All: PETER SPAVIN *30/06/99*
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FEOTAL SIMULATOR RESEARCII

1. Design oftestjig to evaluate the possibility of using existing water-soluble gel to couple the movement of a Mylar speaker diaphragm to the ultrasound transducer of a foetal monitor under test.

a. Design of suitable control and drive electronics to prove the above principle.
b. Sourcing of required materials
C. Design and production of a PCB for the above circuitry.
d. Assembly and testing of the above unit.

The above unit was assembled and tested using a standard foetal monitor as used in hospitals. (14 Hours) It was found that a coupling/affenuation medium was required in addition to the water-soluble gel to correctly interface with the foetal monitor.

Various manufacturers of silicon sheet were contacted via telephone and their literature was requested. as it was thought that this would be the best material to ~lfil this role. Samples of the varioLls grades of silicon were requested and evaluated with the above mentioned testjig. Also existing silicon compounds readily available on the market where moulded and evaluated as a coupling/attenuation medium. The outcome of the evak~ations was a silicon sheet of type (**********) available from (**********). (10 Hours)

Ti was found that the water soluble gel used to couple the speaker movement degraded quite quickly and resulted in a liquid which was of no use as a coupling medium. An alternative coupling medium was required which maintained its coupling properties indefinitely and did not degrade. Evaluations were performed on the following gel (**********) and this was found to be satistactory. (2 hours)

The testjig was extensively evaluated with the above materials and found to produce controllable pulse rates and amplitudes on the foetal monitors under lest. (4 Hours) More extensive investigation of this method resulted in us finding that the pulse rates detected by the foetal monitors were not due to physical movement of the speaker diaphragm but were due to radio frequency coupling from the speaker coil to the ultrasound transducer. This was investigated fi~rther and it was found that the pulse waveform produced by the dnve electronics and used to drive the speaker was distorting at the rising/falling edge and producing radio frequenc~. harmonics which were being coupled to the transducer under test through the air. The circuitly was adjusted to damp these harmonics and the test jig re-evaluated. It was then found that the movement of the speaker diaphragm, which contained the gel coupling, was not enough to be detected by the foetal monitor. Hence this method was abandoned. (6 Hours)

2. Evaluation of source crystal transducer driven with 3MHz carrier wave and frequency modulated about this mean frequency. Note: The foetal monitor under test uses a carrier frequency of 3N.I~1z.

a. An ultrasound transducer of the type used on foetal monitors was coupled to the monitor under test's transducer using standard water-soluble gel.
b. A signal generator capable of producing a 3MHz sinusoidal carrier wave with varying frequency modulation about this nominal frequency was used to drive the source transducer.
c. This experiment was set tip and evaluated to see if it would produce the necessary pulse rates on the foetal monitor. ~e depth of frequency modulation was varied in the source transducer.

The above evaluation was performed and it was noted that a pulse rate could be registered on the foetal monitor under test. It was obsened that the monitor under test interpreted this frequency modulated carrier as a Doppler sllif~ in it's own transducer and registered this as a foetal pulse rate. However on closer inspection it was found that this phenomenon was again due to air coupling and did not warrant a tri~e physical foetal movement, therefore it could not be used as a true test of foetal iii onitors in hospitals. (4 Hours)

The above research made it obvious that what was required was true physical movement mechanically coupled to the transducer of the monitor under test

3. Evaluation of a cam driven svstem coupling physical movement to the unit under test using the above coupling medium (**********)

a. Design of a motorised cam driven system.
b. Sourcing of suitable materials
C. Construction of the above system using a geared DC motor cam, movement plate, coupling chamber and housing.

The above experiment was constn~cted and this method was evaluated. It was found that the foetal monitor under test registered a heart rate, which was indeed due to simulation of physical movement. Van mg the RPM of the DC drive motor could van~ the heart rate. The only problem with this method was that the foetal heart rate could not be accelerated or decelerated and the depth of movement could not be varied.

It is of paramount importance that foetal monitors be checked for their ability to register accelerations and decelerations. Also it is desirable to be able to adjust the amplitude of physical movement and hence detemi inc the sensitivity 0£ the monitor under test. Therefore this experiment showed the possibility of simulating a foetal heart movement but with the limitations above. (8 Hours)

4. Because of the problems encountered with containing the coupling gel as used above it was decided to research and investigate alternative gel mediums which would not he so ditticult to contain.

a. Various mamifacturers were approached by telephone and the possibili~ of the supply of a semi-solid inert gel was discussed. These manufacturers did not have a gel with these qualities available.

b. An Internet search was performed for possible gel suppliers but with disappointing results. (6 Hours)

c. It was observed that a possible suitable gel was used in existing product's on the market, one of these products was purchased and disassembled the resulting gel was then prepared for extensive evaluation.

5. Evaluation of the discovered semi solid inert gel.

The Gel was cut in to a circular disc and placed over the transducer of the monitor under test. It was observed that small movements of a metal disc placed on top of the gel and placed directly opposite the test Iransducer where detected bv the monitor under test. These movements produced a good simulation of foetal heart wall movement without the disadvantages of the other type gels, which need to be contained because of their ~uid nature. It was decided that this type of gel would be ideal as the coupling medium for the foetal transducer. The manuf~cturer of this gel was contacted in the LSA and the possibility of suppk and custom moulding of the gel was discussed, the response was favourable. A method was needed to provide electricallv controllable movement of the metal disc coupled to the transducer of the monitor under test, inctuding the ability to provide accelerations and decelerations of these movements. (3 Ilours)

6. Research in to possible linear transducers to provide the required controllable movement.

a. Various manufacturers were approached via telephone and the Inten~et. ~e possibili~ of a suitable linear transducer was discussed with them and relevant information was requested and evaluated. (15 Hours)

b. Most of the devices investigated were found to be unsuitable mainly because of the size of the units and the inherent complexities of coupling them to the metal disc and gel.

c. One distributor in the UK had within his range a set of devices available from a U.S niamifactiirer. These devices were of small size and provided controllable movement. The distributor was re-contacted and the use of a suitable device was discussed, a sample of this linear actuator was requested.

7. Design of a testjig including basic dnve electronics and adjustable housing tor the linear actuator gel etc.

a. The materials for the test jig were sourced and a suitable jig was constructed including a means of adjusting the depth of gel between the movable plate and the transducer under test. Suitable basic drive electronics were constructed and tested. (Variable pulse counter stepper dnver + signal generator) (~ hours)

b. The jig was evaluated with a foetal monitor and it was found that noise was generated when using a multi pie number of steps to move the actuator this was unsatisfacto~:
and could not be used as representation of a foetal heart wall movement. However

when using only one step forward and one-step back~ the monitor tinder test detected this movement as a pulse rate. ~lie rates of forward/back movements were accelerated/decelerated using the signal generator and the ability of the foetal monitor to detect these variations was tested. It was found that an acceleratioty'deceleration threshold existed where the monitor under test would not record the heart rate. Ihis provided a qualitative test of the monitor~s limitations regarding the detection of these important variations. I~e monitor under test was ntn over 24 hours and the long term trend detection was evaluated using a ramp up in heart rate and a ramp down in heart rate. The charts obtained were examined over this full test period and found to be excellent. (12 Hours).

c. Due to the noise limitations of this acttiator. (One forward' one back). It was decided to investigate an aettiator with a much smaller step movement and the ability to be micro-stepped. This would hopefully reduce the noise to acceptable levels when using multiple step drive and would enable control of the amplittide of heart wall movement simulation.

d. The distributor of the evaluated actuator was again approached and a more precise actuator was imported and purchased from them.

7. Evaluation of precise micro-stepping linear actuator.

a. Research and study in to the principles of micro-stepping linear actuators.
b. Collection of information relating to micro-stepping (contacting manufacturers and requesting information using the telephone/intranet) and associated drive hardware. (30 1 lours)
c. Design and construction of suitable drive hardware. (3 Hours)

d. Design of suitable microprocessor interface hardware (using existing simulator PCB). (3 Hours)

e. Design of suitable microprocessor sof~vare code to enable controllable micro-stepping ofthe linear actuat()r.(~0 hours)

f. Experimental testing ofabi)ve system on foetal heart monitor. (12 Ilours) Conclusions of in icro-

stepping system.

Even with micro stepping selected, it was found that the motor noise still influenced the foetal monitor under test and even though the monitor responded correctly,. this was due to the noise rather than the movement. This was proven by placing the monitor transducer in various positions relative to the stepper dnve (including at the side of the stepper drive). Ihis result was unacceptable, as the actual movement of the foetal wall is the desired parameter to be simulated.