

Heliprobe® System

Instructions For Use

Product names

Heliprobe® Analyzer

Article number: HPU-011

Heliprobe® BreathCard™

Article number: HPC-001

Classification

Heliprobe® Analyzer is classified as general *in vitro* Diagnostic medical devices and CE-marked according to IVD Directive 98/79/EC.

Heliprobe® BreathCard™ is classified as Class A *in vitro* Diagnostic medical devices and CE-marked according to Regulation (EU) 2017/746.



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1. Symbols

Listed symbols are used in the Instructions for Use and product labelling for Heliprobe® Analyzer and Heliprobe® BreathCard™.



Conformité Européenne



Manufacturer



In vitro diagnostic medical device



Serial number



Catalogue number



Batch code



Date of manufacture



Caution









Do not use if package is damaged and consult *instructions for use*



Do not re-use



Use-by date

	Upper limit of temperature
	Temperature limit
	Keep away from sunlight
	Keep dry
	Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i>
	Dispose as electrical and electronic waste

2. Intended use and intended users

Heliprobe® System is intended for diagnosis of *Helicobacter pylori* infection in the gastrointestinal tract (stomach and duodenum) using the non-invasive ¹⁴C Urea Breath Test.

2.1. Heliprobe® Analyzer

Heliprobe® Analyzer is used to detect ¹⁴C in the Heliprobe® BreathCard™ in conjunction with the ¹⁴C Urea Breath Test (UBT) of a patient. The analyzer is part of Heliprobe® System.

Heliprobe® System is intended for professional use within medical healthcare facilities by trained medical staff, primarily in hospital or laboratory environments.

2.2. Heliprobe® BreathCard™

The Heliprobe® BreathCard™ is intended for the manual collection of breath specimen from lay persons under the supervision of healthcare professionals in clinical or laboratory environments, in order to capture ¹⁴C-labelled CO₂.

The Heliprobe® BreathCard™ is a device of the Heliprobe® System that is intended, with a non-invasive ¹⁴C Urea Breath Test (¹⁴C-UBT), for the qualitative detection of *Helicobacter pylori* causing infections in the gastrointestinal tract (stomach and duodenum).

The Heliprobe® BreathCard™ is intended for lay persons from the general adult population, under the supervision of healthcare professionals.

3. Classification

Heliprobe® Analyzer is classified as general *In vitro* Diagnostic Medical Devices and CE-marked according to IVD Directive 98/79/EC.

Heliprobe® BreathCard™ is classified as Class A *In vitro* Diagnostic Medical Devices and CE-marked according to Regulation (EU) 2017/746.

4. Important user information

Heliprobe® System is intended for professional use within medical healthcare facilities by trained medical staff, primarily in hospital or laboratory environments.

Heliprobe® System includes following products intended for use together:
Heliprobe® BreathCard™ – for breath test sampling
Heliprobe® Analyzer – equipment for measuring and analyzing breath tests
HeliCap™ – ¹⁴C-urea capsule

Heliprobe® System is validated for use with the included products. Other similar products shall not be used.

NOTE

User information and instructions for HeliCap™ are found in the leaflet provided with the HeliCap™ package. Please contact the Market Authorization Holder of the HeliCap™ for further information.

5. Package contents – Heliprobe® Analyzer

Heliprobe® Analyzer
Protection Card
Power supply adapter
Heliprobe® System Instructions for Use
USB-stick with translations of Instructions for Use

NOTE

Heliprobe® BreathCard™ and HeliCap™ are not supplied with Heliprobe® Analyzer. These products are ordered and supplied separately.



6. Safety and precautions

Heliprobe® Analyzer

Always keep the device connected to power with a Protection Card inserted between measurements.

Only use the power supply provided with the product (refer to 15. Technical specifications).

Do not place the analyzer in close proximity to sources of strong electromagnetic radiation or radioactivity as these may interfere with proper operation.

Do not disassemble or alter any part of the analyzer.

Service and repair must only be performed by Kibion GmbH.

Do not insert or poke any objects into the card slot of the analyzer other than the Heliprobe® BreathCard™ or Protection card.

In case of suspected contamination of the analyzer, contact your local distributor. Do not attempt to de-contaminate the analyzer.

The analyzer is designed and tested to CISPR 11 Group 1 Class B. In a domestic environment, it may cause radio interference. If so, take measures to mitigate the interference.

Heliprobe® BreathCard™

Preparation of the Heliprobe® BreathCard™

Do not use the Heliprobe® BreathCard™ if the single package is damaged.

Keep Heliprobe® BreathCard™ in the single package (envelope) until use.

Avoid scratching the plastic filter shield (mylar) when removing Heliprobe® BreathCard™ from the package.

Use a non-erasable pen for the identification of the sample.

Do not use a sharp pen for the identification of the sample. Where the bodyfoil shows signs of alteration (e.g. punctures) after the identification of the sample, do not use Heliprobe® BreathCard™.

Sample collection with the Heliprobe® BreathCard™

Handle Heliprobe® BreathCard™ with care.

Avoid touching the plastic filter shield (mylar) when handling Heliprobe® BreathCard™ as it is very thin and sensitive to damage.

The reactivity filter and the indicator pad inside Heliprobe® BreathCard™ contain lithium monohydroxide (LiOH), which may cause irritation in the respiratory tract and eyes on contact.

To avoid contact with LiOH:

- Do not disassemble Heliprobe® BreathCard™
- Never inhale through Heliprobe® BreathCard™. Remove Heliprobe® BreathCard™ Card from the mouth if you must take a fresh breath.
- Do not bite the Heliprobe® BreathCard™.
- Exhale into Heliprobe® BreathCard™ with an even pressure. Avoid blowing too hard.
- Ensure that the two air outlets on Heliprobe® BreathCard™ are free so that exhaled air can pass freely through.

Do not damage the plastic filter shield (mylar).

NOTE

In case of contact or suspected contact with LiOH, rinse the affected area immediately with water.

Contact your local sales representative for further information and to report adverse effects.

Further information regarding the hazards associated with LiOH are available in the section “Materials” of these “Instructions for Use”.

Do not expose Heliprobe® BreathCard™ to humidity or fluids.

Avoid getting saliva into Heliprobe® BreathCard™ during exhalation.

Do not drink or eat between exhalations during the test.

Only use the validated substrate (see section 3.2) for the sample collection.

Do not use the Heliprobe® BreathCard™ too early or too late after swallowing the substrate.

Exhale into the Heliprobe® BreathCard™ until the indicator changes color from orange to yellow.

Analysis of the Heliprobe® BreathCard™

Gently squeeze out any excess air without touching the plastic filter shield (mylar).

Insert the Heliprobe® BreathCard™ into the Heliprobe® Analyzer with care.

Only use the validated instrument (Heliprobe® Analyzer) for the analysis of the Heliprobe® BreathCard™.

Disposal

Replace Heliprobe® BreathCard™ in its package/envelope prior to disposal.

Dispose according to local rules or guidelines.

NOTE

Sampled Heliprobe® BreathCard™ from an infected patient typically gives about 200–2000 counts. This is expected to contain between 0.2–1.6 kBq ¹⁴C (0.005–0.05 μCi).

Miscellaneous

Heliprobe® BreathCard™ is for single use only.

Do not use expired Heliprobe® BreathCard™.

Heliprobe® System ¹⁴C Urea Breath Test radioactivity is very low. ¹⁴C emits low energy β-radiation with a range of 24 cm in air and 0.25 mm in plastic.

1 capsule of substrate (see section 3.2) contains 37 kBq (1 μCi) ¹⁴C-urea, which gives a dose of 2.5 μSv. Most of the ¹⁴C urea is excreted in the urine. Only a minor part is exhaled as ¹⁴CO₂. Heliprobe® BreathCard™ sampled from an infected patient typically contains 0.2–1.6 kBq (which corresponds to 200–2000 counts) and gives a maximal dose of 0.2 μSv. The upper limit for occasional exposure is < 20 μSv/hour. The upper limit for continuous exposure is < 2 μSv/hour.

NOTE

No protection or precautions are required for the safe handling of Heliprobe® BreathCard™.

7. Product description

7.1. Heliprobe® Analyzer

Heliprobe® Analyzer is a small desktop instrument easily operated from an upper front panel. Operational status and test results are shown on the display. A printer can be connected to the analyzer.

Heliprobe® Analyzer contains two Geiger-Müller counters, an upper and a lower, mounted to create a slot for inserting Heliprobe® BreathCard™. An optical sensor detects proper insertion of Heliprobe® BreathCard™. The Protection Card must always be kept inserted in the slot between measurements.

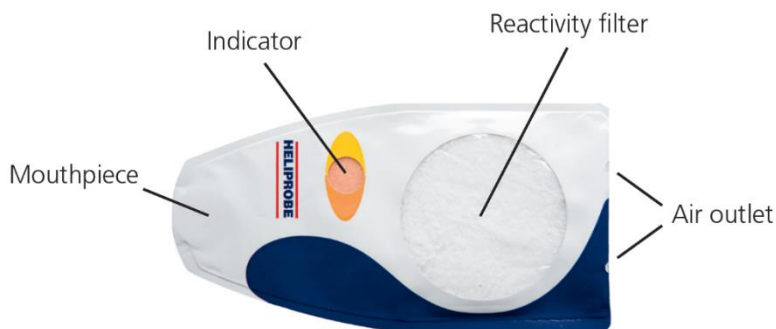


Diode light	Status indication
Constant green	Stand-by mode Press any key or insert Heliprobe® BreathCard™ to activate
Flashing green	Ready for measurement
Flashing yellow	Measurement in progress
Constant red	Error

7.2. Heliprobe® BreathCard™

Heliprobe® BreathCard™ is a single-use device for ¹⁴C Urea Breath Test sampling allowing *Helicobacter pylori* detection. Heliprobe® BreathCard™ is only compatible with the Heliprobe® Analyzer.

Heliprobe® BreathCard™ consists of an aluminum foil integrating a mouthpiece for exhaling, two reactivity filters (upper and lower) for adsorbing CO₂ and a color indicator to show completion of sampling. Two air outlets allow the exhaled air to pass through. Heliprobe® BreathCard™ is single packed in an aluminum envelope to protect it from damage and humidity, then packed by 5 in a secondary packaging. Each breath sample on Heliprobe® BreathCard™ can be identified using a non-erasable pen.



Component	Function
Mouthpiece	Air inlet facilitating the breath sample collection.
Indicator	Colored indicator allowing the user to know when the sampling is completed by changing its color from orange to yellow. The indicator pad is protected by a thick, resistant membrane. ⚠ Contains LiOH.
Reactivity filter	Core pad of the Heliprobe® BreathCard™ that chemically adsorbs the CO ₂ from the exhaled air. The reactivity filter is protected by a thin, resistant membrane (mylar). ⚠ Contains LiOH.
Air outlet	Outlets allowing the reduction of the pressure inside of the Heliprobe® BreathCard™ during sample collection, while retaining enough air to ensure an adequate capture of the ¹⁴ CO ₂ .
Bodyfoil	Outer layer of the Heliprobe® BreathCard™ for easy handling.

LiOH



Hazard statement(s)

H301

Toxic if swallowed.

H314

Causes severe skin burns and eye damage.

Precautionary statement(s)

P260

Do not breathe dusts or mists.

P270

Do not eat, drink or smoke when using this product.

P280

Wear protective gloves/ protective clothing/ eye protection/ face protection.

P303 + P361 + P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304 + P340 + P310

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

8. Principle of operation

Helicobacter pylori produces urease, an enzyme that catalyzes the hydrolysis of ^{14}C -urea to $^{14}\text{CO}_2$ and NH_3 . $^{14}\text{CO}_2$ is excreted in exhaled air while NH_3 and excess ^{14}C -urea are excreted in urine. Under healthy conditions (absence of *Helicobacter pylori*), ^{14}C -urea is not hydrolyzed and no $^{14}\text{CO}_2$ will be present in exhaled air. Hence, $^{14}\text{CO}_2$ is only present in exhaled air during *Helicobacter pylori* infection.

8.1. Urea Breath Test (UBT) sampling

The patient swallows a HeliCap™ capsule containing ^{14}C urea (1 μCi) and wait 10 minutes before exhaling into Heliprobe® BreathCard™ where the reactivity filters adsorb the CO_2 . The indicator changes color from orange to yellow to indicate when the reactivity filters are saturated, and sampling completed.

8.2. Analysis

The analysis principle is based on measuring β -radiation from $^{14}\text{CO}_2$ sampled in Heliprobe® BreathCard™. Radiation is measured (as counts) and the result is presented as Heliprobe 0 = not infected, Heliprobe 1 = borderline and Heliprobe 2 = infected.

When the analyzer is turned on, background radiation is continuously measured by both the upper and lower Geiger-Müller counters during 40 cycles of 50 seconds each. To ensure correct background value, the analyzer should always be kept on with a Protection Card inserted between the measurements.

An optical sensor detects when Heliprobe® BreathCard™ is inserted into Heliprobe® Analyzer, and the measurement can only start if it is properly inserted. Pressing the start key starts a measurement cycle of 250 seconds. The two Geiger-Müller counters detect ^{14}C radiation from the upper and the lower reactivity filters. Due to the short range of β -radiation, radiation from the upper filter can only be detected by the upper Geiger-Müller counter and radiation from the lower filter only by lower counter. The average background values from the upper and lower counters (BGR 1 and BGR 2) are subtracted from the upper and lower sample measurement values (d_1 and d_2). The adjusted values are merged to a total value ($d_1+d_2=d$) and the result is presented on the display. In case of a total value between 25 and 100 counts, the analyzer automatically re-measures Heliprobe® BreathCard™ to confirm the result.

Cut-off values		
Heliprobe 0	Not Infected	$d \leq 25$ counts
Heliprobe 1	Borderline	$25 \text{ counts} < d < 50 \text{ counts}$
Heliprobe 2	Infected	$d \geq 50$ counts

NOTE

Heliprobe® System ¹⁴C Urea Breath Test is a qualitative test. The result is presented as infected, borderline, or not infected based on clinically established cut-off values. The measured count value shall not be used to assess the degree of infection or bacterial load.

9. Installation and set-up

Unpack and place Heliprobe® Analyzer on a stable and horizontal surface. Ensure there is no disturbance from sources of strong electromagnetic radiation or radioactivity since this may affect its performance. Default settings are pre-installed, and no calibration is required. In general, no adjustments are necessary.

Set-up the analyzer according to section 9.1 or 9.2. Date and time can be adjusted according to section 9.3 if necessary.

After set-up is complete, check and note the background value. This may be useful for monitoring variation in background radiation.



NOTE



If Heliprobe® Analyzer must be disconnected or if the power fails, set-up must be performed according to the procedure described in section 9.1 or 9.2 to regain the correct background value.

9.1. Quick start

1. Connect the supplied power adapter to Heliprobe® Analyzer (via the lower rear panel) and to the electrical outlet.
2. Insert the Protection Card.
3. Wait for at least 34 minutes to obtain the correct background value.
4. The analyzer is ready for test measurement when the diode light is green.


9.2. Alternative set-up

1. Connect the supplied power adapter to the electrical outlet but do NOT connect it to the analyzer yet (disconnect if already connected).
2. Press and hold the *Start/Stop* key  and connect the power supply to the lower rear panel of the analyzer. The analyzer is now in a mode where settings can be adjusted.
3. **Set-up** menu appears in the display. Press the Confirm key .

4. **Choose menu, clear start?** appears in the display.
5. Press the *Confirm* key  or the *Menu* key  to proceed through the settings workflow. See the flow chart for further details.








NOTE

If **clear start** is performed, or if no current background value is present in the software memory, a background measurement starts automatically. The red diode lights up to indicate that the background measurement has started and continues to light during the measurement. When the green diode lights up, the analyzer is ready to use.

6. When **Set-up completed, exit?** appears in the display, insert the Protection Card and press the *Confirm* key .
7. Wait for at least 17 minutes (1000 seconds) for background measurement. The diode light is red during this measurement.
8. The analyzer is ready for use when the background measurement is complete and the diode light changes to green.

9.3. Adjustment of date and time

Date and time can be adjusted as follows:

1. Proceed through steps 1–4 above (9.2).
2. When **Choose menu, clear start?** appears in the display, press the *Menu* key  until **Choose menu: Set clock?** appears.
3. Press *Confirm* key .
4. Set the current date and time by pressing the *Print* key  (to lower) or the *Menu* key  (to raise) the digits in the display. Use the *Confirm* key  to proceed to the next digit.
5. Proceed through the menu by pressing the *Menu* key  until **Set-up completed, exit?** appears.
6. Press *Confirm* key .
7. Insert the Protection Card and wait at least 35 minutes (2000 seconds) for background measurement.

10. Default settings






Operation	Default setting
Initial background measurement at set-up	20 cycles of 50 seconds (1000 seconds)
Continuous background measurement	40 cycles of 50 seconds (2000 seconds)
Background value	Mean value of 40 cycles of 50 seconds
Background cut-off	250 counts per 250 seconds
Heliprobe® BreathCard™ measurement	250 seconds
Automatic re-measurement of values between 25–100 counts	Up to 3 additional cycles of 250 seconds

NOTE

Default settings are validated for optimal function and correct results. Kibion recommends NOT changing any default settings. In case the environmental background is higher than the cut-off value (250 counts), the cut-off value can be increased in the set-up menu. Always contact your local sales representative for guidance before changing any settings.

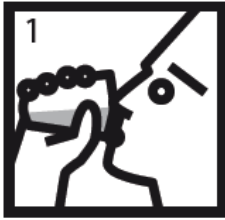
10.1. Changing default settings

To change settings, proceed as follows:

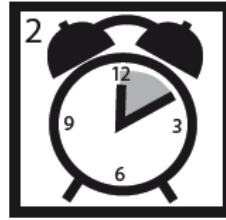
1. Follow steps 1–4 in section 9.2.
2. Proceed through the menu using the *Menu* key  and use the *Confirm* key  to select/confirm the mode to be changed.
3. Use the *Print* key  or *Menu* key  to adjust the settings/digits.
4. Proceed through the menu until **Set-up completed, exit?** appears on the display.
5. Press *Confirm* key .
6. Insert the Protection Card and wait for at least 35 minutes (2000 seconds) for background measurement.
7. The analyzer is ready for use when the background measurement is completed, and the diode light turns green.

If **clear start** is performed, or if no current background value is present in the software memory, a background measurement starts automatically. The red diode lights up to indicate that the background measurement has started and continues to light during the measurement.

11. Measurement and analysis



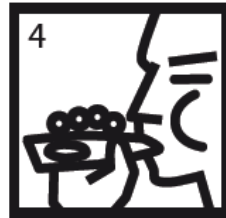
Swallow



Wait



Open pack



Exhale



Insert





Start

11.1. How to perform a Heliprobe® UBT test

1. Swallow a HeliCap™ capsule with a glass of water and wait for 10 minutes.
2. Open the package and remove the Heliprobe® BreathCard™. Exhale into the Heliprobe® BreathCard™ until the indicator changes color from orange to yellow (1–4 minutes). Ensure that the two air outlets are free and allow exhaled air to pass through.

NOTE

Do not inhale through the Heliprobe® BreathCard™. Remove Heliprobe® BreathCard™ from the mouth if a fresh breath of air is needed. Do not drink in between.

3. Gently squeeze out any excess air without touching the plastic filter shield (mylar).
4. Remove the Protection Card and insert Heliprobe® BreathCard™ into the slot with the mouthpiece facing outwards and the indicator side facing upwards. The display shows: “**ready to measure, standard program**”.
5. Press the Start/Stop key  to start the measurement and analysis.
6. The display shows “**measuring**” and indicates the time remaining (seconds).
7. When measurement and analysis are completed, two beeps sound and the result is automatically shown (for 20 seconds) on the display as: Heliprobe 0, Heliprobe 1 or Heliprobe 2.
8. To recall the result, press the *Confirm* key  without removing the Heliprobe® BreathCard™.

Grading	Disease status	Cut-off values (counts)
Heliprobe 0	Not Infected	$d \leq 25$ counts
Heliprobe 1	Borderline	$25 \text{ counts} < d < 50 \text{ counts}$
Heliprobe 2	Infected	$d \geq 50$ counts



Note or print* the results and remove the Heliprobe® BreathCard™. Measurement and analysis are now finalized.


Insert the Protection Card and keep the analyzer turned ON.

* To obtain printouts, a suitable printer must be connected. Contact your local distributor for guidance.

NOTE

When the measured value is between 25 and 100 counts during the first and second measurement, the instrument will automatically re-measure Heliprobe® BreathCard™ (up to three additional measurement cycles) to secure the results. Measurement can therefore take longer. The obtained result is the mean value of the additional measurements. Thus, borderline results are always confirmed by re-measurement.

11.2. View measurement values

To view the measured count values, press the *Confirm* key 




d1 = Activity emitted from the upper reactivity filter of the Heliprobe® BreathCard™

d2 = Activity emitted from the lower reactivity filter of the Heliprobe® BreathCard™

d = (d1+d2) – BGR : total activity

t = measuring time

To view the background value, press the *Confirm* key .

LONG BGR 1 = Most recent average background value for Geiger-Müller counter 1

LONG BGR 2 = Most recent average background value for Geiger-Müller counter 2

12. Error messages

Display message	Function
Testing GM-tube	Automatic control of GM-tube functions
GM-tube OK	GM-tube work properly
GM-tube error Diode (left side) shows red light	GM-tube does not work properly No measurement can be performed. Contact your local sales representative.
Too high background Diode (left side) shows a red light	Background is above cut-off value(250 counts). No measurement can be performed. Contact your local sales representative.

13. Service and maintenance

Heliprobe® Analyzer does not need regular service. However, we recommend checking the background value at least once a year or if contamination is suspected.

Always check the background value if the analyzer has been moved or re-installed.

If necessary, clean the outer part of Heliprobe® Analyzer using a damp cloth and mild detergent. Do not rinse or immerse the analyzer in water or any other liquid.

If the instrument malfunctions or needs repair, please contact your local distributor.

All service and repair must be performed by Kibion.

14. Disposal

Heliprobe® Analyzer should be disposed as electronic and electrical waste.

Replace Heliprobe® BreathCard™ in the single package prior to disposal according to local regulations or guidelines.

NOTE

Sampled Heliprobe® BreathCard™ from an infected patient typically gives about 200–2000 counts. The expected radioactivity in Heliprobe® BreathCard™ sampled from an infected patient is approximately 0.2–1.6 kBq ¹⁴C (0.005–0.05 μCi).

15. Technical specifications

Heliprobe® Analyzer	
Detector	GM-tubes and window 50 mm in diameter mounted face-to-face. Internal high voltage, 520 V Lifetime 10E8 pulses: results in approximately 30 years longevity (high-usage and high-background)
Display	LCD, 16 positions x 2 rows, background illumination
Acoustic indication	Beeper
Operating voltage	9 V DC (stabilized), external power supply
Power consumption	5 W
Measuring sensitivity	Activity of 25 Bq (¹⁴ C) enclosed in the same sample condition as Heliprobe® BreathCard™ gives 1 pulse per second.
Operating Temp./humidity range	0° – 50°C / Max 95% RH
Operating Maximum altitude	2,000 meters above sea level
Storage and transport Temp./humidity range	0° – 50°C / Max 95% RH
Dimensions	150 x 130 x 140 (width x height x depth)
Weight	4.39 kg
Serial output	Serial output RS 232, Protocol, Baud rate 9 600, No parity 8 data bits, 1 stop bit. Pin2 TXD / Pin3 earth GDN / Pin4 RXD
Power supply	Mascot 3823-90: Input 100-240V AC, Output 9V DC, max. 1.33 A

16. Troubleshooting

Issue	Possible cause	Recommendation
Background too high	Analyzer may be contaminated.	Return the analyzer for service. Contact your local sales representative. Never try to clean inside the analyzer or the card slot. The GM-tubes are very sensitive any may be damaged.
Background too high	Environmental background radiation may be high.	Ensure there is no radiation from other equipment or sources in the surroundings. Move the analyzer to another location. If the natural environmental radiation is high, adjust the background cut-off value. Always contact your local sales representative for guidance when performing this procedure.
Measurement value or background value is strange	Protection Card not inserted properly.	The Protection Card should always be inserted between measurements and the analyzer kept ON.
GM-tube does not work	GM-tube may be damaged or broken.	Contact your local sales representative.
Display does not work properly	Electrical malfunction.	Contact your local sales representative.
Measurement value is negative	Can occur if the stored background value is higher than the sample value.	The result is Heliprobe 0. Check the background value.
Measured value varies when Heliprobe® BreathCard™ is re-measured	Background radiation may vary.	Heliprobe® BreathCard™ with low activity is relatively more affected by variation in background than cards with high activity. This normal variation in background radiation does not affect the results significantly. Check the background value.
How can I verify '0' level	Perform a breath test without taking any Helicap.	Result should show 0
How can I verify '2' level	Since its radiation is stable, a highly positive (>250 counts) Heliprobe® BreathCard™ can be kept and used to verify level '2'. However, the card must be stored properly.	Level '2' can be verified although the count value may differ between measurements.

17. Customer support and contact information

Please contact your local distributor or Kibion GmbH for support.

⇒ info-bremen.kibion@mayoly.com

⇒ +49 421 278650

18. Serious incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

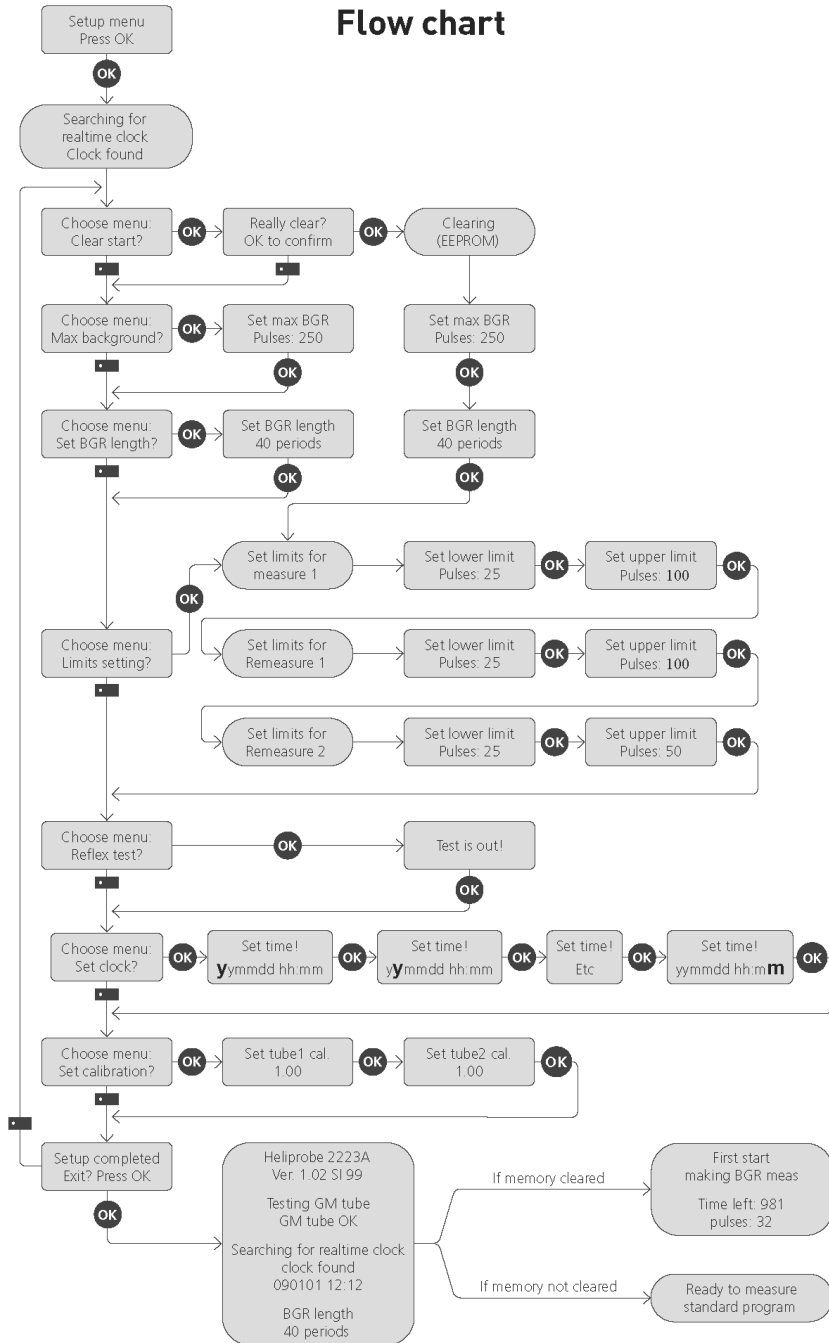
The manufacturer must be contacted at the following email address:

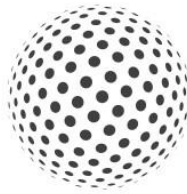
⇒ quality.kibion@mayoly.com

For Europe, the contact points of the competent authorities are available on the website of the European Commission:

⇒ <https://ec.europa.eu/tools/eudamed>

Flow chart





kibion