

3.4 Analysis results

| | | |
|---------------------------------------|---------------------|-------------|
| Negative result (Not infected) | Value < 25 cpm | Heliprobe 0 |
| Borderline result | 25 < Value < 50 cpm | Heliprobe 1 |
| Positive result (Infected) | Values ≥ 50 cpm | Heliprobe 2 |

3.5 Borderline results

In case of borderline results, the instrument will automatically re-measure the BreathCard™ to confirm testresults. 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 ¹⁴C-Urea doze is 1 µCi, this corresponds to a body exposure of 0, 0006 mSi (which is less than an ordinary x-ray).

4.2 ¹⁴C isotope

The ¹⁴C isotope emits low energy of β-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. Safty Concideration

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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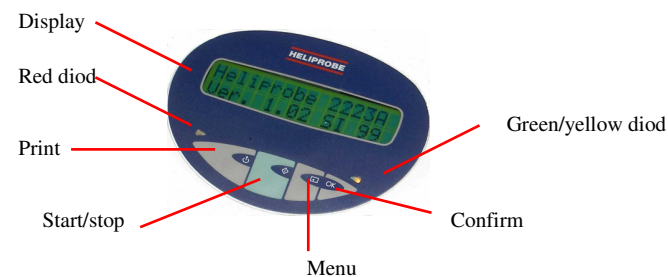
HELIPROBE™

User instruction for Heliprobe™ System

1. Heliprobe™ Analyzer

The instrument contains two GM-tubes which are used to detect ¹⁴C radioactivity whenever BreathCard™ is inserted into the slot. For detailed information see "Heliprobe™ Analyzer – Instrument Manual" (Ref no: 101-01)

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.

3. BreathCard™ & HeliCap™

3.1 Patient preparations

Before use, please read the HeliCap™ package leaflet.

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

The whole procedure takes about 20 minutes to complete.



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



Wait 10 minutes



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



Instructed 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 signal two beeps and the result will be presented on the display as a Heliprobe™ grading (Heliprobe 0; Heliprobe 1 or Heliprobe 2). By 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