Instructions for use

Kibion® Dynamic

base / pro / performance

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Contact
Kibion GmbH
Haferwende 31
28357 Bremen
Germany

Email: info-bremen.kibion@mayoly.com
Telephone: +49 (0) 421 27 86 5-0

CE IVD

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1. Important Information

Before commissioning, the user manual and the safety instructions must be read and observed.

1.1. Symbols

This product complies with the requirements of Council Directive 98/79/EC on medical devices for In Vitro Diagnostics use.

All instructions in the user manual must be observed!

Indicates the manufacturer of the product.

Safety instructions for the protection of a personnel.

Safety instruction regarding electrical hazards.

Important Information

Instruction concerning the protection of the equipment.

Labelling of electrical and electronic equipment that must be disposed of in an environmentally friendly manner in accordance with § 7 electrical and electronics equipment law.

GHS05 Corrosive effect E.g. • Skin-caustic, Catalogue. 1• Corrosive to metals, Catalogue. 1

1.2. Classification

The Kibion® Dynamic devices are classified as IVD „Other products“ according to the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic medical devices.

1.3. User group

The group of Kibion® Dynamic devices are intended for use by trained health care professionals in medical practices, hospitals, and laboratories.

1.4. Incident reporting

Serious incidents related to the device shall be reported to the manufacturer and to the competent authority of the member state where the user and/or the patient is established.

2. Safety

The safety instructions must be observed. Follow the instructions for your own safety.

2.1. General safety instructions

All persons involved in the installation, commissioning, control and repair of the device and its components must have read and understood the operating instructions and particularly the chapter "Safety instructions". If necessary, in-house training must be carried out, considering the technical qualifications of the persons involved.

Prior to the initial operation of the device, the operator must ensure that all safety relevant conditions are fulfilled.

The devices may only be maintained and operated by persons who are familiar with this type of work, who are aware of the dangers and who have the necessary qualifications. The relevant safety and accident prevention regulations as well as the generally recognised safety and accident prevention rules must be observed.

2.2. Operational safety

Working methods must be avoided which,

- could pose a threat to the life and physical condition of the user or third parties;
- could affect the device itself or devices in the vicinity;
- help to disregard safety instructions;
- impair the safety and function of the device.

Never remove or disable safety devices!

Maintenance and repair work may only be carried out when the device is disconnected from the power supply!

Housings must be closed during operation and may only be opened for troubleshooting!

The Kibion® Dynamic devices must only be used for measurements of human breath gas samples.

When handling breath gas samples appropriate hygienic measures must be taken.

When filling the breath bags or the tubes, as well as when connecting and removing them from the devices, users are instructed to wear protective gloves. This also applies to the disposal of the sample containers.

2.3. Hazard warnings

The devices must not be used in the presence of explosive or flammable gases, anaesthetic gases or nitrogen oxides and laboratory oxygen.

The filter material in Kibion® Dynamic base, pro and performance contains soda lime. This has corrosive properties. If the filter is damaged, the manufacturer or his local representative must be contacted.

2.4. Warranty conditions

Any use other than the intended use as well as unauthorized modifications of the device or its components which are included in the delivery of Kibion, exclude any liability of the manufacturer for resulting damages.

The warranty or guarantee by the manufacturer expires if the filter replacement and annual maintenance with technical inspection are not carried out according to the specifications. See 8.2.

3. Function

The Kibion® Dynamic base uses the non-dispersive infrared spectroscopy method - NDIRS for short - to analyze respiratory gases. It is a method in which metabolized organic substances can be detected in the breath if CO_2 is an end product. To be able to provide evidence, the starting substances to be metabolized are labelled with the stable isotope ^{13}C. This allows them to be selectively determined in the exhaled air via the CO_2 molecules. This method is suitable for detecting *Helicobacter pylori* in the stomach. The Kibion® Dynamic base thus serves as a diagnostic aid.

From the measurements of the $^{12}CO_2$ and $^{13}CO_2$ concentrations, the device determines their quantity ratios and the resulting "δ" ratios, resp. DOB values (see A.1), without simultaneously recording absolute "δ" values. This is a semi-quantitative method of measuring DOB values.

4. Devices

4.1. Kibion® Dynamic base

Article Nr. 8031

4.1.1. Intended use

The Kibion® Dynamic base is an infrared analyser for the determination of the isotope ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples and its variation over time.

4.1.2. Expected Service Life

The Expected Service Life of the Kibion® Dynamic base is 8 years.

4.1.3. Description

The Kibion® Dynamic base measures the $^{13}CO_2$ and $^{12}CO_2$ concentrations of the breath air samples with isotope infrared spectrometry (IRIS). The sample collection is performed by filling the breath bags or sample tubes, which are attached to four ports on the front of the analyser. Control and recording of the measurement data are done by an integrated user software. The Kibion® Dynamic base has an integrated PC.

The device has two USB interfaces, which allow the connection of Windows® compatible input devices (e.g. keyboard, mouse, barcode reader).

Furthermore, the Kibion® Dynamic base has two RJ-45 Ethernet interfaces:

4.1.4. Equipment

Front side:

- Colour touch screen
- 4 ports for connecting breath gas containers.

Rear side:

- Main switch
- RJ-45 connector for communication with an extension unit
- RJ-45 connector for communication with a local network
- 2 x USB interface
- Hose connection for the sample gas supply line from an extension unit:
  1. exhaust air
  2. access from extension unit
  3. fresh air supply

Dimensions: 280x325x380 mm^3.
Weight: approx. 13 kg.

4.1.5. Scope of delivery

- Kibion® Dynamic base
- Power cable
- User Manual
- Bag adapter (for a needle device)

4.1.6. Types of construction

- Bag device
- Needle device

4.2. Kibion® Dynamic pro

Article Nr. 8032

4.2.1. Intended use

The Kibion® Dynamic pro is an extension unit of the Kibion® Dynamic base to increase the number of breath samples that can be connected simultaneously for analysis.

4.2.2. Expected Service Life

The Expected Service Life of the Kibion® Dynamic pro is 8 years.

4.2.3. Equipment

Front side:

- 16 ports for connecting breath gas sample containers

Rear side:

- Main switch
- RJ-45 connector for communication with the Kibion® Dynamic base
- Hose connector for the sample gas supply to the Kibion® Dynamic base

Dimension: 500x325x380 mm^3
Weight: ca. 11,5 kg

4.2.4. Scope of delivery

- Kibion® Dynamic pro
- Power cable
- Connecting hose
- RJ-45 cable

4.2.5. Types of construction

- Bag device
- Needle device

4.3. Kibion® Dynamic performance

Article Nr. 8033

4.3.1. Intended use

The Kibion® Dynamic performance is an extension unit of the Kibion® Dynamic base and enables the automatic analysis of up to 120 breath gas samples in test tubes. It is to be used exclusively for Helicobacter pylori analysis with the Kibion® Dynamic base.

4.3.2. Expected Service Life

The Expected Service Life of the Kibion® Dynamic performance is 8 years.

4.3.3. Equipment

Front side:

- Drawer with sample carrier for 120 tubes
- 3 LEDs to indicate the operating status

Rear side:

- Main switch
- RJ-45 connector for communication with the Kibion® Dynamic base
- Hose connection for the sample gas supply to the Kibion® Dynamic base

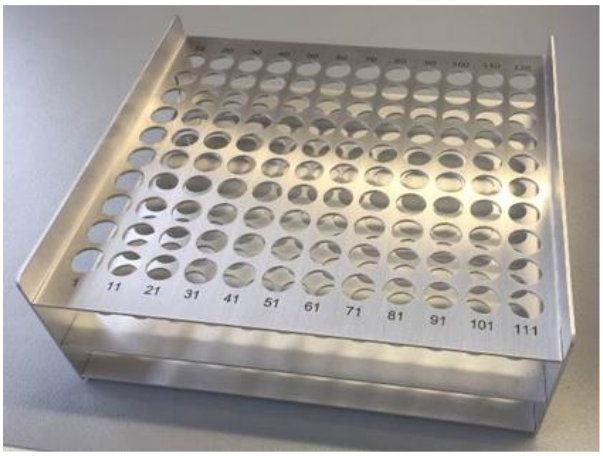
Dimension: 500x325x600 mm^3
Weight: ca. 27 kg

4.3.4. Scope of delivery

- Kibion® Dynamic performance
- Power cable
- Gas guide hose
- RJ-45 cable

4.3.5. Sample carrier

The sample carrier for 120 tubes is in a drawer. To open the drawer, a light pressure must be applied to the front centrally. The sample positions are marked numerically on the carrier.



The sample carrier can be removed from the instrument, so that the sample tubes can be loaded outside the Kibion® Dynamic performance.

Close the sample carrier before operating the measuring process.

Compatible tube dimensions:

Total length	80 - 110	mm
Diameter	14.5 - 16.5	mm
Diameter cover	12 - 22	mm
Tube cap height	4 - 30	mm
Septum thickness	0 - 20	mm

The control of the sample intake and the measuring process is done by the user software of the Kibion® Dynamic base.

The drawer is locked during the measurement process. Opening the drawer is only possible when the needle is in the park position. The closing status of the drawer is detected by a sensor and displayed by LED on the front side.

5. Commissioning

5.1. Conditions at installation site

Strong magnetic and electromagnetic fields can influence the measurement of the infrared analyser or even lead to the damage of the components. Therefore, please make sure that no such devices are operated in the immediate vicinity of the Kibion® Dynamic base installation site.

The Kibion® Dynamic components can be operated under normal laboratory conditions. The room temperature must be in the range of 15-25 °C, with minimal variations, and the relative air humidity < 70% RH.

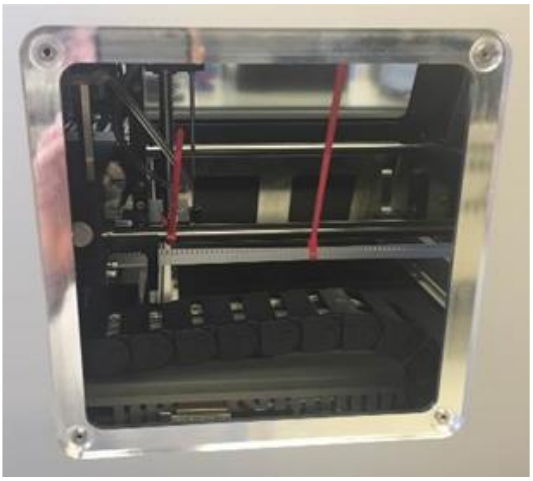
5.2. Setting up the devices

The Kibion® Dynamic components must be placed on a stable base with a flat surface. This must not be exposed to vibrations or potential shocks.

To ensure sufficient air circulation, there must be 20 cm free space to the sides of the devices.

The installation location for the extension units Kibion® Dynamic pro and Kibion® Dynamic performance must be directly next to the Kibion® Dynamic base to ensure the shortest possible guidance path for the breath gas sample.

The Kibion® Dynamic performance has transport locks (cable ties) which must be removed before using the device. Two of them can be removed via the service flap on the back of the device.



Two more cable ties for fixing the sample carrier can be removed via the open front flap.

5.3. Connection of the components

The extension units (Kibion® Dynamic pro or Kibion® Dynamic performance) must be connected to the middle gas connection of the Kibion® Dynamic base via a gas hose.

Also connect the extension unit to the ethernet port marked with “PRO-Unit” of the Kibion® Dynamic base using the supplied RJ-45 ethernet cable.

5.4. Power supply

The devices must be connected to an insulated grounded power outlet of 115-230 VAC/10A with a grounded power cable.

5.5. Switching on the components

Once all components are connected, switch on the Kibion® Dynamic base using the main switch on the back side. The Kibion® Dynamic performance and pro are also switched on by the main switch on the back side.

5.5.1. Warming phase

After switching on the power supply, the Kibion® Dynamic base must heat up for at least 12 hours before it can be used for measurements. This is necessary because the infrared analyser must reach a defined and stable temperature of higher than 50°C.

For this purpose, the instrument must remain in the switched-on state for at least 12 hours before a sample measurement is performed.

The heated Kibion® Dynamic base must remain switched on during routine operation. This also applies to longer breaks in operation!

The correct function of the instrument can only be guaranteed if the heating time is observed

5.6. Transport

For any relocation of the Kibion® Dynamic instruments, please contact Kibion or your local representative for further information.

6. Operating Software

The operating software on the Kibion® Dynamic base can be used to control and perform all measurement functions for base, pro, and performance samples. The software allows the display of all necessary parameters and is equipped with report functions, export functions and a LIS interface. The software runs on a Windows® operating system and is started automatically after pressing the main switch on the Kibion® Dynamic base.

The software is operated via a touch screen. Alternatively, data can be entered using a conventional keyboard and a computer mouse, which can be connected via USB.

6.1. Control Elements

The software can be operated completely via the touch screen. Text can also be entered using integrated virtual keyboards.

Calling up a virtual keyboard that can be used to edit text.

Send data reports to a printer.

Export of data to an external data carrier via a USB interface.

Exiting the software and restarting the Kibion® Dynamic base and software.

Exiting the software and switching off the Kibion® Dynamic base.

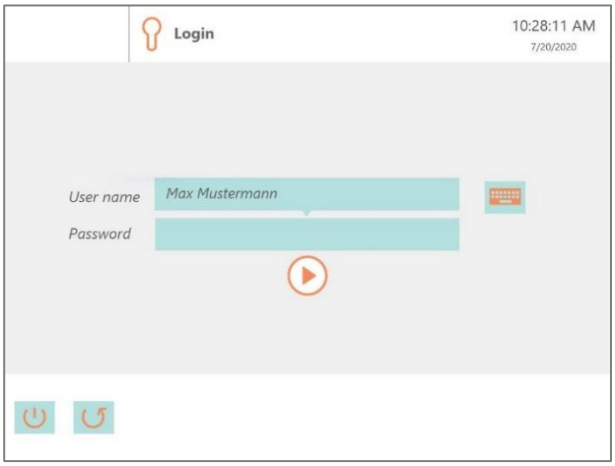
Confirmation of data on one page and calling up the next page.

Return to the previous level or page.

Manual sending of the result data set to a LIS.

6.2. Login

When the device is switched on, the user software is started automatically. This can take a few minutes. The application starts with the login screen:

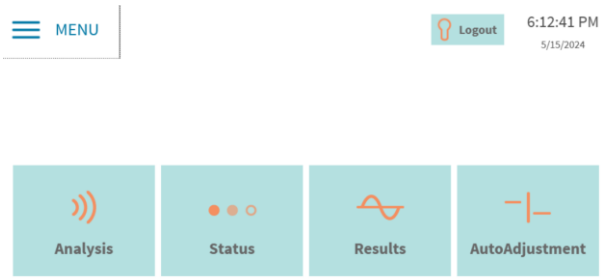


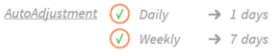
After entering username and password the software can be operated. Confirmation can be done by pressing the arrow key.

Further new usernames and passwords can be created with extended access rights. Please contact Kibion service for this.

6.3. Main menu

The main menu represents the work surface for daily use. It contains four areas for the routine activities: Measurement, status, results and routines.





6.3.1. Analysis

With this function you can enter and start measurement process of breath gas samples. This requires that all necessary settings for test types and connected devices must be made beforehand. For the creation of additional test types please contact your local Kibion service.

Make sure that the necessary concentration adjustment and the daily auto adjustment have been performed. If this has not been done, perform the routine measurement (see 6.3.4).

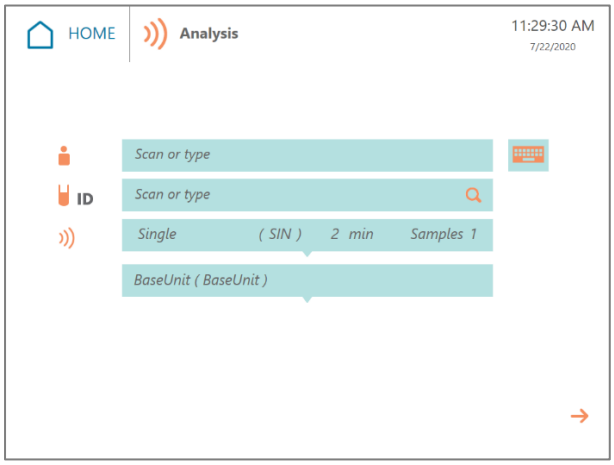
For registration of planned measurements there are two options for the input mask of the patient data and sample parameters:

- The regular display;
- The list display.

The desired input mask is defined in the measurement settings.

Regular Input Mask

The regular input mask starts with the information about the desired test type and the identification of the samples:



Data that can be entered to identify the samples:

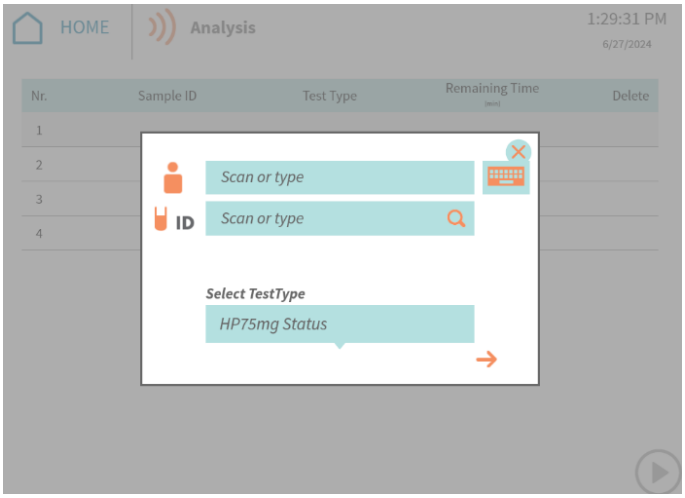
ID number or name of the patient; (Manual entry or scanning is possible)

ID ID of the same sample (optional)

Defined test type from a drop-down menu

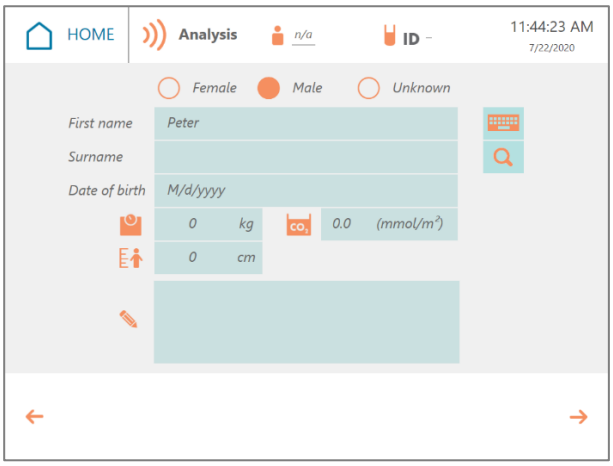
Selection of the instrument to which the samples are connected

When connecting to the LIS, the patient's name or ID is inactivated because this information is sent by the LIS through bidirectional transmission.



If the user needs to enter this information manually, the "Allow to encode the patient id" field must be selected. The patient ID field is then enabled.

After confirmation extended entries are possible, if they are required e.g., for evaluation of the measured data.



What information is mandatory depends on the selected test type and the corresponding settings.

Meaning of the symbols:

Patient weight

Size of the patient

Comment field

After confirming the entered data, the display shows the ports to which the breath bags or glass vials must be connected, depending on the preselected connection device (base, pro or performance unit)).

NOTE: To measure sample vials, a device with needle connections is necessary. Only vials with fixed lids are to be used.

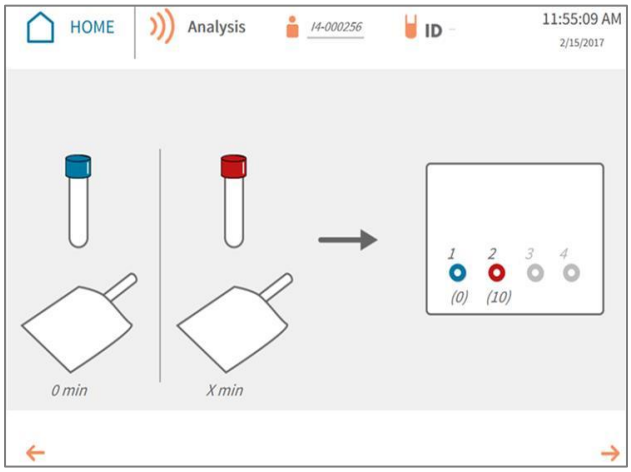
If a LIS is used, all samples, patient and orders are registered in the LIS system first.

Then, to launch the analysis with the Kibion system, only the SID must be entered by the user. The LIS automatically sends the Patient ID and the requested test.

NOTE: It is very important to not modify manually information sent by the LIS in the Dynamic system.

The following instructions are manual entry of analysis.

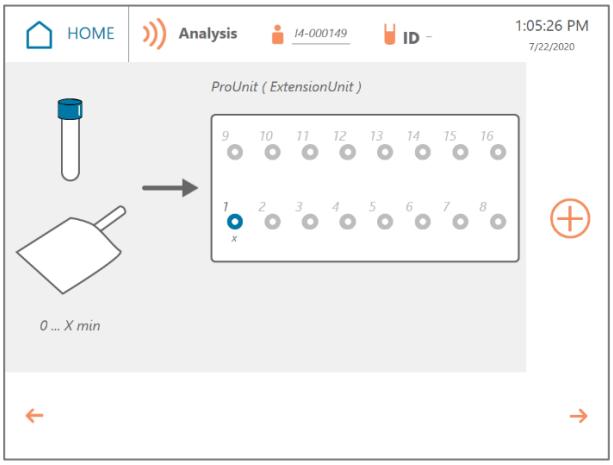
Analysis on Kibion® Dynamic base:



Connect the samples as shown in the figure. Confirm the correct connection and start the measurement with the right arrow key.

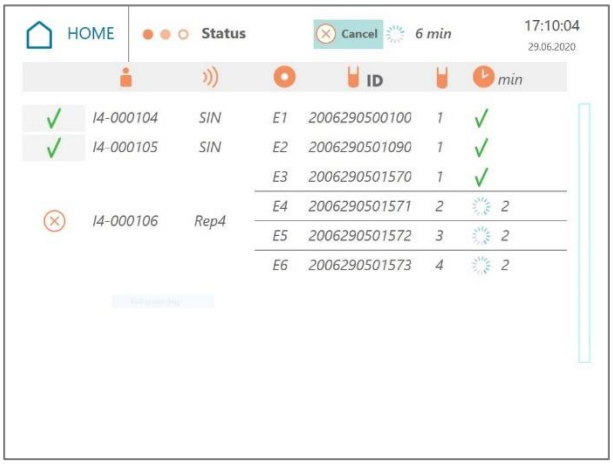
A further test can be prepared during the running measurement by creating them as described above.

Analysis on Kibion® Dynamic pro:



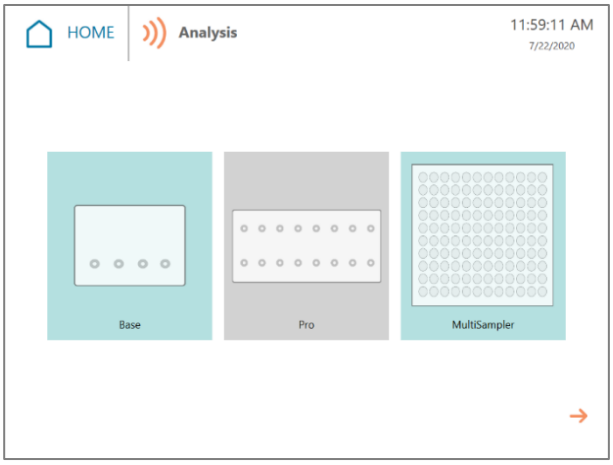
Connect the samples as shown in the figure. To add more tests, press the ⊕ key.

When the test series is complete and the measurements have started, the progress is displayed on the screen. See below an example:



Extended input mask/list

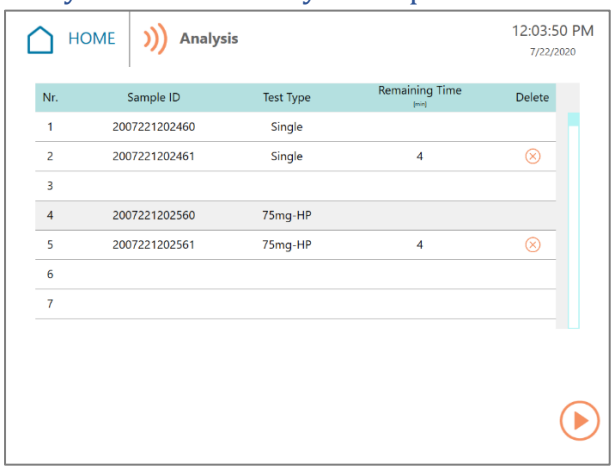
If the list view has been set up, the first step is showing which devices are connected and available for analysis:



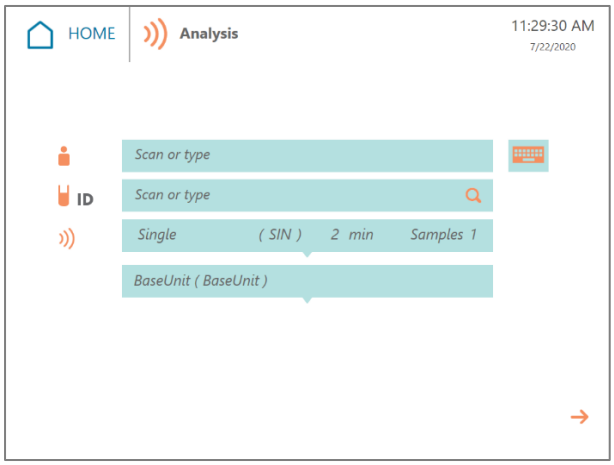
The configured devices that are available for analysis are highlighted in colour.

After selecting the instrument, a list appears in which all possible ports or sample locations are displayed as numbered lines.

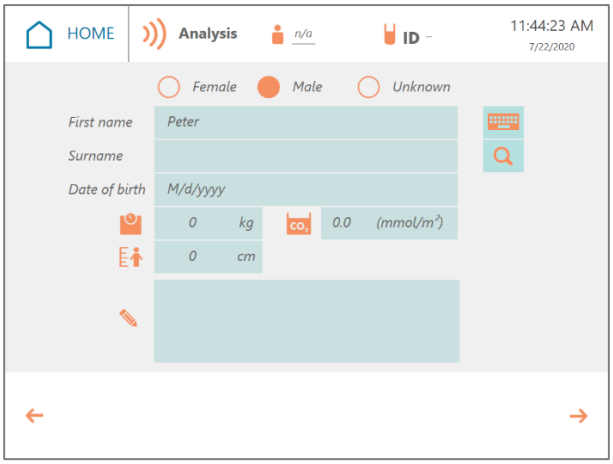
Analysis on Kibion® Dynamic performance:



By double-click on a free space, the registration of a planned analysis is initiated. Subsequently, the desired test type and the identification of the samples is specified:



After confirmation, additional information can be entered, if necessary, for e.g. for evaluating the measurement data.



Which information is mandatory depends on the test type and the associated settings.

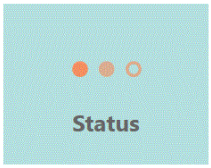
If the registration of the analysis is completed, further entries can be added to the list.

After completing the list, if no further analysis needs to be entered, start the analysis process by clicking the right arrow.

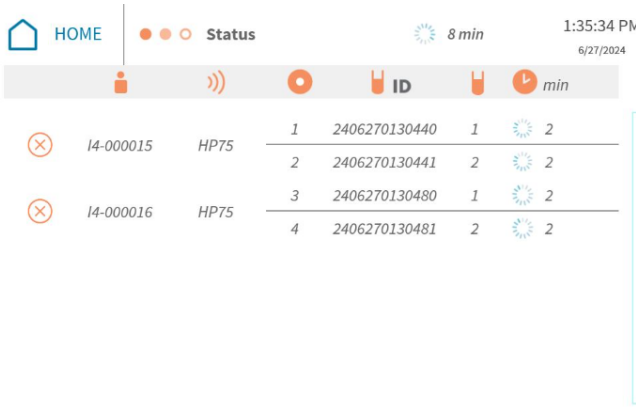
Samples that were not evaluated because of the low CO_2 concentration can be repeated after the entire analysis series has been completed. See 6.3.3

NOTE: It is very important to not disturb the device during the performance of the analysis. Use of USB key, printer, etc., is not recommended during the run. They can be used after the run is ended.

6.3.2. Status

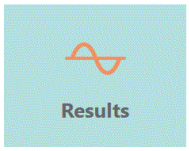


Under status it is possible to see the current running analysis.



A measurement in progress can be interrupted here at any time. Completion of a test series is indicated by a green tick.

6.3.3. Results



Qualitative test results of completed measurements can be consulted on this menu.

As depicted in the picture below, the qualitative test results contain the patient ID, the type of test carried out and the validated qualitative result in the column “Eva.”

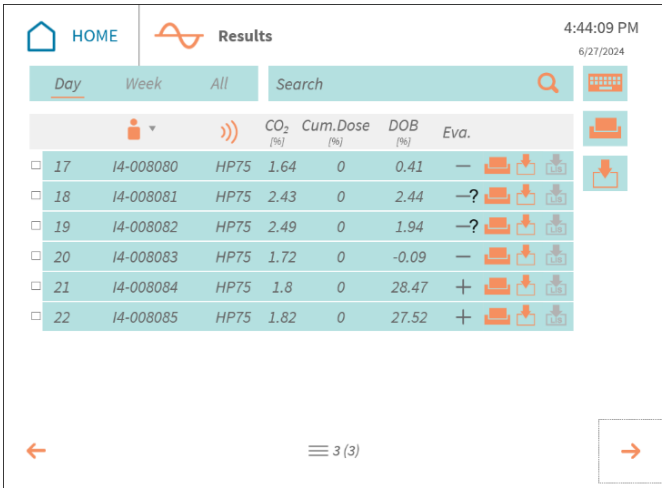
Qualitative results are assessed according to the protocols recorded in the system, for which negativity, positivity and grey zone thresholds have been set based on the associated urea breath test substrates.

Other data are provided and may be used to further assess the results, such as the:

- “CO_2[%]”: the percentage of CO_2 contained in the sample, which may give an indication of the conformity of sampling and/or the conformity of sample management during transport or storage. For example, this case may be highlighted by a question mark if a significant variation in the percentage of CO_2 between the two samples of a patient is observed;
- “DOB[‰]”: delta over base line which provides the difference between the results before and after ingestion of the substrate, and which is expected to be positive. A negative DOB result may therefore indicate an inversion of samples during the analysis.

The protocols recommended by the substrate suppliers are stored by default in the device by Kibion®. Any modification or new protocol creation could be done on request (kibion.service@mayoly.com) under the sole responsibility of the healthcare establishment, by defining internal conditions and/or thresholds.

These results, as well as those highlighted with a question mark, require the interpretation of the healthcare professional in the healthcare laboratory.



Interpretation aid:

Result	Conclusion
< Treshold Minimum	Negative
Treshold Min. <result< Treshold Max.	Grey Zone
> Treshold Maximum	Positive
-? or +?	To be confirmed
With very low DOB	To be retested

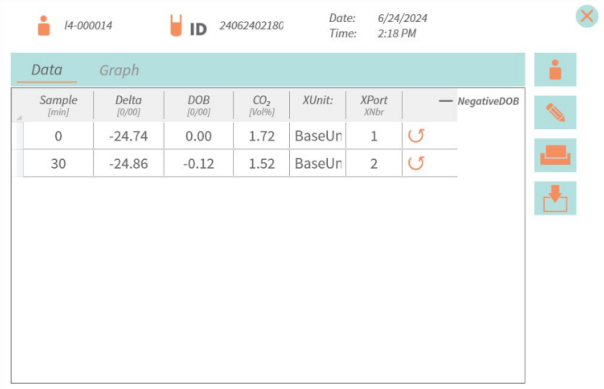
It is possible to filter the displayed list of results according to "Day", "Week" or "All".

A search for an ID or a test type can be done via the "Search" field. It is also possible to print and

export measurement results. The printout of daily reports is possible here. Day-specific time periods can be selected. Manual sending of result data records to a connected LIS is also possible in the result list.

Further details on individual analysis results can be displayed by selecting the corresponding result line.

Example:



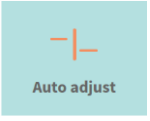
The result is displayed under the Data-tab as a list with numerical values of Delta, DOB and CO_2. Concentration, with the place used for the test (unit and position). Graphical display as a function of time is also possible via the Graph-tab.

A list of results (selected by tick or period) and the graph can be printed from here. It is also possible to export the list as a pdf or csv file to an external hard drive via the USB interface.

In case of doubtful or invalid analysis, this test can be repeated by the user using the second pair of samples.

In the graphical representation, the DOB values are plotted as a function of time.

6.3.4. Auto adjustments



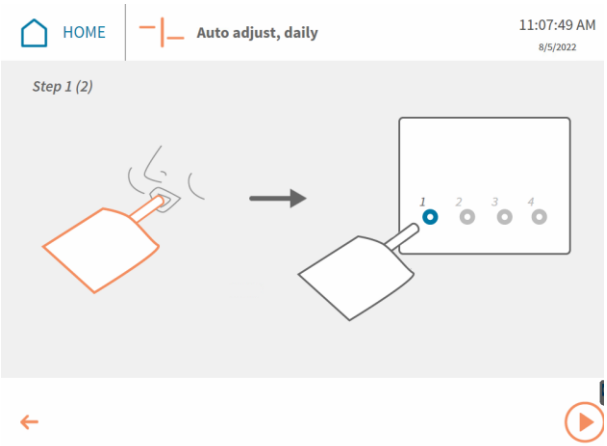
For correct measurement, the analyser must be subjected to regular auto adjustment and concentration adjustment measurements. Valid auto adjustment measurements must be available before samples are measured. Daily auto adjustment must be performed every working day before the first test. Weekly concentration adjustment shall be performed every 7 days.

If one of the auto adjustment measurements has not been performed or if the period has expired, a warning is displayed.

NOTE: The auto adjustments require breathing gas quantities that make the use of bags necessary. To enable the connection of breath bags to a Kibion® Dynamic base with needle connections, please use the bag adapter (Article no. 5810310kd).

Daily auto adjustment

The daily auto adjustment is an auto adjustment of the delta value. A valid monthly concentration adjustment is required for daily auto adjustment.



Execution:

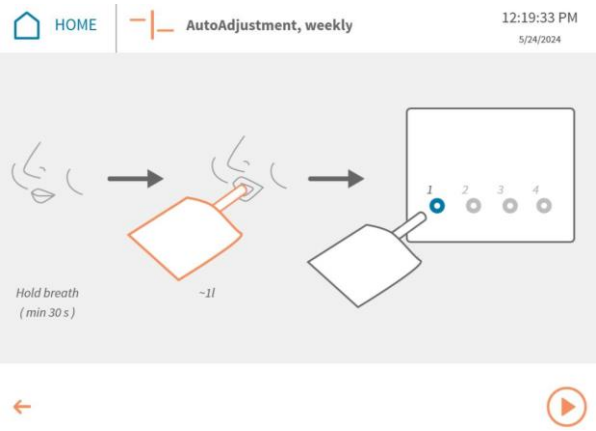
1. Press the "Daily" button.
2. Take a breath bag.
3. Take a deep breath and wait a short time.

4. Exhale into a breath bag and fill it (a single chamber or double chamber bag shell be used).
5. Connect the breath bag to the port that is set up for routine. By default, it is port 1 and can be changed in "User Interface".
6. Start the measurement with the arrow button.

The progress of the auto adjustment is displayed. A notification of the completion is given at the end of the measurement.

Weekly Concentration Adjustment

This weekly measurement takes into account the dependence of the delta value δ on the CO_2 concentration in the sample gas (see Appendix 1). The measuring chamber must be filled with breathing air with a high CO_2 concentration. During the measurement, the concentration is gradually reduced by supplying CO_2-free air and the dependence of the delta value $\delta(K_{CO2})$ on the CO_2 concentration is recorded.



Execution:

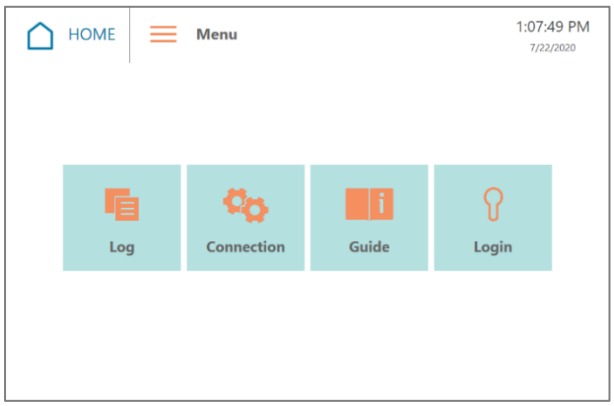
1. Press the "Weekly" button.
2. Hold your breath up to 30 seconds.
3. Exhale into a breath bag and fill it. A single chamber bag is needed to have sufficient volume.
4. Connect the breath bag to the port that is set up for the routine. By default, it is port 1.
5. Start the measurement with the arrow button.

The measurement takes about 35 minutes, and a progress bar is showing progress. The progress is also shown in the status bar at the bottom of the screen.

NOTE: After completing the concentration adjustment, examine the graph of the measured values. The graph shall have no jumps or peaks and should show a continuous course. If this is not the case, there may be a malfunction of the analyser. In such a case, contact your service technician.

6.4. Submenu

The submenu can be reached from the main menu, via MENU. This menu offers supporting options in daily work:



6.4.1. Protocol

The Kibion® Dynamic base logs various operational events, which can be viewed here and saved to an external hard drive via the export icon:

- System log
- Routine log
- Error log

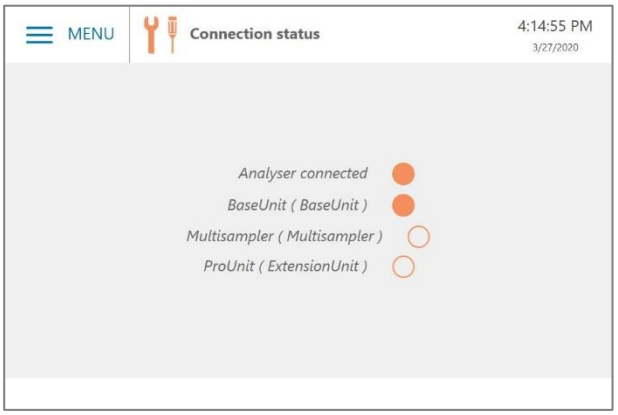
The system log contains the data of all logins and logouts at the Kibion® Dynamic base and logs the time stamp, username, and event.

In the auto adjustment log the completed monthly adjustment procedures are recorded with time stamp and username.

The error log is used to record irregular events that can be caused by errors in the device or software as well as errors in the breathing gas samples. The data logged here is used to find the cause of the errors.

6.4.2. Connection

This interface is used to check the existing connection status between the application software, and the essential components required for the analysis. In addition to the connection to the infrared analyser, the connection to the extension units is also displayed. A positive connection is represented by an orange dot and a negative one by a white circle. The status can be changed manually.



6.4.3. Instructions

Here you will find an instruction manual in electronic form.

6.4.4. Registration for the additional menu

Via "Registration" you can access areas which are subject to restrictions. The access rights are defined according to the role. A distinction is made between the following roles:

- Operator
- Researcher
- Supervisor
- Service
- Manufacturer

A login with password is required for access.

7. Error Messages

In case of malfunction, please contact your local distributor or service technician for assistance.

Assistance by remote control is possible. It shall only be used by trained, qualified and authorized person. To allow the access by remote it is necessary to access the Windows® system. It shall be done only for this purpose.

Below is the list of error messages, notifications, and service messages that may appear on the screen, along with descriptions and actions to be taken.

Error	Description and Action
Temperature too low. Continuation is automatic.	- The system is not yet at operating temperature. If this temperature is reached, it will continue automatically. - If the message is still visible after more than one hour, please contact your local representative.
No connection to the internal IO-Board possible.	- This can be caused by changes to the Windows network adapter settings. Please ensure nothing has been changed. - Restart the system and wait at least 10 minutes before you log in again - If the message still appears, please contact your local representative.
No connection to the external IO-Board possible.	- Check the power supply of the extension unit/performance. - Check the network cable between the base, extension unit or performance - This can be caused by changes to the Windows network adapter settings. Please ensure nothing has been changed. - Restart the system and wait at least 10 minutes before logging in again. - If the message continues to appear, please contact your local representative.
No connection to the analyser possible.	- This can be caused by changes to the Windows network adapter settings. Please ensure nothing has been changed. - Restart the system and wait at least 10 minutes before logging in again. - If the message continues to appear, please contact the responsible representative.
Self-test is faulty.	- Restart the system and wait at least 10 minutes before logging in again. - If the message continues to appear, please contact the responsible representative.
The device is not auto adjusted. Are you sure you want to continue?	- The daily auto adjustment and/or the concentration adjustment is not valid anymore. - Check the routine status in the lower right corner of the screen and perform the requested measurement.

Sample Flushing– Time out	- Restart the system and wait at least 10 minutes before logging back in. - If the message continues to appear, please contact your representative.
Low CO2	- Is the sample properly connected? - If a certain number of samples (single-digit percentage range) are taken, this can unfortunately not be ruled out and is due to the sampling process. - The message can be configured in the "User Interface". - If the message appears with too many samples, a defect may be present, please contact your representative.
Passwords not identical. Please repeat.	- First password and second password do not match.
Password must be at least 5 characters long.	- Entered password is too short.
Device service is necessary.	- The service interval is stored in the instrument settings. - Please contact the responsible representative or the company Kibion.
Filter exchange necessary.	- The filter change interval is stored in the device settings. - Please contact the responsible representative or the company Kibion.
No connection to pro or performance possible?	- Is the Kibion® Dynamic base connected via LAN cable to pro or performance unit? - Are the units switched on? - Have the network settings been changed? - Connect the unit manually under "Connection" or check the status. - If the message still appears, please contact the responsible representative.
Initialization of the performance unit failed	- Is the Kibion® Dynamic performance switched on? - Restart the devices. - Check the connections between the devices. - Have the network settings been changed? - If the message still appears, please contact the responsible representative.

8. Maintenance

8.1. Cleaning

The Kibion® Dynamic components must be cleaned from the outside with a dry cloth.

The housing and the sample connections can be disinfected with a wet cleaning cloth (70% ethanol). Sprays must not be used.

Disinfectants used on the instruments must not contain ammonia or acetone.

8.2. Filter change

The filter element shall be changed once a year.

9. Accessories

The operation of the Kibion® Dynamic System requires further accessories to take breathing gas samples and to feed them into the analyser.

9.1. Breathbag

9.1.1. Intended use

The Breathbag is a non-automated device intended for the manual collection of breath specimen from lay persons under the supervision of healthcare professionals in a clinical or laboratory environments, in order to contain 13C and 12C-labelled CO2. The Breathbag is a device of the Kibion® Dynamic System that is intended, with a non-invasive 13C Urea Breath Test (13C UBT), for the qualitative detection of *Helicobacter pylori* causing infections in the gastrointestinal tract (stomach and duodenum).

The Breathbag is a single use consumable intended to be used with the Mouthpiece [Kibion GmbH - REF: 8007 / Catalogue n°: 0K50503].

There are two versions of breath bag:

9.1.2. Double chamber-breathbag

Article No. 8005

Volume: 2x 100 ml
Size: 200 mm x 170 mm
Connection: Hose

It is to be used for single use and disposed of as packaging waste.

9.1.3. Single chamber-breathbag

Article No. 8004

This breath bag must be used for the daily and weekly routine measurements.

Volume: 1,3 L
Size: 300 mm x 150 mm
Connection: Hose

It is to be used for single use and disposed of as packaging waste.

9.2. Mouthpiece

Article No. 8007

9.2.1. Intended use

The Mouthpiece is to be used with Breathbag for sampling of breath test samples for analysis by Kibion Dynamic and IRIS analysers and under the supervision of trained medical staff.

9.2.2. Description

The mouthpiece contains a unidirectional valve so that air can only flow in one direction. It is for single use only.

After use it must be disposed of as packaging waste (material PE, hygienically single packed).

9.3. Bag adapter

Article Nr. 5810310kd

9.3.1. Intended use

The bag adapter is used to attach a breath bag to a Kibion® Dynamic base with needle connections for daily auto adjustment and monthly concentration adjustment.

9.3.2. Description

The bag adapter consists of two metal parts screwed into each other, into which a so-called septum made of rubber is clamped. The septum forms the tight connection with the needle connection of the device.

9.3.3. Use

The septum end of the adapter is placed on the needle connection so that the needle penetrates the septum and a connection sealed against ambient air is created. It is important to note that the mark (see arrow in the figure) is approximately at the level of the front plate.

A bag can then be placed on the free end of the adapter and used as a sample reservoir for the analyser.

9.3.4. Maintenance

The septum is a disposable product. It must be replaced after use. To replace it, unscrew the metal parts and replace the septum.

9.3.5. Disinfection

The adapter can be cleaned and disinfected with a damp cloth (70% ethanol).

9.4. Other specimen receptacles

The Kibion® Dynamic System may be operated with additional specimen receptacles, most notably tubes specifically designed for Urea Breath Tests.

9.4.1. Validated tubes

The following collection tubes have been validated for use with the Kibion® Dynamic System:

- Labco Exetainer® Breath Vials

Body Diameter	15,25 + 0,15 mm
Vial Height - vial Only	96,75 + 0,50mm
Vial Height - with Cap*	~ 101,00 ° 0,50 mm
Normal Capacity	~ 12 ml

- BD VACUTAINER® for Mayoly Spindler

Body Diameter	16 mm
Vial Height - vial Only	100 mm
Normal Capacity	~ 12 ml

9.4.2. Tube compatibilities

Additionally, the following tube dimensions are compatible with the needle devices:

Total length	80 - 110 mm
Diameter	14,5 - 16,5 mm
Diameter cap	12 - 22 mm
Height of tube cap	4 - 30 mm
Septum thickness	0 - 20 mm

Note: Kibion GmbH is not liable for the use of specimen receptacles not validated with the Kibion® Dynamic System. Validation of assays including other specimen receptacles fall under the responsibility of the user.

A.1 Appendix

Measuring principle

For the analysis of the sample gas, filtered infrared radiation is shining through the filled measuring chamber. By recording the $^{12}CO_2$ and $^{13}CO_2$ absorption spectra by means of an infrared detector, statements can be made about the $^{12}CO_2/^{13}CO_2$ ratio.

The quotient of the $^{12}CO_2$ and $^{13}CO_2$ concentrations in a mixture of both gases leads to non-linearities of the characteristic curves of the individual components. The measured absorption spectra are influenced by the total concentration of CO_2 in the measuring chamber. This dependence (also called cross-dependence) must be taken into account when measuring δ. Which is why it is regularly recorded as a measurement curve for a so-called concentration adjustment.

Measured values

a) Isotope ratio (R)

$$R = \frac{^{13}C}{^{12}C}$$

b) Delta (δ) [‰]

$$\delta = (\frac{R}{R_{PDB}} - 1) \cdot 1000$$

R_{PDB} is the international PDB standard. The value was obtained from a calcium carbonate of a fossil belemnitella from the Pee Dee Formation in South Carolina:

R_{PDB} = 0,01123686 MF_{PDB} = 0,011112 δ = ±0 ‰

Natural values for R of living organisms depend, among other things, on diet. A variation in the average R value in humans by region can thus be determined:

Europeans:	R = 0,0109537	MF = 0,010835	δ = −25,5 ‰
Americans:	R = 0,01102	MF = 0,0109	δ = −19,3 ‰

c) Delta over base line (DOB) [‰]

$$DOB = \delta_t - \delta_0$$

δ_0: δ before ingestion of the test meal (base line)
δ_t: δ at time t after ingestion of the test meal.

Since the absolute value for delta is not required for diagnostics, but the relative values DOB, no calibration against a calibration gas is performed with the Kibion® Dynamic base. Instead, an ordinary breath sample is taken, and this is equated with a standard value. This adjustment is made during the daily auto adjustment.

Concentration adjustment

To be able to take into account the cross-dependence of the concentrations of $^{12}CO_2$ and $^{13}CO_2$ in the measured values, an adjustment measurement is carried out. This measurement, which must be carried out monthly, is necessary because the value δ depends on the CO_2 concentration (K) in the sample.

To determine the δ(K) ratio, a large bag of breathing air with a high CO_2 concentration is connected. The CO_2 concentration must be higher than 3.5 vol%. The process starts by flushing the measuring chamber with CO_2-free air. Breathing air is then pumped from the bag into the measurement chamber until the target of 3.5 vol% is reached. The valves close and the measurement begins. Starting at high vol% of CO_2, CO_2 -free air is now added in small steps and the δ is determined as a function of the $^{12}CO_2$ concentration (K). The result is a measurement series $\delta_n(K_n)$, which can be plotted as a graph.

The differences between δ_n and the defined standard value -26 ‰, corresponding to an ordinary breath sample, determines the correction term as a function of the concentration K_n.

$$\delta_m = \delta_n - 26$$

The corrected measurement series $\delta_m(K_m)$ is recorded for the adjustment of δ in the subsequent sample measurement.

Daily auto adjustment

A regular auto adjustment to the value δ = -26 ‰ for an ordinary breath sample is carried out by the daily auto adjustment measurement. Any deviation from the values measured in the concentration adjustment is determined and used as a further correction factor in the calculation of δ:

$$\delta = \delta_{Measure} + \delta_m + \delta_d$$

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