Instruction for Use

Kibion® Dynamic

Kibion® Dynamic Base
Article. No 8031

Kibion® Dynamic Pro
Article. No 8032
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PLEASE NOTE

To preserve the protection afforded by the equipment, please read this Instruction for use prior to any handling of the equipment.

If the equipment is used in a manner not specified in this Instruction for use, the protection provided by the equipment may be impaired.

This Instruction for Use is valid for Kibion Dynamic Base and Pro running software version 1.5.0.4.

PRODUCT

Kibion® Dynamic Base
Article No. 8031

Kibion® Dynamic Pro
Article No. 8032

MANUFACTURER

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1. SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="before" alt="CE" /></td>
<td>Conformite Europeenne</td>
</tr>
<tr>
<td><img src="before" alt="i" /></td>
<td>Read the instructions for use</td>
</tr>
<tr>
<td><img src="before" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="before" alt="Warning" /></td>
<td>Warning</td>
</tr>
<tr>
<td><img src="before" alt="Disposal" /></td>
<td>Disposed as electronical waste</td>
</tr>
</tbody>
</table>
2. PRODUCT DESCRIPTION

2.1 Intended use and intended user

Kibion Dynamic is an InfraRed ISotop Analyser for $^{13}\text{C} \text{O}_2$ in breath test samples. (Infrarot Isotopen Analysator für $^{13}\text{C} \text{Atemgasanalyse}$).

Kibion Dynamic devices are used for measurement and comparison of the isotope ratio $^{13}\text{C} \text{O}_2/^{12}\text{C} \text{O}_2$ in breath test samples for In vitro diagnostic purposes.

Kibion Dynamic devices are intended to be used by trained staff, mostly in hospital and or laboratory environment.

2.2 Classification

Kibion Dynamic Base and Pro are classified as general/other In Vitro Diagnostic medical devices and CE-marked according to the European In Vitro Diagnostic medical device directive 98/79 EC.

2.3 Components

<table>
<thead>
<tr>
<th>Kibion Dynamic Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Power cable</td>
</tr>
<tr>
<td>• Instruction for use</td>
</tr>
<tr>
<td>Kibion Dynamic Pro</td>
</tr>
<tr>
<td>• Power cable</td>
</tr>
<tr>
<td>• Tube</td>
</tr>
<tr>
<td>• Ethernet cable</td>
</tr>
</tbody>
</table>

2.4 Accessories

<table>
<thead>
<tr>
<th>Article</th>
<th>Article No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Double Breathbag, 2x 0.1L volume, 200 mm x 170 mm, with connecting hose, for single use, disposal as packaging garbage.</td>
<td>8005</td>
</tr>
<tr>
<td>Single Breathbag, 1.3 L volume, 300 mm x 150 mm, with connecting hose, for single use, disposal as packaging garbage.</td>
<td>8004</td>
</tr>
<tr>
<td>MouthPiece with one-way valve as hygiene barrier for single use (material PE, hygienically packed), disposal as a packaging garbage.</td>
<td>8007</td>
</tr>
<tr>
<td>Glas vials for breath samples with fixed cap (up to 17 mm in diameter with at least 10 mL volume). Supplied in the Diabact® UBT kit</td>
<td>Not supplied separately</td>
</tr>
<tr>
<td>Fuses, T2AH250VAC, IEEC/EN60127-2/5, 5*20mm</td>
<td>Not supplied by Kibion</td>
</tr>
</tbody>
</table>
3. PRINCIPLES OF OPERATION

Kibion Dynamic is using non-dispersive IR-spectroscopy (NDIR) a broad-band light source and acoustic-optical detectors which are sensitive only to those wavelengths at which the gases to be measured are IR-absorbing. With two such detectors, individually sensitive to the absorption spectra for $^{12}\text{CO}_2$ and $^{13}\text{CO}_2$, the concentrations of these two gas components to be related to each other for $^{13}\text{C}/^{12}\text{C}$-isotope ratio determination are measured. The IR-absorption spectra of the asymmetrical stretch oscillation modes of both the $^{13}\text{CO}_2$ and $^{12}\text{CO}_2$-molecules are separated almost completely. The concentrations of $^{13}\text{CO}_2$ in breath gas are in the range of 50 to 500 ppm, where $^{12}\text{CO}_2$ accordingly is at concentrations of 0,5 to 4,5 Vol.%. Within that device, every measurement of the gas components IR-absorption is related to a full energy measurement of the IR-light source, available by a reference gas cell filled with a non-IR-absorbing gas.

4. KIBION DYNAMIC SOFTWARE

Kibion Dynamic Software is based on WINDOWS operating systems and provides routines for calibrations, for sample definitions and measurement control. The database provides standardized procedures for breath and records for patient data and test results.

5. USER INFORMATION

5.1 Safety and precautions

Kibion Dynamic must only be used with Kibion Breathbag or glass vial.

Protective gloves should be used while handling human samples.

Do not disassemble or alter any part of the unit.

Do not place anything on the top of the Kibion Dynamic devices.

Installation must be conducted by Kibion or by trained staff from the local distributor.

Kibion Dynamic devices must be placed and installed on a stable surface without any vibrations.

Kibion Dynamic devices must be handled with care and do not expose to any shocks or outer damage.

Service and repair must only be conducted by Kibion or by trained staff from the local distributor.

Do not use disinfections containing ammonia or acetone.

The filtermaterial in the Kibion Dynamic Base filter contain sodalime which should be handled as a corrosive chemical. Please, contact you local distributor or Kibion in case of any filter damage or leakage of LiOH.

The device should not be used in the presence of explosive gases, flammable, anesthetic gases mixed with air, oxygen or nitrous oxide.
Do not use the device in proximity to sources of strong electromagnetic radiation as these may interfere with the proper operation.

5.2 General use and disinfection
The device is intended for the exclusive use with breath test samples.
The outer casing of the device can be cleaned using a dry cloth.
Disinfection of the outer casing and sample ports can be done using a cloth wetted in 70 % ethanol. Do NOT spray ethanol on the device.
After mains failure, the device can be disturbed in function. To overcome this, restart the device and wait 12 hours till temperature stability is assured.

5.3 Moving and transport
Turn off and unplug the device.
Any moving of the device must be done in horizontal position.
Handle the device with care and avoid any shocks.
If the device must be transported contact you local distributor for information.
Re-installation of moved or transported device should be performed according to installation instruction (see chapter 5).

6. INSTALLATION

NOTE:
Kibion Dynamic devices should be installed for stationary use.
Ensure the power plug is accessible for disconnection in case of emergency.
Kibion Dynamic devices should be operated at laboratory indoor conditions (temp 15-25 °C, humidity < 70% rH).

6.1 Installation of Kibion Dynamic Base
a) Kibion Dynamic Base should be placed on a solid and stable table or rack on an even surface to avoid any vibrations or disturbance. The devices must be placed so that there is at least 20 cm space around the device to assure enough air circulation and to avoid overheating.

b) Connect the device to a grounded power supply using the supplied power cable.

6.2 Installation of Kibion Dynamic Pro
c) Kibion Dynamic Pro should be placed on a solid and stable table or rack on an even surface to avoid any vibrations or disturbance.

d) Place the Kibion Dynamic Pro within 50 cm distance to the Kibion Dynamic Base.
e) Connect the device to a grounded power using the supplied power cable.

f) Connect the gas tube to the connector on the backside of the Kibion Dynamic Pro.

g) Connect to the middle tube connector on the Kibion Dynamic Base.

h) Connect the delivered network cable to the Ethernet port on the Kibion Dynamic Pro and the Ethernet port next to the center of the Kibion Dynamic Base.

7. WARMING UP – TARGET TEMPERATURE

Turn on the device and keep it ON for at least 12 hours for warming up and reach constant target temperature.

**NOTE:**
Target temperature must be reached to ensure measurement specifications. To preserve the reached target temperature the Kibion Dynamic devices should be kept ON when it is in routine use.

8. INITIAL OPERATION

8.1 Interfaces

Kibion Dynamic Base has two USB ports for multiple usages. HID-Devices can be connected if they are plug & play compatible to Windows 7. Printers can be connected directly to the device.

Kibion Dynamic Base has two RJ-45 connectors for connection to local LIS-systems. Please contact your local distributor for assistance.

Kibion Dynamic Pro has one Ethernet connector for communication with the Base unit and one connector for gas connection to the Base unit.
8.2 Operation overview

Kibion Dynamic is easily operated from a touch screen. User inputs are added using a keyboard, screens can be printed and shown content exported to an USB-stick directly by touching buttons with symbols on the screen.

Key-board

Open the key-board by pressing the key-board button.

Print.

Print the viewed screens by pressing the printer button.

Export

Export data to a connected USB-stick by pressing the export button.

Restart

Restart the device by pressing the restart button.

Switch

Switch OFF by pressing the switch button.

8.3 Log-In

Switch ON

A log-in view appear.

Default user name is “Max Mustermann”

Enter the password “1234567”.

Press the arrow symbol for next step

The main menu view appears from where all main functions are accessed.
Fig. 1 Log-in view

Fig. 2 The main menu view from where all main functions are accessed.
9. MEASUREMENT

9.1 Calibration

The device must be regularly calibrated for correct measurement function. A valid calibration must exist before a test can be started. If the calibration has not been performed accordingly the measurement will be rejected and the device shows an error message for missing calibration.

There are two types of required calibrations, daily and monthly calibration. The daily calibration must be performed every day prior the first test of the day. The monthly calibration should be performed every 30 days.

9.2 Perform calibration

Press the Calibration button in the main menu.

The calibration view appears.

Fig. 3 Calibration view from where the calibration is operated.

Daily calibration

1. Press the Daily calibration button.
2. The view shows a guide for how to perform daily calibration (Fig. 4).
3. Exhale into a Breathbag and fill it with “normal” breath air (single or double bags works for this purpose).
4. Connect the Breathbag to Sample Port 1 (on the left side).
5. Press the arrow to start the daily calibration.
A progress bar shows the calibration progress (Fig. 5) “Calibration successful” is shown when the calibration is completed (Fig. 6).

Fig. 4. The view for daily calibration guides you how to take a sample and connect the BreathBag.

Fig. 5. The calibration progress is shown.
Fig. 6. Calibration successful is shown when the calibration is completed.

**Monthly Calibration**

1. Press the Monthly calibration button.
2. The view shows a guide for how to perform a monthly calibration (Fig 7).
3. Hold your breath for at least 30 seconds.
4. Exhale into a 1L single Breathbag and fill the bag with “normal” breath air.
5. Connect the Breathbag to Sample Port 1 (on the left side).
6. Press the arrow to start the monthly calibration.

The calibration takes about 35 minutes and a progress bar shows the calibration progress (similar as in Fig. 5)

“Calibration successful” is shown when the calibration is completed (Fig.6)
9.3 Measuring samples

Select and press the “Analysis"button in the main menu.

The analysis set-up view appears (Fig 8).

1. Type patient name or identity using the key-board on the screen or scan the identity using a bar code reader connected via USB to the Base-unit.
2. Enter the patient ID (optionally).
3. Select the defined test types from a drop-down menu.
4. Select whether to run the analysis on the Base unit or the Extension Unit (Pro).
5. Press the arrow to the right to continue.

The patient set-up view appears (Fig 9).

6. Enter specific patient data for the internal database (if applicable, not mandatory).
   
   **NOTE:** All fields are optional.

7. Press the right arrow to continue.
Fig. 8. The view for analysis set-up.

Fig. 9. Patient set-up view.
A view appears showing which sample ports the breath bags or glass vials should be connected to. Depending on which unit is selected, Base or Extension unit (Pro), the connection looks different (Fig 10 and Fig 11).

**NOTE:**
Glass vials with a fixed cap can only be used on Kibion Dynamic equipped and with needles. For connection, the glass vial should be pushed upon the needle until the end of the duct.

8. Connect the samples according to the instruction in the view.
9. Press the arrow to the right to start the measurement.

Additional tests can be added during the ongoing measurement by setting-up tests for analysis as described above.
If you are using the Extension unit (Pro) press the + to open the analysis main menu for adding more tests.

Fig. 10. View showing the sample connection to the Base unit.
Fig. 11. View showing the sample connection to the Extension unit. The + is used for adding more tests.

A view showing the progress of the measurement appears (Fig. 12).

Fig. 12. The view of measurement progress.

The measurement can be stopped anytime by pressing the “Cancel” button. Please choose in the pop-up window by clicking “Retry” to start the same sample again or “OK” to go on with the next sample.
9.4 Results

1. Press the “Result” button in the main menu to view the results from the analysis (Fig 1).

2. The results can be filtered by selected by pressing Day”, “Week” or “All”.

3. Search for an ID or Test-Type can be done by the “search” symbol in the upper right corner.

4. Press the” Print” symbol for printing the results at the connected printer.

5. Individual detailed result can be shown by pressing on a selected result row.

![Result view](image)

Fig. 14 Result view. Filter the result by Day, Week, All all or Search for a specific result.
Fig. 15. Graphic view of a selected result.

8. Press on a row in the result list to view detailed results from the selected test.
9. The result from a selected test can be shown either as listed DOB value by pressing Data or as a graph by pressing Graph.
10. Press the “Print” symbol to print the selected result on the connected printer.
11. Press the “Export” symbol to export data to as a pdf.file.

10. SAMPLE COLLECTION FOR MEASUREMENT

Breath test samples can be collected using breathbags or glass vials. Breathbags are supplied as 0,1 L double bags 1,3 L single bags (see 2.4). Glass vials are currently only provided with the Diabact® UBT kit.

10.1 Breathbag sample collection
1. Ensure the BreathBag is completely empty and do not have any air inside.
2. Remove the blue stopper cap from the BreathBag hose and connect a MouthPiece to the hose.
3. Exhale into the Mouthpiece and fill the Breathbag with breath air.
4. Remove the Mouthpiece and plug in the blue stopper cap in the hose or connect the Breathbag to the sample port for measurement.

NOTE:
Handle sampled breathbags and vials with care and avoid any damage which may cause leakage.
10.2 Glass vial sample collection

Perform the breath sampling according to the instruction provided with the kit.

11. TROUBLESHOOTING

In case of any malfunction of Kibion Dynamic devices, please contact your local distributor for support.

In case of a power failure please, make sure that Kibion Dynamic has been warmed up for at least 12 hours before use. Follow the information stated in the chapter 7, “Warming up”.

11.1 Error messages

<table>
<thead>
<tr>
<th>Errors</th>
<th>Description and actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature too low, continues automatically</td>
<td>• Wait until the system continues automatically.</td>
</tr>
<tr>
<td></td>
<td>• If the message is still on the screen after one hour or more please contact your local distributor.</td>
</tr>
<tr>
<td>No connection to internal IOBoard</td>
<td>• Ask for changes at the network adapter-settings.</td>
</tr>
<tr>
<td></td>
<td>• Restart the complete system and wait at least 10 minutes without touching it.</td>
</tr>
<tr>
<td></td>
<td>• If the message still appears please contact your local distributor.</td>
</tr>
<tr>
<td>No connection to external IOBoard</td>
<td>• Check the power cord and that the Pro-unit is switched on</td>
</tr>
<tr>
<td></td>
<td>• Check the network-cable connection between Base- and Pro-unit.</td>
</tr>
<tr>
<td></td>
<td>• Ask for changes at the network adapter-settings.</td>
</tr>
<tr>
<td></td>
<td>• Restart the complete system and wait at least 10 minutes without touching it.</td>
</tr>
<tr>
<td></td>
<td>• If the message still appears please contact your local distributor.</td>
</tr>
<tr>
<td>Connection to analyser lost</td>
<td>• Ask for changes at the network adapter-settings.</td>
</tr>
<tr>
<td></td>
<td>• Restart the complete system and wait at least 10 minutes without touching it.</td>
</tr>
<tr>
<td></td>
<td>• If the message still appears please contact your local distributor.</td>
</tr>
<tr>
<td>Self test failed</td>
<td>• Restart the complete system and wait at least 10 minutes without touching it.</td>
</tr>
<tr>
<td></td>
<td>• If the message still appears please contact your local distributor.</td>
</tr>
<tr>
<td>The device is not calibrated. Are you sure you want to continue?</td>
<td>• No valid calibration exists.</td>
</tr>
<tr>
<td></td>
<td>• Check the calibration status displayed at the menu-screen in the lower right corner and perform the required calibration.</td>
</tr>
<tr>
<td>Sample flushing timeout</td>
<td>• Restart the complete system and wait at least 10 minutes without touching it.</td>
</tr>
</tbody>
</table>
12. SERVICE AND MAINTENANCE

Kibion recommend to perform service with an interval of 12 months to ensure safe use and flawless function of the Kibion Dynamic devices. The service must only be carried out by a Kibion service technician or by certified service technician authorized by Kibion.

Life time of the Kibion Dynamic devices are 10 years.

13. TECHNICAL INFORMATION

13.1 Analytic data

<table>
<thead>
<tr>
<th></th>
<th>Kibion Dynamic Base</th>
<th>Kibion Dynamic Pro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproducibility</td>
<td>&lt;0,5‰</td>
<td>&lt;0,5‰</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td></td>
<td>(standard deviation)</td>
</tr>
<tr>
<td>URA profiler</td>
<td>URA Smallest</td>
<td>N/A</td>
</tr>
<tr>
<td>Sample measurement</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>(min/sample)</td>
<td></td>
<td>(min/sample)</td>
</tr>
<tr>
<td>Sample ports</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Stability</td>
<td>&lt;0,5‰</td>
<td>&lt;0,5‰</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td></td>
<td>(standard deviation)</td>
</tr>
</tbody>
</table>
13.2 Technical data

<table>
<thead>
<tr>
<th></th>
<th>Kibion Dynamic Base</th>
<th>Kibion Dynamic Pro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width * Height * Depth</td>
<td>280 * 320 * 380 (mm)</td>
<td>500 * 320 * 380 (mm)</td>
</tr>
<tr>
<td>Weight</td>
<td>13 (kg)</td>
<td>11.5 (kg)</td>
</tr>
<tr>
<td>Electrical connections</td>
<td>100-120/200-240 (VAC) 50-60 (Hz)</td>
<td>100-120/200-240 (VAC) 50-60 (Hz)</td>
</tr>
<tr>
<td>Power consumption</td>
<td>0.12(kW)</td>
<td>0.12(kW)</td>
</tr>
<tr>
<td>Mains switch with two fuses</td>
<td>2 x 2 A</td>
<td>2 x 2 A</td>
</tr>
<tr>
<td>Gas connections</td>
<td>1 gas connection</td>
<td>1 gas connection</td>
</tr>
<tr>
<td>Data transfer</td>
<td>2 RJ-45, 2 USB</td>
<td>1 RJ-45</td>
</tr>
</tbody>
</table>

13.3 Environmental working and storage conditions

The Kibion Dynamic devices are intended to be used in normal indoor laboratory environment (see below). Storage and transport conditions are the same as working conditions, although higher or lower temperature (+5 °C - 50 °C) for a shorter time period may not affect the devices. Please contact your local distributor or Kibion for guidance.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>+ 15 °C to + 35 °C</td>
</tr>
<tr>
<td>Humidity</td>
<td>&lt;70 % rH</td>
</tr>
</tbody>
</table>

14 DISPOSAL

The Kibion Dynamic devices should be disposed as electrical and electronical waste in accordance with the WEEE directive and/or applicable national or local policies relating to obsolete electronic equipment.
ADDENDUM

15.1 „Delta“ and “DOB” – value; definition and comments

The „Delta“-value of a breath sample $R_S$ describes the $^{13}$C/$^{12}$C-ratio at the carbon dioxide of the particular breath sample in relation to the $^{13}$C/$^{12}$C-isotope ratio of the world wide accepted carbon isotope standard X „PD-Belemnite“ (PDB) - carbonate material with its $^{13}$C/$^{12}$C-ratio stated as $R_{PDB} = 0,0112372$ .

$\Delta$ = (( $R_S$ / $R_{PDB}$ ) - 1) x 1000 ( ‰) “Delta per mille”

The “Delta Over Base”- value = “DOB”-value describes the change of the „Delta“-value at the $CO_2$ of the breath gas, which at a certain time after the ingestion of a $^{13}$C-labelled substrate will develop, related to that $Basal-Delta$-value, which was measured at the individuals breath prior to the ingestion of the $^{13}$C-labelled substrate.

Basal-Delta-values at the $CO_2$ in human breath worldwide are between -28.0 and -23.0 Delta per mille. In essence, these $^{13}$C/$^{12}$C-ratios are by 28.0 to 23.0 per mille lower than the $^{13}$C/$^{12}$C-ratio of the PDB-carbon isotope standard.

$DOB$ = $\Delta_{sample} - \Delta_{basal}$

15.2 Evaluation and explanation of data

A test should not be evaluated if the sign “too low CO2” is shown in the result window.

Values shown in the database should be plausible, discard the particular test otherwise.

Plausible values:

In case of implausible values, the correct placement of samples to the connectors should be checked.
16 CUSTOMER SUPPORT AND CONTACT INFORMATION

Please contact your local distributor or Kibion for any support.

Local Distributor contact details (if applicable)

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