

### 3.4 Analysis results

<b>Negative result</b> (Not infected)	Value $\leq$ 25 cpm	Heliprobe 0
<b>Borderline result</b>	25 < Value < 50 cpm	Heliprobe 1
<b>Positive result</b> (Infected)	Values $\geq$ 50 cpm	Heliprobe 2

For numerical value remove the card and press the **Confirm** key  
d1=BreathCard™ activity from upper pad (cpm)  
d2=BreathCard™ activity from lower pad (cpm)  
d= (d1+d2) total BreathCard™ activity per measurement (cpm)  
t=measuring time

### 3.5 Borderline results

In case of borderline results, the instrument will automatically re-measure the BreathCard™ to confirm test results. A mean value will be calculated and a final result will be presented. This situation may require up to 750 seconds to be completed.

## 4. Dosage formula

### 4.1 Pharmaceutical formula

The <sup>14</sup>C-Urea doze is 37 kBq (1  $\mu$ Ci), this corresponds to a body exposure of 0,0006 mSv (which is less than an ordinary x-ray).

### 4.2 <sup>14</sup>C isotope

The <sup>14</sup>C isotope emits low energy of  $\beta$ -radiation.

## 5. Warning and error indication

Examples of errors that could have occurred:

- Too high background radiation level compared to setup value
- Unexpected variation in background radiation during the measurement
- Damaged sensor.

**NOTE!** In case of error, please contact service personnel or our local distributor.

## 6. Safety Consideration

BreathCard™ contains concentrated alkaline that can irritate the respiratory tract. Do not inhale through BreathCard™. Do not disassemble, manipulate or otherwise come into contact with the inside of BreathCard™.



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# HELIPROBE®

## User Manual CE

Instruction for Heliprobe® System, Urea Breath Test, intended for diagnosis of gastro duodenal *Helicobacter pylori* infection.

## 1. Heliprobe® Analyzer

The instrument contains two GM-tubes which are used to detect <sup>14</sup>C radioactivity whenever BreathCard™ is inserted into the slot. For detailed information see "Heliprobe® Analyzer – Instrument Manual" (Ref no: 101)

### 1.1 Front Panel



The diodes show the status of the Heliprobe® Analyzer:

- **Constant green light** – stand-by-mode. To activate; press any key or insert BreathCard™.
- **Intermittent green light** – the instrument is ready for measurement.
- **Intermittent yellow light** – the measurement in progress.
- **Constant yellow light** – the measurement is complete.
- **Constant red light** – internal system error (see chapter 3).

### 1.2 Printer Activate key

Transfers Heliprobe® data to a printer, if connected.

### 1.3 Start/stop key

Initiates or stops the analyzing of inserted BreathCard™.

#### 1.4 Menu key

By pressing the **Menu** key, a selection of programming possibilities can be chosen.

#### 1.5 OK Confirm key

Press twice for measurement of background radiation level.

#### 1.6 Power supply

The power supply is connected to the lower back side of the Heliprobe® Analyzer.

#### 1.7 Protection Card

The Protection Card has the same shape as BreathCard™. The card is of great importance for correct background radiation level measurement and should always be inserted between measurements.

#### 1.8 Connection of printer

A printer can be connected to the unit.

### 2. Getting Started

The first time Heliprobe® is installed or moved to another location, setup installation should be completed, in order to adapt the instrument to the actual background radiation environment.

#### 2.1 Setup

- Hold the **Start/Stop** key while connecting the power supply to the instrument.
- The display will show the text: Setup menu. Press the **Confirm** key.
- Confirm by pressing the **Confirm** key.  
If the **Confirm** key is not pressed within 40 seconds, the Heliprobe® Analyzer will restart automatically.
- The program will run into the setup mode with a “loop-to-loop” function, according to the key function (described in the instrument manual).

#### 2.2 Repair mode

In case of short power losses and if the Heliprobe® Analyzer hasn't been moved, the system can be re-powered without activating the setup mode. In this case, connect power, make sure that a Protection Card is inserted and wait for minimum 35 minutes.

### 3. BreathCard™ & HeliCap™

#### 3.1 Patient preparations

Before use, please read the HeliCap™ package leaflet. Before performing the test the patient should fast for at least 6 hours. After treatment with antibiotics or bismuth salts one month should pass. At least one week should pass after treatment with acid inhibitors.

#### 3.2 Test procedure (as described in the SPC for HeliCap™)

The whole procedure takes about 20 minutes to complete.



Instruct the patient to swallow the HeliCap™ with approximately 50 ml of water.



Wait 10 minutes



Open the BreathCard™ envelope and take out the BreathCard™.



Instruct the patient to exhale softly through the BreathCard™ mouthpiece. The BreathCard™ must be removed from the mouth in order to speak or inhale. Exhaling through the BreathCard™ must continue until the indicator membrane changes from orange to yellow. This usually takes 2-4 minutes.

#### 3.3 Reading



Remove excess air by gently pressing BreathCard™ between your hands before inserting the card into the Heliprobe® instrument. The display will show “Ready to measure”.



Press the green **Start/Stop** key and the analysis will start. The measurement will last for 250 sec.

When the measurement is completed the Heliprobe® Analyzer signals two beeps and the result will be presented on the display as a Heliprobe® grading (Heliprobe 0; Heliprobe 1 or Heliprobe 2). By removing the card and then pressing the **Confirm** key, the numerical value will be displayed.

The result will be shown on the display until the measurement is confirmed by pressing the **Confirm** key. The results may be printed by pressing the print key, providing a printer has been connected to the Heliprobe® Analyzer.