Table of Contents

Table of Contents ..... **i**
Instruction **2**
1.1 Intended Use 2
1.2 Ability and Experience Required 3
1.3 Operation and Store Environment 3
1.4 Subject Effect on the Use of the Instrument 3
1.5 Limitation and Contradiction 3
1.6 Safety Warnings 4
1.7 Cross-Contamination 5
Getting Started **6**
2.1 Components Description 7
2.2 UBREATH® Breath Gas Test System 8
Perform a Test **14**
3.1 Powering on/off 14
3.2 System login 14
3.3 Instrument setting 15
3.4 Preparation before measurement 16
3.5 Record viewing 20
3.6 Report printing 20
Quality Control **21**
4.1 Calibration of environmental parameters 21
4.2 Quality control calibration 21
Product Maintenance **24**
5.1 Battery charging 24
5.2 Change battery 25
5.3 Change Sensor 25
5.4 Cleaning 26
5.5 Maintenance 26
5.6 Storage conditions 26
5.7 Transportation method 26
Electromagnetic Compatibility **27**
Troubleshooting Guide **31**
Specifications **32**
Index of Symbols **34**
Warranty Condition **35**
Warranty Card **36**

Instruction

Welcome and thank you for choosing **UBREATH® Breath Gas Test System** (Model BA200) from the **e-LinkCare.**

It is the responsibility of user to follow the rules of safety as established for their protection and for the protection of their patients as described in this manual. Please take special note of the following to ensure an accurate test result is carried out:

- Take enough time to carefully read the user manual before using the measurement system.
- Use only the **UBREATH® Patient Filters** with the **UBREATH® Breath Gas Test System**.
- The **UBREATH® Patient Filters** are disposable and for single patient use only. Do not clean or reuse them.
- Use only the rechargeable battery supplied by **e-LinkCare**.
- Remove the battery from the device if it will not be used for 4 weeks or more.
- Keep the instrument and sensor out of water. Ensure that no liquid is spilled or dropped the instrument or sensor. See the maintenance and cleaning section for proper cleaning procedures.
- Store the instrument at a temperature of -25 °C ~ 55 °C and at a relative humidity of 0 ~ 80%. Operate the instrument in a dry area at 5°C ~ 35°C.
- Ensure stable operating conditions by avoiding placement of the instrument in direct sunlight, near sources radiating heat, or ventilation.
- Do not try to repair the instrument. Any attempt will make the warranty invalid and performance according to the specifications cannot be guaranteed.

1.1 Intended Use

UBREATH® Breath Gas Test System (Model BA200) quantitative measures Nitric Oxide (NO) and Carbon Monoxide (CO) in human breath, as an adjunct to establish clinical and laboratory assessments of inflammatory processes such as asthma, chronic respiratory disease, or as monitored treatment in smoking cessation clinics.

UBREATH® Breath Gas Test System is suitable for children, and adults 18 years and older. UBREATH® Breath Gas Test System cannot be used with infants or by children under the age of 7, as measurement requires patient cooperation.

The UBREATH® Breath Gas Test System is intended for prescription use and should only be used as directed in the UBREATH® Breath Gas Test System User Manual by trained healthcare professionals. The measurements are intended for interpretation by healthcare professionals and for use in a healthcare environment, where patients will complete measurements under supervision.

WARNING: The measurement is taken to evaluate airway inflammation and should be used in conjunction with other clinical and laboratory evaluations where appropriate when making a diagnosis or treatment plan.

1.2 Ability and Experience Required

Medical personnel who conduct the breathing gas tests by using UBREATH® Breath Gas Test System and interpret the result should be able to identify technically flawed curves and distinguish valid from invalid tests. Training, knowledge and understanding of breathing gas tests are essential for all medical personnel involved.

Breathing gas tests are required healthcare personnel with varied backgrounds and credentials, ranging from doctors, physicians, healthcare professions to medical assistants.

In most of cases, the healthcare provider may also require skills to explain, demonstrate and coach the subject to achieve an acceptable result.

WARNING: Operate **UBREATH®** Breath Gas Test System as stated in this manual. E-linkcare accepts no responsibility for damaged equipment or faulty results, if the instrument is not handled according to this manual.

1.3 Operation and Store Environment

Ensure stable operating conditions by avoiding placement of the device in direct sunlight, near sources radiating heat, or ventilation. The instrument operates under the following conditions:

- Temperature range of 5 ~ 35°C.
- Relative humidity range of 0-80%, non-condensing.

Store the instrument in its original shipping packaging and in a location free from dust, free from excessive moisture or water splash, and away from excessive heat, cold, or dry conditions. Do not put the instrument on the tall or unstable surfaces.

WARNING: If the instrument is exposed to unsuitable environmental conditions, this could cause the device to malfunction and to give incorrect results.

1.4 Subject Effect on the Use of the Instrument

The breathing gas test should only be carried out when the subject is at rest and in good health, and thus in a suitable condition for the test. The subject must make a complete forced expiration, in order to have a meaningful test result.

1.5 Limitation and Contradiction

By following the instructions outlined in this Use Manual, you will be able to use your UBREATH® Breath Gas Test System to see how well your lungs are working. However, the breathing gas test is not recommended to perform if the subject presents with following conditions:

- Active hemoptysis.

- Active pulmonary tuberculosis.
- Not drained through thoracic cavity pneumothorax.
- Cardiovascular disease, or recently with myocardial infarction or pulmonary embolism.
- Recently with eye surgery, such as cataract etc.

An analysis of the results is not by itself sufficient to make a correct diagnosis of the clinical condition of a subject. A detailed clinical history of the subject is also required, together with the results of any other test(s) suggested or prescribed by a doctor. Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.

WARNING: The user is responsible for the test acceptability. Special attention must be paid in the case of elderly people, children and handicapped people.

1.6 Safety Warnings

Operate **UBREATH®** Breath Gas Test System as stated in this manual. E-linkcare accepts no responsibility for damaged equipment or faulty results, if the equipment is not handled according to this manual. The UBREATH® Breath Gas Test System (Model BA200) is a non-invasive device and is safe in both construction and use. However, to ensure accurate performance, there are certain safety issues need attention to when use the instrument, please follow the following guidance carefully:

- Do not use UBREATH® Breath Gas Test System in the proximity of areas where volatile substances such as organic fluids or disinfectants are being used. Special attention should be paid to aerosols and disinfection baths (either open vessels or ultra-sonic baths). Do not use the instrument in the presence of flammable anaesthetic, vapours or liquids.
- Keep the instrument and sensor out of water. Ensure that no liquid is spilled or dropped on the instrument or the sensor.
- Do not use a damaged UBREATH® Breath Gas Test System or damaged components.
- Make sure to use the correct measurement method, otherwise incorrect results might be obtained.
- Always use a new patient filter or nasal filter for each patient. Reuse between patients could increase the risk of cross-contamination or cross-infection.
- The breathing handle must not be used after the expiration date.
- UBREATH® Breath Gas Test System should not be used adjacent to or stacked with other equipment.
- Keep the Breath Gas Test System and all associated parts out of reach of children.
- Use only original disposable and accessories from manufacturer.

WARNING: The product warranty does not cover product failure or damage resulting from use with non-approved accessories. E-linkcare takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by e-linkcare.

Accessory to Medical Equipment (IEC 61010-1)

Accessory equipment connected to this product must be certified according to the respective IEC standards (i.e.,61010-1) for medical equipment. If in doubt, consult the technical services department or your local dealers.

1.7 Cross-Contamination

To avoid exposing the patient to the critical danger of cross-contamination, a single patient filter can be used for one patient measurement only.

WARNING: It is importance to use a new filter for each patient for every test. The characteristics, accuracy and the hygiene of the patient filters can only be guaranteed if it has been conserved beforehand in its original sealed packaging. Due to the plastic material, expired filters and breathing handles should be disposed local regulations.

It is highly recommended to use gloves when replacing patient filters and washing hands after touching them.

Getting Started

Your UBREATH® Breath Gas Test System is carefully inspected and packed for shipping. However, it is a good practice to thoroughly inspect the outside of the package for damage. If any damage is noted, please notify the local distributor and return the damaged instrument back to them directly.

Carefully remove the package cover and inspect the kit box and check meter and accessories.

It is important to save all the original packing materials for being properly packed if it needs to be returned for servicing or repairing.

Please check that the product packaging is complete, and the product list is as follows:

Standard Accessory Name	**NO.**
Instrument	1
Breathing handle with cap	1
Type-C USB cable	1
User's manual (include Warranty Card)	1
LP606090x2P rechargeable lithium battery	1

Optional Accessory Name	**NO.**
Patient filters	1
Nasal filters	1
Power adapter	1
Nitric Oxide (NO) Sensor	1
Carbon Monoxide (CO) Sensor	1
OTG Cable	1

Note: *Only accessories and parts supplied by e-linkcare may be used.*

2.1 Components Description

Instrument

Breathing handle with cap

Nasal filter *

Patient filter*

Nitric Oxide Sensor *

Carbon Monoxide Sensor *

Power adapter*

Type-C USB cable

OTG cable *

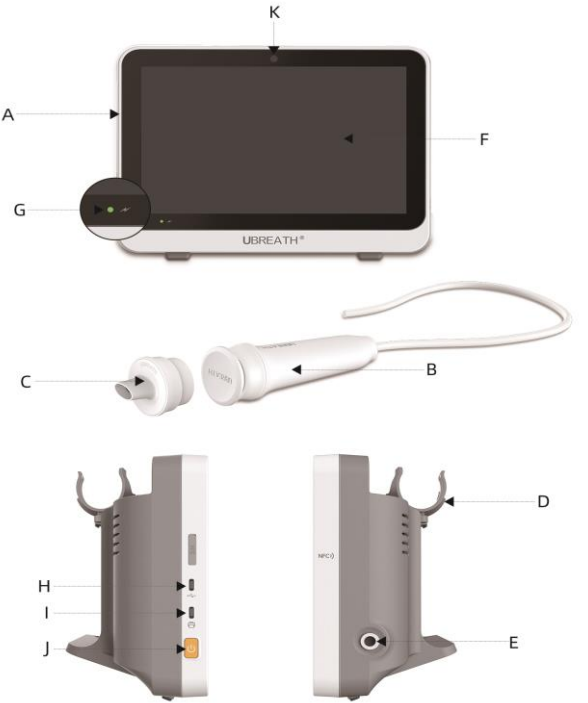
Note: *"*" means these components need to be purchased separately and is not included in the Instrument package.*

2.2 UBREATH® Breath Gas Test System

The UBREATH® Breath Gas Test System analyzes the composition and concentration of exhaled gases from the human body through highly sensitive electrochemical sensors for nitric oxide and carbon monoxide.

2.2.1 Introduction of UBREATH® Breath Gas Test System

Overview of UBREATH® Breath Gas Test System



A: Instrument: Breath measurement.

B: Breathing Handle: Used to filter inhaled ambient gases to ensure that the exhaled gas components come from the human body.

C: Patient filter: Filters remove such as the moisture, bacteria, viruses in the exhalation, and special dedicated it to personal use only.

D: Handle Holder: Placement for the breathing handle.

E: Breathing Handle Port: Connect the Breathing Handle and Instrument.

F: Liquid Crystal Display (LCD): Displays or manipulates the test process and the test results.

G: Indicator Light: Indicate the power condition.

H: Power charging port: Charging cable connector.

I: Printer connection port: Port for printer, connect to the printer via OTG cable.

J: Power button: Long press this button to switch on and off. Click this button to switch between rest screen and wake-up.

K:Camera: Scan barcode and QR code.

2.2.2 Connecting the Accessories

Check before use

(1) Check whether the packaging of the patient filter is intact, it is forbidden to use if it is damaged.

(2) Check the expiration date of the patient filter, and it is forbidden to use it after expiration.

(3) Before use, please charge UBREATH® Breath Gas Test System in advance.

Installation of Sensor

Carefully place the instrument on a flat and stable table, unscrew the screws on the back panel of the instrument, remove the bottom cover and disassemble the back panel of the instrument.

Check whether the sensor aluminum can package is completely sealed. Pull up the tab and open the top cover carefully, remove the sensor from the aluminum can.

Precautions:

Open the sensor can carefully. The inside of the opening may have sharp edges.

Warning:

- The sensor must be stored in the original unopened package or installed in a UBREATH® Breath Gas Test System.
- The sensor aluminum can should be completely sealed. If there is any air leakage or damage in the package, please contact the supplier or manufacturer in time.
- Do not touch or clean the white sensor film at bottom side.

According to the instructions of the slot, put the corresponding Sensor into the tank (the NO Sensor is put into the NO tank and the CO Sensor is put into the CO tank). Rotate the yellow swivel knob locking device clockwise until locked.

Installation of battery

Open the battery cover of the instrument, take out the special battery (Model: LP606090x2P) which only use the properly rechargeable battery supplied by e-linkcare included in the package, insert the battery connector plug into the battery connector socket in the direction indicated by the positive and negative poles (red for positive, black for negative) and then place the battery into the battery compartment. Close the instrument battery cover and secure it by tightening with a screwdriver.

Precautions:

- This product uses a rechargeable battery. When not in use for a long period of time, it is important to disconnect the battery and it is recommended that it is charged every six months.
- Do not plug or unplug the charging adapter with wet hands before or after charging.
- Please ensure that the yellow knob is horizontal before closing the battery cover.

Installation and disassembly of handle and filter

(1) Installation

Step 1: Insert the air guide tube of the breathing handle into the breathing handle port in the direction arrow indicated.

Step 2: Remove the sealing cap from the breathing handle and attach the patient filter to the breathing handle as shown.

Note: *The interfaces are tightly connected to prevent air leakage.*

(2) Disassembly

Patient Filter: Remove the patient filter from breathing handle as shown in the reverse direction in the diagram above. If not continuing to test, place the sealing cap of the breathing handle, back over the handle to avoid dust or other gases entering the handle.

Breathing Handle: Remove the tube of the handle from the instrument of the apparatus by pressing down on it with your hand at the handle fitting.

Perform a Test

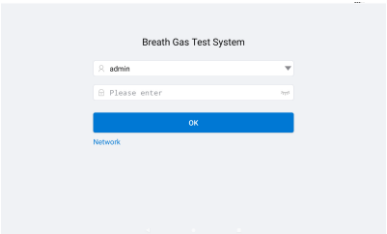
3.1 Powering on/off

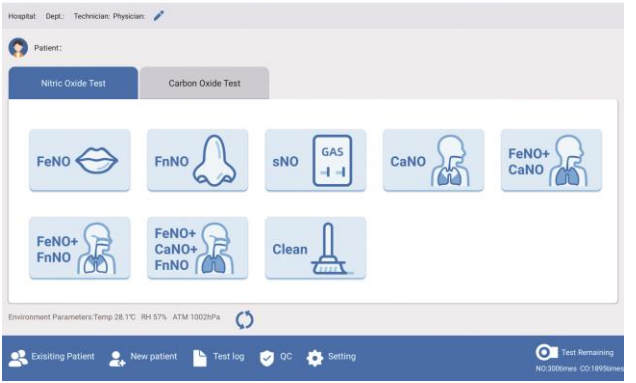
Long press and hold the Power On/Off button on the side of the instrument for about 3 seconds as show in the diagram, the screen lights up and the instrument is switched on.

Press and hold the Power On/Off button to the switch it off according to screen prompt. In standby mode, short press the power switch key to light up the screen.

3.2 System login

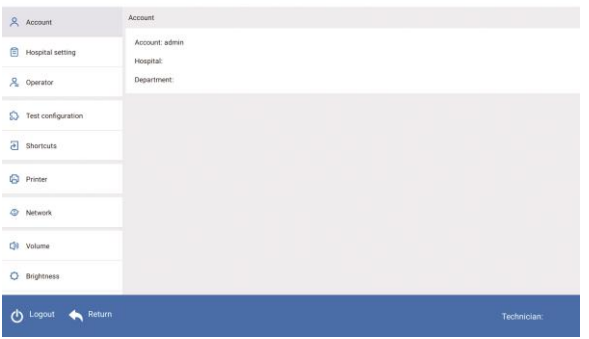
The instrument is switched on and enters the login screen. The instrument is automatically calibrated for the environmental parameters when switched on. If there is a change of testing environment in the process, please refresh the relevant parameters manually again before use.





3.3 Instrument setting

When logging in for the first time, you can set up your account information by clicking on the “Settings” button on the main screen, as show in the picture. You can also set the instrument volume, brightness, time, screen sleep and network as required. At the same time, the desired measurement mode can be selected at the test configuration.

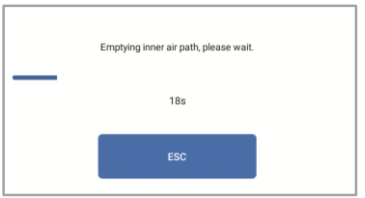


3.4 Preparation before measurement

3.4.1 Emptying of airways

Before the first test after turn on, please click the "Clean" button to empty inner air path, as shown in the diagram. When emptying, the breathing handle should be attached to the patient filter.

Automatically jumps back to the homepage when the inner air path has been emptied.

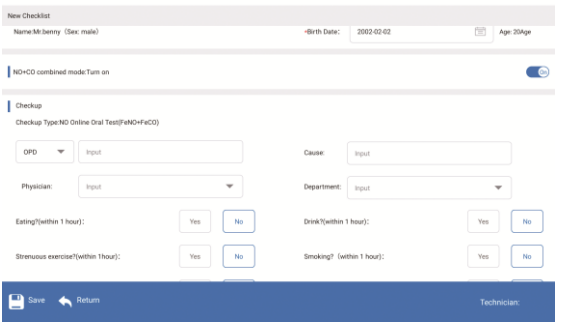


Precautions:

- Routinely, it is recommended to perform an air circuit emptying after each handle reconnection to the instrument, or before the first test after turning it on every day.

3.4.2 Subject information entry

Before test, you should to confirm the checklist information by clicking on "New patient" in the main interface to add or directly select existing patient information, as shown in the picture. Click on the "Save" button.



According to testing you needs, click on the corresponding test item function in the main interface, and follow the interface and voice prompts to perform the measurement operation.

Testing items	Functions
eNO measurement	On-line oral breath measurement ($FeNO_{50}$, $FeNO_{200}$) On-line nasal breath measurement (FnNO) Off-line sample gas measurement (sNO)
eCO measurement	On-line oral breath measurement (FeCO) Off-line sample gas measurement (sCO)

Depending on the settings, the user can choose to measure eNO and eCO as a single item or eNO and eCO simultaneously.

3.4.3 On-line oral breath measurement

In the main interface, click "FeNO" to enter the on-line oral breath test interface. Select the name of the subject, confirm the checklist, and enter the measurement mode.

Replace the subject with a new patient filter and attach it to the breathing handle. Take care that the ports are tightly connected to prevent air leakage.

Hand the breathing handle to the patient and instruct the patient to follow the on-screen instructions. Click on the "Practice" mode to allow the subject to practice inspiratory breathing and observe if the subject passes. Once the subject has mastered exhalation, click on "Start" to enter the formal measurement mode.

Oral breath sampling

(1) Adjust breathing, empty the lungs by breathing out thoroughly.

(2) Quickly hold the patient filter to ensure that the edge of the filter is tightly wrapped by lips to avoid air leakage. Follow the instructions on the screen to inhale deeply to the total lung volume, and then immediately exhale at a corresponding uniform rate of flow, as shown.

(3) After successful exhalation sampling, the instrument automatically starts the analysis and calculation. When the analysis is completed, a test report is automatically generated.

(4) Click on "Create Report", to view the report and print the report.

Precautions:

- Subjects should not eat, drink, smoke, exercise strenuously or perform pulmonary function tests one hour before sampling, and should not consume special foods such as broccoli, kale, lettuce, celery, water radish, smoked or pickled foods within three hours prior to testing;
- Ask about and record any hormonal or antibiotic medications taken in the last three days;
- The accuracy and repeatability of the test may be affected by leakage, change of breath, breath-holding or spitting during exhalation;
- The patient filter for breath sampling should be specially used by special person.

3.4.4 On-line nasal breath measurement

This product provides the nasal breath measurement technique recommended by international standard guidelines. Nitric oxide gas is produced by inhalation of air through the nasal passages and brought out of the nasal cavity and sinuses at a constant flow rate of 10mL/s through one nostril by means of a nasal filter (optional). In order to prevent the gas from being inhaled in the lower respiratory tract, the method of blowing with a whistle in the mouth is used to cooperate with the nasal breath measurement.

Nasal breath measurement operation

In the main interface, click on "FnNO" to enter the on-line nasal breath test interface. Select the name of the subject, confirm the checklist, and enter the measurement mode.

(1) Replace a new nasal head for the subject and attach it to the nasal filter (the nasal head and the nasal filter should be specially used by special person). Take care that the connections are tightly connected to prevent air leakage.

(2) Prepare the subject for the test by having the nasal exhalation head block one nostril.

(3) Explain the exhalation requirements to the subject: hold the whistle in the mouth, hold the tube part of the nasal filter, plug the nasal exhalation head tightly into one nostril and keep the other nostril open, inhale deeply into the mouth and then blow the whistle and hold it (do not change breath in between) until the exhalation sampling is complete. See the picture for the nasal exhalation position;

(4) Click on "Start". Inhale and blow according to the screen operation instructions, the instrument will start to pump and sample. After the sampling is completed, the instrument starts to analyze.

Note: *Keep the exhalation tube connected to the nasal filter during the analysis.*

(5) After the analysis is completed, the instrument displays the test results. Click on "Print" to preview and print the report.

3.4.5 Off-line sample gas measurement

The Off-line sample gas test technique consists of two parts: breath sampling and sample analysis. The advantages of Off-line testing technology over On-line testing technology are as follows:

(1) Multiple breath samples can be taken, making it particularly suitable for subjects who have difficulty meeting breath requirements, such as children, the elderly and critically ill patients;

(2) Sample gas can be collected at locations away from instrument (including wards, outpatient clinics, workshops, schools, etc.);

(3) Consistent with tightly controlled on-line analysis results and better repeatability.

Off-line gas measurement operation

In the main interface, click on "sNO" to enter the off-line sample gas measurement mode.

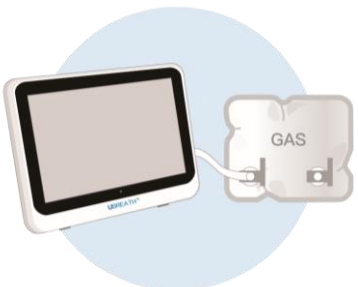
(1) Select the name of the subject and basic information, confirm and save the checklist and enter the measurement mode.

(2) Connect the sampling gas bag (sample gas has been collected through the sampler) tightly to the instrument (see Figure). Take care to ensure that the connection ports are tightly attached to prevent air leakage.

(3) Click on "Start", and the instrument will start pumping automatically.

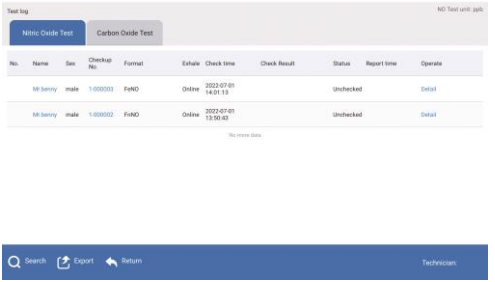
(4) When the pumping is completed, the analysis calculation is started automatically. When the analysis is completed, the test report is automatically generated.

(5) After clicking on “Create Report”, the test report can be printed directly.



3.5 Record viewing

Click on the "Test log" button at the bottom of the homepage to enter the inspection records interface (see Figure), view all the check records, or search for them by keyword.



3.6 Report printing

Connect the instrument to the printer and click on the "Print" button to print the report directly when the print status is shown as connected. (The printer can be connected in multiple ways: via WIFI or direct via USB print port on the instrument via an OTG cable).

Note: *The report is based on the final pattern produced by the instrument.*

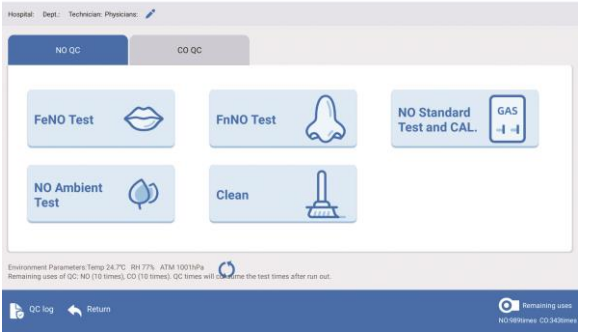
Quality Control

4.1 Calibration of environmental parameters

UBREATH® Breath Gas Test System will automatically calibrate the environmental parameters when it is turn on. If the environment is changed during the test, please click on the "REFRESH" button to update the environment parameters before the test (see Figure).

4.2 Quality control calibration

Click on the "QC" button at the bottom of the main interface, verify the identity, enter the account password, and then enter the quality control mode interface to operate the quality control test calibration and query the quality control records.



The quality control calibration mode mainly includes the following quality control functions:

Quality control project	Function
Nitric oxide (NO) quality control	FeNO Test FnNO Test Nitric Oxide (NO) Standard Test and CAL. Nitric Oxide (NO) Ambient Test
Carbon monoxide (CO) quality control	FeCO Test Carbon monoxide (CO) Standard Test and CAL

4.2.1 Inspection and calibration of standard gas

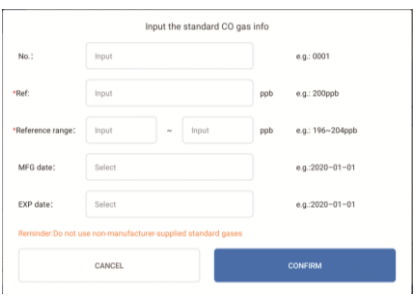
The inspection and calibration operation for nitric oxide (NO) standard gas is the same as that for carbon monoxide (CO) standard gas. The following Figure takes an example of nitric oxide (NO).

(1) Connect the standard sample gas bag with a known concentration to the instrument via the exhalation tube. Ensure that the valve of the sample bag is open. Take care that all connectors are tightly connected to prevent air leakage.

Note: *To ensure the accuracy of the inspection, please empty the inner gas path before the inspection operation.*

(2) In the "QC" interface, click on "NO Standard Test and CAL".

(3) Enter the relevant information for standard gas to be tested according to the interface requirements (see below). After checking, click on "CONFIRM" to enter the measurement interface.



(4) Click on the "Start" button. The instrument starts pumping automatically. When the pumping is complete, the instrument automatically starts the analysis and calculation. When the analysis is completed, the inspection values and results for standard gas are displayed.

(5) Click on “Create Report” to preview the report format. If the printer is connected, press the "Print" button to print the QC report directly.

When the inspection result does not pass, it is necessary to check whether the operation is correct. If calibration is required, click on the "Start CAL." button, and the instrument will be automatically calibrated. When the calibration is complete, the screen indicates "CAL. Success", and the instrument calibration is completed.

Precautions:

- Inspection and calibration should be carried out carefully and under the guidance of qualified personnel.
- When calibrating, it is necessary to confirm and enter the administrator's operation password again before calibrating.

4.2.2 Inspection of ambient gas

When it is necessary to check the NO concentration in the environment, the "NO Ambient Test" function can be used.

(1) In the quality control mode interface, click on "NO Ambient Test".

(2) Put the instrument in the natural environment to be tested, and open the breathing handle cap to ensure that the pipework is clear.

(3) Click on the "Start" button. The instrument will automatically pump and collect ambient gas for testing.

(4) After the analysis and calculation are completed, the measurement results are displayed.

Product Maintenance

5.1 Battery charging

(1) Installation of charging adapter, cable and instrument before charging

Plug one end of the charging cable into the Type-C port of UBREATH® Breath Gas Test System, and the other end into the charging adapter via the USB plug to complete the installation of the charging adapter, charging cable and instrument. Connect the AC power supply for charging.

After the charging adapter, charging cable and instrument are installed, the indicator light of the instrument flashes "orange" for a second while charging is in progress and turns green and stops flashing when charging is completed.

Note: *Before use, ensure that the battery of UBREATH® Breath Gas Test System is fully charged. When charging, the ambient temperature should be within the range of 0 ~ 45°C, otherwise it will affect the battery life.*

(2) Disassembly of charging adapter, cable and instrument after charging

After charging, unplug the charging adapter from the power outlet in time. Please do not touch the plug for about 10 seconds, and then unplug one end of the charging cable from the instrument Type-C USB port and the other end of the USB plug from the charging adapter.

If any item is missing or damaged, contact your local distributor or manufacture.

5.2 Change battery

If the rechargeable battery is no longer charging properly, malfunctioning, or requires charging more frequent than normal, then it needs to be replaced. The battery is placed in the compartment on the back of the instrument, the steps are as follows:

(1) Turn off the instrument;

(2) Open the battery cover;

(3) Remove the old battery and insert a new battery (Only rechargeable batteries supplied by e-Linkcare may be used. *Model LP606090x2P*). Refer to Section 2.2.2 Battery installation for details.

(4) Close the battery cover.

Precautions:

- UBREATH® Breath Gas Test System uses rechargeable lithium battery, be sure to disconnect for long term storage without use. It is recommended that the battery is charged every six months to maintain battery life.
- Before and after charging, it is forbidden to plug and unplug the charging adapter with wet hands.

5.3 Change Sensor

If the test remaining of sensor is below a certain number, please contact the supplier to place an order.

When the software interface appears "Valid Times of NO or CO Sensor Have Expired", it indicates that the number of test the sensor has been used has reached the limit value, it can no longer be detected properly and needs to be replaced with a new sensor. The steps for sensor replacement are as follows:

(1) Turn off the instrument;

(2) Open the compartment on the back of the instrument using a screwdriver. Turn the swivel to release the Sensor.

(3) Remove the old sensor.

(4) Replace with a new sensor. Refer to Section 2.2.2 “Installation of Sensors" in the manual.

(5) Turn the swivel to lock.

(6) Attach the back cover of the instrument and tighten with the screwdriver fixing screws.

Precautions:

- Please inform the manufacturer or distributor to recycle the used sensors in time, and do not dispose of them as they may cause environmental pollution.

5.4 Cleaning

UBREATH® Breath Gas Test System does not require special cleaning. The breathing handle should be disinfected every time the instrument is used for a period of time.

Cleaning method: Use a cotton cloth or swab dipped in a little water or mild soapy to clean and wipe the outer surfaces of the instrument, avoiding the use of disinfectants containing alcohol or similar organic volatiles to clean the instrument.

Note: *Do not use spray disinfectant to disinfect breathing handle and instrument.*

5.5 Maintenance

After the instrument is used every day, it needs to be cleaned and turned on for testing after each day's use. UBREATH® Breath Gas Test System does not require special cleaning and maintenance.

Precautions:

- Do not use aerosol or spray disinfectant to clean the instrument.
- Since large amounts of ethanol or similar organic volatiles can cause permanent damage to the sensor, use disinfectants with caution and avoid using disinfectants containing ethanol or similar organic volatiles around the instrument.
- Do not touch or clean the sensor membrane.
- Do not clean the sensor: Cleaning the sensor with a disinfectant containing ethanol or similar organic volatiles may cause permanent damage to the sensor.
- Please turn off the power and do not charge when cleaning.
- If the product is not used for a long time, wipe the dust with medical gauze and put it in the packaging box for storage.

5.6 Storage conditions

The instrument must be stored with its outer packaging. Store UBREATH® Breath Gas Test System in a clean, well-ventilated indoor environment without corrosive gases at -20°C ~ +55°C, and 0 ~ 80% relative humidity. Take care to prevent rain, moisture, dust and pressure.

5.7 Transportation method

Requirements for transport conditions: The transport should be packed in the same way as the company leaves the factory, and must also ensure that there are no strong collisions, high falls and breakage. Take care to prevent rain, moisture, dust and pressure during transportation.

- Transportation temperature: -20°C ~ +55°C.
- Relative humidity: ≤ 80% RH.
- Atmospheric pressure: 700 hPa ~ 1060 hPa.

Electromagnetic Compatibility

As the UBREATH® Breath Gas Test System is a medical device, special precautions regarding electromagnetic compatibility (EMC) are required and must be installed and used in accordance with the EMC information specified in these instructions.

It is important that the UBREATH® Breath Gas Test System is properly configured in accordance with the User Manual provided herein and is used only in the configuration as supplied. Changes of modifications to the UBREATH® Breath Gas Test System may result in increased emissions or decreased immunity of the device in relation to EMC performance.

The UBREATH® Breath Gas Test System should be used only with the accessories and cables (USB cables, adapter and patient filter) other than those supplied by the manufacturer.

The use of accessories and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

Note that portable and mobile HF communication systems may interfere with this instrument. Do not staple or use the instrument close to mobile phones or other devices generating or electromagnetic fields, and none of the UBREATH® Breath Gas Test System accessories should be used with other equipment. This could result in malfunction of the medical device and may create a potentially insecure situation.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The UBREATH® Breath Gas Test System is intended for use in the electromagnetic environment specified below. The customer or the user of the UBREATH® Breath Gas Test System should assure that it is used in such an environment.

<table>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment -guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The UBREATH® Breath Gas Test System uses RF energy only for its internal function. Therefore, its RF missions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group A</td><td rowspan="3">The UBREATH® Breath Gas Test System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and Manufacturer's Declaration –Electromagnetic Immunity

The UBREATH® Breath Gas Test System is intended for use in the electromagnetic environment specified below. The customer or the user of the UBREATH® Breath Gas Test System should assure that it is used in such an environment.

Guidance and Manufacturer's Declaration –Electromagnetic Immunity

Immunity Test	**Compliance Level**	**Electromagnetic environment -guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±4 kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient /burst IEC61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC61000-4-5	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5% U^T (> 95% dip in U^T) For 0.5 cycle 40% U^T (60% dip in UT) for 5 cycles 70% U^T (30% dip in U^T) for 25 cycles<5% U^T (> 95% dip in U^T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UBREATH® Breath Gas Test System requires continued operation during power mains interruptions, it is recommended that the UBREATH® Breath Gas Test System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field EC61000-4-8	3 A / m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment
NOTE: U^T is the AC mains voltage prior to application of the test level.		

The UBREATH® Breath Gas Test System is intended for use in the electromagnetic environment specified below. The customer or the user of the UBREATH® Breath Gas Test System should assure that it is used in such an environment:

Immunity Test	Compliance Level	Electromagnetic environment -guidance
Radiated RFIEC61000-4-3	3V/m 80 MHz to 2.5 GHz	d= 1.2√P 80MHz-800MHz d= 2.3√P 80MHz-800MHzz3 Where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters(m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range*. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitter, an electromagnetic site survey should be considered.

If the measured field strength in the location in which the UBREATH® Breath Gas Test System is used exceeds the applicable RF compliance level above, the UBREATH® Breath Gas Test System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the UBREATH® Breath Gas Test System.

*Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V / m.

Recommended Separation Distance

The UBREATH® Breath Gas Test System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the UBREATH® Breath Gas Test System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UBREATH® Breath Gas Test System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts (W)	Separation Distance in Meters (m) according to Frequency of Transmitter		
	150 KHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equipment applicable to the frequency of the transmitter, where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

Troubleshooting Guide

The following table refers some of the issues that can occur with your Test & Measurement products and provides useful troubleshooting steps to help you resolve an issue yourself.

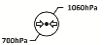
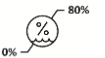
Ault Phenomenon	Cause	Solution
Failed to power on	The battery is completely exhausted or the battery is not connected	Reuse after charging or properly connecting
Charging without display	Type-C USB port is not tightly plugged, poor contact of charging cable or faulty charging adapter	Re-plug Type-C USB port or replace charging cable and charging adapter
Statement: This product will always be repaired by our technicians, who will be provided with circuit diagrams, lists of components, illustration, correction details, or the necessary information to repair the equipment components as specified by the manufacturer.		

Specifications

Name	UBREATH® Breath Gas Test System
Model	BA200
Input power	DC5V 2A
Battery requirements	1 x 3.7V LP606090x2P rechargeable lithium battery
Battery charge	10000mAh, support continuous work for more than 6 hours after full charge
Nitric oxide measurement	Measurement range: 0 ~ 4000 ppb; Accuracy: ±2.5 ppb for measured values ≤ 50ppb ±5% for measured values > 50ppb Within the measurement range, correlation coefficient r ≥ 0.990； Repeatability: ≤50 ppb, SD<1.5 ppb； >50 ppb, CV<3.0%； Repeatability of measurement points within a single measurement: ≤50 ppb, SD<0.5 ppb; >50ppb,CV<1.0%; Lowest detection limit: 1.0 ppb; Measurement time: < 40 s.
Carbon monoxide measurement	Measurement range: 0 ~ 250 ppm; Accuracy: ±1.0 ppm for measured values ≤ 20ppm ±5% for measured values > 20ppm Within the measurement range, correlation coefficient r ≥ 0.990； Repeatability: ≤20 ppm, SD ≤0.6 ppm >20 ppm, CV<3.0% Repeatability of measurement points within a single measurement:≤20 ppm, SD< 0.2 ppm; >20 ppm, CV<1.0%; Low detection limit: 1.0 ppm; Measurement time:<40 s.

Detection items	Single detection item: on-line oral breath measurement($FeNO_{50}$) on-line oral breath measurement($FeNO_{200}$) on-line nasal breath measurement(FnNO) off-line sample gas measurement(sNO) CaNo measurement on-line oral breath measurement(FeCO) off-line sample gas measurement(sCO) Joint detection items: FeNO + CaNo, FeNO + FnNo, FeNO + CaNo + FnNo
Quality control project	Nitric Oxide (NO) Standard Test Nitric Oxide (NO) Ambient Test Carbon monoxide (CO) Standard Test
Operating environment	Temperature: 5°C ~ 35°C Relative humidity: ≤80% RH, no condensing Atmospheric pressure: 700 hPa ~ 1060 hPa
Transportation storage condition	Temperature: -20°C ~ 55°C Relative Humidity: ≤80% RH Atmospheric pressure: 700 hPa ~ 1060 hPa
Overall dimensions (Length × Width × Height)	259 × 115× 200mm
CPU	Eight-core ARM Cortex-A53 processor
Memory	16GB EMMC+2GB LPDDR3
Display screen	10.1-inch IPS touch screen, 1200*1920 resolution
Scanning head	1300M pixels supporting bar code and QR code
Classified by degree of protection against incoming liquid	IPX0

Index of Symbols

	Please refer to the manual for other warnings		Charging
	Keep out of rain & damp conditions		LP606090X2P Specification:3.7V 10000mAh rechargeable battery
	Temperature limit of the environment where medical devices can be safely exposed.		The Device includes a Radio Frequency (RF) transmitter (Bluetooth)
	Fragile		Transport and storage atmospheric pressure limitation
	Standby, power on		Transport and storge humidity limitation
SN	Serial number	+ −	Positive and negative poles of power supply
	Charging indication		

Warranty Condition

UBREATH® Breath Gas Test System (Model BA200) together with its standard accessories is guaranteed for a period of 3 years, while the battery is guaranteed for 1 year. The warranty is effective from the date of purchase as shown on the relevant sales invoice or proof of purchase.

This equipment must be checked at the time of purchase, or upon delivery, and any claims must be made immediately in writing to the manufacturer.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts. All batteries and other consumable parts are specifically excluded from the terms of this warranty.

This warranty is not valid, at the discretion of the manufacturer, in the following cases:

- If the failure is due to improper installation or operation of the machine, or if the installation does not comply with the current safety norms of the country of installation.
- If the product is used in a manual different from that described in the User Manual for which it is intended. If any alterations, adjustments, modifications or repairs have been carried out by persons not authorized by the manufacturer.
- If the fault is caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by an improper power supply or instrument connection method.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The customer is responsible for all costs associated with shipping and customs charges, as well as the delivery of the goods to and from the manufacturer or distributor. Any equipment or accessory returned must be accompanied by a warranty card with detailed explanation of the defect or problem found. If equipment is to be returned to the manufacturer, written or verbal permission must be obtained before returning any equipment to the distributor.

Warranty Card

For records, also write the purchase date of your product here.

Date of purchase: _____

Model Number: _____

Meter Serial Number: _____

The problem description: _____

_____

You expect:

☐Replace a new device

☐Return after maintaining

Note: This warranty applies only to the meter in the original purchase and does not apply to the battery supplied with the meter.

Local Dealer Information:

Contact Address：

Contact Name：_____

Contact Cellphone Number:_____

Address:_____

City:_____

State/Province/Region:_____

Postal Code:_____

Thanks so much for your kind support!

Effective Date: 2022-08-01