Sunvou

Breath Senses Health

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Sunvou

Nano Coulomb Breath Analyzer
Sunvou-HA1101

User Manual

Sunvou Medical Electronics Co., Ltd.

Contents

Intended Use

Nano Coulomb Breath Analyzer Sunvou-HA1101 measures Nitric Oxide (NO) in human breath. Nitric Oxide is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath (FeNO), can be measured by Sunvou-HA1101 according to guidelines for NO measurement established by the American Thoracic Society. Measurement of FeNO by Sunvou-HA1101 is a quantitative, non-invasive, simple and safe method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FeNO levels. Sunvou-HA1101 is suitable for children, approximately 7- 17 years, and adults 18 years and older.

Sunvou-HA1101 is intended for prescription use and should only be used as directed in the User Manual by trained healthcare professionals.

Precautions

The device is a portable device for precision measurements. During operating, transport and storage, please pay attention to:

- Use the device at room temperature. The device is not suitable for use in outdoor and wild places without protection. Avoid excessive high or low temperature, Do not place the device in direct sunlight.
- Avoid exposure to dust or liquids, and the container of liquids shall not be placed on the device. Objects filled with liquid such as vases shall not be placed on the device. Neither the device nor the consumables shall be immersed in water or other liquids.
- Avoid humidity, humidity will affect the performance and operating life of the device.
- Avoid dropping the device or subjecting it to any impact, avoid placing the device in a high place. Be careful when handling the device.
- Avoid weights, heavy objects shall not be placed on the device to avoid crushing.
- Avoid open flames and burning. The device will generate heat during normal operation, so it should be placed in an open or ventilated place. The temperature of the device may rise above the ambient temperature, so try to avoid placing the device on a bed, sofa, carpet or other soft surfaces.
- Avoid electric shock / lightning, do not try to disassemble or repair the device by yourself. In case of lightning weather, try to disconnect the external power connection.
- The device shall be place away from air pollution sources, especially the interfering gases.
- Do not clean the product with disinfectants. Clean the surface of the device according to Maintenance section of this manual.
- Avoid using ultraviolet light to sterilize the device.
- The mouthpiece is single-use disposable. the manufacturer is not responsible for the measurement errors, or all other consequences caused by the repeated use or cross use of the mouthpieces.
- The interchangeable sensors in the device may cause harm to the environment or human body. Do not open the sensor casing in the device without permission or put the sensor into the mouth.
- Third-party spare parts or accessories may affect the performance of the device and even damage the device. Any defects caused by using third party parts and accessories are not included in the warranty.

- When the device is not in use, the breathing tube must be always connected to the handpiece.
- Disassembling of the device will void warranty, the manufacturer may reject the maintenance and service of disassembled devices and will not be responsible for the adverse consequences.
- Improper turning off may cause data loss or system errors. Please turn off the device according to this manual.
- It is recommended to keep the original packaging for future transport. The possible equipment damages caused by other packaging are not included the warranty.
- The user must handle and operate the device according to this manual, the manufacturer is not responsible for any damages or incorrect results caused by incorrect use.

  The battery in the sensor should not be removed.
- Sensor operating life: Nano Coulomb NO sensor is high sensitivity electrochemical sensor. To maintain the accuracy of the device, the device will automatically number the measurements of the sensor. When the number of measurements reaches the limit, the device will prompt to replace the sensor. The limit of measurements is printed on the label of the sensor.
- The device and sensor can be recycled and disposed in accordance with the environmental regulations of the territory where the device is used.
- The device is disconnected from the power grid through the power adapter.
- When necessary, the manufacturer may provide corresponding circuit diagrams, component lists, drawing notes, calibration instructions, or other materials necessary for repairable equipment parts as required.
- In case of any error, turn off the power first and contact the technical support personnel of the manufacturer or the local representative as soon as possible.
- The instructions in this manual are only applicable to this model.

Safety information:

- Be sure to read the "Precautions" above.
- The sensor in the device is sensitive to changes in ambient temperature and humidity and can perform best only under stable conditions. Please refer to section Operating Conditions under Technical Data Sheet for recommended operating conditions. Avoid fluctuating conditions, see "Precautions" above.
- Make sure the vents on the back of the device is not covered or sealed.
- If the lithium battery in the devices is handled properly, may increase the risk of overheating, smoke or fire. Do not open, squeeze, heat above 60℃ or burn.
- Strong electromagnetic interferences from radio frequency transmission or strong electrical waves may interrupted the operating or affect the performance of the device. If an error occurs, it is necessary to readjust the operating environments.

About the User Manual

Nano Coulomb Breath Analyzer Sunvou-HA1101 User Manual, Version 0.2, September 2024

The User Manual provides instructions on how to operate Nano Coulomb Breath Analyzer

Parts and Accessories

Name		Model/Specifications	Intended use
Nano Coulomb Breath Analyzer		Sunvou-HA1101	Breath measurements and analysis
NO sensor		Sunvou-HD1101	Use with analyzer for NO measurements
Power adapter		5V ⎓ 2.0A	Power supply
Filter	Handpiece	/	Use with analyzer for online breath sampling
	Mouthpiece	SV-EBFH	

Nano Coulomb Breath Analyzer

NO sensor

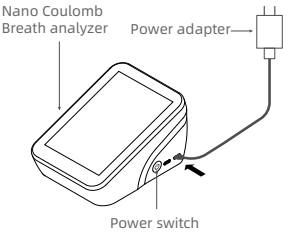
Handpiece

Mouthpiece

Breathing tube

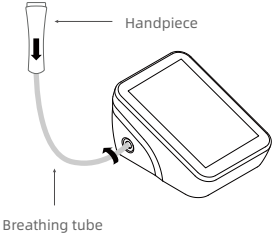
Power adapter

Measurements Preparation

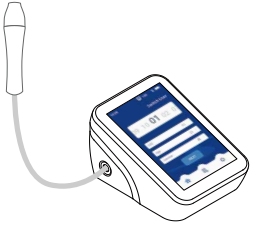


1. Connect the breathing tube, power adapter to the Nano Coulomb Breath Analyzer (the "device").

Note: Please charge 2 hours before first use. It is recommended to connect the power adapter during use.



2. Unpack the handpiece package and connect it tightly with the breathing tube as shown.

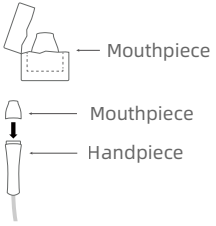


3. Power on: Press and hold the power switch until the screen lights up.

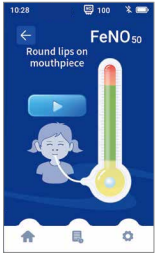
Shut down: After the measurements are completed, press and hold the power switch until the display is off, and the device will automatically shut down.

$FeNO_{50}$ measurement

1.Swipe left and right to select the user number and fill in the information (skip if the information has already been filled), click NEXT



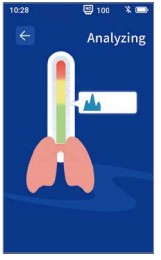
2.Unpack the mouthpiece, take it out and attach tightly with the handpiece as shown in the figure, then ready for measurement.



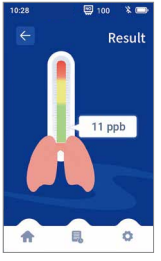
3.Round the lips on mouthpiece tightly to avoid air leakage, and press ▶

$FeNO_{50}$ measurement

4.Exhale continuously like blowing a whistle. Avoid air leakage, keep the ball within the green zone until the device automatically starts analysis.

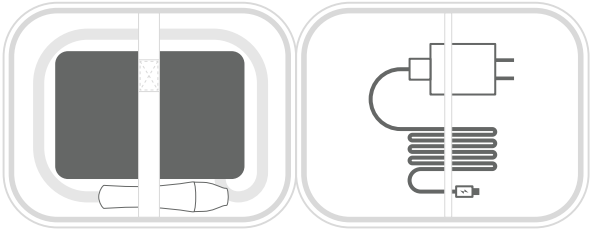


5. Analysis takes approximately 20 seconds. Do not disconnect the handpiece during the analysis process.



6.Measurement result is displayed after analysis.

Press ← at the upper left corner to return to exhalation interface, and follow step 3; If you need to switch the user , you can press ⌂ at the lower left corner to return to the "Switch User" menu, and follow step 1.



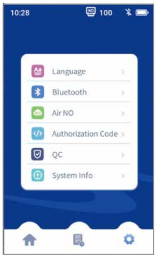
7. After Shutdown, you can place the device back in the carrying case as shown in the figure.

Data

Press button at the bottom of the Home Screen to view records of the current user.

Press"Switch User"to view other user's records.

Settings



Press button at the bottom of the Home Screen, enter "Settings" menu.

"Authorization code" and "QC" can only be used by authorized technical service personnel.

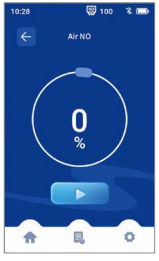
Language

Enter "Settings" Menu, press "Language", enter the menu of language selection.

Bluetooth

Enter "Settings" Menu, press "Bluetooth" to turn on or off Bluetooth. After this function is on, the Bluetooth connection status is displayed at the upper right corner of the screen.

Settings



Air NO

Enter "Settings" Menu, press "Air NO", enter the menu of air NO measurement.
Click ▶ .

NOTE:

Do not disconnect the handpiece during air NO measurement.

System Info

Enter "Settings" Menu, press "System info". Information such as device number is displayed.

Sensor Replacement

If the number of remaining measurements is low, please contact the manufacturer or the distributor to order replacement sensors. When " NO tests depleted," displays on the screen, it indicates that all measurements of the current sensor have been used. A replacement sensor needs to be installed. Before replacing the sensor, please make sure the device is turned off! Follow the following steps to replace sensor.

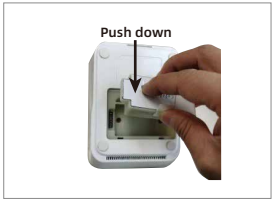
1.Remove the current sensor

(1) Turn device upside down. Remove the screw from the cover with a coin or a flat-head screwdriver.

(2) Remove the sensor compartment cover, then Hold the handle strip of the sensor and pull out the sensor vertically.

2.Install replacement sensor

(1) Unpack the replacement sensor, remove the sealing cap of the sensor.



(2) Align the sensor cavity of the device, insert the unpacked replacement sensor, and press the sensor down tightly.

(3). Put the sensor compartment cover back on and tighten screw.

Maintenance

1. DO NOT open the device (other than the sensor compartment).If the internal parts of the device need to be maintained and repaired, they must be sent back to the manufacturer for repair. Opening the device without authorization will void the warranty and service terms.

2. Each measurement should be done with a new mouthpiece or nasal filter.

3. Clean and disinfect: Clean the device with a clean, soft, damp cotton cloth or damp absorbent cotton. It is recommended to use disinfectant wipes (with a quaternary ammonium salt content (w/v) of 0.18%~0.22%) to disinfect the surface of the device. DO NOT use ethanol, isopropanol or similar disinfectant to clean the device. DO NOT wipe the parts with wordings, so as to avoid illegibility.

4. Instructions for transport and storage:

CAUTION!

Always use the original package for transportation and storage. Make sure there is no collision, falling from height.

Temperature range: -40 ~ +55℃

Humidity range: ≤93%

Atmospheric pressure range: 700 to 1060 hPa

Make sure the storage conditions are appropriate. The device shall be stored in a well-ventilated room without corrosive gas. Make sure the storage room is rain proof, moisture-proof, dust-proof and without stacking weights on top of the device package.

5. FAQs and solutions

Please refer to the following table if the device cannot operate normally. If the error code persists, contact Technical Service.

Code	FAQs	Solutions
E01	Device self-checking failed, please restart	Restart the device
E02	NO sensor not connected	Reinstall the sensor correctly. Please refer to the Sensor Replacement of this User Manual.
E03	NO tests depleted	The number of remaining measurements is displayed behind the icon at the top of the menu. If all measurements are used up, please replace the sensor.
E04	Bluetooth disconnected	Check the Bluetooth connection and reconnect
E05	NO sensor expired	Please replace the new sensor
E10	Power low, please charge	Connect the power adapter
E11	Try again	The sampling flow rate is too low, try again
E12	Try again	Try again
E13	Try again	Try again
	Low charge	Power on after 30-60 minutes of charging
None	Abnormal shutdown or failure to turn on	Charge it in time and then turn it on

Technical Data Sheet

1 Operating Conditions

Temperature：5℃ ~ 35℃

Humidity range：≤80% RH (non-condensing)

Atmospheric pressure: 700-1060hPa

Supply voltage: input AC100-240V ±10%; output DC5V 2.0A

Supply frequency：50Hz/60Hz ±1Hz

Internal power supply (lithium battery) voltage：DC3.635V

2 Technical specifications and Symbols

（1）Classification by the type of protection against electric shock: Class II internal electric source：DC3.635V

（2）Classification by the degree of protection against electric shock: Application part of Class BF

（3）Classification according to the degree of protection for liquid inlet: IPX0

（4）Non-AP, APG type equipment

（5）Classification by operation mode: Continuous operation

（6）Input Voltage: 100-240V±10% ,frequency 50Hz/60Hz, Output Voltage DC5V 2A

（7）Input power：35 VA

（8）Device does not have the application component of protection for defibrillation discharge effect

（9）Device has signal input/output components.

（10）Non permanently installed equipment.

（11）Dimensions: height140mm width100mm depth 78mm

（12）Weight: 0.7kg

（13）Electric safety: Compliant to the relevant requirements IEC 60601-1:2012,IEC 60601-1-2:2007,IEC 60601-1-11:2015 electrical standard.

（14）Production date and service life: The production date and service life shall be determined and marked in the corresponding product label.

Symbols and instructions used in the user manual

Symbol	Instruction
	Please refer to the attached document
	Application part of Class BF
	Class II

Symbol	Instruction
	Alternating current
	Direct current

3 Performance specifications

Performance specifications of Nano Coulomb Breath Analyzer (Sunvou-HA1101) are as follows:

Index	NO sensor
Measurement range	0 ~ 3000ppb
Lower Detection Limit	3ppb
Accuracy	±3ppb for Measured Value < 30ppb ±10% for Measured Value ≥ 30ppb
Precision	Relative Standard Deviation < 10%

Appendix
Electromagnetic Compatibility requirements

⚠ Caution

Pay attention to the field electromagnetic environment, as the product may be affected by the field electromagnetic field .The installation and use of products should be far away from products or facilities that emit strong magnetic waves, such as radio towers, high-frequency electrotome, nuclear magnetic resonance equipment, etc.

This product may cause electromagnetic interference to other electrical equipment on site. However,this product meets the requirements of electromagnetic compatibility standards and the electromagnetic environment instructions.

⚠ Caution

Portable and mobile communication RF devices may affect the use of this product.

⚠ Caution

The device should not be used in close proximity to or stacked with other devices. If it must be used in close proximity or stacked with other devices, observe and verify that it can work properly under the configuration used.

⚠ Caution

With the exception of sensors and cables sold by the manufacturer as spare parts for internal components, the use of non-specified sensors and cables may result in increased emission interference or reduced anti-interference of the equipment or system.

⚠ Basic performance description for EMC measurement: The product performance meets the requirements and can ensure normal operation.

The product conforms to IEC 60601-1-2:2007, IEC 60601-1-11:2015 electrical standard.

EMC Data

Guidance and manufacturer's declaration - Electromagnetic immunity and electromagnetic emissions

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
Nano Coulomb Breath Analyzer (Sunvou-HA1101) is intended for use in the electromagnetic environment specified below. The customer or the user of Nano Coulomb Breath Analyzer (Sunvou-HA1101) should assure that it is used in such an environment.		
Emissions measurements	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Nano Coulomb Breath Analyzer (Sunvou-HA1101) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Nano Coulomb Breath Analyzer (Sunvou-HA1101) is suitable for use in all establishments, including domestic establish- ments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
Nano Coulomb Breath Analyzer (Sunvou-HA1101) is intended for use in the electromagnetic environment specified below. The customer or the user of Nano Coulomb Breath Analyzer (Sunvou-HA1101) should assure that it is used in such an environment.			
IMMUNITY measurements	IEC 60601 measurements level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 IEC 61000-4-11	<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) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<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) for 25 cycles <5% U_T (>95% dip in U_T) for 5s <5 % U_T(>95 % dip in U_T)for 5s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the measurements level.			

Table 3

Guidance and manufacturer's declaration–electromagnetic immunity – for life-supporting ME equipment and ME systems (Not Applicable)

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity – for ME equipment and ME systems that are not life-supporting			
IMMUNITY measurements	IEC 60601 measurements level	Compliance level	Electromagnetic environment– guidance
IEC 61000-4-6Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3V/m	Portable and mobile RF communications equipment should be used no closer to any part of Nano Coulomb Breath Analyzer (Sunvou-HA1101), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80MHz ~ 800 MHz $d = 2.3\sqrt{p}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b 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.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast 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 Nano Coulomb Breath Analyzer (Sunvou-HA1101) is used exceeds the applicable RF compliance level above, Nano Coulomb Breath Analyzer (Sunvou-HA1101) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Nano Coulomb Breath Analyzer (Sunvou-HA1101). b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Table 5

RRecommended separation distances between portable and mobile RF communications equipment and the ME equipment or ME system – for life-supporting ME equipment and ME systems (Not Applicable)

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment or ME system – for life-supporting ME equipment and ME systems (Not Applicable)

Recommended separation distances between portable and mobile RF communications equipment and Nano Coulomb Breath Analyzer (Sunvou-HA1101)			
The Nano Coulomb Breath Analyzer (Sunvou-HA1101) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nano Coulomb Breath Analyzer (Sunvou-HA1101) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nano Coulomb Breath Analyzer (Sunvou-HA1101) as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz~80MHz $d = 1.2\sqrt{p}$	80MHz~800MHz $d = 1.2\sqrt{p}$	800Hz~2.5GHz $d = 2.3\sqrt{p}$
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 metres (m) can be estimated using the equation 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.			