



kibion

KIBION[®] DYNAMIC

¹³C BREATH TEST ANALYSER

Diagnosis of *Helicobacter pylori* infections



Help prevent chronic *Helicobacter pylori* infections and the development of gastric cancer

More than half of the world's population harbour the stomach bacterium *H. pylori* in their upper gastrointestinal tract. Most of these individuals show no signs of symptoms or distress but in others, *H. pylori* is recognised as the main etiological factor for chronic gastritis, peptic ulcers and possibly gastric malignancies.

Accurate early diagnosis followed by appropriate treatment with antibiotics can nevertheless alleviate much suffering and even prevent life-threatening diseases.

A modern, modular instrument

Kibion® Dynamic is a technology platform for diagnosing *H. pylori* infections faster and from smaller sample volumes than in its predecessor "IRIS" (reduction from about 50 mL to below 10 mL). Based on the gold standard Urea Breath Test (UBT) it represents a modern, modular instrument for the analysis of breath samples in *in-vitro* diagnostics.





Detecting *H. pylori* is this simple

Kibion® Dynamic offers laboratories and hospitals speed plus simplicity. No PC is required. A modern touch-screen interface gives access to all key functions and pictograms guide users step-by-step. From measurement to result takes no more than four minutes.

Auto-adjust the instrument

Daily auto-adjustment requires a normal breath sample. Selecting auto-adjustment in the main menu displays a pictogram to guide users. Exhale into the bag or tube, connect it to a sample port and press the arrow button. Auto-adjustment runs automatically and takes just two minutes.

Analyse patient samples

Selecting analysis opens a screen to enter test identifier data, either via the touchscreen keyboard or a barcode scanner. The next screen allows patient specific data to be entered for the internal database. All patient specific fields are optional. On-screen set-up assistance ensures accurate data input and activation. Once again, a pictogram shows users exactly where to connect the sample.

Touching the arrow button starts the analysis while selecting Status displays its progress. Approximately two minutes is all that is required. Additional samples can be initiated during this time.

View the results

Selecting result in the main menu opens the results database. All results can be searched or filtered. Selecting a specific result opens a detailed view as a graph or list. Results can be printed, filed to a journal, exported to a computer or downloaded to a USB stick.

Swedish design German quality and reliability

Kibion® Dynamic began life as a blank sheet of paper in the capable hands of an internationally recognised industrial design agency. To this we added our own specialist know-how plus the invaluable input of leading gastrointestinal clinicians and testing laboratories in Europe and the Middle East. We simply asked them what functions would add true value to their everyday use of breath test analysers. Then we assembled the final product at our own manufacturing facility in Germany.

Design and performance speak for themselves.



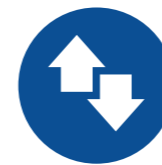
Touch-screen with quick navigation

Like all other functions, Kibion® Dynamic's user interface has been designed upon user and operator comments. Its touch-screen enables direct menu navigation. Set-up assistance is promoted via dialog boxes for key data input and activation while input and validity checks ensure smooth operation. Results are shown as graphic displays.



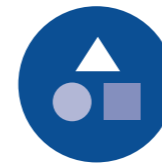
Easy-to-use

Kibion® Dynamic Software provides touch-controlled routines for auto-adjustments, sample definitions and measurement control. Its database records and stores patient data and test results. With the separately available barcode reader, all common 2D barcodes of tubes can be captured, ready to be tested.



Connectivity

Full integration plus complete connectivity to local infrastructures greatly simplifies result generation and reporting. A built-in, fully-fledged computer eliminates the needs for laptop or desktop computers, for example. Furthermore, devices such as a keyboard, mouse, scanner or printer can be integrated into the workflow via USB or LAN connections. Bidirectional integration with LIS is possible allowing to retrieve patient information and test requirements from the laboratory system.



Modularity

Kibion® Dynamic handles numerous ¹³C breath samples with its extension devices Kibion® Dynamic Pro (for bag and tube samples) and the Dynamic Performance (for tube samples). Moreover, its set-up, operation, results generation and reporting can be fully customised to meet individual end-user needs.



High-capacity throughput

When testing demand increases, the Kibion® Dynamic Base can be supplemented with the innovative extension devices Kibion® Dynamic Pro (up to 16 additional ports equal to 8 patients) or Dynamic Performance (up to 120 tubes equal to 60 patients).



Robustness

The mechanisms of the Kibion Dynamic have been developed in such a way that it can withstand very high loads over long periods of time. For example, the axes of the Dynamic Performance are made of steel and the stainless steel needle can be replaced if necessary.

Well-proven technology at its most advanced

Kibion® Dynamic breath test analyzer measures the $^{13}\text{CO}_2$ and $^{12}\text{CO}_2$ concentrations of breath samples and relates their ratios to the PDB- ^{13}C stable isotope standard.

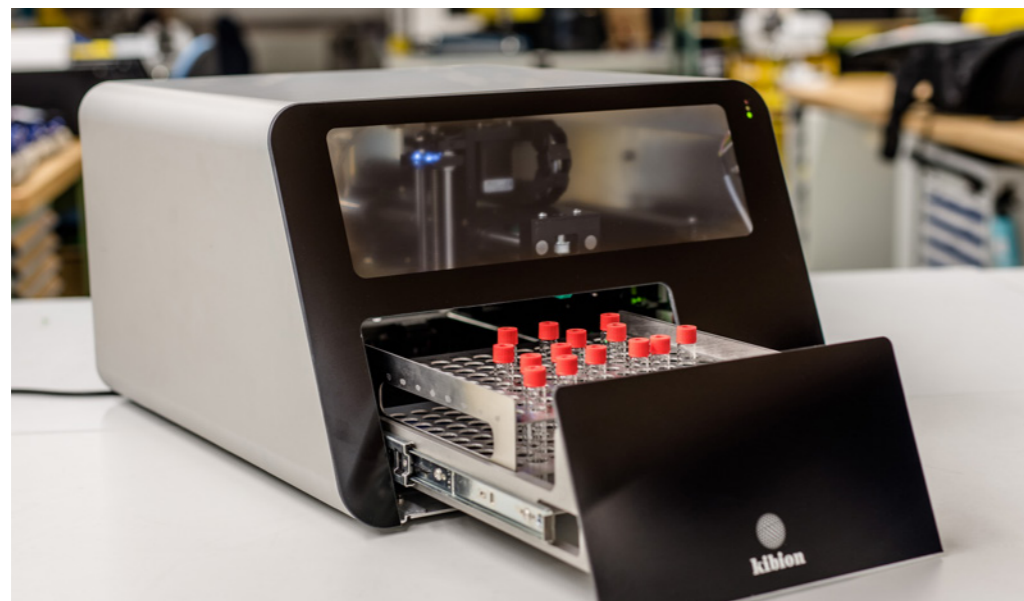
Taking the Urea Breath Test

^{13}C Urea Breath Test is used for primary diagnosis and post-treatment follow-up of *H. pylori* infections. It has only few side effects and it measures active infection. The individual to be tested simply swallows ^{13}C -urea. If present, *H. pylori* metabolises ^{13}C -urea to $^{13}\text{CO}_2$ and ammonia via the enzyme urease. The $^{13}\text{CO}_2$ is then transported in the blood to the lungs. When the patient exhales after a defined time this $^{13}\text{CO}_2$ is captured in a sample bag or tube. (If *H. pylori* is absent, the ^{13}C -urea is simply absorbed and subsequently voided.)

Analysing the breath test sample

Kibion® Dynamic analyses ^{13}C -urea breath samples using Infrared Isotope Analyzer (IRIS) technology. Measurements are made directly on breath samples from sample bags or sample tubes connected to the instrument panel, either on the base unit or the high-throughput extensions (pro or performance). No separation of water or isolation of CO_2 is required prior to analysis. Standard BreathBags have a volume of 120 ml breath gas, which is sufficient for several measurements per sample. Standard tubes have 12 ml, which is sufficient for one measurement.

IRIS technology measures the isotope ratio $^{13}\text{C}/^{12}\text{C}$ in a breath sample to calculate the relative deviation of the ratio in the sample compared to the ratio in a reference material (usually denoted by $\delta^{13}\text{C}$).



Technical information

Analytical data	CE IVD	CE IVD	CE IVD
	Kibion® Dynamic Base	Kibion® Dynamic Pro	Kibion® Dynamic Performance
Reproducibility	< 0.5	N/A	N/A
IRIS analyzer	URASmed	N/A	N/A
Sample measurement	2 min/sample	2 min/sample	2 min/sample
Sample ports	4 (= 2 patient samples)	16 (= 8 patient samples)	120 (= 60 patient samples)
Stability	< 0.5 (standard deviation)	N/A	N/A

Technical data	Kibion® Dynamic Base	Kibion® Dynamic Pro	Kibion® Dynamic Performance
	Width x height x depth (mm)	280 x 320 x 380	500 x 320 x 380
Weight (kg)	13	11.5	27
Electrical connections	100-120/200-240 (VAC) 50-60 (Hz)	100-120/200-240 (VAC) 50-60 (Hz)	100-120/200-240 (VAC) 50-60 (Hz)
Power consumption (kW)	0.12	0.12	0.12
Main switch with 2 fuses	2 x 2 A	2 x 2 A	2 x T2A (250 VAC)
Gas connections	1	1	1
Data transfer	2 RJ-45, 2 USB	1 RJ-45	1 RJ-45

Laboratory working and storage conditions

	Kibion® Dynamic Base	Kibion® Dynamic Pro	Kibion® Dynamic Performance
Temperature (°C)	15-35	15-35	15-35
Humidity (% rH)	< 70	< 70	10-75

Install Kibion® Dynamic in a vibration and movement-free environment.

Kibion GmbH, part of Mayoly Spindler

Kibion GmbH and Mayoly-Spindler are world's leading providers of fast and reliable urea breath tests as well as analytical equipment for the detection of the stomach ulcer-causing bacterium *Helicobacter pylori*.

Kibion sold breath test analyzer systems to more than 50 countries, with the EU and the Middle East being the largest markets.

Since 2016 Kibion GmbH has been part of the French pharmaceutical company Laboratoires Mayoly Spindler which sells the substrates for *H.pylori* diagnostics internationally.

Kibion GmbH is certified according to EN ISO 13485.

Read more about Kibion at www.kibion.com.



A COMPANY OF



Kibion GmbH
Haferwende 31
28357 Bremen
Germany

info.kibion@mayoly.com
www.kibion.com

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