DYNAMIC CENTRE OF MASS INFANT BREATHING MONITOR- THE DCOM APNOEA MONITOR.

Dr. H. Holden 2013.

Background:

This article describes a unique type infant breathing monitor.

While studying Grant's Anatomy as a medical student I noticed the remark that infants are primarily diaphragmatic breathers. It dawned on me that with an infant lying flat that there would be a centre of mass shift on the horizontal axis parallel to a mattress surface, simply because the air filled lungs and the chest cavity have a lower density than the abdominal contents.

Also this shift in centre of mass would be proportional to the tissue mass displaced and that would be proportional to the depth of each breath. Also as the mass shift was perpendicular to the gravity field, other forces related to infant motion and environmental vibration would be cancelled from the derived signal.

If the centre of mass was detected the derived signal magnitude would become completely independent from any objects of any size, shape or consistency placed between the infant and the sensor system in the mattress because these do not alter dynamic centre of mass shifts, only the total static mass.

This is not the case for any other type of non contact infant breathing monitor. Force detecting monitors types, or microphone (sound) detection types of monitor are affected by the thickness and consistency of the materials between their sensor and the infant because energy is absorbed in this pathway. Also the signal amplitude information (data) in all other kinds of non contact breathing monitor becomes relatively useless for respiration and minute volume assessment and only the breathing frequency spectrum data is preserved. However for accurate breathing monitoring, without false alarms, both the amplitude and frequency data must be measured accurately and in fact multiplied together to yield the minute volume.

I was also aware of technical problems associated with standard non-contact breathing monitors such as the capacitance pad where the signals it acquires is very variable in level and the result is false alarms. An infant could be breathing shallowly with a high rate or deeply with a lower rate and still be ok but the movement or pressure sensing pad could not use the signal amplitude for any reliable purpose, only the signal or breathing frequency has any application.

What was needed was a "derived signal" that was proportional to the depth of each breath and not affected by objects placed between the detector in the infant's mattress and the infant. This way the signal amplitude (or tidal volume) and frequency or breaths per minute (breathing rate)

could also be multiplied to create the wanted measured variable which is the "minute volume" (volume of air breathed per minute by the infant) as this is the variable which needs to be measured to compare with an allowable reference value before sounding an apnoea alarm.

I abandoned any contact method to detect breathing as wires/tubes etc are too hazardous in the infant's crib.

I had also been interested in infant breathing monitoring as I was nearly a SIDS baby myself, my mother discovered me not breathing, unresponsive and cyanotic looking in my crib. Luckily for me she had only recently been on a first aid course and learnt CPR and she obviously got to me in time. I was hospitalised for a while after that and recovered with no damage, so the doctors said.

I designed and built the Dynamic Centre Of Mass (DCOM) breathing monitor and trialled it with a ventilated "artificial infant" and also trialled it with real infants in the Neonatal Unit of the National Women's Hospital in NZ in 1989. This was the subject of my 6th year elective as a Trainee Intern. My Preceptor Dr. Stephen Wealthall also had a custom designed computer where the many hours of breathing recordings (recorded on a slow speed Tanberg Tape Recorder) could be analysed.

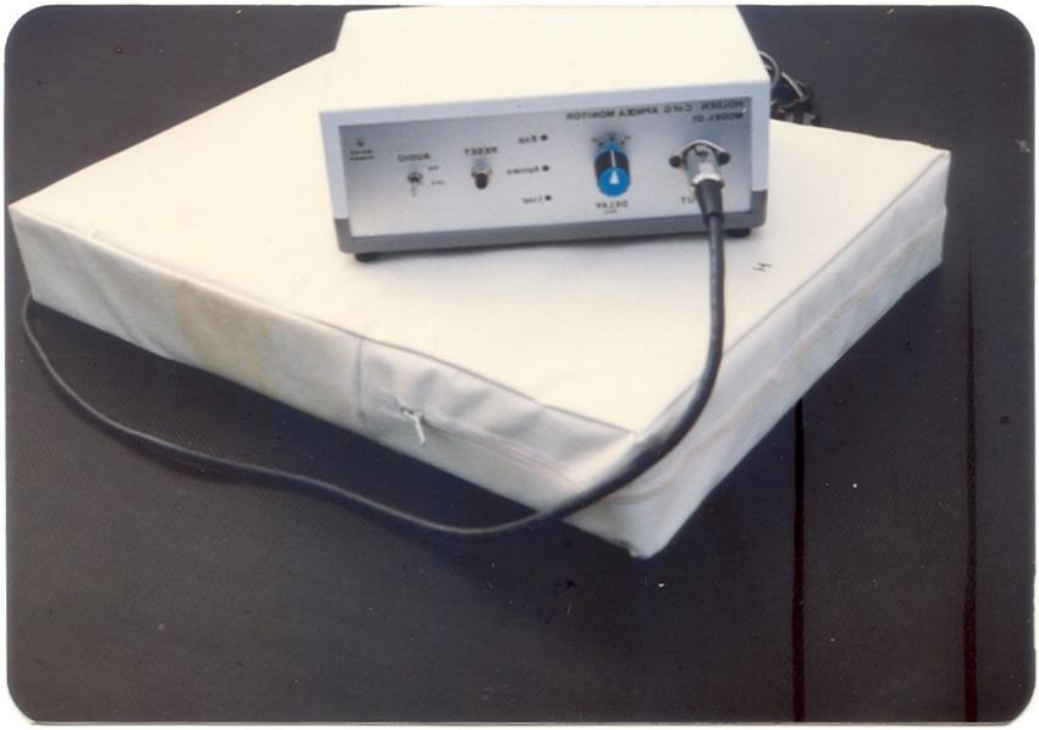
When the project was complete I took it to the Director of the COT Death Society in Auckland in 1989. She told me the society was little interested in breathing monitoring (although they were using a system of attachments with nasal prongs for high risk cases) and the money that was raised by the society was earmarked for research into the causes of cot death. I argued that it might be some time before all the causes were known and with good false alarm free monitoring some lives could probably be saved. My thinking being that if the baby stops breathing it is better to know about it and try to do something about that in the first few minutes, rather than finding the baby lifeless 4 hours later. Somewhat discouraged by that I went on to pursue my usual medical studies and became an Ophthalmologist. However I put my monitor to good use at home:

I used the monitor on two of my daughters for the first 18 months of their lives. During this phase two features were added. My wife quickly noticed it was difficult to remember to switch the unit off and on. If the baby was taken out of the crib the monitor would alarm after 30 seconds depending on where the apnoea timer was set. Also if it was forgotten to put the alarm back on after the baby was returned to the crib it would serve no purpose. She asked if it could be made automatic. It was a very easily modification as not only was the dynamic centre of mass signal available by subtraction of the sensor data, but by addition of the data it could easily be determined if the baby was in or out of the crib, so simply the alarm was inhibited automatically when the baby wasn't there. This meant the monitor could be forgotten about for daily use, it was quite a remarkable improvement. One daughter had event free monitoring (zero apnoeas)

while a greater than 30 second apnoea occurred with one daughter, but the load alarm appeared to wake her up.

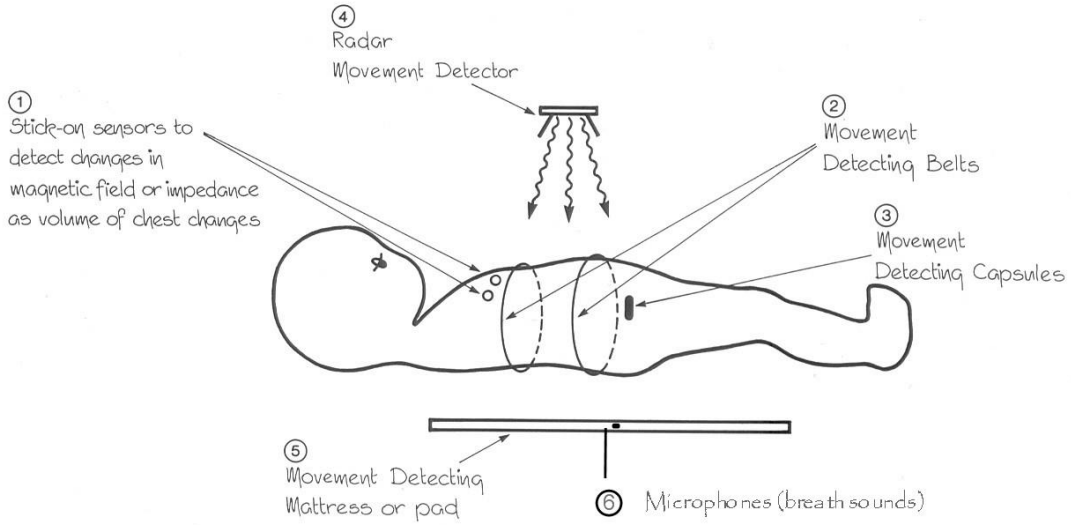
Another modification involved sending the output from the monitor to the master bedroom as two LED's which would light on inspiration and expiration alternately and this was very comforting to see in the night when one was wondering if the baby was ok. The state of sleep or wakefulness of the baby could also be seen because with quiet sleeping the expiration & inspiration timing is very regular.

Further modifications included additional sensors to allow for any infant rotation in the crib and a digital minute volume readout. However the basic DCOM principle remained the same. The following images are scans from my elective report relating to this project. Initially a photo of the control unit and the mattress that went in the bottom of the baby's crib:

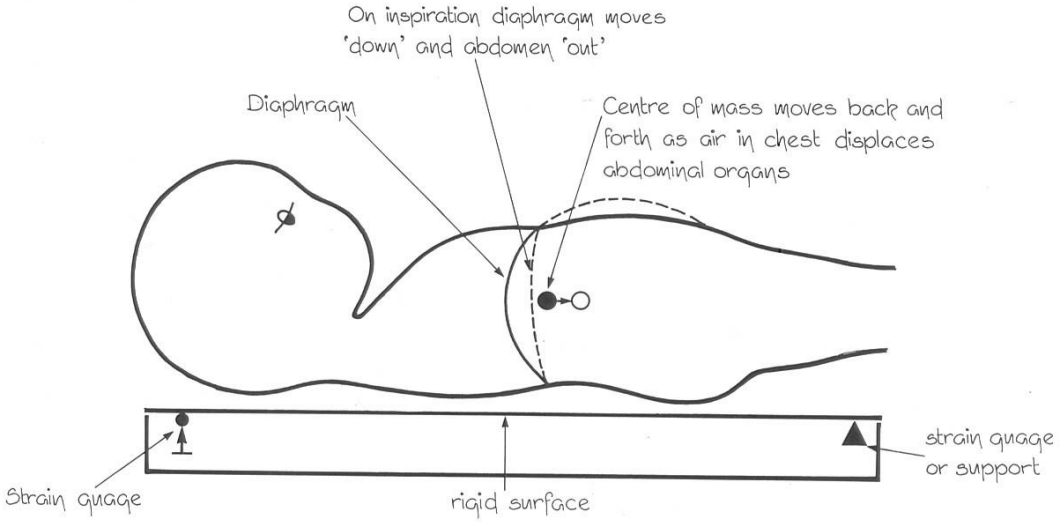


The following diagrams indicate some of the features. All of the details are in the report.

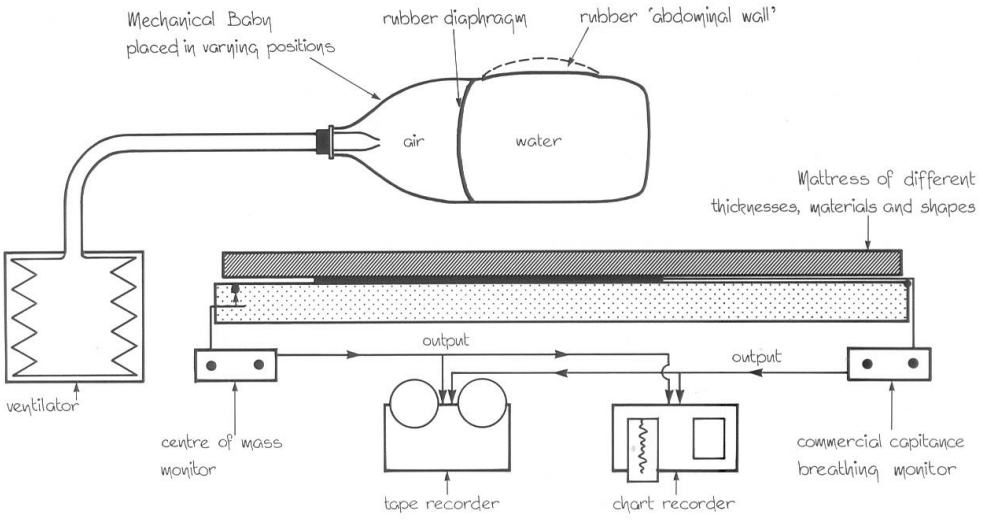
PRESENT METHODS OF MONITORING BREATHING PATTERNS IN INFANTS WITH ABNORMALITY OR RISK OF COT DEATH



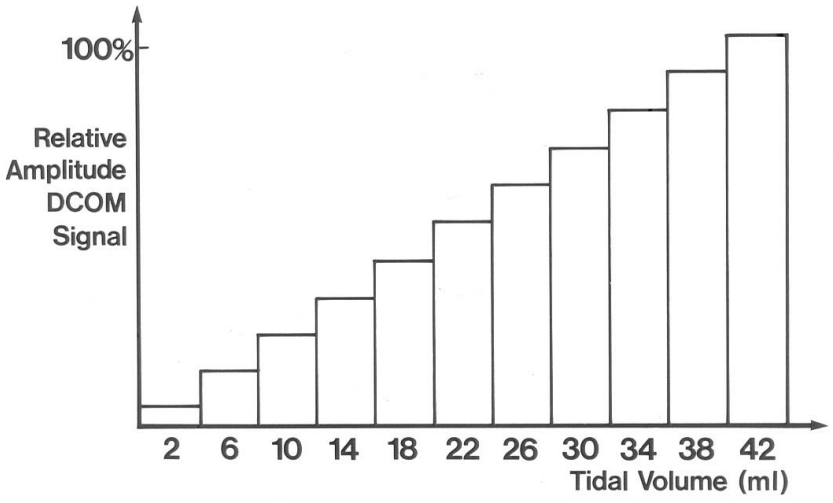
DYNAMIC CENTRE OF MASS BREATHING MONITOR

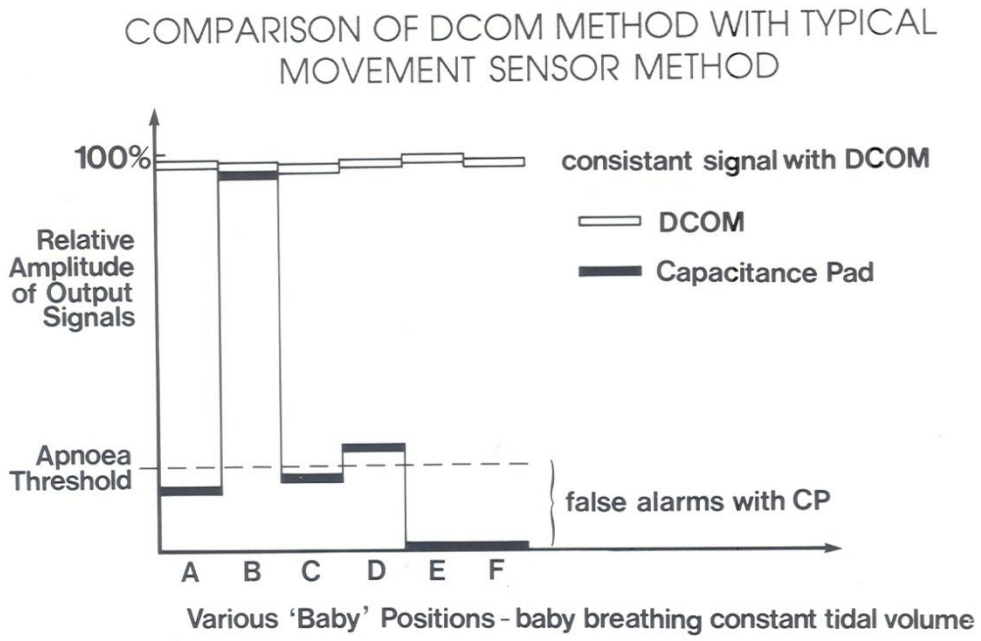


TEST BED FOR EVALUATION OF DYNAMIC CENTRE OF MASS BREATHING MONITOR



DYNAMIC CENTRE OF MASS SIGNAL AGAINST TIDAL VOLUME





The following is a scan of my elective report which should still be on file in the Auckland Medical School Library:

TRAINEE INTERN
ELECTIVE REPORT

HUGO R HOLDEN

A NEW METHOD OF MONITORING INFANT RESPIRATION

Supervisor - Prof R Norris
Preceptor - Dr S R Wealthall

FIRST QUARTER 1989

1) Copy of my Trainee Intern Elective Report.

A) A brief abstract of the project.

B) A report on the project, and conclusions .

C) A detailed physical science analysis of the DCOM monitor with supporting experimental results , and models of breathing to analyse monitor function.

D) A comparison of two monitoring methods , the DCOM monitor and the conventional movement sensitive monitor. (also contains experimental results)

E) A photograph of the prototype apparatus , contained with this copy:

YES

NO

F) Copy of two articles from Devices and Diagnostic's Letter.

H.R. HOLDEN : ELECTIVE REPORT 1989

ABSTRACT: A NEW METHOD FOR MONITORING INFANT RESPIRATION

This elective is a self-generated research project carried out at the National Women's Hospital - evaluation of a new method for monitoring infant respiration.

In early 1988 I designed and built a new type of infant breathing monitor (apnoea monitor) which deviated entirely from the principles upon which existing apnoea monitors operate. The motivation for the design and construction of the new apparatus was derived from the knowledge of the problems associated with existing monitors. The design of the new apparatus was intended to overcome the significant problems of the existing monitors.

The purpose of the elective was to evaluate the new method of monitoring breathing by individual assessment of the new monitor and by comparison with existing monitors.

For this purpose a biomechanical model of an infant was construc ted and driven by a ventilator machine to act as a contro lled signal source. An electromechanical servosystem (robot) was constructed to generate specific characteristics of motion, and infants on existing apnoea monitors on ward 11A at National Women's Hospital were simultaneously monitored with the new monitor. Data was recorded on magnetic tape and paper chart for analysis.

Experimentation and evaluation of the conventional monitor system popular in New Zealand, the movement sensitive pad (electrical capacitance pad) reveals that both the magnitude and the waveform of the signal they derive is inconsistent and unreliable.

The conventional non-invasive monitors (nothing attaches directly to infant) and most invasive systems (aside from intubation or plethysmograph or barometric chamber) are unable to determine if the infant is hypo or hyperventilating as the information required, tidal volume multiplied by breathing frequency cannot be determined with any precision. The same lack of precision applies to the detection of apnoea.

The design concept of the new monitor was to derive in a non-invasive manner, a signal closely related to the tidal volume, and moreover use a signal transduction method which is not significantly influenced by variables such as infant position, mattress thickness, consistency and volume of bed clothes etc. This would mean that an estimation of minute volume could be made, and apnoeas could be reliably indicated.

Both theoretical analysis and practical experimental results show this has been obtained. The new monitor achieves this by measuring dynamic centre off mass shifts in the horizontal plane while the infant is lying.

Technical descriptions with experimental results are appended to the elective report.

The results of this study open up wide areas of research possibilities, as this type of new monitor, the DCOM (dynamic centre of mass) monitor could also be a useful diagnostic tool.

A NEW METHOD OF MONITORING INFANT RESPIRATION

My elective at National Women's Hospital was spent researching the properties of a new type of non-invasive infant breathing monitor (which I designed and built in 1988) and researching the characteristics of existing non-invasive breathing monitors (apnoea monitors) in routine use in the Neonatal Intensive Care Unit.

This work involved the construction of a biomechanical model of an infant driven by a mechanical ventillator , an electro-mechanical movement/force generating mechanism (robot) and the simultaneous use of the new monitor and existing monitors on infants in the intesive care unit .(Ethical Committee permission obtained, and information and consent forms were provided to parents) .

The basis of the study was to determine the functional properties of the new system of monitoring infant breathing and the function of the existing systems, by way of individual assessment and comparison.

Data was collected in two forms:

1. on dual channel magnetic tape (while monitoring infants simultaneously on the new monitor system and existing conventional system)

2. directly onto paper chart when using the biomechanical model and the robot.

The tape recorded data, which may have consisted of 20 minutes to 8 hours recording of a breathing infant was also selectively transferred to paper chart for analysis.

Background to the design of the new monitor system:

Medical instru mentation can always be improved and upgraded, and one area where this is especially so is in the instrumentation available today for monitoring infant breathing, and detecting infant apnoea.

The FDA is in the process of setting standards for these instruments because, "a lot of apnoea monitors don't work[1]." This article also states how John Yount, co-chairman of an apnoea monitor standards committee of the American Association for the Advancement of Medical Instrumentation (AAMI) cited a study of 12 apnoea monitors, some of major manufacturers, ranked low in detecting apnoea, the worst being correct 38.8% of the time, the best correct in 98.4% of the time. Presently there are no mandatory standards for apnoea monitors and manufacturers often never provide performance characteristics of their equipment. The National Institutes of Health panel urged in 1986 that the manufacturers should provide performance data, and that new low cost equipment needs to be developed[2].

A large range of different types of apnoea monitor have been designed and tried over the past two decades. Each has their own characteristic problem. I broadly divide these devices into two groups; "invasive" and "non-invasive". This means direct contact to infant (e.g. wires/electrodes, nasal prongs, tubes, stick-on sensors) = invasive systems, and remote detection systems, (movement sensitive mattress for baby's crib, movement sensisite pad to be placed beneath infant's matress. A radar system was once used. These are non-invasive systems.

In general it might appear , that the invasive monitors would be best at providing good data, however the popular Transthoracic, Electrical Impedance Monitor (electrodes attached to the infant's body), 'the gold standard' in a system of no standards is known for false positive = false alarms, and false negative = not alarming when infant is not breathing[3]. Other invasive monitors, e.g. the stick on movement sensor (pressure capsule) are attached to the infant's abdomen and detect local movement. The signals derived are dependent on the location they are placed, they are sensitive but non specific for breathing movements. The nasal prongs detect nasal air flow, the proportion of which may vary with mouth breathing. The point being that attachment of a device to an infant (except an endotracheal tube) does not necessarily allow for accurate and consistent detection of breathing. All of the invasive monitors represent a danger to the infant; straps, tubes, wires have potential to harm the infant, and need to be connected/reconnected if the infant is to be cared for normally. In the uncontrolled home environment invasive monitoring is much more dangerous. (There is data in the literature on hazards, e.g. reported electrocution.) The non-invasive monitor allows a totally 'free' infant, not attached to a device. Of the systems described, the radar method proved of little practical value, and the methods of non-invasive monitoring available consist of movement detectors, in the form of a movement sensitive pad to be placed beneath the infant's mattress, or a movemet sensitive mattress. A version of the movement sensitive mattress popular 10 years or so ago consisted of a mattress containing air channels. Infant movements, e.g. those of breathing cause local pressure changes on the mattress surface and caused small air currents to flow, and these were detected by a small thermistor bead. these fell into disuse for various reasons and the popular device used now is the movement sensitive pad (the electrical capacitance pad). These consist of a laminate of electrically charged metal plates in a compressible casing. Electrical potentials are generated when the structure is compressed (or its geometry alters) because of the change of electrical capacitance.

The movement sensitive pad (capacitance pad) is the most widely used non invasive breathing monitor method in New Zealand. these devices are sensitive to local movements of the infant which generate pressure on the pad to generate a signal. The amount of signal produced by them depends on the material, bedclothing, mattress material, infant clothing, both the position in which they are placed with respect to the infant, and on the anatomical position of the infant.

For example, with a supine infant (most breathing movements away from the mattress as the ventral surface of the infant's abdomen moves up and down with breathing) and thick mattress materials and bedclothing between the infant and the pad, the pad may not be influenced enough by the movements of breathing for the monitor to detect a signal. On the other hand, with the infant lying on its side or prone, large amounts of pressure change are coupled to the pad as the infant's abdomen is better coupled to the pad mechanically. Therefore, the electrical signal provided from the movement sensitive pad (or any other local movement detector) varies considerably in level with the factors mentioned above, and is in <u>no way quantitative</u> with respect to actual infant breathing.

<u>Why is this a problem</u>? - because to indicate that an infant is not breathing adequately a threshold level of signal amplitude is required to be defined below which the signal is deemed not to be present so as to ultimately sound an alarm. When non-specific factors such as infant position, bedclothing mattress material and thickness cause massive alterations of level there are <u>usually two outcomes</u>:

(1) the breathing movements coupled to the movement sensor pad are small, the infant in quiet breathing does not result in sufficient signal, therefore the signal falls below threshold and the monitor alarms after the set period = false alarms. False alarms are frequent with this type of pad, largely for this reason. False alarms place incredible stress on the caregivers of the infant, make monitoring in the home situation intolerable, and in the hospital situation difficult.

(2) the breathing movements coupled to the movement sensitive pad are excessive, e.g. baby physically close to sensor lying prone on it, with a thin mattress (or no mattress) between the infant and the pad. (Due to the frequent false alarms, caregivers often place the pads directly beneath the infant; especially the small infants in the intensive care unit, to gain more signal pick-up and less false alarms). However in this operating mode, even the smallest of infant movements, not even necessarily related to breathing, generate a large signal due to better mechanical coupling between the infant and the pad. This is frankly dangerous to the baby, as the baby may become thoroughly asphyxiated long before it becomes totally motionless and all mechanical movements fall to zero and the alarm sounds.

In summary then, the movement detector is not a satisfactory device for reliably detecting apnoea, (despite the fact that the manufacture and supply of these devices to hospitals and the community worldwide is a multi-million dollar industry). Essentially they are not scientifically sound. It is not possible to calibrate them, because a given movement of the surface of an infant is not specific to breathing tidal volumes. A variable mechanical coupling to the pad caused by infant position and material around the infant further affects the detection process. Not only that but the mechanical construction of the pad is such that its electromechanical properties are altered by local pressure and material around the infant. It is not surprising therefore that manufacturers of these devices are not forthcoming with performance data.

The fundamental problem with the movement sensitive method of detecting breathing: the information that is really required to monitor infant breathing is not available by movement sensitive methods. This information is the product of depth of breathing (tidal volume) and breathing frequency. It is this that determines the minute volume of the infant. If the level of the signal derived is variable, and not consistently related to tidal volume (as in movement sensitive methods including most "invasive" methods), then even if the breathing frequency is derived with some accuracy the information is inadequate. Manufacturers of monitor systems have tried to get around this to a degree by building in algorithms which pick up significant differences in interbreath interval, or count the number of "missed" breaths. This is often why they are called breathing frequency monitors. For a breath to be deemed as "missed", it must have fallen below a threshold level of amplitude. If the amplitude of the signal is inconsistent and not directly related to the tidal volume many of the "missed" breaths will be lower amplitude breaths. The point is that the conventional non-invasive monitor has no way of determining if the infant is hyper, or hypoventilating - as signal may be derived in both cases to indicate s atisfactory breathing to the monitor's discrimination system, and therefore no alarm will sound.

THE NEW MONITOR

The intention of the design of the new non-invasive apnoea monitor system was to deviate radically from the concept of infant surface movement detection and derive a signal specifically related to breathing in a quantitative manner, and moreover to have a method of signal transduction not significantly influenced by materials around the infant or the infant's anatomical position, (supine, prone, or on side) or the infant's position on the device.

The new monitor's operation revolves around two basic principles:

(1) the infant is largely a diaphragmatic breather.

(2) in the lying position, diaphragmatic contraction displaces abdominal organs in the horizontal plane (and air enters the thorax).

Therefore there is a whole body centre of mass shift of the infant, directly proportional to diaphragmatic displacement and closely related to tracheal air flow. The new monitoring method is a device which measures the position of the infant's centre of mass, but moreover is specific to the dynamic shifts of the infant's centre of mass in the frequency range (spectrum) of breathing. It is called the DCOM monitor - (the Dynamic Centre of Mass monitor) (photo of device in appendix). This means that the average position of the infant's centre of mass is not important and not measured, only dynamic shifts from equilibrium which are caused (in the sleeping infant) by diaphragmatic movements of breathing. This is equivalent to the device ignoring all of the infant's mass (plus mass of objects associated with the infant) and only measuring mass (tissue) which shifts in the horizontal plane in the frequency range of breathing say 10 to 100 per minute.

This is a quantitative method. Both theory and practical experiment show that the measured centre of mass shift is directly proportional to tidal volume, but the incredible aspect of this method and principle, is that the dynamic centre of mass shifts are a property of the infant and its breathing, and the transducer mechanism used to measure these is specific for the shifts of mass and totally uninfluenced by any objects placed between the infant and the transducer mechanism, or the position of the infant , lying on side, supine or prone. (Proven with biomechanical model).

Therefore placing any objects, say a 1 cubic metre block soft latex rubber between the infant and this new transducer system, has no effect on the level of the detected signal. The reason for this is that the transducers can only "see" the position of the centre of mass as if it were acting through one specific point in space, and are "unaware" of the density, distribution or consistency of the matter contributing to the total mass of the system. The dynamically shifting centre of mass is converted to a dynamically changing electrical signal which is amplified and "measured" to determine the infant's depth and rate of breathing. This new system has the properties of a perfect apnoea monitor - a threshold for alarm can be accurately set (as external variables around the infant have been largely eliminated), and the signal in both waveform and amplitude is a reflection of actual infant breathing. Therefore the theoretical false positive rate for detecting apnoeas is zero and the false negative rate nearly zero.

At first thought it might seem that the transducer mechanism to measure the position of the infant's centre of mass, or measuring horizontal mass shift would be complicated - but it is extremely simple, safe, and elegant. All that is required in the minimal model is two rigid panels of material rectangular in shape and with force transducers sandwiched between the ends of the long axis. (See technical description of monitor appended.) The rigid panels are of course not sensitive to local pressure produced by infant surface movements (which as pointed out are non-specifically related to breathing) and serve the purpose of integrating all the mass that rests on them. The transducer/s "experience" the total mass as if it acted at a point anywhere along a line perpendicular to the long axis of the structure and at some position between the transducers. The average position of the centre of mass is not important and will vary with infant position, bladder, bowel, stomach contents etc, but the dynamically changing character of this position with breathing is the measured signal. The knowledge of the average position of the centre of mass has theoretical uses in vibration cancellation as indicated in the technical description.

The DCOM monitor is a calibratable device. A given mass shift in grams results in a given output in volts. This means that results and measurements can be standardised and reproduced. This is not possisble with existing apnoea monitor apparatus. (FDA estimates cost of an apnoea monitor standard at 1 million dollars and 10 person years staff time[4].) This DCOM monitor should obviate a lot of this expense as it can be specifically defined from first principles the function of the DCOM monitor should perform. No other existing non-invasive, or many invasive monitors will reach its standard. It is not possible to set up testing protocols and get reproducible results on the existing non-invasive apnoea monitors.

Page 14 of the appended technical description of the DCOM monitor is a plot of the relationship between tidal volume and signal derived by the DCOM monitor prototype. Page 2 of the appended Comparison of the DCOM monitor and the Movement Sensor method shows how vairable the signal level derived by the movement sensor is under various operating conditions compared with the DCOM monitor.

Another feature of the DCOM monitor is that the electrical sign of the derived signal (positive or negative) accurately indicates the phase of respiration - inspiration or expiration, no other existing non-invasive apnoea monitor is specific enough to the actual character of breathing to determine this. (The relationship between signal level and tidal volume can be worked out theoretically for a model infant, see technical description appended page 12). This could be applied to real infants and the calibration constants worked out. Further research is required to determine the practical differences between the biomechanical model constructed and the real infant.

Not only is the character of the signal indicative of the phase of breathing but the waveshape of the signal is meaningfully related to actual infant breathing. This has implications in the field of respiratory function analysis.

Conclusions

Supported by theoretical expectations and practical experiment.

1. The DCOM monitor method enables the volume per breath that an infant inspires (breaths in) and expires (breaths out) = "TIDAL VOLUME" to be measured. No other non-invasive monitor has this property. This is because the signals derived by movement sensitive devices depend on the infant's position, infant clothing, mattress thickness and consistency, i.e. the degree of mechanical coupling between the infant and the movement sensitive device.

2. The signal derived by the DCOM monitor is not significantly influenced by any materials placed between the infant and the DCOM transducer system, nor is it significantly dependent on the position of the infant while the infant is lying.

3. The DCOM monitor system is capable of measuring the volume of air breathed by the infant per minute: = TIDAL VOLUME multiplied by breaths per minute. (the diagnostic and research implications of being able to obtain this information in a reliable and non-invasive manner are far reaching).

4. That conventional movement sensitive pads are greatly influenced by materials placed between them and the infant. (Manufacturers recommend placing pressure pad beneath the mattress). Therefore the signal depends on the mattress thickness and bedclothes.

5. The anatomical position of the infant greatly affects the signal pick up by the conventional movement sensitive pads (capacitance pad).

6. The analogue signals from the movement sensitive pad are inconsistent in both amplitude and waveshape. (I have a hypothesis for this - not included here).

7. Conventional infant breathing monitors are designed to alarm after a given period of time when the signal level falls below a certain value. An infant may breath very rapidly with a low tidal volume or breath very slowly with a large tidal volume and achieve exactly the same number of litres per minute of air intake. Therefore a problem arises: if an unreliable signal amplitude is being detected (it does not relate to the volume per breath that the infant takes in) then the amplitude of the signal can not be meaningfully related to the frequency at which the infant is breathing. Therefore the infant's air intake per unit time is not known. To help counter this problem, conventional monitors may have built in algorithms to alarm after a fixed number of missed breaths, or to measure breath to breath interval and look for significant variations from normal. However, this is not satisfactory, as the amount of air taken up by the infant per unit time is not known. The result of this is that the infant may be breathing adequately to satisfy the conditions where the alarm does not sound, but inadequately breathing so that it becomes progressively hypoxic. Both the theoretical and the practical experimental results of the DCOM monitor indicate that the system is able to quantify and measure infant tidal breathing volumes. This information, in conjunction with the frequency at which the infant is breathing (this data is easily obtained from the signals derived by the DCOM monitor system) can provide a readout of the number of ml/minute of air that the infant is breathing. This information is also the data that really needs to be processed to determine if the infant is breathing adequately, and therefore if an alarm should be sounded.

8. The observations regarding the DCOM monitor are perfectly predictable from the simple physical science principles on which the DCOM monitor operates.

9. The observations regarding the movement sensitive pads (electrical capacitance pads) are also predictable from the physical principles and physical construction of the pad.

The above information opens up many areas of future research. A very large range of infant illnesses are associated with abnormal breathing. The DCOM monitor system represents a way of quantifying and recording breathing in a totally non-invasive way. This possibly very appropriate to sick neonates in intensive care units. Apart from the DCOM monitor's suitability as an apnoea monitor, data indicates that this method has immense potential as a diagnostic tool, and for research into the properties of infant breathing.

General Comments on this Elective

This elective project was self-generated and essentially a research project. I found that this elective period was an ideal time to look into an area in which I was particularly interested. I would recommend to any student interested in pursuing a research project of any nature, that the elective quarter is a good time to do it. It provides the necessary time and freedom to concentrate on an idea, without the usual ever present feeling that there is a venue to attend or an assignment to hand in before a deadline.

Dr S.R. Wealthall was my elective preceptor and he has enormous wisdom and experience in the field of infant breathing and monitoring. He provided the sound scientific advice which made the evaluation of the monitor possible. It is very easy to get sidetracked down specific pathways in research, especially when new information springs up constantly. I also had the opportunity to make friends with the engineers in the Electronics Department at the National Women's Hospital; Chris Rust , Philip Lacey , and Leslie Pillinger . They put up with me using their workshop and tools and they provided helpful ideas and advice. The ward staff in 11A were also helpful and despite obstacles such as overcrowding and lack of space, accommodated me and my monitoring equipment when monitoring infants in the ward.

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Literature cited:

1) Devices and Diagnostic's Letter .
October 3 1986 .
"Apnoea Monitors,Ventilators could be standardised first "

2) Devices and Diagnostic's Letter .
October 3 1986 .
"Apnoea Monitors Need Better Equipment , N I H Panel Urges"

(the above two articles are appended)

3) ConsensusStatement
National Institutes of Health Consensus Development Conference on Infantile Apnoea and Home Monitoring, Sept 29 to Oct 1, 1986 .
Pediatrics Vol 79, No.2. Feb 1987 .

4) Apnoea Monitor Standard Cost To Exceed $1 Million.
Devices and Diagnostic's Letter .
Dec 2 1988 .

APPENDIX.

1. Detailed technical analysis of the DCOM monitor.
   (contains some experimental results)

2. A comparison of the DCOM monitor and the movement sensor method for monitoring infant breathing and detecting apnoea.

3. Appended Devices and Diagnostic's Letter.

Monitor Description Technical Part

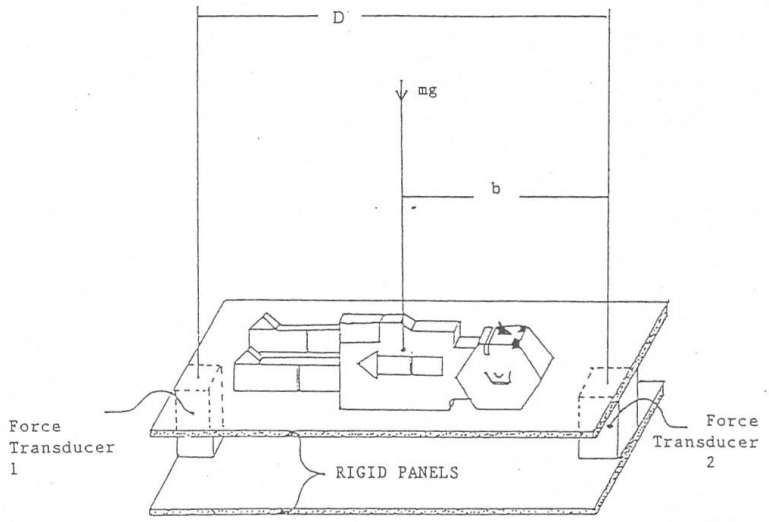
The following is a technical description of the monitor and has been kept as simple as possible while conveying enough information to fully understand the principle. The details of the electronics are not given, but these are not critical to the nature of the invention and the electronics can take a number of possible forms while carrying out the functions described.

The Transducer

The transducer for this new monitor is simple, safe and elegant. Two (or more) strain gauge devices are sandwiched between two rigid plates of material to form the body of a mattress, or a structure to be placed beneath an infant's existing mattress, or even beneath the infant;s crib.
The strain gauges are placed at the extreme ends of the long axis of the mattress, well off centre of the infant's centre of mass. The strain gauge is a device which converts a force F Newtons into a given voltage E volts with the linear relationship E=KF, where K is a constant. The strain gauge used in the research prototype are of the load cell type like those used in electronic scales for weighing. Other types may be used.

FIGURE 1

BASIC ARRANGEMENT

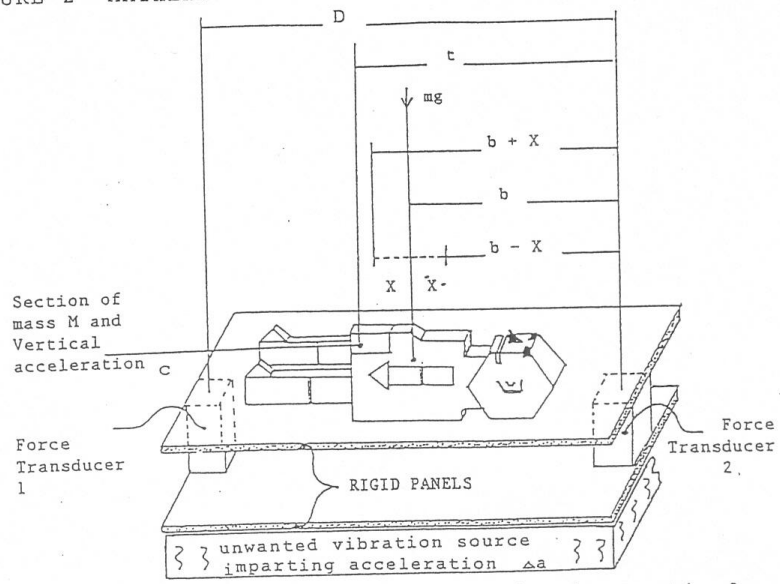


D = the distance between the transducers (in metres)
b = the average position of the infant's centre of mass (in metres) with respect to force transducer 2.
The transducers are subject to the infant's weight as acting through the infant's centre of mass with a magnitude of mg , where m is the infant's total mass (in kilograms) and g is the value of gravity at the earth's surface of 9.8 metres sec^{-2} .

Therefore tranducer 1 experiences a force of ;
$F_1 = mgb/D$ NEWTONS.
and transducer 2 experiences a force of;
$F_2 = mg(D-b)/D$ NEWTONS.

However when the infant is breathing, diaphragmatic displacement of abdominal organs results in a horizontal shift of mass therefore the length b is "modulated" by breathing and this is reflected in the forces F_1 and F_2.

FIGURE 2 MATHEMATICAL DESCRIPTION.



Δa is an acceleration in the vertical plane and perpendicular to the mattress as is gravity.

X = the displacement (in metres) from the average position b of the infant's centre of mass due to the diaphragmatic movements of breathing.
X varies with time corresponding to both frequency and depth of breathing and may be positive or negative in direction with respect to b. X is a funtion , let ΔX symbolise this.

Other contingencies are included in FIG 2 above as follows:
Δa is an acceleration variable,corresponding to an unwanted vibration beneath the infant's mattress or crib which might interfere with the detection of breathing signal.
Also, variables M, c, and t, where M is a mass variable corresponding to a part of the infant accelerating in the vertical plane,perpendicular to the mattress surface with an acceleration c,and this mass being a distance of t from transducer 2.
M(in kilograms), c(in metres sec^{-2}), t(in metres).
This may correspond,for example, to some of the contents of the infant's abdomen,moving toward and away from the mattress surface with breathing.Although the forces created by these accelerations may correspond to breathing the magnitude of them varies greatly withthe position of the infant such as supine prone or lying on her side. It is better to largely cancel these components as will be shown.The magnitude of the forces applied to the transducers from these accelerations are Mct/D to transducer 1, and Mc(D-t)/D to transducer 2. These forces can be directly added to the forces on the transducers caused by the horizontal mass shifts because they are parallel vectors , and can be added scalarly . This will be shown later . . .

The above varibles may now be introduced into the equations for F_1 and F_2 given on the previous page.

The equations for the forces can now be re-written containing the variables.

$F_1 = m(g + \Delta a).(b + \Delta X) / D + Mct/D$

$F_2 = m(g + \Delta a).(D - (b + \Delta X)) / D + Mc.(D-t)/D$

Therefore the voltages (electrical potentials) available for signal processing are;

$E_1 = Km.(g + \Delta a).(b + \Delta X) / D + KMct/D$

$E_2 = Km.(g + \Delta a).(D - (b + \Delta X))/D + KMc.(D - t)/D$

(as in general the transducer performs E = KF)

Therefore if E_2 is subtracted from E_1

EQUATION 1:

$$E_1 - E_2 = \underset{\text{first component}}{Km.(g + \Delta a).(2b - D)/D} + \underset{\text{second component}}{2Km.(g + \Delta a).\Delta X/D} + \underset{\text{third component}}{KMc.(2t-D)/D}$$

And if E_1 and E_2 are added

EQUATION 2:

$E_1 + E_2 = Km(g + \Delta a) + KMc$, which integrated with time to remove vibrations (Δa) and objects moving on the transducer (acceleration c) gives the total weight Kmg which is identical to the principle of electronic scales. KMg (has units of volts

It can be seen from equation 1 that the signal has three components, the first $Km(g + \Delta a).(2b - D)/D$ will have a value of zero when $b = D/2$. This means that the presence of Δa in this component is not a problem. In practice b is close to $D/2$ because the infant's centre of mass is near the centre

of/..

of the mattress. It is possible to electronically calculate the value of b as the value of m (the weight of the infant) can be derived by processing equation 2, and the value of K, g and D are known constants.

This means that the component of the electrical signal $Km(g + \Delta a).(2b - D)/D$ will be small as b is approxiamately equal to D/2 in practice and can be eliminated entirely by electrical cancellation. This is desirable as then most vibration components under the infant's mattress, will be eliminated from the signal. (The damping of vibrations outside the infant's crib is usually carried out by bedclothing and mattress materials, and electronically with low pass filtering, which also serves the purpose of removing signals caused by the the infant's heartbeat or other higher than breathing frequency vibrations).

The desired component of the signal is the second term of equation 1, $2Km.(g + \Delta a)\Delta X/D$. Although it contains the vibration acceleration Δa, this component is zero if ΔX (the shift in the infant's centre of mass in the horizontal plane) is zero, so Δa only has the effect of being superimposed proportionally on the desired breathing signal, and not capable of producing signal when breathing has stopped and ΔX equals zero. This prevents unwanted vibrations stopping the alarm from sounding when the infant has stopped breathing.

The third component of equation 1, $KMc.(2t - D)/D$ is the component derived from part of the infant accelerating vertically on the mattress, shifting the infant's centre of mass in the vertical plane. The magnitude of it depends

on/..

on the acceleration, c, of the mass,M, being accelerated.

Although the acceleration,c, is derived from breathing movements, it varies if the infant is prone, supine or lying on side.

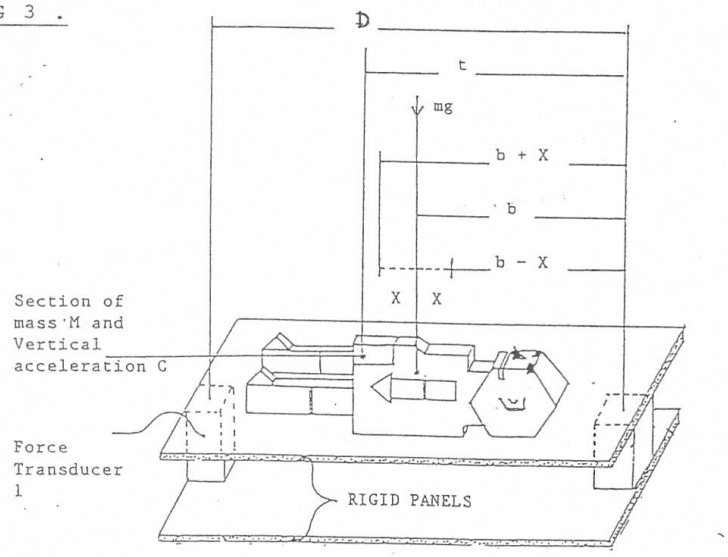
As can be seen by using E_1-E_2, this signal is also reduced because in practice, t, like b, will be close to D/2 making this component less significant. The exact value of t will be similar to b , and in the case of a biomechanical model of an infant could be calculated . More research is required to find an algorithm to calculate it in the real infant .

The signal is best processed as described above . The reason for this is that a horizontal shift of mass results in the force increasing on one transducer , while decreasing on the other by the same amount .(signals out of phase)
On the other hand , the unwanted components of the signal , caused by vertical accelerations of parts of the infant ,and interfering vibrations are in phase on the two transducers.
Subtracting one transducer signal from the other therefore results in doubling the value of the wanted signal , while reducing the value of the unwanted signals.

Prototype used in my experimentation

My prototype contains one transducer, and does not have the above described refinements of vibration and acceleration signal cancellation. The simplified arrangement is shown in the diagram below:

FIG 3 .



An electrical potential E_1 from transducer 1 has the following value (ignoring vibration)

$$E_1 = Kmgb/D + Kmg\Delta X/D + KMct/D$$

The/..

The first term is a constant and is differentiated out electronically, the second term $Kmg\Delta x / D$ is the desired signal corresponding to breathing and is electronically amplified. Note that this signal is not dependent on length b, unlike the constant component. It depends on the shifts of the infant's centre of mass, which moves with a function, Δx, around point b. Both g (gravity) and D (length between supports or transducers) are known constants.

The third term $KMct/D$ which is the signal derived from acceleration, for example of the infant's abdomen upwards and downwards away and toward the mattress surface depends on the infants rate of breathing, as this determines the the acceleration , c , of the vertically moving mass M .

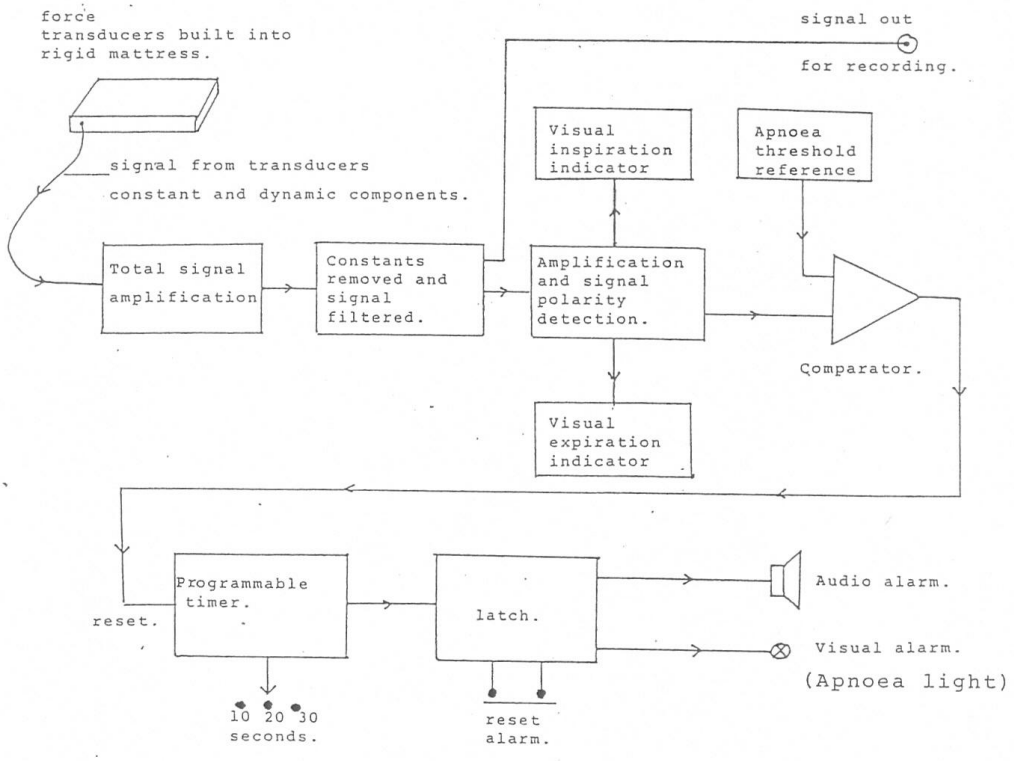
An analysis of this component , and its significance will be given later .

Calculations show that this is less than 10% of the horizontal centre of mass signal at 20 breaths/min, and this has been verified by experimentation. In fact on inspiration the infant's abdomen bulges laterally as well as vertically, so it is not possible to calculate an exact figure for a given infant. In addition the whole characteristic of the acceleration component of the signal changes with position of the infant. This is one reason for the theoretical advantage of the two transducer method, which largely

eliminates/..

eliminates this component. This component in the one transducer prototype is so small that it does not interfere with the evaluation of the centre of mass monitor as the dynamic component $Kmg\Delta x/D$ is the bulk of the signal, and $KMct/D$ is small. I have included this information for completeness of the physical science principles, rather than practical importance.

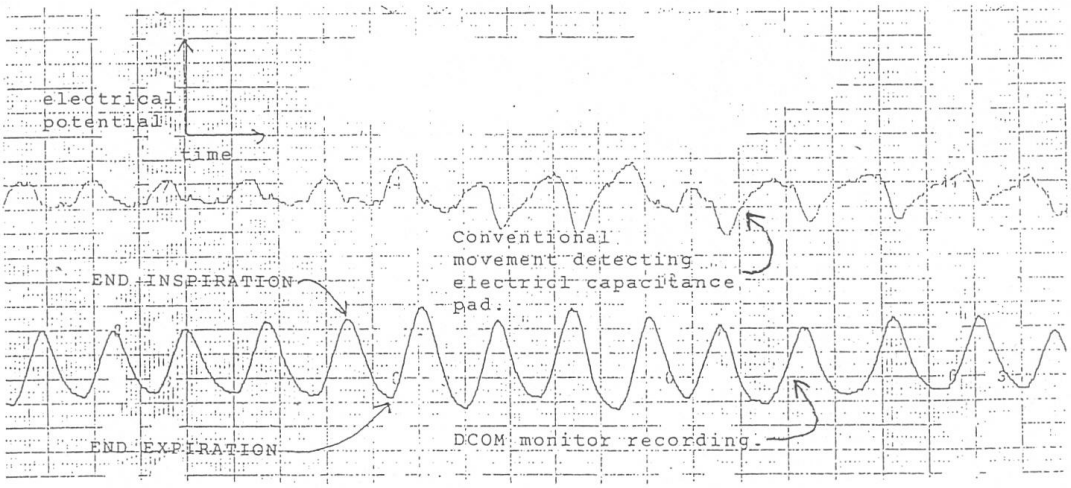
The electronic processing (the unit shown in the photograph) is as follows:



DCOM monitor electronics.

The filtering performs the function of removing higher than respiration frequency vibrations. The signal is detected for polarity. When the infant's diaphragm is moving toward his feet, $Kmg\Delta x/D$ is positive going, therefore the "inspiration" lamp on the monitor is illuminated, when the infant expires the signal is negative going, the expiration lamp on the monitor is illuminated. These signals reset a timer which can be set for any delay, in the prototype, 10, 20 and 30 seconds are the options. If no signal is present for the set period the audio alarm system latches in and the "Apnoea" light is illuminated. This indicates that the infant has not been breathing for the set period of time.

Below is a sample recording of both the centre of mass technique(the DCOM monitor), and the conventional movement detecting electrical capacitance pad monitor operating simultaneously monitoring a sleeping infant.



The astute physicist will have noted that this DCOM monitor relies on the infant's long axis being roughly in line with the long axis of the mattress. However, even if the infant is 30° to the long axis, the component in the long axis of the mattress is still 87% of the maximum (as Cosine 30° = 0.87). In practice most cribs and incubators maintain the infant's long axis in rough alignment with the mattress or crib or incubators long axis. However this situation may be easily remedied by another one or two transducers along the other axis of the mattress.

In summary then,
The infant's weight and the weight of any material associated with the infant,clothing beding,mattresses etc, rest ultimately on the rigid panel supported at its extremities by transducers.
The transducers experience a summated force which indicates a total weight acting at one point on the surface of the rigid panel, this is regardless of the density or consistency,or overall distribution of the infant and associated matierials involved.
The infant's center of mass is modulated by breathing in the horizontal plane while lying,this center of mass shift is detected by the transducers.When the mass shifts in one direction , one transducer experiences an increasing force, the other transducer a decreasing force(two transducer method). However both unwanted vibrations and acceleration signals produce forces that increase on both transducers simultaneously so by subtracting one transducer signal from the other, the wanted center of mass shift signal is doubled and the unwanted components largely cancelled.

The prototype used for experimentation contains one transducer and the removal of vibrations or other signals outside the frequency range of breathing are filtered out with conventional electronic methods.

HOLDEN DCOM APNOEA MONITOR

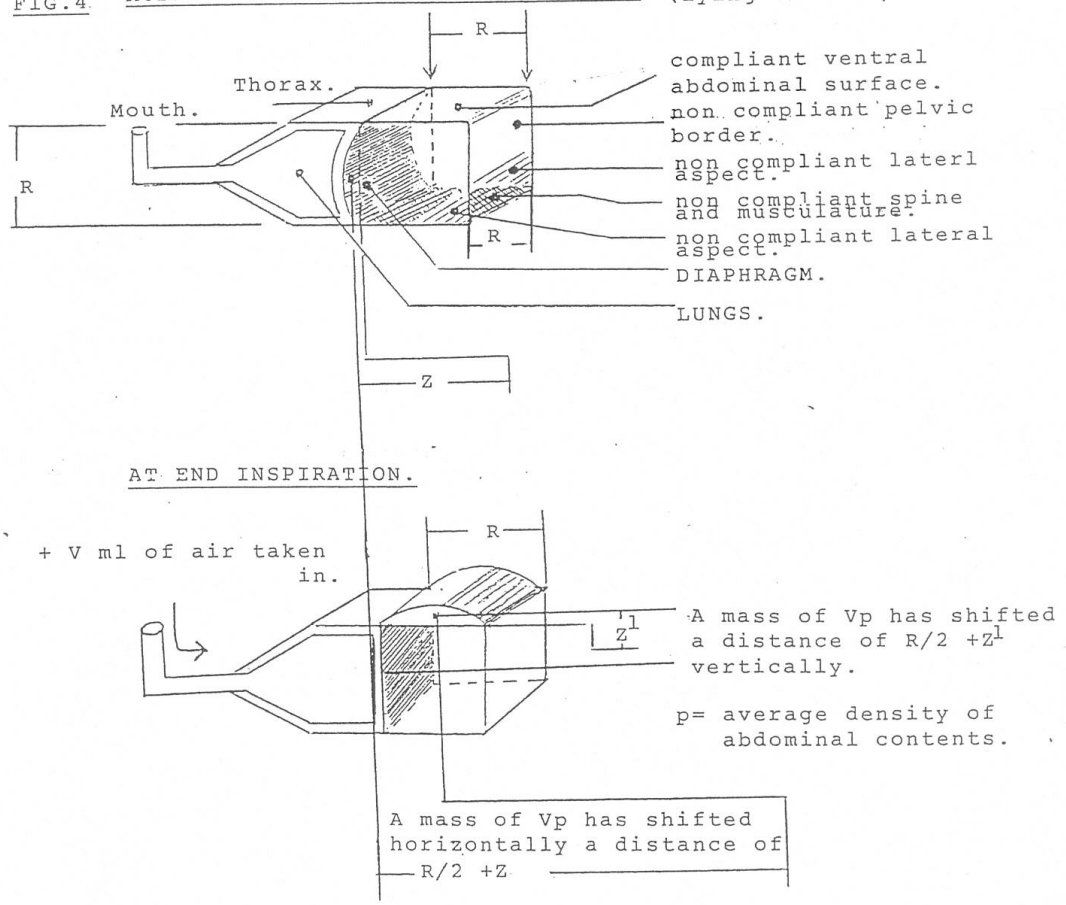
MODEL TO RELATE TIDAL BREATHING VOLUME TO MASS SHIFT AND THEREFORE THE SIGNAL DERIVED BY THE DCOM MONITOR.

It is possible to analyse the DCOM monitor function to relate the shift of mass to actual volume per breath taken by the infant.

As the DCOM monitor electronics ultimately eliminates the constant component of the sgnal derived by the transducer system,and only processes the changing component of the signal in the frequency range of breathing,then one only needs to consider the part of the infant's mass which moves in the horizontal plane with breathing.

The following model of a breathing consists of an infant lying on its back (supine), and it is assumed that the volume of air taken in per breath is equal to the volume of abdominal contents displaced by the diaphragm. The abdomen is taken to be cubic, of dimension R^3 .

FIG.4 MODEL OF INFANT AT END EXPIRATION. (lying on back)



The size of Z and Z^1 are uknown and depend on the curvature of the diaphragm and ventral surface of the abdomen . However, this is not a problem as both Z and Z^1 are small with respect to the size of R .
The horizontal shift of mass Vp is very close to R/2 .(this is also true if the infant is lying on side, or prone) .

The mass Vp also shifts vertically when the infant is lying on its back (supine) . The shift of this mass is also close to a distance of R/2 . This generates the acceleration signal described earlier. If the infant is lying on her side this signal is not generated . As this represents a mechanism by which the total signal level may vary with the position of the infant , it is better largely eliminated with the processing of the two transducer method previously described.
It will be shown shortly how the proportion of this signal in the single transducer prototype was calculated for the worst case condition , the infant lying supine.

The model above enables the amount of electrical signal to be directly related to the volume per breath(tidal volume)of the infant .

The signal generated on the single transducer mechanism by a mass of Vp kilograms shifting a distance of R/2 metres backwards and forwards horizontally in the frequency range of breathing is

$E = KVpgR/2D$ peak to peak. (units VOLTS)

constants removed .
acceleration ignored.
vibration ignored.

V = tidal volume (units millilitre ml)

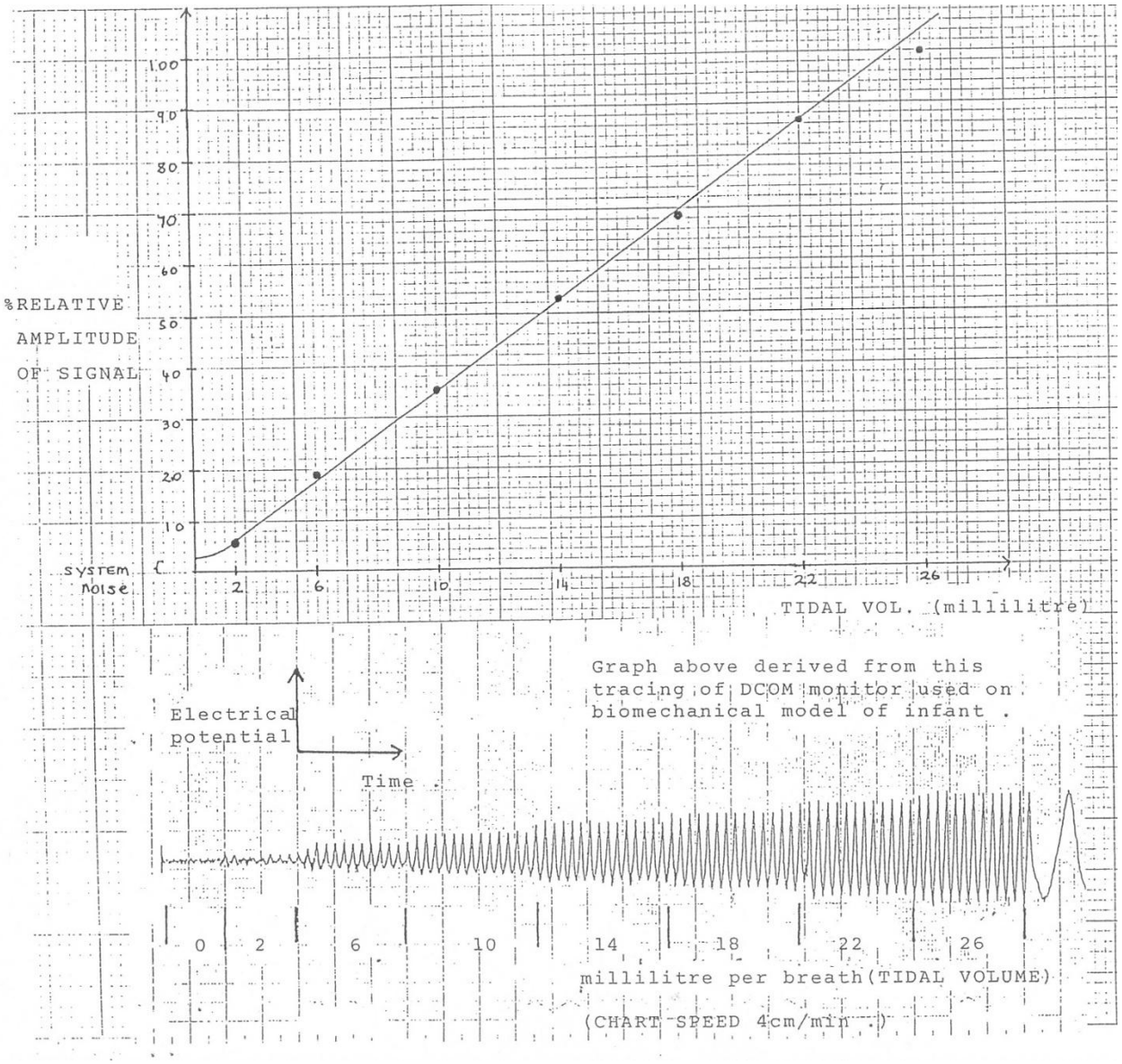
K = transducer constant. (units VOLTS per NEWTON)

g = gravity (9.8 $msec^{-2}$) (or NEWTON/Kilo.)

p = average density of infant's abdominal contents (kilo/ml)

D = distance between transducer and support.(see fig 3)

The approximate value of R can be determined from a series of infants , so this value can be known for a given aged infant.
The most important outcome of this analysis , is that the signal generated , E , is directly proportional linearly to the infant's tidal breathing volume , V .
Although there are errors in the calculated values of p and assumptions regarding the geometry of the infant's abdomen R^3 , and assumptions that all the tidal breathing volume is converted to an equal volume of shifting mass, this is not important because the DCOM monitor may be calibrated against a biomechanical model of an infant breathing a known volume . A plot of this is shown on the next page , using the 2.5Kilo biomechanical model breathing a range of volumes up to 26ml .


%RELATIVE
AMPLITUDE
OF SIGNAL
100
90
80
70
60
50
40
30
20
10
system noise
2
6
10
14
18
22
26
TIDAL VOL. (millilitre)
Graph above derived from this tracing of DCOM monitor used on biomechanical model of infant .
Electrical potential
Time .
0
2
6
10
14
18
22
26
millilitre per breath(TIDAL VOLUME)
(CHART SPEED 4cm/min .)

The above graph shows how the signal derived from the DCOM system is directly proportional to infant breathing volumes.

This is an incredible achievment for a non invasive breathing monitor , and also this relationship is not altered by any materials placed between the infant (possibly excluding the absurd such as bags of fluid that resonate in the frequency range of breathing) and the upper rigid panel of the DCOM transducer arrangement. The only requirement being that the total weight of the infant comes to rest on the DCOM transducer system . As both the depth and frequency of breathing can be determined precisely with the DCOM system it has the properties of a perfect apnoea monitor.

Why are these properties so desirable ?

Conventional infant breathing monitors are designed to alarm after a given period of time when the signal level falls below a certain value. An infant may breath very rapidly with a low tidal volume or breath very slowly with a large tidal volume and achieve exactly the same number of litres per minute of air intake. Therefore a problem arises : if an unreliable signal amplitude is being detected (it does not relate to the volume per breath that the infanttakes in) then the amplitude of the signal can not be meaningfully related to the frequency at which the infant is breathing .Therefore the infant's air intake per unit time is not known .

To help counter this problem , conventional monitors may have built in algorithms to alarm after a fixed number of missed breaths , or to measure breath to breath interval and look for significant variations from normal . However , this is not satisfactory , as the amount of air breathed by the infant per unit time is not known. The result of this is that the infant may be breathing adequately to satisfy the conditions where the alarm does not sound , but inadequately breathing so that it becomes progressively hypoxic. (short of oxygen).

Both the theoretical and the practical experimemtal results of the DCOM monitor indicate clearly that the system is able quantify and measure infant tidal breathing volumes. This infomation , in conjunction with the frequency at which the infant is breathing (this data is easily obtained from the signals derived by the DCOM monitor system)can provide a readout of the number of mls per minute of air that the infant is breathing. This information is also the data that really needs to be processed to determine if the infant is breathing adequately , and therefore if an alarm should be sounded .

The above information opens up many areas of future research. A very large range of infant illnesses are associated with abnormal breathing . The DCOM monitor system represents a way of of quantifying and recording breathing in a totally non-invasive way.This is possibly very appropriate to sick neonates in intensive care units.

Appart from the DCOM monitor's suitability as an apnoea monitor, data indicates that this method has immense potential as a diagnostic tool , and for research into the properties of infant breathing.

METHOD OF CALCULATING ACCELERATION COMPONENT OF THE SIGNAL FOR THE SINGLE TRANSDUCER PROTOTYPE

As explained in the information associated with FIG.4 the worst case condition with the infant supine , the vertical displacement of mass Vp , has an approximate amplitude of R/2 peak to peak .

Assuming a sinusoidal pattern of breathing , the vertical movement of this mass is ,

$$\text{DISPLACEMENT (vertical)} = (R/4)\,\text{Sin}wT$$

Therefore , $$\text{ACCELERATION} = -(R/4)w^2\text{Sin}wT$$

Referring to FIG.3 , this results in a force on the transducer of ,

$$\text{FORCE} = (M(R/4)w^2\text{Sin}wT)t/D$$

Therefore the electrical component of the signal corresponding to vertical acceleration of mass is

$$E_{(accel)} = -(KVp(R/4)w^2\text{Sin}wT)t/D$$

as in the case of FIG4., M = Vp.

GENERAL EQUATIONS:

$d=A\text{Sin}wT$
$v=Aw\text{Cos}wT$
$a=-Aw^2\text{Sin}wT$

d=displacement
v=velocity
a=acceleration
A=amplitude
w= angular frequency or $2.\pi.f$
f=frequency in Hz.
T= time in sec.

As explained on page13 ,the electrical signal produced by horizontal mass shift of lenth R/2 , is ,

$$E_{(mass\ shift)} = KVpgR/2D \text{ , peak to peak.}$$

Again assuming a sinsoidal pattern of breathing , this may be re-written as ,

$$E_{(mass\ shift)} = (KVpgR/4D)\text{Sin}wT$$

As $E_{(accel)}$ generated by vertically accelerating mass Vp , and $E_{(mass\ shift)}$ generated by horizontal displacement of mass are parallel vectors they may be added scalarly as indicated earlier.

Therefore the ratio of accelerational to mass shift signal in the single transducer prototype , in the worst possible case , (supine infant model of FIG4. is ,

$$E_{(accel)}/E_{(mass\ shift)} = (w^2D/g)\,t/D$$

In the experimemtation with the biomechanical model and the single transducer prototype, the breathing rate was kept down to 20min^{-1} = 0.33Hz ,and t kept to approx D/2 , so that the ratio above, was

$w^2D/2g$. The dimension of D in the prototype is 0.4 metres .

Therefore , $E_{(accel)}/E_{(mass\ shift)} = \frac{(2.\pi.0.33)^2(0.4)}{2(9.8)}$

$= 0.088$

Therefore , although the prototype does not have the refinement of acceleration cancelation, the acceleration component of the signal is small even in the worst case situation desribed. This meant that the acceleration compent of the signal could be ignored in the experimentation with the DCOM monitor and the bio mechanical model.

A COMPARISON OF THE DCOM monitor AND THE

MOVEMENT SENSOR METHOD FOR MONITORING INFANT BREATHING AND DETECTING APNOEA.

The DCOM monitor lends itself to precise calibration; a given shift of mass in the horizontal plane results in a proportional electrical potential being generated. This is an incredible achievement in the field of non-invasive infant breathing monitoring.It is not possible to calibrate the movement sensitive monitor because its signal output at any time depends on local mechanical factors such as infant mattress thickness,infant bedclothing, infant positioning,or anything else which may alter the infant's mechanical coupling to the sensor device.

The movement sensor used to demonstrate the problems of this common method of monitoring infant breathing was the "electrical capacitance pad" They essentially consist of thin sheets of metal electrically insulated from each other to form the plates of an electrical capacitor. The capcitance is inversely proportional to the distance between the plates. Therefore, if the structure is compressed mechanically, the capacitance alters.The breathing movements of the infant cause local pressure changes and therefore alters the capacitance of the pad in sympathy.
The relationships for a capacitor;

$q = CV$. Where q is the charge in COULOMBS, C is the capacitance in FARADS, and V is potential in VOLTS.
The electrical capacitance pad is charged on the average with a charge q so that dynamic changes in capacitance (caused by infant movements) result in an inversly proportional changing voltage, which is processed by the unit's electronics.

In the field of invasive infant breathing monitoring, pressure or strain sensitive devices are directly attached to the infants abdomen. The signals derived from these devices also depend on where and how they attach to the infant(again a non-quantitative measure of breathing) They also have the disadvantage that the infant is at risk with the direct attachment of devices and wires.

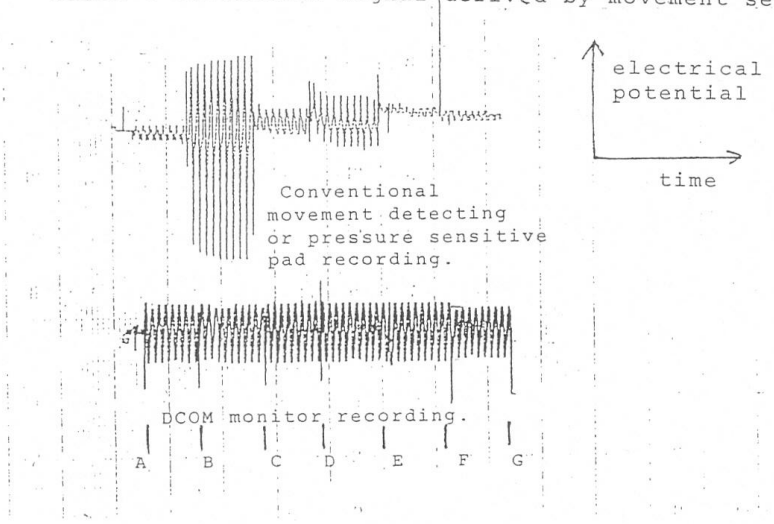
The following data and experimental results were obtained during the DCOM monitor evaluation I am currently working on.

A major advantage of the DCOM monitor method is its insensitivity to local pressure changes produced by infant abdominal wall movement, unlike the existing movement sensitive method. Also the physical property of the infant's breathing modulating its centre of mass is uninfluenced by objects, even an entire crib placed between the infant and the mattress (both theory and practical exp confirm this). The signal therefore is to a large degree standardised to a given infant or semi-quantitative. This is a significant advance in apnoea monitor technology.

Below is a tracing of the DCOM monitor and the conventional movement sensitive monitor . This was performed using an "artificial infant" (a biomechanical model of a 2.5 kilo infant) driven by a mechanical respirator. The infant was moved into various positions , and various objects were placed between the infant and the monitor transducer systems as will be described on the next page.

The tracing clearly shows the variability of the signal level derived by the movement sensitive method compared to the DCOM monitor method under various operating conditions.

FIG 1 . Unreliable signal derived by movement sensor.

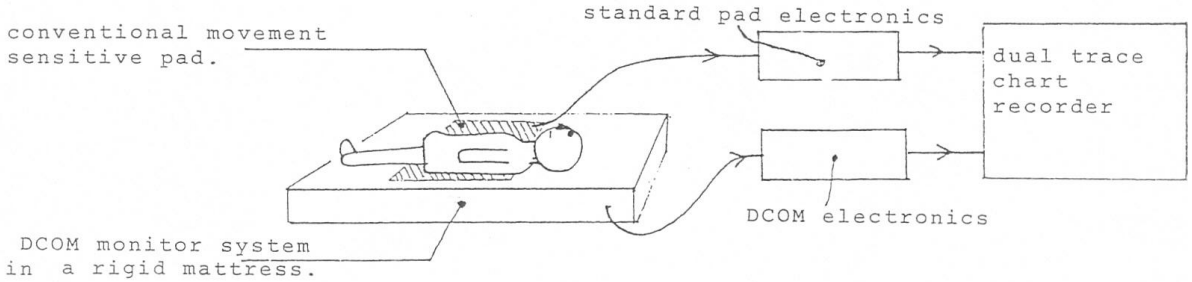


The record above is of a conventional movement sensitive monitor, (electrical capacitance pad), and the DCOM monitor operating simultaneously to monitor the breathing of an "artificial infant" which is a biomechanical model of an infant with a mechanical construction providing a thorax, diaphragm,and abdomem that resembles, as closely as possible a real infant.This model is driven by a mechanical ventilator designed to ventilate real infants.

For the recording above the "infant"was breathing at a rate of 17 per minute and with a volume of 25cc per breath. The recording was stopped before each re-positioning of the "infant"and restarted after the disturbance had settled.

Section A to B, (AB), the infant is lying on its back (supine)directly on the movement sensitive pad, and both infant and pad rest on the DCOM monitor mattress.(the DCOM monitor function is not affected by the presence of objects between it and the infant)

Arrangement shown in diagram below:



Section (AB) shows that the signal obtained from the movement sensor is relatively small.Two reasons account for this; with the"infant" on its back, most of the movements resulting from breathing appear as abdominal movements which do not contact the pad surface, and secondly experimental evidence indicates that weight focussed locally on the pad has a detrimental effect on its function.(the manufacturers of these pads recommend that the pad be placed beneath the infant's mattress). Good signal is obtained from the DCOM monitor.

Section (BC) the "infant" is now lying on its side,the rythmic breathig movements of the abdomen are now well coupled to the pad and the signal obtained from the pad has increased markedly.
The "infant" being on its side has not affected the signal obtained by the DCOM monitor.

Section (CD), the infant is again on its back, as in (AB), however this time a 5cm thick soft rubber mattress has been placed directly beneath the "infant" and on top of the movement sensor pad and theDCOM monitor mattress.(the pad is now operating in accordance with manufacturer's recommendations).The addition of the rubber mattress has slightly increased the signal obtained from the movement sensitive pad,possibly due to increased surface area of coupling of "infant" movement to the pad.
The addition of the 5cm thick soft rubber mattress has not affected the signal obtained by the DCOM monitor.

Section (DE) , the "infant" is now lying on its side again, and the 5cm thick soft rubber mattress beneath the "infant" is included.The signal obtained from the pad hasincreased a little on that obtained during (CD) because the abdominal wall is now better coupled to the pad as the "infant is lying on its side.However the signal obtained is less than that seen

in (BC),where the "infant" is also lying on its side but the 5cm thick soft rubber mattress is not included.
The signal derived by the DCOM monitor remains unaffected.

Section (EF) and (FG), represent the"infant"lying on its back and on its side respectively. The "infant" now rests on a 15cm thick soft pillow which rests on the movement sensor and theDCOM monitor mattress. The movement sensor is unable to detect the breathing movements adequately and the signal is very small even when the "infant" is on its side,(FG), because the thick 15cm mattress prevents the movement being coupled to the movement sensitive pad.
As can be seen the presence of the thick 15cm pillow does not significantly affect the signal obtained by the DCOM monitor.

CONCLUSIONS:

The recording from the movement sensitive pad shows

The signal derived from the pad varies in amplitude depending on the position of the infant. (compare (AB) with (BC) or (CD) with (DE).)

The signal derived from the pad varies with the thickness of the material placed between the infant and the pad. In comparing (AB) and (CD), the addition of material,5cmthick,resulted in increased output,however,the addition of 15cm of material resulted in a loss of signal.

The recording from the DCOM monitor system shows

The signal derived by this method is not significantly influenced by either; materials present between the infant and the DCOM monitor mattress or the way the infant is lying.

What this means in terms of breathing monitoring and the detection of APNOEA

To monitor breathing effectively, and to detect apnoea(pause or cessation of breathing) the signal derived must consistently relate to the character of the actual breathing.To define that an infant has stopped breathing, or is breathing inadequately ,a threshold level must be set below which the alarm will sound after a specified period.
If the transduction method of obtaining signal depends on changing variables such as infant position and materials around the infant,as with a movement sensor,then the amplitude of the signal can not be relied on to indicate the extent or depth of breathing.In practice, this results in many false alarms (this places great stress on the caregivers).This may encourage the user to place the movement sensor closer to the infant (gains more signal hence less false alarms), however this may be dangerous to the infant, as small movements, not specifically related to breathing may generate enough signal to prevent the monitor from alarming,so that the infant is thoroughly asphyxiated by the time the alarm sounds.

The DCOM monitor provides the solutions to the problems cited above, and provides a method of accurately detecting apnoea,as well as producing a consistent representation of infant breathing activity,which has the potential for clinical use.

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APNEA MONITORS NEED BETTER EQUIPMENT, NIH PANEL URGES

Manufacturers of neonatal apnea monitors should publish performance characteristics of the devices for physicians and strongly consider trying to develop low-cost pulse oximeters for the machines, as well as abdominal strain gauges and non-impedance sensors. Monitors also should be able to recognize and alarm for prolonged apnea.

Those are some of the recommendations made in an Oct. 1 final report(*) of a panel of specialists convened at the National Institutes of Health in Bethesda, Md., for a consensus development conference on infantile apnea monitoring in the home. The 13-member panel also urged adoption of voluntary performance standards within two years, and if not, FDA-mandated standards for the Class II devices.

The report says the "few isolated problems" with breathing frequency monitors have been "largely corrected." But the panel said physicians should only recommend home monitoring for premature infants, babies with specific respiratory diseases or conditions, or children who experience "an apparent life-threatening event" that requires resuscitation.

Siblings of babies who die of sudden infant death syndrome, and infants of drug-addicted mothers should not be monitored at home, the panel concluded. The panel also discouraged the promotion and distribution of over-the-counter monitors that parents can use without a physician's guidance.

APNEA MONITORS, VENTILATORS COULD BE STANDARDIZED FIRST

Neonatal apnea monitors, ventilators and tubing might get FDA's attention first for performance standards now that the Devices Center is reevaluating the standards program in light of limited resources, staffers said. Although the devices are among six for which FDA has issued its intent to get standards (D&DL, 7/4, page 1), the devices might be rank-ordered, primarily because "a lot of apnea monitors don't work,"

an FDA topsider said, and anesthesia machines (ventilators) have been associated with numerous deaths and injuries (D&DL, 4/4, page 4). The remaining devices, cardiac monitors, central nervous system shunts and vascular graft prostheses, could receive secondary attention, one FDAer said.

> Devices Center Director John Villforth said such a ranking does not now exist, but said the process is being reevaluated with FDA Commissioner Frank Young now that the Center faces the prospect of devoting much staff and money to write standards for all six devices. Preparing standards for apnea monitors alone could take four years and 30 staffers, an FDAer said.

John Yount, co-chairman of an apnea monitor standards committee of the American Assn. for the Advancement of Medical Instrumentation (AAMI), told a conference Sept. 29 at the National Institutes of Health that if his group makes no progress in developing a standard by September 1987, he will disclose the names of companies whose monitors failed to detect breathing lapses in a test he conducted recently.

In the study of 12 apnea monitors, Yount said some of the major manufacturers of apnea monitors ranked low in detecting apnea, the worst being correct 38.8% of the time; the best one detected breathing loss 98.4% of the time. Yount was castigated by Rey Gorsuch, Healthdyne's vice president for research and development, who said the test was not scientifically sound.

> Yount, of Oregon Health Sciences U., said his committee's task is formidable. To draft industry standards for electro-cardiograms, it took AAMI about four to five years. An effort to create standards for fetal heart monitors failed after three years, he added, due to internal disagreement on the committee. Villforth, however, said he felt the voluntary effort to date "was going very good."

On a final note. One interesting discovery was made while ventillating the artficial infant. More pressure drive was required and more work (energy/sec) was required to ventilate the model infant while it was lying on its stomach and less work was required with it lying on its back for the same minute volume.This is because the structures of the abdominal wall are more compliant that the back and spine area, so this reduces the overall abdominal compliance with the anterior abdomen applied with the body weight to a rigid surface. This indicates that an infant could beome more quickly fatigued and this might be one of the reasons why keeping a baby on its back has reduced the incidence of sudden infant death syndrome.

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