FINAL REPORT

NASA CONTRACT NAG-1-2123

ODURF Project # 191331

Commercialization and Industrial Development

for the Fetal Heart Rate Monitor

January 30, 2000
(Revised February 17, 2000)

Stephen A. Zahorian, Principal Investigator
Department of Electrical and Computer Engineering
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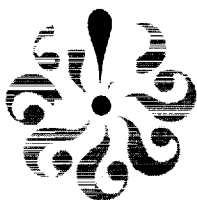
OBJECTIVES

The primary objectives for this task were to continue the development and testing of the NASA/ODU passive acoustic fetal heart rate monitor, with the goal of transferring the technology to the commercial sector. Areas of work included:

1.   To assist in the development of a new hardware front end electronics box for the fetal heart rate monitor, so as to reduce the size of the electronics box, and also to provide for a "low-frequency" and "high-frequency" mode of operation. To make necessary changes in the operating software to support the two modes of operation.

2.   To provide an option for a strip chart recording for the system, so that medical personnel could more easily make comparisons with ultra sound strip chart recordings.

3.   To help with continued testing of the system.

Accomplishments

1a. Functional Description of Hardware

A block diagram of the hardware is given in Figure 1. The first stage of the hardware consists of a bank of seven charge amplifiers, each of which is directly connected to one of the seven sensors on the sensor belt. One of the seven amplified sensor signals is then selected, using a multiplexor controlled by the parallel port of the personal computer used for the system software. The selected signal is then filtered in one of two modes: in mode 1, (direct contact mode, or broad band mode) the signal is band pass filtered from 20 Hz to 400 Hz using 4-pole Butter worth lowpass and highpass filters connected in cascade; in mode 2 (fluid propagation), the signal is bandpass filtered from 80 Hz to 400 Hz, again using 4-pole Butterworth lowpass and highpass filters. In both modes the signal is amplified by a final stage of adjustable amplification ranging from a gain of 1 to 11. In the fluid propagation mode, there is an additional gain of 10, to compensate for the overall reduced signal in this mode. The user of the equipment must select one of the two modes, and also must adjust the final gain.

The main changes in this version of the hardware, versus the previous version, are the option for the two filtering modes. Additionally the multiplexing is done immediately after the charge amplifier stage, so there is only one filter set for each mode, rather than seven separate filters, as in the previous version.

One reason for considering the higher frequency mode of operation is that the background noise appears to be much higher in the low frequency range. An illustration of the background noise is given in Figure 2, which shows the noise spectrum, using B&K 2032 Analyzer with the belt on the balloon, and no applied signal. Notice that the noise is much higher for the range from approximately 10 Hz to 60 Hz.

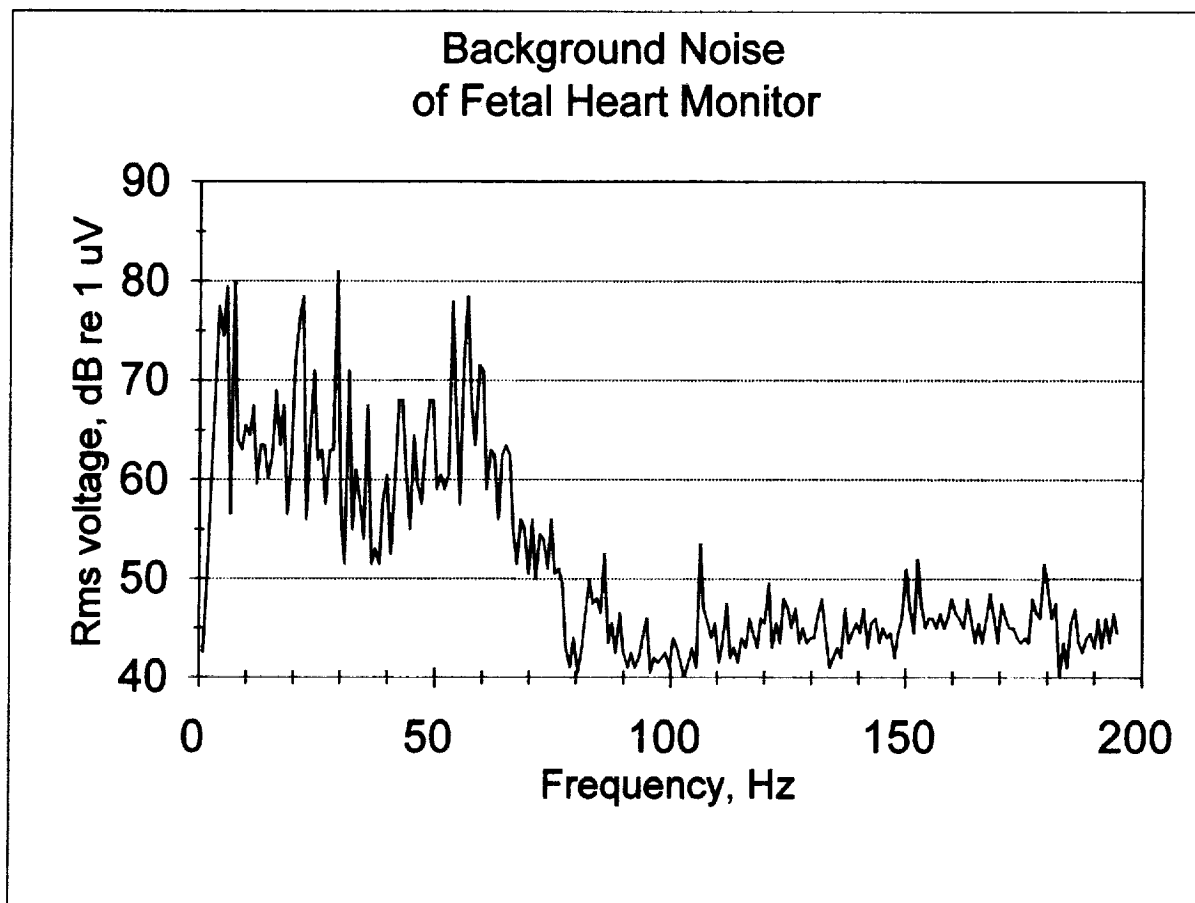Figure 1. Block diagram of front-end electronics
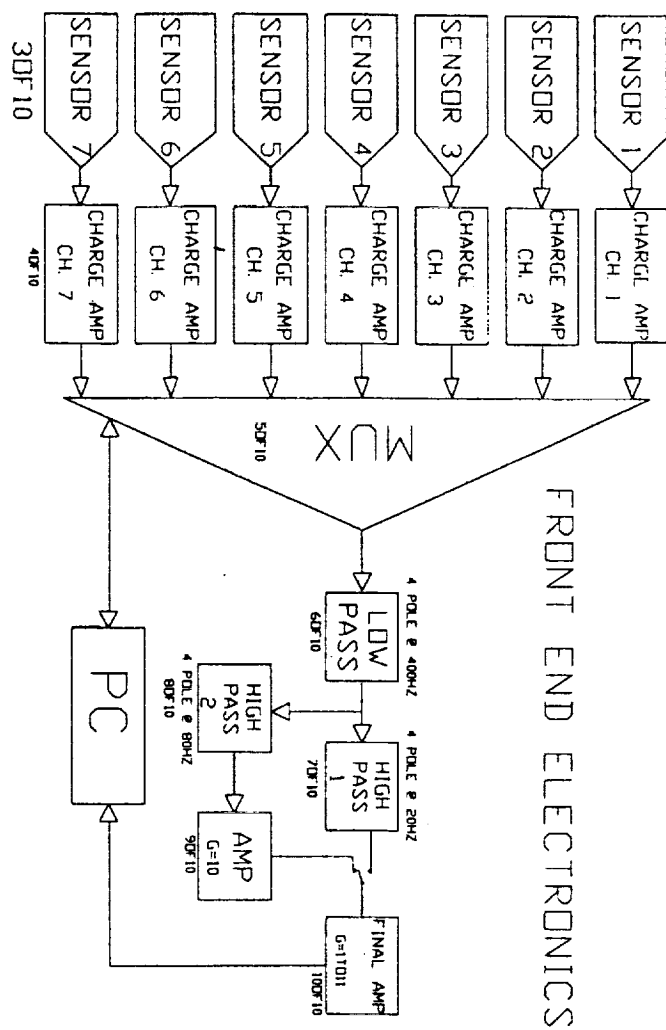
Figure 2. Noise spectrum obtained with sensors on balloon, and no applied signal.

1b. Functional description of the software

The entire software program is a 32-bit windows application, compatible with Windows 95, Windows 98, and Windows NT.   Code was developed using Microsoft Visual C/C++, version 5.0 (although it can also be compiled and built with version 6.0).   The general features of this code were described in some detail in the November 1998 report and will not be repeated here.   In this report, mention is made only of the changes need to accommodate the two modes of operation in the new modified front-end box.   The main changes were simply to allow additional digital filtering settings.

The bandpass filters available are:

1. 16-50 Hz
2. 20-50 Hz
3. 20-100 Hz
4. 20 – 400 Hz
5. 80-400 Hz
6. 250-400 Hz
7. 80-110 Hz
8. 110-160 Hz
9.. 160-250 Hz

The intention was that each of the first 4 filters above be used in the broadband mode (mode 1). The last five options are for testing with the fluid propagation mode. Note that each filter is a 124th order FIR linear phase filter.

Some additional small refinements were added to the windows program , primarily to make the program easier to use. The current version of the FHM software is VER23, last updated on 8-19-99.

2. Addition of strip chart recorder option.

In order to create paper records more similar to those used by the medical personnel who work with ultrasound fetal recorders, a provision was made to create strip chart type recordings. The basic hardware for the digital strip recorder is a thermal printer, using continuous-feed roll paper--MFE Instruments Model MP-404X (4042, or 4044, or 4046). This instrument connects to the serial port of the PC, and uses "standard" Epson style graphics commands. In order to make the charts look very similar to those created by ultrasound recorders, the scales were chosen to be the same---- 3 cm per minute in the horizontal direction, and a range of 30 BPM to 240 BPM in the vertical direction. The resolution of the printer is 256 dots spanning the vertical direction. The effective resolution is 1 dot for each BPM. There are two basic modes of operation--- in one mode the strip chart is created simultaneously while the fetal recording is made on the computer. In the other mode, the chart can create at a later time from stored waveform files. A sample chart is given in Figure 3.

The user must choose which serial port the thermal printer is connected to. This option is available with a pull down menu. The user must set the correct baud rate of the serial port, usually 9600 BPS, for the printer. This rate is set with switches inside the printer. The rate selected on the printer then must be matched on the serial port of the computer, using the control panel in windows 95/98 or Windows NT. These adjustments need to be made once only. Before actual use, the printer must be ready, or transmitted data will be lost. Also, note that extensive error checking was not included in the code---for example, there is no out of paper check.
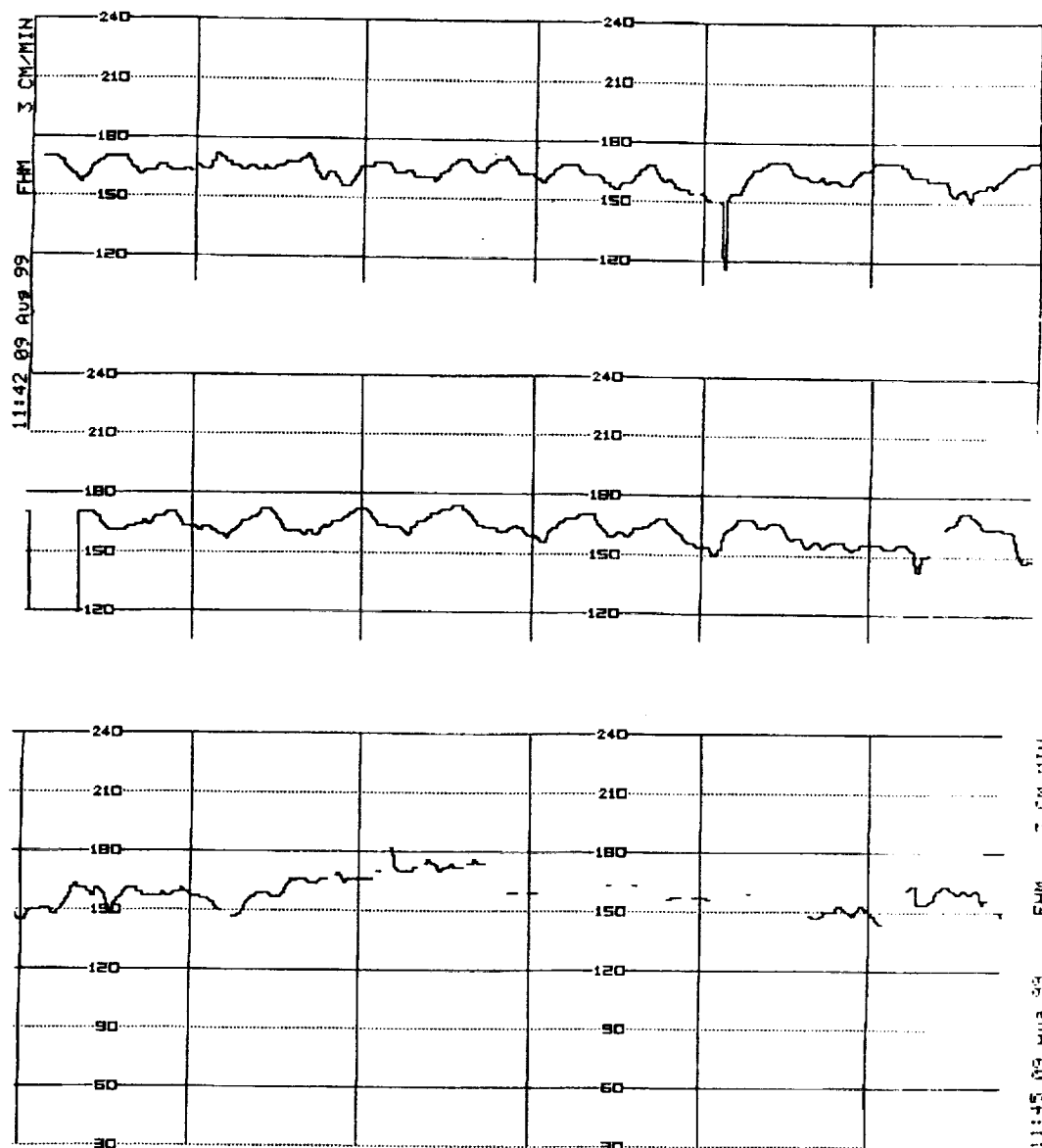
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Figure 3. Sample strip chart printed with thermal printer. Note that originally the three traces appeared on one long continuous trace.

The PC must be connected to the printer with a standard serial port cable. The printer does not come pre-wired with a serial port connector. Instead it has a 40-pin ribbon cable. To configure the printer for connection to a serial port, the following connections must be made:

Printer ribbon cable #	DB9 serial port pin #
28 (Rx data)	3 (Tx data)
30 (Data Set Ready)	6 (Data Set Ready)
33 (Chassis ground)	Connector body
34 (Signal ground)	5 (Signal ground)

A brief summary of the code needed to control the printer is as follows. Printing the vertical axis at the beginning of the chart first initializes the chart. In operation, the program "collects" data for eight points on the paper in the horizontal direction. The program then transmits graphics commands to print a vertical "slice" which is eight bits wide and spans the vertical distance of the graph. Thus, in effect, the software creates an 8 by 256 binary bit map of the image which must be printed for a particular time slice. This corresponds to 256 bytes of data, plus a few bytes of commands, which must be transmitted for each update of the chart. Note that the axes, numerical values, and all other labeling information, as well as the actual heart rate tracing, must be updated each time the printer is written to. All of this updating is done in the "background" with details of timing taken care of by the operating system, so the printing does not interfere with real time operation of the instrument The 8 by 256 bit map data, preceded and followed by some printer control commands, is then sent to the serial port to which the printer is attached.

3. Experimental verification

Several tests were made at EVMS during 1999. Testing was performed on 12 different different patients. A summary of these tests is given in Table 1. On approximately 80% of these patients, reasonably good fetal heart rate records were obtained, as judged by comparison with the ultrasound recordings that were made immediately preceding the acoustic fetal heart rate tests, and the general appearance of the acoustic fetal heart rate charts which were obtained. Some of these good recordings did require the use of the new high frequency mode. Representative results from the fetal heart rate tracings, printed as screen captures from the computer program, are given in Figures 4-6.

Table 1. SUMMARY OF TESTING AT EVMS

Patient	Frequency band	Channel	Gestational age	Notes
1	LF	1	39 weeks	
2	LF	1	36	
3	LF & HF	1	36	a
4	LF & HF	3	38	b
5	No test			
6	HF	1	34	
7	LF & HF	1	38	c
8	HF	7	34.5	d
9	HF	1	37	e
10	HF	1	37.5	e
11	No test			f
12	LF	7	36	

Notes

a   Twins. Posterior baby only.
b   Simultaneous ultrasound and acoustic tests.
c   Patient slightly on right side.
d   Merit threshold 0.3. Min rate 100. Max rate 200.
e   Merit threshold 0.3.
f   Interference from maternal heart beat.
LF 16-50 HZ   HF 80-110 Hz

Figure 4   Fetal heat rate tracing from file EVMS1.DEC (patient 1, LF filter). The actual times are from 3 minutes to 21 minutes in the recording sessions (skip time = 3 minutes).
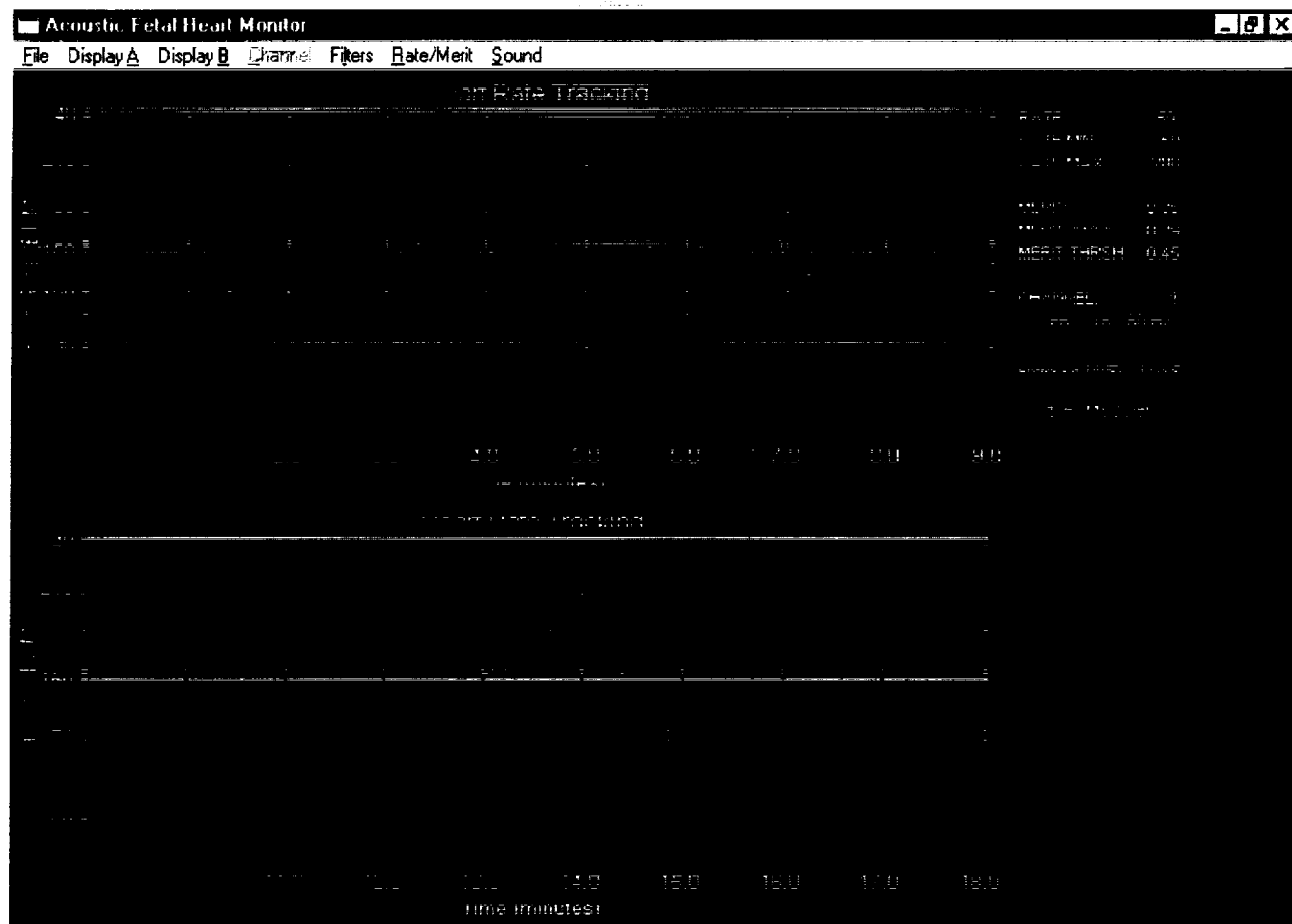
Figure 5. Fetal heat rate tracing from file EVMS2A.DEC (patient 2, LF filter). The actual times are from 3 minutes to 21 minutes in the recording sessions (skip time = 3 minutes).

Figure 6.   Fetal heat rate tracing from file EVMS6A.DEC (patient 6, HF filter).   The actual
times are from 3 minutes to 21 minutes in the recording sessions (skip time = 3 minutes).

In addition, in Atlanta, a total of 31 files were collected from 23 different patients. Some of these also resulted in "good" data. However, the inexperienced personnel did have difficulties properly adjusting the sensor belt, choosing correct filter settings, etc. Therefore, many of these recordings do not appear to be "good" fetal heart rate tracings.

Conclusions

Considerable additional work was done on the acoustic fetal heart rate monitor. In order to make this monitor commercially viable, it still must be shown that the monitor performs comparably to an ultrasound unit. More work is needed to improve the preservation of beat-to-beat variability in the tracing, and overall accuracy of tracking.