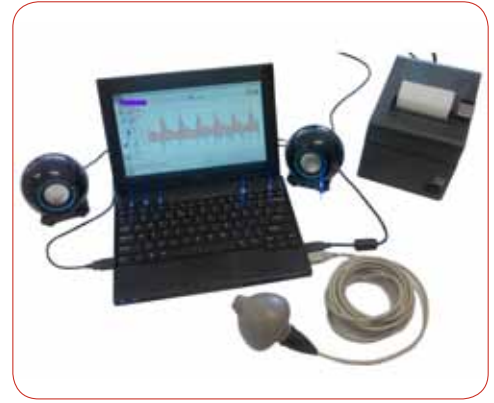


# Umbilical artery doppler analyser

Country of origin | South Africa

## Health problem addressed

Placental insufficiency is a major cause of intrauterine growth restriction. Doppler ultrasound to assess the flow velocity of the umbilical artery of the fetus with poor growth is the only method of antenatal surveillance that has significantly improved perinatal outcome, but Doppler technology is often unavailable at the primary care level.



## Product description

The technology uses Doppler waveform analysis for reliable and cost-effective antenatal screening in low-resource environments. The technology measures blood flow in the umbilical artery of the fetus at greater than 24 weeks gestation. From such a measurement, decisions can be made about the ability for the placenta to provide sufficient nutrients and oxygen in order to sustain adequate fetal development. The ultrasonic Doppler probe connects to the USB port of a standard Pentium PC or laptop on which proprietary software is installed. The product consists of a graphic user interface, operational software and the physical mechanical parts of the probe (hosing, acoustic nose, etc.). The external speakers, printer, and notebook are off the shelf products. The system allows for a database facility, serial monitoring, plotting and printing of results, quality assurance and remote expert support. A 3G data connection (integrated SIM card) is necessary if remote expert support is desired.

## Developer's claims of products benefits

2D ultrasound with Doppler mode are available at secondary and tertiary care facilities in South Africa but operation requires sonography skills and training. Sonographers are expensive and scarce in South Africa. This system is based on continuous-wave technology, which is easier to use and already proven to be as reliable as the more expensive and larger duplex mode machines found in ultrasound units. By introducing the simple-to-use Doppler to primary antenatal care, it is anticipated that this device could significantly reduce the numbers of referrals to a higher level of care.

## Suitability for low-resource settings

The system requires little management and few consumables apart from the gel to operate the probe and thermal printer paper if maternity case records are to be maintained. The system is rugged as well as water and acid resistant. It has demonstrated that simple PC-based, continuous wave Doppler ultrasound device operated by a midwife at the antenatal study clinic is effective in identifying patients at risk for placental insufficiency and in excluding pregnant women from additional tests for fetal well-being.

## Operating steps

Enter patient details, palpate to determine fetal orientation, apply gel to probe and move it across the abdomen to detect umbilical blood flow with good audible signal. Record measurement, review waveform diagram and plotted indices, follow clinical management suggestions. Save patient file, print result and staple into the maternity case record.

## Regulatory status

Two external audits for ISO 13485 are scheduled for November and December 2013. The audit for CE marking is scheduled for February 2014.

## Future work and challenges

Future work and challenges include training device operators in conducting waveform Doppler measurement, establishing a medical device management system to support devices in the field, developing a reliable remote expert support (telemedicine) feature for quality assurance and assistance of clinical personnel in the field, and pursuing liability insurance system accreditation and tender-based procurement by Departments of Health.

## Use and maintenance

**User:** Nurse, midwife

**Training:** Yes

**Maintenance:** Daily cleaning/removal of any gel from keypad and probe by the nurse

## Environment of use

**Settings:** Rural, urban settings, primary (health post, health center), secondary (general hospital)

**Requirements:** Access to electricity to charge the battery of the notebook because the probe is powered directly from the computing device via USB connection. A lockable treatment or storage room against theft protection during hours when the clinic is closed. 3G connection if remote expert support is desired.

## Product specifications

**Dimensions (mm):** 300 x 250 x 70

**Weight (kg):** 2.2 (includes notebook, probe, speakers, charger, and thermal printer)

**Consumables:** Transmission gel, thermal printer paper

**Life time:** 10 years

**Shelf life:** 1 year

**Retail Price (USD):** 2400

**List price (USD):** 1100

**Other features:** Software use, telemedicine capability, mobile, capital equipment

**Year of commercialization:** Anticipated 2014

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