History of Umbiflow

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Whilst Umbiflow initially was counter-trend, on account of its computer based implementation, with the advent of powerful mobile devices in the late 2000’s, it was proposed that Umbiflow could be reconfigured to work on not just desktop or notebook PCs but also mobile platforms such as Tablet PC or Smart Phone. Initial development work to this end resulted in a Windows 7-based Tablet PC version being developed and this system was exhibited at the Health Summit in Washington DC in December 2011.

Summary

Umbiflow is an ultrasound system designed to measure blood flow in the umbilical artery of 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.

For further information contact: info@umbiflow.com
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;
- Empowerment of health care workers – can now conduct diagnostic measurements that previously required a specialist;
- Reduced stress / worry of pregnant women through avoidance of an avoidable referral.

Benefits to the higher care levels include:

- Reduced hospital admissions with associated admission costs;
- Reduced patient burden in specialist clinics (e.g. Fetal Evaluation Clinic);
- Reduced costs associated with secondary level tests that require specialised medical staff involvement.

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.

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 mandate 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 encourages 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 handheld 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 bloodflow 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.

Prevalently the only way to determine the fetal growth rate at the primary care level in South Africa is by measuring the symphysion-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. The patient consequently does not have to travel to a referral clinic for a Doppler and small-for-gestational-age fetuses can be managed at a clinical location in the vicinity of the patient, and thus benefit the patient.

History of Umbiflow

Umbiflow’s development was funded by the South African National Research Foundation, by the Council for Scientific and Industrial Research (CSIR) as well as the South African Medical Research Council (MRC). A first prototype was developed and tested in clinics in the Western Cape Province of South Africa and Tygerberg Hospital (the teaching hospital for Stellenbosch University and, specifically, its O&G Department), who conducted the Umbiflow tests. This ratified the premise that the Umbiflow system 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.

Umbiflow was developed with a view to its placement at South Africa’s 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. With a large rural or semi-rural population and large numbers of people living at low income levels in South Africa, Umbiflow has the potential to make a significant impact on both the patient and the healthcare system.

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