

# Gastromotal®

<sup>13</sup>C-Octanoic acid breath test to determine gastric emptying rate

## Features of Gastromotal®

- Non-radioactive.

Scintigraphy involves the use of radioactive isotopes. <sup>13</sup>C is a stable isotope and therefore inherently safer than a test using a radioisotope.

- Cost effective.

The <sup>13</sup>C-Octanoic Acid test can be performed at a lower cost than scintigraphy and is more accurate than ultrasound imaging.

## Indications for the use of Gastromotal®

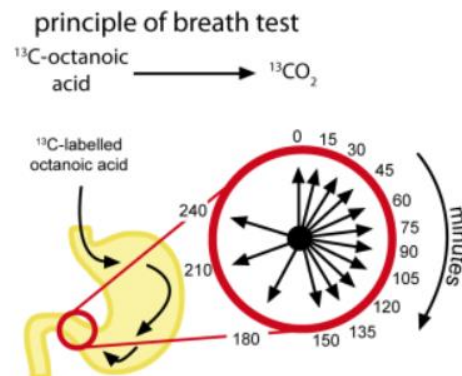
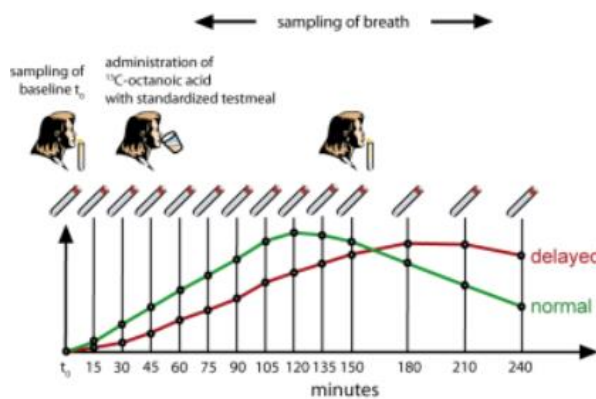
Gastromotal is a breath test indicated for in vivo diagnosis of solid-phase gastric half emptying time in gastric motility disorders.

Gastric motility is affected in a number of clinical conditions including diabetes, non-ulcer dyspepsia, GERD and some post-operative conditions. The recent development of drugs affecting gastric motility has increased the level of interest in the process.

The application for European marketing authorization is in progress. A final clinical trial proving patient benefit is currently performed. The kit is currently available for use on a named patient basis and for research applications providing the appropriate ethical permissions and licence exemptions are in force.



## Test Principle and Protocol of Gastromotal®



The techniques currently available to determine gastric emptying (scintigraphy and ultrasound imaging) have significant deficiencies, so a new and better test will be of considerable value. Ghoo et al. (*Gastroenterology*, Vol 104, 1640-1647, 1993) described a  $^{13}\text{C}$ -Octanoic Acid breath test in which the substrate is incorporated into an egg test meal and the appearance of  $^{13}\text{CO}_2$  in the breath is monitored.  $^{13}\text{C}$ -Octanoic Acid occurs as part of naturally occurring components in foods such as butter so no adverse effects are to be expected. Mathematical analysis of the excretion curve using a procedure developed at INFAI permits the gastric emptying rate to be determined. The test provides a non-invasive approach to the identification of patients with gastric motility problems and the evaluation of promotility drugs.

After an overnight fast the patient ingests  $^{13}\text{C}$ -Octanoic Acid mixed with raw egg yolk, cooked and served with bread, butter and 150 ml of coffee or tea. In this form the  $^{13}\text{C}$ -Octanoic Acid is not released until it reaches the small intestine, where it is absorbed and rapidly metabolised in the liver. The  $^{13}\text{CO}_2$  produced appears in the breath almost immediately and is sampled by asking the patient to blow through a straw into glass tubes, which are sealed and stored for analysis. Two breath samples are collected immediately before the test, 10 breath samples at 15 minute intervals after the test meal and a further three at 30 minute intervals covering a total measurement period of 240 minutes. The tubes are sent for  $^{13}\text{CO}_2$ -analysis at a qualified laboratory and the excretion curve is mathematically analysed to differentiate normal and reduced gastric motility. Two parameters are calculated and reported (Gastric Emptying Coefficient and Gastric Half Emptying Time) using a mathematical procedure and software package developed by INFAI.

Since the test accurately defines the time at which solid material arrives in the small intestine, the preparation of the test meal is crucial to the efficacy of the test. If the test meal is incorrectly prepared the label may be washed out of the stomach in the liquid phase which would mask reduced gastric motility.

### Publications

- Ghoo YF, Maes BD, Geypens BJ, Mys G, Hiele MI, Rutgeerts PJ, Vantrappen G (1993): Measurement of gastric emptying rate of solids by means of a carbons-labeled octanoic acid breath test. *Gastroenterology* 104(6): 1640-7.
- Pfaffenbach B, Wegener M, Adamek RJ, Wissuwa H, Schaffstein J, Aygen S, Hennemann O (1995): Non-invasive  $^{13}\text{C}$  octanoic acid breath test for measuring stomach emptying of a solid test meal—correlation with scintigraphy in diabetic patients and reproducibility in healthy probands. *Z. Gastroenterol.* 33(3): 141-5.
- H. Steinbrede, S. Aygen, C. Steinborn (1997): KC 11458, a new motilin agonist, is effective in the acceleration of gastric emptying in healthy male volunteers *Gut* 29: A155
- Choi, MG., Camilleri M., Burton DD., Zinsmeister AR., Forstrom LA., Nair KS. (1998): Reproducibility and simplification of  $^{13}\text{C}$ -octanoic acid breath test for gastric emptying of solids. *Am. J. Gastroenterol.* 93: 92-98.
- Maes BD., Spitz B., Ghoo YF., Hiele MI., Evenepoel P, Rutgeerts PJ. (1999): Gastric emptying in hyperemesis gravidarum and non-dyspeptic pregnancy. *Aliment Pharmacol Ther* 13: 237-243.
- S. Aygen, Method for determining gastric evacuation using a  $^{13}\text{C}$ -labelled test meal, European Patent EP 1 553 987 B 1.