

UltraE

UltraE

UltraPeace-Instant H. Pylori Urea Breath Test Kit System

User manual

Ver. 1.0



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I. Introduction

Thank you for choosing the UltraPeace-Instant H. Pylori Urea Breath Test Kit System (abbreviated as “UBT-P100” in the following). Please read the instruction manual carefully before use. The UBT-P100 is manufactured by UltraE. and sold by its authorized distributors. If you have any questions or valuable feedback about our product, please call our company or contact your local distributor. We will assist you as soon as possible.

II. System Information

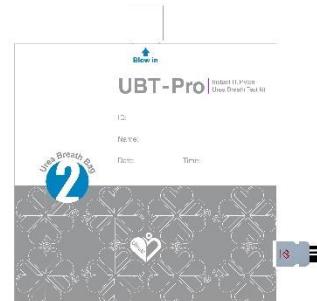
- Product Name: UltraPeace-Instant H. Pylori Urea Breath Test Kit System
- During the testing process, urea is supplied by Panion & BF Biotech Inc., which is not included in the product components.
- Overview:
 - Non-invasive testing method
 - Obtain results within 45 minutes
 - Assess treatment effect before and after ingestion
 - Automatic judgment on the result
 - Simple operation and portable (easy to carry)
- Picture:



Breath Ammonia Analyzer (UP100)



Breath Bag (UP100B) No.1



Breath Bag (UP100B) No.2

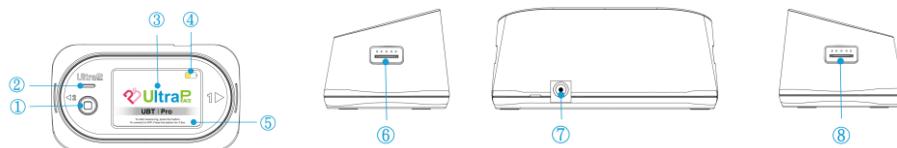
- Components of Breath Ammonia Analyzer (UP100):

- ① Breath Ammonia Analyzer (UP100): 1 unit
- ② Power Adaptor: 1 unit
- ③ Control Strip: 1 unit
- ④ Instruction for User (IFU): 1 unit

- Components of Breath Bags (UP100B): 1set

- ① Breath Bag No.1: 1 unit
- ② Breath Bag No.2: 1 unit
- ③ Straw for Blowing: 2 units
- ④ Breath Bag Insert: 1unit

■ Button Functions and Appearance



Top view

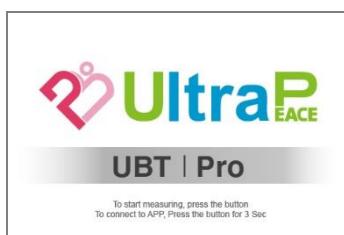
Right side

Back

Left side

- ① Multi-function Buttons: Power On/Off, Start or Cancel Measurement
- ② Signal Light: Displays Power On and Power Status
- ③ Main Screen: Displays the Operation Process
- ④ Battery Indicator: Displays the current battery level of the device.
- ⑤ Operational Guidance: Instructional Guidance with Progress Updates
- ⑥ Port 1: Breath Bag No.1
- ⑦ Charging Port: Device Charger Socket
- ⑧ Port 2: Breath Bag No.2

■ Screen Display Instructions



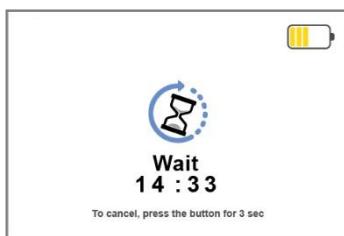
Power-up Screen



Insert Breath Bag No.1 Guidance



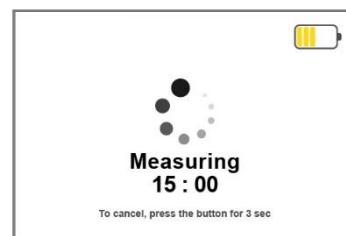
Take Urea Guidance



Wait for 15 Minutes After Taking Urea



Insert Breath Bag No.2 Guidance



The Screen of Measuring



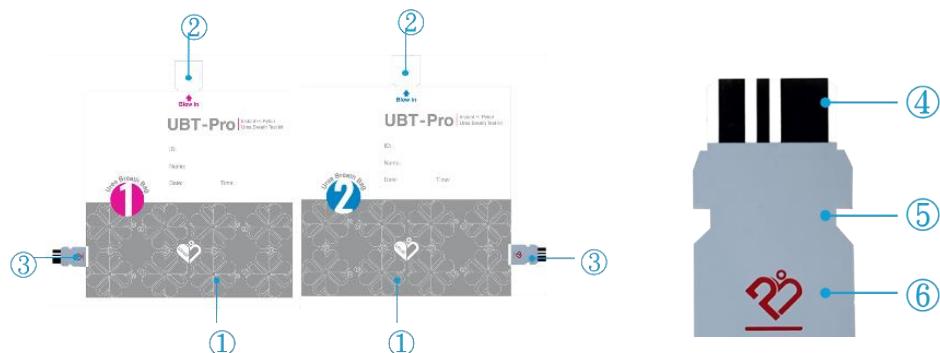
Positive Result



Negative Result

■ The Appearance of Breath Bags (UP100B No.1 and No.2)

The UBT-P100 operates on the principle of electrochemistry. The breath bag contains an ammonia sensor. When the ammonia gas in the exhaled breath comes into contact with the reaction zone of the sensor, it induces a change in electrical potential. Therefore, the presence or absence of *Helicobacter pylori* can be determined based on the change in ammonia concentration after ingesting urea. This information is displayed on the screen of UP100. The exhaled volume of breath bag is 1.5 liters.



- ① Breath Bags: Area for collecting exhaled breath gas.
- ② Exhalation Port: Location for inserting the straw.
- ③ Ammonia sensor
- ④ Ammonia sensor Contact Point: For inserting to the port on the analyzer and signal transmission.
- ⑤ Device Slot Locking Area: Mechanism to prevent the sensor from dislodging after insertion into the analyzer.
- ⑥ Handheld Area: Location for gripping the sensor.

■ Health Information

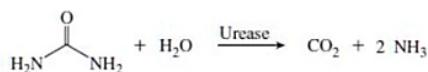
Helicobacter pylori (*H. pylori*) is a motile, spiral-shaped bacterium commonly found in the stomach. Approximately half of the global population is infected with *H. pylori*, with most infected individuals being asymptomatic. However, some people may develop gastric ulcers or even gastric cancer as a result of *H. pylori* infection. Additionally, individuals may experience symptoms such as excess stomach acid, concurrent antral gastritis, and duodenal ulcers. Therefore, discussions about the symptoms, detection methods, and treatment options for *H. pylori* infection are crucial. The concentration of ammonia exhaled by the human body typically falls within the range of 450-2990 ppb (parts per billion). However, there is no significant difference in the exhaled ammonia concentration between healthy individuals and those infected with *H. pylori* when urea is not ingested. Therefore, it is necessary to ingest urea and compare the ammonia concentration before and after ingestion to determine the presence of *H. pylori*.

Reference :

- J Thomas Lamont, MD. Patient education: *Helicobacter pylori* infection and treatment (Beyond the Basics). UpToDate. Retrieved Nov 24, 2022 (from <https://www.uptodate.com/contents/helicobacter-pylori-infection-and-treatment-beyond-the-basics>)
- Bayrakli I, Turkmen A, Cem Kockar M. Feasibility Study of Using Breath Ammonia Analysis Based on Off-Axis Cavity-Enhanced Absorption Spectroscopy with External Cavity Diode Laser for Noninvasive Real-Time Diagnosis of *Helicobacter Pylori*. Appl Spectrosc. 2016 Aug;70(8):1269-77. doi: 10.1177/0003702816654052. Epub 2016 Jun 13. PMID: 27296306.

■ Technology/Principle:

When the stomach is infected with *Helicobacter pylori*, the orally given urea is hydrolyzed by the enzyme urease of *H. pylori* and carbon dioxide and ammonia gas is expired in breath. By analyzing the concentration of ammonia gas expired through breath and comparing it with the baseline value before drinking urea. It can help to determine the presence of *Helicobacter pylori* infection. The enzyme urease catalyzes the conversion of urea to ammonia and carbon dioxide:



Utilizing patented developed nanoporous hydrogel membrane to capture ammonia gas from exhaled breath, the gas undergoes hydrolysis on the electrode surface. Through electrochemical detection, the pH value of the gas is obtained, enabling the calculation of ammonia gas concentration in the exhaled breath.

III. Website

<https://www.ultraehp.com/EN/>

IV. Indications for Use

UltraPeace-Instant *H. Pylori* Urea Breath Test Kit System (UBT-P100) is intended for use to continually and non-invasively measure changes in the ammonia ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach. UBT-P100 is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients. UBT-P100 consists of the Breath Ammonia Analyzer (UP100) and the Breath Bags No.1 / No.2 (UP100B). The device is for use by trained health care professionals. To be administered under a physician's supervision.

V. System Settings

■ Device Power Supply

- ① This product has two power supply modes: internal battery and external power adaptor.
- ② This product uses an AC/DC power adaptor as the device power supply.
- ③ When the screen displays  , it indicates low battery level. Please charge immediately.

■ Charging Steps



Step 1 Connect the power adaptor to the socket.



Step 2 Insert the AC/DC power adaptor plug into the device power socket.



Step 3 The screen displays  , indicating that the charging is normal.

■ Cautions:

- ① The machine comes equipped with a rechargeable battery from the factory. Please do not replace the battery yourself.
- ② Before testing, check the battery level to avoid interruptions during the testing process due to power failure.
- ③ Do not charge for extended periods of time.
- ④ The device contains a battery. Please dispose of it in accordance with local regulations.

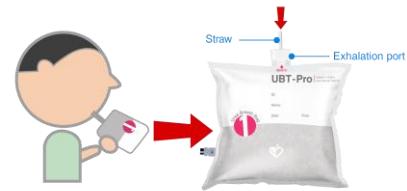
VI. Operation Steps



Step 1 Press and hold the multifunction button for 3 seconds to power on. The screen will display the startup screen.



Step 2 Press the multifunction button briefly to enter measurement mode. The screen will display the "Insert Bag No.1" guidance, indicating that the breath test can begin.



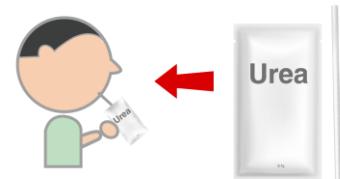
Step 3 Collect 1st baseline breath sample, instruct patient to hold their breath for 4-5 seconds, and then exhale into the BASELINE breath bag No. 1 until completely full.



Step 4 Immediately, connect sensor of breath bag No1. with device.



Step 5 After correctly inserting the bag, the screen will automatically switch to the "Take Urea" guidance. If it does not switch to the urea guidance, the bag has not been correctly inserted into the port.



Step 6 Take urea solution with the straw and wait for 15mins (Pour 30mL water to dissolve urea)



Step 7 Press the multifunction button to start the 15-minute countdown for the reaction time.



Step 8 After the 15-minute countdown on the waiting screen ends, the screen will guide to insert breath bag No.2.



Step 9 Collect 2nd breath sample, instruct patient to hold their breath for 4-5 seconds, and then exhale into the POST INGESTION breath bag No.2 until completely full.

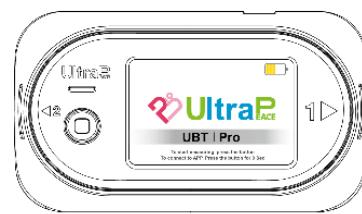
UltraE



Step 10 Immediately, connect sensor of breath bag No. 2 with device.



Step 11 After the 30-minute test period, the device will calculate the signal difference before and after taking urea, displaying a positive or negative result as figures below. Dispose of the used breath bags according to local waste disposal regulations.



Step 12 After completing the test, press and hold the multifunction button for 3 seconds to return to the startup screen. Then, press and hold the multifunction button for 5 seconds to power off.



Negative Result



Positive Result

VII. Analysis Result

■ The Test Method

The difference of NH₃ in pre- and post-ingestion breath samples is determined by the UP100 analyzer.

■ Calculation of Results

The results are provided as Delta Over Baseline. After completing the test, the device will calculate the potential values obtained from Port 1 and Port 2 automatically. The DOB value is determined by subtracting the potential of Port 2 from the potential of Port 1.

The function of DOB is below:

$$DOB(mV) = Port\ 1\ (mV) - Port\ 2(mV)$$

■ Determination of the Cutoff Point

The cutoff point is the level (threshold) used to discriminate between H. pylori-infected and uninfected individuals.

The Delta Over Baseline cutoff point was determined to be 60mV in a controlled study of 30 adult asymptomatic and symptomatic patients (12 infected and 18 uninfected). The study was conducted in Taiwan using a reference standard called the Proto C-13 Urea Kit. The cutoff point was evaluated by determining the original Helicobacter Pylori Testing System test result (DOB) threshold at which positive and negative patients, as determined by the Breath Ammonia Analyzer (UP100), were best distinguished. Figure 1 shows the UltraPeace-Instant H. Pylori Urea Breath Test Kit System (UBT-P100) test cutoff point graphically, which distinguishes H. pylori-positive and negative patients.

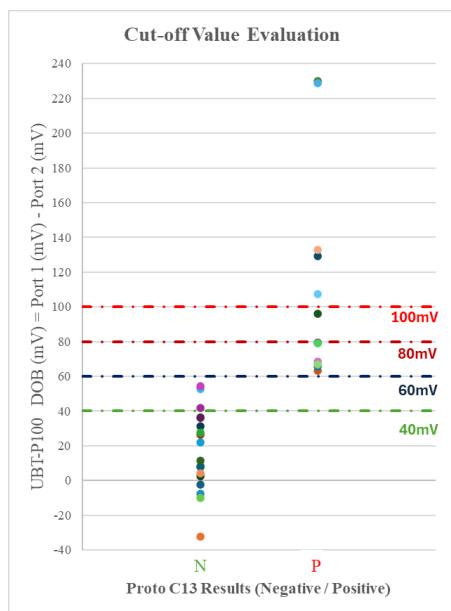


Figure 1 below shows the UltraPeace-Instant H. Pylori Urea Breath Test Kit System cutoff point graphically, which distinguishes H. pylori-positive and negative patients.

■ Interpretation of Results

UltraPeace-Instant H. Pylori Urea Breath Test Kit System (UBT-P100) test result of Delta Over Baseline greater or equal to 60mV is interpreted as diagnostically positive, indicating the presence of urease associated with H. pylori.

UltraPeace-Instant H. Pylori Urea Breath Test Kit System (UBT-P100) test result of Delta Over Baseline less than 60mV is interpreted as diagnostically negative, indicating the absence of urease associated with H. pylori.

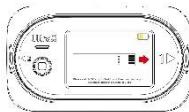
The 60mV Delta Over Baseline cutoff point applies to both initial diagnosis and post treatment monitoring of *H. pylori* infection in adult and pediatric patients.

VIII. System Quality Control

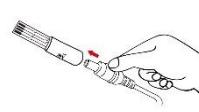
- The UltraPeace-Instant *H. pylori* Urea Breath Test Kit System (UBT-P100) undergo rigorous quality assurance procedures before leaving the manufacturer. However, to ensure correct functioning of UBT-P100 in the field, please use control strip to undergo quality check every week. The method of quality control test is as follows:
- Quality Control
 - ① The quality control test strips are used to verify that the system is functioning properly.
 - ② The method of quality control test:



Step 1 Accessing Quality Control Screen



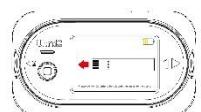
Step 2 The screen will display the "Insert control strip 1"



Step 3 Connect the control strip to the DC jack power cord.



Step 4 After switching the control strip to Port 1, insert it into port 1 of UP100.



Step 5 After waiting for ten seconds, the screen will display the "Insert control strip 2"



Step 6 After switching the control strip to Port 2, insert it into port 2 of UP100.



Step 7 Wait for approximately 10 seconds, and the device will automatically read. (QC pass or failed)



Step 8 If there is an abnormality in the quality control, please suspend usage. You can double-check the quality control process for any errors or contact your distributor.

IX. Maintenance and Cleaning

■ Device Maintenance and Cleaning

- ① Please use a damp cloth to wipe the outer casing of the device and avoid getting the strip port and power socket wet.
- ② Please do not immerse the entire device in water for cleaning.
- ③ Please keep the device as dry as possible and avoid any liquid from splashing onto the device.

■ Device Storage



- ① Please do not store the device in damp or directly sunlight-exposed environments.
- ② Please store the device body in an environment with temperatures between 10°C (50 °F) and 40°C (104 °F), and relative humidity between 20% and 60%.
- ③ The device should be protected from collisions and falling onto the ground.

④ Please do not disassemble the device by yourself.

■ Breath Bags Storage

① Breath bags should be stored in an environment with temperatures between 10°C (50 °F) and 40°C (104 °F), and relative humidity between 20% and 60%.

② Before use, check the expiration date on the packaging and ensure that the package is not damaged.

③ Immediately use after opening.

④ Before using the breath bag, check for any damage and dry your hands before use.

⑤ Do not wet the strip portion of the breath bag. If the electrode part is wet, dry it first before inserting it into the device port.

X. Limitation

■ The values measured by this product are for reference only.

■ Please follow your doctor's instructions for medication and do not self-diagnose or change your medication.

■ Do not use expired breath bags, as this may result in incorrect results.

■ Intended Patient Population:

① Patients aged ≥ 20 , undergoing testing for Helicobacter pylori infection.

② Individuals with initial or follow-up appointments for indigestion.

③ Patients with conditions such as peptic ulcers, significantly abnormal chronic gastritis, gastric lymphoma, etc., requiring eradication of Helicobacter pylori.

④ Individuals with a family history of gastric ulcers, gastric cancer, or cases where family members or partners have Helicobacter pylori infection.

■ Intended User Population: Trained health care professionals.

■ Intended Use Environment: Healthcare institutions include clinical laboratories and gastroenterology departments.

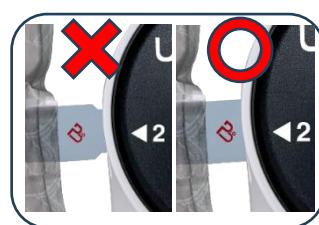
XI. Cautions



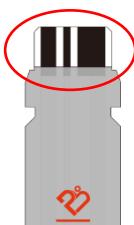
① The breath bags must be fully inflated.



② When inserting the sensor into the device, please ensure it is facing forward and insert it according to the positions for Breath bag No.1 and Breath bag No.2. Do not remove the sensor during testing, as this may lead to erroneous results.



③ When inserting the sensor into the device, ensure it is facing forward. The sensor's contact point must be fully inserted into the port, and the device slot locking area must be properly engaged (as shown in the diagram), otherwise, the test may produce inaccurate results.



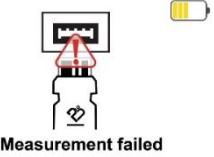
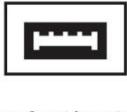
④ Avoid touching or scratching the sensor contact point with your hands.

XII. Troubleshooting and Error Handling

If following the instructions below does not resolve the issue, or if the problem is not listed, please contact your distributor for a solution. Do not attempt to resolve the issue yourself.

■ Error Message Interpretation

Warning messages and other information will be displayed in code form on the device screen. The table below provides warning codes and suggested actions for each code. If warnings persist, please contact your local distributor for technical support.

Error code	Display on the screen	Course of Action
E01	 Measurement failed <small>Error code: E01</small>	<p>Measurement failed</p> <p>If the sensor falls off, please retest.</p>
E02	 Strip failed <small>Error code: E02</small>	<p>Strip failed</p> <p>If the sensor is ineffective, please retest with a new breath bag</p>
E03	 Breath failed <small>Error code: E03</small>	<p>Breath failed</p> <p>The baseline is too high, please retest.</p>
E04	 Bag 2 not inserted <small>Error code: E04</small>	<p>Bag 2 not inserted</p> <p>Bag No.2 is not inserted, please retest.</p>
E05	 Low Battery <small>Error code: E05</small>	<p>Low Battery</p> <p>Low battery, please charge before starting the measurement again.</p>

■ Abnormal Condition Troubleshooting Guide

- ① No display when powering on
 - ❖ Device power depleted: Please connect the charger to recharge.
 - ❖ Device malfunction: Please contact the distributor.
- ② Unable to charge
 - ❖ Battery malfunction: Please contact the distributor.
- ③ No reaction when the strip inserted
 - ❖ Incorrect insertion direction: Ensure the electrode contact point of the strip is facing upwards, then reinsert, making sure the device port locking area is properly engaged (strip slot locking area fully inserted).
 - ❖ Damaged strip: Replace with a new set of breath bags and retest.

- ❖ Device malfunction: Please contact the distributor.
- ④ The test result is different from usual
 - ❖ If the result differs from previous tests, confirm the following conditions are resolved before retesting with a new set of breath bags.
 - ❖ Test strip not fully inserted: Ensure the device slot locking area is properly engaged (strip slot locking area fully inserted).
 - ❖ Breath bag leakage: The bag may have leaked due to external force during operation.
 - ❖ Moisture on the strip electrode contact point: The contact point may be damp, interfering with signal transmission.
 - ❖ Damaged strip: Replace with a new set of breath bags and retest.
 - ❖ Device malfunction: Please contact the distributor.

XIII. Security

FCC Warning:	
Class B: (Section 15.105) General Warnings (Applicable to All Products and Finished Goods)	
<i>Class B: (Section 15.105)</i>	
FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT	
<p>This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:</p> <ul style="list-style-type: none"> -Reorient or relocate the receiving antenna. -Increase the separation between the equipment and receiver. -Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. -Consult the dealer or an experienced radio/ TV technician for help. 	
(Section 15.21)	
CAUTION:	
<p>Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.</p>	
<p>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p>	
<p>RF exposure warning</p> <p>The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.</p> <p>The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.</p>	

XIV. Version Information

Software Version	Date
0.1.2	2024/3/27

XV. Symbols

Symbol	Referent
	In vitro diagnostic medical device
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Keep away from sunlight
	Keep dry
	Fragile, handle with care
	Caution
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Temperature limit
	Serial Number
	Humidity Limitation
	Prescription Use Only

XVI. Technical support

■ The specifications of breath bags

Product Name	Breath Bag
Model	UP100B
Size	200mm(L) / 200mm(W)
Operating Environment	15-30°C (59-86 °F)
Storage Environment	10-40°C (50-104 °F), Relative humidity 20-60%
Test Duration	45 minutes (including waiting time before taking urea)
Cut off value	60mV
Shelf-life	2 years

■ The specification of Breath Ammonia Analyzer (UP100)

Product Name	Breath Ammonia Analyzer
Model	UP100
Size and Weight	154mm(L) / 88mm(W) / 70mm(H) 300g
Input Power Supply	Type : DC Jack Voltage : 4.7-5.5V Current : 2A
Adapter	Input I/P : AC 100-240V, 50/60Hz, 0.3-0.17A Output O/P : DC 5.0V, 2.0A, 10W
Battery	Type : Lithium polymer battery Voltage : 3-4.2V Capacity : 2500mAh
Charging Duration	Charging from 0% to 60% takes 1 hour.
Continuous Operation Time	Up to 6 hours of continuous operation
Display Screen	Type : TFT/LCE Size: 3.5 inches Resolution : 480*320
Sound	Buzzer alert sound
Device Storage Environment	10-40°C (50-104 °F), Relative humidity 20-60%
Device Operating Environment	15-30°C (59-86 °F), Relative humidity 20-60%
Measurement Range	Ammonia concentration greater than 0.5 ppm
Precision	Coefficient of variation, CV \leq 10%
Performance	Overall agreement \geq 95%

XVII. Company Information

Manufacturer: UltraE Co., Ltd.

Address: No. 251, Guozhong Rd., Dali Dist., Taichung City 412023, Taiwan (R.O.C.)

Customer Service Hours: Monday to Friday, 08:30 - 17:30

Customer Service Phone: +886-4-2407-9045

Fax: +886-4-2407-7240

Email: UltraE@ultrae.com.tw