Oxford Medical Diagnostics Breath Ketone Device for monitoring type 1 diabetes

TECHNOLOGY

The Oxford Medical Diagnostics (OMD) Breath Ketone Device is a hand-held ‘point of care’ spectroscopic breath analyser for monitoring blood ketone levels in adults and children with type 1 diabetes mellitus. It detects the early signs of diabetic ketoacidosis, and can also be used to monitor patients at risk of developing gestational diabetes. It is intended to be used by a health professional in primary care, a hospital, or home setting, as an alternative to the current finger prick test.

Patients breathe into the device, which then analyses the breath contents and measures the acetone level in parts per million (ppm). An algorithm is used to convert the reading into an equivalent blood ketone measurement in millimoles per litre (mmol/l), or milligrams per decilitre (mg/dl).

According to the company, the principal component of the device is the optical sensor, which is based on cavity enhanced absorption spectroscopy. The technology involves the coupling of laser absorption spectroscopy with an optical cavity (two parallel highly reflective mirrors). The laser light bounces back and forth between the mirrors so that the overall path length of the light beam extends to a few kilometers. This allows more time for absorption and increases the sensitivity of the device. The wavelength of laser is chosen to optimise the system for the detection and measurement of acetone.

The company expect CE marking in Q4 2014 and UK launch in Q1 2016.

POTENTIAL FOR IMPACT

In type 1 diabetes, the pancreas does not produce insulin, a hormone that regulates blood glucose levels. High blood glucose levels can lead to diabetic ketoacidosis when a severe lack of insulin means the body cannot use glucose for energy, and it starts to break down body tissue as an alternative energy source. Ketoacidosis is due to high concentrations of ketone bodies, formed by the breakdown of fatty acids and the deamination of amino acids.
Ketoacidosis can be smelled on a person's breath. This is due to acetone, a by-product of the decomposition of acetoacetic acid (a common ketone produced in humans). A build up of ketones will cause the body to become acidic, leading to organ damage.

Type 1 diabetes is also known as juvenile diabetes or early-onset diabetes, because it often develops before the age of 40, usually during teenage years. People with type 1 diabetes need to have daily insulin injections for life, and monitor their blood glucose levels through regular blood tests. Children with type 1 diabetes need at least four finger prick tests a day, and sometimes up to 10 in very small children.

If proven to be effective, the OMD breath ketone device may offer patients a painless, non-invasive test for monitoring blood ketones in patients with type 1 diabetes.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**

No published papers or abstracts were identified for this alert.

**COMPANY INFORMATION**

OMD is currently performing the next phase of clinical trials in collaboration with the Diabetes Trials Unit, University of Oxford, and Addenbrookes Hospital in Cambridge. The company has undertaken internal studies on the clinical validity and clinical utility of the device. The trials have included type 1 diabetics and fasting individuals in order to provide information on the clinical utility of the device. Clinical validity testing of the device, by comparison to a ‘gold standard’ mass spectrometer is ongoing.

**INFORMATION FROM**

This Alert is based on information from the company and a time-limited internet search.