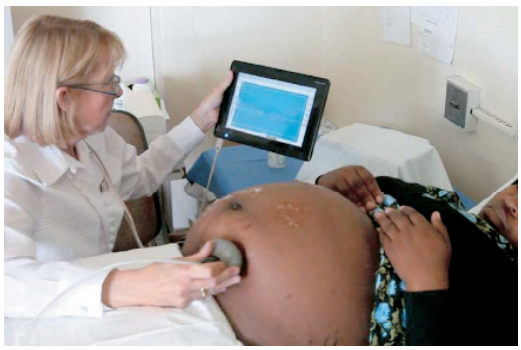
UMBIflow

PRODUCT OVERVIEW

Mobile-connected Doppler analyser for fetal health evaluation in low-resource settings



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Background

This document summarises Umbiflow, and provides partners and stakeholders with an introduction to its functionality, clinical value and commercial potential. It is part of the CSIR and SAMRC mandates to provide product solutions that meet real market needs, and Umbiflow is specifically designed to create maximum impact in the healthcare environment by providing system efficiency and improved patient care. The CSIR and SAMRC encourage collaboration with device manufacturers and management organizations, public relations, distribution and marketing partners.

What is Umbiflow?

Umbiflow is a sophisticated portable continuous wave Doppler with bi-directional indication of blood flow velocity in the umbilical cord. This type of ultrasound Doppler technology allows health care practitioners to assess placental function, which is, in essence, its ability to supply sufficient oxygen and nutrition to the growing fetus. The Doppler measurement is used to recommend specialist intervention should the fetus be at risk. Umbiflow was specifically designed for use by nursing staff and midwives at primary health care facilities and antenatal clinics in remote and low-resource settings.

Umbiflow consists of a self-contained software programme and a vascular transducer in the form of a hand-held probe that plugs into the USB port of a computer (desktop, notebook or tablet). The USB port provides power to the probe and facilitates the signal transfer to a software application. The software processes the Doppler ultrasound signals to generate a high-quality waveform depiction of the umbilical blood flow, and automatically calculates the so-called "resistance index" (RI) which can be directly linked to the functioning of the placenta. The blood flow in the umbilical cord is also audible in the loudspeakers and a digital interface allows the user to print the test results. Umbiflow is connected via the mobile network, and allows for remote expert monitoring so that centrally located obstetricians can provide support to nurses in the field in real-time. The measurements taken at the clinic are automatically and securely uploaded to a central server for information sharing across different levels of care, and potential interoperability with other devices. The telemedicine aspect of the solution also provides the additional benefits of quality assurance, system surveillance as well as electronic health record management.

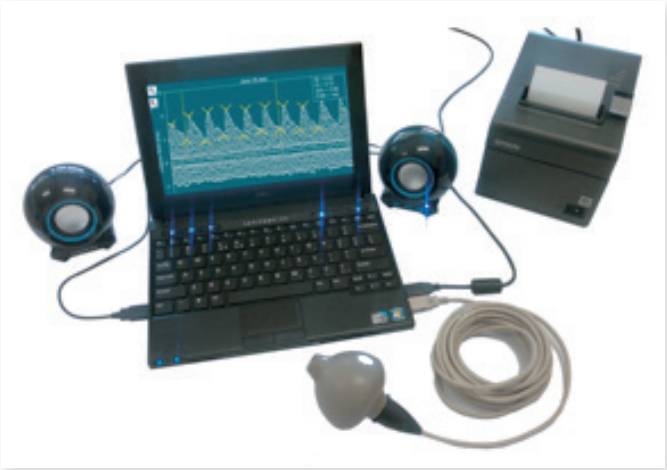


Figure 1 shows an example of the ultrasound probe plugged into a notebook via a USB-connector cable. Attached to the notebook is a thermal printer for result print-outs, and external speakers for audio amplification of signals.

Why Umbiflow was developed

Presently the only way to determine the fetal growth rate at the primary care level in South Africa is by measuring the symphysus-fundal height manually by use of a technique involving a tape measure to determine the distance across the mother's abdomen from the pubic bone to the top of the uterus. Through serial assessment this technique can effectively determine a growth trend but cannot distinguish between a constitutionally small and healthy fetus and a pathologically small and therefore compromised fetus. The consequence is that all fetuses measuring small for their gestational age are being referred to a higher level of care for Doppler, the well-proven technology to differentiate between the two types of small-for-gestational-age fetuses. At a higher level of care more expensive (pulsed-wave) imaging Doppler ultrasound is typically available, including additional modes of ultrasound, but operating this technology requires subspecialist training as a sonographer.

Our simple-to-use continuous-wave Doppler, on the other hand, allows midwives and nursing sisters to effectively manage a routine antenatal course for pregnant women at the primary health care level, and thereby has the potential to greatly reduce the number of unnecessary referrals. At the same time, the device can detect placental insufficiency in what appear otherwise to be low risk pregnancies. This ensures referral for further testing and intervention, where necessary, to save the at-risk fetus.

Why is it important to continuously assess the placental function during gestation?

Adequate placental blood flow via the uterine and umbilical arteries supplies oxygen and nutrients to the baby. If the placental function is compromised, this will have a direct effect on the fetus-growth. Abnormally slow growth of a fetus is referred to as "Intrauterine growth restriction" (IUGR) and is associated with an increased risk of illness and death in the perinatal period. The causes of IUGR can be maternal, placental or fetal. A fetal weight that is below the 10th percentile for gestational age, as determined through serial SF-measurements or an imaging ultrasound, provides clinical suspicion of IUGR. If the mother is small, it may be normal for her to have a small fetus; this is constitutional SGA, not IUGR.

At the primary care level, pregnant mothers are referred to the secondary level if they are considered to be a "high risk" patient or if their fundal height measurement raises concerns. At the secondary level, a number of tests are done, one of which is the measurement of the umbilical blood flow and its link to abnormal fetal growth. Umbiflow was developed for this latter set of patients; those who are not initially classified as high risk, but who develop a clinical suspicion of IUGR during their antenatal care.

In a nutshell Umbiflow was developed to determine the velocity of umbilical blood in a fetus and to do so at the primary health care level, at low cost, by a primary health care worker.

Benefits of Umbiflow to the primary antenatal care level include:

- Speed of diagnosis – done immediately at the primary level;
- Avoidance of unnecessary referrals – Doppler measurement done at primary not secondary level;
- Enhanced detection of placental insufficiency in otherwise healthy pregnancies leading to intervention to reduce the chance of stillbirth;
- Empowerment of health care workers to conduct diagnostic measurements that previously required a specialist.

Benefits to the higher care levels and patients include:

- Reduced hospital admissions and costs associated with secondary level tests for unnecessary referrals;
- Increased care for patients previously regarded as low risk but demonstrated to have an abnormal Doppler reading;
- Reduction in the stillbirth rate.

The use of Doppler ultrasound to measure umbilical blood flow has been shown in literature to reduce the perinatal mortality rate amongst the population of high risk pregnancies by an average of 38%, and to also achieve a range of other benefits associated with reduced secondary level admissions. More recently, studies have shown that routine screening of low risk pregnancies with Doppler ultrasound and intervention, where required, can significantly reduce the perinatal mortality rate.

Umbiflow was developed with a view to its placement at primary level antenatal clinics (including Maternal Obstetric Units) as a means of quickly assessing whether SGA fetuses are either healthy-small or sick-small, with the aim of better informing the referral decision. It has also demonstrated its value in detecting and thereby saving at-risk fetuses.

The portable nature of Umbiflow suits Medical GPs (particularly outside the major population centres); travelling mid-wives, and other settings where home births are common.

History of Umbiflow

Umbiflow's development was funded by the South African Department of Science & Technology, through the National Research Foundation's Innovation Fund, the Council for Scientific and Industrial Research (CSIR) and the South African Medical Research Council (SAMRC). A first prototype was developed and tested in clinics and Tygerberg Hospital in the Western Cape, South Africa. This demonstrated that the Umbiflow device could accurately measure the Resistance Index (RI) of the umbilical blood flow and provide suitable data to guide the referral decision at a low cost. It also demonstrated that the technology could be adopted and operated by midwives at antenatal clinics.

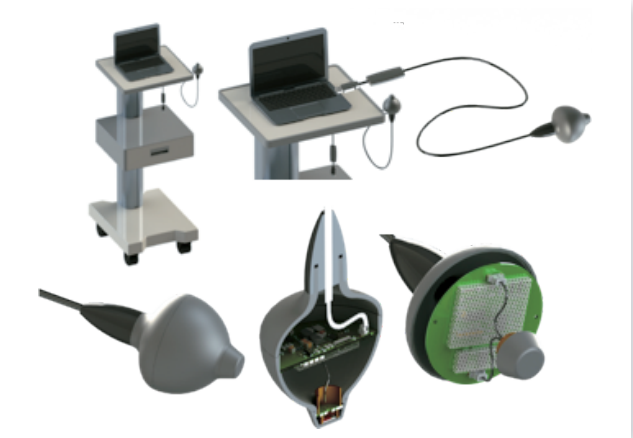


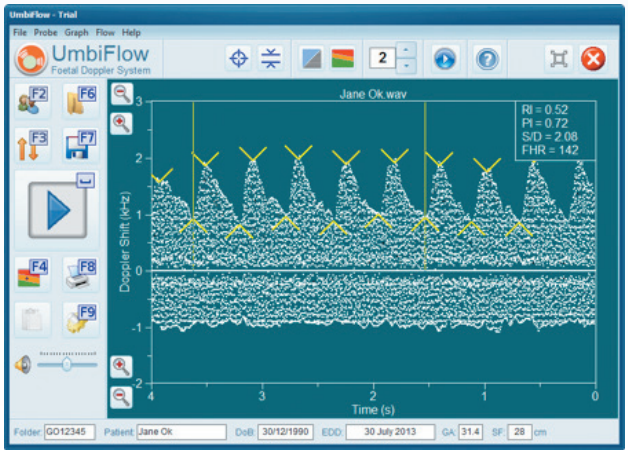
Figure 2 : The extended system including a medical trolley.

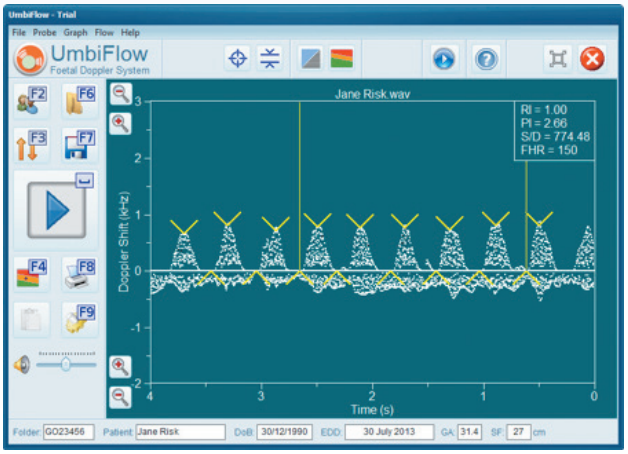
History of Umbiflow

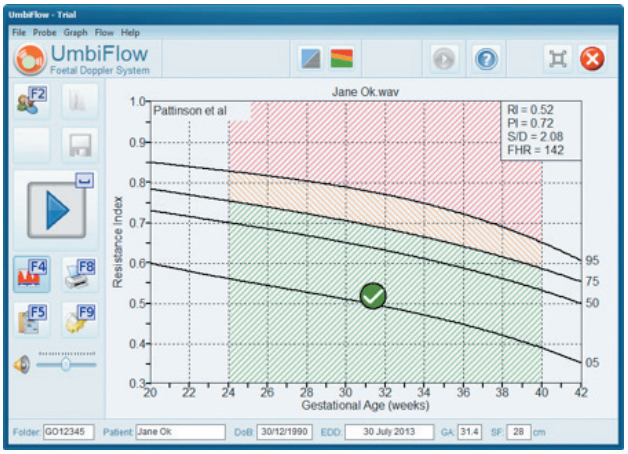
The results of the clinical trial to establish technical validity were made known at a conference of the International Perinatal Doppler Society in 2001. Medical journal publications of the final prototypes being used were published in 2005 (South African Medical Journal, January 2005, Vol. 95, No. 1, pp. 62-64), in 2007 (The Journal of Maternal-Foetal and Neonatal Medicine, March 2007, Vol. 20, No. 3, pp. 233-239), and in 2015 (PLoS One, 2015, Vol. 10., No. 11).

The technology has been further developed and adapted to incorporate the latest mobile and information technologies.

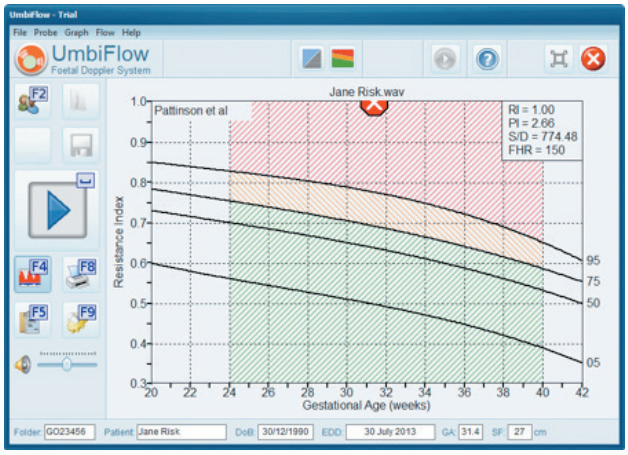
A more recent study on >2,800 women classified as having low risk pregnancies in Mamelodi, South Africa, has demonstrated that the prevalence of abnormal Doppler readings is 10-fold higher than in developed countries. The study further demonstrated that, by applying routine screening of such low risk pregnancies with Umbiflow to detect abnormalities, referral for management as high-risk cases and intervention, where required, the overall stillbirth rate can be significantly reduced (in press: South African Medical Journal).







The screenshot above is an example of normal umbilical artery blood flow velocity including the waveform and plotted Resistance Index (RI) in the screenshot below.



The screenshot above is an example of abnormal umbilical artery blood flow velocity including the waveform and plotted Resistance Index (RI) in the screenshot below.

Summary

Umbiflow is an ultrasound system designed to measure blood flow in the umbilical artery of primarily third trimester fetuses for the purpose of assessing placental function. Such an assessment is able to differentiate between healthy and sick small-for-gestational-age fetuses and, if done at the primary health care level, brings a range of benefits to both the primary and secondary levels of care and to the patients.

Umbiflow was developed by joint SAMRC and CSIR teams, and has been tested at primary care level for its accuracy and effectiveness in influencing perinatal outcomes.

An ISO 13485 quality system has been implemented at CSIR and the process to obtain a CE Mark for Umbiflow is near completion to facilitate market entry.

For further information contact: info@umbiflow.com