ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gastromotal 90 mg oral liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One pre-filled syringe contains 90 mg of 1-^{13}C-caprylic acid.

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral liquid
Clear, colourless to slightly yellow, oily liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

The test should be performed in the presence of a qualified person.

Gastromotal is a breath test.
The breath test is a single administration.

The recommended dose for patients from the age of 18 is one single dose of 90 mg of 1^{13}Ccaprylic acid.
For performance of the test procedure a standardised test meal is required. The test meal (250 kilocalories) consists of: 1 fried egg, 2 slices of white bread (60 g), 150 ml drink (water) and 5 g fat (margarine).

The patient has to have fasted for over 6 hours, preferably overnight. The test procedure takes approximately 240 minutes.

In case it is necessary to repeat the test procedure, this should not be done until the following day.

It is important to follow the instructions for use described in section 6.6 adequately, otherwise the validity of the outcome will become questionable.

Use in Children and adolescents
Gastromotal is not recommended for use in children below age 18 due to a lack of data on safety and efficacy.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

There is insufficient data on the diagnostic liability of Gastromotal to recommend its use in patients with chronic liver insufficiency.

If the patients vomits during the test procedure, necessitating the repetition of the test, this should be done in fasted condition and not before the following day, as stated in section 4.2.

4.5 Interaction with other medicinal products and other forms of interaction

Gastromotal is influenced by all medicinal products that affect gastric emptying and motility, such as gentamycin, cefoxitin, nonelectrolytes, chloroacetaldehyde.

4.6 Pregnancy and lactation

There are no adequate data from the use of Gastromotal in pregnant and nursing women. The dose of 90 mg caprylic acid used in the breath test is equivalent to that contained in one glass full-fat milk. According to WHO reports, average daily intake of caprylic acid in the US is 200 mg. Caprylic acid is a food additive. Regarding excretion in milk high percentages of medium-chain fatty acids are found in human milk with caprylic acid comprising 1.2 % of total fatty acids content.

After oral application 1-^{13}C-caprylic acid by performance of the breath test, the caprylic acid is metabolised completely to carbon dioxide. Remaining traces of 1-^{13}C-caprylic acid are neglectable in comparison with the daily average intake of caprylic acid.

Therefore, it is not expected that the test procedure may be harmful during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Gastromotal has no influence on the ability to drive and use machines.

4.8 Undesirable effects

There were no adverse reactions reported during the clinical trials.

4.9 Overdose

Due to the fact that only 90 mg of 1-^{13}C-caprylic acid is delivered, an overdose is not expected. Inappropriate intake like drinking the oral liquid without the test meal can benumb the taste buds. In this case, it is recommended to gargle immediately with water several times.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other diagnostic agent, ATC-code: VO4CX

For the amount of 90 mg of 1-^{13}C-caprylic acid, which is administered per unit in the course of the breath test, no pharmacodynamic activity is described.

^{13}C-octanoic acid, a medium-chain fatty acid is incorporated in an age-specific and standardized test meal and is ingested by the patient. Octanoic acid carries a carboxyl group in which a normal ^{13}C atom is replaced by the stable isotope ^{13}C. Gastric emptying rate is the rate limiting step for delivery of ^{13}C-octanoic acid in the duodenum. ^{13}C-octanoic acid is then readily absorbed and metabolized into

$^{13}CO_2$ appearing in breath. The rate of appearance of $^{13}CO_2$ in expired air represents the rate of gastric emptying.

5.2 Pharmacokinetic properties

The orally applied 1-^{13}C-caprylic acid is metabolised to carbon dioxide. Any increase in $^{13}CO_2$ will be measured by isotopic analysis.

Absorption and distribution of $^{13}CO_2$ is faster than the decomposition reaction. Therefore, the rate limiting step in the whole process is the cleavage of 1-^{13}C-caprylic acid in the intestine.

5.3 Preclinical safety data

In a single-dose toxicity study in mice 1-^{13}C-caprylic acid was non-toxic at an oral dose of 5,000 mg/kg. Using allometric scaling this corresponds to a no-toxic-effect level of 400 mg/kg and a safety margin of 200. No other toxicity studies have been conducted with 1-^{13}C-caprylic acid. Caprylic acid has regulatory approval as a food additive and is commonly consumed as foods or food components.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

No specical storage conditions.

6.5 Nature and contents of container

A test set contains the following parts:

No.	Component	Quantity
1	One pre-filled syringe (1 ml volume, glass type 1, rubber closure type 1) containing 90 mg 1-^{13}C-caprylic acid	1
2	Labelled sample glass- or plastic- containers for sampling, storing and transporting the breath samples for analysis:	
	Sampling time: 00-minute-value	2
	Sampling time: 15-minute-value	1
	Sampling time: 30-minute-value	1
	Sampling time: 45-minute-value	1
	Sampling time: 60-minute-value	1
	Sampling time: 75-minute-value	1
	Sampling time: 90-minute-value	1
	Sampling time: 105-minute-value	1

	Sampling time: 120-minute-value Sampling time: 135-minute-value Sampling time: 150-minute-value Sampling time: 180-minute-value Sampling time: 210-minute-value Sampling time: 240-minute-value	1 1 1 1 1 1
3	Bendable straw for collection of the breath samples into the corresponding sample containers	1
4	Data sheet for patient documentation	1
5	Barcode labels and sticker	1

6.6 Special precautions for disposal and other handling

Preparation of test meal:
An egg has to be cracked in a small non-stick pan (greased with a little margarine if necessary) without mixing the yolk and the white parts. The pre-filled syringe containing the 1-^{13}C-caprylic acid should be removed from the package and the contents injected into the egg yolk. It should be mixed very carefully into the yolk for homogenization. It should be avoided to mix the white and the yolk. Heat shall be applied gently until the yolk and the white parts of the egg solidify. The so prepared egg should be served with 60 g white bread, 5 g margarine, 150 ml of water. The test meal should be taken within 5 minutes. If the test needs to be repeated, this should not be done until the following day.

1. The test should be performed in the presence of a qualified person.
2. Each patient should be documented according to the provided data sheet. It is recommended to perform the test with the patient being in a resting position.
3. The test starts with the collection of samples for the determination of the baselinevalues (00minutevalues):
   - The straw and the two sample containers with the label: "Sampling time: 00-minutevalue" should be taken out of the test set.
   - The stopper has to be removed from one of the sample containers, the straw unwrapped and placed into the container.
   - Now the patient should breathe gently through the straw until the inner surface of the sample container steams up.
   - Under continuously breathing the straw has to be pulled out and the container immediately closed with its stopper.
     (If the sample container remains open for more than 30 seconds, the test result might be falsified.)
   - The sample container has to be hold upright and the barcode label marked "00-minute-value" should be sticked round the sample container so that the lines of the bar-code are horizontal.
4. Now the second sample container (Label: "Sampling time: 00-minute-value") should be filled up with breath by following the same procedure as described above.
5. Then the patient should start to eat the test meal. The meal should be finished within 5 minutes. The time of finishing the meal must be noted.
6. For the next 150 minutes breath samples are collected every 15 minutes using the same procedure. The corresponding bar-code labels should be used for each sample. The last three sampling points (180 min, 210 min and 240 min) are collected at 30 minute intervals.
7. All 15 breath sample containers should be placed back into the original packaging. Finally the package should be sealed with the sticker provided.
8. The package has to be sent to a qualified laboratory for analysis.

- Analysis of breath samples and testing specification for laboratories

The portion of $^{13}CO_2$ in the breath samples is determined by isotope-ratio-mass-spectrometry (IRMS).

The analysis of the $^{13}C/^{12}C$ratio in carbon dioxide of breath is an integrated part of the diagnostic kit Gastromotal. The accuracy of the test strongly depends on the quality of the breath analysis. The specification of mass spectrometer parameters like linearity, stability (reference gas precision), and precision of measurement are fundamental for the accuracy of the system.

It has to be ensured that the analysis is carried out by a qualified laboratory. The method validated in the application is as follows:

- Sample preparation for IRMS

To determine the $^{13}C/^{12}C$ratio of carbon dioxide in breath by mass spectrometric analysis the carbon dioxide must be separated from the breath and introduced to the mass spectrometer. The automatic preparation system for isotope mass spectrometers which is dedicated for breath test analysis is based on a gas-chromatographic continuous flow separation technique.
Water is removed from the sample by means of a Nafion water trap or the gas-chromatographic preparation system that separates the individual gases in a gas chromatographic column with Helium as eluent. Passing the column the separated gas species of breath are detected by an ionisation detector. The fraction of carbon dioxide gas, identified by its characteristic retention time, is introduced to mass spectrometer.

- Mass spectrometric analysis

To analyse the separated carbon dioxide sample gas its molecules must be ionised, formed into a beam, accelerated by an electric field, deflected in a magnetic field, and finally detected. These five processes take place in the analyser of a mass spectrometer, which consists of three separate sections: the source, flight tube, and collector. Ionisation, beam formation and acceleration all occur in the source, magnetic deflection takes place in the flight tube and detection takes place in the collector.

- Sample Inlet

For introduction of the carbon dioxide into the analyser many sample inlet systems are available. For breath test analysis the individual balancing of the carbon dioxide of the sample to a reference standard gas is essential. This ensures the high accuracy of this system, as calculation of the isotopic content in carbon dioxide is done with respect to an independent standard.

- Specifications for determining $^{13}C/^{12}C$ratios

The breath test concept relies on the administration of a specifically ^{13}C-labelled caprylic acid whose metabolite utilisation is monitored by measuring $^{13}CO_2$ in the expired breath gas.
The mass spectrometer must be capable of:

Multiple replicate analysis:	Minimum of 3 replicate analyses on the same sample during operation
Security access:	Storing of operating parameters and of results under security access to avoid later manipulation
Adjustment:	$^{13}C/^{12}C$-ratio with respect to PDB (Pee Dee Beliminate)
Sample loop:	< 200 µl

The principle tests to verify the specifications are linearity, stability (reference gas precision), and precision of measurement.

All mass spectrometers for breath analysis must comply with the following specifications:

Linearity:	≤ 0.5 ‰ for breath samples varying between 1 % and 7 % CO_2-concentration
Stability:	≤ 0.2 ‰ on 10 consecutive pulses

Precision of measurement: ≤ 0.3 ‰ for ^{13}C at natural abundance using a 10 ml breath sample container with 3 % CO_2 breath concentration

Alternatively, any other suitable-evalidated method may be used, carried out by any objectively qualified laboratory.

Using the INFAI software the mass spectrometric analysis finally leads to the diagnosis of a normal, delayed or very delayed gastric emptying. This distinction is based upon the following characteristic parameter: $t_{½}$ (min)

	normal	**delayed**	**very delayed**
$t_{½}$ (min)	< 90	90-120	> 120

7. MARKETING AUTHORISATION HOLDER

INFAI, Institut für biomedizinische Analytik & NMRImaging GmbH
Universitätsstraße 142
D44799 Bochum
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

{DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

{Carton}

1. NAME OF THE MEDICINAL PRODUCT

Gastromotal 90 mg oral liquid

2. STATEMENT OF ACTIVE SUBSTANCE(S)

90 mg 1-^{13}C-caprylic acid

3. LIST OF EXCIPIENTS

None

4. PHARMACEUTICAL FORM AND CONTENTS

Oral liquid

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use after preparation of a test meal

Please read enclosed instructions for use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

None

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

-

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

None

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

INFAI, Institut für biomedizinische Analytik & NMR-Imaging GmbH
Universitätsstr. 142
D-44799 Bochum
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. MANUFACTURER'S BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. BRAILLE

Exempted from Braille

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Injection syringe}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Gastromotal 90 mg oral liquid
1-^{13}C-caprylic acid

2. METHOD OF ADMINISTRATION

Oral use after preparation of a test meal

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

90 mg 1-^{13}C-caprylic acid

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gastromotal 90 mg oral liquid
1-^{13}C-caprylic acid

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. WHAT GASTROMOTAL IS AND WHAT IT IS USED FOR

Gastromotal is for diagnostic use only.

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

Why do you need to take the Gastromotal?
You may suffer from dyspepsia with currently unknown reason. Delays in gastric emptying often cause dyspeptic inconvenience. An examination of gastric emptying is therefore important.

- Your doctor wants to confirm whether you are suffering from delayed gastric emptying.

How does the test work?
All foods contain a substance called ^{13}carbon (1 % ^{13}C). This ^{13}carbon can be detected in the carbon dioxide you breathe out of your lungs. The actual amount of ^{13}carbon in the breath will depend on the kind of food that you have eaten. The test starts with the collection of samples for the determination of the baseline-value (for medical or healthcare professionals: see further information at the end of this leaflet under “The following information is intented for medical or healthcare professionals only, Special Instructions for Use”).

These samples will be analysed to measure the “normal” amount of ^{13}carbon content in the carbon dioxide in your breath.

You will be asked to eat the test meal. For the next 240 minutes following the test meal, 13 samples of your breath will be collected and the amount of ^{13}carbon in the samples measured as before. The results will be compared and a significant increase in the amount of ^{13}carbon will suggest your doctor that you are suffering from dyspepsia with currently unknown reason.

2. BEFORE YOU TAKE GASTROMOTAL

The outcome of this test might be affected by certain medical conditions. Please tell your doctor about any condition and illness that is currently affecting you or was affecting you in the past even if it appears to be unrelated to your dyspeptic complaints.

Do not take Gastromotal
Contraindications are not known.

Take special care with Gastromotal
- If you suffer from chronic liver insufficiency please tell your doctor because there is insufficient data on the diagnostic reliability of Gastromotal in such case.

- if you vomit during the test procedure, necessitating the repetition of the test, this should be done in fasted condition and not before the following day.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Gastromotal is influenced by all medicinal products related to gastric emptying and motility, such as gentamycin, cefoxitin, nonelectrolytes, chloroacetaldehyde. Please ask your doctor.

Pregnancy and breast-feeding
Side effects are not expected if Gastromotal is used during pregnancy or lactation.
Ask your doctor for advice before taking any medicine.

Driving and using machines
Gastromotal has no influence on the ability to drive or to use machines.

3. HOW TO TAKE GASTROMOTAL

You should perform the test in the presence of your doctor or another qualified person.

Dosage
The following information applies, unless your doctor has otherwise prescribed Gastromotal. Please follow the instructions for use, as otherwise the Gastromotal may not work properly.

How much Gastromotal should be used and how often?
Patients from the age of 18 take the content of one syringe with 90 mg for one test.

How and when should Gastromotal be used?
You must have fasted for 6 hours before application, preferably overnight.

The test procedure lasts approximately 240 minutes. If the test needs to be repeated, this should not be done until the following day.

Essential items not supplied with Gastromotal
The preparation of a standardised test meal is required for carrying out the test. 1 egg, 2 slices of white bread (60 g), 150 ml drink (water) and 5 g fat (margarine) are necessary to prepare the standardised test meal (total calories content approx. 250 kcal).

Preparation of test meal
The test should be performed in the presence of a qualified person.

Break an egg in a small non-stick pan (greased with a little margarine if necessary) without mixing the yolk and the white parts. Remove the syringe containing the 1-^{13}C-caprylic acid from the package and inject the contents into the egg yolk. Mix it into the egg yolk being very careful not to mix the white and the yolk. Apply heat very gently until the yolk and the white parts of the egg solidify. Serve the egg with 60 g white bread, 5 g margarine and 150 ml of water. The test meal should be taken within 5 minutes.
If the test needs to be repeated, this should not be done until the following day.

If you take more Gastromotal than you should
Because only 90 mg of 1-^{13}C-caprylic acid acid is provided overdose is not to be expected. Inappropriate intake like drinking the oral liquid without the test meal can benumb the taste buds. In this case, it is recommended to gargle immediately with water several times.

IN CASE OF DOUBT DO NOT HESITATE TO CONSULT YOUR DOCTOR.

If you forget to take Gastromotal
Not applicable.

4. POSSIBLE SIDE EFFECTS

No side effects are known.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE GASTROMOTAL

Keep out of the reach and sight of children.

Do not use Gastromotal after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Gastromotal contains:
- The active substance is 1-^{13}C-caprylic acid.
  One pre-filled syringe contains 90 mg 1-^{13}C-caprylic acid.
- There are no other ingredients.

What Gastromotal looks like and contents of the pack
Gastromotal is a clear, colourless to slightly yellow, oily oral liquid.

Content of the Test Set

No.	Component	Quantity
1	One pre-filled syringe (1 ml volume) containing 90 mg 1-^{13}C-Caprylic acid	1
2	Labelled sample glass- or plastic- containers for sampling, storing and transporting the breath samples for analysis:	
	Sampling time: 00-minute-value	2
	Sampling time: 15-minute-value	1
	Sampling time: 30-minute-value	1
	Sampling time: 45-minute-value	1
	Sampling time: 60-minute-value	1
	Sampling time: 75-minute-value	1
	Sampling time: 90-minute-value	1
	Sampling time: 105-minute-value	1
	Sampling time: 120-minute-value	1
	Sampling time: 135-minute-value	1
	Sampling time: 150-minute-value	1
	Sampling time: 180-minute-value	1
	Sampling time: 210-minute-value	1
	Sampling time: 240-minute-value	1
3	Bendable straw for collection of the breath samples into the	1

	corresponding sample containers	
4	Data sheet for patient documentation	1
5	Barcode labels and sticker	1

Marketing Authorisation Holder and Manufacturer
INFAI, Institut für Biomedizinische Analytik und NMR-Imaging GmbH
Universitätsstraße 142
D-44799 Bochum
Germany

This leaflet was last approved in MM/YYYY.

The following information is intented for medical or healthcare professionals only:

Special Instructions for Use

1. Each patient should be documented according to the provided data sheet. It is recommended to perform the test with the patient in a resting position.
2. The test starts with the collection of samples for the determination of baseline-values (00-minute-values):
   - The straw and the two sample containers with the label: "Sampling time: 00-minute-value" should be taken out of the test set.
   - The stopper has to be removed from one of the sample containers, the straw unwrapped and placed into the container.
   - Now the patient should breathe gently through the straw until the inner surface of the sample container steams up.
   - Under continuously breathing the straw has to be pulled out and the container immediately closed with its stopper.
     (If the sample container remains open for more than 30 seconds, the test result might be falsified.)
   - The sample container has to be hold upright and the bar-code label marked "00-minute-value" should be sticked round the sample container so that the lines of the bar--code are horizontal.
3. Now the second sample container (Label: "Sampling time: 00-minute-value") should be filled up with breathby following the same procedure as described above.
4. Then the patient should start to eat the test meal. The meal should be finished within 5 minutes. The time of finishing the meal must be noted.
5. For the next 150 minutes breath samples are collected every 15 minutes using the same procedure. The corresponding bar-code labels should be used for each sample. The last three sampling points (180 min, 210 min and 240 min) are collected at 30 minute intervals.
7. All 15 breath sample containers should be placed back into the original packaging. Finally the package should be sealed with the sticker provided.
8. The package has to be sent to a qualified laboratory for analysis.

ANALYSIS OF BREATH SAMPLES AND TESTING SPECIFICATION FOR LABORATORIES

The breath samples, collected in 10 ml glass- or plastic sample containers are analysed by isotope ratio mass spectrometry (IRMS).

The analysis of the $^{13}C/^{12}C$-ratio in carbon dioxide of breath is an integrated part of the diagnostic kit Gastromotal. The accuracy of the test strongly depends on the quality of the breath analysis. The

specification of mass spectrometer parameters like linearity, stability (reference gas precision), and precision of measurement are fundamental for the accuracy of the system.

It has to be ensured that the analysis is carried out by a qualified laboratory. The method validated in the application is as follows:

Sample preparation for IRMS
To determine the $^{13}C/^{12}C$-ratio of carbon dioxide in breath by mass spectrometric analysis the carbon dioxide must be separated from the breath and introduced to the mass spectrometer. The automatic preparation system for isotope mass spectrometers which is dedicated for breath test analysis is based on a gas-chromatographic continuous flow separation technique.

Water is removed from the sample by means of a Nafion water trap or the gas-chromatographic preparation system that separates the individual gases in a gas chromatographic column with Helium as eluent. Passing the column the separated gas species of breath are detected by an ionisation detector. The fraction of carbon dioxide gas, identified by its characteristic retention time, is introduced to mass spectrometer.

Mass spectrometric analysis
To analyse the separated carbon dioxide sample gas its molecules must be ionised, formed into a beam, accelerated by an electric field, deflected in a magnetic field, and finally detected. These five processes take place in the analyser of a mass spectrometer, which consists of three separate sections: the source, flight tube, and collector. Ionisation, beam formation and acceleration all occur in the source, magnetic deflection takes place in the flight tube and detection takes place in the collector.

Sample Inlet
For introduction of the carbon dioxide into the analyser many sample inlet systems are available. For breath test analysis the individual balancing of the carbon dioxide of the sample to a reference standard gas is essential. This ensures the high accuracy of this system, as calculation of the isotopic content in carbon dioxide is done with respect to an independent standard.

Specifications for determining $^{13}C/^{12}C$-ratios
The breath test concept relies on the administration of a specifically ^{13}C-labelled caprylic acid whose metabolite utilisation is monitored by measuring $^{13}CO_2$ in the expired breath gas.

The mass spectrometer must be capable of:

Multiple replicate analysis:	Minimum of 3 replicate analyses on the same sample during operation
Security access:	Storing of operating parameters and of results under security access to avoid later manipulation
Adjustment:	$^{13}C/^{12}C$-ratio with respect to PDB (Pee Dee Beliminate)
Sample loop:	< 200 µl

The principle tests to verify the specifications are linearity, stability (reference gas precision), and precision of measurement.

All mass spectrometers for breath analysis must comply with the following specifications:

Linearity:	≤ 0.5 ‰ for breath samples varying between 1 % and 7 % CO_2-concentration
Stability:	≤ 0.2 ‰ on 10 consecutive pulses
Precision of measurement:	≤ 0.3 ‰ for ^{13}C at natural abundance using a 10 ml breath sample container with 3 % CO_2 breath concentration

Alternatively, any other suitable-evalidated method may be used, carried out by any objectively qualified laboratory.

Using a special software the mass spectrometric analysis finally leads to the diagnosis of a normal, delayed or very delayed gastric emptying. This distinction is based upon the following characteristic parameters: $t_{½}$ (min)

	normal	**delayed**	**very delayed**
$t_{½}$ (min)	< 90	90-120	> 120