/- 2.25) msec., respectively. Paired samples t-test shows no difference between STV240 and stvECG. Nevertheless, STV16 is significantly higher than STV240 and stvECG. Our results are similar to those described in the literatura [1].

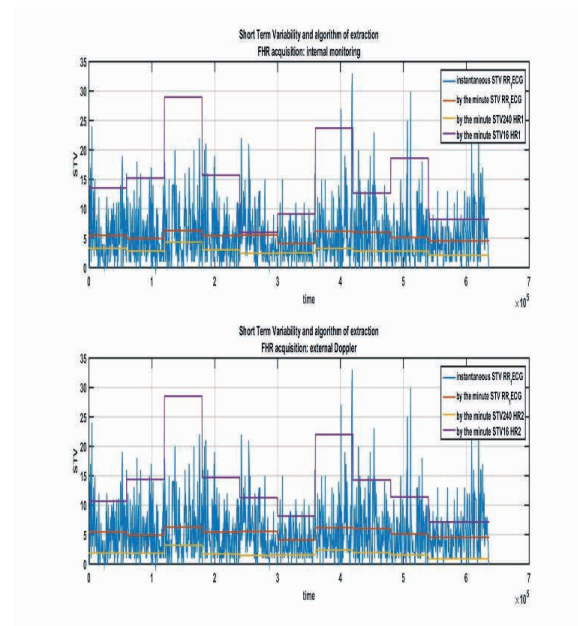


Figure 5. Comparison of STV (msec.) from: instantaneous variability (fetal ECG signal), average by the minute and STV16 and STV240 algorithms: top internal monitoring, bottom down US Doppler

Tables 1 and 2 describe the level of reliability of STV measurements carried out by the STV16 and STV240 algorithms with regard to values calculated from the ECG

by Intraclass Correlation Coefficients. All C-1 ICCs become significant for $p=0.05$ (all series show consistency between them). A-1 ICC shows total agreement between STV240 and ecgSTV but does not become significant between STV16 and the other two: STV16 overestimates ecgSTV (also STV240) as shown in the Bland-Altman plots in Figure 6 and the difference increases for high STV figures.

Consistency	ICC C-1	confidence interval 95%	P
ECGstv vs STV240	0.33	0.04-0.57	0.01
ECGstv vs STV16	0.36	0.07-0.59	<0.01
STV240 vs STV16	0.65	0.44-0.79	<0.01

Table 1. Consistency among measurements

Agreement	ICC A-1.	confidence interval 95%	P
ECGstv vs STV240	0.32	0.04-0.56	0.01
ECGstv vs STV16	0.24	-0.05-0.51	0.06
STV240 vs STV16	0.42	-0.09-0.73	0.07

Table 2. Agreement among measurements

CONCLUSIONS

STV16 is a well established algorithm evaluating short term variability. It has proven its effectiveness in adverse perinatal outcome recognition in predelivery assesment of fetal wellbeing but not during labour. Its design was empirically based on the basis of computational and storage capacity in the devices available at the time of its implementation and not on a pathophysiological basis such as fetal electrophysiological activity [3].

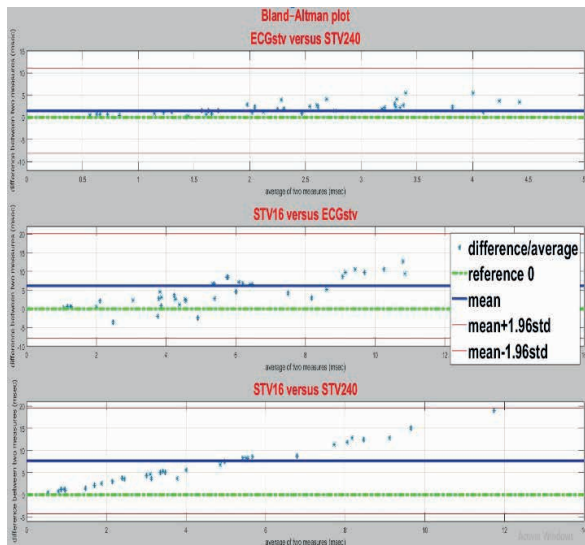


Figure 6. Bland-Altman plots: top ECGstv versus STV240, middle ECGstv versus STV16, bottom STV240 versus STV16

Improving assisted interpretation in cardiotocography needs to explore new methods of computerized analysis and machine learning models [4]. For that purpose, it is essential to have suitable records with raw signal/traces similar to those provided by the device developed.

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