Biomedical Instruments for Fetal and Neonatal Surveillance

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Abstract. Specialised instruments have been developed to aid the care of the fetus and the newborn baby. Miniature sensors using optical, electrical, chemical, mechanical and magnetic principles have been produced for capturing key measurands. These include temperature, pressure, flow and dimension, as well as several specific molecules such as glucose, oxygen and carbon dioxide. During pregnancy ultrasound imaging and blood flow techniques provide valuable information concerning fetal abnormalities, fetal growth, fetal breathing and fetal heart rate. Signal processing and pattern recognition can be useful for deriving indicators of fetal distress and clinical status, based on biopotentials as well as ultrasound signals. Fetal pH measurement is a critical requirement during labour and delivery. The intensive care of ill preterm babies involves provision of an optimal thermal environment and respiratory support. Monitoring of blood gas and acid-base status is essential, and this involves both blood sampling for in vitro analysis as well as the use of invasive or non-invasive sensors. For the future it will be vital that the technologies used are subjected to controlled trials to establish benefit or otherwise.

1. Introduction
Since the middle of the last century there have been significant efforts to develop sensors and instruments to provide timely information on the status of the fetus during pregnancy and birth and the ill newborn baby under intensive or special care [1]. Despite these efforts many developments in sensors and various aspects of signal processing did not lead to clinically usable devices and so there are still important un-met needs. Consideration of successes and failures may point the way to the establishment of new and more viable research programmes.

The requirements for sensors and instruments for use in the fetus and in the newborn have some general similarities but there are also important differences. These become apparent by considering the temporal progression from pregnancy, through labour and delivery, then beyond into the intensive care of the ill newborn baby. In pregnancy the real technical challenge is to carry out surveillance of the fetus who is totally concealed from direct view. Firstly, it is important to be able to monitor the growth and development of the fetus to detect intra-uterine growth retardation (IUGR) and to detect malformations. Nearer to birth it may be important to be able to detect fetal distress so that timely clinical action can be taken and during delivery it is possible to make direct contact with the fetus. Monitoring the baby immediately after birth may involve measurement of all key physiological processes, especially breathing, blood oxygenation, and cerebral oxygen delivery.
When making measurements to assess fetal and neonatal status it is possible to use invasive or non-invasive techniques. Although invasive sensors can provide a direct measurement of the variable of interest they have potential risks and therefore non-invasive methods are generally preferred. Nevertheless, despite this apparent advantage, non-invasive techniques by their very nature as indirect approaches have many limitations and perhaps this is why many non-invasive sensors and instruments do not have the reliability, specificity, precision and accuracy for clinical use. Further research on both invasive and non-invasive methods is therefore still needed.

2. Ante-Partum Fetal Assessment
The examination of the fetus during pregnancy is an important phase of maternal and fetal care and sensors and instruments have long played very visible roles in this. Traditional assessment of fetal well-being was based on the mother’s own perception of fetal movements, counted manually in a defined period and this can still play a role. Also, fetal heart sounds were traditionally detected manually with the fetal stethoscope, and from these the fetal heart rate (FHR) could be estimated. Subsequently phonocardiograph (PCG) sensors allowed such sounds to be electronically recorded and processed. These sensors are essentially microphones and it was found that significant improvements could be achieved with compliance matched inductive transducers [2]. These can have a frequency response flat to within 3 dB from 0.1 Hz to 200 Hz. Appropriate adaptive filtering can separate fetal heart sounds (>10 Hz) from fetal breathing movements (0.5 Hz to 2.0 Hz) as well as eliminating the influence of maternal breathing movements [3]. Although fetal phonocardiography had lost popularity in recent years, new work describes a low cost monitor for home use based on phonocardiography and advanced signal processing [4]. Maternal uterine contractions can occur at various stages of pregnancy and these can be recorded with a guard-ring applanation transducer or by processing the uterine electromyography (EMG) signals. Single EMG bursts have been found to correlate well with mechanical activity [5]. Combined FHR and contraction recording, cardiotocography (CTG), allows suspicious patterns of heart rate to be recognised.

Attachment of conductive electrodes to the maternal abdomen allows the ECG from both the fetus and the mother to be recorded. Signal processing to extract the smaller fetal ECG has advanced over the last half century increasing the success rate for deriving clinically useful data on FHR and FHR variability. The methods used include template matching, artificial neural networks. The fECG allows more precise calculation of beat-to-beat variability than that possible with the fPCG.

Ultrasound instruments for imaging and physiological measurement represent a vital part of intra-partum fetal surveillance [6]. Other imaging techniques, including X-ray computed tomography and magnetic resonance imaging (MRI), may also be used for fetal assessment and these can provide clear anatomical images. There have also been attempts to use near infra-red radiation to interrogate the fetal brain via the maternal abdomen (see Fig 1) [7]. Laser diodes or filtered white light act as transmitters, and solid state detectors are placed at two positions. Current high performance ultrasound instruments can, firstly, measure gross fetal dimensions (bi-parietal diameter, crown-rump length, limb size, etc) and amniotic fluid volume can be estimated. 3D and 4D ultrasound can now allow detailed

![Figure 1. NIRS monitoring of the fetal head via the maternal abdomen. (© Peter Rolfe).](image-url)
examination of fetal organs (heart, kidneys, liver, etc.). By combining ultrasound imaging with Doppler processing it is possible to measure arterial and venous blood flow and superimpose this in colour on top of an anatomical image.

Simple ultrasound instruments having a transducer hand-held or fixed onto the maternal abdomen allow fetal heart activity to be detected and heard, and appropriate signal processing then allows fetal heart rate (FHR) and FHR variability to be calculated. To allow the mother to remain mobile these basic FHR monitors can be made small and portable and can be connected to radio-telemetry. This can be useful both in the home and in the hospital.

3. *Intra-Partum Monitoring*

During labour and delivery the aim of surveillance is to detect early signs that the fetus might be asphyxiated and as a result is at risk of serious brain damage. Even in recent times, birth asphyxia, defined as a severe disturbance of oxygen supply to the fetus, has been said to be an unsolved problem of perinatal medicine [8]. In many cases where the fetus requires surveillance during delivery the mother will already be connected to a cardiotocograph so that beat-to-beat FHR and uterine contractions are being monitored, as above. This is most usually by means of an ultrasound probe for deriving the FHR information with an external contraction sensor. Direct access to the fetus during labour can then allow intra-uterine pressure to be measured directly with a catheter-tip pressure sensor or an external transducer connected to a water-filled cannula. The fetal ECG allows more precise calculation of FHR variability, and has generally been found to be more reliable than ultrasound [9].

The earliest approaches using electrodes attached to the maternal abdomen were generally unreliable and so the fetal scalp electrode became the standard. The original adaptation of a surgical clip [10], with two Ag/AgCl surfaced penetrating tines allowing contact with sub-epidermal tissue and a further Ag/AgCl wire which comes into contact with surrounding amniotic fluid acting as the reference, was an important development. Subsequently, the ‘spiral’ design of Hon [11] in which a stainless steel helical needle, attached to a short cylindrical plastic body, is screwed into the fetal scalp, has been more popular but is of course invasive. Thus there has been a recent return to the maternal abdominal attachment with independent component analysis [12]. In one approach an array of 12 electrodes is fixed to the maternal abdomen and the fECG is extracted by blind source separation [13] and analysed for beat-by-beat variability and ECG morphology.

In addition to the interest in monitoring FHR and variability there has been considerable effort to develop methods that are capable of giving more direct indications of fetal asphyxia. One line of research has been to process the fECG waveform to extract the ST segment and look for elevation. The so-called STAN monitor emerged from this work. Also, over more than three decades, chemical analysis has been developed. Primarily the latter has centred on the use of fetal pH measurement to detect acidosis, a reliable indicator of fetal asphyxia. Fetal scalp capillary blood sampling with *in vitro* remains the routine method for this, despite many attempts to develop electro-chemical and fibre optic pH sensors for insertion into the fetal scalp to allow continuous monitoring. Furthermore, efforts to develop sensors for fetal scalp oxygen and carbon dioxide measurement using heated transcutaneous sensors have not led to widespread clinical use. However, optical sensors for measurement of blood oxygen saturation in the fetal scalp based on pulse oximetry has been accepted by several clinical departments as a useful technique. Although the feasibility of using near infra-red spectroscopy (NIRS) for intra-partum monitoring of fetal cerebral oxygenation has been established this method has not yet moved from the status of being a research tool [7].

4. *Neonatal Intensive Care*

The ill preterm baby under intensive care will require attention to thermal balance, nutrition and cellular oxygenation. At birth resuscitation with a bag and mask, using oxygen-enriched air, can be guided with cardio-respiratory monitoring achieved with electrodes applied by light suction to record the ECG and trans-thoracic impedance [14]. The baby must be prevented from losing heat from its wet surface and, after drying, overhead infra-red warmers are useful and the baby’s core temperature must
be measured. Umbilical cord samples allow an initial assessment of pH and the laboratory blood gas analyser, situated as close as possible to the neonatal unit, is perhaps one of the most important instruments to provide intermittent indications of blood gas and acid-base balance. Subsequently, arterial or capillary samples will be needed, or blood gas sensors must be used for continuous monitoring.

Figure 2. PO2/PCO2 sensor, and 3 electrodes for ECG and trans-thoracic impedance monitoring.

Babies needing on-going care after initial resuscitation are primarily pre-term babies with respiratory distress syndrome (RDS), having immature lungs (surfactant depletion), recurrent apnoea, possible hypoxaemia and risk of hypoxic-ischaemic brain injury. Apparatus is needed for both therapy and measurement and these two tasks need to be considered together so that appropriate equipment designs can be produced. Firstly, thermal control of these babies is vital and monitoring of rectal temperature or skin surface temperature is essential and is often carried out as part of the incubator or radiant warmer control system. Adjusting the environmental temperature to keep the baby in the thermo-neutral zone is important in order to minimise oxygen demands. Secondly, respiratory therapies are needed and these range from the simple provision of increased inspired O2 concentration, then the application of continuous positive airway pressure, through to complex mechanical ventilation. All of these therapies need to be controlled carefully and therefore key physiological variables must be measured and monitored [15].

Once again, choices between invasive and non-invasive measurement techniques must be made. The insertion of umbilical artery and/or vein catheters allows simple repeat sampling of blood without the on-going need for capillary sampling. It also allows direct continuous blood pressure monitoring as well as the additional insertion of chemical sensors. However, the procedure may be hazardous due to thrombus formation. Recently, fibre optic sensors for PO2, PCO2, pH and temperature combined into a single catheter, that were developed nearly two decades ago, have gained clinical acceptance in some centres [16]. There have also been developments in biomaterials to overcome the problems of protein adhesion to catheter surfaces [17].

Non-invasive methods have been developed in order to overcome hazards and instability of invasive methods. Transcutaneous PO2 and PCO2 monitoring was very popular between the late 1970s and the mid 1990s. However, problems related to possible skin trauma by the heated sensor and the need to re-calibrate the sensor frequently meant that it was gradually displaced by pulse oximetry for oxygen saturation monitoring. However, there are theoretical concerns regarding the use of oxygen saturation for assessing arterial oxygenation due to the flattening of the oxy-haemoglobin binding curve at saturation values above approximately 92%. This makes it important to ensure that pulse oximetry instruments have adequate precision and accuracy. The use of pulse oximeters still leaves the need to assess arterial PCO2 and this is particularly important during mechanical ventilation. In view of the influence of arterial PCO2 on cerebral circulation the use of transcutaneous PCO2 monitoring has been used in some centres. An additional approach is to use end-tidal CO2 monitoring with, for example, an infra-red gas analyser or a mass spectrometer. In fact the recording or display of the end-
tidal CO₂ waveform is useful for assessing ventilation/perfusion. In addition, it is also useful to
determine changes in pulmonary compliance and resistance when a baby is being mechanically
ventilated. Some mechanical ventilators can automatically calculate these parameters from in-built
pressure and volume sensors.

Hypoxic-ischaemic brain injury is a major consideration in neonatal intensive care and there have
been considerable efforts over the last three decades to develop measurement techniques that could
provide clinically relevant physiological data [18]. Ultrasound imaging and Doppler blood flow
measurement are key techniques for detecting intra-cranial haemorrhage and for assessing cerebral
blood flow. Near infra-red spectroscopy (NIRS) has been used to monitor cerebral oxygenation non-
invasively [7] and non-invasive measurement of intra-cranial pressure has also been achieved [19].

5. Conclusion
Developments in instrumentation science and technology over the last half-century have created
a huge array of devices aimed at improving the clinical care of the fetus and the newborn baby. Only
over the last decade or so have there been carefully planned and conducted clinical trials of the sensors
and instruments that have become available. An example is the assessment of fetal ECG monitoring
during labour, where the value of ST segment analysis has been demonstrated.

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