A New, Lightweight Fetal Telemetry System

The HP Series 50 T fetal telemetry system combines both external and internal monitoring of the fetus in a small, lightweight transmitter that is easy and comfortable for the patient to carry. It is useful for monitoring in labor, monitoring of high-risk patients, monitoring in transit, antepartum nonstress testing, and monitoring in the bath.

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Electronic fetal monitoring records fetal heart rate, uterine activity, and fetal movements onto a trace, allowing obstetrical clinicians to better assess fetal well-being and the adequacy of fetal oxygenation.

In today's high-tech hospital environment it is easy to overlook the fact that the majority of pregnant women who are admitted to the hospital to give birth are not sick, but are experiencing a natural event, the delivery of their babies. With this in mind, many hospitals worldwide are anxious to create a more friendly environment in their labor and delivery departments by reducing the amount of technology at the patient's bedside. This reduction in technology can present a problem. Although patients want a more natural environment, the nursing staff still wants to be able to oversee fetal well-being during labor and delivery. There has to be a balance between these two goals, and monitoring of the fetus via telemetry offers a solution.

Telemetry monitoring of the fetus involves connecting a patient to a radio frequency transmitter, which she is able to carry (Fig. 1). This transmits the fetal information via UHF radio frequencies to a receiver connected to a fetal monitor. The monitor records the information as if the patient were connected directly to it. The fetal monitor and receiver can be placed in a central location for the nursing staff to view the fetal information, and need not be in the patient's room, thereby reducing the perception of technology at her bedside.

Fig. 1. The HP Series 50 T fetal telemetry system transmitter is lightweight and comfortable to wear.

Fetal monitoring with telemetry has been available for the past ten years. Until now, these telemetry systems only allowed either external monitoring of the fetus such as ultrasound detection of the fetal heart rate, or internal methods such as direct monitoring of the fetal heart rate by means of a scalp electrode. Very few systems offered both of these methods, and those that did were large and heavy for the patient to carry, and had a very low battery life.

The Hewlett-Packard Series 50 T fetal telemetry system (HP M1310A) is a new lightweight, space-saving telemetry system. It combines both external and internal monitoring of the fetus in a small, lightweight transmitter that is easy and comfortable for the patient to carry. Because the patient is not connected directly to the fetal monitor, a number of additional clinical applications can be addressed, including monitoring in labor, monitoring of high-risk patients, monitoring in transit, antepartum nonstress testing, and monitoring in the bath.

Monitoring in Labor. The technology used in the HP Series 50 T ensures that the product can be used in the very earliest stages of labor, before the membranes have ruptured, right up to and during the second stage of labor when the baby is being delivered. This means that the patient is free to move around from the onset of labor, while a reliable, continuous fetal trace is available for overseeing fetal well-being. Allowing the patient to walk around can be beneficial for the patient, especially when the delivery is long, and can even help reduce the pain of her contractions.

Monitoring of High-Risk Patients. When a high-risk patient has been admitted to the hospital for observation before the birth of her baby, it is often desirable to provide continuous monitoring of the baby to ensure its well-being. However, this is not normally practical because it would mean connecting the patient to a fetal monitor and confining her to bed for long periods of time. Using the HP Series 50 T fetal telemetry system, the patient is free to walk around, and the nursing staff has a constant overview of fetal well-being.

Monitoring in Transit. Besides being compatible with all HP fetal monitors produced since 1982, the HP Series 50 T fetal telemetry system can use the standard transducers of the HP Series 50 family of fetal monitors. This is useful, for example, if an emergency occurs and the patient needs to be transported to the operating room for a Caesarean section. In certain countries it is a legal requirement to provide continuous monitoring of the fetus from the time the patient leaves her room to the delivery of the baby. By disconnecting the transducers from the fetal monitor and connecting them to the transmitter of the HP Series 50 T, continuous, uninterrupted monitoring of the fetus is ensured.

Antepartum Nonstress Testing. Nonstress testing is performed during the patient's regular visit to the clinic or hospital during her pregnancy. By allowing the patient to ambulate and record the fetal heart rate via ultrasound, nonstress testing can be performed without having to confine the patient to bed, thereby allowing her freedom of movement and the ability to socialize with the other patients.

Monitoring in the Bath. It is becoming more common for a patient to be given a bath during labor to help reduce the pain of her contractions. Before the introduction of the HP Series 50 T fetal telemetry system, there was no safe way of providing a continuous overview of fetal well-being while the patient relaxed in the bath. This meant vital information on the fetus could be missed. By using the HP Series 50 T in conjunction with the standard watertight "blue" ultrasound and TOCO† transducers from the HP Series 50 family of fetal monitors, the nursing staff can be assured of a continuous recording of fetal information even when the patient decides to take a bath.

Fetal Monitoring Measuring Methods and Principles

The parameters measured in fetal monitoring applications are fetal heart rate, fetal movements, and maternal labor activity.

The fetal heart rate is continuously monitored on a beat-to-beat basis and recorded together with the maternal uterine activity and optionally the fetal movements on a fetal trace recorder.

There are two established methods to measure the fetal heart rate. One is to process the fetal ECG by using a fetal scalp electrode and measuring the time distance between two QRS complexes. This method is invasive and can only be used if the membranes have ruptured and the fetal scalp is accessible to attach the scalp ECG electrode. This is true only for the last few hours before delivery.

The second method of measuring fetal heart rate is to calculate the heart rate from a Doppler-shifted ultrasound signal by measuring the time distance between two signal complexes resulting from fetal heart motion. A 1-MHz pulsed ultrasound signal is emitted towards the fetal heart and the ultrasound waves are Doppler shifted by the moving parts of the heart and reflected. The reflected and Doppler-shifted signal is received again and demodulated by a 1-MHz clock signal. After filtering and amplification (by approximately 80 to 106 dB), only the low-frequency Doppler-shifted signals in the range of 100 to 500 Hz remain. These signals are fed to a loudspeaker to give the user audible feedback about the correct transducer positioning. Compared to the relatively simple algorithms needed for the heart-rate calculation from the ECG signal (the ECG signal is a well-defined, easy-to-recognize signal) the algorithm for the ultrasound signal is much more complex. The ultrasound Doppler signals contain a lot of different pulses as a result of reflections from different moving parts of the heart during one heart period. These pulses change their shapes and amplitudes depending on the angle between the ultrasound beam and the heart. Therefore, a simple peak-searching algorithm cannot accurately calculate the fetal heart rate from the ultrasound Doppler signal on a beat-to-beat basis, so a more complex algorithm using the autocorrelation function of the ultrasound signal is used. The autocorrelation function determines the similarity between all the pulses of two consecutive heartbeats. The distance between two points of highest similarity is then used to calculate the actual fetal heart rate. This method reaches a heart rate trace quality comparable to that of a trace derived from an ECG signal (the ECG signal is recognized as the "gold" standard for fetal heart rate monitoring). The advantage of the ultrasound Doppler method is that it is a noninvasive method and can be used from the twentieth week of gestation up to delivery and no direct access to the fetus is necessary.

Fetal movements can also be detected from the ultrasound Doppler signal. The fetal movement signals differ from the Doppler heart rate signal in that they have a much higher amplitude and a lower frequency. The higher amplitude is because of the bigger size of the moving areas (e.g., the fetal arms and legs) and the lower frequency is because of the lower velocity of the fetal movements compared with those of the fetal heart.

For measuring maternal labor activity (uterine activity), there are two established methods. The IUP (intrauterine pressure) method measures, as the name implies, the absolute pressure in the uterus by inserting a pressure transducer into the uterine cavity. This can be a precalibrated pressure sensor mounted in a catheter tip or a saline-solution-filled catheter with a pressure sensor connected outside. This method is invasive to the mother and can only be used if the membranes are ruptured. The second method is an external noninvasive method (external TOCO) which measures the relative hardness of the abdominal wall and the underlying uterine muscle. This method provides relative values and not absolute pressures like the IUP catheter. The pressure sensor in both transducers is based on a resistive bridge with four pressure-sensitive elements. The bridge gives a high pressure sensitivity but needs differential excitation and a differential signal amplifier.

Wireless Data Transmission

There are many possibilities for wireless data transmission from one location to another. Each method has its individual advantages and disadvantages when analyzed for a specific application. We looked at infrared and radio frequency transmission and evaluated their advantages and disadvantages for the fetal telemetry application.

† TOCO is an abbreviation for tocograph or tocodynamometer, an instrument for measuring and recording the expulsive force of uterine contractions in labor. It is usually written in uppercase letters like the abbreviations for the other fetal measuring methods: US = ultrasound, ECG = electrocardiogram, IUP = intrauterine pressure.

Infrared light is widely used as a data transmission method because of its simplicity and the fact that no regulatory approvals are necessary. However, for the fetal telemetry application, its use is not possible because the transmitting range is very limited and secure data transmission is only possible on a line-of-sight basis. This means that the transmitter cannot be covered by clothes or a bed cover and the transmission range is limited to one room. These conditions cannot be guaranteed during labor and delivery because the patient can walk around and change her position freely. Another disadvantage from the technical standpoint is the relatively high power consumption of an infrared system when used in a continuous transmission mode, which is necessary for continuous monitoring.

Radio frequency transmission, another very widespread transmission method, overcomes most of the problems of infrared transmission when it is designed carefully and an appropriate frequency range is chosen. Frequencies below 100 MHz will result in large antenna dimensions (the wavelength is 3 meters at 100 MHz) if high efficiency is needed (this is a strong requirement because of the battery-operated transmitter). On the other hand, frequencies above 1 GHz result in a wavelength (<30 cm) at which antennas become more and more directional, signal generation requires more space and power, and it takes special processes to build printed circuit boards that can handle such high frequencies.

A major disadvantage of radio frequency systems is that individual approval for each country is required and many different requirements and boundaries are given by all the national laws. These requirements must be fulfilled to obtain country approvals and should be covered by one design to avoid many special product options. Thus, the resulting design must meet the most stringent specification of all the different national standards for each requirement. A positive aspect for Europe is the upcoming harmonization within the European Community (EC) where one standard will be used for all European community members. At the moment, Germany, France, and Italy have converted this standard into national law (others will follow—a limit of two years is given for all countries to convert this standard into national law). This means that for these countries only one standard is valid.

The decision was made to use radio frequency data transmission.

The following items and specifications have been set up for a telemetry design to meet all the requirements for worldwide use:

- The frequency must be configurable in the range of 405 MHz to 512 MHz.
- The radio frequency (RF) power must be adjustable in the range of 1 mW to <10 mW.
- The spurious emissions must be <-36 dBm for frequencies <1 GHz and <-30 dBm for frequencies >1 GHz worldwide, and must be <-54 dBm in Europe in the frequency ranges 42 to 68 MHz, 87 to 118 MHz, 162 to 230 MHz, and 470 to 862 MHz.
- The RF bandwidth must be <25 kHz worldwide and should be <12.5 kHz for Japan (25 kHz would be acceptable but is not preferred)
- The transmitter must be capable of sending a special identification code after power-up for Japan.
- The RF stability over temperature (-10 to +55°C) and humidity (5 to 95% R.H.) must be better than ±3.5 kHz for the U.S.A. and better than ±2.5 kHz for Europe and Asia.

However, to design and build a radio frequency transmitter that meets all the above specifications requires extensive engineering manpower, testing, and design iterations. Therefore, we decided to reuse an existing RF transmitter and receiver for our fetal telemetry application.

After examining all possibilities, we found a good candidate in the RF parts of the HP M1400 adult ECG telemetry system. The RF parts of this telemetry system had all the approvals needed, and its highly modular design (RF parts were strictly separated from the application-specific elements) allowed us to pick up only those parts needed for our fetal application. The only modification needed was a small adaptation of the receiver's digital control software (which provides automatic frequency control—AFC—and the bitstream recovery of the digital protocol used to transfer the ECG waves). This software had to be modified to execute only the AFC function when used for the fetal application and not the bitstream recovery. It was even possible to modify the software so that it automatically switches to the correct application so that the same software can be used for the adult telemetry system and the Series 50 T. By reusing the adult RF parts, we dramatically reduced the engineering effort and only had to concentrate on the bandwidth specification (which is mainly determined by the modulation) and the special Japanese ID code.

The reused parts are the voltage-controlled crystal oscillator (VCXO) in the transmitter and as the local oscillator on the receiver side, the line amplifier as a receiver RF preamplifier, the receiver module, and all antenna parts (antennas, combiners, splitters, power tees).

Data Transmission and RF Modulation

To get low adjacent channel emission, the -6-dB RF bandwidth should not be wider than ±8 kHz for a 25-kHz channel spacing. This gives a margin of ±4 kHz for frequency drifts caused by temperature, humidity, and aging.

The adult ECG telemetry system uses digital Gaussian minimum shift keying frequency modulation (GMSK-FM) with a 9600-bit/s data rate. The resulting -6-dB RF bandwidth is approximately ±8 kHz.

Because the processing power needed to calculate the heart rate from the ultrasound Doppler signal is not available in the telemetry transmitter, the ultrasound Doppler signal is transmitted to a receiver, which feeds it to a connected fetal monitor, which does all the signal processing. The telemetry system only acts as a wireless analog front end for the fetal monitor. The HP Series 50 fetal monitors sample the signals at a 1.6-kHz sample rate with 12-bit resolution. To transmit the ultrasound signal as a digital bitstream, the required data rate is 12 bits $\times$1600 samples/s = 19200 bits/s for the ultrasound signal alone. Together with the uterine activity signal and the necessary framing and checksum overhead a minimum data rate of 22 kbits/s is required. This data rate does not include any redundancy needed for error correction.

To fit into the 25-kHz channel bandwidth, this data rate must be compressed to 9600 bits/s. This requires highly sophisticated data compression circuitry. The data stream resulting from a sampled ultrasound Doppler signal does not contain as much redundancy as the ECG, which does not change rapidly except for the short duration of the ECG QRS pulse. To fit into a 12.5-kHz channel spacing an additional data reduction down to 4800 bits per second is needed.

We decided to transmit the heart rate signal (ultrasound Doppler or ECG) with standard direct FM modulation. The uterine activity signal together with some status signals—battery status, nurse call function, serial number, and transducer modes (ultrasound or ECG and external TOCO or IUP)—are transmitted as a digital bitstream. This information is transmitted four times per second. Every data block is secured with an 8-bit checksum (CRC). A data block always starts with the serial number of the transmitter. This serial number,which is the same for the transmitter and the corresponding receiver, is used by the receiver to synchronize itself with the datastream and to verify that the data is coming from its own transmitter. This ensures that signals from two different patients using the same RF frequency are not mixed. The overall data rate for the digital transmitted signals is 200 bits/s. This data stream is transmitted as a frequency shift keying (FSK) signal with a 1600-Hz signal for a logic 0 and a 2400-Hz signal for a logic 1. This signal, added to the heart rate signal, frequency modulates the RF carrier. The amplitude of the composite signal determines the required RF bandwidth and can easily be adapted to meet the 12.5-kHz channel spacing requirements.

RF Bandwidth

The resulting RF bandwidth can be estimated as follows. The modulation signal is composed of two components: (1) the ultrasound Doppler signal or the ECG signal and (2) the FSK subcarrier signal. The modulation spectrum is illustrated in Fig. 2.

The RF FM modulator has a sensitivity of 1.6 kHz/V, which is the specification of the reused RF oscillator from the adult ECG telemetry system. The ultrasound signal has a bandwidth BW_{lf} = 500 Hz and an amplitude of 1.875 V_{p-p} which produces an RF carrier shift of 1.6×1.875 = 3.0 kHz. The corresponding modulation index is β = frequency shift ÷ modulating frequency = 3.0 kHz/500 Hz = 6. The ECG signal has a bandwidth BW_{lf} = 100 Hz and a carrier shift of 3 kHz, so the modulation index is β = 3.0 kHz/100 Hz = 30.

The FSK signal has as its highest frequency a 2.4-kHz sinusoidal carrier. Its amplitude produces an RF carrier shift of 1.5 kHz. The modulation index is β = 1.5 kHz/2.4 kHz = 0.625.

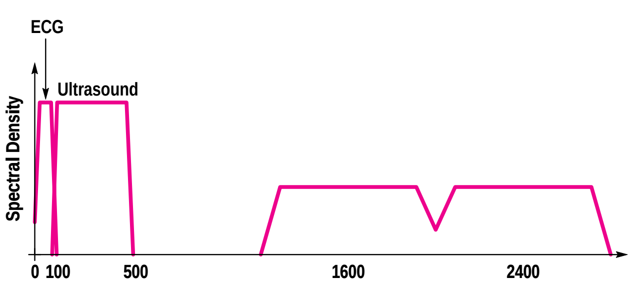

Fig. 2. Modulation signal spectrum of the HP Series 50 T fetal telemetry system transmitter.

For a modulation index less than one the RF bandwidth is approximately $BW_{rf} = 2BW_{lf}$. Only the Bessel functions of orders 0 and 1 have significant values (>0.01), so they represent 99% of the RF energy, or in other words, outside this bandwidth the signal is 20 dB down from the maximum at center frequency. Thus, the −20-dB RF bandwidth of the FSK carrier is 2×2.4 kHz = 4.8 kHz. For a bandwidth where the signal is 40 dB down (99.99% of the RF energy is within this bandwidth) the Bessel function of order 2 is also of interest and the −40-dB RF bandwidth of the FSK carrier is 4×2.4 kHz = 9.6 kHz.

For a modulation index greater than one, the RF bandwidth is approximately $BW_{rf} = 2(\beta+1)BW_{rf}$ for a bandwidth where the signal is 20 dB down. For a bandwidth where the signal is 40 dB down this bandwidth doubles again: $BW_{rf} = 4(\beta+1)BW_{lf}$.

With a modulation index of 6, the ultrasound signal produces an RF bandwidth of BW_{rf} (−20-dB) = 2(6+1)500 Hz = 14×500 Hz = 7 kHz or BW_{rf} (−40-dB) = 4(6+1)500 Hz = 28×500 Hz = 14 kHz.

With a modulation index of 30, the ECG signal has an RF bandwidth of BW_{rf} (−20-dB) = 2(30+1)100 Hz = 6.2 kHz or BW_{rf} (−40-dB) = 4(30+1)100 Hz = 12.4 kHz.

Thus, the overall RF bandwidth is mainly determined by the ultrasound signal or the ECG signal and not by the FSK signal.

The amplitude ratio between the heart rate signal and the FSK signal was chosen so that as the field strength at the receiver input goes down, the signal-to-noise ratio of the FSK signal decreases before the heart rate signal is affected. The receiver detects bit errors in the digital data stream and suppresses the heart rate output signals to the fetal monitor when errors occur. Thus, the fetal monitor always shows either the correct heart rate values or no value, but never displays wrong values, which may lead to a misdiagnosis.

Telemetry Transmitter

Fig. 3 shows the components of the HP Series 50 T fetal telemetry system.

A high priority for the telemetry system design was to support the same transducers as used by the HP Series 50 fetal monitors. Customers can use the transducers they normally use with their fetal monitors and can switch between standard monitoring and telemetry monitoring simply by replugging the transducer connectors from one device to the other. Repositioning and reapplying the transducers on the patient are not necessary and the switch can be performed in a few seconds. This compatibility was no problem with the ultrasound and uterine activity transducers, but the fetal monitor ECG transducer required more detailed investigation to design circuitry to handle this transducer in the telemetry transmitter.

The HP M1357A fetal ECG transducer is an active transducer in which the complete ECG preamplifier and its floating power supply are incorporated in the transducer legplate. Since the telemetry transmitter is battery powered, this floating, highly isolated preamplifier is overdesigned for

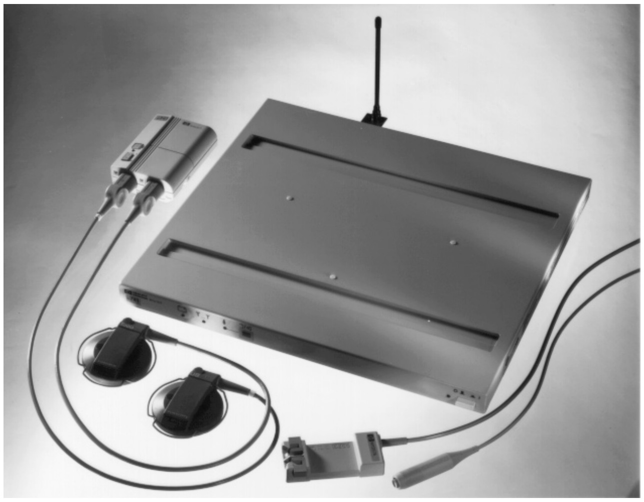

Fig. 3. Transmitter, transducers, and receiver of the HP Series 50 T fetal telemetry system.

telemetry use. However, it is mandatory for use on a mains-powered fetal monitor, since patient safety requires all transducers that have direct contact with the patient via electrical conducting electrodes to be floating.

The M1357A transducer requires a 10V peak-to-peak power supply signal with a frequency between 100 and 250 kHz. The ECG signal is transferred on the same wires by power load modulation, which means that the transducer varies its load on the driving circuit with the amplitude of the ECG signal. A circuit had to be designed that is capable of driving the HP M1357A transducer with a 10V peak-to-peak signal at 250 kHz, sensing the load current, and operating from a 5V supply. A bridge driving circuit built with digital 74AC14 inverters running at 250 kHz was found to be capable of delivering the required drive signal with enough power to supply the transducer. The load current is sensed by a 5-ohm resistor in the ground connection of the 74AC14 drivers. Fig. 4 shows the ECG transducer driver circuit.

A major consideration when designing a telemetry system is the power consumption of the transmitter. It runs from batteries and therefore a goal is to make the operating time as long as possible with one set of batteries. The low-power design of the HP Series 50 T transmitter extends the operating time to more than 40 hours of continuous operating with ultrasound and external TOCO transducers connected. The power source is three AA alkaline cells. This is two to three times longer than competitive fetal telemetry systems. When used with NiCd batteries, the operating time is comparable with competitive systems, but the weight of the HP Series 50 T transmitter is only half that of the lightest competitive transmitter.

In addition to weight and operating time, another major aspect of telemetry system design is transmitter size. To get the best use of the available volume, the HP Series 50 T transmitter uses double-sided surface mount technology on the printed circuit boards. This reduces the board space by 40 to 50% compared to single-sided technology and makes the HP Series 50 T transmitter the smallest and lightest of all competitive fetal telemetry transmitters.

Fig. 5 is a block diagram showing all major functions of the transmitter. A microcontroller is the heart of the transmitter. This seemed to be the best solution, considering all of the required features such as Japanese ID code transmission after power-up, nurse call function, serial number handling, analog hardware control depending upon the type of transducer (ultrasound or fetal ECG, TOCO or IUP), battery status, and CRC calculation for every data frame. The microcontroller gives more flexibility than an ASIC and the development time was shorter. With an appropriate controller it is possible to execute the fetal movement detection algorithm in the transmitter, thereby saving transmission capacity of the RF channel by transmitting only the movement detection bit instead of the fetal movement Doppler signal.

Microcontroller Features

We chose the Mitsubishi M37702-M2 16-bit controller. This controller has true 16-bit processing power and many integrated peripheral functions, and is low in cost. It has 512 bytes of internal RAM and 16K bytes of ROM. There are eight independent 16-bit timers. Five of these have their inputs and outputs accessible on pins, can individually select the input clock from a predivider, and can run in several modes including timer, counter, pulse width modulator, one-shot, free-running, or triggered from input pins or software. The controller also has an independent watchdog timer,

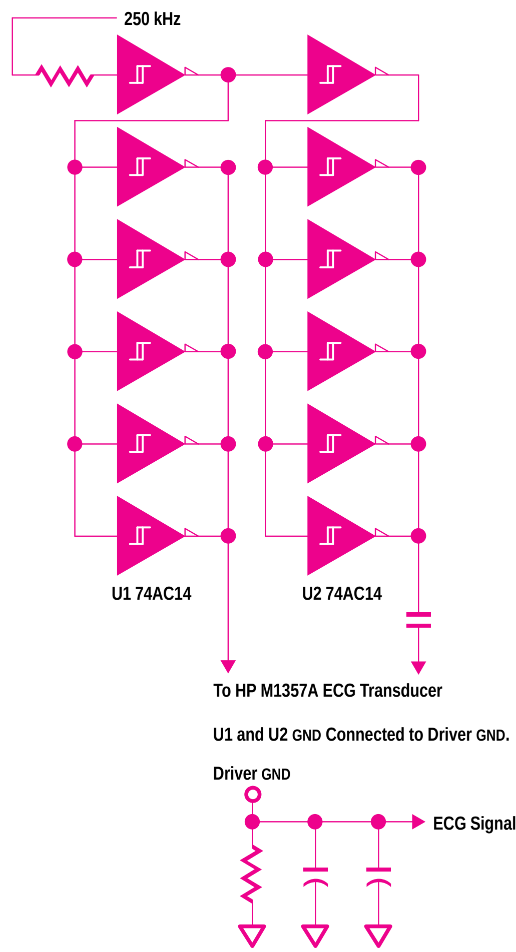

Fig. 4. HP M1357A ECG transducer driver.

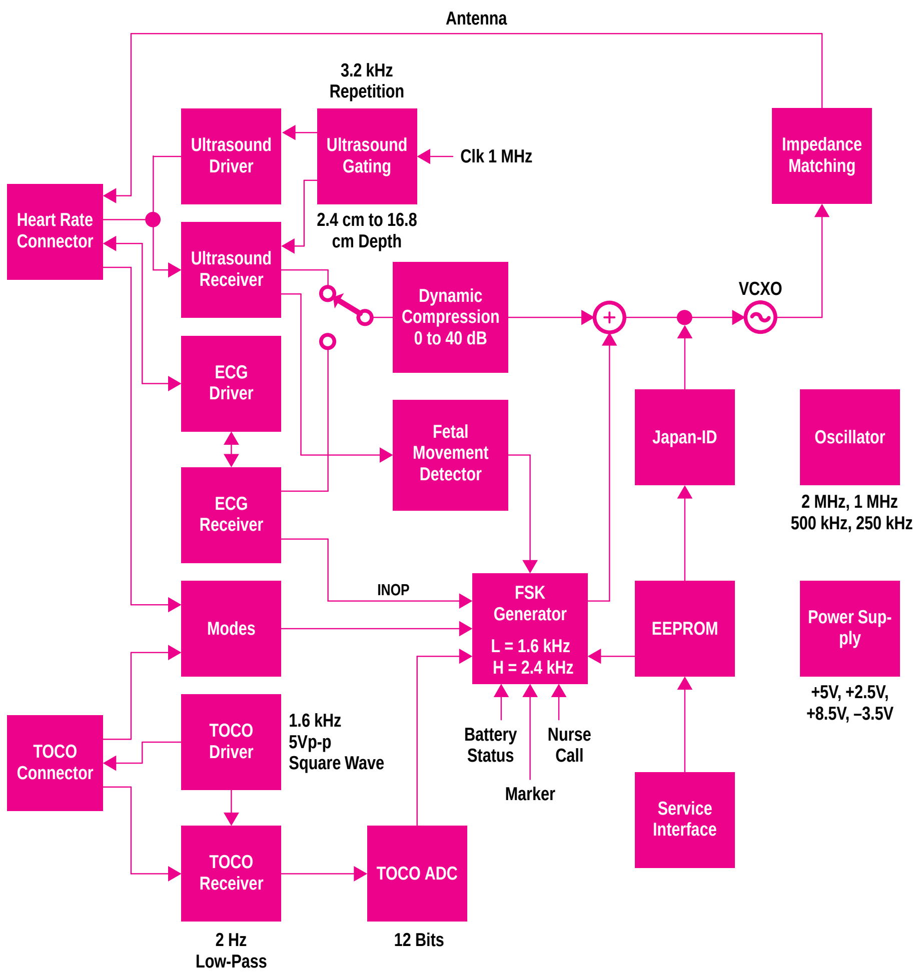

Fig. 5. HP Series 50 T fetal telemetry system transmitter block diagram.

eight channels of 8-bit analog-to-digital converters, and two independent synchronous or asynchronous serial communication channels. The package is a plastic quad flatpack with 80 pins. The rich set of integrated peripherals on the controller chip allowed us to save a lot of hardware that would otherwise be needed outside the controller.

The controller is available with 8-MHz, 16-MHz, or 25-MHz input clock speed. The processing power needed in the HP Series 50 T transmitter allows a reduction of the clock frequency to 2 MHz. When running with the 2-MHz input clock and all peripheral functions active, the M37702 controller consumes only 1.5 mA with a 5V power supply.

Three timers (one in timer mode, two in one-shot mode) are used to produce the gating signals for the pulsed ultrasound Doppler channel. Fig. 6 shows the resulting gating signals. With a sound velocity of 1500 m/s in human tissue, the resulting ultrasound sensitivity over depth can be calculated. The minimum depth is determined by the delay time between the end of the ultrasound transmit pulse and the start of the receive gate pulse, which is t_3 in Fig. 6. With t_3 = 32 µs, $d_{min} = (1500 \times 10^3 \times 32 \times 10^{-6})/2$ = 24 mm. The maximum depth is determined by the time between the start of the transmit gate and the end of the receive gate, which is $t_2 + t_3 + t_4$ = 224 µs. The depth is then $d_{max} = (1500 \times 10^3 \times 224 \times 10^{-6})/2$ = 168 mm. The factor of 2 in these calculations results from the fact that the ultrasound wave propagates first towards the reflecting object located at depth d and then back again to the transducer.

Two timers are used to produce clock signals needed in the ECG amplifier and the TOCO transducer excitation circuitry. One timer is used to produce the 1600/2400-Hz FSK signal. One timer in count mode, together with an external first-order sigma-delta modulator (one comparator and one flip-flop), forms a 12-bit analog-to-digital converter for the uterine activity signal.

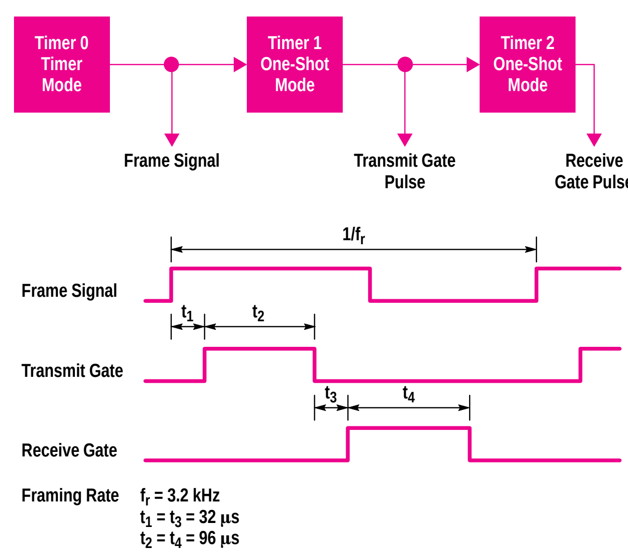

Fig. 6. Ultrasound Doppler gating.

One serial communication channel in synchronous mode is used to control a serial EEPROM to store the serial number, some calibration constants, the country option codes, and the power-up ID code for Japan. The second serial communication port is used as a production and service port to read out internal signals, to program the EEPROM, and to send messages during power-up if self-test failures are detected.

The A-to-D converters are used to monitor the battery voltage, to measure the ultrasound Doppler or ECG signal amplitude to control the signal gain, to measure the fetal movement signal amplitude, and to measure some test voltages during the power-up self-tests.

Uterine Activity Measurement Circuitry

The uterine activity transducers are built with four pressure-sensitive resistors in a bridge configuration. This bridge configuration requires a differential excitation voltage and a differential sensing amplifier. The bridge resistors are in the range of 300 to 1000 ohms. The requirement of compatibility with standard fetal monitor transducers did not allow the use of a new transducer with a higher impedance to reduce the drive power. The IUP transducers are active and need a drive voltage of at least 5Vdc or 5Vac at >1 kHz. The resulting power consumption for the 300-ohm type is then $P = V^2/R = 25/300 = 83.3$ mW.

A circuit can be designed that reduces this power level to 45 mW. The disadvantage is a sensitivity reduction by 6 dB, that is, the sensitivity is halved. This can be compensated by doubling the gain of the sensing amplifier. A 5Vac excitation at 1.6 kHz (half the repetition frequency of the pulsed ultrasound Doppler to avoid interference between the TOCO drive circuitry and the ultrasound demodulator) was chosen instead of a simpler dc drive circuit because low-power operational amplifiers running on 5V or less with high dc precision have not been available for reasonable prices. The labor activity signal, which is a signal with a bandwidth from dc to <2 Hz, is obtained by a synchronous demodulator running at 1.6 kHz and a low-pass filter. By using ac excitation, the sense amplifier can be built with simple and inexpensive TL062A amplifiers.

Fig. 7 shows the implementation of this circuitry. The TOCO excitation applies power (+5V and ground) for the first half of a 1600-Hz square wave (50% duty cycle). During the second half, the excitation drive is switched off. This halves the power consumption of the TOCO transducer resistive bridge. A differential amplifier senses the bridge signal, amplifies it, and converts the differential signal into a single-ended signal. The input capacitors settle to the bridge output voltage during the active drive phase of the excitation driver and discharge to a middle value during the nondriving phase through the bridge resistors, In this way, the sensing amplifier input picks up a 1600-Hz signal with half the amplitude compared to a full-bridge excitation driver. The signals are illustrated in Fig. 8.

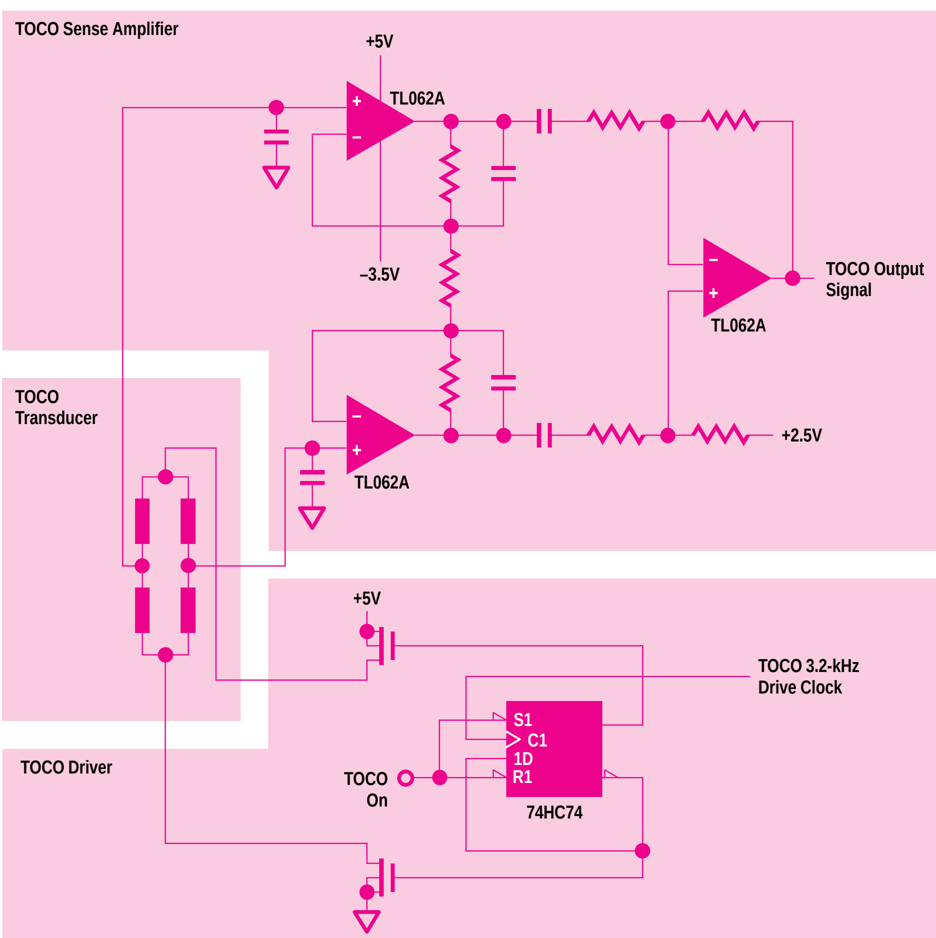

Fig. 7. TOCO driver and sense amplifier.

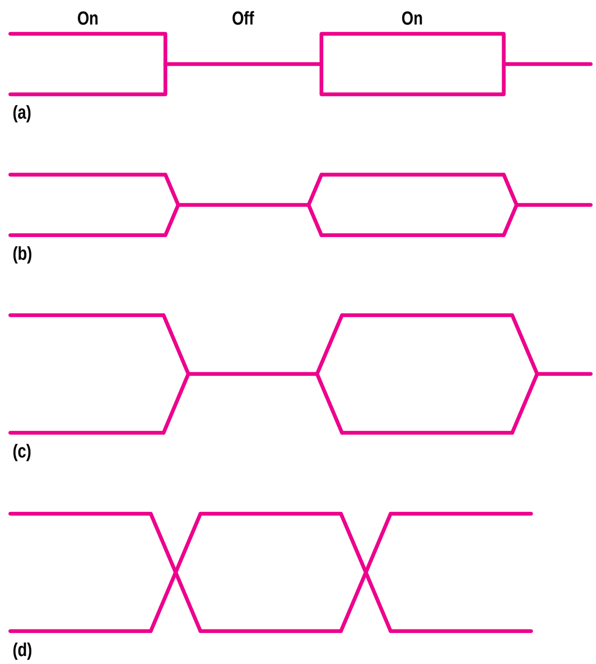

Fig. 8. TOCO signal waveforms. (a) Excitation signal. (b) Sense amplifier differential input (low bridge differential signal). (c) Sense amplifier differential input (high bridge differential signal). (d) Sense amplifier differential input with true bridge excitation.

Power Supply

An essential part of a battery powered handheld device is the power supply. The fetal telemetry transmitter is designed to run with three AA-size alkaline batteries or rechargeable NiCd accumulators. The new and more environmental friendly NiMH accumulators are also supported.

The input voltage is from 2.5 to 4.8 volts. The power supply must provide the following output voltages:

- +5V. Main supply voltage for all digital and most analog circuits
- +2.5V. Virtual ground for 5V single-supply analog circuits
- +8.5V. Supply for some operational amplifiers and the ultrasound receiver preamplifier
- −3.5V. Negative supply for a few operational amplifiers to increase the signal dynamic range.

The power supply is a switched-mode type delivering a stable (±1%) +5V output from the batteries. All other voltages, which need only a few milliamperes, are built with charge pumps or simple buffered voltage dividers. The switched-mode power supply runs at 250 kHz in a pulse width modulation mode. The 250-kHz switching frequency has the advantage that only small inductors are needed. Part of the power supply is also the main crystal-controlled clock oscillator running at 4 MHz. All other clock signals are derived from this master clock. The oscillator and the power supply are designed to start with input voltages as low as 2.0V. The efficiency of the power supply varies between 70% for low (2.5V) input voltages and 82% with a 4.5V input. Fig. 9 is a diagram of the transmitter power supply.

Japanese ID Code

Japanese radio frequency laws require that a special identification code be transmitted every time the transmitter is switched on. The code bitstream is modulated on a subcarrier with a speed of 1200 or 2400 bits/s or is direct FSK or GMSK modulation of the radio frequency carrier signal at 1200, 2400, or 4800 bits/s for FSK and 2000, 4000, or 8000 bits/s for GMSK modulation. The bit rate must be accurate within a tolerance of ±200 ppm. The code is composed of (1) >100 bits of alternating ones and zeros, (2) a 31-bit maximum-length pseudorandom noise code sequence, (3) 51 ID code bits (provided by the regulatory agency, this code is unique for every transmitter and contains information about the device manufacturer and the product, and a unique serial number that has nothing to do with the normal product serial number), (4) a 12-bit checksum calculated from the 51 code bits by a special polynominal division.

In the HP Series 50 T transmitter, this code is stored in the EEPROM during the production final test. During a power-up sequence, this code is read by the transmitter microcontroller and transmitted as a 1200-bit/s FSK signal before starting normal transmission. The code in the EEPROM is also secured by a checksum. If this checksum is corrupted, the transmitter will not start normal transmission as required by the regulatory agency. This feature is only active for Japanese options (also stored in the EEPROM) and is ignored for all other countries.

Modulation Circuits

The modulation circuits have a twofold responsibility. One is controlling the RF bandwidth with its amplitude and frequency characteristics and thus maintaining conformity with RF regulatory requirements. The other is making the best use of the available RF bandwidth to get the best possible signal-to-noise ratio for the transmitted signals.

Fig. 10 shows the modulation circuits. The circuitry consists of three subcircuits: a programmable-gain amplifier, a limiter, and a low-pass FSK shaping filter.

The programmable-gain amplifier adjusts the heart rate signal amplitude to a value that corresponds to 60% of the maximum allowable RF bandwidth. The margin of 40% is to accommodate the often rapidly changing signal amplitude, especially for the ultrasound Doppler signal. The gain of the amplifier is controlled by a regulator algorithm implemented in the M37702 controller. The current signal amplitude is measured with one of the integrated A-to-D converter channels, and from this value an appropriate gain is calculated for the programmable-gain amplifier. This amplifier consists of an operational amplifier with an 8-bit multiplying D-to-A converter in its feedback path. So as not to change the gain too much during one heart period (which could lead to a wrong heart rate calculation for the affected beat), the new gain value is adjusted linearly over two seconds. Therefore, the 40% margin is provided so that the amplifier does not overdrive the signal too often.

The limiter circuit following the programmable-gain amplifier clips the signal to well-defined limits in the case of a suddenly

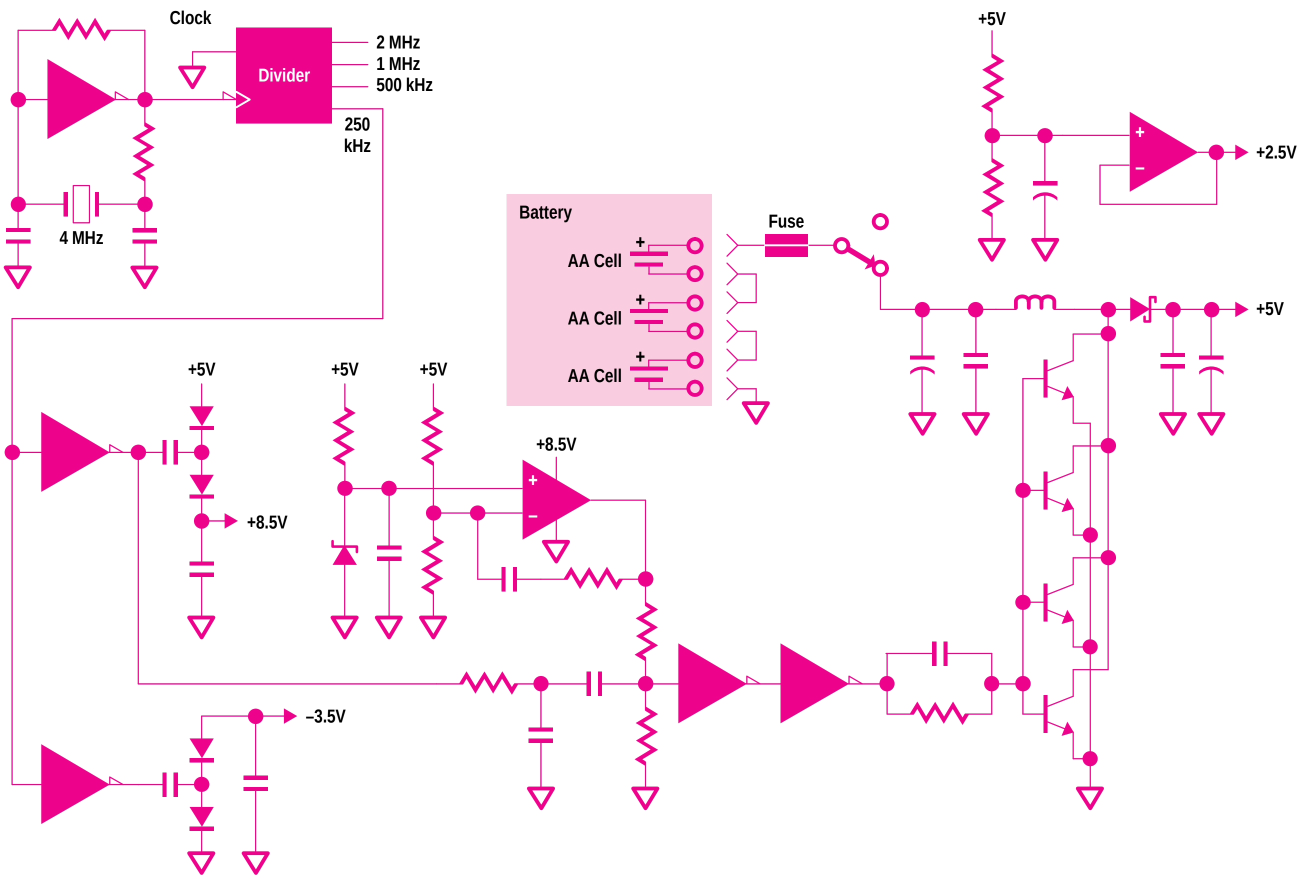

Fig. 9. Transmitter power supply.

increasing input signal to the programmable-gain amplifier. The low-pass filter, which also acts as a bandpass filter and a summing amplifier for the square wave FSK signal, removes the overtones resulting from the clipping and thereby ensures that the modulation has a well-defined RF bandwidth.

Telemetry Receiver

The recovery of the digital bitstream in the FSK signal is the main task of the receiver. The FSK signal is extracted from the composite signal (FSK and heart rate signal) by an analog bandpass filter with 1400-Hz and 2600-Hz corner frequencies. The recovered sinusoidal FSK signal is converted into a square wave by a comparator. All subsequent recovery tasks are implemented in a Mitsubishi M37702-M2 microcontroller (the same type as used in the transmitter).

Digital data recovery can be divided into two main tasks: FSK signal demodulation (recovering the single bits from the 1600/2400-Hz input signal) and synchronization with the

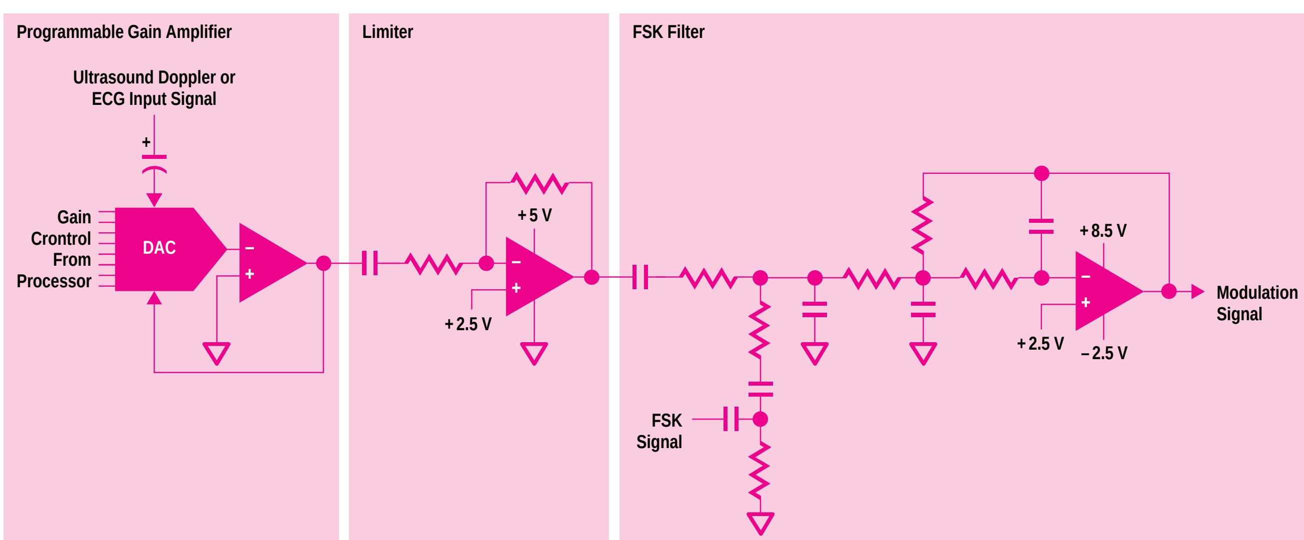

Fig. 10. Transmitter modulation circuits.

transmitted data frames. Fig. 11 shows the FSK signal demodulation scheme, which is completely implemented in the microcontroller.

The pulse period measuring circuitry is composed of two microcontroller timers. The first timer is configured as a retriggerable 250-μs one-shot and the second is configured for pulse period measurement. The incoming FSK square wave signal first triggers the one-shot, which suppresses very short periods between two positive edges in the incoming signal and triggers the pulse period measurement timer. The timer generates an interrupt whenever a new pulse period measurement is complete. For noise rejection, the period values are low-pass filtered and all period values that are outside the limits for a 1600-Hz or 2400-Hz input frequency are rejected. This greatly improves the signal recovery for noisy input signals.

The integrate and dump block sums all of the incoming period values. After five milliseconds, which is one bit time, the sum is reset by a dump signal delivered by the bit clock recovery digital phase-locked loop. Before reset, a comparator decides if the received bit was a logic one or a zero.

The phase-locked loop block recovers the bit clock from the incoming data stream and generates the sample and dump signals, which are phase synchronized with the incoming data clock. Only input sequences consisting of one or two equal bits (bit patterns 010, 101, 0110, and 1001) are used for the phase tracking. The one- or two-bit detector produces a reference signal whenever one of the four bit patterns is detected in the incoming bitstream. The detector measures the time between changes in the incoming period signals and checks to see if this time falls within the limits for one or two bit times (4 to 6 ms for one bit and 9 to 11 ms for two bits).

To extract the individual frames from the recovered bitstream, the structure shown Fig. 12 is used. The recovered bits are shifted into a 50-bit-deep serial in, parallel out shift register, which is the length of one frame. A complete frame can be stored in this shift register and all of its bits analyzed at once.

The header search algorithm looks for a valid header pattern in bit positions 36 to 48. The header pattern is derived from

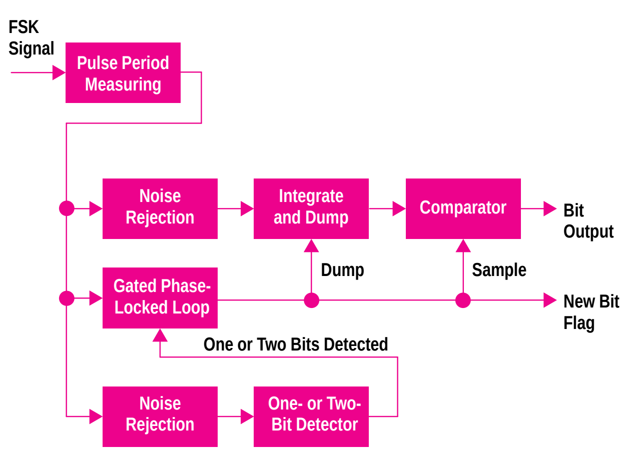

Fig. 11. FSK signal recovery scheme implemented in the HP Series 50 T fetal telemetry system receiver.

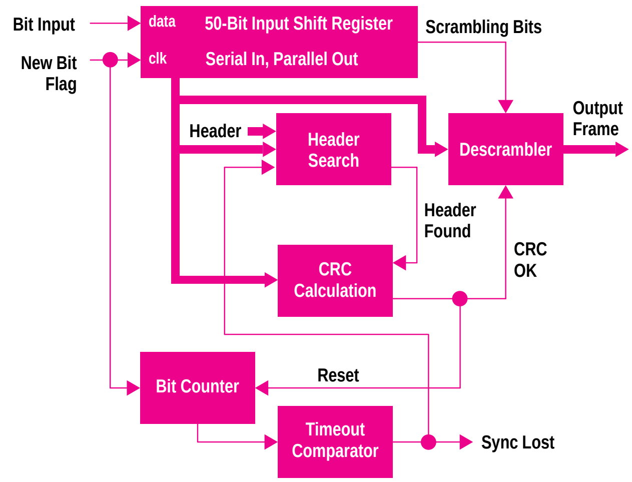

Fig. 12. Data stream recovery in the HP Series 50 T fetal telemetry system receiver.

the system serial number (transmitter and receiver have the same serial number stored in their EEPROMS). Bits 49 and 50 are used to identify whether a frame has been scrambled before transmission. The scrambling is done if the original frame did not contain enough single or double bit patterns for the clock recovery phase-locked loop. The scrambling is done by inverting every second bit in the frame.

If a valid header (original or scrambled as indicated by the scrambling identification bits) is found, the complete frame is checked for a good CRC pattern by the CRC calculation block. If the CRC is OK, the complete frame is deassembled into the original information and saved, the header search is disabled for a complete frame, and a synchronization done flag is set.

If the CRC is not OK for more than two frames, the header search is enabled again and the synchronization lost flag is set. The time since the last correct CRC is measured by a bit counter. If more than 100 bits are received without a correct checksum, the synchronization process is restarted.

Test Strategy

To ensure maximum reliability and safety, extensive self-tests are executed each time the transmitter and receiver are powered up. Not only are the easy-to-test digital parts checked, but also most of the analog hardware. This is done by generating artificial signals, feeding them into the different analog signal paths and measuring the response of each path. All these tasks are performed by the onboard M37702 controllers in the transmitter and the receiver. The results obtained are checked against limits. If any deviation is detected, a clear failure message is sent out over the integrated service port (RS-232 line) to assist in troubleshooting, and the transmitter or receiver tries to restart. This ensures that a faulty device does not go into normal operation and that no incorrect data is transmitted or displayed by the attached fetal monitor. Tests have shown that about 80% of all part shorts or opens are detectable in the analog processing parts. This is a very high number for power-up analog tests. Achieving such a high error detect rate was only possible through the use of a powerful microcontroller. The software for self-test and service support is about 40% of the complete software package.

Production testing of the transmitter and receiver is divided into two parts: single component or board testing before final assembly and final test of the completely assembled device.

The loaded boards are tested by an automatic test system. Connection to the circuitry on a board is made by a needle bed adapter which allows stimulation and measurement of every net and every component on the board. The goal of this test is to verify that all components are loaded correctly and have the right values. If a component fails, the tester reports the component, its location and the detected failure. For surface mount boards, most failures are bad solder joints and shorts between pins. To test complex parts like RAMs, A-to-D converters, microprocessors, and microcontrollers, a library model of the part describing its behavior on predefined stimuli is required. To check for good solder joints, a model that toggles every pin of a component as input or output is sufficient. Unfortunately, such a model was not available for the M37702 controller, which is an 80-pin device in a quad flat package. To test this component, we implemented special software in the controller itself, which can be activated by the test system by pulling a pin to +5V. This pin is checked by the software during the power-up cycle and the special test software is entered if the pin is pulled high. The special software mirrors the input pins to the output pins. The test system only has to apply a test pattern to the inputs and then check for this pattern on the corresponding output nets.

The HP Series 50 T fetal telemetry system uses the same final test equipment as the Series 50 fetal monitors. Most of the final specification tests are similar or identical to the Series 50 fetal monitor tests. Therefore, we implemented a production and service interface identical to those of the fetal monitors. Only a few tests had to be added to cover the telemetry-specific specifications. The test itself is highly automated and controlled by a workstation computer. This computer controls the measurement equipment, performs the measurements, prints the results and stores the results in a database. This allows continuous production process control by calculating the Cpk value (a value that describes the production process capabilities) for each test specification to check the stability of all production processes. This also makes it possible to detect test result drift resulting from part changes before a test result completely fails the specification. This process control procedure is supported by ISO 9001 and EN 46001 certification rules, and it really increases the product quality and stability, which the customer can directly see.

Support Strategy

The HP Series 50 T fetal telemetry system can be used as a standalone unit with a local antenna, or the receiver can be connected to an existing antenna system. When connected to an antenna system the coverage area is increased. The design of antenna systems and the connection of the Series 50 T to an antenna system is the responsibility of HP customer engineers. For standalone systems the system is designed to be installed by the customer (plug-and-play). The acceptance tests needed to ensure proper functionality are built into the firmware and can easily be performed by the customer. In case of any problems the customer can call the HP medical response center. The response center engineer has the ability to give troubleshooting instructions and find the defective assembly.

All of the low-frequency assemblies can be replaced onsite or on the repair bench. The RF assemblies (400 to 500 MHz) can only be repaired on the repair bench because high-precision RF instruments are needed to do RF troubleshooting. Special service software is available to assist in troubleshooting. This software provides check data for transmission, monitors field strength, and transfers serial numbers when needed for repair.

The support features were implemented with minimal effort because the support requirements were discussed with field support personnel and their inputs were considered by R&D in the design phase.

Error Detection and Display

The HP Series 50 T is designed to show any software malfunction through the use of red LEDs in a certain sequence. Hardware failures can be troubleshot by the response center by telephone by following certain procedures and noting the results.

The processor boards of both the transmitter and the receiver run self-test routines after power-on to test hardware functionality and software integrity. After power-on, the receiver switches on all LEDs for one second to test them, and then returns to normal operation. If the power-on test fails, all LEDs stay lit, indicating an error condition. After power-on, the transmitter switches on a red LED hidden behind the positive connection on the middle battery inside the battery compartment. This LED stays on for three seconds, and if everything works it is switched off. If there are any errors this LED stays lit. All this visible information is very helpful to the response center engineer checking for system malfunctions via telephone with the customer. A defective section can be located in a very short time with high accuracy, helping to ensure low cost of ownership for the user.

Troubleshooting Tools

Troubleshooting tools are built into the system to provide an internal error log, reporting on settings and failures. This log can be accessed by software running on a standard PC via an RS-232 connection to the receiver or transmitter. The software log is detailed and includes an interpretation of each error message, so no manual is required.

Should a fetal telemetry system need repair, the software to test the internal functions and do simple troubleshooting is built into the unit. On the repair bench, during onsite repair, or during biomedical testing, it is only necessary to connect the system to a standard PC and start the service software to have the built-in troubleshooting help available. The connection between the PC and the transmitter or receiver is a 3-wire RS-232 interface. All transmitter and receiver responses can be tested. For hardware replacements, such as the transmitter or receiver CPU board, the serial number of the system needs to be written to the new board using the service software. To avoid typing errors, we decided to read the serial number from the nondefective unit (transmitter or receiver) and transfer it to the new unit (receiver or transmitter). In the case of intermittent failures the PC running the service software can be connected to the system and the PC can collect the error log overnight. The service software is designed to be totally self-describing with all reported messages interpreted, thereby avoiding error codes, which require error tables to find the problem description. The main screen of the service software shows the following information:

```
* * * * * M1310A Service Software Rev.A.01.0   * * * * *
*                   M A I N   M E N U                   *
*          ~ Program S/N to Transmitter                 *
*          ~ Program S/N to Receiver                    *
*          ~ Power On Selftest                          *
*          ~ Show last errors/warnings                  *
*          ~ Check Transmitter                          *
*          ~ Check Receiver                             *
*          ~ Read SerNum and Revisions                  *
*          ~ Reset Serial Number                        *
*          ~ Read country information                   *
*          ~ EXIT                                       *
*                                                       *
* * * * * * * * * * * * * * * * * * * * * * * * * * * * *
*         Select with <up>, <down>, <enter>             *
* * * * * * * * * * * * * * * * * * * * * * * * * * * * *
```

The following represents the first screen to program the serial number to the transmitter:

```
* * * * * M1310A Service Software Rev.A.01.00 * * * * *
*               Program S/N to Transmitter              *
*                                                       *
*          ~ follow the steps <ENTER>                   *
*    = >  (1)    plug cable to RECEIVER                 *
*         (2)    READ S/N from RECEIVER                 *
*                RCVR-S/N is : ..........               *
*         (3)    plug cable to TRANSMITTER              *
*                checking XMTR-S/N                      *
*         (4)    WRITE S/N to TRANSMITTER               *
*                XMTR-S/N is : ..........               *
*                                                       *
*          ~ Return to MAIN                             *
* * * * * * * * * * * * * * * * * * * * * * * * * * * * *
*          Select with <up>, <down>, <enter>            *
* * * * * * * * * * * * * * * * * * * * * * * * * * * * *
```

The user is guided step-by-step through the program; no manual is needed.

Installation Acceptance

After installing the fetal telemetry system the performance of the system should be tested. The installation acceptance test is built-in. Overall transmission between the transmitter, receiver, and fetal monitor is checked by creating a synthetic signal. This is a simple operation that can be done by the customer.

The synthetic signal for the acceptance test is generated in the transmitter and shows a test pattern on the fetal monitor. One heart rate transducer and one TOCO transducer can be connected to the transmitter, and the acceptance test gives the appropriate output for the transducers connected. The acceptance test is started by pushing and holding down the nurse call button while switching on the transmitter power. The test runs as long as the nurse call button is pushed. On the fetal monitor a heart rate is measured and a TOCO triangular waveform shows the proper functioning of the overall system. This acceptance test verifies the overall transmission from the transmitter to the receiver via radio frequencies and the transmission from the receiver to the fetal monitor via cable connection. If all the signals are transmitted as expected the fetal telemetry quality is acceptable.

The acceptance test is designed to avoid any need for external test tools or measurement equipment. Because it is easy to perform and no external equipment is needed, this test helps save installation costs and reduces cost of ownership.

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