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Instruction

Welcome and thank you for choosing **UBREATH® PRO** brand **Spirometer System** (Model PF680) from the **e-LinkCare.**

It is the user's responsibility 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:

- Read this entire instruction carefully before attempting use the product.
- Use only **UBREATH® PRO Disposable Flow Transducer** with the **UBREATH® PRO** Spirometer System.
- Please consult with your physician or healthcare professional first if you are suitable for this testing.
- The **UBREATH® PRO Disposable Flow Transducers** are disposable and for single patient use only. Do not clean or reuse them.
- Use rechargeable battery only which is provided by **e-LinkCare.**
- Remove the battery from the device if it will not be used for 4 weeks or more
- Do not immerse the unit with any fluids. See the maintenance and cleaning section for proper cleaning procedures.
- Keep out of reach of children.
- Use and store the device indoor only. Do not expose this device or its accessories to direct sunrays. Keep the temperature between 10-40 Celsius degrees when in use.
- Do not attempt to open or service the device on your own, return the device to distributor for all services. Opening the device case will void the warranty.

1.1 Indented to Use

This **UBREATH® PRO** Spirometer System **(Model PF680)** is intended to test spirometry function evaluation and data management and calculates a series of parameters relating to human respiratory function. (Excluding children under 4 years old).

The **UBREATH® PRO** Spirometer System is intended for doctors or by a subject under the instruction of a doctors or healthcare professionals. **UBREATH®** PRO **brand** Spirometer System is used to by general practitioners, specialists, and health care professionals, in hospitals and clinics, in pharmacies, and in clinical settings in occupational medicine.

WARNING: No person should attempt to use this device without the necessary knowledge and training to understand how this equipment is to be properly utilized and interpreted.

The measurement offered shall only be considered as a tool of screening but not to be treated as reference for diagnostic purposes.

Indications for spirometry function tests include, but are not limited to, the following:

- Shortness of breath;
- Chronic cough;
- Occupational exposure to dust and chemicals;
- Assist in the diagnosis of Bronchitis;
- Assist in the diagnosis of Asthma;
- Assist in the monitoring of bronchodilators;
- Wheezing.

1.2 Ability and Experience Required

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

Spirometry 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: **e-LinkCare** hold no responsibility for any damaged caused by the user of the device failing to follow the instruction and warning altered in this manual.

1.3 Operation and Store Environment

The device has been envisaged for use in hospital / clinical facilities, do not use the device if there are electromagnetic / dirty air currents / wet / flammable gas environments surrounding.

The device is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances. The user and/or the doctor are responsible for ensuring that the device is stored and used in appropriate environmental conditions.

WARNING: If the device 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 Device

A spirometry 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 User's Manual, you will be able to use your **UBREATH® PRO** Spirometer System to see how well your lungs are working. However, a spirometry test is not recommended to perform if the subject presents with following conditions:

An analysis of the results of a pulmonary function test 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.

Any subject with the following symptom or condition is not recommended to perform the test:

- Pneumothorax;
- Hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition);
- Unstable cardiovascular status such as angina (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus;
- Thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure);
- Cataracts or recent eye surgery;
- Recent thoracic or abdominal surgery;
- Nausea, vomiting, or acute illness;
- Recent or current viral infection;
- Undiagnosed hypertension;
- Presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting).

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

The UBREATH® PRO Spirometer System (Model PF680) 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 device, please follow the following guidance carefully:

- Do not sprinkle water or any liquids on the device;
- Keep your portable spirometer dry and avoid exposing it to extremes in temperature or humidity;
- Do not damage the **UBREATH® PRO** Spirometer System;
- Keep the Spirometer System and all associated parts out of reach of children;
- Use only original disposable and accessories from manufacturer;
- Device rechargeable lithium battery life is 500 complete recharge cycles.

WARNING: The thermal paper used for printing is highly inflammable. Keep away from open flames.

Accessory to Medical Equipment (IEC 60601-1)

Accessory equipment connected to this product must be certified according to the respective IEC standards (i.e.,60601-1) for medical equipment. Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anyone, who connects additional equipment to the signal input part or signal output part configures a medical system, and it therefore responsible that the system complies with the requirements of system standard IEC 60601-1-1. Whoever is responsible for securing the unit to a system needs to ensure that the mounting equipment used with this product complies to IEC standard 60601-1. If in doubt, consult the technical services department or your local dealers.

1.7 Cross-Contamination

To avoid exposing the subject to the critical danger of cross-contamination, a single disposable mouthpiece as well as a flow transducer are required to connect a subject to the spirometer.

WARNING: It is importance to use a new flow transducer and mouthpiece for each subject for every pulmonary function test. The characteristics, accuracy and the hygiene of the disposable transducer or mouthpiece can only be guaranteed if it has been conserved beforehand in its original sealed packaging. The disposable mouthpiece / flow transducer both are made of plastic and its disposal after use must adhere to the local regulations and norms in force.

To avoid incorrect functioning and possible damages, do not allow dust or any impurities such as hair, sputum, threads etc. to enter the sensor.

WARNING: It is highly recommended to use gloves when replacing disposable flow transducers and mouthpieces and washing hands after touching them.

1.8 Measured Parameters

Measure-ment	Symbol	Description	Units
FVC	**FVC**	Forced Vital Capacity	L
	FEV1	Volume expired in the 1st second of the test	L
	FEV1%	Forced Expiratory Volume in one second to Forced Vital Capacity ratio	N/A
	PEF	Peak Expiratory Flow	L/s
	FEF25	Forced Expiratory Flow at 25% of FVC	L/s
	FEF50	Forced Expiratory Flow at 50% of FVC	L/s
	FEF75	Forced Expiratory Flow at 75% of FVC	L/s
VC	**VC**	Vital Capacity (expiratory)	L
	VT	Tidal Volume during VC measurement	L
	IRV	Inspiratory Reserve Volume	L
	ERV	Expiratory Reserve Volume	L
	IC	Inspiratory Capacity	L
MVV	**MVV**	Maximum Voluntary Ventilation	L/min
	VT	Tidal Volume during MVV measurement	L
	RR	Respiratory Rate	1/min

Getting Started

UBREATH® PRO Spirometer System (Model:PF680) is a bench-top spirometer designed for professionals that could meet most valuations of pulmonary function tests and give results both on-spot and HIS/LIS connections for the maximum subject satisfaction. It is a powerful and compact measurement device intended for use by a physician (respiratory specialist) to diagnose and monitoring subjects with COPD and asthma, it can calculate more than 15 parameters including FVC, VC, MVV and corresponding breathing profile tests.

UBREATH® PRO Spirometer System (Model: PF680) can operate in standalone mode with a built-in thermal printer, which also helps to be able to streamline subject information flow and its accessibility for doctors as well as improve subject care quality and safety over time.

Your **UBREATH® PRO** Spirometer 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 device back to them directly.

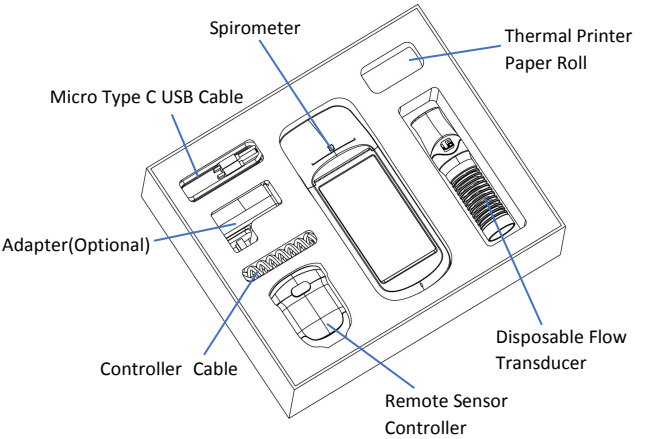
Carefully remove the package cover and inspect the kit box and check meter and accessories.

It is important to save all the original packing material, so the device can be properly packed if it needs to be returned for service or repair.

The original package packaging contains the device with the following accessories:

2.1 Components Description

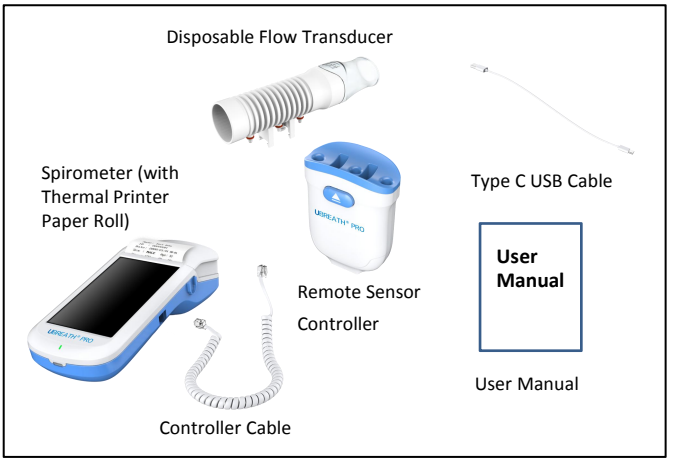
2.1.1 List of Box Contents



Check the list below to ensure you have all accessories received in good condition.

1	Spirometer	x 1
2	Remote Sensor Controller	x 1
3	Disposable Flow Transducer	x 1
4	Controller Cable	x 1
5	Power Adaptor (optional)	x 1
6	Type C USB Cable	x 1
7	Thermal Printer Paper Roller (pre-install in meter)	x 1
8	User's Manual (include Warranty Card)	x 1

2.1.2 Accessory List



A. **UBREATH® Spirometer:** measure a range of respiratory parameters.
B. **Remote Sensor Controller:** Used to receive signal from subjects.
C. **UBREATH® PRO Disposable Flow Transducer (Pouched)**: A disposable item that is used to connect user with spirometer. It's assembled by three parts: throttle pipe, mesh and mouthpiece.
D. **Controller Cable**: Used to connect the Spirometer and remote controller.
E. **Type C USB Cable:** Used to connect with power source for power recharge or data transfer.
F. **Thermal Printer Paper Roller**: Used for report printing
G. **User Manual (included warranty card inside)**: Provides detailed instructions on using the Spirometer System.

Note: *Contact your local distributor for purchasing alternative power adaptor that is applicable in your country.*

2.2 UBREATH® PRO Spirometer System

The **UBREATH® PRO** Spirometer calculates the result and display the pulmonary function parameter result. Please view below diagrams to be familiar with all the parts of **UBREATH®** PRO Spirometer System.

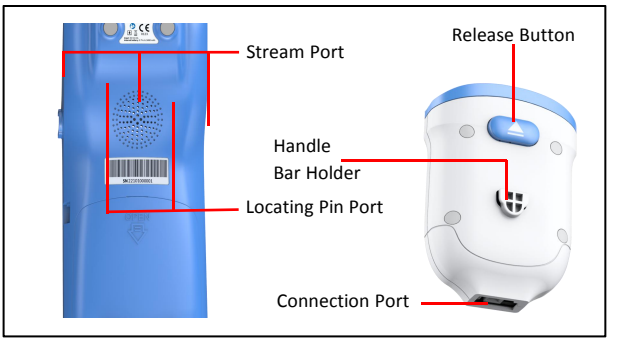
2.2.1 Introduction of UBREATH® PRO Spirometer

A. Overview of UBREATH® PRO Spirometer

a) **Printer Compartment:** Holds the thermal printer inside;
b) **Liquid Crystal Display (LCD):** Shows your test results, and the instruction helps you through the testing process;
c) **Indicator Light:** Tells the working condition;
d) **Controller Holder:** Holds the sensor remote controller at standby mode;
e) **Barcode Reader Button**: Hold this button could scan subject ID or QR code;

f) **Start Button:** To power on or off the device;
g) **Type-C Socket**: Connection port for USB cable;
h) **Connection Port for Remote Sensor Controller:** Connect remote sensor controller with the device;
i) **SN Label**: SN series number;
j) **Speaker:** Tells the audio information to users;
k) **Battery Compartment:** Holds the battery inside.

B. Overview of Remote Sensor Controller



a) **Stream Port:** Air flow tunnel;
b) **Release Button:** Hold this button when disassembling the remote sensor controller from the device;
c) **Handle Bar Holder:** To hang the remote sensor controller on the spirometer at standby mode;
d) **Connection Port:** Connect the remote sensor controller with the Spirometer;
e) **Locating Pin Port**: Lock the flow transducer with the spirometer.

2.2.2 Connecting the Accessories

Before carrying out a test, it is compulsory to connect all the accessory parts into one systematic unit, follow below steps to complete the procedure:

1. Unpack **UBREATH® PRO** Spirometer System, check if all components are in good condition.
2. Connect the controller cable to **UBREATH® PRO** Spirometer System main body until hearing the click which indicates that it has been correctly inserted
3. Connect the other end to the remote sensor controller, again the click will indicate the correction of insert.
4. The flow transducer usually comes with a transparent sterilized bag. Tear the bag and take out the flow transducer then insert the flow transducer into the ports which are located on the head top part of the device. The sound of a click will tell that insertion is complete and correct.
5. For hygiene reasons, do not touch the mouthpiece throughout the process.

WARNING:

1. Use only parts and accessories supplied with the device and available through **e-LinkCare**. The use of accessories other than those specified may result in degraded performance of the device.
2. Verify that there's no foreign bodies present inside the transducer sensor. The insert direction of the transducer must be inserted vertically like the picture shown above.
3. Do not use if the bag is leaking, damaged or the item inside.

2.2.3 Loading the Thermal Paper Roll

Follow the steps to load/change the thermal paper:

1. Open the lid of the thermal paper compartment and remove it from the device;
2. Insert the new roll of paper onto the paper roll holder and close the paper compartment;
3. Pull the paper to the right position and prepare for printing.

WARNING: The thermal paper must be inserted as shown in this picture, pay attention to the direction of the roll hence the printing occurs on the correct side of the thermal paper. To avoid damage to the printer and/or defects in printing, it is recommended to use thermal paper with 57 mm width size.

2.2.4 Switching on/off the Device

Before switching on the device, please check that all the accessories are complete and in good condition.

Long press the start button on the left-hand side of the device for approximately 3 seconds. When the device is turned on, it will beep and a welcome screen will appear.

If you would like to turn if off manually, simply press the start button for 3 seconds when the device on.

Warning： The current test data may lose if attempt to switch off the device during a test by force.

2.2.5 Sleeping Mode

UBREATH® PRO Spirometer has a sleeping mode features to reducing battery consumption. The device will automatically enter sleeping mode if the device is left unattended for 10 minutes. Any gesture applied on the touch screen will awake the device from sleeping mode.

UBREATH® PRO Spirometer will be automatically switched off if the device is left unattended for another 10 minutes while in sleeping mode. You will need to long press the start button for 3 seconds to restart the device.

2.3 LCD Touch Screen

UBREATH® PRO Spirometer System uses an LCD touch screen which allows a more convenient and fast way to use the device. There are a few controls and gestures which you can apply on the screen.

To choose a button or to select a list item, tap on the button or list item on the touchscreen. For every tap, you hear a clicking sound as audible feedback. Also, for every tap, the area or the key that you have tapped is highlighted as visible feedback.

To scroll through lists or move a slider on the touchscreen, drag your finger across the touchscreen.

You can use the touchscreen wearing disposable gloves made of any material. Standard disposable gloves used in hospitals work fine with the touchscreen.

Note: *A pair of disposable gloves are encouraged to wear when Flow transducer is being removed from the* ***UBREATH® PRO*** *Spirometer System.*

2.3.1 Overview of the User Interface

The icons used in the various function screens and their meanings are shown in the following table:

Icons Display

The main menu displays the following icons:

	ID		Date
	Name		Time
	Age		Unit Format
	Sex		Ethnicity
	Height		Ambient Settings
	Weight		Calibration
	Datalist		Linearity Verification
	System Setting		Wlan
	Sensor Status		Language
	The First Test		Firmware Version
	Second Test. Yellow crown stands for the best result		Printing
	The Third Test		

Status Bar

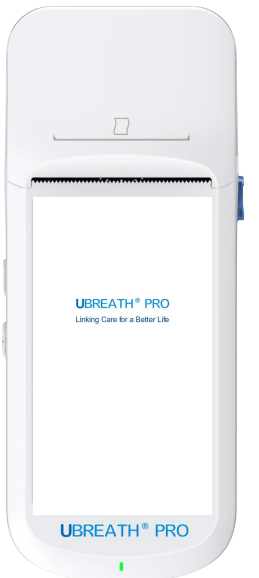
Basic interface elements are used throughout **UBREATH® PRO** Spirometer System for status information and for navigation in the menus and displays the following icons:

Current Date	Current Time	Current Battery Level
2020-01-01	00:00	

2.3.2 Interface

Welcome Screen

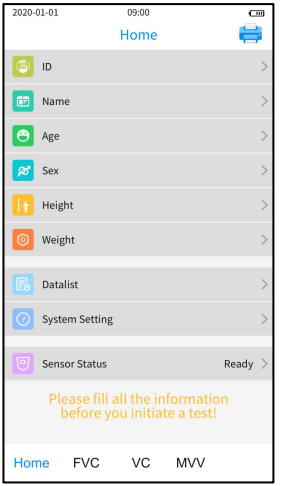
Once the device is switched on, a welcome screen will pop up and a system self-check will be implemented.



Home Screen

The home screen is the starting point when working with **UBREATH® PRO** Spirometer System**.**

The Home screen displays the following icons:



Tap on it and it will lead you to the expanded System Settings page, where you can see:

ID: Indicate the subject number or identification code which is inserted by the user. It can be input manually or through a scanner provided within the device.

Name: Indicate the subject's name, tap on it and enter the name if needed.

Age: Indicate the length of time that the subject has lived. Tap on it and enter subject's date of birth, the system will automatically calculate the age of the subject.

Sex: Identify the gender of the subject. Tap on it and determine if the patient is male or female.

Height: The subject's height without wearing shoes. Tap on it and enter the measurement of height. (Available in Centimeters or Foot & Inch depending on System Setting).

Weight: The subject's weight in KG or Pound. Tap on it and enter the measurement of weight. (Available in KG or Pound depending on System Setting).

Datalist: The historical subject test result list. Tap on it to view the full test result list. You can only view the datalist if there's an actual test stored in the device memory. For more details on viewing test result, refer to Displaying and viewing spirometry testing results on the section 3.5 "Review Historical Data"**.**

System Setting: General configurations of the device.

Sensor Status:

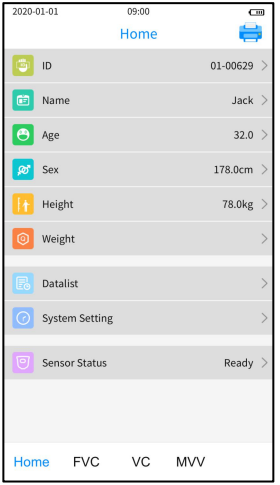
Condition	Status indication
The remote sensor controller is disconnected	Disconnected
The remote sensor controller is connected	Connected
Once it's connected, it will enter warming up process	Warm up
Warm up finished, ready for test	Ready

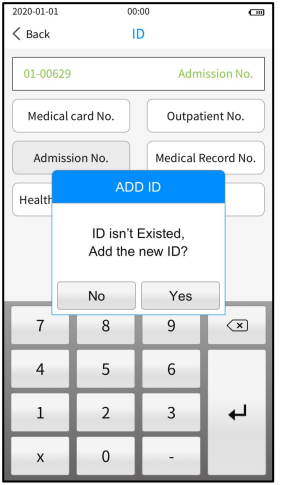
Attention: Warm up process may take up to 5 minutes for the first time when turn on the device. You can only start taking test after warm-up session is completed.

Enter a New ID

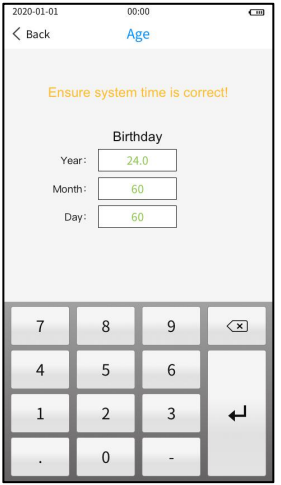
A subject's ID can be entered by following below procedure:

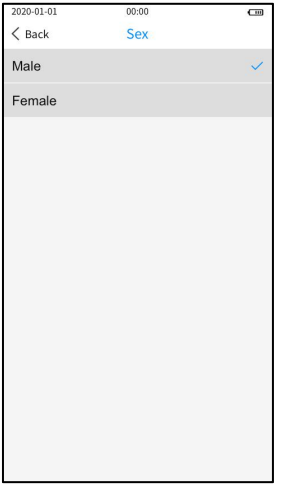
1. Press ID key to enter the ID for the subject, if the ID already exist, the age, sex, height, weight cannot be entered. Otherwise add the ID by using the keypad.
2. Enter age, sex, weight and height accordingly.
3. All information must be filled before initiate a test.



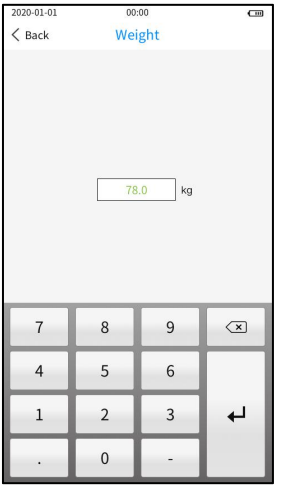


WARNING: Ethnicity of subjects must be entered before entering a new ID.


2020-01-01
00:00
Back
Age
Ensure system time is correct!
Birthday
Year:
24.0
Month:
60
Day:
60
7
8
9
4
5
6
1
2
3
.
0
-


2020-01-01
00:00
Back
Sex
Male
Female


2020-01-01
00:00
Back
Height
178.0
cm
7
8
9
4
5
6
1
2
3
.
0
-


2020-01-01
00:00
Back
Weight
78.0
kg
7
8
9
4
5
6
1
2
3
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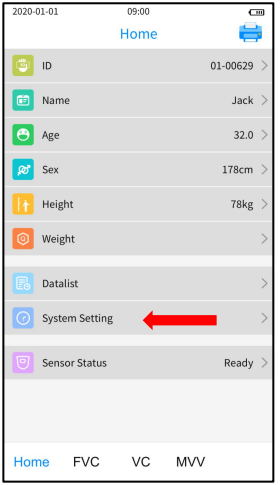
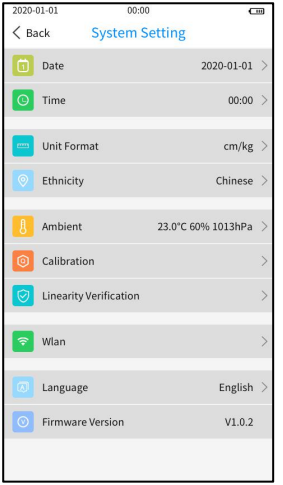
0
-

System Setting

Tab on System Setting and it will lead you to the expanded System Settings page as below, where you can see:





Date: System date in Year Month Day format.

Time: System time in 24H format.

Unit format: Available in CM or Inch for height, KG or Pound for weight.

Ethnicity: This function allows the correction of the predicted values for a subject with the ethnic group to which he or she belongs.

Ambient Setting: This function allows the Ambient Settings (the temperature, humidity and air pressure) before calibrating the flow sensor.

Calibration: This option guides the user to run a calibration check, see details on Section Calibration on the section “Calibration”**.**

Linearity Verification: This option guides the user to run a linearity verification check , see details on Section Linearity Verification on the section “Linearity Verification”.

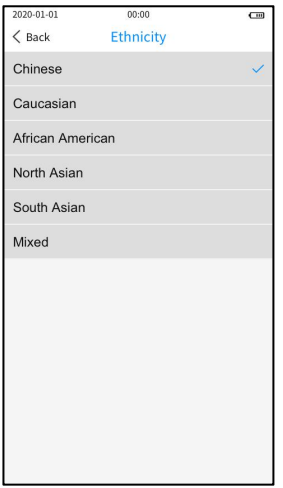
Wlan: Tap on it to connect to PC via WIFI Module.

Language: This option allows operator to choose display language.

Firmware Version: Indicate the version of current internal software.

Ethnicity Setting

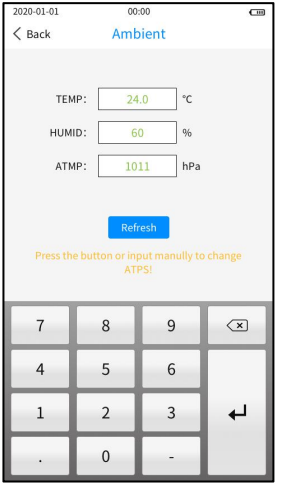
Tap on Ethnicity Settings and it will lead you to the expanded Ethnicity Settings page as below, where you can see:



Ambient Setting

Tap on Ambient Setting to adjust the Ambient Settings (the temperature, humidity and air pressure) to support calibration when perform a test. Or you can tap on “Refresh” to adjust the temperature, humidity and air pressure automatically.

Ambient setting dialog box look like below, use the keypad to enter:

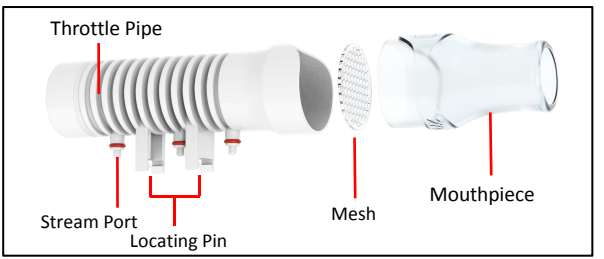


- **TEMP:** Enter the Temperature value. (The value for the ambient temperature.)
- **HUMID:** Enter the Humidity value. (The value for the ambient air humidity.)
- **ATMP:** Enter the Pressure value. (The value for the ambient barometric pressure.)

2.4 UBREATH® PRO Disposable Flow Transducer

To ensure the maximum level of hygiene and safety as well as accuracy, we suggest to always substitute the disposable flow transducer between each patient.

A disposable Flow Transducer included three parts: throttle pipe, mesh, and mouthpiece.



NOTE:

- *Use disposable parts that are not from original manufacturer can cause measurement error and false results.*
- *You must only use **UBREATH® PRO** Flow Transducer by the manufacturer to assure accuracy, and full warranty coverage. Contact your local distributor for purchasing disposable items.*
- *All disposable items included with the device are supplied only as a guide to the correct type and dimensions of the mouthpiece required for this device. To purchase appropriate item, we suggest that you contact your local distributor who supplied the **UBREATH® PRO** Spirometer System.*
- *See the package insert of **UBREATH® PRO** Flow Transducer for more product information.*

Storage and Handling

Please review the following storage and handling instructions:

- **UBREATH® PRO** Spirometer System together with its battery inside can be stored in a place with temperature ranges from -10ºC - 45ºC. Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use **UBREATH® PRO** Spirometer System in a humid place such as a bathroom.
- Do not store the **UBREATH® PRO** Spirometer System and the flow transducer near bleach or cleaners that contain bleach.

2.5 Power Supply (Rechargeable Li-ion Battery)

2.5.1 Recharging the Battery

WARNING: **UBREATH® PRO** Spirometer System is powered by the exclusive rechargeable batteries, batteries supplied by others are not recommended to use. Only use the exclusive recharge cable to recharge. Make sure that the electrical information on the label of the charging unit corresponds to that of the power source.

Follow the steps to recharge the battery:

1. Plug the USB port of USB cable into an electrical outlet by using an electrical adaptor.
2. Plug the other end of USB cable into the type-C socket at the bottom of the device.
3. The LED will start flashing orange when it's recharging; When the charging is completed, the orange LED turns off and green LED lights up.

***NOTE:** The **UBREATH® PRO** Spirometer System is not functional when recharging.*

The user is responsible for evaluating the adaptor that is connected to **UBREATH® PRO** Spirometer System for compliance to IEC60601-1. The power source must be a non-grounded receptacle with two slots.

If the device will be left unattended for a long time, it is suggested to switch off the device and recharge after every three months.

A rechargeable Li-ion battery is installed within the battery compartment when the device is being manufactured. We recommend recharging the battery before use for the first time.

If the battery power drops below 10%, the LED will start flashing orange, the battery bar will show "  ". You may not be able to use **UBREATH® PRO** Spirometer System if the battery is low. Recharge your battery if battery power is low.

2.5.2 Changing the Battery

You may need to change your battery if the device consumes the power abnormally fast. Contact your local distributor to change the battery.

Take the battery out from the battery compartment, replace the battery exclusively provided by **e-LinkCare**.

NOTE: Data saved in non-volatile memory will NOT lost when battery power is low or batteries are removed.

2.6 Information for Correct Use in an Electromagnetic Environment

As the **UBREATH® PRO** Spirometer System is a medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the **UBREATH® PRO** Spirometer 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® PRO** Spirometer System may result in increased emissions or decreased immunity of the device in relation to EMC performance.

The **UBREATH® PRO** Spirometer System should be used only with the accessories (USB cables, adapter and flow transducer) supplied. None of the **UBREATH® PRO** Spirometer System cables should be extended in length by the user.

If any cables are extended by the user or non-approved accessories are used, this may result in an increased level of emissions or decreased level of immunity, in relation to the **UBREATH® PRO** Spirometer System EMC. None of the **UBREATH® PRO** Spirometer System accessories should be used with other devices, as this may result in an increased level of emissions or decreased level of immunity in relation to the other devices' EMC.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions test	**Compliance**	**Electromagnetic environment -guidance**
RF emissions CISPR 11	Group 1	The **UBREATH® PRO** Spirometer System uses RF energy only for its internal unction. Therefore, its RF missions are very low and re not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group A	The **UBREATH® PRO** Spirometer 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.
Harmonic emissions IEC61000-3-2	Not applicable	Power input < 75W
Voltage fluctuations/flickr emissionsIEC6100 0-3-3	Applicable	

Guidance and Manufacturer's Declaration –Electromagnetic Immunity

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

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment -guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/-8 kV contact +/-15 kV air	+/-8 kV contact +/-15 kV 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 +/-1 kV for input /output lines	+/-2 kV for power supply lines [Not Applicable]	Mains power quality should be that of atypical commercial or hospital environment
Surge IEC61000-4-5	+/-1 kV line(s) to line(s) +/-2 kV line(s) to earth	+/-1 kV line(s) to line(s) [Not Applicable]	Mains power quality should be that of atypical 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 U^T) for 5 cycles 70% U^T 30% dip in U^T) if or 25 cycles<5% U^T (> 95% dip in U^T) for 5 s	< 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 atypical commercial or hospital environment. If the user of the **UBREATH® PRO** Spirometer System requires continued operation during power mains interruptions, it is recommended that the **UBREATH® PRO** Spirometer System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field EC61000-4-8	3 A / m	30 A / m	Power frequency magnetic fields should be at levels characteristics of atypical location in atypical commercial or hospital environment
NOTE: U^T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration –Electromagnetic Immunity

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

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment -guidance**
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz &	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the **UBREATH® PRO** Spirometer System, including cables, than the

			recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d= 1.2√P 150kHz-80MHz
Radiated RFIEC6100 0-4-3	3V/m 80 Mhz to 2.7 Ghz	3V/m	d= 1.2√P 80MHz-800MHz d= 2.3√P 800MHz-2.5GHz 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 radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **UBREATH® PRO** Spirometer System is used exceeds the applicable RF compliance level above, the **UBREATH® PRO** Spirometer 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® PRO Spirometer System. *Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V / m.			

Recommended Separation Distance

The **UBREATH® PRO** Spirometer System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the **UBREATH® PRO** Spirometer System can help prevent electromagnetic interference by maintaining a minimum distance

between portable and mobile RF communications equipment (transmitters) and the **UBREATH® PRO** Spirometer 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	8	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23.3

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.*

Perform a Spirometry Test

After subject's profile is entered, now the device is ready to make a spirometry test. Press start button will lead you to FVC testing page by default.

When a test is being performed the display will show the real time Flow/Volume curve or the Volume/Time curve.

WARNING: The device must only be used by qualified personnel with complete knowledge of spirometry tests; this is important for the correct execution of the tests, for the acceptability of measured parameters as well as for the correct interpretation of results.

WARNING: The spirometer captures and presents data reflecting a subject's physiological condition. When reviewed by a trained physician or clinician, this data can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a subject's diagnosis.

WARNING: To minimize chances of a misdiagnosis, it is the physician's responsibility to assure that pulmonary tests are properly administered, evaluated, and interpreted.

WARNING: People may become lightheaded, dizzy, or even faint during a spirometry test. Watch subjects closely. If they choose to stand during testing, keep a chair immediately behind them. If there is any reason for concern, stop the test and take appropriate action.

WARNING: During a spirometry test all the parameters are measured at BTPS conditions (Body Temperature and Pressure, Saturated).

3.1 Prepare a Patient

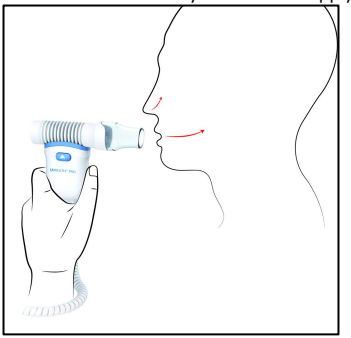
The accuracy of a spirometry test is highly dependent on the subject's understanding and cooperation. Hence it is recommended to explain the entire procedure for the type of effort which is expected to be performed. Remind subjects that the test is painless. Demonstrate at least one effort for the subject for all different breathing maneuvers.

WARNING: Make sure all the accessory items are correctly connected to each other, mouth piece side must face the subject. Make sure battery is charged.

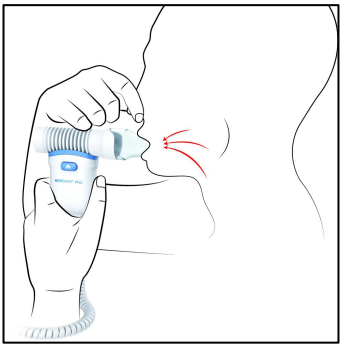
Always check the interior of the flow transducer to ensure that no foreign objects are present.

Instruct the subjects to do the following to prepare for a test:

1. Loosen any tight articles of clothing that might constrict lung function, for example, a tight belt, tie, vest, bra, girdle, or corset, if they will restrict maximal breathing
2. Remove any foreign objects from the mouth, including loose dentures.
3. Insert the mouthpiece into the protruding part of the flow transducer till it fits in perfectly.
4. Hold **UBREATH® PRO** Spirometer System remote sensor controller with one hand. Use the other hand to hold on your nose and apply like a nose clip.



5. Place lips and teeth around a mouthpiece of new flow transducer, sealing their lips tightly around the transducer. Grip slightly with teeth in the groove. The tongue and teeth must be positioned to not obstruct airflow.



6. Keep tongue away from the flow transducer to avoid blocking it.
7. Keep chin slightly elevated so as not to restrict the airway.

8. Do not touch the buttons of during the test to avoid switching off the system or stopping a test too soon.

WARNING: It's preferable that following activities should be avoided before the test:

- Smoking within at least one hour before testing
- Taking alcohol within 4 hours of testing
- Performing vigorous sports within 30 minutes of testing
- Eating a big meal within 2 hours of testing

3.2 Test Posture

It is recommended to use the standing position during spirometry test unless the subject cannot do so because of a safety or health concern such as a history of fainting or an illness. Take the following safety precaution if the subject uses stand position:

- Place a sturdy chair without wheels behind the subject
- Watch the subject during testing for signs of light-headedness
- Place a hand on subject's arm or back if needed to steady them

WARNING: If the subject experiences light-headedness, fainting or any other signs of distress during the test, the subject should be conducted in the seated position or test should be terminated.

If the subject uses seated position to perform a test:

- The subject should sit upright.
- The testing position should be documented, and future test should be conducted in the same seating position.
- If a wheelchair is used, the wheels should be locked.

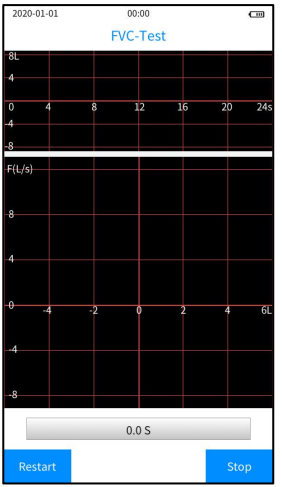
3.3 Take a Spirometry Test

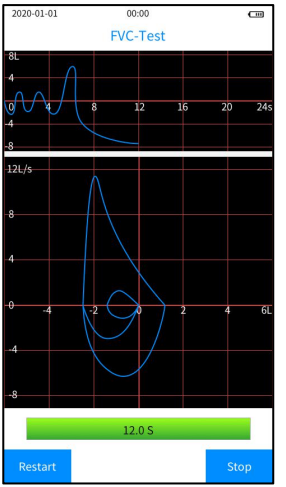
All the subject's profiles must be entered before making a spirometry test.

Tap and choose from the selection of available spirometry tests:

- FVC to perform the FVC test (Forced Vital Capacity)
- VC to perform the VC test (Slow Vital Capacity)
- MVV to perform the MVV test (Maximal Voluntary Ventilation)

FVC





It is recommended to explain, demonstrate and actively coach the subject to perform the test to obtain a meaningful result:

Explain the purpose of the test to see the maximal volume of gas that can be expired as forcefully and rapidly as possible after a maximal inspiration to total lung capacity.

Demonstrate:

1. How to use mouthpiece
2. How to hold remote sensor controller with one hand and use the other hand to help with manually occlude of the nares
3. How to fill the lungs slowly then blast out immediately
4. How to keep exhaling as long as possible
5. Exaggerating each step if helpful

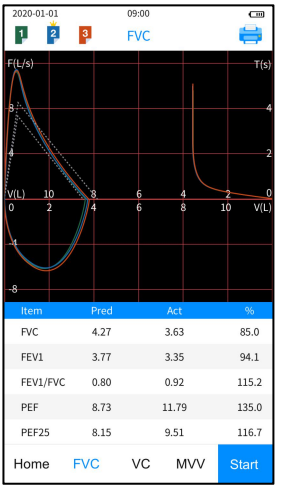
Coach the subject to perform the maneuver

Once the subject is ready, instruct the patient to do the following:

1. Tap on FVC icon on the bottom part of screen to initiate the FVC test.
2. Hold the remote sensor controller vertically with one hand.

3. Insert the mouthpiece well into the mouth beyond the teeth, being careful to ensure that air cannot escape from the sides of the mouth.
4. Press the “Start” button, the system will beep and instruct to begin the test.
5. Make several breaths through the disposable flow transducer.
6. Then inspire slowly as much air as possible and then use the hand to hold on the nose and apply like a nose clip, then expire all the air as rapidly, forcefully and completely as possible. Continue to expire one breath until it reaches 6 seconds or it is fully recorded. Then instruct the patient to inspire fully, as rapidly as possible. Press the “Stop” button to complete the test. During testing the Flow/Volume curve is synchronized displayed.
7. Press restart button for two more trials without remove the mouthpiece.
8. The device will show the best effort with a crown on top of it.

At the end of the test, a comprehensive report will show below the curves, each item included in the blue row represents the following:



Item: Indicate the type of parameter.

Act: Indicate the actual test results of the test.

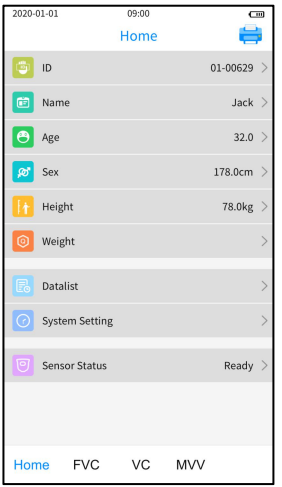
Pred: Indicate the predicted value based on patient’s profile.

%: indicate the percentage of actual value compare to predicated value.

***WARNING*:**
The performance of the Spirometer can be affected by the patient spitting or coughing into the Spirometer during expiration or by extremes of temperature, humidity and altitude.

VC

Again, it is recommended to explain, demonstrate and actively coach the subject to perform the test to obtain a meaningful result:



Explain the purpose of the test: to see the volume change between a full inspiration and a maximal expiration.

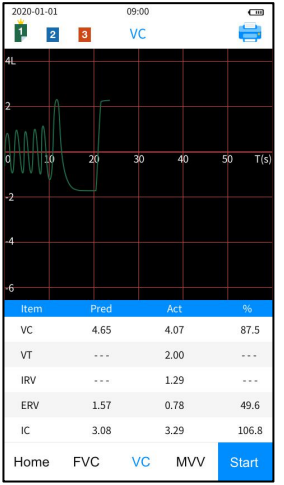
Demonstrate:

1. How to use mouthpiece;
2. How to hold the spirometer with one hand and use the other hand to help with manually occlude of the nares;
3. How to fill the lungs slowly with a full inspiration
4. How to keep expiring slowly and maximally
5. Exaggerating each step if helpful

Coach the subject to perform the maneuver

Once the subject is ready, instruct the patient to do the following:

1. Tap on VC icon on the bottom part of screen to initiate VC test.
2. Place the device on the table and hold the remote sensor controller vertically with one hand.
3. Insert the mouthpiece well into the mouth beyond the teeth, being careful to ensure that air cannot escape from the sides of the mouth.
4. Press the “Start” button, the system will beep and instruct to begin the test.
5. Make at least 5 tidal breaths several breaths, then instruct the patient to exhale maximally and inhale maximally. Use the other hand to hold on your nose and apply like a nose clip, then subsequently expire as much air as possible.
6. The test stops automatically after 60 seconds or tap on “STOP” button to terminate the test. During testing the volume/time curve is displayed.
7. After the whole VC test procedure finished, the device will automatically show the curves made and display related parameters such as IRV / ERV / IC.
8. Repeat step 4 and 5 for two more times, 2 minutes of rest is recommended between each test.
9. The device will show the best effort with a crown on top of it.
10. At the end of the test, a comprehensive report will show below the curves, each item included in the blue row represents the following:



Item: Indicate the type of parameter.

Act: Indicate the actual test results of the test.

Pred: Indicate the predicted value based on patient's profile.

%: indicate the percentage of actual value compare to predicated value.

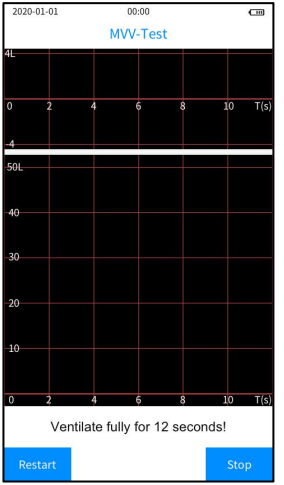
MVV

Again, it is recommended to explain, demonstrate and actively coach the subject to perform the test to obtain a meaningful result:

Explain the purpose of the test: to see the maximum volume of air a subject can breathe over a specified period.

Demonstrate:

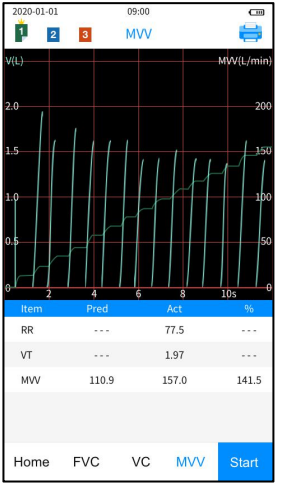
1. How to use mouth piece;
2. How to hold the spirometer with one hand and use the other hand to help with manually occlude of the nares;
3. How to fill the lungs with a full inspiration and blast all air out;
4. How to keep expiring as long as possible;
5. Exaggerating each step if helpful.



Coach the subject to perform the maneuver

Once the subject is ready, instruct the patient to do the following:

1. Make several breaths at rest before the test.
2. Tap on MVV icon on the bottom part of screen to initiate the MVV test.
3. Place the device on the table and hold the remote sensor controller with one hand.
4. Insert the mouthpiece well into the mouth beyond the teeth, being careful to ensure that air cannot escape from the sides of the mouth.
5. Press the “Start” button, the system will beep and instruct to begin the test.
6. Start the test by making a series of forced inspirations and expirations, breathing as deeply as possible. The test automatically stops gathering data after 12 seconds. During testing the volume/time curve is displayed.
7. At the end of the test the display shows the curve made and related parameters such as RR & VT.
8. Repeat step 5 and 6 for two more times. It is recommended to have at least 5 minutes of break between each trial.
9. The device will show the best effort with a crown on top of it.
10. At the end of the test, a comprehensive report will show below the curves, each item included in the blue row represents the following:



Item: Indicate the type of parameter.

Act: Indicate the actual test results of the test.

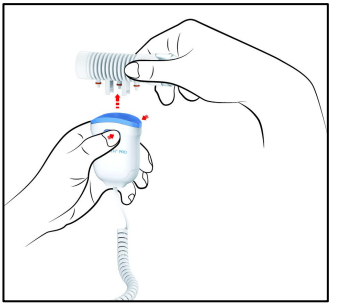
Pred: Indicate the predicted value based on patient's profile.

%: indicate the percentage of actual value compare to predicated value.

3.4 Finish a Test

Follow the below procedure to finish a test:

1. Press the release button to unlock the locating pins while pulling the flow transducer vertically up simultaneously.
2. Discard the flow transducer directly into a waste container.



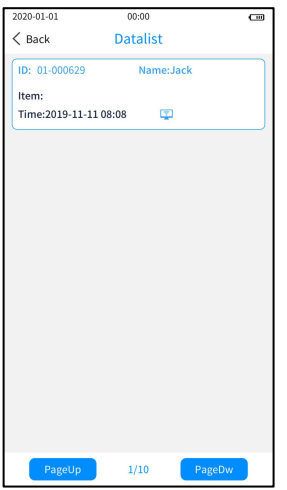
3.5 Review Historical Data

Displaying and viewing the historical spirometry testing results

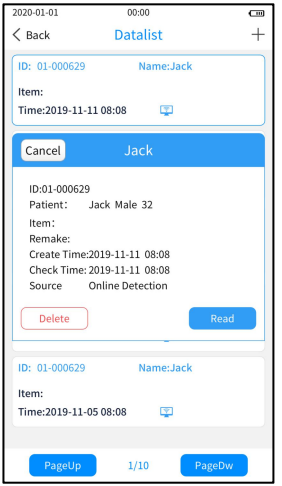
Once the test is completed. The spirometry tests results are recorded in the memory of the device.

To display and view the historical testing results, follow the steps below:

- Return to Home screen, tap on Datalist to review the subjects list, the screen will show like below:



- The detail of the subject's test information will be shown when tap on one data, a menu with 3 options "Read" " Delete" "Cancel" will display like follow:



- To delete subject's current test result from memory, press "Delete".
- To go back to data list, press "Cancel".
- To review the details of selected subject's (for example: patient 01-00629) historical test result, press "Read", it will lead you to the previous page with selected subject information listed. The screen will look like below:

- Press FVC, VC and MVV on the screen to review this patient's testing report respectively.

- Press "PageUp" and "PageDw" button for more test results.

Note: *Once the data has been deleted, it cannot be recovered.*

3.6 Test Validation

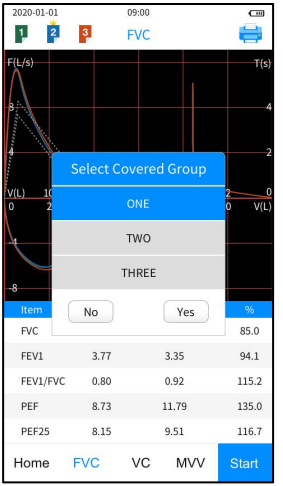
The goal of spirometry testing is to obtain accurate measurements of lung function. A "Valid" test includes at least three technically "acceptable" maneuvers. Once three acceptable curves are recorded, consistency or repeatability of results is evaluated. When the subject records three acceptable curves with repeatable results, the test is valid and can be concluded.

If all three tests cannot meet the requirement of test result validation, the subject will need to attempt a few extra trials (No more than 8 trials in total) until the correct data is collected.

Follow the steps below to repeat the test and replace the invalid test result:

- Tap on the parameters that a patient wishes to repeat the test.
- Follow the testing procedure accordingly.

- After the test is finished, the following screen will show with options
- Select “First” if you would like to replace the first testing record
- Select “Second” if you would like to replace the second testing record
- Select “Third” if you would like to replace the third testing record
- Or select “No” to cancel.
- Keep testing until all trials are valid. (No more than 8 trials)



WARNING: The valid test results can be achieved by most healthy subject, however if three acceptable results have not been recorded within five attempts, check that the if the subject is able to proceed since some individuals with obstructive airways disease may experience too much discomfort to continue.

3.7 Test Acceptability

The spirometry test interpretation is required based on the Forced Vital Capacity (FVC) test according to the ERS standard.

A curve is considered acceptable when the subject performs all aspects of the forced expiratory maneuver correctly. Acceptable spirometry test curves display maximal inhalations, hard initial blasts (free of hesitation and cough in the first second), complete exhalations, and maximal effort throughout the maneuver. Common problems such as incomplete inhalations, hesitations, coughs in the first

second, weak expiratory push, and early terminations could cause unacceptability of the test result.

However, following condition shall be assessed when evaluate the tests:

- Cough during the initial second
- Glottis closure
- Effort that is not maximal throughout
- Mouth piece air leaking
- Mouthpiece obstructed by tongue or foreign body

3.8 Test Repeatability

Three acceptable curves in a well-performed test usually have repeatable shapes and consistent results among the maneuvers. Evaluation of the consistency or “repeatability” of the measurements is the final step in determining whether a test is valid and complete. Values for FVC and FEV1 are considered repeatable when the largest FVC minus the second largest FVC and the largest FEV1 minus the second largest FEV1, taken from acceptable curves, are both 0.15 L (150 ml) and less.

Lack of repeatability is often caused by failing to inhale maximally before each maneuver. Repeatable results can be recorded by most healthy subject when they consistently exert a maximal effort for each maneuver attempted, and every effort should be made to record a valid test. However, subject with airway obstruction sometimes have difficulty achieving repeatability, and as a result, non-repeatable test results should not be excluded from interpretation. Failure to achieve repeatability should be documented and considered during interpretation of results.

3.9 Interpreting Test Result

The three key spirometry measurements (the FVC, FEV1 and FEV1/FVC ratio) for a given individual are compared to reference values. The reference value is based on healthy individuals with normal lung function, and it tells the doctor the values that would be expected for someone of the same sex, age and height. To find the reference value on your spirometry report, look for the column marked “Predicted” value on the screen.

3.10 Print Test Report

UBREATH® PRO Spirometer System enables you to print any test performed and stored in the archive.

To print the testing results stored in the archive, simply tap on the corresponding test parameters then press to print.

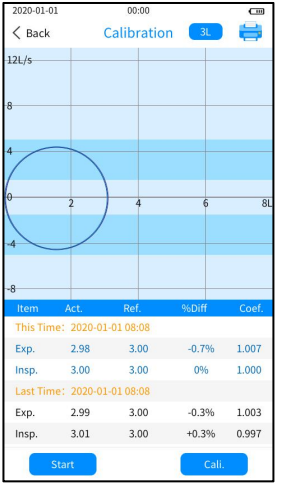
The printout report includes a header line with the date, time, subject profile, detailed test results etc.

The thermal print paper roll can often be bought from your local medical suppliers, they are usually 57mm in width size, make sure the diameter of each roll should not be exceeded than 30mm.

Calibration

When the **UBREATH® PRO** Spirometer System is in use, the users should always verify its accuracy by frequently checking its performing maintenance procedures at regular intervals (not required, but optional).

The following picture shows the “Calibration" screen.

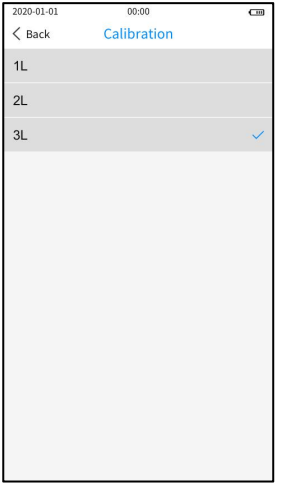


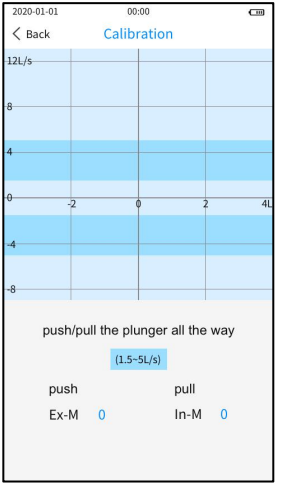
You may need a syringe and adaptor separately. Contact your local distributor for more information.

The **UBREATH® PRO** Spirometer System calibration simulates inspirations and expirations for same flow levels each to ensure the product performance.

Follow the below procedure to complete the calibration:

1. Tap on "3L” button, you will have three options to choose from different volume of syringes, select the right syringe that you are using. Press “Back” button to go back to previous menu.
2. Connect the syringe and the adaptor to the new **UBREATH® PRO** Disposable Flow Transducer, avoid any cross infection.
3. Press “Start” button to initiate a quality control, a following screen will pop up to guide you through the process.





4. Pull the piston all the way out at a steady speed of 1.5 - 5L/s.
5. Push the piston all the way in again with the same speed.
6. Repeat step 4 and 5 for more than three times until the Ex-M and In-M both show 3, the spirometer can calculate the average value of flow and calibration factor.
7. Press “Start” to run the calibration test again if needed or tap on “Calibration.” to update the calibration factor.
8. Once the pull and push ＜ 3 times, must not calibrate. You will need to run the Calibration again.
9. When “Diff” item display ＞10% or ＜-10%, must not calibrate. You will need to run the Calibration again.
10. When the test value is discrete, indicate the consistency is bad and ensure not leak between the disposable flow transducer and syringe.
11. If there is no calibration value or the calibration is done, please run the calibration after test.

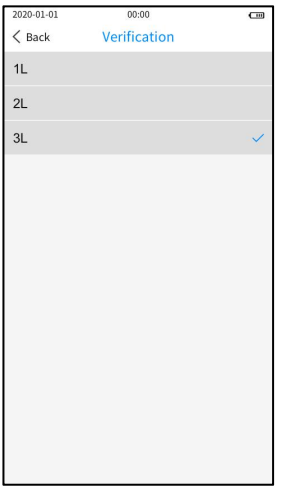
Attention: *Calibration is an important part of good laboratory practice to ensure the device working properly and testing results are accurate.*

Linearity Verification

The **UBREATH® PRO** Spirometer should never be outside accuracy limits unless damaged or in a fault condition. In this event, please see troubleshooting. In normal use, calibration traceability certification is recommended as a part of the routine annual service.

Press "Linearity Verification" screen using the keypad to bring you into the Linearity check verification screen in the system setting model.

1. Select Precision Syringe from the top of screen and tap the volume of the calibrated syringe (1L, 2L, 3L) you are using. Using a 3L calibrated syringe as default setting.



2. Pump air through the flowhead to bring it to ambient temperature. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated with ambient by pimping air.

3. Press "Start" at the bottom of screen to start the Linearity verification.

   Attention: *Every spirometer has been calibrated and verified by Pulmonary Waveform Generator in factory inspection. The spirometer has been saved the default data. Once you want to start a new verification test, there is a*

pop-up window notice for your attention. Press "YES" to move on the verification procedure.

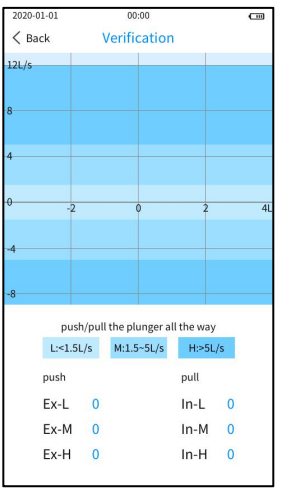
4. Follow the voice instruction and perform low, medium and high flow linearity verification on the spirometer. Pump air into the flowhead at a slow rate of 0 ~ 1.5 L/s, immediately withdraw the syringe at a slow rate. This manoeuvre should show on graph between the light blue area. Repeat for the slow rate three times.

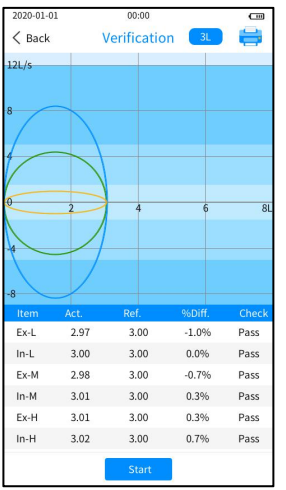
5. Repeat for the procedure outlined for a medium flow rate (1.5 ~ 5.0 L/s), high flow rate (5.0 ~ 12.0 L/s). This manoeuvre should show on the graph between the area, if it is a correct manoeuvre the test number and the FVC values will be updated in the table. Repeat for the medium rate and high flow rate each three times.

6. When the numbers of In-L, In-L, Ex-M, In-M, Ex-H, In-H are all displayed as 3 or > 3, the instrument exits after automatic verification is completed, and confirms whether the average value is 3.0 ± 3% [2.91 L - 3.09 L].

7. If a linearity check report is required, tap the Printer at the top of screen for report printing.

8. During the test, you can press the "Back" button for return and exit at any time.





Maintenance

5.1 Care and Cleaning

The **UBREATH® PRO** Spirometer System does not require regular special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the device. Take care to avoid getting liquids, dust or other foreign bodies into the device through the flow sensor or data ports. It is recommended that you store the device back in the case after each use.

The operations to perform periodically are:

- Changing the **UBREATH® PRO** Disposable Flow Transducer between tests.
- Charging the battery with safety.

The follow precautions are needed to pay attention to:

- Avoid exposing the **UBREATH® PRO** Spirometer System to direct sunlight during use;
- Avoid operating the spirometer in dusty conditions or near to heating appliances or radiators;
- Do not keep the spirometer in a damp place or expose it to extremes of temperature;
- Do not direct the transducer holder towards a strong light source whilst operating the spirometer;
- Check the AC charger for compatibility with local power rating.
- The **UBREATH® PRO** Spirometer System is a precision electronic instrument. Please handle it with care.

5.2 Replacement Items

The **UBREATH® PRO** Spirometer System is a device that requires very limited maintenance, however the follow accessories need to be replaced if needed.

- **UBREATH® PRO** Disposable Flow Transducer
- Thermal printing paper roll
- Rechargeable battery

Despite the thermal printing paper roll which can be bought from your local general medical suppliers, the **UBREATH® PRO** Disposable Flow Transducer and Rechargeable battery are exclusively from **e-LinkCare**. Contact your local distributor to enquires from them.

WARNING: The maintenance operations set forth in the User's Manual must be carried out carefully. Failing to observe the instructions contained in the manual may cause errors in measurement or in the interpretation of measured values. Modifications, adjustments, repairs, and reconfiguration

must be carried out by the manufacturer or authorized persons. In case problems arise do not attempt to personally repair the unit.

The setting of configuration parameters must be carried out by qualified personnel. In any case the risks pertaining to incorrect settings do not constitute a hazard for the subject.

5.3 Charging the Battery

The rechargeable battery of **UBREATH® PRO** Spirometer System usually can last for an entire working day. To fully charge the battery after a day of work, it's recommends recharging overnight. In addition, you can also charge multiple times during the day between spirometry tests.

To charge **UBREATH® PRO** Spirometer System, always use the USB cable released by the manufacturer.

Troubleshooting Guide

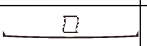
The following table refers some of the issues that can occur with your Test & Measurement products and provides useful troubleshooting steps to help you resolve an issue yourself.

CONDITION	POSSIBLE SOLUTIONS
UBREATH® PRO SPIROMETER SYSTEM DOES NOT SWITCH ON	Check that battery is correctly inserted in the compartment on the back of the instrument. If it is correctly positioned then replace it with new one.
THE DEVICE (SENSOR) IS NOT RESPONDING	Disconnect and reconnect the transducer, make sure all accessories are connected correctly
REPORT DOES NOT PRINT PARAMETERS OR GRAPHS	Check print and parameters settings

Specifications

Feature	Specification
Size	Spirometer: about 206 × 86 x 72 mm Sensor Handle: about 81 x 59 x 34 mm Flow Transducer: about 138 x 34 x 47 mm
Weight	575 g (including flow transducer)
Measuring Sensitivity	0.025 L/s
Measuring Resolution	Volume: 0.01 L Flow: 1 L/s
Dynamic Resistance at 14 L/s	< 0.35 kPa/(L/s)
Measurement Principle	Pneumotachograph
LCD display	5.0“, 480 × 854 pixels, 262 K colors
Test Storage Capacity	Up to 200 records
Printing Option	Built-in printer
Battery Life	Approximately 500 complete charge cycles
Power Supply	3.7 V lithium battery
Input Power	≤ 10 W
FVC	Range of measurement: (0.5 - 8) L, Accuracy: ± 3% or ± 0.050 L (take the largest value) Repeatability: ≤ 3% or ≤ 0.050 L (take the largest value)
VC	Range of measurement: (0.5 - 8) L, Accuracy: ± 3% or ± 0.050 L (take the largest value) Repeatability: ≤ 3% or ≤ 0.050 L (take the largest value)
PEF	Range of measurement: (0 -14) L/s, Accuracy: ± 3% or ± 0.17 L/s (take the largest value) Repeatability: ≤ 5 % or ≤ 0.17 L/s (take the largest value)
FEV1	Range of measurement:(0.2 - 8) L, Accuracy: ± 3% or ± 0.050 L (take the largest value)
Classification	IIa MDD 93/42/EEC Appendix IX Rule10

Classification according to the type of applied part	Type BF Applied Parts
Classification according to the type of protection against harmful ingress of water	IPX0
Operating Environment	10 - 35℃, 30% - 80% RH
Storage Environment	-10 - 45℃, ≤ 80% RH, storage in clean and ventilated room.
Operating altitude	0 - 1400 meters (1060 hPa - 850 hPa)

Index of Symbols	
	Consult instructions for use
	Store between -10ºC - 45ºC (14°F - 113°F)
	Use by
LOT	Lot Number
	Manufacturer
EC REP	Authorized Representative
STERILE EO	Sterilized using Ethylene oxide
MODEL	Model Number
REF	Catalog #
SN	Serial Number
	Do not dispose along with household waste
	Fragile, handle with care
	This Side Up
	Keep away from sunlight and heat
	Keep Dry
	Humidity Limitation between 10% - 80%
	Thermal printer report
	Do not reuse (single-patient use)
	Release button
	Barcode reader
	Medical electric equipment that includes a radio frequency transmitter and emits non-ionizing radiation
	Instrument classification: Type BF applied part

Warranty Condition

UBREATH® PRO Spirometer System **(Model PF680)** 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 shown on the relevant sales invoice or proof of purchase.

This device 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 guarantee.

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

- If the fault is due to an improper installation or operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilized differently from the use described in the User's Manual. If any alteration, adjustment, modification or repair has been carried out by personnel 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 the mains, or by a product to which the instrument has been connected.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The customer is responsible for the transportation and for all transport and customs charges as well as for delivery charges of the goods both to and from the manufacturer or distributor. Any device or accessory returned must be accompanied by a warranty card with detailed explanation of the defect or problem found. If units are to be returned to the manufacturer then written or verbal permission must be received before any device are returned 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: 2021-05-23