Development of Doppler ultrasound for measuring the neonatal heart rate at birth.

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Development of Doppler ultrasound for measuring the neonatal heart rate at birth

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Declaration

This is to certify that I am responsible for the work submitted in this thesis, that the original work is my own and that neither the thesis nor the original work has been submitted to this or any other institution for a higher degree. I independently conceived the concept of the use of the fetal Doppler on the neonate and all the studies in this thesis. I am responsible for and participated in all the research in this thesis. I have not been enrolled for another university, or other academic or professional organisation whilst undertaking my research degree.

I am aware of and understand the University's policy on plagiarism and certify that this thesis is my own work. The use of all published or other sources of material consulted have been properly and fully acknowledged.

The data presented in this thesis was obtained by myself at Sheffield Hallam University and Sheffield Childrens Hospital. I prepared and executed the work described and the data analysis and interpretation are entirely my own work.

The work undertaken towards the thesis has been conducted in accordance with the SHU principles of Integrity in Research and the SHU Research Ethics Policy.

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Dedication

The research is the product of collaboration, and I thank my principal collaborators Professor Reza Saatchi and Professor Heather Elphick for their advice and guidance. I am grateful to Claire Tongue and Samya Armoush for their guidance in obtaining the Research Passport. I thank Professor Heather Elphick for all her work in organizing and obtaining ethical approval as Principal Investigator of the clinical study and to Professor Saatchi for guidance and assistance in recruiting subjects for the adult study. I thank Sarah Shortland and Lowri Thomas for recruiting the babies whose data was used in this study. I am grateful for the support and patience of my wife. The work is dedicated to the unknown number of babies who have died or survived with disability because of an unknown heart rate value at birth and subsequent early cord clamping.

Abstract

The heart rate of a newborn baby is a very important measure of its health and is routinely required to be documented at every birth. The imprecise measurement and lack of real-time documentation of the neonatal heart rate at birth has been recognised for many years but auscultation still remains the recommended method in routine births. The heart rate of the fetus is measured and documented during pregnancy and labour by Doppler ultrasound but immediately after birth the heart rate is measured by auscultation. Auscultation is well recognised to be inaccurate and undocumented in real-time.to obtain the beats per minute heart rate. The contrast with determining and documenting the fetal heart rate with the neonatal heart rate is remarkable. Recently a new ECG device has been developed in an attempt to provide more continuous monitoring and documentation of the neonatal heart rate has been developed. There has also been investigation of the use of a hand-held foetal Doppler recently to determine the neonatal heart rate immediately after birth. It was found to be very effective but has not been seriously considered by the International Liasson Committee On Resuscitation. One reason may be the fact that, unlike the ECG, but similar to a stethoscope, the Doppler is not hands-free, as it requires one member of the resuscitation team to keep the transducer on the neonatal chest. Experience of over 50 years shows that even the slowest and weakest fetal hearts can be detected by Doppler ultrasound.

This research was to develop and test a hands-free version of a hand-held fetal Doppler device and to test this device for accuracy and functionality on adults and neonates. The initial study was carried out on healthy adult volunteers using a standard hand-held fetal Doppler device. The Doppler heart rate was compared with the ECG heart rate and found to have good correlation. The Bland Altman Plot of Doppler vs ECG showed all but two measurements were within the 95% confidence intervals.

A problem with documentation and the need for a hands-free transducer was highlighted.

This initial study fuelled the drive to construct a modified Doppler device to be hands-free and document electronically the heart rate results in real time. The problem of precise documentation of both the Doppler heart rate and the ECG heart rate was explored. A further modification was required and the final device tested in a second adult study. This showed much improved ease of use during the investigation, excellent correlation and that the Doppler usually determined the heart rate consistently before the ECG.

The final part of the study involved using the modified hands free Doppler device on neonates at the Children's Hospital Sleep Unit and comparing the Doppler heart rate with that of the hospital ECG. This demonstrated that the modified Doppler device was truly hands-free and, in the opinion of the parents, highly acceptable for use on their neonate.

Contents

Publications and Presentations

Winter Poster presentation 2022 - Industry and Innovation Research Institute, Sheffield Hallam University. *Doppler ultrasound to measure neonatal heart rate immediately after birth*. David J R Hutchon.

Hutchon, D. (2022) The Use of Foetal Doppler Ultrasound to Determine the Neonatal Heart Rate Immediately after Birth: A Systematic Review. *Children* 9, 717.

19th International Conference on Condition Monitoring and Asset Management CM2023, Northampton.
12th September 2023. *Neonatal heart rate monitoring at birth with hands-free fetal Doppler*. D Hutchon, Sheffield Hallam University.

Child Health Technology Conference 2023 *A Hands-free neonatal Doppler to determine the heart rate immediately after birth.* David Hutchon, Heather Elphick, Reza Saatchi. Sheffield Hallam University & Sheffield Childrens Hospital NHS Trust.

Abbreviations

BPM – Beats per minute
CTG – Cardiotocograph
ECG – Electrocardiogram
NICE – National Institute for Health and Care Excellence
ILCOR – International Liasson Committee on Resuscitation

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Chapter 1 Introduction

A number of methods of accurately measuring and documenting the neonatal heart rate at birth have been explored by the International Committee on Resuscitation (Wyckoff et al, 2022) for neonatal life support were unable to specifically recommend the Doppler ultrasound. They continue to recommend auscultation or for high risk neonates, the standard ECG, to determine the neonatal heart rate in the delivery room immediately after birth.

Doppler ultrasound has been used almost exclusively to determine the fetal heart rate for the last 50 years, so it is difficult to understand why it was never considered for the neonatal heart rate until about ten years ago. The fetus cannot be seen and the intervening maternal abdominal tissue and uterus clearly increases the difficulty in determining the position and direction of the fetal heart. In contrast, the site of the neonatal heart is known to be directly below the anterior chest wall. The first evidence of the use of a fetal Doppler device to determine the neonatal heart rate was published about ten years ago. Clinical use for the neonate after birth was published in 2016 followed by four other studies (Hutchon, 2022). These studies formed the basis of the systematic review included in the work of this thesis. The systematic review provided clear evidence Doppler provides excellent neonatal heart rate measurement, better than the ECG considered the gold standard for determining the heart rate.

The directional ultrasound probe is necessary to locate the fetal heart but is not needed for the neonatal heart. It was considered that a simple modification of the fetal Doppler device would result in a simple flat light transducer which rests on the neonatal chest without manual handling. This would be an advantage over the fetal Doppler probe which requires constant attention. The need for constant handling by one of the attendants may be the reason the standard fetal Doppler has not been readily adopted since the recent clinical studies showing how effective it can be.

1.1 Background

Obstetricians are rightly obsessed with the foetal heart rate. It is the primary parameter of the health of the fetus available to the obstetrician in real time. During labour the fetal heart rate is routinely monitored with the cardio-tocograph (CTG). There is the expectation of identifying features which indicate distress from lack of oxygen in the fetus and with the aim that a timely rescue delivery can be undertaken to prevent injury to the neonate. Features such as the rate, beat to beat variability, accelerations and decelerations all indicate the health of the fetus during labour. Although the fetal ECG has been investigated in an attempt to identify features of fetal hypoxia, the assessment of the fetal condition is based on the fetal Doppler heart rates in clinical practice. Thus some precision of the heart rate such as beat to beat variability is available from the Doppler heart sounds.

1.2 Assessment of health at birth

Birth is one of the most dramatic change that the body makes any time during life and a time when there is the highest risk of injury and death.

1.2.1 Transition at birth from placental to pulmonary respiration.

The heart rate of the baby immediately after birth remains the major parameter determining its health and is one measure indicating whether or not there is the need for assistance in transitioning from placental to pulmonary respiration. Only the rate is taken into account and none of the features of the fetal heart rate are considered. In the fetal circulation the left and right ventricles function in parallel. The respiratory circulation of the placenta is also parallel to the systemic circulation. This means that the output of the two ventricles can be different. After birth respiratory function is transferred to the lungs and the left and right ventricles function in series. This means that the output of the two ventricles must be equal once the foramen ovale and ductus arteriosus close. The output of the ventricles is largely dependent upon the heart rate. The output of each ventricle is heart rate x stroke volume. The stroke volume depends on the preload of the heart. Thus a reduced preload or reduced heart rate will result in a reduced cardiac output. The integrity of the brain is dependent upon a normal circulation. The brain can tolerate hypoxia more successfully than it can tolerate the ischaemia of a poor circulation.

In clinical practice neither the cardiac output nor the cerebral circulation can be measured, however the heart rate, which is a good measure of the cardiac output can be measured. However for it to be clinically useful, the heart rate must be measured accurately.

The most recent statement from the International Liaison Committee on Resuscitation (Wyckoff et al, 2022) states that newborn infants who are breathing or crying and have good tone and an adequate heart rate should undergo delayed clamping of the umbilical cord. The decision therefore whether or not to intervene in a physiological transition with early cord clamping requires an accurate measurement of the heart rate. Furthermore, the authors state that if, despite efforts to optimize ventilation, the newborn has a persistent heart rate less than 60/min or asystole, then chest compressions are needed. (Wyckoff et al, 2022). So accurate heart rate measurement is critical to the care provided to a newborn baby if the guidelines are to be followed. It is possible therefore that chest compression, a serious intervention, may be started on an erroneous heart rate measurement. If the heart rate is not documented in real time, audit of the clinical intervention is not possible.

1.2.2 Hypovolaemia of early cord clamping

International Committee on Resuscitation recognises that clamping the umbilical cord early after birth has a number of adverse effects on the circulation. Firstly it causes a sudden increase in the afterload of the heart followed by a marked fall in the preload of the heart. These two effects result in bradycardia and a fall in the cardiac output. The cerebral circulation has the greatest fall as a result of the intervention of early cord clamping. Rapid fluctuations in the cerebral circulation may lead to cerebral haemorrhage and brain injury.

These adverse effects must be prevented if possible by accurate assessment of the condition of the neonate at birth.

1.3 Doppler technology

In clinical practice throughout the world all the sophisticated Doppler technology used during labour is abandoned as soon as the baby is delivered, and in most situations, measurement of the neonatal heart rate returns to the basic method of auscultation of the neonatal chest. To determine the heart rate requires that the audible sounds of the neonatal heart are counted over a fixed period of time. A clock must be observed at the same time as counting the heart sounds and then mental multiplication to reach the heart rate. The recommended method is to count over 6 seconds and multiply by 10 or to count over 10 seconds and then multiply by 6.

The advantage of auscultation is that it only requires a readily available stethoscope and can also be used to confirm aeration of the lungs. However, it is intermittent and undocumented in real time. Palpation of the umbilical artery is possible but is no longer recommended. The inaccuracy of auscultation is well recognised (Owen C, 2004), (Kamlin C, 2006), (Chitkara R, 2013), (Hawkes, 2016) and there have been a number of attempts recently to address this. Several technologies for accurately measuring and documenting the neonatal heart rate at birth have been developed. These include the dry electrode ECG which is placed across the neonatal chest. Another is reflectance mode green light photopleththysmography on the neonatal forehead incorporated into a head cap. The International Liasson Committee on Resuscitation (Wyckoff et al, 2022) however found there was insufficient evidence to specifically recommend either of these. The other potential alternatives considered by ILCOR included the digital stethoscope. The digital stethoscope can both count and record the heart rate. ILCOR also rejected audible Doppler ultrasound, but it is unclear why as they did not reference any of the relevant papers between 2014 and 2020, nor did they appear to consider the systematic review published in Children in 2022. (Hutchon.2022)

1.4 ECG technology

The ECG is considered the gold standard for the neonatal heart rate however it has significant weaknesses, especially in the severely asphyxiated compromised neonate. In these babies it is possible for pulseless electrical activity of the heart (PEA) to confuse the clinicians. PEA is where the electrical activity of the heart is insufficient to stimulate the myocardium to contract. However on the ECG trace it appears that there is a slow heartbeat. Doppler ultrasound does not have this problem, indeed pulseless electric.al activity was identified using ultrasound. (Luong et al., 2019)

Currently, for the high-risk neonate in high resource settings, ILCOR recommends the standard ECG is used for determining the neonatal heart rate in the delivery room. However these ECG devices are expensive and not yet widely available especially in low resource settings. In contrast, the audible Doppler hand-held ultrasound device is both low cost and readily available in all but the very lowest resource settings.

1.5 Clinical practice

The investigator's interest in accurate measurement of the neonatal heart rate started in 2004 when the investigator first became concerned about the harm of early cord clamping at birth. Early cord clamping was a routine at that time and recommended practice throughout the world. It was part of the active management of the third stage of labour which was thought to reduce the risk of maternal haemorrhage. It was never seriously considered that early cord clamping might have some harmful effects for the neonate although it had already been shown that early cord clamping caused a neonatal bradycardia. (Fleming et al, 2011) (Hutchon, 2016). Indeed standard normal range charts were derived from babies subjected to this routine practice. Thus the standard charts showed a significantly lower “normal” range from that of the “normal” range of the healthy fetus who had not been subjected to early cord clamping. While the normal fetal HR range is derived from Doppler ultrasound, the neonatal HR is determined from auscultation or sometimes the ECG !

1.5.1 Recommended practice

With a change in recommended practice to avoid early cord clamping by NICE in 2014 (NICE, 2014) it became increasingly important to accurately measure and document the neonatal heart rate during the first minute after birth especially if the neonate was not breathing satisfactorily. However now, after more than 10 years since the change in NICE guidelines, many babies continue to be harmed by early cord clamping (Bewley et al, 2024). Neonatal resuscitation guidelines consider assistance with breathing a priority especially in a neonate with a slow heart rate.

1.5.2 Resuscitation with an intact cord

Accurately determining the heart rate of the neonate immediately after is critical to providing optimal care at birth. If the heart rate and condition of the neonate is satisfactory early cord clamping should be avoided. However if the heart rate is not satisfactory AND there are facilities to provide resuscitation or assistance with transition from placental to pulmonary respiration then assistance should be provided with the cord intact. During this time continued measurement of the neonatal heart is required to determine whether or not the intervention is being successful. Continued use of the Doppler allows a constant measure of the heart rate rather than the intermittent result of auscultation.

A majority of compromised babies needing resuscitation are delivered by caesarean section. Delivery by caesarean section can be facilitated by a customised mobile resuscitation trolley which allows the neonate to remain close to its mother with the umbilical cord intact (Hutchon, D., & Bettles, N., 2016). This requires that all the equipment used on the trolley is sterile, including any equipment used to monitor the neonatal heart rate. The Doppler can be readily used within the sterile area of caesarean section by placing it inside a sterile polythene sheath, as the ultrasound passes through polythene in the same way it passes through the plastic of the transducer head. Thus a continuous record of the neonatal heart rate would be available from the moment of birth until the completion of resuscitation if the Doppler ultrasound heart rate monitor is used.

1.6. Doppler ultrasound for the NEONATAL heart rate

The use of Doppler ultrasound for determining the neonatal heart rate raises a number of questions. Despite Doppler ultrasound being used for the fetal heart rate for over 40 years, there was nothing published about extending the use to the neonate until 2013. (Hutchon 2013) (Goenka et al., 2013) Was this because it would not function well in the neonate ?

1.6.1 Uncertainties of neonatal Doppler heart rate

Would the standard fetal Doppler device, such as the widely used Sonicaid SR2, made by Huntleigh, in Cardiff function on the chest of the neonate? Would it require a change in the focus of the transducer in order to register the neonatal heart which is only one centimetre below the skin of the chest ? What is the optimal frequency of the device for the neonate and is it different from the optimal frequency for the fetus. In principle the lower the frequency the greater the depth of penetration of the ultrasound beam. The fetal Doppler needs to be able to function from between a few centimetres from the heart to as much as 20 centimetres. The Fetal Doppler Ultrasound device operates at a frequency of between 3.5MHz and 5MHz. At this frequency it does not pass well through a gas space. There is no gas within the uterus and fetus during pregnancy, but shortly after the baby is born, the lungs fill with air as pulmonary respiration commences. Might this gas interfere with the transmission and reflection of the ultrasound ? However in the fetus and in the neonate the heart is immediately posterior to the sternum and anterior ribs and there is no intervening lung tissue. Thus there is no reason why the Doppler ultrasound will not be reflected from the rapidly moving valves of the heart and back to the sternum in the same way as the ultrasound is reflected from the fetal heart. Doppler ultrasound can detect the movement of the fetal heart from before 16 weeks when the heart is a few millimeters in size and pumping a tiny volume of blood. It becomes steadily easier to detect the fetal heart with Doppler as the organ grows.

Clearly the neonatal heart immediately after birth is the same size as it was in the fetus minutes earlier.

1.6.2 Initial development of the neonatal Doppler

Whether or not the standard fetal Doppler device functioned on the neonatal chest needed to be investigated. Can the Doppler heart sounds could be heard with an ultrasound transducer on the chest wall? A low cost 2.5 MHz fetal Doppler was purchased to initiate this investigation. It was found to function perfectly when placed over the heart of the investigator.

1.6.3 Initial testing of the neonatal Doppler

In 2010 there was no published evidence for the use of Doppler ultrasound after birth. Eventually the opportunity arose for the investigator and permission was obtained to test the fetal Doppler on newborn piglets. Piglets are about 500g at birth (about the same size as the smallest premature human baby) and they have no significant skin hair which might interfere with the ultrasound transmission. Over a few hours the fetal Doppler was applied to 20 piglets immediately after birth. Most of the piglets were very active and moving round to try to obtain their first meal. Their progress could not be interfered with. However, there were a sufficient number of piglets that remained sufficiently still for the Doppler transducer to be held on their chest long enough to document their heart rate. This study showed that the Doppler device readily measured the heart rate in these tiny newborn piglets within seconds after birth. (Hutchon, 2013)

1.7 Published Clinical Studies

A literature search in preparation for publishing the piglet study, identified a poster study, just published at the American Pediatric Society meeting. (Goenka et al., 2013) This study compared precordial Doppler ultrasound with auscultation and ECG in <u>human</u> newborn babies.

Although the fetal Doppler probe works just as effectively on the neonate as on the fetus, the long handle of the fetal probe is a hinderance. The long handle on the fetal probe is needed to provide and maintain the correct direction towards the fetal heart, in a fetus which cannot be seen. In the neonate, however, the position of the heart is immediately behind the anterior chest wall and the same position normally used to auscultate the heart. The presence of the stalk can interfere with the direction and the carer may put unnecessary pressure on the transducer and onto the neonatal chest. However, if the transducer was separate from the handle (but still connected to the electronics within) would it still function satisfactorily? This was one of the early questions to answer.

1.7.1 Need for improved equipment

Given the published evidence of the harm that was caused to babies at birth by early clamping, (Martinello et al, 2017) why were clinicians continuing to intervene in what is clearly a physiological process during transition from placental to pulmonary respiration immediately after birth. While delayed cord clamping is now widely recommended throughout the world, one reason the placental circulation is cut off by early cord clamping is the perception that neonate needs assistance with transition. This assessment is often down to the uncertainty by the birth attendants of the true condition of the neonate and especially its true heart rate.

All guidelines are based on the findings of research. The guidelines produced by the International Liasson Committee on Resuscitation prides itself on the its thorough assessment and analysis of all the best evidence to guide its recommendations. However the strength of any recommendation depends upon the strength of the evidence base. A weak evidence base results in a weak recommendation.

The evidence for the continued use of the continued use of auscultation is essentially because of the lack of evidence, in the view of the ILCOR authors, of other methods for determining the neonatal heart rate at birth. For some reason even the latest 2022 recommendation does not seriously consider the use of Doppler ultrasound despite published evidence of its efficacy since 2014.

A change towards accurate measurement and documentation of the neonatal heart immediately after birth could result in a significant change in clinical practice at birth.

The evidence that early cord clamping at birth caused harmful changes in the neonatal circulation has been known for over 20 years but the ILCOR guideline failed to take this into account, perhaps because the evidence of harm was not considered strong enough (Martinello et al, 2017). Now the guidelines have moved to promote a physiological transition for the neonate at birth during transition, but continue to advise the harmful intervention based upon the weak measurement of the neonatal heart rate using auscultation. Not only is this measurement of the neonatal heart rate inaccurate, it is not documented in real-time and is not available for audit or review. Such weak evidence would not normally be tolerated in research.

Some evidence is based on the heart rate measured by ECG but this is inevitably limited. An ECG cannot be used within the sterile field of caesarean section so heart rates are only measured after the umbilical cord has been clamped and a patho-physiological transition has resulted. Although in theory an oximeter could be used within the sterile field at caesarean section it is well recognised that it does not function properly in a compromised neonate and does not function satisfactorily in the first minute after birth. Therefore there is no method currently in use to accurately measure the heart rate of neonate immediately after birth at caesarean section. This is of particular concern for the potentially compromised neonate.

1.7.2 Physiological teaching and understanding

When early cord clamping was routine, healthy babies usually started to breath and cry quickly after birth. Physiological textbooks explained this was down to the **hypoxia** resulting from cord clamping. However, for the neonate who has a continued supply of oxygenated blood from the placental circulation, there is **no sudden hypoxia** to stimulate the respiratory centre. (Hutchon, 2016) These babies therefore may not breath quickly after birth because they remain perfectly well oxygenated for a short time. A normal or increasing heart rate is an indication that the baby is healthy. Stimulation may be all that is required. (Mercer, 2022) for the neonate to commence breathing. Currently the heart rate is neither measured accurately nor are the values properly documented. This means that audit, review and research are very limited.

1.7.3 The need for "hands-free" monitoring

Why Doppler ultrasound has not been used after birth for the neonate is a mystery. The use of a handheld fetal Doppler device for determining the heart rate of a newborn was first investigated in 2013 (Hutchon, 2013) (Goenka et al., 2013). Studies since 2017, included in a systematic review, shows evidence that a standard Fetal Doppler ultrasound device works perfectly on the newborn immediately after birth (Hutchon, 2022). Yet there appears to be little further interest in the approach either by the professionals or by those guiding clinical practice. These studies all used a standard portable fetal Doppler ultrasound device with a hand-held directional probe to assist in location of the fetal heart. The ECG and oximeter provides hands -free monitoring of the neonatal heart rate once the sensor has been applied to the neonate's body. This Thesis investigates whether removing the handle from the transducer allows the transducer to function normally and determine the neonatal heart rate lying on the neonatal chest "hands-free" without the attention of a carer.

1.8 Aim and Objectives

The aim of this study is to develop a user friendly, effective and accurate method for determining the neonatal heart rate immediately after birth in the clinical environment. This study presents the results of a medical engineering project followed by a clinical investigation of the customised technology.

The objectives are:

(i) To modify a fetal Doppler ultrasound device to perform as a hands-free neonatal heart rate device.

(ii) To provide an accurate real-time documentation of the heart rate data.

(iii) To determine the accuracy and practicality of the modified prototype device to determine the heart rate in adults.

(iv) To determine the accuracy and practicality of the modified prototype device to determine the heart rate in neonates.

(v) To determine the view of the parents on the use of the prototype device in their neonates.

(vi) To provide a prototype Doppler device suitable for use at caesarean section.

1.9 Outline of the Thesis

Chapter 1; Introduction The background to monitoring the neonatal heart and clinical practice.

Chapter 2; Literature Review. This provides a summary of the Systematic Review of the use of a fetal Doppler device to measure the neonatal heart rate at birth published in Children.

Chapter 3; Initial healthy adult study. The use of a low cost standard fetal Doppler device to determine the accuracy of the heart rate in the adult.

Chapter 4; Development of a hands-free Doppler device with wireless data acquisition. The modifications to the electronics of the low cost fetal Doppler device.

Chapter 5; Second adult study with modified device. The use of the modified equipment in adults to test its practicality and accuracy.

Chapter 6; Sheffield Childrens Hospital Study. The use of the modified equipment on neonates during Sleep Studies to determine the feasibilty and accuracy of the equipment to determine the neonatal heart rate.

Chapter 7; Summary and strengths and weaknesses of the study. The hands-free Doppler is an accurate and hands-free method for determining the neonatal heart rate at birth. It has not been demonstrated in a real clinical situation.

Chapter 2 Literature Review

A systematic review of the published evidence on the use of the fetal Doppler ultrasound device to determine the neonatal heart rate was carried out. Although the fetal Doppler has been in common clinical use throughout the world for over 40 years to monitor the fetal heart rate during pregnancy and labour, the first publication of any use of a Doppler device in the neonate was not until 2014.

2.1 Method

A thorough search of the literature revealed a significant amount of work on the subject had been carried out since 2014. Using the search terms "neonatal", "Doppler" and "heart rate" in Medline, ten studies were identified. Two were excluded as not relevant and another one because no new data was identified. Two studies in piglets were excluded. This left five published studies which were included in the review. The references of these papers were also used to identify any further possible work. A total of five relevant studies were included in the review.

Exclusions included one study by Dyson et al. (2016) describing the use of vascular Doppler of the aorta to determine the neonatal heart rate. Another by Lemke et al. (2011) measuring blood flow of the umbilical stump, was excluded.

2.2 Results

The review paper containing no new original data was excluded. Of the remaining studies, five were in human subjects. One excluded study referred to the use of precordial Doppler at birth in the text, but provided no data. In a personal communication from one of the authors, Prof Anup Kateria, at Sharp, San Diego, he reported that, during his research using Doppler ultrasound to measure the neonatal heart rate, they had had difficulty in maintaining the standard fetal Doppler probe on the neonatal chest. They also reported that this required the full attention of one of the neonatal resuscitation team. This in contrasted with the ECG which, once applied, is hands-free and does not require any continued attention.

2.3 Summary

In summary, the use of a standard foetal Doppler with a 2 MHz (one study) or 3MHz probe placed on the neonatal chest to determine the neonatal heart rate at birth in five studies were included in the review. The subjects included term and preterm babies, healthy babies and babies requiring resuscitation after both vaginal and caesarean section delivery. There was a total of 460 babies investigated. Although the data is limited, what evidence there is shows that the fetal Doppler has a significant potential for a more accurate and quicker acquisition of the heart rate immediately after birth than any other method. The results showed that the method was as accurate as the ECG and often provided a result earlier than the ECG. It always provided a result before oximetry, (Mizumoto H et al., 2012) which under-estimates the heart rate initially. Oximetry depends upon the peripheral circulation of the skin in the neonatal hand or foot. Inevitably in a compromised neonate the peripheral circulation in the hand or foot will be poor.

2.4 Analysis

All these published studies were conducted with a standard commercially available fetal Doppler device. The heart rate measurements were documented either by real-time clinical documentation (3 studies) or by video recording (2 studies).

Clinical recording provides no opportunity to validate the results and is open to clinical bias and mis-interpretation. Video recording is more satisfactory but still may have an element of error. Neither clinical documentation nor videorecording are acceptable for accurate documentation in a real-time in a clinical environment. Thus there is a need for real-time direct documentation of the neonatal heart rate with any clinically acceptable Doppler device. The development of the modified hands-free Doppler with remote real time documentation of the Doppler heart rate for use in the Children's Hospital study is described later.

All the studies in this systematic review obtained ethical approval for extending the use of the device for the newborn baby. Before these devices can be used in normal clinical practice at birth for the neonate, the manufacturers will need to broaden the intended use of their equipment to neonates as well as the fetus. There is however plenty of evidence for efficacy and safety in these studies for the manufacturers to make the change. Table 1 (Hutchon, 2022)

Study	Study Design	Comparisons
Zanardo and Parotto (2019) [3]	Observational study of 102 newborns (43 preterm) and 21 requiring resuscitation	ECG vs. 3 MHz Doppler
Shimabukuro et al. (2017) [4]	Prospective cross-sectional study of 33 term neonates at elective caesarean section	ECG vs. 3 MHz Doppler
Agrawal et al. (2021) [5]	Prospective multicentre study, 131 healthy neonates > 34 weeks	ECG vs. 2 MHz Doppler
Goenka et al. (2013) [6]	Prospective study of 92 stable newborns > 37 weeks, 1–8 min after birth	ECG and pulse oximetry vs. 3 MHz Doppler
Kayama et al. (2020) [7]	Prospective study of 102 newborns up to 72 h after birth, 21 during resuscitation, from 23 weeks to term gestation	ECG vs. 3 MHz Doppler

Table 1 - Summary of studies included in the systematic review (Taken from *Children 2022, 9, 717. https://doi.org/10.3390/ children9050717*)

This Systematic Review is published in *Children [Hutchon, D. The Use of Foetal Doppler Ultrasound to Determine the Neonatal Heart Rate Immediately after Birth: A Systematic Review. Children 2022, 9, 717. https://doi.org/10.3390/ children9050717,* and contains the full detailed evidence.

2.5 Advantages of Doppler ultrasound

There are several advantages of Doppler ultrasound over either auscultation and ECG. At birth neonate is wet and at risk of hypothermia if left exposed. The preterm baby is sometimes wrapped in a polythene bag and placed under an overhead warming lamp. Doppler ultrasound will pass though the polythene provided there is good contact with the neonatal skin and transducer. Thus the standard care for the preterm neonate can be provided while still monitoring the heart rate with Doppler ultrasound. This would not be possible with the ECG or oximetry.

The application of the ECG (2 or 3 electrodes) takes considerably longer than the application of a Doppler transducer which can be applied immediately after birth. There is a significant latency period of 1 to 2 minutes before a reliable signal display is obtained from the ECG. This interval may interfere with the optimal care of the neonate during the first minutes after birth.

2.6 Safety

Auscultation, oximetry, ECG and Doppler ultrasound all have an established safety record. In particular, intrapartum monitoring (CTG) with Doppler ultrasound has been used in millions of births throughout the world over the last 30 years. Colour Doppler examination of the neonatal heart has been used for a number of years and there have been no adverse effects reported, in particular with the use of the Doppler ultrasound gel. There have been concerns about the ECG electrodes, which can cause irritation or pain to the neonatal skin when applied for longer than a few minutes. (Agrawal et al., 2021)

Chapter 3 Initial Healthy Adult study

The initial study was designed to compare the accuracy of the Doppler heart rate device with the ECG heart rate in adult volunteers.

3.1. Method.

Information sheets were prepared describing the study in straight-forward language. These sheets described the nature of the research and asking for the help of volunteers. Consent sheets for involvement in the research were prepared. A Converis application for Ethical approval was submitted.

Once the ethical approval was obtained, staff members of Materials and Engineering Research Institute (MERI) at Sheffield Hallam University were approached, provided with an information sheet describing the research and then asked if they were interested in being involved. The volunteers signed their consent after verbally confirming they had read and understood the information sheet provided.

The volunteer was asked to sit close to a table. A standard unmodified fetal Doppler probe, (U3-02 Banghjan fetal heart rate instrument, Shen Rui Medical Ltd), coated with ultrasound gel, was applied to the skin of left anterior chest of the subject and the position and direction adjusted until typical Doppler heart sounds were heard. When satisfactory heart sounds were audible and the heart rate displayed on the Doppler device, the volunteer was then asked to place their fingers on the Kardiomobile ECG device on the table in front. Simultaneous measurements of the Doppler and ECG heart rate were made on each subject. Three 30 second runs were made consecutively on each subject.

The Doppler heart rate was documented by videoing the Doppler display on an iPad. Both the U3-02 and the iPad were supported within a custom designed support. The ECG heart rate was recorded using the Kardiamobile. (Figure 1) This device records the ECG signal sending it to an App on a nearby iPhone. The quality of the ECG was visually checked and confirmed that the software reported the heart rate accurately.

The video of the Doppler display was used to determine the heart rate from the Doppler display value. The results for each subject were entered into a XLS sheet.

Figure 1 Kardiomobile (Image from ebay.)

3.2 Results.

The study was conducted on 16 adult volunteers. The age of the volunteers was between 21 and 77 years. All were male apart from one as they were recruited from an Engineering Department. In two of the subjects no valid ECG could be obtained and in one subject an ECG was only valid in two of the three runs of measurement. This resulted in a total of 41 measurements for analysis. Correlation between the two methods was assessed by a scatter plot of the two measurements (Figure 2), the paired two sample means Student T-Test (Table 2), a box and whisker plot (Figure 3) and a Bland Altman plot. (Bland & Altman, 1986) (Figure 4). Student t-test: Paired two sample for means is shown in Table 2.

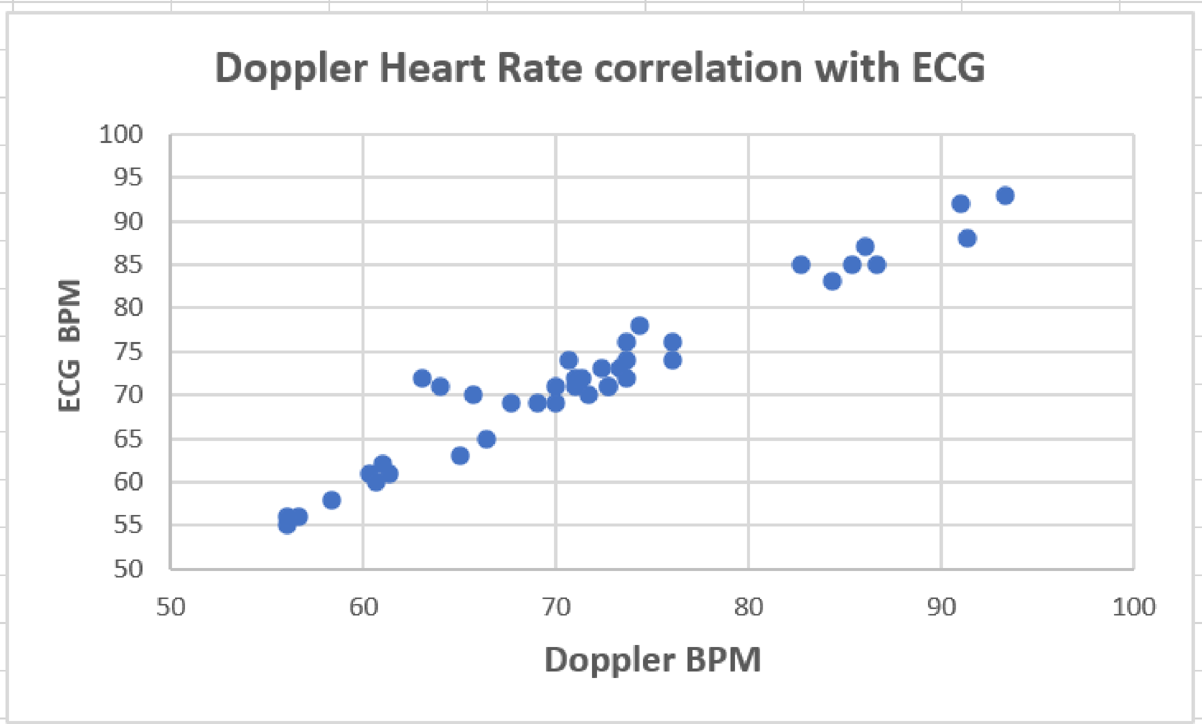


Figure 2 This scatter plot shows good correlation between the results of the Doppler and the ECG Heart rates in first adult study.

The paired samples t-test assumes that the differences between the pairs is approximately normally distributed and there are no extreme outliers. (Table 2) The analysis was carried out on the 14 subjects who had three valid comparisons between ECG and Doppler.

Table 2 First Adult study results. Student t-test: Paired two sample for means.

t-Test: Paired Two Sample for Means		
	Variable 1	*Variable 2*
Mean	72.5	72.57
Variance	100.5	106.57
Observations	14	14
Pearson Correlation	0.99	
Hypothesized Mean Difference	3	
df	13	
t Stat	-9.9	
P(T<=t) one-tail	9.60E-08	
t Critical one-tail	1.77	
P(T<=t) two-tail	1.90E-07	
t Critical two-tail	2.16	

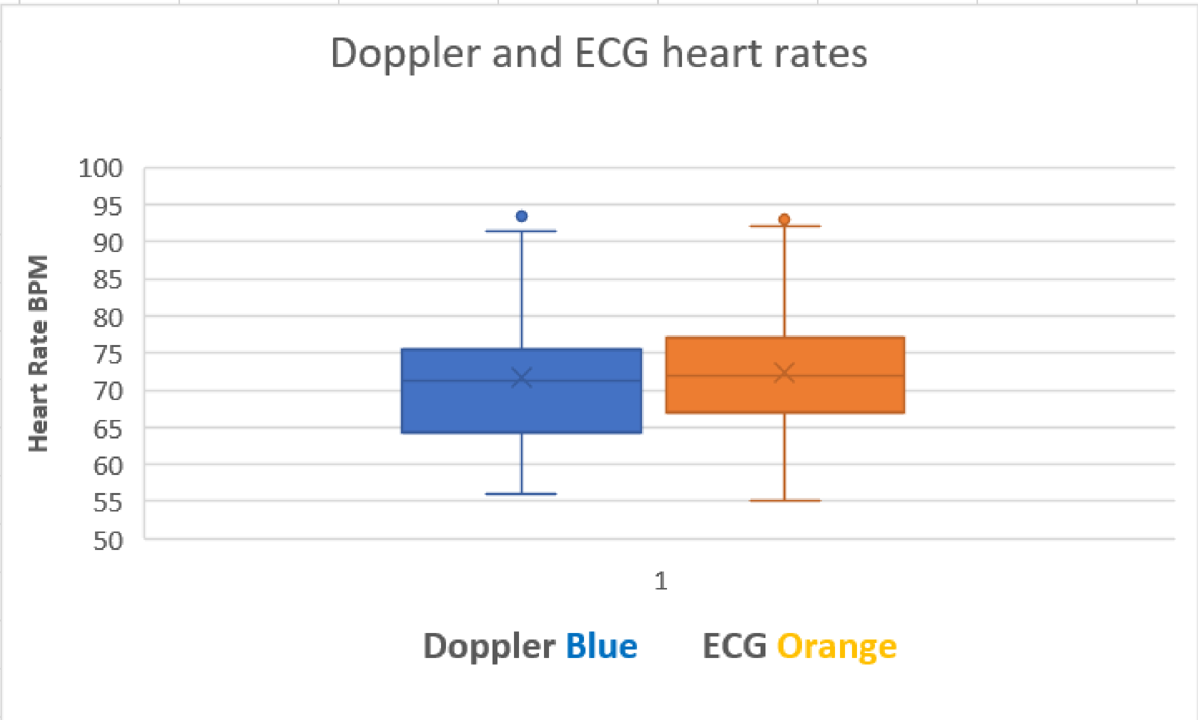


Figure 3 Box plot of results of 14 subjects (all with 3 valid results) showing median, upper and lower quartile range and minimum and maximum values.

3.2.1 Bland Altman plot

The Bland–Altman plot is used to compare two clinical measurements each of which produced some error in their measures. The ECG is considered the GOLD standard for heart rate measurement but even the ECG must not be considered without error. The Bland Altman plot takes into account the potential variability of the ECG as well as the Doppler heart rate in this study. (Figure 4)

The absence of extreme outliers is confirmed in the Bland Altman graph.

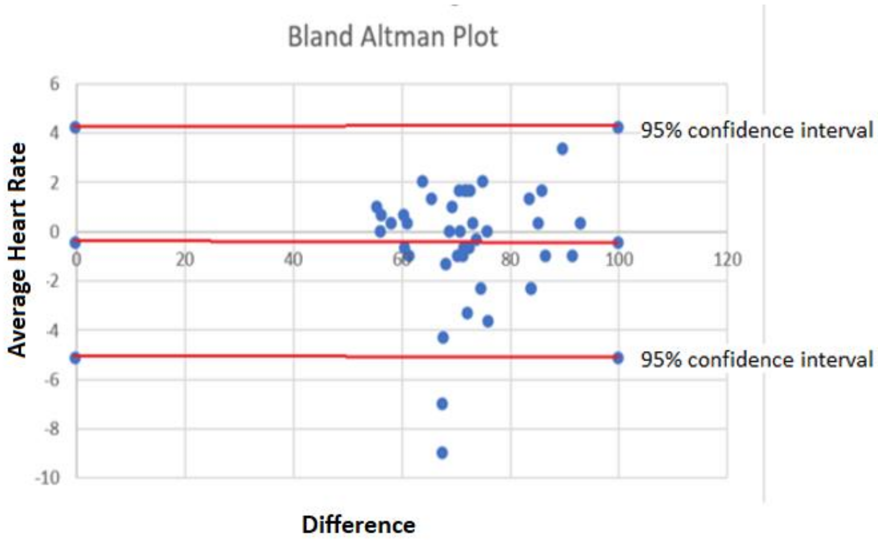


Figure 4 Bland Altman Plot of Doppler vs ECG showing 95% confidence intervals.

The Bland Altman plot of the 42 data points is from the 14 subjects and shows two outliers. The two outliers show a heart rate of 7 bpm and 9 bpm of the Doppler lower than the ECG. This may have represented beats missed by the Doppler.

Visually there is excellent correlation between the heart rate determined by the Doppler and the ECG. This was confirmed using Students t Test – Paired Two Sample for Means which showed no significant difference between the Doppler and ECG rates, because the P-value is less than 0.05 (Table 2) which means the null hypothesis is rejected and there is no significant difference in the means of each sample. The excellent correlation is confirmed on the Bland Altman Plot, with all but two values falling within the 95% confidence intervals.

3.3 Limitations

This small initial study showed excellent correlation between the Doppler and the ECG for determining the heart rate. It shows that the Doppler is very reliable and in fact the only problem with obtaining a heart rate was using the ECG. It also however demonstrated a potential problem with the use of a fetal Doppler for the neonate in a clinical environment and documentation problems for use of this particular low-cost device in any future clinical study.

Firstly, the fetal Doppler hand probe was difficult to maintain on the chest directly over the chest with sufficient accuracy. It was sometimes uncomfortable for the researcher to maintain the precise position and direction when the subject was sitting erect. Although the neonate will be prone, the probe handle is likely to be difficult to keep in place on the neonatal chest. This might also be the case in clinical practice where the clinician would find it uncomfortable to maintain the Doppler probe on the neonatal chest. Secondly keeping an adequate but not excessive pressure was also difficult. Excessive pressure may be of particular importance in clinical practice for neonates when pressure on the chest will inhibit respiration. As the clinician becomes tired, they may find it difficult to avoid excessive pressure on the neonatal chest. Thirdly documentation of the heart rate using video was effective but would not be practical in clinical practice.

It was clear that a much more secure method for documenting the Doppler heart rate was needed. Some Doppler devices in common clinical use, such as the Huntleigh SR2, do record the Doppler heart rate onto a memory card. Unfortunately, the low cost U3-02, Fetal Doppler did not have this feature. All my investigations had been initiated with these low cost devices. This significant weakness of the device had to be overcome if the research work was to proceed. This required the medial engineering element of the research.

Chapter 4 Wireless device development

A number of approaches to document the Doppler heart rate in real time were considered. Might it be possible to identify a point in the electronics feeding the heart rate value to the LCD display? However investigation using an oscilloscope in the University Materials and Engineering Research Institute (MERI) laboratory failed to identify any digital signals within the circuit board close to the liquid crystal display unit.

An alternative approach which was considered was to record the audible Doppler heart sounds. This recording could be listened to and the heart rate calculated (as for the normal auscultation method described earlier) but this is clearly not a significant improvement over auscultation with a stethoscope.

Computer analysis (for example in MATLAB) of the Doppler heart sound wave is also a possible solution but generating the heart rate independently of the Doppler device is not a direct comparison of the use of Doppler with ECG heart rate. In addition, it would have required the development of sophisticated hardware and software to provide this in real time and unlikely to have been possible to incorporate the electronics into the original Doppler device case.

A third possibility considered was to use character recognition of the Doppler heart rate display. Character recognition software is widely available. This however could require equipment which might have obscured the display and make direct comparison difficult and require even more complex hardware and software. It also seemed a clumsy solution and unlikely to be possible for use in a clinical environment.

4.1 Development of the modified Doppler device

The final option chosen to explore was to find a method of reading and documenting the heart rate result directly from within the device electronics or LCD display itself but still using the low cost Doppler device.

The first adult study had also demonstrated the need for a hands-free transducer. It was difficult and uncomfortable for the investigator to keep the directional probe over the heart. As the direction and position of the adult heart and the neonatal hart are known there is no need for the handle of the fetal Doppler. There was a need for a hands-free version which could be flat and rest on the chest over the heart without attention. It was thought that the surface tension of the thick ultrasound gel would keep the light transducer in place provided wire connecting the transducer to the Doppler device wire was flexible enough and of sufficient length.

4.2 The low cost U3-O2

The low cost U3-O2 Doppler device was used to develop the wireless documentation of the heart rate. The device details were printed in Chinese shown in Figure 5 and translation was required. The details of the device are below.

Figure 5 Label on reverse of Doppler equipment

The translated packaging states
“Fetal Doppler - Fetal Heart Rate Monitor U3-02 Digital display

Features: Ultra-sensitive & waterproof ultrasound probe. Featuring loudspeaker and 3.5mm jack. Easy to use and portable. Multiple modes and fetal heart rate display.
Temperature 5 – 45 degree C. Humidity 9% - 85%   Keep dry   Atmospheric pressure 50kPa – 106 kPa
L/N: T21051305
D/C: 20210521

Frequency 2.5MHz
Fetal heart rate instrument   - Brand is " Banghjan" made by Shen rui medical ltd
It has manufacturing permission 20172983
Medical equipment product number   20182230732
Registration of product 20182230732

Company address
Shen Zhen,
BaoAn district,
Fu Yong Street,
Fu Yong LiXin Hu"

4.3 Function of LCD display

LCD displays require very low power. When a potential difference is applied across the crystal it becomes opaque. However, this potential across the segment also initiates migration of the crystals, which leads to failure of the crystal in time. It becomes permanently opaque. In practice this is overcome by using a very short alternating potential difference across each segment of the seven numerical segment displays. Any migration of the crystals in one direction is avoided. The display is powered within a matrix, usually a number of common lines and seven digital lines for each digit. Both the common lines and digital lines have a square wave signal. Each digital segment is associated with only one of the common lines. When the square wave of the digital line is out of phase with the common line, the segment is opaque as a result of an alternating potential on either end of the liquid crystal segment. When the square wave of the digital line is in phase with the common line, the segment is clear as there is no potential difference across that specific segment. Using this information it might be possible to interpret the signals generating the LCD.   A search of the Internet provided a possible solution to reading the LCD of the U3-O2.

4.4 Direct reading of the LCD

A search of the Internet identified two systems which described how to reverse engineer an LCD driver to determine the displayed values. One used the Atmeg 6666 while the other used an Arduino which is also based on the Atmeg. (Clothier, accessed 2022) The investigator was already familiar with the Arduino Uno and the processing language (an embedded C++) of the Arduino IDE, so this approach was investigated further.

The article explained how only one common line signal needed to be read and this was used to simulate the timing of the other common lines which are timed from this one signal within the Arduino software. Seven digit lines are required to completely identify each of the three figures displayed. Clothier explained that his solution only worked with a two-phase system and explained that another approach was necessary on a three phase system. The three phase signals are not sufficiently separated to use a simple approach. Unfortunately the author did not elaborate on how the three phase signal system could be interpreted, and a further search of the Internet did not provide any information. Whether the U3-O2 LCD was driven by a two phase or a three phase signal needed to be established at an early stage.

4.5 Dismantling the U3-02

The first step was to determine whether the LCD of the U3-O2 was driven by a biphasic or triphasic signal. The Doppler device was dismantled and the supply to the LCD identified. In order to determine the signals which were driving the digital display, the LCD needed to be separated from the rest of the electronics. (Figure 6)

4.5.1 Soldering and Desoldering

The liquid crystals of the LCD are very easily damaged by heat and initial attempts to desolder resulted in damage to the LCD. Access to the LCD is very restricted. Fortunately, the devices are low cost (£15) so it was possible to experiment with other different approaches to eventually find a successful method. The intact LCD was finally separated undamaged from the electronics by cutting the connecting wires, which were very inaccessible, with very fine wire cutters. Once the LCD was removed, these were then reconnected to longer wiring with very careful soldering and using a heat sink on the LCD connection to reduce the risk of heat damage. The wires from the Doppler circuit to the LCD were then reconnected via a breadboard and confirmed to be working correctly. (Figure 6) This also enabled interrogation of the signals from the U3-O2 and it became possible to directly drive the LCD from an Arduino Uno (using an alternating pulsed wave) to confirm correct identification of the wires driving each segment. The wires which were the common lines and which were the segment lines were thus clearly identified. This allowed completion of the matrix to establish which segments of the LCD were driven by which common and which lines.

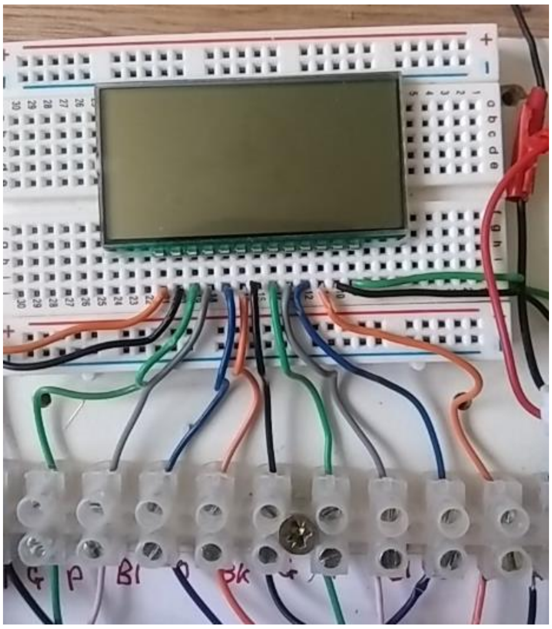


Figure 6   LCD separated from U3-02 and reconnected via a breadboard

4.5.2 Interpretation of LCD signals

This provided the first stage for interpreting the signals from the U3-O2 which were driving the LCD. Investigation of the signals driving the LCD by an oscilloscope was carried out. (Figure 7)

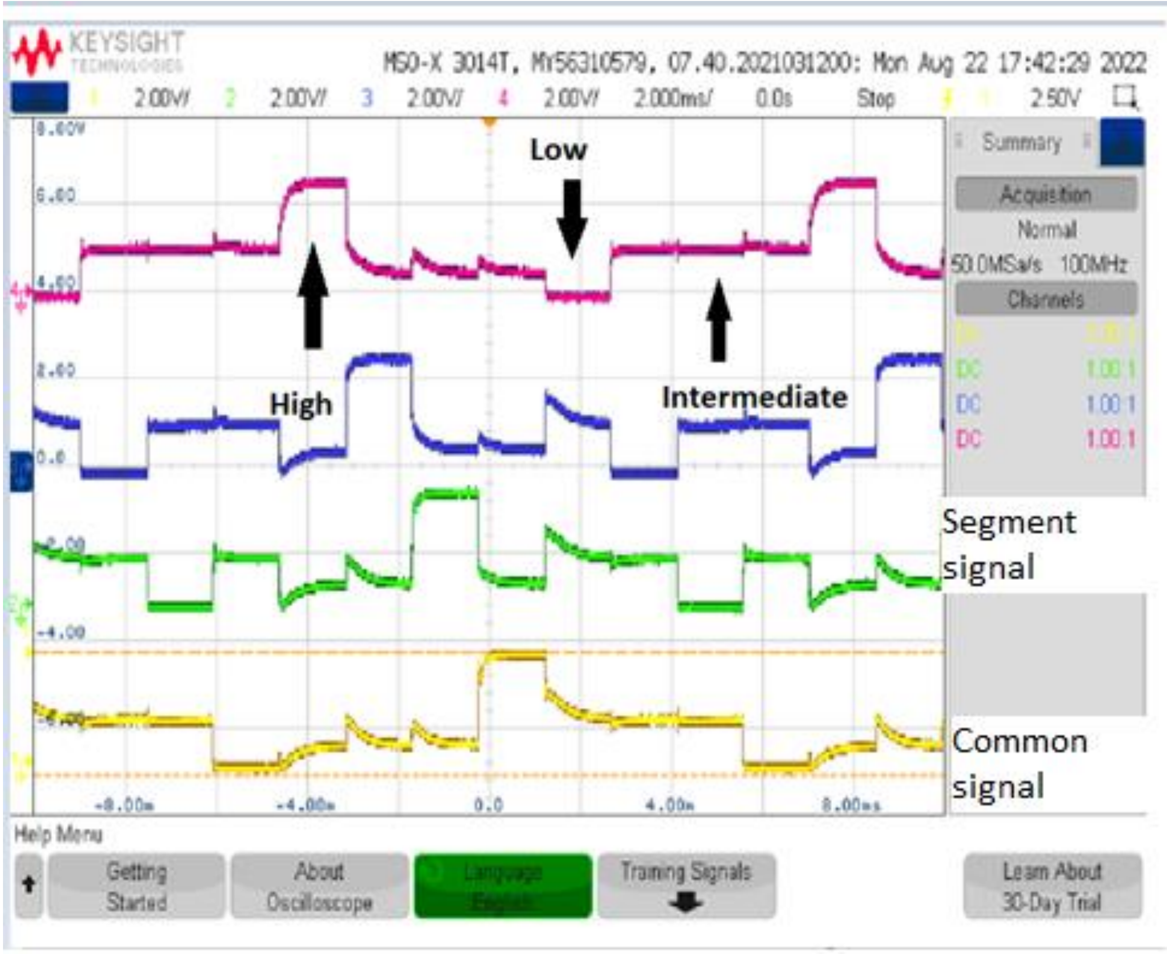


Figure 7 Oscilloscope showing 3 phase cycle. The red, blue, and green graphs are the segment lines, and the yellow graph is one of the COM lines.

When signal 2 (blue) is high and signal 1 (yellow) is low (or 2 low and 1 high), the segment supplied by this combination of the matrix is opaque. As can be seen the intermediate signal levels results in times when both are between the high and low or one is high but the other only intermediate. Although it may not affect the actual opacity of the LCD, it makes interpretation of the signals by the microprocessor very complicated.

Unfortunately, this preliminary investigation showed a three-phase signal driving the LCD as shown above. While the intermediate values do not interfere with the function of the LCD, the intermediate values do make interpretation of the signal very uncertain.

The possibility that measuring the mean potential (PD) across each crystal segment would identify when the segment was opaque (ie ON) and that this might be measured by the analogue digital converter (ADC) of the Arduino. Unfortunately exploration of this approach showed that the ADC in the Arduino was not fast enough to respond. While the segment is on, the potential difference should be higher than when it is off. However, this potential difference is alternating and after many measurements of the display it was identified that there was no consistency and showed a whole range of values. Therefore the mean potential difference was not consistent across all segments of the display and the precise potential difference was actually dependent upon the number of segments being driven (opaque) at any one moment.

4.5.3 Reading the LCD with a two phase signal

The system described by Kurt E. Clothier, published the article in www.instructables.com was chosen as the basis for the direct LCD read. The source code for the Arduino Uno was available at the GitHub Repository. The interpretation of the two phase binary signal is explained by Clothier (Clothier, accessed 2022). Clothier explained how these binary signals could be analysed and the 7 segment display identified and converted to the number. As explained above, for each digit there is a common electrode and a specific electrode for each segment and the precise arrangement had to be determined by exploring the signals on the oscilloscope associated with each number displayed.

The article only explained the interpretation of the two-phase signal and provided no other information on how to interpret the three phase signals. No reference was provided in this article and no other information could be found searching the Internet for the interpretation of the three phase LCD.

4.5.4 Conversion of the three-phase signal to a two-phase signal with op-amp comparators

One solution was to find a way to determined how the three-phase common signal could be converted into a two-phase signal. The three-phase signal was converted to a two-phase signal using two of the op amps within the LM339N quad op amp as comparators. Figure 8 A comparator works by a simple concept. Each op amp has 2 inputs, an inverting input and a noninverting input. If the inverting input voltage is greater than the noninverting input, then the output is drawn to ground. If the noninverting input voltage is greater, then the output is drawn high to VCC. Thus intermediate voltages are drawn either high or low depending on the threshold voltage set by a resistor on the two inputs. The voltage for the input was adjusted by a fixed resistor and by a variable resistor. The variable resistor was adjusted so that the three-phase signal could be seen to convert to a two-phase signal on the oscilloscope. With only one comparator in the circuit the signal still sometimes had a third phase component but with a second comparator in series the signal became perfectly biphasic. Figure 9. This circuit only needed to be included in one of the common lines as the computer simulates the timing of the other common lines as explained below.

LM339 19.177 mm × 6.35 mm

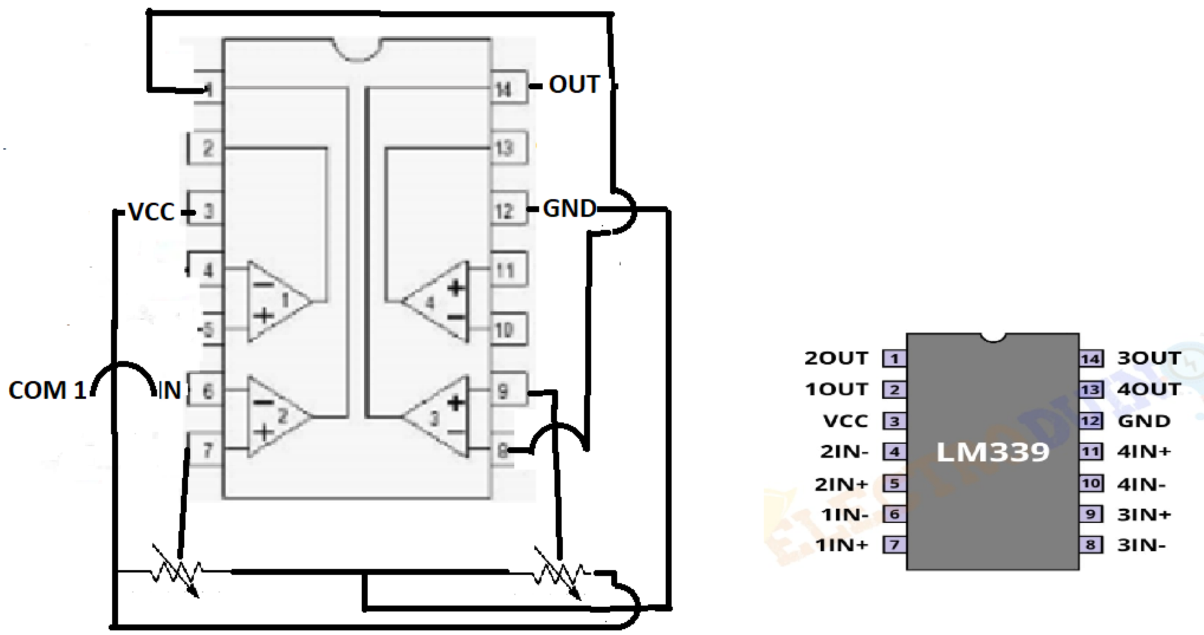


Figure 8 LM339 Quad op-amp circuit. Two of the op-amps were used as comparators in series to convert the three-phase signal in COM1 to a two-phase signal.

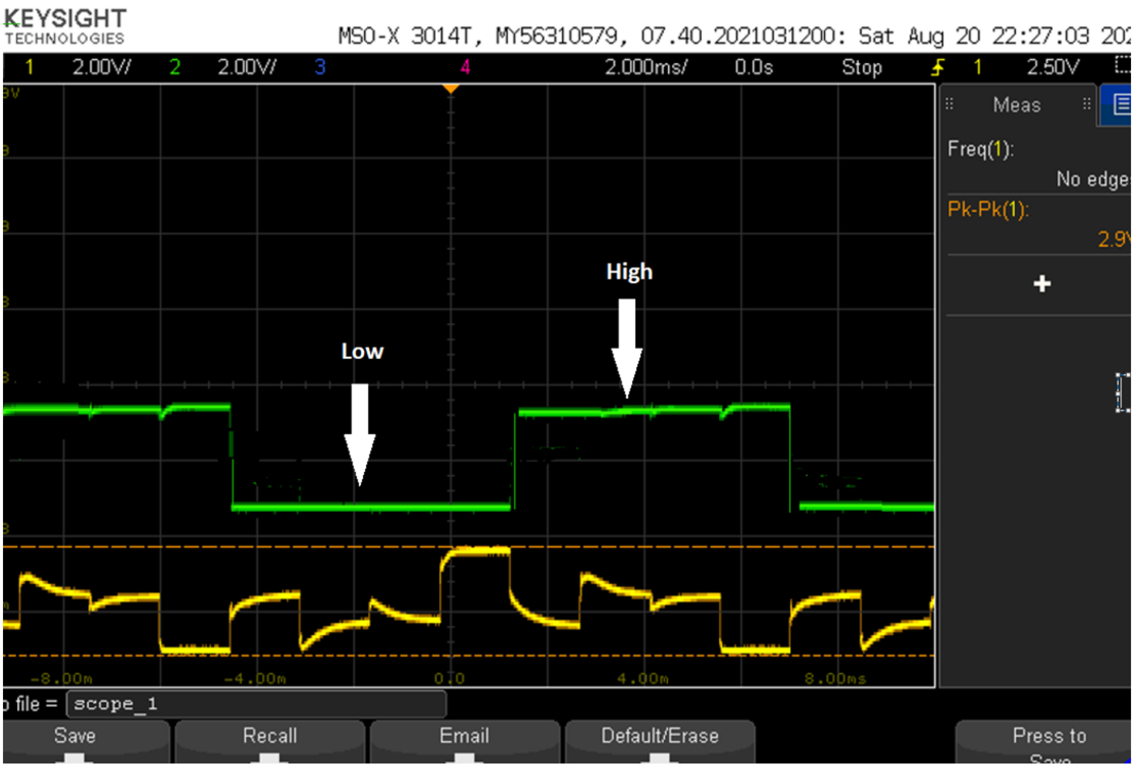
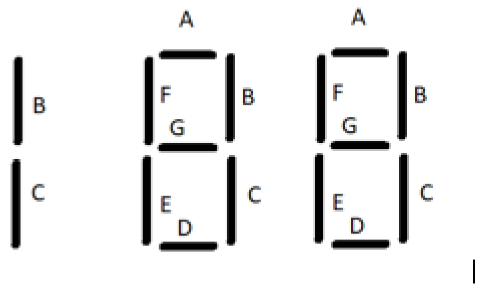


Figure 9 Two phase cycle (green) complared with three phase cycle (yellow) after including two comparartors in the green signal.

Converting the common line into a two-phase square wave thus made it possible to use the Kurt E. Clothier systems described above. As explained it is only necessary to determine the timing of one of the common signals. Either the rising edge or the falling edge can be used to determine the timing. The rising edge was found to be more stable and by determining this in one of the common lines, the timing of the other three can be generated within the software.

The timing of the four common lines was determined on the oscilloscope. Thus detecting the rising edge of one of the common lines allowed the timing of the others and to measure when each of the other three common lines would be high. An interrupt procedure was written to identify the rising edge of the first common line every 30 cycles. An interrupt must be used so that rest of the program can run without missing the rising edge at the start of each cycle. During each high phase of the common lines, actual and simulated, the state of each of the digital lines was then determined. In order to determine which segments are opaque requires knowledge of which segment is driven by which common line and which digital line. A matrix was completed (Figure 10) to determine which segment was driven by which common line and which digital line. This was achieved by removing common lines and digital lines during a known display and also providing an alternating potential difference between a common line and a digital line to identify which segment was affected. There were found to be four common wires driving the 16 digit-lines of the three digits.



	Digit 2	Digit 2	Digit 1	Digit 1	Digit 1	Digit 0	Digit 0	Digit 0
LCD line	8	7	6	5	4	3	2	1
COM1			1E			0E		
COM2	2B			1F	1B		0F	0B
COM3	2C			1G	1C		0G	0C
COM4			1D	1A		0D	0D	

Figure 10 The matrix generated to identify the lines driving the three digits of the LCD

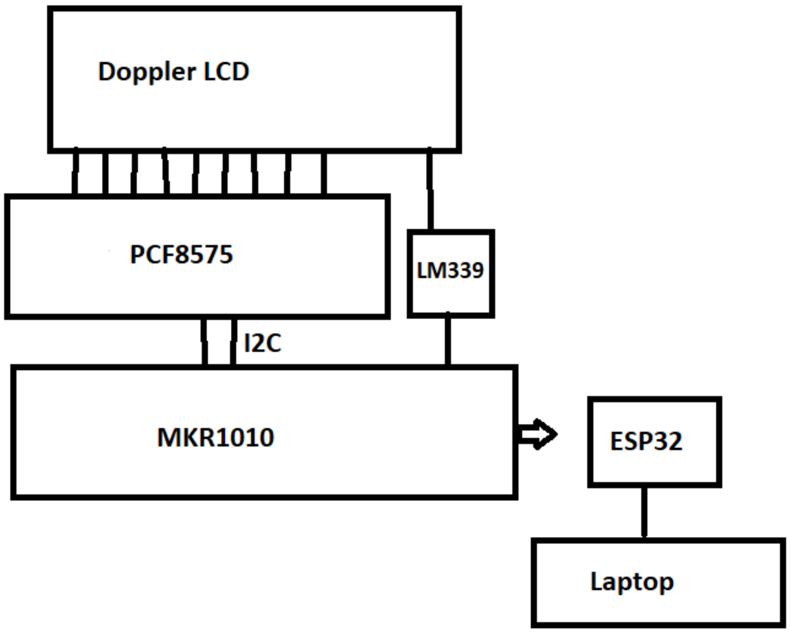


Figure 11   Block diagram of LCD reading system

As explained by Clothier (Clothier, accessed 2022), the Arduino does not have sufficient parallel ports for all the digits. To overcome this all the required parallel signals need to be converted to serial signals.

The PCF8575 which is a 16-bit I/O expander was selected. (Figure 12) This converts the 16 digital signals driving the LCD to a serial signal and then transmits the data by IC2, which is a serial data transmission protocol which can be interpreted by the Arduino or alternative microprocessors, such as the MKR1010 (Figure 13) or ESP32 (ESP32).

Figure 12 PCF8575 40.8mm x 17.7mm x 4.5mm

Figure 13 MKR1010 61.5mm x 25mm

Figure 14 ESP32 50mm x 37mm x 4mm

The serial signals suppling 16 segments consisting of two 7 segment displays plus the two segments of the 100 display. Therefore, with the system devised, it is not possible to display values greater than 199. This was not considered a significant limitation as the heart rate of a neonate up to one year of age is very unlikely to be above 170 bpm, especially in an essentially healthy neonate.

4.5.5 The software program.

This is available at the GitHub Repository (GIThub) The code was carefully examined and adjusted to meet the specific three digits which were to be interpreted from the LCD display of the U3-O2.

The program identifies when the one common line (COM1) changes to high (a rising edge). This generates an interrupt and the state of all the segment lines be read at this stage. After an interval (identified by experiment for the U3-02) the state of the other common lines are read and from this all the active segments are determined and the value of each of the three

digits generated from the software. The precise interval between each common line was adjusted within the software for an optimal and consistent interpretation.
The ESP32 (Figure 14) was programmed to receive the wireless signals from the MKR1010 (Figure 13) and the ESP32 transferred the data via a USB cable to the laptop.

4.5.6 Testing

A program for the Arduino was written to generate “heart” sounds with rates from 60 to 180. This was used to stimulate the transducer of the U3-O2 and provide a heart rate output on the LCD display. This program was used to confirm that the expected rate was displayed by the LCD and that the Arduino output was of the same value. The program was modified and delay values between each of the three common lines within the microprocessor program were adjusted to provide a consistent output for each heart rate value.

4.6 Quality test of device based on Japanese standard check.
(Japanese Industrial Standard CRM:0413041)

To meet this standard, the device should be able to accurately and quickly measure a fetal heart rate that changes in steps, with the duration of each step being 20 seconds. Heart rate sounds start at 60 beats/minute, then 80 beats/minute, then 100 beats/minute, then finally 120 beats per minute, and with a similar decreasing sequence.

The short program was written on the Arduino Uno generating a short sharp sound, similar to that produced by the Doppler device. The sounds were generated at the above intervals of 20 seconds. This was fed into a small speaker and the Doppler transducer placed on the speaker. The Doppler device responded to the speaker vibrations and displayed the heart rate which was then documented via the LCD read and wireless transmission. The graphs Figure 15 show good correspondence with the changes in the frequency sound rates as generated by the Arduino and confirmed a rapid and accurate response by the modified Doppler device to the frequency changes generated by the Arduino software.

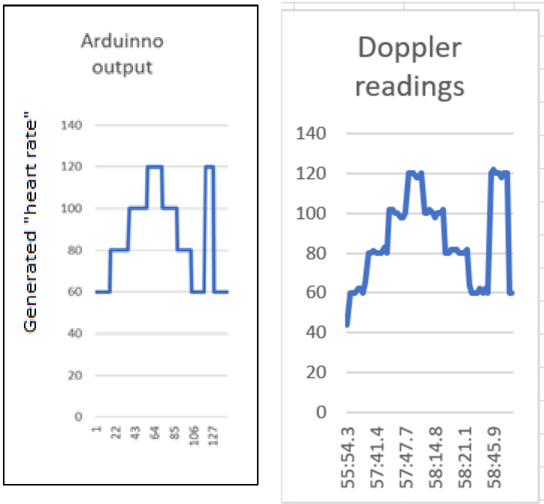


Figure 15 Japanese standard showing Arduino output and rate recorded from the hands free Doppler.

4.7 Insertion of the electronics into the original U3-02 case.

Once it was established that direct reading of the LCD was possible, a way needed to be found to miniaturise the design and replace it inside the original U3-02 case. A device which would send the heart rate reading for documentation was needed and, to be acceptable in a clinical environment, contained within the original case of the U3-02.

The Arduino Uno is clearly much too large but had the advantage of being workable during development with a breadboard circuit. Initially the ESP32 was used. The ESP32 has a WiFi module for wireless transmission of the data.

The LM339 quad voltage comparator was mounted on a small copper perf board for electronic protyping together with two trimming variable potentiometers and one fixed potentiometer. A variety of configurations were experimented with to fit all the electronics into the original U3-02 case. It became clear that the additional electronics could only be fitted into the case if the battery case was removed. Obviously this presented a problem with a power supply but an initial prototype was completed using an external battery. When this was completed and found to work the problem with the power supply was addressed.

The MKR-1010 is based on the Arduino but is much smaller and includes a WiFi unit but also includes a charger for its LiPo single cell 3.7v battery. This battery can be used to power the other components as well as the Doppler device- electronics.

The system was rebuilt with the MKR-1010 (Figure 16) and the software modified to fit with this processor and compiled with the Arduino IDE.

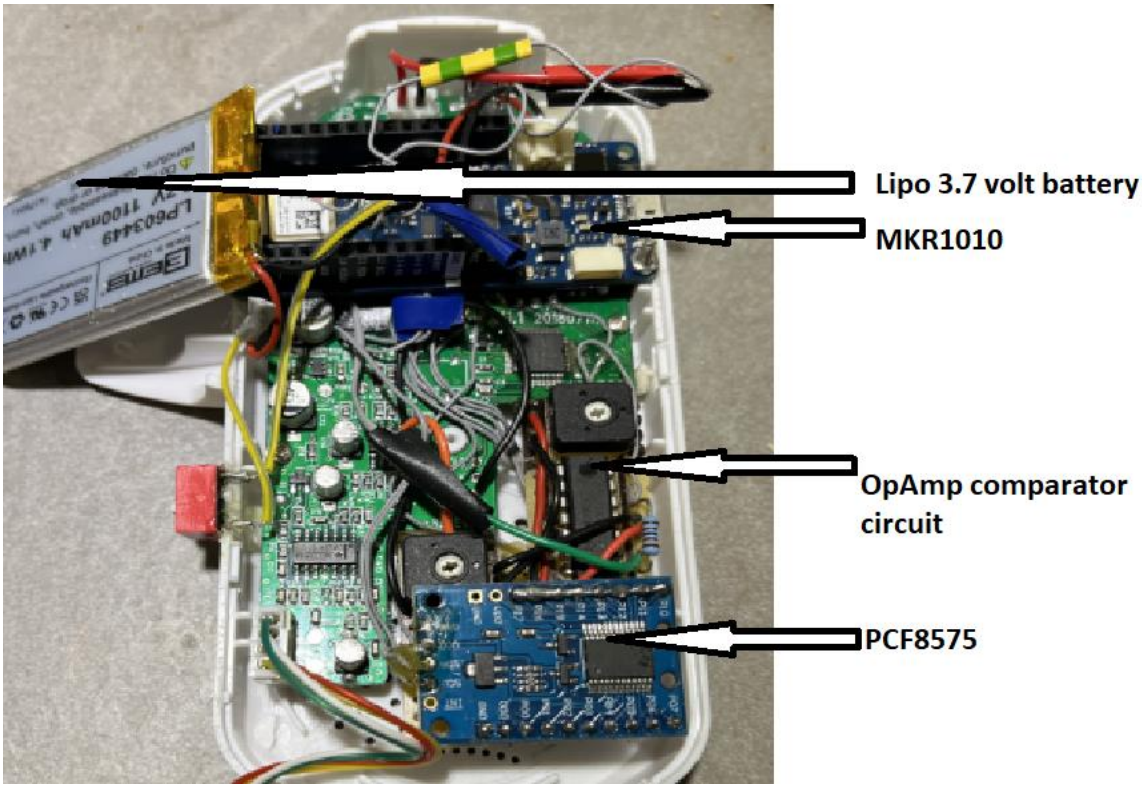


Figure 16 The additional electronics fitting inside the original case.

A number of layouts of the components were considered until an arrangement was found where all the components could be fitted into the original case. There was access to the MKR1010 for USB charging and data transfer from the side of the case. An external switch was added to isolate the battery when not in use or not charging the battery.

4.8 The Doppler device function

Doppler ultrasound depends on the Doppler principle named after the Austrian physicist, Christian Andreas Doppler (Katsi V., et al.,2013). Christian Doppler described the principle in which a sound wave is compressed or stretched when it is reflected from a moving surface. The same effect occurs when the siren of an ambulance is heard by a stationary pedestrian. While the ambulance is approaching the pedestrian the sound is compressed and the pedestrian hears a higher frequency sound than is the actual siren. As the moving ambulance passes, the tone of the sound is heard to fall by the pedestrian. This is the effect of compression of the sound wave leaving the ambulance as it approaches the pedestrian and stretching of the wave as it moves away from the pedestrian.

The fetal Doppler device transmits a high frequency sound wave, for example 3 million cycles per second in the fetal Doppler and this passes through the tissues of the maternal abdomen, the amniotic fluid, the tissues of the fetus and some of the wave energy is reflected from the surface of one of the heart valves. If the heart valve is moving towards transducer the reflected frequency of the wave is higher than the original wave. The reflected wave then returns to the transducer with a frequency which is either higher or lower than the original frequency depending on whether the reflecting surface was moving towards or away from the wave. The difference between the transmitted frequency and the reflected frequency is then converted into a typical audible frequency and output from the fetal Doppler device. The sounds are very similar to those of the audible heart sounds of the fetus which can be heard by a Pinard stethoscope held against the maternal abdomen.

The ultrasound is generated by a transducer which converts electrical energy into a mechanical expansion. This expansion then generates a pressure wave in the adjacent tissue. The changes depends upon the piezoelectric effect of the **crystal/ceramic element at the end of the ultrasound probe.** An **ultrasound transducer** converts electrical energy into mechanical (sound) energy and back again, based on the piezoelectric effect. This piezoelectric transducer is a flat disc which lies just under the plastic surface of the circular head of the hand held transducer. The round transducer is split into two halves, one as a transmitter, the other as the receiver. Either can act as the transmitter or the receiver. When a potential difference is placed across the two surfaces of one of the flat transducer semicircles an expansion wave is sent through the plastic to the surface and into the maternal abdomen. The reflected wave is then detected by the other half of the semicircular transducer. The electronics detects the difference in frequency between the transmitted frequency and the receiving frequency and convert this into an audible sound.

4.9 The hands-free doppler probe

The concept of removing the transducer from the handle and reconnecting it with long soft flexible wires to the electronics within the handle is simple, but not as simple in practice as explained previously. However there was still a question whether the system would continue to work normally with the transducer separated from the electronics by 15cm of wiring ?

In theory the small light transducer should be able to remain on the skin of the neonatal chest without any attention with the surface tension of the thick ultrasound gel. The stability of the separate transducer with ultrasound transducer can be demonstrated on the hand or the front

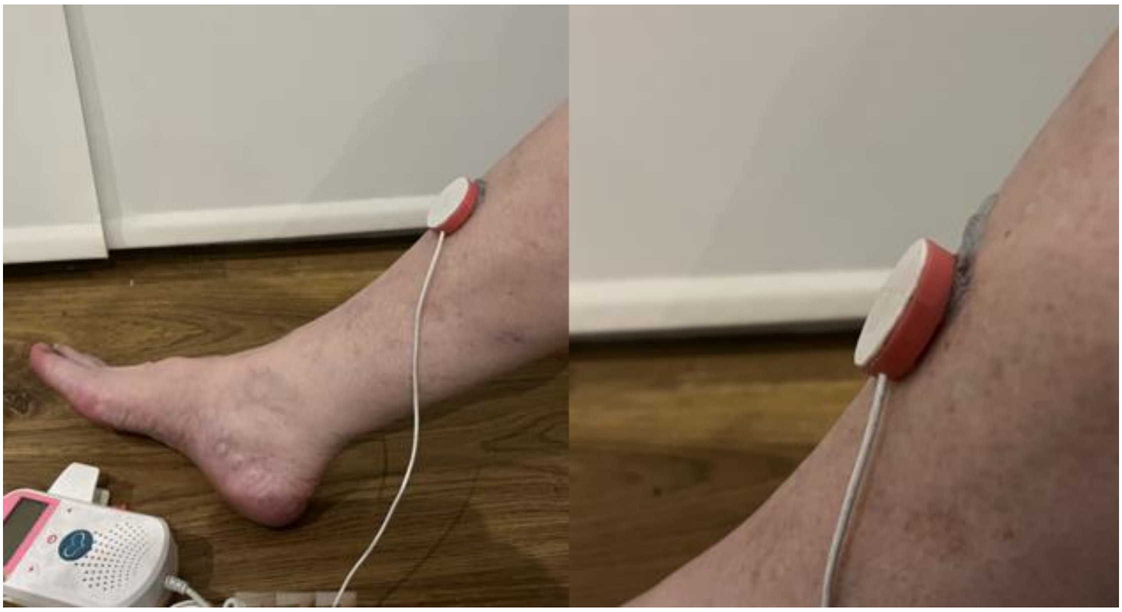


Figure 17 This shows the transducer coated with the thick ultrasound gel. It still remains on the skin at an angle of about 45 degrees.

of someone's leg. It was found that the transducer remained completely still even with the leg tilted at 45 degrees.

4.9.1 Replacing the Doppler transducer on the end of long soft flexible wire

These piezo electric crystals are very delicate and readily damaged by heat so direct soldering is not simple. No soldering was directly onto the transducer so the original wire was left as long as possible. The transducer is very easily damaged by heat. The connecting wire also needed to be very flexible and thus the wires needed to be very thin. Fortunately, these soft, thin wires are readily available on the low cost earphone plugs. These earplug wires are soft and flexible enough to allow the transducer to remain on the skin with the surface tension of the ultrasound gel and remain unmoved.

4.9.2 Soldering the hands-free transducer.

The wires within each sheath are strengthened with plastic. Both this plastic and the enamel coat insulation are a problem for easy soldering.
Experimentation to find the optimal way to tin and solder these fine wires was required. The soldering iron needed to be at 400 degrees centigrade in order to melt the enamel and then tin the copper wiring. Excessive heat however and excessive time resulted in the thin copper wiring being damaged and fragmenting. It was found to be very important to remove all the plastic supports prior to soldering. Then to avoid excessive heat both parts to be soldered had to be held close together and completely still until the solder had set. It was also very important that the soldering iron was applied to the joint for the minimal time to avoid any damage to the transducer with a heat sink on the side of the transducer.

After the wires were soldered, the joints were strengthened by an epoxy glue.
Once this was completed the Doppler device was tested and found to function normally.

4.10 Plastic covering

Next new plastic covering for the transducer and the handle, were designed and 3d printed. This required learning the computer design program SOLIDWORKS, 3D CAD Design Software SolidWorks and create a STL file for printing on a university 3-D printer.

Finally the hands-free neonatal Doppler ultrasound device with wireless documentation was completed and ready for a clinical trial. (Figure 18)

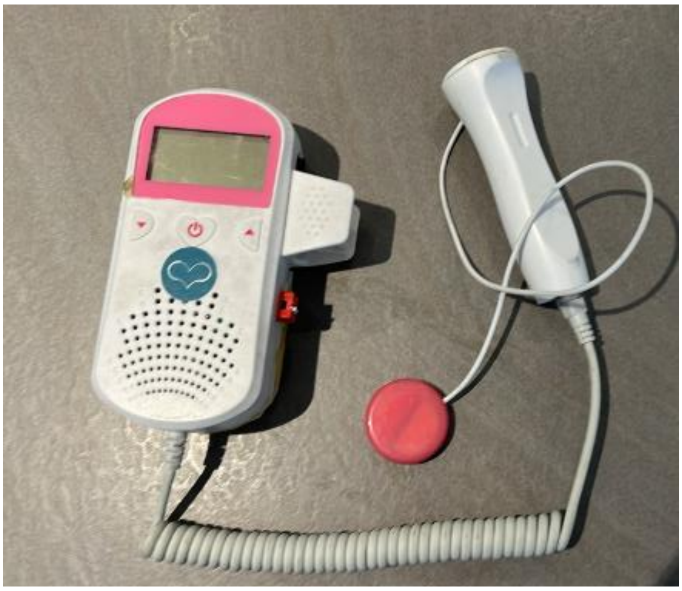


Figure 18 Modified wireless, hands-free, U3-02 replaced in case. External battery switch is visible.

4.11 Incorporation of an ECG electrode.

The accuracy of the Doppler heart rate was compared with the heart rate of the ECG and found to be compatible. Clearly this requires the application of the two ECG electrodes and the Doppler transducer. When comparing the two results the timing of the application of the Doppler and the ECG needed to be known.

The ECG requires at least two electrodes on either side of the heart. If one electrode is placed on a finger of the right hand, and the second on the surface of the Doppler ultrasound transducer a valid ECG can be obtained. A wire on the surface between the two transducers was inserted. This required carefully drilling a hole between the two transducers and the wire was connected to the earth line going to the Doppler electronics. The earth of the electronics within the Doppler device was fed into to one lead of the ECG while the other lead was provided by an electrode on a finger of the right hand.

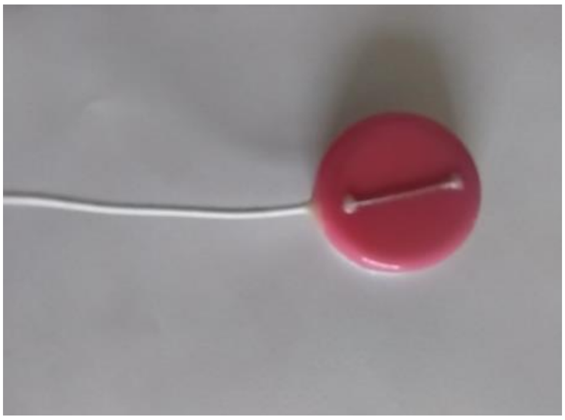


Figure 19 Hands-free ultrasound Doppler with ECG electrode.

Testing this approach showed a normal ECG signal was provided immediately the transducer was placed on the chest and at the same time as the Doppler heart sounds could first be heard. (Figure 20)

Figure 20 Doppler heart rate and simultaneous ECG heart rate with ECG electrode (left) incorporated into Doppler transducer. The ECG is showing a heart rate of 80 BPM while the Doppler (right) is showing 79 BPM.

Chapter 5; Second Adult Study with modified device

5.1 Method

This formed the second part of the Initial Adult study and the functioning hands free Doppler with integrated ECG electrode was tested as an extension of the first adult study
The modified wireless Doppler device was used with a CONTEC portable ECG device which was held within a customised case connecting the two ECG electrodes in place. (Figure 21)

The volunteers were asked to lie semi-prone on a chair with an adjacent platform on their left side. Each subject had one ECG electrode fixed to a finger of their right hand which they rested across their lower abdomen The hands-free transducer was coated with ultrasound gel and placed on the subject’s left chest over the left edge of the sternum, The surface tension of thick ultrasound gel was confirmed to be sufficient to keep the transducer in place. The Doppler device was placed on an adjacent table on their left side close enough to avoid any tension on the connecting wire between the transducer and the Doppler handle. As soon as the Doppler transducer was placed on the subject's chest, the two lead ECG circuit was completed and recording of the ECG commenced. Immediately following this, Doppler heart sounds could be heard and a heart rate displayed on the Doppler device. The heart rate values were then transmitted wirelessly to a nearby computer for documentation of the value and together with a time stamp. The ECG automatically recorded the heart rate during this time for runs of 30 seconds and was also time-stamped. The newly developed hands-free wireless modified Doppler was being used to test its suitability for the planned study at the Children's Hospital.

In one adult volunteer the Doppler transducer (with integrated ECG electrode) was placed on and then removed from the chest at short intervals four times. On placement of the transducer on the chest the ECG circuit is completed and on removal it is interrupted. Thus the ECG and Doppler have theoretically exactly the same opportunity to obtain a signal and generate a heart rate.

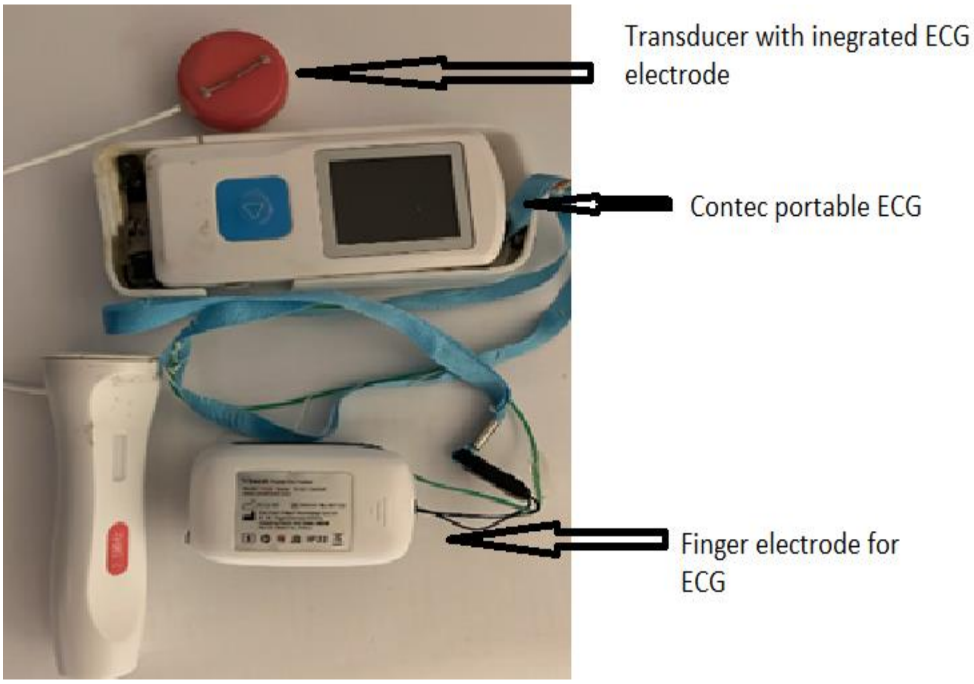


Figure 21 Customised case for the Contec ECG to allow connection to finger electrode and built-in Doppler transducer chest electrode.

5.2 Results

There were four volunteers included in the second adult study which compared the Doppler heart rate with the ECG taken with the integrated ECG electrode and then wirelessly transmitted and documented the Doppler heart rate results on the nearby PC. The ECG was documented on the Contec portable ECG device. (Figure 22)

Figure 22 Documentation on the Contec is shown above. The ECG is continuous on the four tracings visible on the screen as seen by the time stamps 00:00:00, 00:00:06, 00:00:12 and 00:0018 indicating each ECG run is 6 seconds long.

5.2.1 Heart rate correlation

Four adult subjects were studied with the wireless Doppler device. Correlation between the Doppler and ECG was excellent and all four results well within the 95% confidence intervals as seen in the Bland Altman chart**.** (Figure 23) Clearly such a small number is not statistically significant but did demonstrate the ease and functionality of the system. One typical tracing shows very close correlation between the ECG heart rate and the Doppler heart rate. (Figure 24)

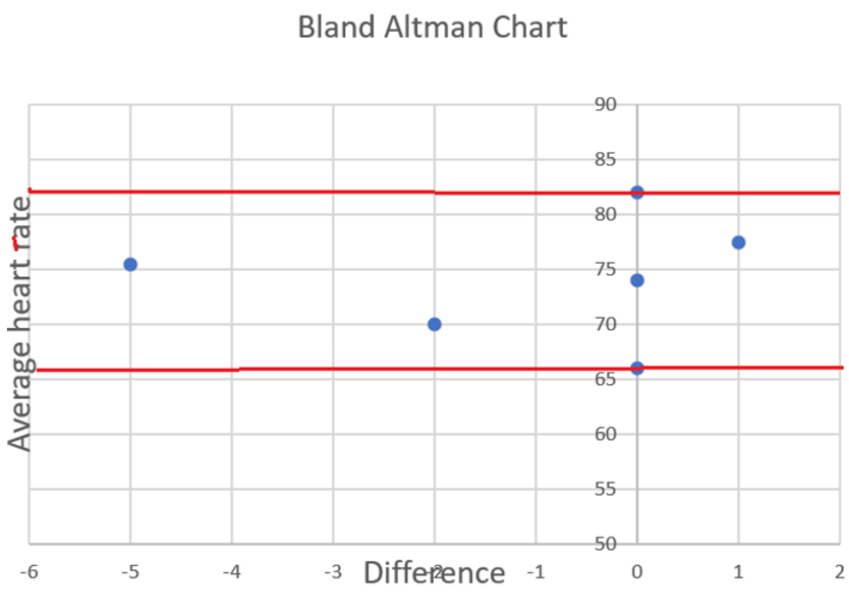


Figure 23 Bland Altman correlation of the four subjects studied with the hands-free Doppler device and ECG. The red lines represent the mean +/- 1'96SD, the 95% confidence intervals.

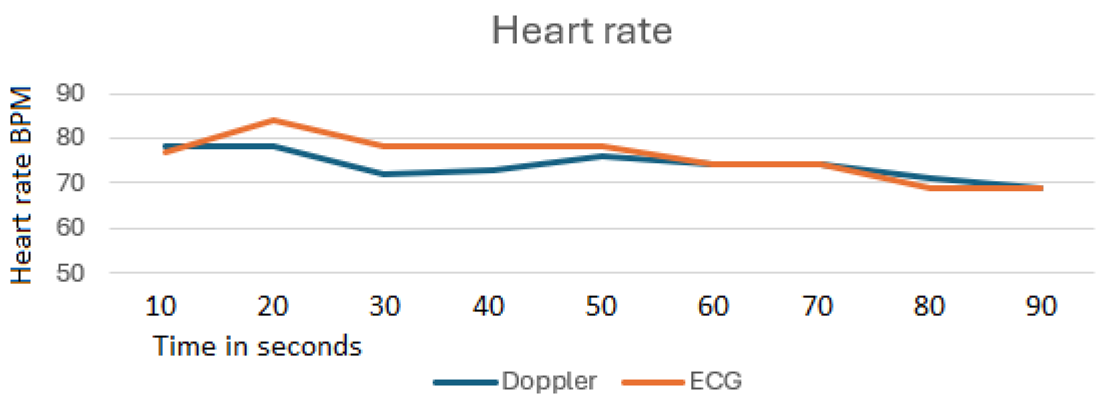


Figure 24 Doppler vs ECG with integrated ECG electrode. Subject 2

5.2.2 Time to acquisition of heart rate

A very important factor in the clinical determination of the heart rate, especially in the apnoeic infant with poor muscle tone, is the time it takes to determine the heart rate. Theoretically determining the heart rate is possible simply by auscultation using the time between the first two detected heart beats. However this would be very inaccurate and it is recommended that during auscultation the heart sounds are counted for 6 seconds and multiplied by 10 to obtain the rate of beats per minute. At the very best this could be expected to provide a heart rate within 8 seconds with auscultation. In the studies included in the systematic review (Hutchon, 2022), the time for the Doppler device to display a heart rate was between 3 and 5 seconds and for the ECG between 5 and 10 seconds. The ECG was consistently longer to display a heart rate than the Doppler, but the Doppler was only slightly slower than auscultation. (Goenka et al., 2013) The Doppler is likely to have based the rate on the whole 5 seconds before displaying the result. In the auscultation method an alternative is to count the heart sound over 10 seconds and multiply the result by 6.   This obviously takes longer and the mental calculation of multiplying by 6 is likely to take several seconds and in addition introduces a risk of miscalculation.

Figure 25 shows that the Doppler heart rate (blue) is consistently displayed several seconds before the ECG (orange). It also shows that the ECG heart rate stops as soon as the transducer is removed while there is a latent period before the Doppler heart rate ceases. However the persistence of the Doppler reading is not clinically relevant as the Doppler sounds discontinue immediately the transducer is removed. The faster acquisition of the Doppler of a few seconds may not be clinically relevant but this study clearly shows the Doppler is consistently quicker at providing the heart rate by several seconds. Also in clinical practice two ECG electrodes need to be applied to the baby before the ECG has any opportunity to determine the heart rate. In contrast the Doppler only requires the application of the single transducer.

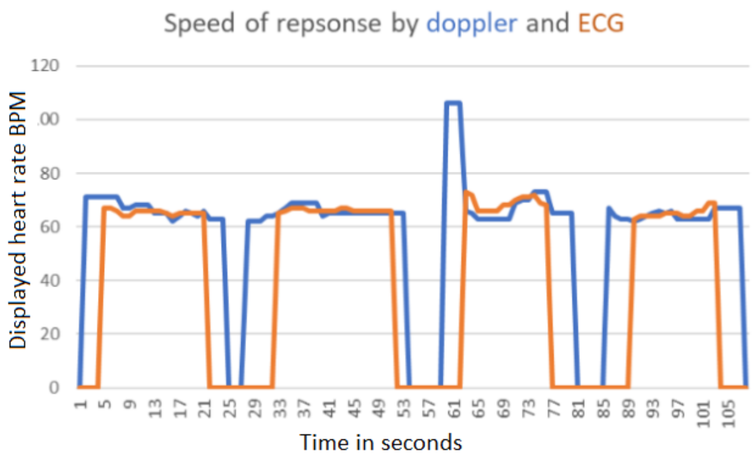


Figure 25 Ultrasound transducer with integrated ECG electrode. Blue line is Doppler display. Red line is ECG display.

This finding agrees with that of the clinical studies included in the systematic review. (Goenka et al., 2013) (Shimabukuro et al., 2017) (Zanardo & Parotto, 2019) (Kayama et al., 2020) (Agrawal et al., 2021)

5.2.3 Comparison of Doppler and ECG in the clinical studies of the systematic review.

In all the five studies included in the systematic review (Hutchon, 2013) the Doppler was compared with the ECG heart rate. Both the Doppler device and the ECG were standard equipment, and the Doppler was consistently found to provide a heart rate before the ECG. Reading time from placement therefore included the time since the US probe was placed on the chest until the HR was written. The ECG time was measured from the time the device was placed on the chest and the right wrist until the value was displayed in the screen. A reliable HR measurement was considered in the ECG monitor when clearly QRS complexes were visible. Detection time from birth was considered as the total time from the birth to the reliable detection of the HR for each method. Clearly it takes less time to place the Doppler transducer on the newborn chest than it does to place one ECG electrode on the chest and another on the right wrist.

The typical heart sounds of the Doppler ultrasound device are easily identified and familiar to obstetricians and midwives, and no doubt neonatologists would also soon become familiar with Doppler sounds in the same way. However recognising a valid ECG “PQRS” signal on a screen is not nearly as simple especially as the screen might not be readily visible to all the attendants. Logically, it seems much easier therefore to validate the Doppler sounds and digital heart rate display than it is from the visual ECG trace.

Chapter 6 The Sheffield Children's Hospital Feasibility Study

Professor Heather Elphick, Consultant in Respiratory Medicine Sheffield Children's Hospital was approached and the problem of acquisition of the neonatal heart at birth explained. The hands-free wireless data transfer Doppler ultrasound device was demonstrated to her and her research team. This study was only possible following the development of the clinically acceptable hands-free Doppler which had direct acquisition and transmission of the heart rate to a nearby computer as described above.

A joint research project was agreed to show whether the use of precordial Doppler ultrasound on babies to determine the heart rate was feasible. Babies up to one year of age attending the sleep unit were considered suitable to show whether the Doppler ultrasound was feasible. These babies have an ECG during the sleep study, and this provides the ideal opportunity to test the accuracy of the Doppler with the ECG which is generally considered the gold standard for the heart rate. Although clearly not newborn babies, they are still small enough to provide assessment of how feasible it is to place the hands free Doppler transducer on its chest, to determine the heart rate and for an assessment of the stability of the hands-free device.

6.1 Method

Information sheets were prepared describing the study in plain language avoiding any technical terms when possible. These sheets described how there was a need for accurate measurement of their baby's heart rate at birth and the study was to, investigate the use of the hands-free fetal Doppler over a few minutes during the start of their babies sleep investigations. Consent sheets for involvement in the research were prepared. A summary of the nature and importance of the research was provided verbally before asking for the parent/legal guardian signed consent to involve their child to be involved during their planned sleep study. Risk assessment was completed. A Converis application for Ethical approval was submitted and an IRAS submission, together with Professor Heather Elphick, was prepared and submitted.

Since it was intended that the researcher would attend the sleep unit and apply the Doppler device to the neonatal chest is was necessary to obtain a research passport and be cleared to be able to attend these babies. The Disclosure and Barring Service application was completed and an application for a research passport submitted.

6.1.1 DBS (Disclosure & Barring Service) fully enhanced both child and adult was obtained on 8th March 2023.

6.1.2 A Research Passport application was submitted and **A letter of access for research** to the Sheffield Children's Hospital was obtained from the Children's clinical research facility (CCRF) on 25th April 2023.

6.1.3 Recruitment

Recruitment commenced in July 2023.

Babies attending for sleep studies at the Sheffield Childrens hospital study were recruited. These babies have suspected sleep apnoea. The sleep study includes an overnight ECG and oximetry

6.2 Procedure

Two of the Research Sleep House research officers identified babies up to one year of age scheduled for sleep studies. The research officers verbally approached one or both of the parents with information about the Doppler study. If the parent expressed an interest in their child taking part in the research, they were provided with a patient information sheets at least 48 hours before the baby's planned admission. When the parents had verbally agreed to be involved in the research, the investigator was informed of the day and time of admission to the Sleep Unit.

The first subject of the research was carried out on 25th July 2023 and the last subject on 21st December 2023. The investigator attended the Sleep unit when the baby was expected to be admitted. The investigator approached the parent(s) and introduced themselves. The investigator confirmed that the parents had read and understood the information sheet and that they had agreed to take part in the research. The parents, having recently had their baby, were often familiar with the Doppler ultrasound device. It had been used to determine the fetal heart rate, and they were readily able to understand the technology and the safety of Doppler ultrasound.

One of the parents was then asked to confirm their understanding and agreement by signing the consent form.

The ultrasound gel had been pre-warmed by placing it in a babies bottle warmer before the baby arrived at the unit. The warmer had been purchased specifically for the study. The Doppler transducer was cleaned with a “Huggies” baby wipe and immediately before the transducer was placed on the neonatal chest with a layer of the warmed ultrasound gel on the transducer surface.

Once the ECG had been set up by the Sleep House staff and confirmed to be recording, the hands-free Doppler was placed on the neonate’s chest. The transducer was placed just to the left of the sternum over the heart and the position adjusted until a good Doppler heart sound was heard. The transducer was left in place for up to five minutes. The Doppler sounds were audible to the parent(s) and a heart rate value displayed on the Doppler device. The heart rate values, together with a time stamp, were transferred to the nearby laptop computer by the modified Doppler device as previously explained. The hands-free transducer was allowed to rest on the neonatal chest without attention.

A few of the babies were quite active and curious about the wires leading from the transducer. They tried to catch the wires and this was the only reason that the Doppler transducer was sometimes disturbed and in two babies needed to be replaced. The babies were normally prone in the cot for the sleep study but one baby needed to be settled to sleep for the purpose of the Doppler study, by the mother breast feeding.

The babies were ready for bed and usually in a baby grow. Access to the chest was easy with minimal disturbance to their clothing. The transducer, coated with a little warm ultrasound gel, could be placed on the left side of the chest just under their clothing.

6.2.1 Age of subjects

A total of eleven babies were recruited aged between one month and 12 months. (Table 3) In all but one subject there was an ECG heart rate to compare with the Doppler heart rate leaving ten babies with data for comparison between the Doppler and the ECG. This number was lower than the planned 15 but was considered only marginally below the expected attrition rate of 5% and sufficient to provide assessment of feasibility of the approach.

Table 3 Subjects SCHDOP10 and SCHDOP11 were recruited while under 1 year but appts cancelled and rearranged.

Subject	Age
SCHDOP01	11 months 15 days
SCHDOP02	5 months 19 days
SCHDOP03	11 months 16 days
SCHDOP04	9 months 18 days
SCHDOP05	10 months 15 days
SCHDOP06	8 months 21 days
SCHDOP07	8 months 25 days - No ECG
SCHDOP08	11 months 19 days
SCHDOP09	1 month 1 day
SCHDOP10	1year 14 days
SCHDOP11	1year 11 days

6.3 Results

6.3.1 ECG analysis

The raw ECG data for the full night study of each subject was provided.   This was about 12 hours of data, The data was made up of 256 data points per second and documented with a time stamp. This resulted in a very large data file (about 11 megabytes) for each subject.

First the time stamp at the start of the Doppler file was correlated with the same time stamp on the ECG file. (Table 4) The ECG heart rate was extracted from the raw data. Initially MATLAB was used. MATLAB has the facility to measure the frequency of an ECG cycle. This requires detecting the R wave and MATLAB measures the frequency of the R wave. However the height for the R wave of the ECG wave. In many of the subjects there was significant variation in the height of the R wave is not always consistent and this made the determination of the frequency of the r wave inaccurate. In fact inspection of the ECG was required to identify the inaccuracy. Another approach was required.
Small sections of the raw valid ECG data were identified by the timestamp to be at the same time as the Doppler signals. (Figure 26) This ECG data was transferred to an EXCEL

spreadsheet and the interval between two R waves used to calculate the ECG heart rate. Thus only good quality PQRST signals were used.

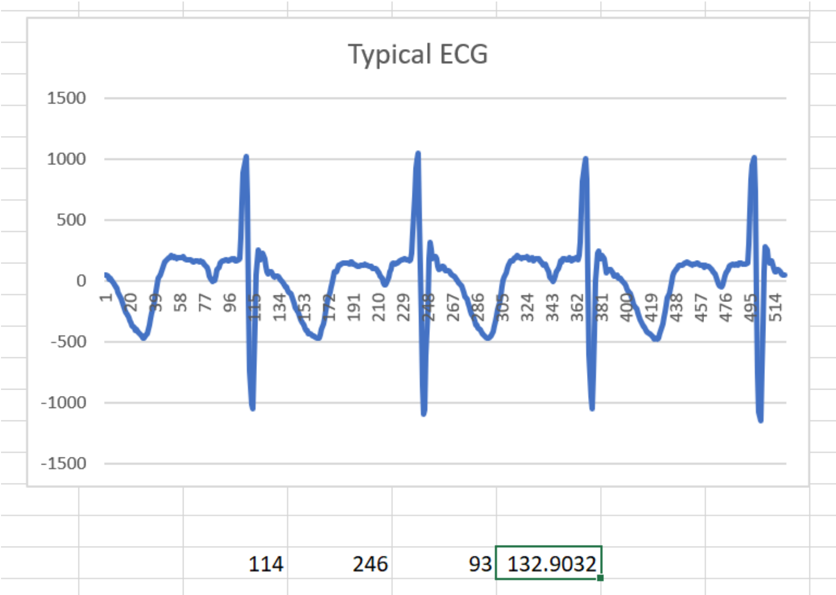


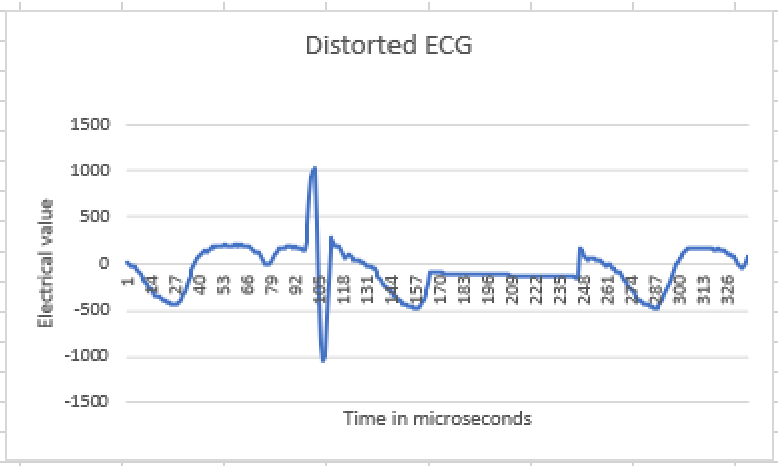
Figure 26 The hospital data set provided each ECG data point every 4 microseconds - 19:38:09,223 to 19:38:09,227 so there were 250 data points per second. The heart rate (BPM) = (250 x 60)/interval between two r waves

Table 4 Typical ECG data provided with voltage value and time stamp.

ECG1		
21.12.2023	20:12:01,664;	33
21.12.2023	20:12:01,668;	83
21.12.2023	20:12:01,672;	85
21.12.2023	20:12:01,676;	82
21.12.2023	20:12:01,680;	55
21.12.2023	20:12:01,684;	62
21.12.2023	20:12:01,688;	9
21.12.2023	20:12:01,691;	-58
21.12.2023	20:12:01,695;	-91
21.12.2023	20:12:01,699;	-98
21.12.2023	20:12:01,703;	-140
21.12.2023	20:12:01,707;	-127
21.12.2023	20:12:01,711;	-129
21.12.2023	20:12:01,715;	-159
21.12.2023	20:12:01,719;	-155
21.12.2023	20:12:01,723;	-141
21.12.2023	20:12:01,727;	-109
21.12.2023	20:12:01,730;	-118
21.12.2023	20:12:01,734;	-100
21.12.2023	20:12:01,738;	-129
21.12.2023	20:12:01,742;	-123
21.12.2023	20:12:01,746;	-114

6.3.2 ECG quality

The ECG is generally considered to be the gold standard for the heart rate however this study suggests that the Doppler ultrasound may in fact be more of a “gold” standard than the ECG. During the adult study there was one subject when the ECG could not be obtained, and another when the ECG quality was poor while the Doppler results for both appeared reliable. Thus the analysis consisted of complete data from only eight subjects because ECG data for comparison during all periods when Doppler data appeared to be valid. Raw ECG data from some of the subjects at The Sheffield Children’s Hospital study showed runs of distorted signals as shown in figures 27 and 28 As a result only segments where the ECG signal was visually validated could be included.



Fogure 27   Typical distorted ECG signal

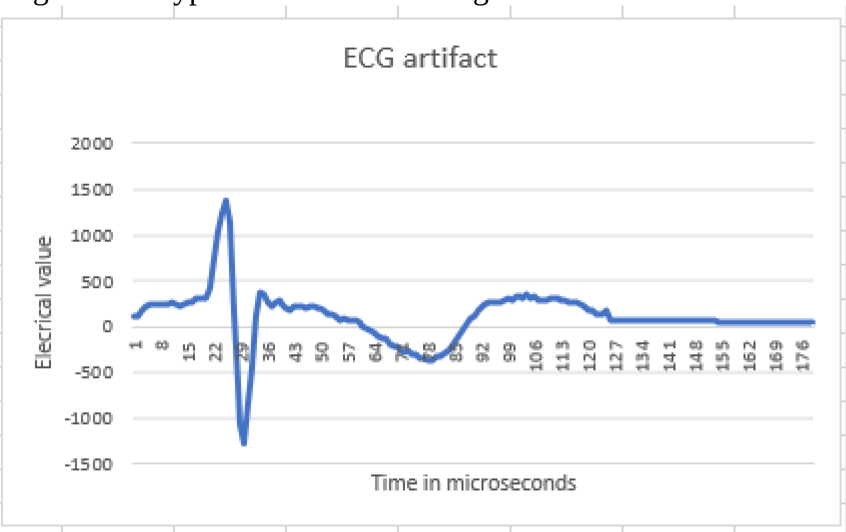


Figure 28 ECG artifact

This demonstrates that although the ECG is considered the gold standard for the neonatal heart rate, in reality the signal may be significantly distorted and the rate provided by the electronics may be an artifact. While there were mainly short segments of a distorted ECG signal, there were also some significantly longer segments. While this was also true of the Doppler signal, it is simpler to identify a false Doppler sound signal and/or to estimate the heart rate from the auditory signal produced even if this is distorted sufficiently to prevent accurate analysis by the electronics.

6.3.3 Heart rate determination and comparison of ECG and Doppler comparison

This required inspection of **six heart rate data** points equally distributed between the start and end of one minute of each of the Doppler data sets using the time stamp on the each of the data sets. The equivalent data points were then identified within the ECG data. The heart rates generated from the Doppler data and the ECG data were compared. The six data points (of Doppler and ECG heart rate) were taken from each subject during one minute of recording from the 10 subjects for which data was available. In two subjects there were only 4 simultaneous results for both ECG and Doppler, and in one subject only 5 simultaneous results. This left a total of 57 data points from the ten subjects.

6.3.4 Heart rate comparison between ECG and Doppler

The 57 data points available are shown on the Bland Altman correlation chart. Only two results fall outside the 95% confidence interval. (Figure 29). Correlation between the two rates was often excellent. (Figure 30)

These two results are outside the confidence interval. Both show an unusually slow heart rate on the Doppler probably indicating an artifact on the Doppler. The Doppler may have halved the rate during these two measurements. While this is important, this artifact would be readily detected by attendants hearing the Doppler sounds, whereas a similar artifact in an ECG would be undetectable.

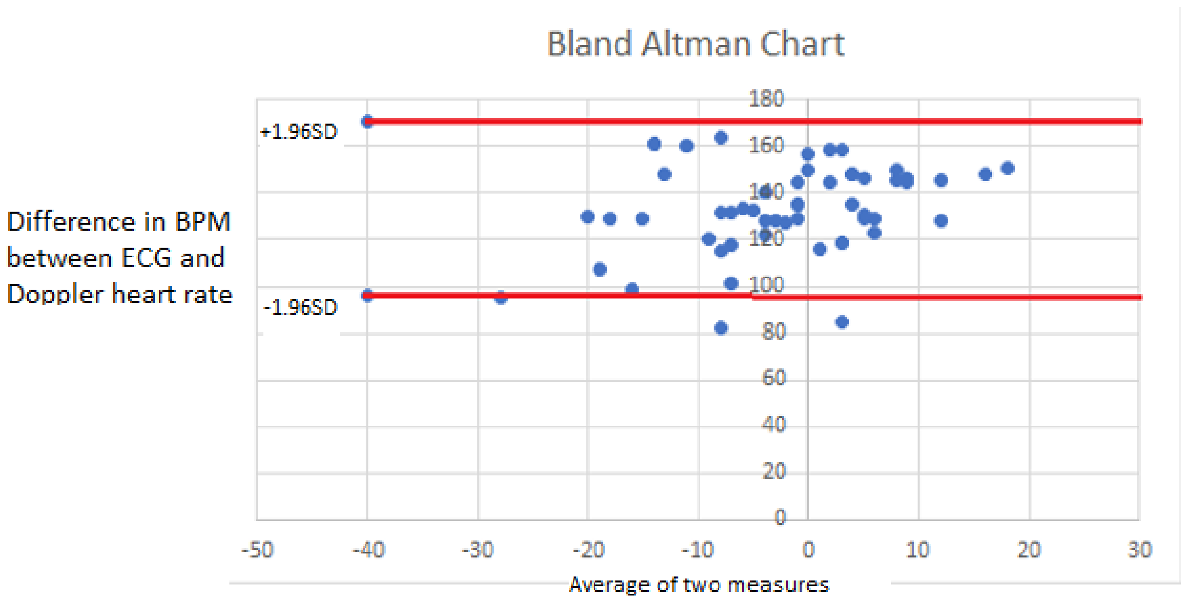


Figure 29 Bland Altman distribution of 57 data points

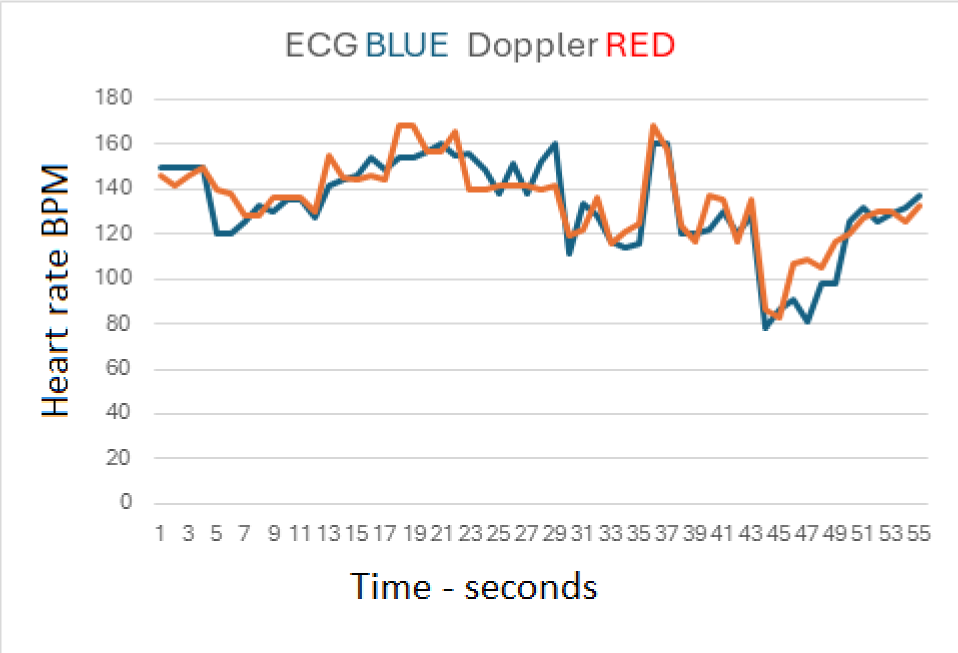


Figure 30 Typical heart rate results of neonate.

6.4 Parent opinion survey

During pregnancy all the mothers would have experienced hearing their baby's heart during pregnancy and labour. All the mothers recognised the Doppler heart sounds of their baby during the study and found hearing the Doppler sounds reassuring. None of the parents considered that their baby had experienced any distress or discomfort during the application of the Doppler to their baby's chest. They were pleased to have had the opportunity be involved in the research and looked forward to hearing the results.

Despite significant movement by a few babies, the Doppler transducer remained in place on the neonatal chest helped by the surface tension of the thick transducer gel, usually under the baby's night attire.

6.5 Stability of the hands-free transducer

These 11 neonates demonstrated the value of the hands-free device which usually remained on the neonate's chest without attention. The neonate remained in their sleeping clothes and the neonate's chest only needed to be exposed sufficiently place the transducer over the heart and usually underneath the clothing. The transducer remained in place, providing a satisfactory Doppler signal despite movement of their body. Any loss of the typical Doppler sounds alerted the investigator of the need to adjust the position of the transducer. This would be similar in a clinical situation.

Chapter 7 Modification of Huntleigh SR2

The opportunity arose to modify a Huntleigh Sonicaid SR2, one of the commonest fetal Doppler devices used in hospitals in the UK. The transducer is not soldered to the handle as is the case in the U3-02. Instead the transducer is fitted to the handle with a plug and socket. (Figure 31) This specific plug and socket is one that is already used in other devices and is readily available and used on the AM2302 amongst other sensors. This was available from RS Components (Figure 32) and I was able to remove the socket from the sensor and for use the plug and socket connection to extend the transducer.

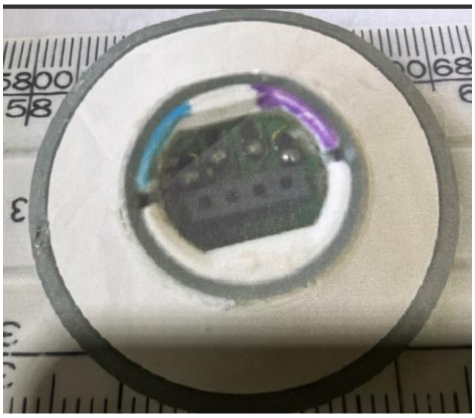


Figure 31 The socket on the transducer of the SR2.

Figure 32 The Grove sensor with plug and socket available from Rapid Electronics Ltd

7.1 Completion of the modification

This allows extension wiring between the transducer and the handle without permanently interfering with the original device. The plug and socket were incorporated into custom-designed covers for the transducer and handle which were 3D printed from a ST file. This also provides a simple solution for Huntleigh to modify their device without altering any of the manufacturing of the original fetal Doppler device. (Figure 33)

7.2 The next anticipated clinical study

The Sleep Unit study at the Childrens Hospital was expected to be a step towards the next stage of the study to use the Doppler device on healthy neonates at birth. The modification of Huntleigh SR2 provided an ideal opportunity. The latest Huntleigh SR2 includes the facility to record and document the heart rate onto an integral memory card. Inspection of the files on the memory card showed that the file started with the date and time of the recording followed by heart rate values. This finding therefore confirmed that device could be used for a clinical trial.

Figure 33 The modified Huntleigh SR2 Doppler device

I proposed to test out the device within a sterile sleeve at caesarean section. (Figure 34) The Directorate Research Co-ordinator at the Jessop Wing Research Executive was approached through Prof Stephen Radley and I was invited to present my proposal to the group. Unfortunately a few weeks later I was informed that the clinicians felt that that their current method (unspecified) was satisfactory. This is clearly an opportunity for future research.

7.3 Involvement of the industry

The SR2 is made in Cardiff. The investigator has made a number of approaches to Huntleigh (including two visits to the Cardiff unit) to try to interest them in the use of their device on the neonate at birth. Unfortunately Huntleigh will not engage in any discussion. An email sent by Professor Reza Saatchi was also ignored. The reason for the reluctance of Huntleigh to engage is a mystery and it is my hope that this thesis will help to instil interest in the possibility of an enormous commercial opportunity for a fetal/neonatal Doppler by Huntleigh or any other manufacturer.

Figure 34 Modified Huntleigh SR2 contained inside sterile polythene sheath (Medline Probe Cover PU,18X CN 39269097) for use at caesarean section, with the flat hands-free transducer.

Figure 35 Transducer separated by long connecting wire.

Clearly the SR2 must meet the medical standards ISO 13485 – Medical Devices.
This requires during manufacture the regulatory requirements must be met. Logically manufacturers must be making minor adjustments to their medical devices all the time. The investigator has tried to establish precisely what a manufacturer needs to do in order to change their fetal heart rate monitor to a hands-free neonatal heart rate monitor. As illustrated above, modifying the SR2 to a handsfree device simply requires the manufacture of a plug and socket customised to fit the handle and transducer, and connected by soft flexible wiring. Huntleigh already have a range of intra-operative single use vascular probes which the **user** can fit directly to the. (Figure 36)

vascular Dopplex device

Figure 36 Huntleigh single use vascular probe

7.4 Doppler heart rate at caesarean section

Many babies that are suffering intrapartum hypoxia need a rescue delivery by emergency caesarean section. These babies often need resuscitation. Ideally the caesarean birth is provided before there is significant hypoxia leading to an apnoeic and asphyxiated neonate but in practice this is not possible, and this ideal cannot always be expected in reality. Therefore, to distinguish accurately between those requiring resuscitation, and thus separation from their mother and early cord clamping, accurate measurement and documentation of the neonate’s heart rate is required. Currently this cannot be carried out with available technology.

The stethoscope is unsatisfactory and in reality, cannot be adequately sterilised. Compromising the sterile field of the caesarean by a non-sterile stethoscope is not acceptable.

Other forms of measuring the heart rate are even less capable of being sterilised. However, a portable fetal Doppler device inside a sterile sheath is a simple and obvious solution. The Doppler can function normally through a sterile polythene sheath. The approach is already used during vascular surgery when measurement of the blood flow is required.

Although not essential, the hands-free modified version, developed in this study, makes the use of neonatal Doppler during caesarean section particularly simple. Knowing the fetal heart rate immediately before commencing a caesarean birth is very important. There is the inevitable delay between preparation of the abdominal skin and the actual birth of the neonate and continued monitoring of the fetal heart rate is possible with a sterile Doppler ultrasound transducer during this time which is unlikely to be less than 3 minutes. With a sterile Doppler transducer (as explained above) the fetal heart rate can be checked after the abdomen is prepared and draped and before the incision in the skin or the uterus is made. As soon as the neonate can be delivered onto the mother's abdomen or thighs, wrapped in a towel or polythene and the flat transducer can be placed on the neonatal chest. The direction and position of the flat transducer is easy to maintain on the neonatal chest. The mother (and father) is able to hear her babies heart rate as well as the neonatal team and the obstetrician. There is increasing understanding of the importance of parental involvement which includes being aware of the health of their child. Lack of knowledge about the health of their newborn baby results in significant anxiety and dissatisfaction about the care of their newborn baby. An audible Doppler signal and accurate heart rate display should allow clear decisions to be made by the obstetrician or the neonatologist based on an accurate heart rate. Further the heart rate will be documented for future review, audit and potentially research.

Any study in a clinical environment and potentially altering clinical decisions, demands the highest level of equipment.

7.5 Future work

There are a number of advantages of the Doppler over other forms of heart rate monitoring immediately after birth. The technology is already widely available, and the systematic review (Hutchon, 2022) shows that a standard fetal heart rate monitor functions well at birth. The technology has an extensive safety record and is low cost.

A major advantage of the Doppler device over other forms of heart rate monitoring at birth such as ECG is the ease with which the equipment can be used safely within the sterile field at caesarean section. Although a vaginal birth is not considered sterile, the equipment ujsed at a vaginal birth must be at least clinically clean. Thus the use of the doppler within a sterile polythene sheath would meet this standard. Many babies with fetal distress undergo an emergency caesarean section and these babies have a high risk of requiring resuscitation. Accurately determining the heart rate in these vulnerable neonates is particularly important. As demonstrated by this study, the Doppler ultrasound probe can be placed inside a sterile polythene sheath and safely used within the sterile field. This is because ultrasound is readily transmitted through the thin polythene membrane. There must be direct contact with the transducer and the neonatal skin and this this can be ensured by a layer of ultrasound transducer gel on each side of the sterile polythene sheath. The wet surface of the newborn baby provides good transmission of the ultrasound so gel on the outside surface of the sheath may be unnecessary.

Monitoring of the neonatal heart rate by ECG and oximetry is used at caesarean section during intact cord stabilisation and resuscitation (Concord Neonatal, 2024) but this requires delineating a non-sterile area for the equipment, the neonate and the carers attending the neonate. The non-sterile area needs to be clearly separate from the sterile field of the surgery but there will be a small risk of the line being breached. There is no such problem with the Doppler device inside a sterile polythene sheath.

Chapter 8 Conclusion and further work

8.1 Conclusion

The study confirms that a fetal Doppler ultrasound provides an effective way of measuring the neonatal heart rate. The modification of a transducer to a small flat light sensor demonstrated that this was much more user friendly and effective than the handle which is provided in all fetal heart Doppler devices. The study confirms that this small transducer will lie on the neonatal chest hands-free without attention from the carer and of particular value when the neonate is requiring resuscitation. with this approach there is the potential for a much improved measurement of the heart rate of the neonate at all births, including low risk births and births in low resource settings. The simple modification of removing the transducer from the handle significantly enhances the user friendliness and safety of the device. Making the transducer hands-free has the potential to match the convenience of the ECG but with much improved reliably interpreted in a clinical situation. The low cost of the device makes it ideal for low resource settings throughout the world. However, it does not compromise on function and should be welcomed also in high resource settings.

Since the fetal doppler was developed for use on the fetus in utero, the handheld fetal Doppler currently is not approved for use on the neonate. For all the five studies published and included in the systematic review, approval for use of the device on a neonate was given as part of the ethical approval for the study. This work has shown that it is relatively simple to remove the separate the transducer from the handle to allow a hands-free transducer. This provides evidence that provided there is the demand by clinicians, any manufacturer of a fetal Doppler device could readily provide a neonatal version at very little development cost.

There is no question that currently the neonatal heart rate is poorly measured in clinical practice and not properly documented at most births despite being the major parameter used to guide care of the neonate by authorities around the world such as ILCOR. Current recommendations are therefore based on a small number of studies when the neonatal heart rate has been measured. With routine use of a neonatal Doppler our understanding of the neonatal heart rate in healthy and in asphyxiated neonates could be considerably improved. This is of particular importance with the current compromise in practice between the benefits of avoiding early cord clamping at birth and the need for resuscitation remote from the side of the mother.

8.2 Caesarean Section

The majority of significantly asphyxiated babies are delivered by emergency caesarean section and by definition many these asphyxiated babies will need resuscitation. Currently there is no satisfactory method of determining the heart rate of the neonate immediately after caesarean birth because any equipment used must be sterile to be used within the surgical field. Even a stethoscope, although it is now considered to be suboptimal to determine the neonatal heart rate, is not readily sterilised. So even the basic method for determining the heart rate is not available before the neonate is moved from the sterile operative field. The neonatal heart rate cannot therefore be determined until after the cord is clamped and cut. An ECG or the oximeter probe is even less amenable to sterilisation. However, the Doppler ultrasound probe works well through polythene and is already used covered with a sterile polythene sheath during vascular surgery. This presents an ideal opportunity to accurately determine the health of babies at caesarean section. Indeed this was the final stage of the proposed study.

The study has clearly demonstrated the potential weakness of the ECG. It might be possible for an experienced clinician to quickly recognise a valid or invalid ECG signal however it is very difficult to be able to determine the actual heart rate with any accuracy. Further if the ECG device provides an electronically calculated heart rate, the heart rate provided to the clinician, it may be completely impossible for the clinician to determine whether or not the value is an artifact. On the other hand the sounds of a valid Doppler ultrasound are readily recognised by experience obstetricians and an estimate of the rate can usually be made.

8.3 Integrated ECG electrodes

The incorporation of the ECG electrode into the ultrasound transducer has never been reported previously. It showed the possibility for a further significant advance in neonatal heart rate monitoring at birth. While the ECG may be less reliable than Doppler immediately after birth, it still provides important additional information and a back-up for the heart rate being measured and documented by the Doppler device. If the second ECG electrode is incorporated into the oximeter on the right arm or right foot of the neonate then after the application of only the two sensors of the Doppler and oximeter, there is the availability of three measurements of the neonatal heart rate. Each have their own strength. The ECG is considered the Gold standard for the heart rate, the Doppler sound provides evidence for the movement of the heart and cardiac output, and the oximeter a measure of the oxygen saturation.

8.4 Audit and Research

While the researcher is confident that Doppler ultrasound to determine the neonatal heart rate immediately after birth would provide a much improved measurement and documentation, there is a well understood need by the profession for better equipment and documentation. When this is achieved there could be significant improvement in the care of vulnerable neonates with a fall in mortality and morbidity. The cost of brain damage at birth worldwide is enormous in both financial and human terms and even a small reduction in this damage would be welcomed. Inappropriate early cord clamping is often the result of poor assessment of the heart rate of the neonate. Early cord clamping is known to result in a increased hypoxic ischaemic insult on the neonatal brain. It will require a large study to determine whether or not using the hands-free Doppler at birth to determine the neonatal heart rate changes the practice of early cord clamping, or affects the need for resuscitation. Ultimately such research might demonstrate whether or not there is any reduction in birth brain injury often leading on to cerebral palsy.

Any new technology takes time and money to be rolled out into clinical practice. It needs to show safety and efficacy. The fetal Doppler having been used world-wide for over 40 years and its safety is established. It only requires to be proven that it is effective in measuring the neonatal heart rate. This study and the systematic review published by the investigator should together provide sufficient evidence for at least further clinical evaluation and study.

With the fetal Doppler being widely available throughout the world, the opportunity is already here for effective monitoring of the neonatal heart rate immediately after birth simply using the feal Doppler. When the manufacturers of fetal heart rate monitors learn of the use of their devices for the neonatal heart rate, it will take little additional effort or cost for them to offer a neonatal Doppler option or more specifically a convertible hands-free neonatal Doppler to their fetal Doppler range. Such a device will be particularly attractive to low resource settings allowing the fetal Doppler to function also as a hands-free neonatal heart rate Doppler as soon as the baby is born.

Once it is realised as an important technology for accurately measuring and documenting the neonatal heart, clinicians, especially neonatologists are likely to embrace the technology and realise the opportunity it opens up to providing resuscitation with an intact cord, especially at caesarean section.

8.5 Weaknesses

The number of subjects in all the studies was low. The initial adult study was however just sufficient to demonstrate the need for a hands-free device. In the second adult study there were only four subjects and the intention was to confirm the function of the modified equipment. It was possible to show the system was significantly more user friendly and the hands-free Doppler remained in place without the continuous attention of the researcher. The Childrens Hospital study was also smaller than ideal which was partly due to the relatively small number of neonates attending the Sheffield Hospital Sllep house for sleep investigation. One recruit was lost because the Doppler heart rate measurement was completed before there was a satisfactory ECG heart signal being documented. The study also showed that providing raw ECG data, which was sometimes invalid made a direct comparison of the heart rate invalid.

The study failed to achieve the original aim of demonstrating the value using a modified fetal Doppler device in a true clinical situation such as caesarean section. This would have been quite feasible with the modified Huntleigh SR2, especially if Huntleigh had been involved in the research, and would have potentially provided significant evidence for advancing the use of the Doppler ultrasound device for determining the neonatal heart rate. Some progress was made towards this goal while the Sheffield Children's Hospital Sleep House study was underway. All births in Sheffield are at the Jessop Hospital and the research team at this hospital were approached with details of a proposed study to use the modified Huntleigh Doppler device to determine the neonatal heart rate at elective caesarean section. Unfortunately, the planned research meeting was cancelled after the team decided that their current method of determining the neonates heart rate immediately after birth is satisfactory.

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Appendix A

GCP module Certificate of Achievement

NIHR | National Institute for Health and Care Research

Issued by:
Clinical Research Network
Coordinating Centre

CERTIFICATE OF ACHIEVEMENT

David Hutchon

has completed the course:

Introduction to Good Clinical Practice (GCP) eLearning

May 3, 2023

Modules Completed

- Introduction to Health and Social Care Research
- Good Clinical Practice
- Informed Consent
- Data Collection and Documentation
- Safety Reporting
- Summary

This course is worth 4 CPD points.

CPD
The CPD Certification Service

Version: May 2022

Appendix B

Converis ethics application

Accuracy of determining heart rate with precordial doppler vs ECG in adults
Hutchon, David (Faculty of Science, Technology and Art)
ER41987595
Very low risk human participants studies
ii) Doctoral research
Edit | Clone

Approved with Advisory Comments

Risk Assessment

Description of the Process/Activity: Accuracy of determining heart rate with precordial Doppler vs ECG in adults; Hutchon, David - Faculty of Science, Technology and Art; (Very low risk human participants studies)	Location(s): Hallam main campus RA Ref:

Hazard	Who could be harmed?	Existing safety precautions	Risk level	Additional safety precautions needed to reduce the risk level?	Revised risk level	Action by whom?	By when?	Date completed
Mild embarrassment at exposure of chest	Subject	Requirement for exposed chest fully explained in information sheet and consent with opportunity to not take part in study.	Very low	Full explanation of procedure in information sheet. Male participants only and study being carried out by doctor qualified for 50 years. Male	Very low			
Infection	Subject	Surface of ultrasound transducer and surface of ECG cleaned with detergent water between each participant.	Very very low	None required				

		Investigator washes hands between each participant.						

Communication of significant findings		
Method of communication (describe): Referral to published results	Person/people to communicate findings: David Hutchon	Target date(s): September 2022

Appendix C Epigeum certificate of Ethical Research

Appendix D Epigeum certificate of Research Ethics in Practice


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epigeum

Certificate

Number: [illegible]

This is to certify that

David Hutchon

of Sheffield Hallam University

Successfully completed the course

Research Ethics in Practice

Working with human participants	80%
Understanding research ethics approval	100%
Working ethically in challenging circumstances	80%
Working ethically in a global environment	80%

as part of the Epigeum Online Course System with a score of 85%.

Dated: 21 July 2022

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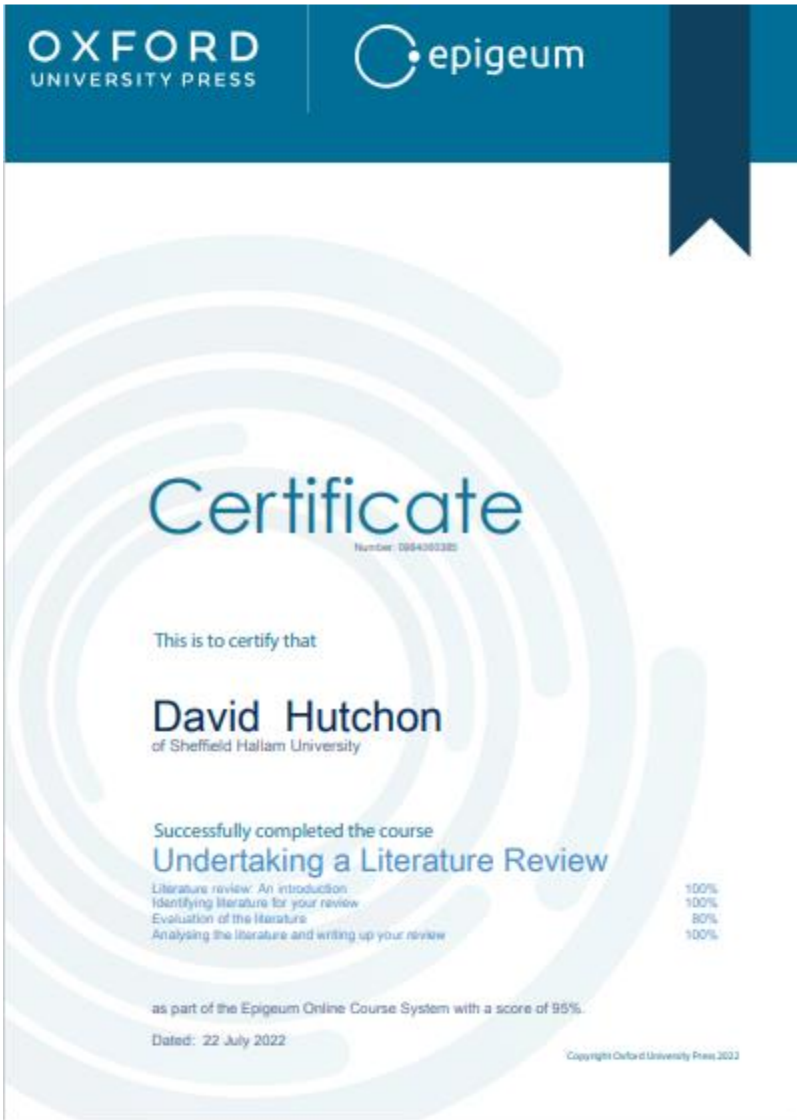
Appendix E Epigeum certificate undertaking a literature review



OXFORD UNIVERSITY PRESS

epigeum

Certificate

This is to certify that

David Hutchon

of Sheffield Hallam University

Successfully completed the course

Undertaking a Literature Review

Literature review: An introduction	100%
Identifying literature for your review	100%
Evaluation of the literature	80%
Analysing the literature and writing up your review	100%

as part of the Epigeum Online Course System with a score of 95%.

Dated: 22 July 2022

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Appendix F Letter of access for research

CCRF
children's clinical research facility
innovative & pioneering treatments for children

D Floor Stephenson Wing

Sheffield Children's NHS Foundation Trust

Western Bank, Sheffield S10 2TH

Sheffield Children's NHS
NHS Foundation Trust

26th April 2023

Dear David Hutchon

Letter of access for research:
SCH-2757- Feasibility study to evaluate a new hands-free doppler heart rate monitor normally used to measure the fetal heart rate

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on the **3rd May 2023** and ends on **3rd May 2026** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from Sheffield Children's NHS Foundation Trust. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving confirmation from the individual organisation(s) of their agreement to conduct the research.

The information supplied about your role in research at the organisation(s) has been reviewed and you do not require an honorary research contract with the organisation(s). We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation(s).

You are considered to be a legal visitor to the organisations premises. You are not entitled to any form of payment or access to other benefits provided by the organisation(s) or this organisation to employees and this letter does not give rise to any other relationship between you and the organisation(s), in particular that of an employee.

While undertaking research through the organisation(s) you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of the organisation(s) or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the organisation(s) in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

Appendix G

Consent sheet for adult study

PARTICIPANT CONSENT FORM

To be completed by the participant:
Please answer the following questions by ticking the response box that applies or answering us verbally

	YES	NO
1. I have **read** the Information Sheet for this study and have had details of the study explained to me.	☐	☐
2. My questions about the study have been answered to my satisfaction and I understand that I may ask further questions at any point.	☐	☐
3. I understand that I am free to withdraw from the study within the time limits outlined in the Information Sheet, without giving a reason for my withdrawal or to decline to answer any particular questions in the study without any consequences to my future treatment by the researcher.	☐	☐
4. I agree to provide information to the researchers under the conditions of confidentiality set out in the Information Sheet.	☐	☐
5. I wish to participate in the study under the conditions set out in the Information Sheet.	☐	☐
6. I consent to the information collected for the purposes of this research study to be used for any other research purposes.	☐	☐

Signature of participant: ______________________________ **Date:** ____________

Name of participant (block letters): __________________________

Appendix H Parent questionaire

Parent questionaire

Study ID: _______

1. How comfortable did your child seem when the Doppler sensor was applied?

On a scale of 1 to 10 (1 being not at all comfortable 10 being extremely comfortable)

1 2 3 4 5 6 7 8 9 10

2. How easy was it to hear the heart rate when the Doppler sensor was on your child's chest?

On a scale of 1 – 10 (1 being very difficult and 10 being very easy)

1 2 3 4 5 6 7 8 9 10

3. Did you find that hearing your child's heart rate was reassuring?

On a scale of 1 – 10 (1 being not reassuring at all and 10 being very reassuring)

1 2 3 4 5 6 7 8 9 10

4. Do you think that using the Doppler sensor for newborn babies in the future is better, as good, or worse than using a stethoscope (the current method)?

On a scale of 1 – 10 (1 being much worse and 10 being much better)

1 2 3 4 5 6 7 8 9 10

5. Please write below any specific comments, good or bad feedback about the Doppler sensor system.

6. Are you happy to be contacted by phone to take part in any group feedback sessions about this study at Sheffield Children's Hospital? Yes/No

Thank you very much for your time completing this questionnaire

Appendix I

IRAS ethics approval project ID 322466

Dr David Hutchon
Sheffield Hallam University
Sheffield S1 1WB
Prof Heather Elphick
Consultant in Respiratory Medicine Sheffield Children's Hospital
Sheffield Children's Hospital
Western Bank Western Bank
S10 2TH

04 April 2023
Dear Dr Hutchon, Prof Elphick

Study title: Feasibility study to evaluate a new hands-free Doppler heart rate monitor normally used to measure the fetal heart rate IRAS project ID: 322466
Protocol number: N/A REC reference: 23/SC/0059

Sponsor Sheffield Hallam University

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter. How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland? HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland. HRA and Health and Care Research Wales (HCRW)

Approval Letter
If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate. Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations? HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures. What are my notification responsibilities during the study? The standard conditions document "After Ethical Review – guidance for sponsors and investigators", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:
• Registration of research

• Notifying amendments
• Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures. Who should I contact for further information? Please do not hesitate to contact me for assistance with this application. My contact details are below. Your IRAS project ID is 322466. Please quote this on all correspondence.

Yours sincerely,
Hayleigh Keating Approvals Specialist

Copy to: Dr Keith Fildes
Converis ethical approval was also obtained

Information sheet for Childrens Hospital Study

Signature of investigator(s): ________________________________ Date: _____________

Name of investigator(s) (block letters): ____________________________

PARENT/LEGAL GUARDIAN INFORMATION SHEET

Study title: Feasibility study to evaluate a new hands-free heart rate Doppler heart rate monitor normally used to measure the fetal heart rate

We would like to invite you and your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what taking part would involve. **One of our team will go through the information sheet with you and answer any questions you might have.** Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen if you and your child take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear.

Part 1

1. What is the purpose of the study?

The main purpose of this study is to make an initial assessment of a modified fetal heart Doppler machine to determine whether it is effective and practical to measure the heart rate of a newborn baby. The equipment is a minor modification of the well used fetal Doppler used to measure the fetal heart rate during labour. The Doppler probe has been modified to provide hands-free use with the transducer resting on the chest and held in place by standard ultrasound gel. In the last few years five studies have shown that a standard fetal Doppler probe held on the neonatal chest are equivalent to the ECG and superior to the oximetry and auscultation. Auscultation (listening with a stethoscope) has been the standard method to determine the neonatal heart rate for the past 60 years, with the oximetry or an ECG being used on sick neonates. Oximetry and ECG are hands-free after the initial application whereas the Doppler needs to be held in place by one of the carers. The modified hands-free Doppler should overcome this limitation. If using the new hands-free Doppler probe leads to comparable heart rates as the ECG, it could potentially become the standard of care for heart rate at birth, replacing the stethoscope or ECG at birth and complimenting the oximeter .

2. Why have we been invited?

Your child has been invited because he or she has been referred for a sleep study and hence is going to undertake testing with the existing diagnosis protocol, using the standard equipment (polysomnography). We would ask to take the opportunity to test the use of the hands-free Doppler on your child. There are no risks for the technology will only require your child to keep a small circular probe (about the size and weight of a 2p piece) on the chest for about 5 minutes. This could be carried out at the start or end of the sleep study or during a nappy change. We hope to recruit 15 children for this study. Since the equipment is intended for newborn babies, only the smallest and youngest children attending for sleep studies will be invited to participate.

3. Do we have to take part?

It is up to you to decide to join the study. We will go through this information sheet with you and answer any questions. If you agree to take part, we will then ask you to sign a consent form.

You will be given a copy of the information sheets and the signed consent and assent forms to keep for your records. You are free to withdraw at any time, without giving a reason. Withdrawing from the study does not affect the standard of care your child will receive.

4. What will happen to my child if we agree to take part?

If you agree for your child to take part in this study, The five minute heart rate recording will take place at the start or end of the sleep study while your child is awake. During a nappy change is also an opportunity but only one of these times will be selected. The Doppler probe applied for the five minutes will be in addition to the equipment for the standard method for diagnosis of the condition your child has been referred for.

A PhD student will set the sensors up, you won’t have to do anything.

We will also ask you to fill in a short questionnaire to let us know what you and your child thought of the sensor.

Specialist doctors will determine whether your child has sleep apnoea. The diagnosis will be based on the standard (polysomnography) method and not on the new sensor results. Subsequently, a comparison of the two diagnostic techniques will be carried out, to determine whether the new sensor got it right.

The research does not last any longer than the current method for diagnosis (1 night's sleep). Your child will not need to visit the hospital more often than for the usual diagnosis and treatment. There will not be any additional measurements (blood test, x-ray, or other) above or over those involved in standard diagnosis and treatment.

Below is a picture of the modified Doppler device. The transducer, pink on the right, has been removed from the probe attached to the fetal Doppler device and connected by a soft flexible wire. The battery powered Doppler device will be placed next to your child close enough for the transducer to remain on their chest, held in place by standard ultrasound gel. This is what it will look like in the study.

.

5. Expenses and payments

There are no expenses or payments for taking part in this research.

6. What happens to the information recorded during the research project

If you and your child agree to take part in the research, your child will be issued with a research ID number rather than using their name. Only Dr Elphick's research team will know which number is issued to which child. They will keep a spreadsheet on an encrypted computer and no-one else will have access to it. It will only be used if Dr Elphick needs to check any clinical details during the course of the research.

7. What are the possible benefits of taking part?

There will be no direct benefit to your child from taking part in this study. If this technology proves to be as good at diagnosing sleep apnoea as the current clinical test, future children could be diagnosed remotely just by using the new sensor at home, without having to have any other sensors attached.

8. What are the risks of taking part?

Every effort will be made to reduce the anxiety which might be felt by some children. Doppler ultrasound is completely safe. If at any time you or your child feels that any distress caused by the study , please don't hesitate to tell a member of staff. We will address the concerns and if necessary abandon the Doppler heart measurement.

9. What are the side effects of any treatment received when taking part?

There should be no side effects at all.

10. What if there is a problem?

Any complaint about the way you or your child have been dealt with during the study or any possible harm you or your child might suffer will be addressed. Detailed information on this is given in Part 2.

11. Will my child's taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. The details on how we establish confidentiality are stated in Part 2.

This completes Part 1 of the parent/legal guardian information sheet.

If the information in Part 1 has interested you and you are considering your child's participation, please read the additional information in Part 2 before making any decision.

IRAS ethics approval project ID 322466

Dr David Hutchon
Sheffield Hallam University
Sheffield S1 1WB
Prof Heather Elphick
Consultant in Respiratory Medicine Sheffield Children's Hospital
Sheffield Children's Hospital
Western Bank Western Bank
S10 2TH
04 April 2023

Dear Dr Hutchon, Prof Elphick

Study title: Feasibility study to evaluate a new hands-free Doppler heart rate monitor normally used to measure the fetal heart rate IRAS project ID: 322466
Protocol number: N/A REC reference: 23/SC/0059

Sponsor Sheffield Hallam University

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter. How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland? HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland. HRA and Health and Care Research Wales (HCRW)

Approval Letter
If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate. Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations? HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures. What are my notification responsibilities during the study? The standard conditions document "After Ethical Review – guidance for sponsors and investigators", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:
• Registration of research
• Notifying amendments
• Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures. Who should I contact for further information? Please do not hesitate to contact me for assistance with this application. My contact details are below. Your IRAS project ID is 322466. Please quote this on all correspondence.

Yours sincerely,
Hayleigh Keating Approvals Specialist

Copy to: Dr Keith Fildes
Converis ethical approval was also obtained

Sheffield Children's NHS
NHS Foundation Trust

Feasibility study to evaluate a new hands-free Doppler heart rate monitor normally used to measure the fetal heart rate

The Doppler Study

STUDY NUMBER: SCH-2757

DATE AND VERSION NUMBER: 19/10/22 Version 1.0

Sponsor's Representative ……………………….. Dated ……………..

Chief Investigator ………………………… Dated ……………..

LAY SUMMARY

During pregnancy, ultrasound Doppler is used to determine the heart rate of the fetus (unborn baby). This has been established practice throughout the world for over 40 years. It is accurate and audible, which means that anyone in the room can immediately hear if there is a problem with the fetal heart rate. After birth the heart rate of the new born baby is traditionally detected using a stethoscope over the baby's chest. This is an inferior technique in that it is only heard by one person, requires a degree of mental arithmetic to calculate the heart rate and is undocumented. In the last few years, studies have shown that the ultrasound Doppler used to determine fetal heart rate can also provide an accurate heart rate in the newborn baby. This can be readily recorded for documentation, can be heard by the whole clinical team (and parents), and is much more sensitive than the human ear if the heart beat is slow or weak.

As the previous studies have shown, the fetal Doppler works very well on the newborn baby but, as with the stethoscope, it requires one dedicated member of the team caring for the baby to keep the ultrasound probe on the chest. It may be difficult to ensure sufficient but not excessive pressure is being applied to the chest and a varying angle may affect the quality of the signal. Ideally, the sensor needs to be hands-free.

Dr Hutchon, under Professor Saatchi's supervision, has developed a modified fetal Doppler probe which provides hands-free monitoring. The probe is linked to the Doppler device by a 12-inch length of soft flexible wiring. The small probe sits on the baby's chest immediately over the heart and is held in place by the normal ultrasound gel used on the mother's abdomen during labour. The gel ensures a good signal and is thick enough to keep the transducer in position. The chest can be covered with a towel or polythene wrap to keep the baby warm. The heart rate is continuously recorded and wirelessly transferred to a nearby computer. As with a stethoscope the probe is cleaned before use to ensure there is no risk of infection.

We propose an initial small study on 15 children being admitted to the sleep unit at Sheffield Children's Hospital where Dr Elphick's clinical team investigates up to 500 children a year. The hands-free Doppler will be placed on baby's chest and the audible signal of the Doppler heart sounds will be used to confirm the best positioning of the transducer. The child's heart rate will be measured over a period of about five minutes with both the hands-free Doppler and with the usual method of monitoring on the sleep unit which uses ECG. The rates from the two systems will be compared to evaluate the accuracy of the research method. Information will also be collected from the parent(s) to determine their opinion on the acceptability of the hands-free transducer. This will help us to establish whether the method can be used as a diagnostic tool for use in the future.

GENERAL INFORMATION

Sponsor: Sheffield Children's NHS Foundation Trust Western Bank Sheffield S10 2TH United Kingdom	**Sponsor's Representative/Contact:** Prof Paul Dimitri Director of Research & Development Phone Fax: Email:
Chief and Principal Investigator: Name – Prof Heather Elphick (Professor of Paediatric Respiratory and Sleep Medicine) Address – Sheffield Children's NHS FT Telephone –Email	**Student investigator:** Name – Dr David Hutchon Address – Sheffield Hallam University Telephone – Email – david.hutchon@student.shu.ac.uk
Co-Investigator: Name – Prof Reza Saatchi Address – Sheffield Hallam University Telephone – Email –	

BACKGROUND

The problem

The heart rate at birth is a key measure of the health of the baby and a major parameter used to determine the level of care required by the baby. Without accurate documentation of the heart rate the care of each individual baby and the best policy care for babies cannot be optimised. Recent changes in immediate care of the neonate at birth have highlighted the importance of avoiding unnecessary intervention. The common practice of routine early cord clamping at birth has changed in all guidelines in recent years with a number of units adopting resuscitation when required with an intact cord. It has been known for many years that early cord clamping caused a marked slowing of the heart rate. Thus accurate measurement and documentation of the heart rate is critical.

In the last few years five studies on neonates have shown that the fetal Doppler transducer, placed on the neonatal chest, provides an accurate heart rate. In babies who are sick at birth the heart rate is the main measure used to identify recovery. In these circumstances the heart rate is often determined by an ECG but it takes time to apply the two or three ECG electrodes, longer than the application of the Doppler probe to the neonatal chest. An oximeter on the neonatal hand or foot is also used but it is well recognised that even in a healthy neonate it can take a minute before it registers the heart rate. This delay is not acceptable. The ECG and oximetry therefore do not provide a satisfactory solution. The fetal Doppler device is used during labour and is therefore still immediately available when the baby is born. Doppler ultrasound is widely used throughout the world during labour even in low resource settings. (Ditai et al., 2021)

Proposed solution

A low cost fetal Doppler probe has been modified so that the small 2cm plastic case with the transducer can be removed and reconnected on the end of a thin flexible connecting wire. This allows the transducer to be placed on the neonatal chest directly over the heart. Electronics have been added to read the LCD heart rate display and wirelessly send the heart rate to a nearby computer for documentation and comparison with the ECG heart rate.

Figure 1 shows the proposed modified fetal Doppler monitor with the transducer on the end of a long flexible wire.

Previous work

It is hard to explain why Doppler ultrasound was not seriously considered to determine the neonatal heart rate at birth previously, having been in routine clinical use for the fetal heart for well over 40 years. Auscultation of the fetal heart is possible but the sounds are weak and can usually be heard only in areas of the mother's abdomen which are close to the fetal chest and heart. The Doppler devices were designed to detect the fetal heart through the mother's abdomen and perhaps it was thought it would not work when the heart was close to the probe and the lungs were filing with air.

The limitations of auscultation were recognised by neonatologists for many years but Doppler ultrasound was never considered as a possible solution until the last five years. Colour flow ultrasound has been used by neonatologist to view blood flow within the heart and major blood vessels even before 2012 so it is difficult to understand why these neonatologist did not realise the possibility of using the technology for the neonate at birth.

A study was carried out on piglets in 2012 in England by the student investigator. At about the same time, unknown to each other, a similar study on healthy neonates was underway in New York State. These are the earliest publications of any consideration of the use a fetal Doppler machine on the neonate at birth. Both these studies showed that the Doppler provided an accurate heart rate. The piglet study indicated that the approach should also work well in very preterm neonates; piglets are normally about 500g at birth, the same weight as the smallest preterm babies who can have a chance of survival.

Proposed study

The Study is the first of a number of proposed studies required to show that the use of precordial Doppler ultrasound using a hands-free transducer to determine the neonatal heart rate at birth is a significant improvement on current practice. The use of the standard hand-held Doppler probe has already been shown to be equivalent to the ECG and superior to oximetry and auscultation. This will be new knowledge demonstrating how the hands-free probe works well without the need for continuous attention. This initial study will take place in the sleep unit at Sheffield Children's Hospital and will involve patients who have been referred for a sleep study. For this study and at this stage, the modified Doppler device and software constitutes an educational research tool rather than a medical device. The safety of Doppler ultrasound has been demonstrated by its worldwide use over the last 50 years.

To prove the superiority of the technology over auscultation, we propose a clinical study with 15 patients. The purpose of this study is to obtain the heart rate over a period of 5 minutes using the Doppler technique and compare it with the ECG heart rate which is the gold standard for heart rate. This will be carried out at Sheffield Children's NHS Foundation Trust (SCH), where over 500 children per year undergo sleep studies for diagnosis of sleep disorders. The study will be supervised by Prof. Heather Elphick who leads a clinical team comprising of 4 consultants, 6 physiologists and 6 technicians/support workers, as well as a research team comprising of 2 nurses and 2 research officers as well as project managers and students.

STUDY OBJECTIVES AND PURPOSE

The aim of this study is to investigate the feasibility, accuracy and acceptability of a hands-free prototype Doppler device.

The thesis will evaluate:

- the accuracy of the system in 15 patients, when compared with the gold standard ECG
- the acceptability of the sensor to the child as viewed by the parent
- any other feedback.

STUDY DESIGN AND SETTING

The study is an exploratory research study looking at the feasibility, acceptability and accuracy of Doppler compared with the gold standard ECG. It will take place in the sleep unit at Sheffield Children's Hospital where relatively well patients are admitted for diagnostic testing.

PARTICIPANTS

Eligible children will be identified by the clinical sleep unit team from the sleep study admissions list. The medical records will be reviewed to confirm that patients invited meet the inclusion criteria. Participants will be children who have already been booked by their clinical team for a sleep study on the sleep unit at SCH for diagnosis or monitoring of a sleep disorder.

Inclusion Criteria

- Patients who have been referred for a cardio-respiratory polygraphy sleep study.

- Patients aged one month up to one year old.

Exclusion Criteria

- Subjects whose parents/legal guardians/carers are not fluent in English, or who have special communication needs.
- Child anticipated to become distressed with additional sensor.
- Child too clinically unwell to take part (as decided by clinical staff).

PARTICIPANT RECRUITMENT

Parents/legal guardians of potential participants will be approached by a Good Clinical Practice (GCP) trained member of the SCH team ahead of their sleep study and sent information sheets and consent forms by email or post. They will be given at least 4 hours to consider taking part so that they can make an informed decision. Online meetings/phone calls will be used to go through study information, answer questions, and take informed consent. Parents/guardians will provide written informed consent on behalf of their child.

PROCEDURES

Clinical sleep study set-up procedure

The child will be set up for their clinical sleep study in the hospital for diagnosis of paediatric sleep apnoea with the standard sleep diagnostic equipment (SOMNOscreen plus). This includes: thermistor, nasal airflow, respiratory impedance plethysmography bands, transcutaneous CO_2, SpO_2, snore, body position, ECG and video.

Research study set-up procedure

During a wake period, at the very start or finish of the sleep study, the hands-free Doppler transducer will be placed on the exposed chest of the subject over the left side of the sternum and moved to identify the loudest heart sounds. The transducer will be left in place, secured by the ultrasound gel. The stability of the transducer will be noted. If the transducer moves sufficiently to lose the heart sounds and heart rate, it will be documented and adjusted to obtain a satisfactory recording once again but the measurement will not continue for significantly more than five minutes. The Doppler heart rate measurements will be time stamped to provide accurate comparison with the ECG.

Parent questionnaire

A questionnaire will be given to the parent to complete. This will enable the study participants to provide their views on sensor acceptability, and any further feedback.

DATA HANDLING AND RECORD KEEPING

Data will be collected and retained in accordance with the Data Protection Act 2018. No personal identifiable information will be passed to any third parties for any reason.

Participants' name, gender, age, and the diagnosis derived from the clinical diagnostic study will be kept securely in a locked filing cabinet and on a spreadsheet saved on a secured, password-protected computer under the supervision of Professor Heather Elphick and will be accessible only by the SCH study team. All information kept on laptop computers as well as removable storage used in this project will be password-protected and encrypted as per the Sheffield Children's NHS Foundation Trust Information governance clearance.

All other clinical information and contact details will be kept in the patient's clinical electronic records and can be accessed by the SCH team only.

Each participant will be given a unique study code and this will link their personal and clinical information with the data used for the study. This code will be stored in a locked filing cabinet and in a secured, password-protected computer and will only be accessible by the SCH team. The physiological data recorded by the standard clinical PSG equipment will be pseudo-anonymised, i.e. personal details will be removed from the signals and only the unique code will be used. A data-sharing agreement for the transfer of the pseudo-anonymised raw data has been signed by both the university and the hospital.

The heart rate computed by the Doppler machine is transferred electronically to a nearby computer every two seconds. The time stamp is added and at the end of the five-minute recording the data is transferred to a prepared spreadsheet as described above.

All of this will be explained in the information sheet that is provided to subjects prior to seeking their consent to participate.

All source documents will be retained for a period of 5 years following the end of the trial. Where trial related information is documented in the medical records – those records will be retained for 5 years after the last patient last visit.

ACCESS TO SOURCE DATA

The sponsor will permit monitoring and audits by the relevant authorities, including the Health Research Authority and Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents.

STATISTICAL ANALYSIS

The study has a target sample size of 15 which is the minimum sample size recommended for a pilot study, allowing for a 20% attrition rate.

After the study is finished, the correlation between the Doppler heart rate and the ECG heart rate will be calculated using the Bland Altman method and Student T test. Based on this comparison we will establish accuracy against the gold standard ECG. The view of the parents of the stability and acceptability of the hands-free device will be reviewed.

Primary endpoint:

Comparison of measurement of heart rate against the ECG.

Secondary endpoints:

Acceptibility of the hands-free device by parents.

SAFETY ASSESSMENTS

The study will be monitored and audited in accordance with the Monitoring Standard Operating Procedures of the Directorate of Research & Innovation at Sheffield Children's NHS Foundation Trust. All study related documents will be made available on request for monitoring and audits by the Sponsor, the Health Research Authority and the relevant Research Ethics Committee.

ETHICAL CONSIDERATIONS

Ethical approval

This project will be conducted in compliance with an NHS Ethics Committee favourable opinion.

GCP

This project will be conducted in accordance with the International Conference for Harmonisation of GCP, and the Research Governance Framework for Health and Social Care (2nd Edition).

Informed consent

Informed consent will only be taken by members of the study team trained in GCP and who are experienced in taking consent.

Withdrawal

Participants will be made aware that this is a voluntary activity and they are free to withdraw at any point without giving a reason and without compromising their healthcare.

Clinical management

No clinical decisions will be made on the basis of this study. Clinical management will continue as usual and any changes in management will be made by the clinical team as a result of direct clinical review.

FINANCE AND INDEMNITY

Participants will not be paid for study activity.

This is an NHS sponsored study. For NHS sponsored research HSG (96) 48 reference no. 2 refers. If there is negligent harm during the study when the NHS body owes a duty of care to the person harmed, NHS Indemnity will cover NHS staff, medical academic staff with honorary contracts and those conducting the study. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

JUSTIFICATION OF FINANCE

This is an unfunded study that is part of a Masters student project. Staff time at SCH has been paid from Dr Elphick's research fund for this preliminary project. For future studies, funding for staff time will be requested.

Heather Elphick will oversee the project at no cost as part of her NHS research time allocation.

JUSTIFICATION OF RESOURCES

All material resources are provided by SHU

REPORTING AND DISSEMINATION

Findings will be reported within the University and the Trust at appropriate departmental meetings and educational events.

Findings will be presented at national and international conferences. Target conferences:

- Child Health Technology 2022
- Neonatal resuscitation meetings

The study will be submitted for publication in a high-quality peer-reviewed journal.

OUTCOMES

We will apply for a grant to extend this work. The project team has extensive experience applying for and securing grants.

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TIMELINE

Task name	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10
Monthly project meetings										
University ethics approvals		M1								
NHS ethics approvals				M2						
Student research passport				M3						
Sleep unit introduction to the project										
Student introduction to sleep unit										
Participant recruitment								M4		
Participant study Doppler heart rate										
Data analysis										
Report writing										M5
Grant writing										M6

M1 (month 2) - University ethics approval

M2 (month 4) – NHS ethics approval

M3 (month 4) – Student research passport

M4 (month 8) – Target recruitment reached

M5 (month 10) – Report completed

M6 (month 10) – Grant application submitted

Appendix J

Appendix K