

The logo for ktn, consisting of the lowercase letters 'ktn' in a bold, sans-serif font, centered within a solid black circle. The background of the slide is a dark blue gradient with two large, thin, white curved lines that sweep across the right side of the page.

ktn

Helicon Health®

Development of the Epigastric Impedance Monitor™

- Case Study

“the gastric equivalent of the ubiquitous ECG”

a non-invasive diagnostic device for detecting stomach malfunction. Patients receive an earlier diagnosis and initiation of more effective treatment whether their problem is functional dyspepsia, diabetic gastro-neuropathy, or post-viral gastro-neuropathy.

The Epigastric Impedance Monitor (EIM) uses the safe bio-impedance principle. This states that *“When a small, electric current passes through a tissue it meets a resistance directly proportional to the volume of the tissue.”*

Figure 1 shows what happens when the current is recorded from a patient who drinks a liquid that is resistant to electricity, such as pure water or water with glucose dissolved in it. As the liquid enters the stomach there is a steep rise in total impedance shown by the sudden peak in the trace.

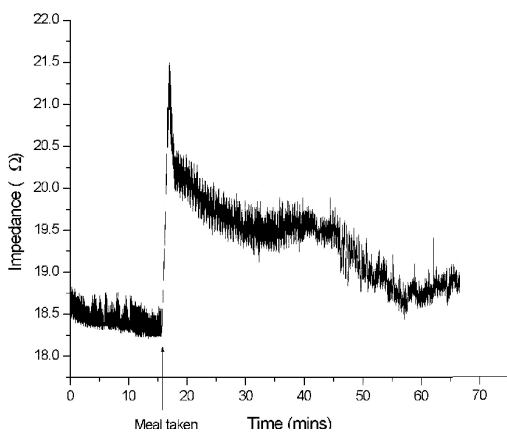


Figure 1: A diagram of an Epigastric Impedance Trace.



The reason for doing this is to record the rate at which the trace descends from the peak because that measures the rate that the liquid leaves the stomach. If it finds an exceptionally slow rate it has detected a malfunctioning stomach. Then, because the monitor does not use any radiation or tubes to swallow, it can be repeated as often as necessary to show the progress of the problem and whether a treatment has had any normalising effect.

EIM waves are detected and quantified in a similar way to brain waves in the electroencephalograph or EEG waves, a mathematical method called Fast Fourier Transform. The EIM trace contains hidden waves that reflect contractions of stomach muscles. The EIM is the only method that simultaneously measures gastric emptying rate and the amount of muscle activity (i.e. motility).

The EIM has been validated in several clinical trials. Its results match scintigraphy and dye-dilution methods for gastric emptying. In volunteers it showed that an upright posture causes faster emptying than lying flat. In pharmacological trials it detected faster emptying and greater motility responses due to the stimulant medicines known as prokinetics

Why is it important?

In adults the symptoms of disturbed gastric function, often labelled dyspepsia, are common. Patients with dyspepsia feel bloated and full, they lose appetite and it may progress to nausea, acid regurgitation with pain in the chest and vomiting and weight loss. The cause is slow gastric emptying which has a physical origin when the muscles or nerves of the stomach are damaged, as in late-stage diabetes or after a viral infection. More commonly it has no physical cause so there are no detectable changes in the tissues. Then it is called Functional or Non-Ulcer Dyspepsia (FD and NUD).

1. What are its advantages and disadvantages?

The key point is that the epigastric monitor is inherently practical to make and operate. It can be regarded as the gastric equivalent of the ubiquitous ECG machine. The specific advantages include non-invasiveness, due to absences of tube or pill swallowing and radiation, so it may be repeated many times. Capital and running costs for users are low due its simplicity, which permits operation by non-technical staff with a few hours of instruction. In practice this means it can be done at short notice when patients actually have symptoms or cancelled at no great cost if symptoms have fluctuated downwards, in complete contrast with so-called gold-standard methods that use isotopes.

Open

We value diversity of opinions, ideas, skills and perspectives.

Creative

We embrace ideas with curious minds and use our insight to uncover opportunity.

Collaborative

We are one team, working together across sectors, people and geographies to drive positive change.

Determined

We are determined to meet challenges with solutions and enable innovators to think and act beyond expectations.



2. Clinical Summary

1. The EIM meets an un-met need by solving a common diagnostic problem, namely detecting stomach malfunction as explained above. Patients receive an earlier diagnosis and initiation of more effective treatment whether their problem is FD, diabetic gastro-neuropathy or post-viral gastro-neuropathy.
2. It facilitates repeated tests to monitor progress and effects of treatments.

Dr J A Sutton. April 2021.



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Prof. Mehdi Tavakoli from the KTN Health Team was contacted by Dr Andrew Sutton, inventor of the EIM. Andrew is a Clinical Pharmacologist with years of experience in Academic Research and leading large pharmaceutical research programmes. Andrew asked for an introduction to a company with the expertise and willingness to take the EIM through its regulatory and clinical trials and onwards to market. Prof. Tavakoli offered to introduce Andrew to Professor David Patterson and Tony Bowden at Helicon Health. The business and personal chemistry was good, and the company has invested in the technology with a programme designed to achieve a fast and successful go to market.

KTN caught up with Tony Bowden, CEO at Helicon Health, to find out more about the programmes of work and their relationship with KTN. Helicon Health is nominated by the UK Department for Industry & Trade in the First100 Digital Health companies.

Hi Tony, can you tell us about the background to Helicon Health? How did the company get started?

Helicon Health started life as a spin out from the UCL Centre for Health Informatics and Multi Professional Education (CHIME) where considerable work was expended on researching and developing standards for electronic health records and interoperability. These research programmes lead to the OpenEHR and other ISO Standards.

Helicon Health operates in the healthcare sector and is unique in the ways it delivers healthcare virtually. Our offering in the High Acuity neo natal intensive care units was awarded the HTN Telecommunications Technology of the Year 2020 for Alder Hey Children's Hospital and Liverpool Women's Hospital. Our programmes with the Epigastric Impedance Monitor is unique in:

- 1) Non-invasively measuring stomach emptying
- 2) Enabling more accurate choice of treatments and dosing
- 3) Be readily available for use in primary care thus avoiding multiple trips to hospital and painful invasive treatments
- 4) The EIM is practical in primary care as it is inexpensive and requires little training for its operators and results are produced immediately.
- 5) Integrate into Electronic Medical Record systems (on technology roadmap)

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What inspired you to join and invest in Helicon Health?

Having spent many years working for big healthcare companies (Initiate (IBM), iSOFT and CSC), I wanted to continue working in the healthcare technology sector – but I wanted to do it more on my own terms and with the full backing of a hugely experienced clinical and innovation team. Helicon Health fitted the bill perfectly.

What are the challenges and opportunities facing your company and the sectors in which you operate?

The challenges facing Helicon Health include funding, manufacturing at scale, clinical trials, regulatory approvals and of course developing viable and sustainable commercial models.

The challenges facing the NHS – long waiting lists – the need to treat patients outside hospital and to avoid invasive procedures wherever possible all support our plans to introduce EIM.

What specific help did KTN give you?

KTN introduced us to the inventor – acting as a marriage broker. KTN has introduced us to Innovate Edge who are providing expert support for commercialization, IP Audit and specialist help with funding.

Have you benefited from receiving funding? If so, how are you utilising this funding support?

We have submitted funding applications and expect to be successful. These will not be sufficient to see us all the way through so we seek further support.

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Would you recommend KTN and what would you describe as the benefits of working with us?

Yes absolutely! KTN has a unique market oversight across both the NHS and innovation sector, with experience in Digital Health, providing invaluable and relevant insight into the feasibility of an innovation. KTN is experienced in accessing the NHS and able to offer suggestions and solutions to overcoming barriers.

Where do you see Helicon Health growing and do you have scope for expansion outside of the UK?

The aim is for Helicon Health to grow sales of EIM in NHS and then around the world. Initial markets include the UK and US, followed by Europe, India and China.

What's next for Helicon Health?

We are growing our existing business very fast and are seeking investment to accelerate our latest technological and regulatory developments and go to market plans.

Find out more about Helicon Health, please visit their [website](#).

Members of the KTN Health Team have been very busy during the pandemic and have been actively involved in supporting many companies, clinicians and academics such as Helicon Health, as well as supporting collaborations and submissions of a number of successful proposals to funding organisations to address key challenges related to Covid-19. To find out more and to get in touch with the team please [click here](#).

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Connecting for
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