

Instruction for Use

IRIS Dynamic



Base unit and the extension unit Pro
REF 8031 **REF** 8032



TABLE OF CONTENTS

1. INSTALLATION..... 3

2. PREFACE..... 4

2.1 INTENDED USE AND CLASSIFICATION 4

2.2 INFORMATION CONCERNING GENERAL USE, CAUTION, DISINFECTION..... 4

2.3 SCOPE OF SUPPLY 4

2.4 ACCESSORIES 5

2.5 MOVING 5

3. INITIAL OPERATION 6

3.1 INTERFACES 6

3.2 OPERATION/HANDLING 6

4. MEASUREMENT 7

4.1 CALIBRATIONS..... 7

4.2 MEASURING SAMPLES 11

4.3 RESULTS 14

5. SAMPLE COLLECTION 15

6. TROUBLESHOOTING..... 15

7. SERVICE AND MAINTENANCE 15

8. DISPOSAL..... 15

9. TECHNICAL INFORMATION 16

9.1 ANALYTIC DATA 16

9.2 TECHNICAL DATA 16

9.3 ENVIRONMENTAL WORKING CONDITIONS (LABORATORY CONDITIONS) 16

10. ADDENDUM 17

10.1 „DELTA“ AND “DOB” – VALUE; DEFINITION AND COMMENTS:..... 17

10.2 EVALUATION OF DATA AND EXPLANATION 17

11. CONTACT DETAILS 18



PLEASE NOTE:

- **In order to preserve the protection afforded by the equipment, please read this IfU prior to any handling of the equipment.**
- **If the equipment is used in a manner not specified in this IfU, the protection provided by the equipment may be impaired.**

1. INSTALLATION

- The IRIS Dynamic must be placed on stable and even surface.
- Connect the IRIS Dynamic with the delivered power cable to a grounded power supply.
- The power plug must be accessible to disconnect power in a case of emergency.
- The IRIS Dynamic must not be covered to assure circulation of fresh air around the instrument. To assure this a space of 20 cm should be left to all sides, the back and top of the instrument.
- IRIS should be operated under laboratory conditions - see details in „Technical information“.
- Protect the unit against vibration during calibration and measurement by placing the IRIS Dynamic on a solid table or rack in an area where no disturbances occur.
- IRIS must be used stationary.
- Only applicable for the IRIS Dynamic pro:
 - Place the IRIS Dynamic pro within 50 cm distance to the IRIS Dynamic base.
 - Connect the IRIS Dynamic pro with the delivered power cable to a grounded power supply.
 - The power plug must be accessible to disconnect power in a case of emergency.
 - Connect the gas tube to the connector on the backside of the IRIS Dynamic pro. Connect it then to the middle tube connector on the IRIS Dynamic base.
 - Connect the delivered network cable to the Ethernet port on the IRIS Dynamic pro and the Ethernet port next to the center of the IRIS Dynamic base.

WARM-UP PHASE

After turning on the power supply, the system needs at least 12 hours before it has reached a constant temperature.

PLEASE NOTE

The Iris device **may not** be switched off after the "warm-up phase" any more, when in routine use.

The specifications can be reached only if the device has reached the final temperature.

Doc. Title; Instruction for Use	Doc. No; Br-328/09	Date; 2016-01	Page 3(18)
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2. PREFACE

2.1 Intended use and classification

IRIS is an InfraRed ISotop Analyser for ^{13}C breath gas. (Infrarot Isotopen Analysator für ^{13}C Atemgasanalyse).

IRIS is used for comparison of the isotope ratio $^{13}\text{C}/^{12}\text{C}$ in breath samples for IVD-purposes.

Intended user

The device is used by trained staff, mostly in hospital and or laboratory environment.

Classification

The device is classified according to the Medical Devices **Directive on in vitro diagnostic medical devices** (MDD 98/79/EC) as “IVD-other” type.

IRIS Dynamic Pro (if applicable)

Intended use:

IRIS Dynamic pro is used to extend the capacity of the IRIS Dynamic base.

Classification:

The IRIS Dynamic pro unit is an accessory to the base unit and shall be treated as in vitro diagnostic medical devices in their own right.

(Ref in DIRECTIVE 98/79/EC)

2.2 Information concerning general use, caution, disinfection

The device is intended for the **exclusive use with Breath samples**.

Protective gloves should be used while handling human samples.

The device is **not suitable** for use in the presence of explosive gases, flammable, anesthetic gases mixed with air, oxygen or nitrous oxide.

The device can be cleaned and disinfected from the outside with a dry cloth. No disinfectant containing ammonia or acetone should be used.

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.

2.3 Scope of supply

- IRIS Dynamic base (checked and prepared for operation)
- Power cable
- Instruction for use
- If applicable:
 - IRIS Dynamic pro
 - Power cable
 - Tube
 - Network cable

Doc. Title; Instruction for Use	Doc. No; Br-328/09	Date; 2016-01	Page 4(18)
---------------------------------	--------------------	---------------	------------

2.4 Accessories

- IRIS Breath bag; REF. No. 8005; with 2 x ca. 0,1 l volume with connecting hose for single use; disposal as packaging garbage.
- IRIS Breath bag; REF. No. 8004; with 1 x ca. 1,0 l volume with connecting hose for single use; disposal as packaging garbage.
- Mouthpiece for the IRIS breathbag; REF. No.8007; with one-way valve as hygiene barrier for single use (material PE, hygienically packed), disposal as a packaging garbage.
- Glas vials for breath samples with fixed cap (up to 17 mm in diameter with at least 10 mL volume).
- IRIS Dynamic Fuses: T2AH250VAC, IEEC/EN60127-2/5, 5*20mm

2.5 Moving

Turn off the system and unplug it.

Transportation of the system must be done in horizontal position.

No physical shocks should occur.

After moving, the device should be installed like a new system.

If the IRIS Dynamic has to be transported, please contact your local distributor for further information.

3. INITIAL OPERATION

3.1 Interfaces

The IRIS Dynamic base holds 2 USB ports for multiple usages. It is possible to connect HID-Devices, if these are plug & play compatible to Windows 7. Also it is possible to connect printers directly to the instrument.

The IRIS Dynamic base also has 2 RJ-45 connectors. These are for connections to local LIS-systems. Please contact your local distributor for assistance.

The IRIS Dynamic pro holds one Ethernet connector for communication with the base-unit and one gas connector for being connected with the base unit as well.

3.2 Operation/handling

The IRIS Dynamic GUI is touchscreen based. All user inputs are conducted directly via the screen.

For inputs the GUI offers an on-screen keyboard, which can be opened by pressing the symbol below.



Printing can be conducted from various screens by pressing the symbol below.

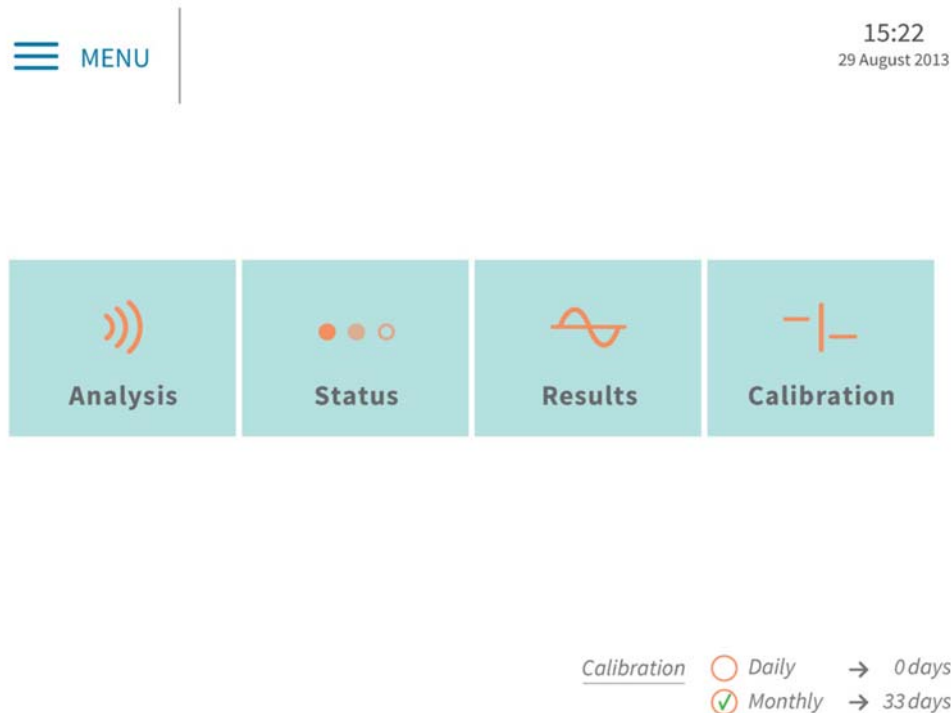


If applicable the following symbol will conduct an export of the shown content to an attached standard USB-stick.



After switching the IRIS Dynamic on, a log-in-screen will appear. The default user is "Max Mustermann" with the password "1234567".

After logging in the central menu-screen will appear.



From this screen all major functions of the instrument can be accessed.

4. MEASUREMENT

4.1 Calibrations

Before conducting measurements calibrations have to be performed. An automatic calibration of the system is conducted automatically on every first use after 24 or more hours and will be performed without further notice.

The operator has to perform 2 different kinds of calibration which are:

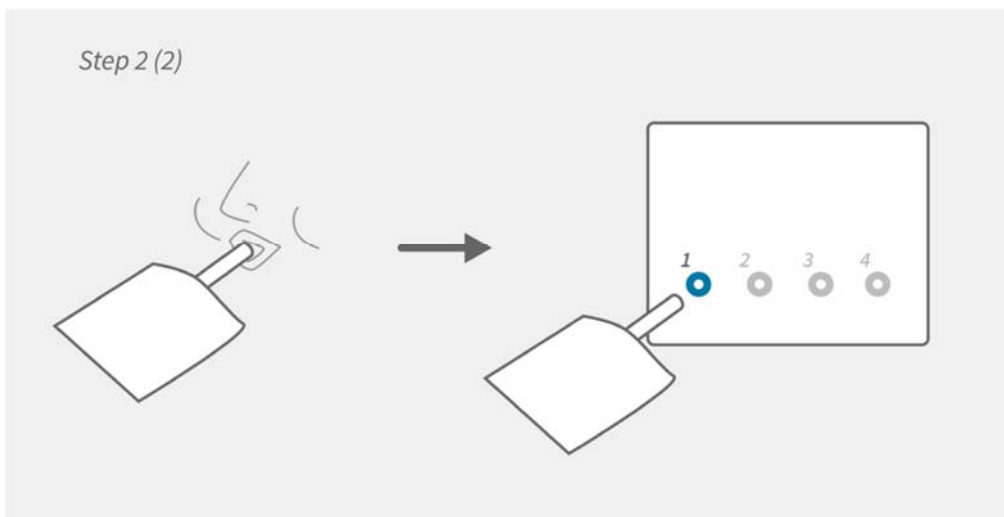
- The daily calibration – every day
- The monthly calibration every 30 days

Without valid calibrations the system will reject to measure and will show a message, pointing at the missing calibrations.

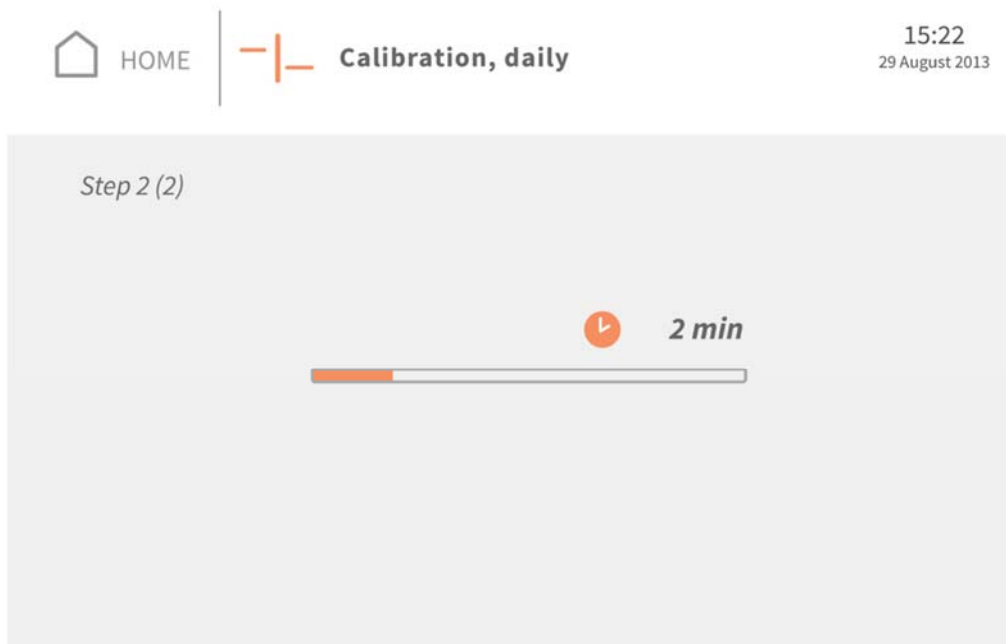
For performing the reference calibrations the operator has to select “Calibration” on the main screen. The system will switch to the calibration screen.



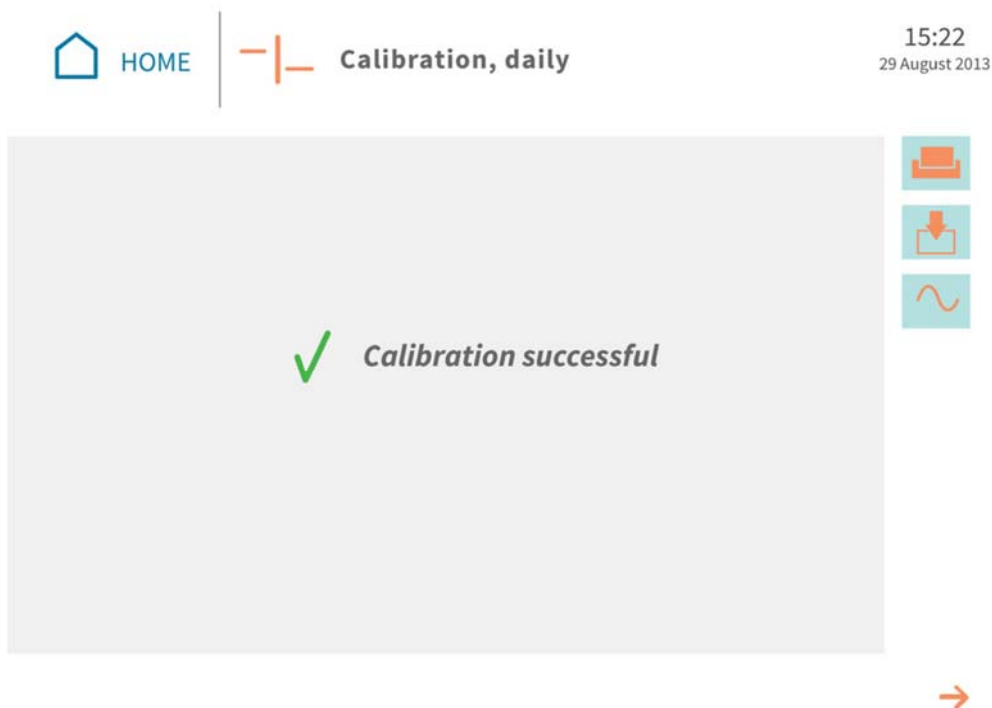
To perform the daily calibration the user has to exhale normal breath into a breath bag and connect it to sample port 1 – which is the port on the left side. After selecting the daily calibration button from the calibration menu the system will show a pictogram to guide the operator in performing the daily calibration.



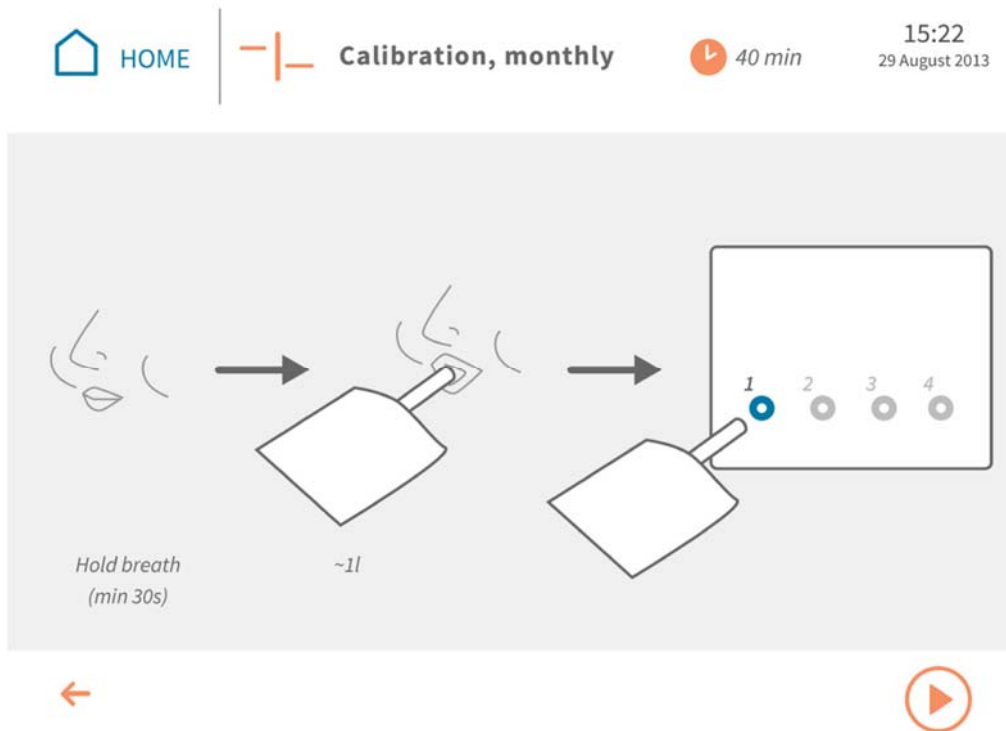
After connecting the breath bag to port one, pressing the arrow will start the calibration process, showing a progress bar.



After finishing the calibration successful the system will show a message.



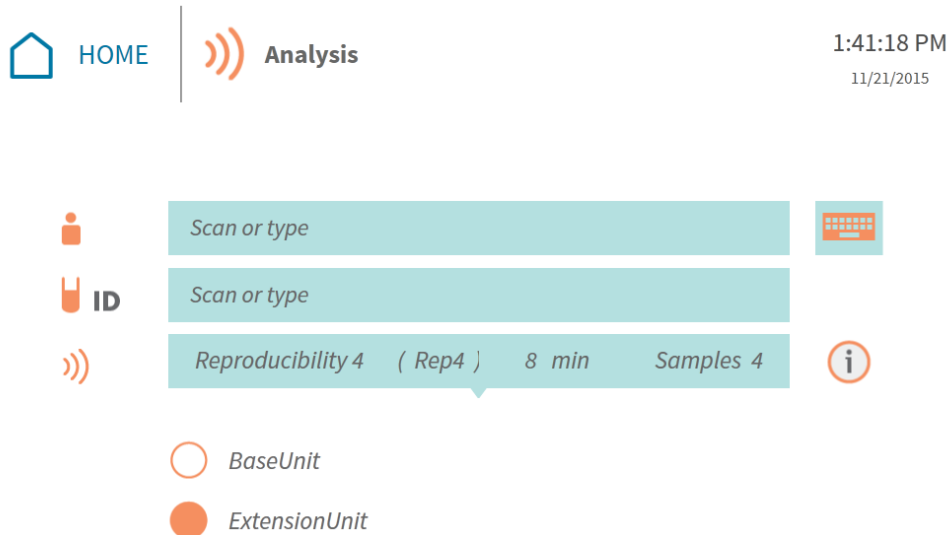
The monthly calibration works in a similar way, with the difference, that the operator needs to hold her or his breath for about 30 seconds before exhaling into a breath bag (preferably a big breath bag with 1 litre volume), which is then also connected to port 1.



This calibration will take about 35 minutes and will also show the aforementioned message after finish.

4.2 Measuring samples

After selecting “analysis” in the main menu, the following screen will appear.



This screen allows to enter a test identifier either via the on-screen keyboard or by scanning with a bar code scanner.

Also a sample ID can be optionally assigned.


The lower line allows to select defined test types from a drop-down menu.

If applicable here it can be chosen whether to run the analysis on the base unit or the Extension Unit IRIS Dynamic pro.

Pressing the right arrow key opens the patient screen.



HOME |
 Analysis
851203-6798
ID 136958
15:22
29 August 2013


Female
 Male


First name: Robert 

Surname: Jonsson

Date of birth: 1985-12-03-6798

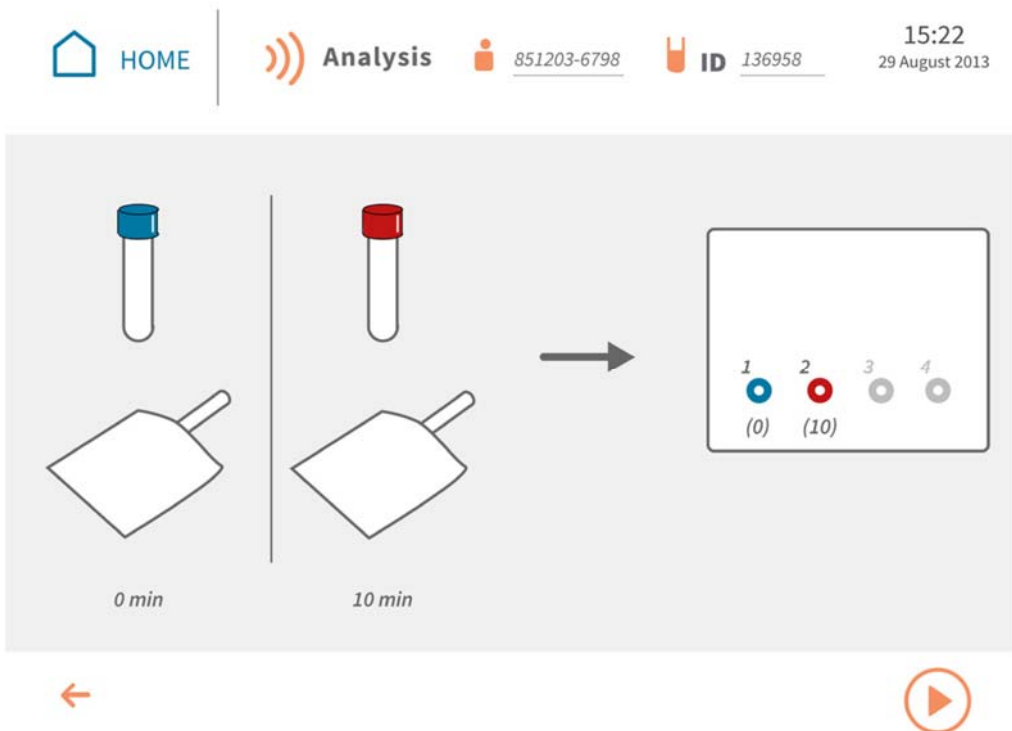
 kg
  mmol BSA/h

 cm

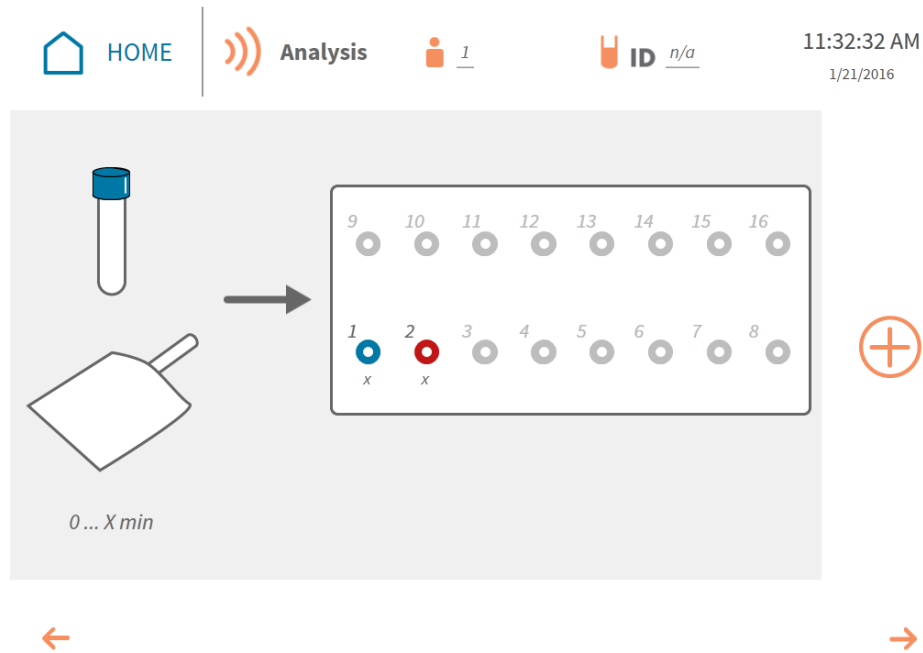

 Lorem ipsum lorem ipsum lorem ipsum lorem ipsum
 Lorem ipsum lorem ipsum lorem ipsum lorem ipsum
 Lorem ipsum lorem ipsum.

← →

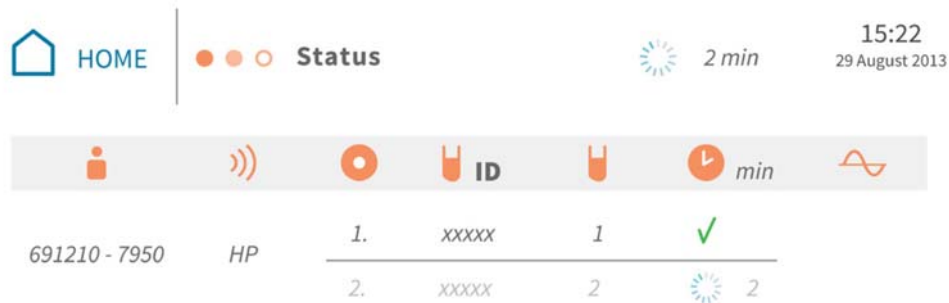
This screen allows to enter specific patient data for the internal database. All fields are optional. Pressing the right arrow opens a pictogram, showing on which sample ports the system expects the breath bags. Below shows the screen for tests on the base unit:



On the IRIS Dynamic Pro this screen shows another pictogram:



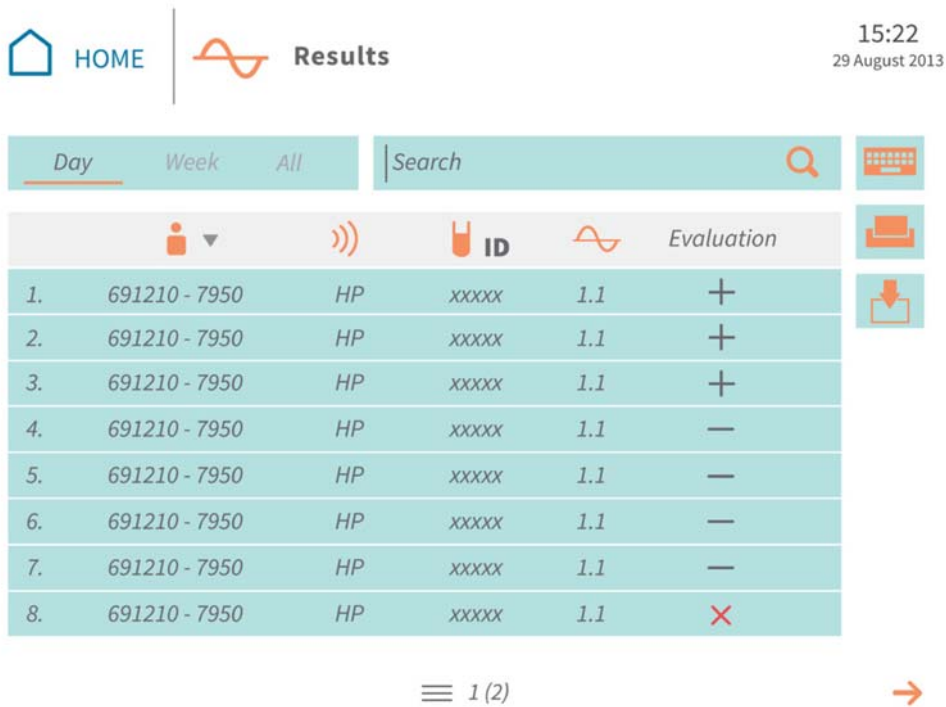
After pressing the right arrow, the measurement starts and a status screen is showing the progress.



While the measurement is running, additional analysis can be initiated the same way as described above.

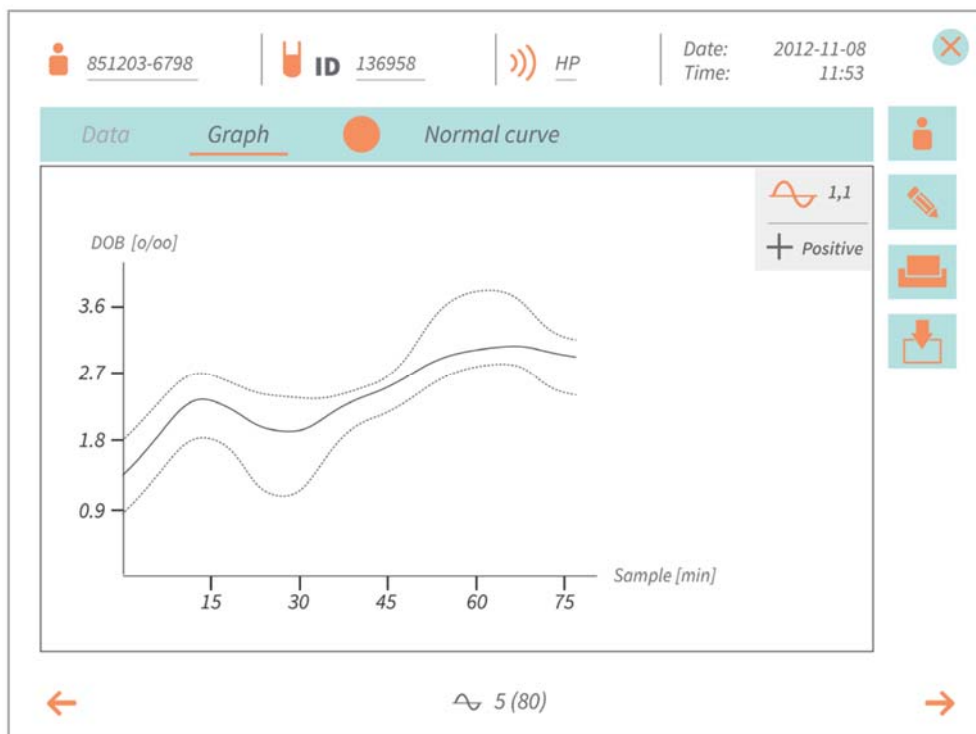
4.3 Results

Pressing the result-button in the main menu will open the result database.



	Day	Week	All	Search	
					15:22 29 August 2013
	Day	Week	All	Search	
				ID	Evaluation
1.	691210 - 7950	HP	xxxxx	1.1	+
2.	691210 - 7950	HP	xxxxx	1.1	+
3.	691210 - 7950	HP	xxxxx	1.1	+
4.	691210 - 7950	HP	xxxxx	1.1	-
5.	691210 - 7950	HP	xxxxx	1.1	-
6.	691210 - 7950	HP	xxxxx	1.1	-
7.	691210 - 7950	HP	xxxxx	1.1	-
8.	691210 - 7950	HP	xxxxx	1.1	×

By pressing “Day”, “Week” or “All” the shown results can be filtered. A search can be conducted in the upper right corner. Pressing the second button in the top right corner will print the results to a connected printer. Selecting a result will open a detailed view of it.



This screen shows either graphical or listed (selectable on top) the details of the specific selected result. It also allows printing out the details to a connected printer.

5. SAMPLE COLLECTION

Breath bag should be emptied completely. Connect a mouthpiece to the bag, the patient should blow up the bag, then keep the bag filled by connecting the small blue stopper to the hose or connect the bag directly to the corresponding hose port. The mouthpiece can be used for other samples of the same patient and has to be disposed after usage. Bags can be stored for up to 1 week.

6. TROUBLESHOOTING

In case of a malfunction, please call your local distributor.

In case of a power black-out, please make sure to let the IRIS Dynamic warm up for at least 12 hours before use.

7. SERVICE AND MAINTENANCE

Kibion recommends a service every 12 months for the flawless function of the Iris device. The service should only be carried out by a Kibion technician or a technician certified and authorized by Kibion.

Projected lifetime of the device is 10 years.

8. DISPOSAL

The device contains electronic printed circuit assemblies. It should be disposed in accordance with any applicable national or local policies relating to obsolete electronic equipment.

9. TECHNICAL INFORMATION

9.1 Analytic data

	IRIS Dynamic base	IRIS Dynamic pro
Reproducibility	<0,5‰ (standard deviation)	<0,5‰ (standard deviation)
URAS analyzer	URASmed	N/A
Sample measurement	2 (min/sample)	2 (min/sample)
Sample ports	4	16
Stability	<0,5‰ (standard deviation)	<0,5‰ (standard deviation)

9.2 Technical data

	IRIS Dynamic base	IRIS Dynamic pro
Width * Height * Depth	280 * 320 * 380 (mm)	500 * 320 * 380 (mm)
Weight	13 (kg)	11,5 (kg)
Electrical connections	100-120/200-240 (VAC) 50-60 (Hz)	100-120/200-240 (VAC) 50-60 (Hz)
Power consumption	0,12(kW)	0,12(kW)
Mains switch with two fuses	2 x 2 A	2 x 2 A
Gas connections	1 gas connection	1 gas connection
Data transfer	2 RJ-45, 2 USB	1 RJ-45

9.3 Environmental working conditions (laboratory conditions)

IRIS Dynamic base and pro	
Temperature	15 - 35 (°C)
Humidity rH	<70 (% rH)

At the place where the IRIS system is installed there should be **no vibrations or other movements** (shock).

Please do not place anything on top of the system.

10. ADDENDUM

10.1 „Delta“ and “DOB” – value; definition and comments:

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

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

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.

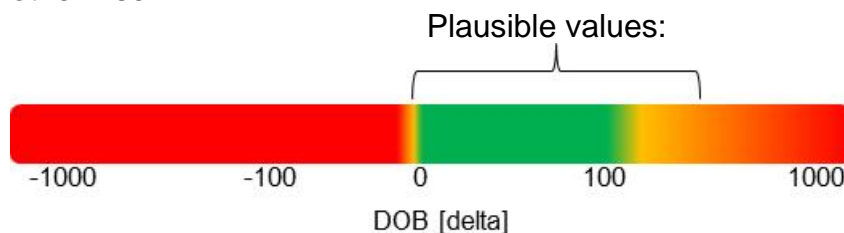
Basal-Delta-values at the CO_2 in human breath worldwide are between - 28.0 and - 23.0 Delta per mille. In essence, these $^{13}\text{C}/^{12}\text{C}$ -ratios are by 28.0 to 23.0 per mille lower than the $^{13}\text{C}/^{12}\text{C}$ -ratio of the PDB-carbon isotope standard.

$$\text{„DOB“} = \text{delta}_{\text{sample}} - \text{delta}_{\text{basal}}$$

10.2 Evaluation of data and explanation

A test should not be evaluated if the sign “too low CO_2 ” is shown in the result window.

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



In case of implausible values, the correct placement of samples to the connectors should be checked.

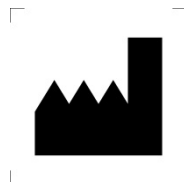
This instruction for use is valid for a device with the following label;



(only applicable for the IRIS Dynamic pro)

11. CONTACT DETAILS

Local Distributor contact details
(if applicable)



Kibion GmbH
Haferwende 31
28357 Bremen
Germany

E-Mail: support@kibion.com
Tel.: +49 (0) 421 27 86 5-0
Fax: +49 (0) 421 27 86 5-20

Doc. Title; Instruction for Use	Doc. No.; Br-328/09	Date; 2016-01	Page 18(18)
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