# USER MANUAL

Examera

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EXAMERA.CA

HER HEALTH IN HER HANDS

# Table of content

## 1. INTRODUCTION

Thank you for choosing Examera. This manual will serve as your guide to getting started with SHETEST. Please, review the entire manual before using the device. If you have any questions about the unit, please let us know and contact us with the mentioned number.

Before you begin to diagnose, it is important to read and understand these instructions for use completely.

**What is the SHETEST device?**

This device can be employed to diagnose two diseases related to the vaginal discharges (VD). People see a doctor for treatment when they have symptoms such as viscous discharge from the vagina or an unusual and unpleasant odor. One of the major causes of these symptoms is the presence of bacterial and fungal infections. After clinical examination and taking samples of the internal vaginal discharge, the doctor diagnoses the nature of the disease by examining various parameters such as the color of the discharge, odor, and acidity (pH).

The device is built with embedded sensors and can measure all required parameters. Using the most advanced algorithms available, it can diagnose two common types of vaginal diseases.

## 2. SPECIFICATIONS

*Table 1: Specification of SHETEST*

| Capabilities | Specifications |
|---|---|
| **Display system** | 3.2 TFT LCD display + Touch control |
| **Interface** | Mobile application |
| **Control unit** | User-friendly application controls operations. |
| **Electronic nose** | There are three different gas sensors for the detection of discharges odor. They provide the ability to detect the smell of the samples. |
| **Color detection** | Equipped with the color sensor in order to detect the color of the sample. |
| **Temperature and humidity display** | Senses the temperature and humidity of the laboratory or room in real-time. |
| **pH sensor** | The sample's pH is measured with an accuracy of 0.5. The effect of temperature on the pH value is also compensated internally. |
| **Two-step artificial intelligence** | At first, the E-nose data pass through the first artificial neural network. Then the outcome with other sensory data will become the input of the second artificial neural network to make the final decision. |
| **Battery** | The built-in rechargeable battery can be charged via a micro-USB port. The battery can work continuously for seven hours. |
| **Sample container** | The device has a special sample container for the user. This container can be sterilized by autoclaves or sanitizers. Also, the container provides isolated area for testing and prevent infection. |

# 3. ELECTRICAL SCHEMATIC

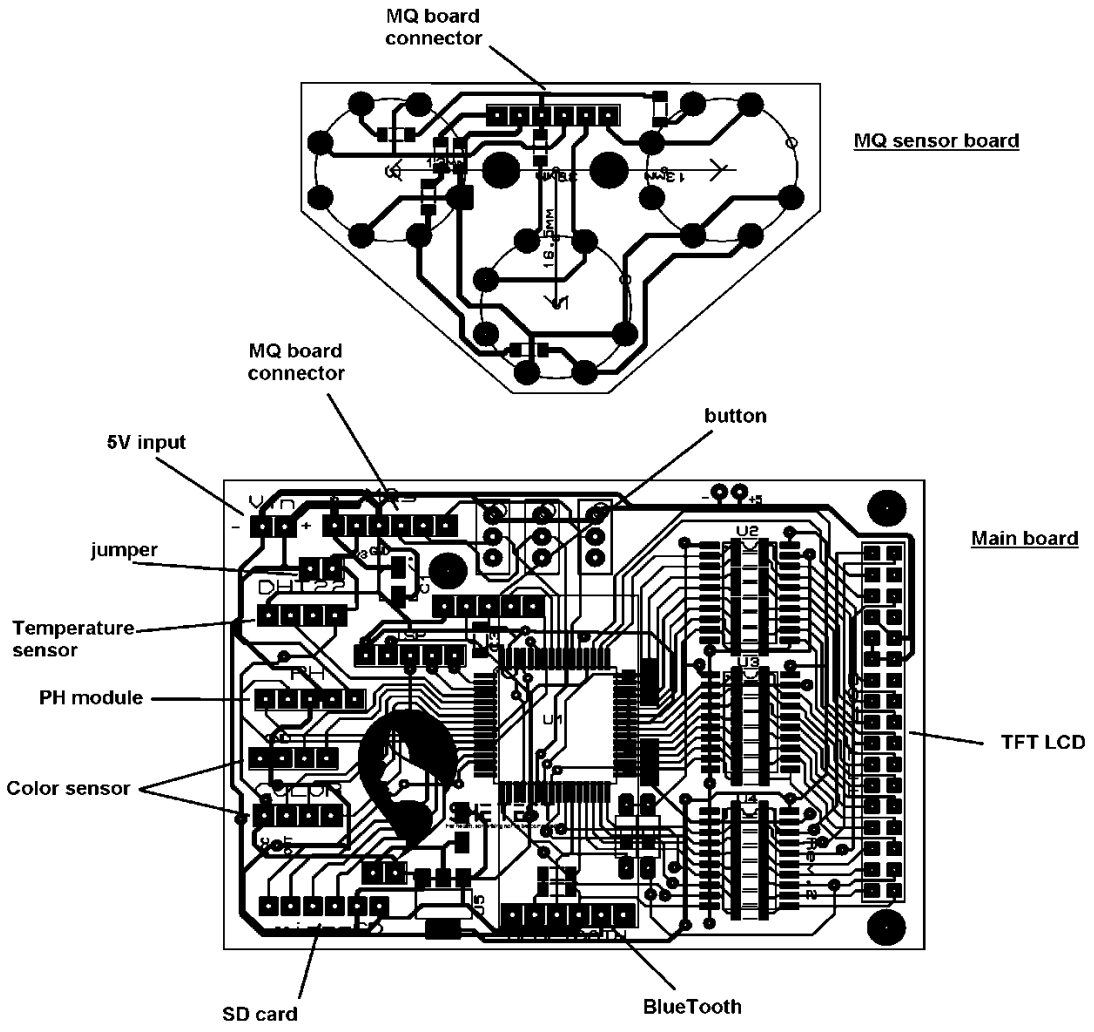



*Figure 1: Electronic circuit overview*

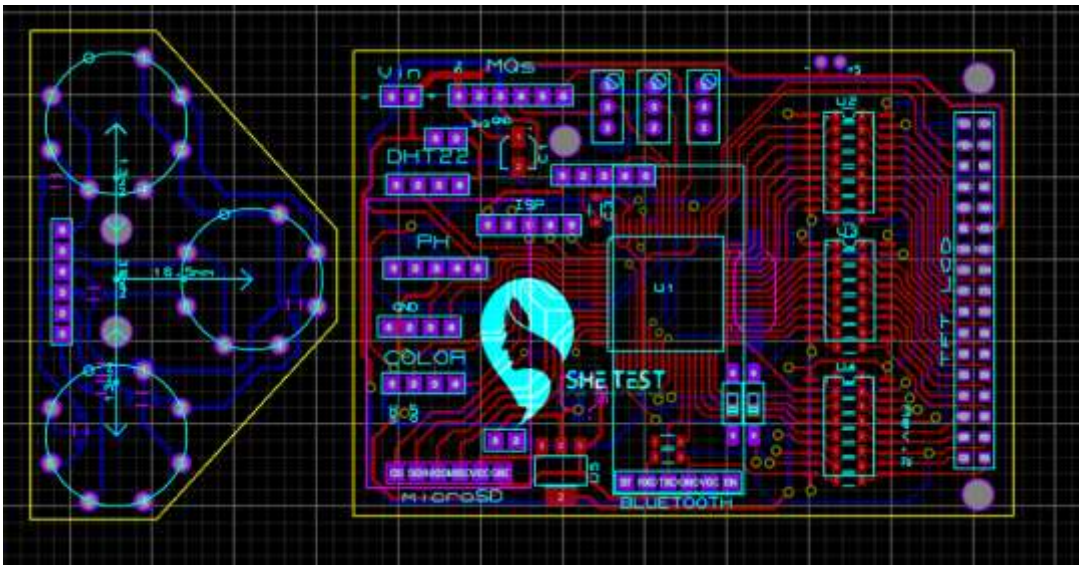


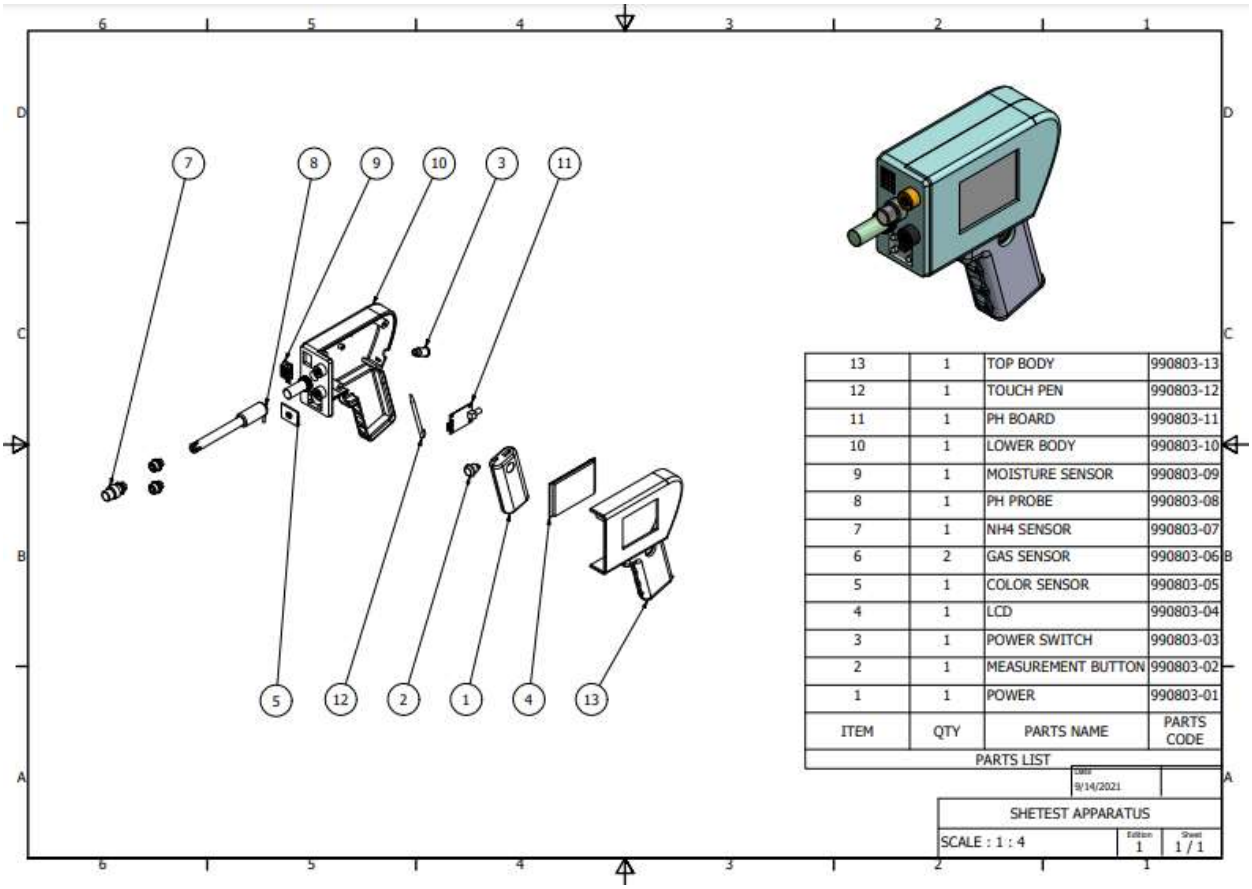

*Figure 2: Printed Circuit Board (PCB) overview*

The Printed Circuit Board (PCB) shows in figure 2.

Input voltage: 5V

Input Current: 1A

## 4. PRODUCT PRESENTATION




| ITEM | QTY | PARTS NAME | PARTS CODE |
|---|---|---|---|
| 13 | 1 | TOP BODY | 990803-13 |
| 12 | 1 | TOUCH PEN | 990803-12 |
| 11 | 1 | PH BOARD | 990803-11 |
| 10 | 1 | LOWER BODY | 990803-10 |
| 9 | 1 | MOISTURE SENSOR | 990803-09 |
| 8 | 1 | PH PROBE | 990803-08 |
| 7 | 1 | NH4 SENSOR | 990803-07 |
| 6 | 2 | GAS SENSOR | 990803-06 |
| 5 | 1 | COLOR SENSOR | 990803-05 |
| 4 | 1 | LCD | 990803-04 |
| 3 | 1 | POWER SWITCH | 990803-03 |
| 2 | 1 | MEASUREMENT BUTTON | 990803-02 |
| 1 | 1 | POWER | 990803-01 |

PARTS LIST

Date 9/14/2021

SHETEST APPARATUS

SCALE : 1 : 4 | Edition 1 | Sheet 1 / 1

*Figure 3: SHETEST presentation*

1. Power bank: Anker, power Core II 6.7 A
2. Measurement button: Push button / RESET metal key switch 12mm diameter waterproof
3. Power switch: Push button / metal switch ON / OFF with red light, diameter 12mm, waterproof, 12 volts.
4. LCD: TFT LCD 3.2”
5. Color sensor: TCS3200
6. Gas sensor: MQ3, TGS813
7. $NH_4$ sensor: MQ137
8. pH probe: Liquid pH Value Detection
9. Moisture sensor: AM2320 SIP Packaged Temperature and Humidity Sensor
10. Lower body
11. pH board
12. Touch pen
13. Top body

## 5. INNOVATON

SHETEST can measure bacterial and fungal infections such as Gardanella bacterial and Candida yeast. The pH, odor, and color of VD is checked by electrical sensors installed in the device. An artificial intelligence network is used to analyze vaginal infection source.

**You can see other advantages as follow:**

- Use of the Artificial Neural Network (ANN) technique for nonlinear modeling.
-The present device also has other advantages such as:
A) Collecting a biological sample (VD) from a patient
B) Electrical quantitative measurement of pH, color, and odor
C) Diagnosing BV with AI machine learning algorithm,
D) Clinically accurate
E) Easy to use
F) Test anytime
G) Safe and secure
H) Home use
I) Employs IoT for data transferring to gynecologists

## 6. EQUIPMENT SAFETY

This device is designed to improve women's health. Any other use of this device is not permitted.

Do not use the device in temperatures below than 15 degrees Celsius and above than 35 degrees.

Do not use the device if it is seriously damaged, including damaging to the trunk of the source wire and sample container. For help or service, contact the after-sales service.

Protect the device from physical damage. A sudden impact on the device may lead to severe damage to the device and failure of the sensors.

Do not open the device.


The sample container of the device has to be sterilized after each use. This container of the device has the ability to be autoclaved.

Do not touch this device with a wet hand to minimize the risk of electric shock.

Keep away from children.

## 7. PREPARATION FOR USE

- Remove the plastic cover of the pH sensor.
- Before and after use, wash the pH probe with distilled or deionized water.
- The device is equipped with chargeable batteries, charge the device before use.

The following steps must be performed to prepare the sample for testing:

1. Pour about 2 ml of distilled water into the pH probe container. This container is connected to the color detection container. Make sure that the distilled water enters the color detection container.

2. Dip the VD sampling swab into the pH container carefully. Make sure most of the sample was transferred to distilled water in the pH container, and the solution in this container and color detection container are homogeneous.

3. Transfer the remaining sample from the swab into the odor detection area of the sample container by rubbing the swab over the surface of the container.

4. Transfer 2 to 3 drops of KOH 10% into this area.

5. Then, place the prepared device on the top of the container properly and run the diagnostic command on the device.

Be sure to carefully clean the sample container and pH probe before each test. For sterilized the sample container, use 70% ethanol or 121 °C and 1 atm autoclave for 20 min. Please keep the pH probe in saturated KCl solution after finishing the tests.

You can use 4.0 and 7.7 buffers to ensure the calibration of the pH probe of the device.

## 8. POSITIONING – GENERAL

- Turn on the instrument and let it synchronize.
- After preparing the sample container, place the instrument in the sample container so that the pH sensor is in contact with the liquid in the sample container.

## 9. GENERAL INFORMATION

The device is built with embedded sensors and has the ability to measure all required parameters. Using the most advanced algorithms available, it can diagnose two common types of VD.

**Diagnostic diseases:**

**Candida albicans**

Candida albicans are part of natural opportunistic pathogenic microorganisms that commonly live in or on the bodies. It can be found in the gastrointestinal (GI) tract, mouth, and vagina.

Most of the time, it does not cause problems, but it can overgrow and cause infections.

Candida albicans is the most common cause of fungal infections in humans. Its species name, Albicans, comes from the Latin word for "white." The yeast fungus appears white when cultured on a plate, and in certain infections, such as thrush, it can cause white patches.

**Genital yeast infection**

Candida albicans is the most common cause of genital yeast infections.

Normally, a type of bacteria called Lactobacillus keeps the Candida in the genital area under control. However, if Lactobacillus levels are disturbed in any way, Candida can overgrow and cause an infection.

You may also develop a Candida infection in the genital area after participating in certain sexual activities, especially those that involve oral-genital contact.

Although otherwise healthy people can also get genital candida infections, the following groups are at increased risk:

- People who have recently taken antibiotics
- People with uncontrolled diabetes
- Immunosuppressed individuals
- Pregnant women
- People who take oral contraceptives or are on hormone therapy

**Symptoms**

Symptoms of a genital candida infection may include:

- A burning sensation during sex or urination
- An itchy or painful feeling in or around the vagina
- Redness, irritation, or swelling around the vagina
- Abnormal VD, which can be either watery or thick and white
- A rash around the vagina
- A rash on the penis

Candida species can also infect the male genitals, often if their partner has a vaginal candida infection. The infection may be asymptomatic but can cause an itchy or burning rash around the tip of the penis.

**Gardnerella vaginalis**

Gardnerella Vaginalis is an infection of the female genital tract caused by bacteria of the strain Gardnerella vaginalis, often in combination with various anaerobic bacteria. It is also called bacterial vaginosis.

## Description

Gardnerella vaginalis was originally described by Gardner and Dukes in 1955. The infection often produces a gray or yellow discharge with a "fishy" odor that increases after washing the genitals with alkaline soaps.

Gardnerella vaginalis is the most common cause of bacterial vaginitis in sexually active mature patients. The patient complains of a foul-smelling, nonirritating discharge; examination reveals a homogeneous, grayish-white secretion. Application of 10 percent potassium hydroxide to the vaginal secretion on a glass slide may release a transient "fishy odor."

## Trigger

The infection is thought to be sexually transmitted. The bacteria are also found in women without a history compatible with a sexually transmitted disease and often cause no symptoms.

## Symptoms

Typical symptoms of infection include a VD associated with a "musty" or "fishy" odor. The amount of discharge is highly variable, and there is little vulvar or vaginal irritation associated with this infection, but the pungent odor is usually the main complaint.

## Diagnosis

A wet specimen of physiological saline mixed with vaginal secretions should be examined under low-light and high-light objectives. Few white blood cells and lactobacilli are found. The characteristic "clue cells" are seen as numerous stippled or granulated epithelial cells. This appearance is caused by the adherence of almost evenly distributed Gardnerella Vaginalis organisms on their surface.
Clumps of G vaginalis organisms may also be noted at the edges of the epithelial cells or floating freely in the preparation. Cultures are rarely necessary to make a diagnosis.

## 10. PROCEDURE

**SHETEST User Interface:**

To set up the device, follow the 6-step instructions:

1) First, press the power button on the back of the device to turn it on.

2) Wait for 1 to 2 minutes, then use the following instruction to calibrate the device.

Calibration can be done in three ways: by using the button in front of the device, the app, and by touching the calibration message displayed on the LCD. Figure 4 shows calibrate sensors message.


*Figure 4: Appeared message on the LCD for calibration*

If the device does not set on the sample container correctly, figure 5 will be displayed on the screen.

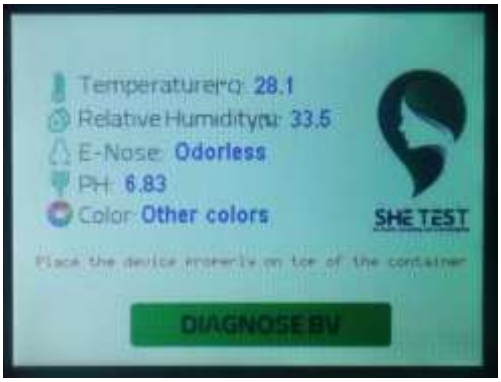



*Figure5: Incorrect position of the device*

3) After calibration, the figure 6 will display to start the test.


*Figure 6: Setting up the device for sampling*

4) Now, the device sensors are ready to be placed on the top of the sample container. (**Note that the pH sensor must be in contact with the liquid in the sample container**).

5) After ensuring proper sensor placement, press the button in the front of the device handle or use the DIAGNOSE BV button that appears on the LCD.

6) After a few moments, the diagnosed disease is displayed as shown in figure 7.

*Figure 7: Displayed test results*

**Note that the images are not taken from the real discharge sample and are only meant to show the steps with the device.**

## 11. APPLICATION

After installing the application, the login screen will be displayed. On this page, enter your account information, including username and password, and click the login button. After a few moments, your account information will be validated. If your account information is correct, you will access the main page, and if the information is incorrect, it will inform you with the relevant message.

If the app is not connected to the device, the application warns that the phone needs to pair with the SHETEST device via Bluetooth. Click on the "Connect" button to display the list of paired Bluetooth phones. After selecting the device Bluetooth, it is connected to the device and is transferred to the home screen.

It should be noted that for the initial connection to the device, you must open the phone's Bluetooth settings page, click the search button, find the device's Bluetooth name and pair the device's Bluetooth.

The device's Bluetooth password for the initial connection is 1234.

Now, if you connect to the device, the information of the device sensors will be displayed in real-time on the main screen. Device information includes temperature, Humidity, E-Nose, pH, Color. To use the device, first, click the calibrate sensors button at the bottom of the page.

A request to calibrate and launch the modules will be sent to the device by clicking on this button. A sampling request is sent to the device by clicking on the Diagnose by button, and the artificial intelligence network is executed.

Based on the information received from the sensors and the analysis performed on this data, the application detects the type of infection and displays it on the screen.

**APP Pages:**

Figures 8 to 13 describe the SkincureX mobile application page.

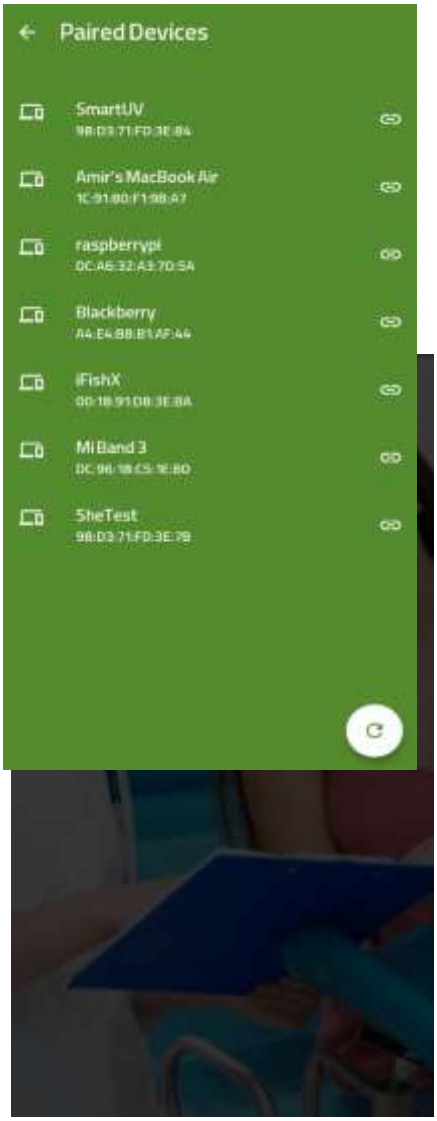



*Figure 8: Splash screen*


*Figure 9: Login to the mobile application page*


*Figure 10: Connection checking*

*Figure 11: List of paired devices*

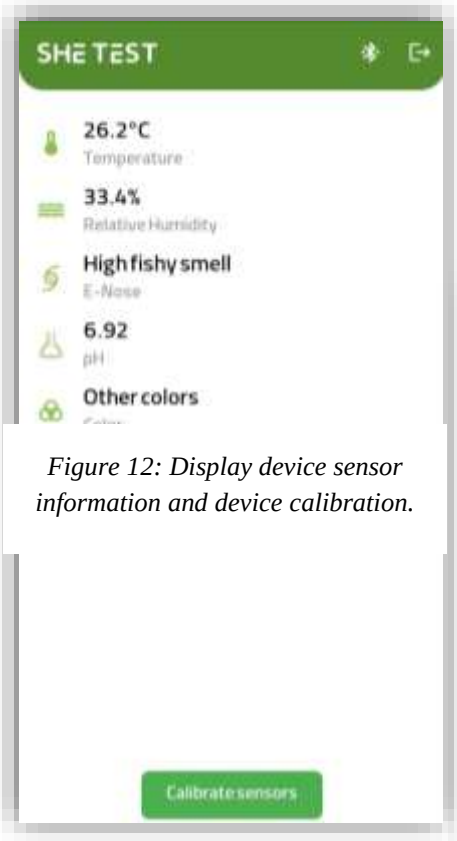



*Figure 12: Display device sensor information and device calibration.*

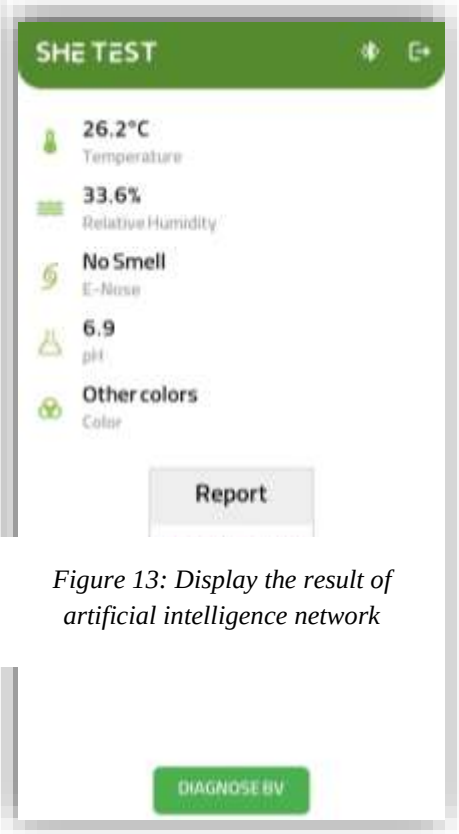



*Figure 13: Display the result of artificial intelligence network*

## 12. CLEANING & MAINTENANCE

The electronic part of the device does not require frequent maintenance, but the sample containers need to be cleaned and sterilized before each test.

To clean the exterior surfaces of the unit, please observe the following points.

Be sure to unplug the power cord from the unit and then clean it.

Do not use pure alcohol, ethanol, benzene, acetone, or wet cloths to clean the surfaces of the unit.

Try to clean the trunk with a cotton cloth only, and dry all areas thoroughly with a clean cloth. You can also use a maximum of 20% alcohol for cleaning.

Use distilled or deionized water to clean the pH sensor.

For maintaining the device, the pH sensor must be in a saturated KCl solution. To do this, fill the sensor cap with saturated KCl solution after using the instrument and place the sensor inside.

The device handle melts at a higher temperature of 180, and it frosts below -10 temperature.

**Gas sensor maintenance:**

Following conditions must be prohibited for the proper function of the gas sensor:

1. Exposed to organic silicon steam: organic silicon steam cause sensors invalid result, sensors must be avoid exposing to silicon bond, fixture, silicon latex, putty or plastic contain silicon environment.

2. High corrosive gas: if the sensors are exposed to high concentration corrosive gas (such as H2S, SOX, $Cl_2$, HCl), it will not only result in corrosion of sensors structure, also causes sincere sensitivity attenuation.

3. Alkali: Alkali metals salt, halogen pollution. The sensor's performance will be changed badly if sensors are sprayed polluted by alkali metals salt especially brine, or be exposed to halogen such as fluorine.

4. Touch water: sensitivity of the sensors will be reduced when spattered or dipped in water.

5. Freezing: avoids icing on the sensor's surface, otherwise the sensor would lose sensitivity.

Following conditions must be avoided:

1. Water condensation indoor conditions: slight water condensation will affect sensor's performance lightly. However, if water condensation on sensors surfaces and keep a certain period, the sensor's sensitivity will be decreased.

2. Used in high gas concentration: no matters the sensor is electrified or not, if a long time is placed in high gas concentration, it will affect sensors characteristics.

3. Long-time storage: the sensor's resistance produces reversible drift. If it's stored for a long time without electrifying, this drift is related to storage conditions. The sensors should be stored in airproof without silicone gel bag with clean air. For the sensors with long time storage but no electrify, they need a long time for stability before using.

## 13. TROUBLESHOOTING

- If the device does not display the first screen after turning it on and 10 seconds, check the following possibilities:

  - The device battery is not charging.
  - The device needs to be restarted.

- If the above two possibilities do not solve the problem, contact us.

- After the device is turned on, if the sensor information is not shown, restart the device.

- If the temperature and humidity sensor (that is set at the front of the handle) encounters a problem and the connection to the board is lost, the device will not work.

- The pH sensor must be in the electrode holder solution. If not so, it may be given inaccurate results.